		_	
	Page 10		Page 12
1	A. I'm being represented by	1	in the room, weren't you? Yes. Yes, you
2	Mr. Chris Hall from Saul Ewing and Lisa	2	were. Sorry if I don't remember entirely.
3	Dykstra from Morgan Lewis.	3	Q. You being?
4	Q. Have you ever been deposed	4	A. I'm sorry.
5	before?	5	Q. Lindsey?
6	A. Yes, I have.	6	A. Lindsey. Lindsey Mills. I'm
7	Q. In what kind of case?	7	sorry.
8	A. One was a many, many years	8	Q. Okay.
9	ago, a Securities and Exchange Commission case	9	MR. HALL: Lindsey Mills.
10	that typical Securities and Exchange	10	THE WITNESS: Lindsey Mills was
11	Commission case. It was, in general, in terms	11	definitely present, yesterday. I just
12	of who said what to whom in various	12	couldn't remember previously. I'm
13	circumstances. And then there was a	13	sorry.
14	subsequent case that was very similar to that	14	BY MR. BEGLEITER:
15	basically.	15	Q. Have you ever testified at a
16	Q. Also involving securities?	16	trial?
17	A. Generally involving securities.	17	A. No, I have not.
18	Q. Were you ever deposed in a case	18	Q. Did you review documents prior
19	involving any medical or pharmaceutical	19	to this deposition?
20	issues?	20	A. Yes.
21	A. No, not at all. The ones	21	Q. And did any of these documents
22	involving securities was simply because I was	22	refresh your recollection?
23	aware of transactions that were ongoing.	23	A. The documents generally refreshed
24	Q. Was Merck a party to those	24	my recollection of things that were happening.
25	cases?	25	They did not necessarily reflect my refresh
	Page 11		Page 13
1	A. The first one, yes.	1	my recollection of actual events that
2	A. The first one, yes.Q. About what year was that case?	2	my recollection of actual events that occurred.
	A. The first one, yes.Q. About what year was that case?A. That was 1980s, early 1990s.	2 3	my recollection of actual events that occurred. Q. I'm trying to understand
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2 3 4 5	 A. The first one, yes. Q. About what year was that case? A. That was 1980s, early 1990s. Q. Have you met with your with your counsel prior to A. Just to correct, Merck was not a party to it, the parties that were involved 	2 3 4 5 6 7	my recollection of actual events that occurred. Q. I'm trying to understand A. I saw well, the refreshing of the recollection that's a fair question. The refreshing of the recollection was that when I saw the documents, I certainly
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	Page 14		Page 16
1	BY MR. BEGLEITER:	1	Q. Did your departure have anything
2	Q. Is there any specific document	2	to do with, we haven't defined yet, but I
3	that you recall?	3	think you'll know, Protocol 007?
4	A. It was the entire ream of	4	A. No, not at all.
5	documents we were looking at.	5	Q. Did it have anything to do with
6	Q. What's your position with the	6	the MMR II vaccine?
7	Bill & Melinda Gates Foundation?	7	A. Not at all.
8	A. I am the Director of the Global	8	Q. I want you to take a look at
9	HIV Program with the foundation.	9	Emini-1.
10	MS. DYKSTRA: Dr. Emini, I think	10	
11	the court reporter is going to ask you	11	(Exhibit Emini-1, Curriculum
12	to slow down just a little bit.	12	vitae, was marked for identification.)
13	THE WITNESS: Oh, I shall. I	13	
14	shall.	14	BY MR. BEGLEITER:
15	BY MR. BEGLEITER:	15	Q. I'd like to show you I'd like
16	Q. How long have you been at the	16	to hand the court reporter and you and your
17	Bill & Melinda Gates Foundation?	17	counsel a document. I don't know how it was
18	A. This July will be two years.	18	marked, but it's marked 00001 EMINI. We'll
19	Q. And would it be correct to say	19	call this Emini-1 for this deposition. Just
20 21	that you're focusing on AIDS research? A. Yes, it is.	20 21	what is this, sir?
21 22	· ·	21 22	A. This is my curriculum vitae as of January 2016.
23	Q. Anything more than just research?A. Well, it is research, the Bill &	23	· ·
24	Melinda Gates Foundation funds research	24	Q. Did you prepare this curriculum vitae?
25	efforts. It also funds what we call delivery	25	A. Yes, I did.
23	errorts. It also funds what we can derivery	23	· · · · · · · · · · · · · · · · · · ·
١.	Page 15		Page 17
1	efforts which is how to get the fruits of	1	Q. As far as you know, is it
2	those research to individuals at risk of HIV	2	accurate?
3	or suffering from HIV infection in specific	3	A. As far as I'm aware, yes.
4	parts of the world that are of focus for the	4	Q. Up to January 2016?
5	foundation. In the case of HIV, that would be Southern and Eastern Africa.	5	A. Yeah, it is.
6			Q. Is it?
7 8	Q. Can you tell me you did work for Merck?	7	A. Yes. It does appear to be the one that I prepared up until that time, yes.
9	A. Yes, I did.	8	Q. And tell me, sir, have there
10		10	been any changes since January 2016 that you
11	Q. Can you tell me approximately when you started and when you ended?	11	would ordinarily put in your curriculum vitae?
12	A. I started in August of 1983 and	12	A. There may very well have been.
13	left at the end of January 2004.	13	There are probably one or two additional
14	Q. And what were the circumstances	14	publications that were published since then
15	of your leaving?	15	that would have wound up on the publication
16	A. It had been 22 years that I was	16	list. And I was recently elected a Fellow of
17	at the company, and I decided that 22 years	17	the College of Physicians of Philadelphia, and
18	was long enough. At the time the company had		that would have been included.
19	a program in place to permit early retirement	19	Q. Congratulations on that.
20	with full benefits associated with early	20	If we can go back, if you can go
21	retirement, and I raised my hand. And since	21	to the "PROFESSIONAL HISTORY" section, which
22	it had been that period of time, I took the	22	begins towards about two-thirds of the way
	1 , 2 55511 515		
	opportunity.	23	down the first page and ends about a third of
23	opportunity. Q. So your departure was amicable?	23	down the first page and ends about a third of the way down the second.
	opportunity. Q. So your departure was amicable? A. Totally amicable.		the way down the second. A. Yes.

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Page 18 Page 20 Q. And just a few questions about research group? 2 your professional history. 2 A. No. It was an independent group. 3 3 Q. You were -- let's go to number A. Yes, please. 4 Looking at Item 10, Director of 4 8. Executive Director of Department of HIV Biology and Immunology at Merck Research Antiviral Research. What were your duties as Laboratories, do you see that? the Executive Director of Department of 7 Antiviral Research? 7 A. Yes, sir. 8 8 Q. Did you have any responsibility A. The same thing. I was 9 9 for clinical trials as a Director of HIV responsible for the research efforts that led 10 Biology and Immunology? 10 to the development of antiviral drugs. 11 A. My direct responsibility was in 11 Q. Did that include mumps research? 12 supportive research. 12 No, these were antiviral drugs. 13 Q. I see. 13 These are chemotherapeutics. These are not 14 A. In supportive research. But the 14 vaccines. 15 clinical, the medical group did not report to 15 Q. Did the Department of Antiviral me at Merck. It was the research group. Research exist before you became the executive 16 Q. When did -- and the research 17 17 director? group would not have included clinical 18 18 A. No, I was actually the founding 19 research? 19 executive director of the Department of 20 20 A. The research group would not Antiviral Research. 21 normally have included clinical research, no. 21 Q. Let's go to number -- you were 22 22 the executive director -- number 7 is you're Q. Can you tell me which one of 23 these numbers was the first time that you 23 Vice President of Vaccine and Biologics 24 began to have any involvement with clinical 24 Research? 25 25 research? A. Yes, that's right. Page 19 Page 21 1 A. Involvement with clinical 1 Q. Was 8 to 7 a promotion? 2 research was, I guess the word I would use is 2 A. From 7 to 8. So when I --3 ancillary in the sense that the nature of how 3 O. 7 to 8. 8 would be -- just to 4 be clear, 8 is further back in time, 7 is more 4 we operated within the organization was an 5 5 open operational collaboration between 6 regulatory and medical research and the 6 A. Yes, I'm sorry, reading 7 7 backwards. Yes. So, yes, it was. I mean, research laboratories, where I was in research group which -- that I was responsible for. So 8 vice president is a higher level than an 9 9 executive director. there would be occasions where in the 10 10 preparation of regulatory documents or in the So after I completed what was 11 conduct of research, they would be in 11 approximately five years as the head of the 12 support -- in the conduct of activities that 12 Department of Antiviral Research, the efforts 13 would be in support of clinical activities 13 we were originally formed to do had, in fact, 14 that would have occurred. 14 largely been completed and then the position 15 15 became available at the head of vaccines Q. Did you -- was there a time in 16 which you had a supervisory role with regard research. I was offered the position. And I 17 to clinical research? 17 took it. 18 18 A. Not in the context of a Q. And as number 8 did you have any 19 clinical -- not in the context of the 19 responsibility, supervisory responsibility for 20 execution of the clinical research, per se. 20 any clinical research? 21 In other words, the execution of the clinical 21 It was the same setup. The 22 protocol. That would have been the 22 medical research group, there's always a 23 23 responsibility of the medical research group. separate operation, a separate reporting 24 24 Q. And did you have any supervisory relationship than the research group. 25 responsibility with regard to the medical I just need a clarification.

6 (Pages 18 - 21)

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	Page 22		Page 24
1	You know a Dr. David Krah?	1	did you have any responsibility in staffing
2	A. Yes.	2	decisions in Mr in Dr. Krah's laboratory?
3	Q. Were you his was there a time	3	MS. DYKSTRA: Objection to form.
4	in which you were a supervisor of Dr. Krah?	4	I'm not sure what time frame you're
5	A. I was he was in my	5	talking about.
6	department, so I was the supervisor of his	6	MR. BEGLEITER: I'm talking
7	supervisor.	7	about the time frame of number 8. I
8	Q. And as a and what did you	8	should have said that.
9	supervise him doing?	9	THE WITNESS: I did not
10	MS. DYKSTRA: Objection.	10	MS. DYKSTRA: I'm sorry, number
11	BY MR. BEGLEITER:	11	8 is antiviral research.
12	Q. What was he doing that you	12	BY MR. BEGLEITER:
13	supervised him for?	13	Q. Number 9 number 7, excuse me.
14	MS. DYKSTRA: Objection.	14	Number 7.
15	BY MR. BEGLEITER:	15	MS. DYKSTRA: Thank you.
16	Q. Go ahead.	16	THE WITNESS: I delegated
17	MS. DYKSTRA: Form.	17	staffing responsibilities to the senior
18	BY MR. BEGLEITER:	18	staff in the department.
19	Q. Okay. What was his job when you	19	BY MR. BEGLEITER:
20	were supervising him? Ask it that way.	20	Q. Who is that? Was there a
21	A. His job was to run a research	21	particular person who had that responsibility
22	laboratory. That was his that was his	22	for Dr. Krah?
23	predominant job, just like everybody else in	23	A. That would have been his direct
24	the group.	24	supervisor which would have been Dr. Alan
25	Q. And was this was he he was	25	Shaw, who would have worked in collaboration
	Page 23		Page 25
1	6	1	Page 25 with Dr. Krah at the laboratory.
1 2	Page 23 doing research into the blood of children who either had mumps or had received mumps MMR II?	1 2	with Dr. Krah at the laboratory. Q. All right. Was this
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Page 28 therefore, in humans to answer a specific 1 second, but that question certainly 2 question. 2 involved 007. 3 Q. Is the purpose to determine --3 THE WITNESS: 007, yes. 4 is the purpose to develop a vaccine? Is the 4 BY MR. BEGLEITER: purpose when it comes to the kind of thing 5 Q. It was important that the MMR II that Dr. Krah was doing to test the vaccine? 6 be safe and effective. Right? 7 What was the purpose specifically? 7 MS. DYKSTRA: Objection. 8 8 A. It could have been, it could THE WITNESS: Well, it was 9 9 have been, it could have been anything. The important that the MMR II, as is true 10 specific purpose of the clinical study is 10 for any vaccine, be safe and effective, defined in the specific goals of the clinical 11 yes, of course. Or for that matter, 11 trial as defined by the protocol of the study. 12 12 any pharmaceutical product. 13 Was one of the purposes of the 13 BY MR. BEGLEITER: 14 clinical trial that Dr. Krah was involved with 14 O. Now, before a clinical trial 15 to assess efficacy of the MMR II vaccine? 15 began at -- withdrawn. Was Protocol 007, had it begun 16 A. I do not recall the exact 16 17 wording of the specific trial goals as defined 17 by the time you arrived -- you became number in the protocols, but it was not to -- it was 18 not to assess efficacy because the vaccine's 19 I do not recollect. 20 20 Have you heard of Protocol 006? effectiveness and efficacy had been defined O. 21 many years previously in a former trial for 21 A. I have no recollection of 006. efficacy. 22 22 Do you recall that there was a O. 23 23 head-to-head trial of Priorix and MMR II? Q. Was it to study the immunogenicity 24 of the vaccine? 24 A. I do recall that there was such 25 25 a trial, yes. It was designed to, best of my Page 27 Page 29 recollection, to study the immunogenicity of Q. Was that trial, to your 1 2 the vaccine using a specific set of assays as recollection, in progress when you became 3 a measure of that immunogenicity, yes. 3 number 7, Vice President of Vaccine and 4 Q. And the assays, if you recall, 4 Biologics Research? 5 were what? 5 A. I do not know. I don't recollect. 6 A. There were two specific assays. 6 Now, in 006, did you make any 7 One was an assay referred to as a plaque 7 scientific -- excuse me, withdrawn. You don't reduction neutralization assay. And the other know what 006 is. 8 9 9 one was an assay that was referred to as an In the study that's done the 10 ELISA assay, both developed to measure 10 head-to-head comparison of Priorix and MMR II, 11 antibody responses elicited by the vaccine. 11 did you make any scientific decisions? 12 Q. Was it designed to study safety? 12 Not to my recollection. 13 MS. DYKSTRA: Objection. 13 Did you make any clinical Q. BY MR. BEGLEITER: decisions with regard to that? 14 14 15 Q. Was it designed to study safety? 15 Not to my recollection. A. 16 You can answer. How about research decisions? 16 Q. 17 It was -- again, it depends on 17 Not to my recollection. 18 what was written and I don't -- I did not 18 Were you on any committees while 19 review the protocol so I don't know what was 19 you were at Merck? 20 written as a specific objective of the study. 20 A. I was on several committees, 21 MS. DYKSTRA: Just to be clear, yes. 21 22 when we're saying it and the study, 22 Q. Can you tell me what committees 23 you're talking about 007? 23 you were on, let's say, from 1997 on? 24 MR. BEGLEITER: Yes, 007. I'm 24 A. I can't give you the specific 25 actually going to switch gears in a 25 details because I don't even remember what

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Page 32 they were called, to be honest with you, 1 Were you involved -- did you 2 because this is well over 20 years ago. Well, 2 make scientific decisions regarding the close to 20 years ago. So but I do recall 3 conduct of Protocol 007? 3 4 certainly being on a research management 4 A. I don't recollect directly, but 5 5 I don't believe I did. committee, I believe it's still referred to 6 Q. How about any clinical decisions that way, which was a -- literally what it 7 regarding the conduct of 007? 7 entails is a research management committee. 8 A. No, I did not because I would 8 I may have served as not 9 not have been permitted to do that. 9 necessarily a committee member but as an 10 Can you explain why you weren't 10 observer to other committees such as Q. permitted? 11 committees related to clinical study design 11 and things of that nature. Chances are I 12 Again, clinical decisions were 13 would have been an observer and an expert, if 13 the responsibility of the medical clinical group. That was not my group and I was not 14 you will, present, but not making any 14 15 decisions. As a matter of fact, now that I 15 responsible for that group. recall back, I was not a formal member of that 16 Q. Do you recall the years '97 to 17 2002 which is number 7 on your list, who was 17 committee. I remember making presentations to 18 in charge of that group? the committee, but I was never a formal member 19 19 I do not recall. of the committee. A. 20 20 Did you make any research Q. Were you involved in any 21 decisions regarding Protocol 007? 21 committees -- committee, I'll give you the A. I made -- I don't recall any name and tell me if you -- it jogs your 22 22 23 recollection, the Critical Assay Subcommittee, 23 specific decisions related to the protocol. 24 CAS? 24 There were activities that went on related to 25 25 the protocol in which I was involved and I remember the committee, but I Α Page 31 Page 33 do not believe I was a member. 1 participated. 2 Q. Did you -- were you consulted by 2 Q. Were you involved in something 3 called the Vaccine Assay Committee? 3 others in the conduct of 007? 4 4 A. I do not recollect, but I don't MS. DYKSTRA: Objection. Form. 5 5 believe I was a member. THE WITNESS: I was consulted Q. Did you -- were you a member of 6 with regards to the assays that were 6 7 developed and run in support of the 7 the Vaccine Marketing Committee? 8 study. 8 A. I don't even recall that 9 BY MR. BEGLEITER: committee, but I doubt I would have been a 10 member because normally someone from research What assets of the assays were would not have been part of the marketing 11 11 you consulted on? 12 committee. 12 Well, the assays were being 13 How about the Vaccine Product 13 conducted in the laboratory of Dr. David Krah, 14 14 and there were some questions that arose with Approval Committee, were you a member of that? regard to the assays. And because it was in 15 15 A. Again, that is probably a my employment relationship, I was obviously 16 marketing and regulatory committee. I don't 16 17 consulted. 17 recall the committee directly, but, again, I 18 doubt I would have been a formal part of it. 18 Q. Do you recall any of what those 19 Q. Did you ever attend any meetings 19 questions were? 20 of committees regarding competition? 20 A. The questions that arose, the 21 ones that I recollect very clearly are the 21 A. I do not recollect any 22 questions that arose subsequent to an FDA 22 specifically. 23 23 Q. Let me go back now to Protocol inspection that occurred of the laboratory in 24 24 007. I asked you questions about Protocol which the FDA inspector noted, if I recall, 25 25 006. four very specific observations that were part

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1	of a formal report from the agency and from	1	Ford-Hutchinson's title, if you recollect?
2	the inspector known as a Form 483. I recall	2	A. I honestly don't recollect. I
3	that correctly because that Form 483 was	3	mean, it was obviously a more senior title
4	because of my level, handed directly to me by	4	than mine, but I can't tell you.
5	the inspector.	5	Q. How did his responsibilities
6	Q. Was it appropriate for the	6	differ from yours?
7	inspector to hand it to you considering your	7	A. He had broader responsibilities
8	responsibilities or should it have been handed	8	over an entire range of departments within the
9	to somebody else?	9	research laboratories, all research
10	A. No, because the inspection was	10	departments. Again, clinical was a separate
11	related specifically to Dr. David Krah's	11	sphere of activities. So was regulatory.
12	laboratory and what was going on in there; and	12	Q. And the vaccine and biologics
13	because I was, as noted, the most senior level	13	research in '97 to 2002 was just involved with
14	person in that reporting relationship, I was	14	clinical research, is that right, clinical
15	the person.	15	studies?
16	Q. So when you said no you began	16	A. No. Again, that was my
17	your answer with no, and people do that all	17	department. That was the one that was
18	the time, so does that really mean yes, you	18	involved with research.
19	were the right person?	19	Q. I see. But that was your
20	A. Yes, I was the right person.	20	responsibility?
21	The answer to your question, no, I was not the	21	A. Research.
22	wrong person.	22	Q. Research. Okay.
23	Q. So tell me, so there was this	23	A. Just as it says. Vaccine and
24	reporting relationship between you and	24	Biologics Research.
25	Dr. Krah?	25	Q. Clinical research?
	Page 35		Page 37
1	A. Well, Dr. Krah, again, was in my	1	MS. DYKSTRA: Objection.
2	department, his direct reporting relationship	2	THE WITNESS: No, clinical
3	was with Dr. Shaw who was my direct report.	3	research was a function of the clinical
4	Q. And who did you report to in	4	research group. There were
5	those years, number 7?	5	collaborative events between my
6	A. I believe, and, again, this is	6	department, vaccine and biologics
7	because I reported to a fairly large number of	7	research, and the vaccine clinical
8	individuals over time because of the 22 years	8	research group. But the responsibility
9	I spent in the company, but upon review of the	9	was the clinical research group for the
10	documents, it appeared that at that time my	10	conduct of clinical studies.
11	direct supervisor was Dr. Anthony Ford-Hutchinson.		BY MR. BEGLEITER:
12	Q. Can you repeat the last name,	12	Q. Were you ever asked to consult
13	please?	13	on compliance defense for MMR II?
14	A. Ford-Hutchinson.	14	MS. DYKSTRA: Objection.
15	Q. Who did Dr. Anthony Ford-Hutchinson	15	BY MR. BEGLEITER:
16	report to?	16	Q. I'm talking, again, in this
17	A. He reported to at the time, if I	17	period from '97 to 2000.
18	recall correctly, was directly to Dr. Edward	18	MS. DYKSTRA: Did you say
19	Scolnick who was the head of the research	19	compliance defense?
20	laboratories. Though by that time, Dr. Peter	20	MR. BEGLEITER: That's what I
1 4U	laboratories. Though by that time. Dr. I etc.		
		21	said, compliance defense.
21	Kim had joined the company. I don't recall	21 22	said, compliance defense. THE WITNESS: It depends on your
21 22	Kim had joined the company. I don't recall exactly the time when that happened. So there	22	THE WITNESS: It depends on your
21 22 23	Kim had joined the company. I don't recall		THE WITNESS: It depends on your definition of the word "compliance" and
21 22	Kim had joined the company. I don't recall exactly the time when that happened. So there was some reporting relationship changes that	22 23	THE WITNESS: It depends on your

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Page 40 those in a number of different ways. 1 which was mine that reported independently 2 BY MR. BEGLEITER: 2 into the head of research. 3 Q. Well, did -- was the regulatory 3 Q. When you began in '07 -- excuse 4 group involved with -- at Merck involved with 4 me, in '97 with that position in biologics and 5 compliance in those years from '97 to '02? 5 vaccine, did you -- had MMR II been licensed, By definition the regulatory as far as you knew? 6 6 7 group is involved with compliance, right. 7 A. MMR II had been licensed for 8 And specifically with regard to 8 Q. many years prior to that. Decades. 9 9 007? Q. Did you know Dr. Hilleman? 10 A. 10 A. Yes, I had the pleasure of Yes. Did you ever -- did they ever 11 knowing Dr. Hilleman. As a matter of fact, 11 Q. the reason I joined the research laboratories 12 come to you and ask you any questions, for any 12 13 guidance, things like that? 13 in 1983 is because Dr. Hilleman was the head, 14 MS. DYKSTRA: Object to the had done all the work that he did. My 14 15 form. 15 interest was in vaccines. THE WITNESS: I do not 16 16 Q. Do you know if in '97 to '02, 17 recollect. In terms of specific 17 while you were with the vaccine and biologics 18 regulatory guidance, I've given -- but research, whether or not Merck had the 19 again, you know, that's a very general 19 exclusive license for mumps vaccine in the 20 term, guidance. So if it were general 20 United States? 21 regulatory guidance, no, because they 21 MS. DYKSTRA: Objection. Form. 22 22 THE WITNESS: Well, yes. And it were the experts in regulatory, so why 23 23 would they come to me for guidance. still does, I believe, yes. 24 BY MR. BEGLEITER: 24 BY MR. BEGLEITER: 25 25 Well, would they come to you, Eliminate that question. Page 39 Page 41 for example, if there was a regulatory 1 A. Yeah. 2 question regarding research? 2 Do you know if, again, in '97 to 3 MS. DYKSTRA: Objection. 3 '02, whether it perceived a potential 4 THE WITNESS: If there was a 4 competitor for that meaning, if Merck 5 regulatory question regarding the 5 perceived a potential competitor for its 6 activities of events that were going on 6 exclusive license for MMR II? 7 in laboratories that are responsible to 7 Merck is an institution. 8 me, yes, they would come to me, of 8 Perception is a human endeavor. So I can't 9 9 course. answer that question the way you posed it. 10 BY MR. BEGLEITER: 10 You can't answer the question 11 Let me understand how it worked 11 what you perceived? at Merck in those five years. People were 12 A. What I personally perceived? 12 13 collaborative. Is that correct? 13 Q. Yes, you're right. I asked if 14 A. There were independent 14 Merck perceived. I'll ask it as you, did you 15 departments that were responsible for various 15 perceive that Merck had a potential competitor? activities. So if we look within the entire A. I did not perceive that. 16 17 vaccine research effort, the entire vaccine 17 We discussed Priorix just for a 18 research and development effort included 18 moment or two in relation to another clinical within the overall responsibilities of the 19 19 trial. Do you -- what was your understanding 20 research laboratories, included the regulatory 20 in the '97 to '02 time period as to what 21 group which reported independently into head Priorix was? 21 of regulatory; the clinical research group 22 MS. DYKSTRA: Object to the 23 which reported independently into the head of 23 form. 24 medical and medical research; and then the 24 THE WITNESS: Priorix was the research group, the fundamental research group 25 GSK version of the vaccine, of Merck's

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1	MMR vaccine.	1	met Dr. Krah.
2	BY MR. BEGLEITER:	2	Q. Do you recollect that he was
3	Q. You understood that Priorix was	3	you supervised him during the period of time
4	GSK, GlaxoSmithKline's version, that there	4	April '97
5	was did you understand that there was	5	A. Yes, I do.
6	potential competition between the two	6	Q to January 2002?
7	vaccines?	7	A. Yes, I do.
8	MS. DYKSTRA: Objection.	8	Q. For that entire period?
9	THE WITNESS: Well, there's	9	A. As to the best of my recollection.
10	certainly competition worldwide between	10	Q. Everything is to the best of
11	the two vaccines, but in the United	11	your recollection.
12	States I did not perceive that as being	12	A. That's true.
13	a competitive issue.	13	Q. All right. Now, with regard to
14	BY MR. BEGLEITER:	14	Dr. Shaw, going back to Dr. Shaw for a second
15	Q. Were you involved with any kind	15	did you see him outside of work? Did you
16	of research outside the United States?	16	socialize?
17	A. Not that I recollect.	17	A. Not routinely in those days, no.
18	Q. Let's talk about Dr. Shaw. When	18	Subsequent to that, after I had left the
19	did you first meet Dr. Shaw? Approximately, I		company.
20	don't need the exact date.	20	Q. And how about with Dr. Krah, did
21	A. I don't recall. Dr. Shaw had	21	you socialize with him?
22	been at the company when I joined, when I	22	A. Never did.
23	joined the company. Met him probably very	23	Q. When was the last time you saw
24	early.	24	Dr. Krah?
25	Q. And when you became	25	A. I have not seen Dr. Krah since I
1	Page 43		Page 45
1	A. Or a little bit thereafter. I	1	left the company, so I can't tell you exactly
2	don't recall exactly.	$\frac{2}{2}$	when, but certainly not since I left the
3	Q. When you became the VP of	3	company.
4	vaccines and biologics research in '97, was he with that division?	5	Q. Did you ever work on any papers with Dr. Krah?
5		6	
6 7	A. With the vaccine, yes. With the	_	A. There were, I believe, some
8	vaccine research division, yes, he was with that division.	7 8	publications, but I can't they would be
9		9	listed in my CV. I don't remember exactly. It was quite a while.
10	Q. Okay. He was with the division	10	•
10	when you left that division in January of 2002?	11	Q. If a paper in these years of April '97 to January of '02, were there papers
12	A. You know, Dr. Shaw also left the	12	written regarding any clinical trials that you
13		13	were involved with?
14	first. I really don't.	14	A. Within that exact period, again,
15	Q. Would you say, though, that for	15	I don't recollect. We would have to look
13		16	through my CV, and you will see it.
16	a good period between April 97 and	10	• •
16 17	a good period between April '97 and January 2002 you were supervising Dr. Shaw?	17	() Was there any paper written
17	January 2002 you were supervising Dr. Shaw?	17 18	Q. Was there any paper written
17 18	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes.	18	regarding the trial where the head-to-head
17 18 19	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes. Q. It may not be to the actual end	18 19	regarding the trial where the head-to-head competition between Priorix and MMR II?
17 18 19 20	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes. Q. It may not be to the actual end but for a good period?	18 19 20	regarding the trial where the head-to-head competition between Priorix and MMR II? A. I don't recollect.
17 18 19 20 21	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes. Q. It may not be to the actual end but for a good period? A. As I said, I don't recall when	18 19 20 21	regarding the trial where the head-to-head competition between Priorix and MMR II? A. I don't recollect. Q. Was there any paper written
17 18 19 20 21 22	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes. Q. It may not be to the actual end but for a good period? A. As I said, I don't recall when we got to 2004 who had left first.	18 19 20 21 22	regarding the trial where the head-to-head competition between Priorix and MMR II? A. I don't recollect. Q. Was there any paper written between written regarding Protocol 007's
17 18 19 20 21 22 23	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes. Q. It may not be to the actual end but for a good period? A. As I said, I don't recall when we got to 2004 who had left first. Q. Let's go to Dr. Krah. Was	18 19 20 21 22 23	regarding the trial where the head-to-head competition between Priorix and MMR II? A. I don't recollect. Q. Was there any paper written between written regarding Protocol 007's results?
17 18 19 20 21 22	January 2002 you were supervising Dr. Shaw? A. During that period I was, yes. Q. It may not be to the actual end but for a good period? A. As I said, I don't recall when we got to 2004 who had left first.	18 19 20 21 22	regarding the trial where the head-to-head competition between Priorix and MMR II? A. I don't recollect. Q. Was there any paper written between written regarding Protocol 007's

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Page 48 recall. directly to me, but he had -- he did have an 2 Q. Now, when you and Dr. Shaw were 2 independent operation. He may have, I don't 3 3 working together sometime during the period of know. April to -- '97 to January of '02, how would 4 I'll ask the questions about 5 you characterize your working relationship Dr. Krah now, the same kind of questions. Was with him? 6 his office and your office in the same 7 A. With Dr. Krah, it was a very 7 building? 8 8 formal --A. Yes, we were all in the same 9 9 O. Dr. Shaw. building. 10 10 A. Dr. Shaw, yeah, the same way. O. How far was his office from your office? Very formal working relationship. He was one 11 11 of my direct reports, and all my direct 12 I would have been on a different 13 reports were very formal relationships. 13 floor, because I was on the floor that had the 14 Q. Did you and Dr. Shaw have 14 office areas. So he was laboratory 1, so he 15 offices in the same building? 15 would have been on one of the lab floors. A. Yes, next door to each other. 16 Your open door policy pertained 16 17 At least during this period, if I remember. 17 to him also. Is that correct? 18 18 Q. And if he wanted to see you -- Pertained to anybody. 19 19 withdrawn. So if he wanted to speak to you, 20 20 Did you have an open door policy did he have to go through a secretary or any 21 with regard to him? Could he just come to see 21 intermediary, any assistant? 22 you when he wished? 22 No. Only insofar if he could 23 I had a general open door 23 find me or he needed to find me if I wasn't Α. 24 policy. 24 immediately available. 25 25 Would you say that with Dr. Shaw Q. In fact, did Dr. Shaw see you Page 47 Page 49 frequently during the time that he worked 1 you had a close working relationship? 2 there close to the four years? 2 A. I had the standard working 3 3 relationship that one would have with one's A. It depends how you define the 4 word "frequently." Besides I can't -- I don't 4 direct reports. know. I mean, obviously there were multiple 5 Q. Did you trust Dr. Shaw? interactions between me and Dr. Shaw and all 6 A. Did I trust Dr. Shaw? 7 Q. Yes, if he told you something, 7 my direct reports and even other people. You 8 did you take it as gospel? 8 know, I was there all the time. Most of the 9 9 A. It depends. We're scientists, time. 10 10 So when you say multiple right, so if he told me a conclusion to Q. 11 interactions, you mean it wasn't a rare event 11 something or statement about something, I would usually ask for the supporting data. for you to be seeing Dr. Shaw? 12 12 13 13 Q. But if he told you a fact, like A. It was not a rare event for me 14 14 a fact regarding personnel, for example, would to see anybody who wanted to see me. Certainly you trust his statement? 15 15 with my direct reports that was true. 16 A. No, particularly when it comes 16 Q. Who other than Dr. Shaw was your 17 17 to -- again, everything. It's such a science, direct report in those four years? 18 A. The ones that I recollect 18 it's everything, right. You always need 19 directly were Dr. John Shiver and Kathrin 19 supporting data, right. So if someone comes, 20 20 and it doesn't matter who it is, and tells me Jansen. Those would be two -- among those 21 21 three, they ran the three major areas. a fact, I always ask for the supporting 22 22 Q. How about Peter Kniskern? information. Or if it's not immediately 23 A. Peter Kniskern, yes. Actually, 23 available and if it's an important fact to 24 24 determine -- that I would like to really now that you mention his name, I believe I --25 I don't formally recollect if he reported determine if it is a fact, I will ask -- I

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1	will go find the supporting data.	1	expiry potency in healthy children 12 to
2	Q. And did you ever find do you	2	18 months of age? Do you recognize those
3	recall anything he ever told you that turned	3	words?
4	out to be unreliable?	4	A. Yes, I do.
5	MS. DYKSTRA: Objection.	5	Q. What do you recognize them as?
6	THE WITNESS: No. I don't	6	A. I recognize them as what would
7	recollect anything like that.	7	likely have been the title of Protocol 007.
8	BY MR. BEGLEITER:	8	Q. Sitting here today, do you
9	Q. Let's go to Dr. Krah now for a	9	understand what the purpose of Protocol 007
10	second. I take it I'll ask the question.	10	was?
11	Did you respect Dr. Shaw?	11	A. Sitting here today and
12	A. Yes, I respected Dr. Shaw. I	12	subsequent to the review of the documents over
13	respected everyone.	13	the last period of time, yes.
14	Q. Let's go to Dr. Krah. Did he	14	Q. And what was that purpose or
15	ever tell you anything that you found to be	15	purposes?
16	unreliable?	16	A. The original purpose, to my
17	A. No, not to my recollection.	17	recollection, of the study was to determine
18	Q. And did you respect him?	18	whether or not the vaccine, if administered to
19	A. As I said, I respected everyone	19	children at various what were, used to be
20	who worked for me.	20	so-called potencies of the vaccine which would
21	Q. Is there anybody that ever	21	have reflected the amount of actual vaccine
22	worked for you that did something that you	22	virus that is in the vaccine, raised
23	lost respect for them?	23	potencies, were capable of eliciting immune
24	A. No, because that would have	24	responses that were reflective of the immune
25	probably losing respect for me means	25	response, that were reflective of the immune
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1	essentially doing something which is overtly	1	response that would be elicited by the
2	wrong. And that I did not, to my	2	vaccine, and to determine whether or not those
3	recollection, see anything like that in those	3	immune responses were equivalent at I
4	years, or for that matter any subsequent years	4	believe there were several levels of potencies
5	or any previous years.	5	that were tested in the study.
6	Q. Did you trust Dr. Krah's ability	6	Q. And it was the expiry potencies
7	to keep you informed of essential goings on in	7	that were being looked at. Is that correct?
8	the lab?	8	A. Well, the study was designed to
9	A. He would have kept Dr. Shaw	9	evaluate three different potencies. Now,
10	informed who, in turn, would have kept me	10	would they how they related to the
11	informed.	11	potential of their being declared as expiry
1		1	1 comg accimea as expiri
	O. So if Dr. Krah told Dr. Shaw	12	potencies was part of the entire larger
12	Q. So if Dr. Krah told Dr. Shaw something important, you would expect at least	12	potencies was part of the entire larger question that was being addressed.
12 13	something important, you would expect at least	13	question that was being addressed.
12 13 14	something important, you would expect at least Dr. Shaw to tell you?	13 14	question that was being addressed. Q. Was one of the potencies that
12 13 14 15	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection.	13 14 15	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the
12 13 14 15 16	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw	13 14 15 16	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II?
12 13 14 15 16 17	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of	13 14 15 16 17	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency?
12 13 14 15 16 17 18	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable.	13 14 15 16 17 18	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's
12 13 14 15 16 17 18 19	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable. BY MR. BEGLEITER:	13 14 15 16 17 18 19	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's say release potency?
12 13 14 15 16 17 18 19 20	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable. BY MR. BEGLEITER: Q. Let me ask you a question. Do	13 14 15 16 17 18 19 20	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's say release potency? A. Well, no. To my recollection,
12 13 14 15 16 17 18 19 20 21	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable. BY MR. BEGLEITER: Q. Let me ask you a question. Do you recall the official title of Protocol 007?	13 14 15 16 17 18 19 20 21	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's say release potency? A. Well, no. To my recollection, the three potency levels that were being
12 13 14 15 16 17 18 19 20 21 22	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable. BY MR. BEGLEITER: Q. Let me ask you a question. Do you recall the official title of Protocol 007? A. No, I don't. I did not review	13 14 15 16 17 18 19 20 21 22	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's say release potency? A. Well, no. To my recollection, the three potency levels that were being assessed were being assessed as potential
12 13 14 15 16 17 18 19 20 21 22 23	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable. BY MR. BEGLEITER: Q. Let me ask you a question. Do you recall the official title of Protocol 007? A. No, I don't. I did not review the protocol.	13 14 15 16 17 18 19 20 21 22 23	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's say release potency? A. Well, no. To my recollection, the three potency levels that were being assessed were being assessed as potential at expiry potency levels. So one of them
12 13 14 15 16 17 18 19 20 21 22	something important, you would expect at least Dr. Shaw to tell you? MS. DYKSTRA: Objection. THE WITNESS: If Dr. Shaw perceived it to be at the same level of importance and supportable. BY MR. BEGLEITER: Q. Let me ask you a question. Do you recall the official title of Protocol 007? A. No, I don't. I did not review	13 14 15 16 17 18 19 20 21 22	question that was being addressed. Q. Was one of the potencies that was being looked at the current potency at the time of MMR II? A. The current expiry potency? Q. Well, the current potency, let's say release potency? A. Well, no. To my recollection, the three potency levels that were being assessed were being assessed as potential

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Page 56 the time. 1 Not to change the question, The 2 Q. And that -- do you recall what 2 question is too broad. So it's difficult for 3 the potency level was of that, of the vaccine 3 me to answer which is why I'm hesitating here. 4 4 The label potency, so are you referring to as --5 I don't know. 5 A. expiry potency or the release potency? It You mentioned now a few times 6 Q. 6 depends. They're two different things. 7 there are three potencies. 7 Q. Did the label, when you were at 8 A. There were three potencies, 4.3, 8 Merck, have an expiry potency on it? 9 9 4.1 and 3.7. A. The label had a potency on it. 10 10 O. 4. --What had -- potency. The question as to A. 4.3, 4.1 and 3.7. Again, that 11 11 whether or not it should be the expiry -formally established as the expiry potency, 12 was from my review of the documents. 13 Knowing what you know, was one that number was a question that had been 13 14 of those potencies the potency on the label? 14 raised by the FDA in previous discussions. 15 The label at the time indicated, 15 Q. So did Merck, as far as you 16 and what raised the question to begin with, know, take the position that that 4.3 was good 16 17 the label that had been present since the 17 enough, was a good number for the potency of virus -- since the vaccine, rather, had been 18 the vaccine at expiry? 19 originally licensed was a potency level of, I 19 A. Its position was that that 20 believe it was 4 -- it was the 4.3 potency 20 number was good enough at expiry and probably 21 level. But what the label said -- again, upon 21 also good enough at original release. Because 22 my review of that original label, it said that 22 the way the original label was written 23 the vaccine contains, you know, 4.3 logs of 23 suggested, this goes back decades, suggested 24 mumps virus. 24 that that number was reflective of the amount 25 25 Q. When you became involved with of vaccine virus that was used to actually Page 57 1 produce the vaccine. Protocol 007, was -- did anyone communicate to you from Merck that there was a desire to 2 Q. Do you know how much virus was 2 3 lower the labeled potency? 3 used to produce the vaccine? 4 4 A. Not that there was a direct MS. DYKSTRA: Objection to form. 5 5 desire to lower the label potency but rather THE WITNESS: No, I don't other to determine if the -- what were likely to be 6 than what it says. So if I were to 7 read the label at face value, what goes 7 the end of shelf life potencies, which would 8 in is -- when it was originally 8 be, of course, the expiry potency, were 9 developed was approximately 4.3 logs of 9 potencies that were capable of eliciting 10 immune responses that would be -- again, mumps virus. 11 remember the assays that one uses are indirect 11 BY MR. BEGLEITER: 12 measures of immune responses -- rather 12 Q. What is -- well, let me ask, do 13 indirect measure of what the effect of an 13 you know what 4.3 logs comes to in terms of 14 immune response might be, it's not the direct 4.3 logs, four logs would be measure. But to determine whether or not 15 16 10,000, so that would be roughly 20,000. there were equivalent abilities to elicit 17 One less document to look at. 17 immune responses to the vaccine. 18 18 Q. Okay. But was -- I understand So approximately 20. Is the 19 that, but I'm asking whether or not anybody 19 scientific way of referring to it, would that 20 20 be -- of the 4.3, would that be 4.3 log10 told you that they wanted to change the label 21 TCID50? 21 potency? 22 22 MS. DYKSTRA: Objection to form. So that would be 4.3 log to the 23 23 BY MR. BEGLEITER: base ten, because there are multiple logs that 24 24 This is, again, the period '97 are not base ten, but that's log to the base Q. 25 10, tissue culture, 50 percent tissue culture 25 to '01.

15 (Pages 54 - 57)

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	Page 58	1	Page 60
1	effective doses.	1	in collaboration of this, yes.
2	Q. Let's return to the 006	2	Q. Were there contracts with these
3	excuse me, to the head to head, the Priorix	3	outside laboratories?
4	versus MMR II. Do you know why that study was	4	A. It depended on the nature of the
5	conducted?	5	study. It could have been research
6	A. I don't recollect.	6	collaborations, it could have been contracts
7	Q. Do you know what the results	7	to do specific work.
8	were?	8	Q. Do you know whether there was a
9	A. I do not recollect directly.	9	contract, whether an outside lab did work on
10	Q. Do you know if they were	10	that head-to-head study of Priorix and MMR II?
11	published?	11	A. I don't recollect.
12	A. I don't recollect.	12	Q. When Merck retains an outside
13	Q. Do you recall who won in that	13	lab withdrawn.
14	head to head?		Were you involved ever with
15	MS. DYKSTRA: Objection.	15	determining whether an outside lab should be
16	THE WITNESS: I don't recollect	16	used in a Merck study?
17	the results.	17	A. I don't recollect in the context
18	BY MR. BEGLEITER:	18	of MMR II or within this time, but other
19	Q. I'm not asking specific results,	19	points of my responsibility there I was
20	I'm asking just a general question. Did	20	involved, yes.
21	either one of them turn out to be a better one	21	Q. What criteria, if you know, were
22	than the other?	22	used by Merck to determine whether or not
23	A. I don't recollect. I really	23	let me finish whether or not an outside
24	don't.	24	laboratory was competent?
25	Q. Were you involved with budgets	25	A. It depended on the work that
	Page 59		Page 61
1	at all?	1	needed to be done.
2	A. Only with regard to the budgets	2	Q. How would Merck go about doing
3	in my own department.	3	the analysis?
4	Q. Did you was there a budget	4	A. It would depend on the work that
5	for Protocol 007?	=	
		5	needed to be done and an assessment would
6	A. That would not have been in my	6	probably be performed of the laboratory and
6 7	A. That would not have been in my responsibility. My responsibility were the	6 7	probably be performed of the laboratory and to make sure that it would maintain the
6 7 8	A. That would not have been in my responsibility. My responsibility were the budgets of the overall department. I would	6 7 8	probably be performed of the laboratory and to make sure that it would maintain the appropriate standards, generated reproducible
6 7 8 9	A. That would not have been in my responsibility. My responsibility were the budgets of the overall department. I would not have been responsible for the budgets of a	6 7 8 9	probably be performed of the laboratory and to make sure that it would maintain the appropriate standards, generated reproducible data. Typical.
6 7 8 9 10	A. That would not have been in my responsibility. My responsibility were the budgets of the overall department. I would not have been responsible for the budgets of a specific study.	6 7 8 9 10	probably be performed of the laboratory and to make sure that it would maintain the appropriate standards, generated reproducible data. Typical. Q. Merck wouldn't contract with an
6 7 8 9 10 11	A. That would not have been in my responsibility. My responsibility were the budgets of the overall department. I would not have been responsible for the budgets of a specific study. Q. Who would have been?	6 7 8 9 10 11	probably be performed of the laboratory and to make sure that it would maintain the appropriate standards, generated reproducible data. Typical. Q. Merck wouldn't contract with an outside laboratory, as far as you know, that
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That would not have been in my responsibility. My responsibility were the budgets of the overall department. I would not have been responsible for the budgets of a specific study. Q. Who would have been? A. The medical research group. Q. And who was in charge of that then, do you know? A. I honestly don't recall. Q. Did you ever review the budget? MS. DYKSTRA: Objection. THE WITNESS: No, I would not review the budget of a clinical study. BY MR. BEGLEITER: Q. While you were at Merck, would	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	probably be performed of the laboratory and to make sure that it would maintain the appropriate standards, generated reproducible data. Typical. Q. Merck wouldn't contract with an outside laboratory, as far as you know, that was incompetent? MS. DYKSTRA: Objection. THE WITNESS: Of course not. BY MR. BEGLEITER: Q. Or lacked integrity? A. Of course not. Q. Was not professional? A. Of course not. Q. Now, you mentioned a few moments ago that there was this difference of opinion between Merck and the FDA regarding the end
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. That would not have been in my responsibility. My responsibility were the budgets of the overall department. I would not have been responsible for the budgets of a specific study. Q. Who would have been? A. The medical research group. Q. And who was in charge of that then, do you know? A. I honestly don't recall. Q. Did you ever review the budget? MS. DYKSTRA: Objection. THE WITNESS: No, I would not review the budget of a clinical study. BY MR. BEGLEITER: Q. While you were at Merck, would outside labs ever do work for Merck? A. That was routine practice.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	probably be performed of the laboratory and to make sure that it would maintain the appropriate standards, generated reproducible data. Typical. Q. Merck wouldn't contract with an outside laboratory, as far as you know, that was incompetent? MS. DYKSTRA: Objection. THE WITNESS: Of course not. BY MR. BEGLEITER: Q. Or lacked integrity? A. Of course not. Q. Was not professional? A. Of course not. Q. Now, you mentioned a few moments ago that there was this difference of opinion between Merck and the FDA regarding the end expiry potency that was on the label? MS. DYKSTRA: Objection.
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	Page 62		Page 64
1	recollection, it was not a difference	1	Merck challenged that mandate, that conclusion
2	of opinion. What it was was that the	2	of the FDA?
3	label indicated that the potency of the	3	MS. DYKSTRA: Objection. Form.
4	vaccine was 4.3 logs of mumps. The	4	THE WITNESS: I don't think
5	vaccine like every pharmaceutical	5	anyone necessarily challenged it. I
6	product has a shelf life. The agency's	6	think that what it was was a question
7	position in the late 1990s was, and	7	that came up which said simply that if
8	this was at a time that they were	8	now this number of 4.3 is to be
9	reviewing their internal rules and	9	considered the end expiry potency and,
10	regulations, took the position that	10	of course, given that, just like any
11	what was listed on the label as the	11	pharmaceutical product, the product
12	potency needed to reflect the potency	12	does decay over time, it's second law
13	at the end of shelf life, hence the	13	of thermodynamics, does decay over time
14	expiry potency.	14	on storage, then the question is, you
15	BY MR. BEGLEITER:	15	know, is the end expiry potentially
16	Q. Do you know what the shelf life	16	somewhat less than 4.3. We don't know.
17	of MMR II was?	17	And, therefore, should the number be,
18	A. I believe it was approximately	18	in fact, lower to really represent end
19	24 months at the time. I believe. I don't	19	expiry potency.
20	recall directly, to be honest.	20	BY MR. BEGLEITER:
21	Q. When you say "approximately,"	21	Q. First of all, when you were
22	you mean because you're not 100 percent sure	22	dealing with the FDA, was there a specific
23	or because	23	division of the FDA that you would deal with?
24	A. No, it's because I'm not 100	24	A. The division at the FDA was the
25	percent certain. Normally the shelf life	25	old division that was referred to as the
	P 62	1	
	Page 63		Page 65
1	would be it wouldn't be 23 months, it would	1	Bureau of Biologics, then became known as the
2	would be it wouldn't be 23 months, it would be 24 months or 36 months, something of that	2	Bureau of Biologics, then became known as the Center for Biologics, Evaluation and Research.
2 3	would be it wouldn't be 23 months, it would be 24 months or 36 months, something of that nature.	2 3	Bureau of Biologics, then became known as the Center for Biologics, Evaluation and Research. It's the same division that is responsible
2 3 4	would be it wouldn't be 23 months, it would be 24 months or 36 months, something of that nature. Q. The people at the FDA that	2 3 4	Bureau of Biologics, then became known as the Center for Biologics, Evaluation and Research. It's the same division that is responsible today for vaccines.
2 3 4 5	would be it wouldn't be 23 months, it would be 24 months or 36 months, something of that nature. Q. The people at the FDA that you that would be withdrawn.	2 3 4 5	Bureau of Biologics, then became known as the Center for Biologics, Evaluation and Research. It's the same division that is responsible today for vaccines. Q. And that Center for Biologics
2 3 4 5 6	would be it wouldn't be 23 months, it would be 24 months or 36 months, something of that nature. Q. The people at the FDA that you that would be withdrawn. There was a question, if I used	2 3 4 5 6	Bureau of Biologics, then became known as the Center for Biologics, Evaluation and Research. It's the same division that is responsible today for vaccines. Q. And that Center for Biologics was known colloquially as CBER?
2 3 4 5 6 7	would be it wouldn't be 23 months, it would be 24 months or 36 months, something of that nature. Q. The people at the FDA that you that would be withdrawn. There was a question, if I used the word before, there was a question about	2 3 4 5 6 7	Bureau of Biologics, then became known as the Center for Biologics, Evaluation and Research. It's the same division that is responsible today for vaccines. Q. And that Center for Biologics was known colloquially as CBER? A. Center For Biologics,
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Page 68 1 O. And then --1 my recollection, but -- no, not to my 2 MS. DYKSTRA: Can he finish? 2 recollection. But it depends, again, what you 3 BY MR. BEGLEITER: 3 defined as end expiry trials. In the 4 Q. I'm sorry, I thought you were 4 development of any pharmaceutical substance, 5 finished. 5 there are studies that are conducted, you A. No. So the agency, taking a 6 6 know, certainly in current last period of 7 conservative position at that time in the late time. Let's go back to, let's call it the 8 1990s, said that number should reflect the end last 20 years. There are studies that are 9 expiry potency. It was a declaration by the typically conducted to determine what should 10 agency. There was no data at that time to 10 be the end expiry potency, however you define support whether or not vaccine that contained, potency, in the label. But that was not the 11 11 actually contained less than 20,000 at end 12 12 standard going back certainly to the 1960s and expiry would not be effective. There was no 13 early 1970s. 14 data to support that. It was simply a 14 Q. Well, are you aware -- there's 15 declaration. 15 no doubt that Protocol 007 was an end expiry Q. Now, the declaration of 20,000 16 16 study. Right? TCID50 --17 17 A. That was to answer a very 18 A. At end expiry. 18 specific question, which was, what would the 19 Q. -- at end expiry, CBER wanted to 19 potency of the -- what would the immunological 20 know if that was true. Isn't that right? 20 potency of the vaccine be. That's what that MS. DYKSTRA: Objection. 21 study was designed to measure. What was the 21 22 THE WITNESS: What do you mean 22 immunological potency of the vaccine at levels 23 by "true"? 23 that were below 4.3. 24 BY MR. BEGLEITER: 24 The vaccine was -- there was 25 In other words, that was what --25 never a question by the agency or by Merck as Page 67 Page 69 if one tested the vaccine, one would find to whether or not the vaccine that was being 1 2 20,000 TCID50? 2 used was effective or not. It was effective. 3 MS. DYKSTRA: Objection. 3 The question was, okay, what level is still --4 THE WITNESS: No, that's not to 4 what level should be present, what level, what 5 my recollection as to whether or not 5 potency level, use that terminology, should 6 that question came up. The question 6 still be present in the vaccine at the end of 7 that came up was whether or not the 7 shelf life that reflects the effectiveness of 8 vaccine would retain potency at what -the vaccine. Because remember, 4.3 was simply 9 that the potency that was present at 9 a declaration, not based on data. 10 20,000 was also retained at levels 10 It was known that the vaccine at 11 below 20,000, on the assumption that if 11 4.3 was effective because it was originally 12 20,000 was considered to be the release designed to have 4.3 in it at release and, 12 13 potency, that there was a likelihood 13 therefore, that was what probably was present 14 that at the end of the shelf life, this 14 at the time that the efficacy studies were 15 effective vaccine would contain less 15 ongoing, but there was no evidence of any loss 16 than 20,000 so, therefore, what is that of efficacy over time. 16 17 number, so that one could actually put 17 Q. Let's maybe have some 18 an end expiry number in the label that 18 definitions. What is immunological potency? 19 was reflective of the actual potency of 19 A. Immunological potency is -- so 20 an effective vaccine. 20 when immunological potency, the question -- so 21 BY MR. BEGLEITER: 21 let's do it -- it's a broad question. So 22 Q. During your time at Merck in the 22 we'll do it in the context of the 007 trial. 23 biologic and -- vaccine biologics research, The 007 trial was designed to 23 24 had there been any other end expiry trials? 24 determine whether or not different levels of 25 Not -- had there been? Not to the vaccine or the vaccine produced that

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Page 72 contained different levels of the mumps virus, 1 was something -- this was a general 2 right, 4.3, 4.1, 3.7 logs, were capable, were 2 concern that had arisen within the each capable of equivalently eliciting immune 3 agency around this time, not just 3 responses as measured, that's a key point, as 4 related to mumps but to every other 4 5 product that they were responsible for measured, that were reflective of the immune 6 regulating over the issue of control. response that would be elicited by the 7 How do you know that the product that 7 vaccine. 8 you make is the same all the time and 8 Q. Can you give me a definition of 9 how do you know that the product that 9 what you mean by "efficacy"? 10 10 you use, that includes the product all A. Efficacy has a very specific definition. It is whether or not -- well, 11 the way up to the end of expiry, is the 11 same all the time with regards again, it depends the context of the product. 12 primarily to its efficacy. 13 But in the context of a vaccine is whether or 13 14 BY MR. BEGLEITER: 14 not the vaccine, okay, is effective in a 15 clinical setting to prevent disease caused by 15 Q. How do you know the -- how do the pathogen against which the vaccine is 16 you know that the FDA was requiring this in 16 17 17 more than MMR II? designed to be effective. 18 18 This was across the industry. Q. Now, let me just see if I 19 19 These questions came up across the industry understand what you said about the direction 20 from the FDA, from CBER. Are you saying that 20 with regards to how does one tighten the 21 language in the label, how does one tighten 21 CBER had no scientific basis, at the time that 22 manufacturing control processes, you know, 22 007 was begun, to direct that Merck have 23 23 this -- have 4.3 TCID whatever at expiry? because there were many issues, and which 24 TCID50, I'm sorry. Because you said a couple 24 were, again, across the industry in general, 25 25 roughly around this time, late 1990s, early of times --Page 71 1 Please be more specific in your 1 2000s. And as a result, language needed to be 2 question. 2 tightened in the labels. This is an example 3 Well, I believe you said that 3 of that. Additional control processes needed Q. to be put into place during manufacturing for 4 the FDA was acting conservatively --4 5 5 Right. a whole number of other vaccines. This was, 6 -- when they required this end 6 again, and it wasn't -- I just want to make 7 expiry study. And I'm asking you whether or 7 the point, it wasn't Merck specific, it was not there was any scientific reason, health 8 industry specific. 9 9 Q. Can you name other vaccines that reason, medical reason to do it? 10 10 were required to tighten up their labels? MS. DYKSTRA: Objection to form. THE WITNESS: To my knowledge, 11 11 A. Well, not just tighten up their 12 labels but tighten up general controls in to my knowledge, and based upon the way 12 13 in which the questions were asked, the 13 general. I will tell you that there was a 14 study was conducted and subsequent 14 major, a major turnover of the vaccine 15 industry in those days as a result of the discussions, you know, between the 15 16 agency and the company, the agency did agency insisting on tighter perspectives. 17 not have a reason to declare 4.3 as a 17 There were vaccines that were marketed that 18 were taken off the market. None of them being requirement because of fear that there 18 19 would be loss of efficacy or that the 19 Merck. Other companies, and we won't go into vaccine was not efficacious at levels 20 20 those details. 21 less than 4.3. There's no evidence for 21 Can you name a vaccine that O. 22 22 was -- where label was tightened and controls that.

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were tightened in this period because of this

I can't name one directly off

23

24

25

agency effort?

A.

The reason why the agency

declared end expiry should be 4.3 was

because the agency was concerned, this

23

24

25

1	Page 74		Page 76
1	the top of my head, but it was general	1	occurred.)
2	activity that was ongoing.	2	
3	Q. Do you know what level of	3	BY MR. BEGLEITER:
4	immunogenicity that was required of the MMR II	4	Q. I've shown you Merck KRA01449029
5	vaccine?	5	through 9040, and ask you what this document
6	MS. DYKSTRA: Objection.	6	is, if you know?
7	THE WITNESS: So, again, not	7	A. This appears to be the label or
8	that I recall at the time itself but in	8	what is also referred to as the package insert
9	reviewing the documents over the last	9	for MMR II. What I cannot tell by just
10	several periods of time, what the	10	looking at it is which year this package
11	agency was looking for was looking for	11	insert came from.
12	an immunological assay that was capable	12	Q. Let me if you go right to the
13	of showing that the vaccine, when used	13	very end, the very end, page 12.
14	at what they were now calling the end	14	A. Issued date is April 1999.
15	expiry value of 4.3, would be able to	15	Thank you.
16	demonstrate at least a 90 percent	16	Q. All I'm going to ask you about
17	seroconversion.	17	this document is the is what the label said
18	BY MR. BEGLEITER:	18	about the seroconversion rate for the mumps
19	Q. Was that 90 percent including a	19	component of MMR II. And if you go to the
20	5 including some	20	carryover paragraph from page 1 to page 2, I
21	A. Variance.	21	think that might have the answer.
22	Q. Some I'm trying to think of	22	MS. DYKSTRA: I'm sorry, do you
23	the word. Some confidence interval?	23	want him to identify anywhere the label
24	A. Confidence interval. It's in	24	talks about seroconversion rate?
25	the report here. Confidence interval which is	25	MR. BEGLEITER: No, I'm asking
	Page 75		Page 77
1	the variance.	1	him just basically to refresh his
2	All biological assays and all	2	recollection.
2			
3	assays in general by definition have	3	THE WITNESS: Okay.
4	confidence intervals.	3 4	THE WITNESS: Okay. BY MR. BEGLEITER:
	confidence intervals. Q. So the 90 percent was with the	3 4 5	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the
4	confidence intervals. Q. So the 90 percent was with the confidence?	3 4	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the carryover sentence
4 5	confidence intervals. Q. So the 90 percent was with the confidence? A. 90 percent would have been the	3 4 5 6 7	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the carryover sentence A. Yes, I have.
4 5 6 7 8	confidence intervals. Q. So the 90 percent was with the confidence? A. 90 percent would have been the point estimate. You would then point	3 4 5 6 7 8	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the carryover sentence A. Yes, I have. Q is your recollection refreshed
4 5 6 7 8 9	confidence intervals. Q. So the 90 percent was with the confidence? A. 90 percent would have been the point estimate. You would then point estimate being the midpoint of the confidence	3 4 5 6 7 8 9	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the carryover sentence A. Yes, I have. Q is your recollection refreshed as to the SCR required of the vaccine?
4 5 6 7 8 9 10	confidence intervals. Q. So the 90 percent was with the confidence? A. 90 percent would have been the point estimate. You would then point estimate being the midpoint of the confidence interval.	3 4 5 6 7 8 9 10	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the carryover sentence A. Yes, I have. Q is your recollection refreshed as to the SCR required of the vaccine? MS. DYKSTRA: Objection.
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4 5 6 7 8 9 10 11 12 13	confidence intervals. Q. So the 90 percent was with the confidence? A. 90 percent would have been the point estimate. You would then point estimate being the midpoint of the confidence interval. Q. Do you recall what the label said about the A. I do not recall what the label	3 4 5 6 7 8 9 10 11 12 13	THE WITNESS: Okay. BY MR. BEGLEITER: Q. Just ask you, having read the carryover sentence A. Yes, I have. Q is your recollection refreshed as to the SCR required of the vaccine? MS. DYKSTRA: Objection. THE WITNESS: This is not the SCR that is required. What it says here is that, very clearly, that
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Page 80 1 observed in the clinical study that is what 007 was, of the ability of the vaccine at 2 being referenced. It is not a 2 three different dosage levels, its ability to 3 requirement. 3 elicit a seroconversion response in young 4 BY MR. BEGLEITER: 4 children, one wants as sensitive a vaccine as 5 O. But this document, is this an 5 possible -- excuse me, as sensitive an assay insert for the vaccine? 6 as possible. If the vaccine were not capable 6 7 Yes, it is. of eliciting a seroconversion of at least 90 8 And this, as far as you know, is 8 percent given the assay that you developed, 9 9 given to every medical center, physician who you wouldn't be able to tell the difference 10 A. Whoever purchases the vaccine 10 between 90 percent or a few percentage points gets an insert because it's in the box. 11 later, because typically the lower the 11 midpoint of what you measure, the wider the 12 And when you answered 90 percent 12 before, what were you reserving to there? 13 13 confidence intervals and it becomes difficult 14 I was referring specifically to 14 to discern what's happening. 15 the context of the 007 clinical trial and what 15 Q. Just to be straightened out, the 16 the agency, the FDA was looking for in terms 16 90 percent you're talking about is pre the 17 of the quality of the assay that was being 17 confidence interval or post the confidence used to assess the immunological response to 18 interval? 19 the vaccine. That's a different situation 19 No, I view it as -- I interpret 20 20 than what's in the label here. This label is it as the midpoint of the confidence interval. 21 reporting data from its original efficacy 21 O. So in other words, it could be 22 study. We need to recall that what you 22 from 95 to 85? 23 23 measure is a function of how you measure it. A. If the confidence interval --24 That the assay that was used back when this 24 Q. If it were 5 percent. 25 clinical study was originally conducted, and, 25 A. -- were 5 percent, it would be Page 79 Page 81 referred to as 90 percent plus or minus 5 again, I need -- I don't know if it's 1 2 appropriately referenced here so we can go 2 percent. 3 back to see when the study was originally 3 MR. BEGLEITER: We can have our conducted, we'll have to read and take a look 4 4 break. 5 5 at it, but I'm certain it was many decades VIDEOGRAPHER: The time is 6 before the late 1990s because that was when 6 10:54. Going off the video record. 7 the vaccine was first licensed. That assay 7 was no longer in existence by the time of the 8 (A recess was taken.) 9 007 study. So a new assay had to be developed 9 and the agency wanted the assay to be 10 VIDEOGRAPHER: The time is sensitive. What I mean by sensitivity, it 11 11 11:09. We're back on the video record. 12 needed to be able to discern a difference in 12 MS. DYKSTRA: Dr. Emini, you 13 the seroconversion rate that could be elicited 13 asked him about the different arms in by 4.3, 4.1 and 3.7. Those were the three 14 the 007 study and what the potencies 15 were in the different arms. I think 15 comparators, right, that were being done. It had nothing to do with what was originally 16 you may want to clarify what they were. 17 done many decades ago. 17 He didn't have anything in front of him 18 18 So the 90 percent you're talking at the time, but he can clarify. 19 about which is post the confidence interval --19 THE WITNESS: I mentioned they 20 A. No, the 90 percent is, I 20 were 4.3, 4.1, 3.7. My apologies. The 21 presume, but the 90 percent, because in the 21 levels that were being tested were 4.9, documents I saw the number that I recollect 22 4.0 and 3.7. 23 was 90 percent, 90 percent is a measure of the 23 BY MR. BEGLEITER: 24 assay sensitivity. So, for instance, if one 24 Q. Now, in going back to the wants to look at -- do a comparison, which is 25 seroconversion rate for a moment, was -- did

21 (Pages 78 - 81)

1	Page 82 CBER ever communicate to you that they were	1	Page 84 assay was capable of measuring a seroconversion
2	looking for a 95 percent seroconversion rate?	2	rate that would be then statistically capable
3	A. To me?	3	of determining a difference in seroconversion
4	Q. Yes.	4	among the three levels of vaccine potency that
5	A. No, there was no communication.	5	were being tested in the protocol.
6	Q. Were you ever told by anyone at	6	Q. But they weren't interested in
7	Merck that they were looking that CBER was		the end result, they were interested only in
8	looking for 95 percent seroconversion rate?	8	the differences?
9	A. Not at all to my recollection.	9	A. They were interested in the
10	Q. Now, when Protocol 007 was in	10	differences because that was the critical
11	development, did a decision have to be made	11	aspect. The three levels of potency that were
12	about which strain of mumps vaccine which	12	being tested give rise to three if they
13	strain of mumps virus was going to be used for	13	would, would they give rise to three different
14	the assays?	14	seroconversion levels.
15	A. Yes.	15	Q. Can you name any of the wild
16	Q. And do you recall sitting here	16	type vaccines excuse me, any of the wild
17	today what the candidates were for let me	17	type strains of mumps that were available?
18	finish the question for the strain for the	18	A. No, I don't recollect them off
19	protocol?	19	the top of my head. The only one I can name
20	A. For the assays?	20	is the one that was in actual use for the
21	Q. For the assays.	21	assay itself.
22	A. For the assays and protocol.	22	Q. And what was the name of that?
23	There were two assays, one was a plaque	23	A. That was referred to as a low
24	reduction neutralization assay, the other was	24	passage Jeryl Lynn strain.
25	an ELISA assay as I said previously. Just so	25	Q. And that was the strain that was
	Page 83		Page 85
1	we're clear, we're always talking two assays	1	used by Dr. Hilleman to come up with the mumps
2	here.	2	vaccine?
3	No, I don't recall what the	3	MS. DYKSTRA: Objection.
4	candidates were other than the fact, and	4	THE WITNESS: So that was the
5	again, this came from my review over the last	5	it was no, it wasn't the exact one.
6	period of time of documents, other than the	6	This was a low passage Jeryl Lynn
7	fact that the candidate had to be a so-called	7	strain. So this was the way in
8	wild type virus. It could not be the vaccine	8	which this was done is that the virus
9	virus itself.	9	was originally isolated from Jeryl
10	Q. And were assays taken	10	Lynn, who happened to be Dr. Hilleman's
11	preliminarily of some of the wild type	11	daughter actually, from was isolated
12	viruses?	12	from Jeryl Lynn and became known as the
13	MS. DYKSTRA: Object to the	13	Jeryl Lynn virus. Then the virus was
14	form.	14	then passaged in cell cultures many,
15	THE WITNESS: I don't recollect	15	many, many times to attenuate it, in
16	the details of any work that was done	16 17	other words, to make it less capable of
17	alama thaga limag	1 /	causing disease but yet still eliciting
1	along those lines.		an immuna raspansa I da nat maall
18	BY MR. BEGLEITER:	18	an immune response. I do not recall
18 19	BY MR. BEGLEITER: Q. And just, again, if you don't	18 19	the exact passage of the Jeryl Lynn
18 19 20	BY MR. BEGLEITER: Q. And just, again, if you don't with regard to these wild type viruses, was	18 19 20	the exact passage of the Jeryl Lynn virus that then became the exact strain
18 19 20 21	BY MR. BEGLEITER: Q. And just, again, if you don't with regard to these wild type viruses, was there an expectation from CBER as to what the	18 19 20 21	the exact passage of the Jeryl Lynn virus that then became the exact strain that is used in the vaccine. The low
18 19 20 21 22	BY MR. BEGLEITER: Q. And just, again, if you don't with regard to these wild type viruses, was there an expectation from CBER as to what the seroconversion rate would be for those wild	18 19 20 21 22	the exact passage of the Jeryl Lynn virus that then became the exact strain that is used in the vaccine. The low passage version was considered to be,
18 19 20 21 22 23	BY MR. BEGLEITER: Q. And just, again, if you don't with regard to these wild type viruses, was there an expectation from CBER as to what the seroconversion rate would be for those wild type viruses?	18 19 20 21 22 23	the exact passage of the Jeryl Lynn virus that then became the exact strain that is used in the vaccine. The low passage version was considered to be, appropriately so, a wild type virus,
18 19 20 21 22	BY MR. BEGLEITER: Q. And just, again, if you don't with regard to these wild type viruses, was there an expectation from CBER as to what the seroconversion rate would be for those wild	18 19 20 21 22	the exact passage of the Jeryl Lynn virus that then became the exact strain that is used in the vaccine. The low passage version was considered to be,

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1	Page 86	1	Page 88
1	it was a virus that if one, in fact,	1	was I don't recollect the exact
2	put it into a child would more likely	2	details of the discussions. What I can
3	than not actually cause disease.	3	say is that both assays were used, the
4	BY MR. BEGLEITER:	4	plaque reduction neutralization assay
5	Q. To be clear, the Jeryl Lynn	5	and the ELISA assay. To be clear, the
6	strain was the strain from which the mumps	6	selection of the assays were not
7	vaccine was developed. Isn't that right?	7	conducted by Merck alone but was always
8	A. The Jeryl Lynn isolate, not the	8	in collaboration with the FDA, because
9	strain, isolate, was the isolate from which	9	the purpose was to answer a very
10	the vaccine was eventually developed. The	10	specific question that the FDA asked us
11	exact strain that was used is a reflection of	11	to answer and, therefore, it was a
12	both the isolate, where it came from, hence	12	decision made by both organizations.
13	Jeryl Lynn, and how many passages it had	13	BY MR. BEGLEITER:
14	undergone in cell culture to attenuate it to	14	Q. Who ran the PRN test for
15	make it the vaccine strain. So a low passage	15	Protocol 007?
16	Jeryl Lynn strain is very different than the	16	A. So the PRN test was being run in
17	Jeryl Lynn vaccine strain.	17	David Krah's was developed and run in David
18	Q. And was there a consideration of	18	Krah's laboratory.
19	something called a cytopathic effect	19	Q. Who ran the ELISA test for
20	neutralization test being used as an assay?	20	Protocol 007?
21	A. Well, the way in which the	21	A. I actually don't recollect if
22	neutralization assay was performed is that one	22	that was in David Krah's laboratory or a
23	takes the indicator virus, which in this case	23	separate laboratory. That, I don't recollect
24	was the low passage Jeryl Lynn strain, one	24	clearly.
25	places it on a sheet of cells. The virus	25	Q. Did you have an understanding
	Page 87		Page 89
1	Q. It's all right if you want to	1	withdrawn.
2	give the answer, but my question was, was that	2	Do you have an understanding
3	considered?	3	that CBER wanted a PRN assay to be conducted
4	A. The reason I'm answering it that	4	for this end expiry study?
5	way, that if you didn't do that, you couldn't	5	A. Well, CBER agreed to the running
6	do the assay.	6	of the PRN assay. So, therefore, I assume that
7	Q. Was there a question about	7	they were comfortable with that decision which
8	whether to use a CPE or a PRN as part of the	8	was made in collaboration with CBER.
9	neutralization?	9	Q. Well, did Merck agree with CBER
10	A. I'm sorry. The reason I didn't	10	when it first suggested a PRN assay?
11	answer the question was you weren't clear in	11	A. No, I don't recollect the details
12	that question. So it's but now I	12	of those initial conversations.
13	understand what you're asking. Not that I	13	Q. Now, were you aware well,
14	recollect.	14	now, did CBER want a 95 percent I'm sorry
15	Q. Now, what assay did CBER want,	15	if this is similar to the question I asked
16	if you recollect?	16	before, but did CBER want a 95 percent
1	· ·	17	seroprotection rate against the wild type
17	MS. DIKSIKA. Objection to form.		
	MS. DYKSTRA: Objection to form. THE WITNESS: I do not recollect	18	isolates?
17		18 19	A. I don't recall if CBER
17 18	THE WITNESS: I do not recollect	19	A. I don't recall if CBER
17 18 19 20	THE WITNESS: I do not recollect those direct discussions with CBER. BY MR. BEGLEITER:	l	A. I don't recall if CBER specifically wanted that number.
17 18 19 20 21	THE WITNESS: I do not recollect those direct discussions with CBER. BY MR. BEGLEITER: Q. Did they want was it Merck's	19 20	A. I don't recall if CBER specifically wanted that number. Q. And you don't recall whether or
17 18 19 20 21 22	THE WITNESS: I do not recollect those direct discussions with CBER. BY MR. BEGLEITER: Q. Did they want was it Merck's and your preference to use the ELISA assay?	19 20 21 22	A. I don't recall if CBER specifically wanted that number. Q. And you don't recall whether or not or do you recall whether or not CPE was
17 18 19 20 21 22 23	THE WITNESS: I do not recollect those direct discussions with CBER. BY MR. BEGLEITER: Q. Did they want was it Merck's and your preference to use the ELISA assay? MS. DYKSTRA: Objection to form.	19 20 21 22 23	A. I don't recall if CBER specifically wanted that number. Q. And you don't recall whether or not or do you recall whether or not CPE was considered as one of the assays?
17 18 19 20 21 22	THE WITNESS: I do not recollect those direct discussions with CBER. BY MR. BEGLEITER: Q. Did they want was it Merck's and your preference to use the ELISA assay?	19 20 21 22	A. I don't recall if CBER specifically wanted that number. Q. And you don't recall whether or not or do you recall whether or not CPE was considered as one of the assays?

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1	MR. BEGLEITER: I'm showing the	1	95 percent, per CBER's expectation." [As
2	witness	2	read]
3		3	Does this refresh your
4	(Exhibit Emini-3, 9/9/99 Memo,	4	recollection that CBER had an expectation that
5	00015686 - 00015689, was marked for	5	there would be a 95 percent seroprotection
6	identification.)	6	rate against wild type virus?
7		7	A. Well, I will take it in terms of
8	THE WITNESS: CPE refers to	8	what it says here, that CBER did have an
9	cytopathic effect. It's not an assay.	9	expectation that it would be able to
10	MR. BEGLEITER: I'm showing	10	demonstrate a 95 percent seroconversion. This
11	Dr. Emini Merck 00015686 to 89.	11	is an inappropriate use of the word
12	THE WITNESS: So what this	12	"seroprotection." It's not the terminology
13	refers to, it refers to an assay that	13	that should be used.
14	is based upon virus elicited cytopathic	14	Q. In looking at this document,
15	effect, or CPE. But what I cannot tell	15	does this refresh your recollection that you
16	from reading this document was they are	16	were a member of the CAS, the Clinical
17	the exact parameters nor the design of	17	A. No, according to this document,
18	the assay itself.	18	I brought a recommendation to the CAS. I
19	BY MR. BEGLEITER:	19	don't recall, as I said earlier, that I was a
20	Q. On page 2, I think you	20	member of the CAS.
21	anticipated me, there's a committee that's	21	Q. Do you know what the do you
22	established to "bring recommendation of which	22	have any recollection of what the independent
23	mumps neutralization assay (CPE or PR) should	23	assays were that confirmed that the
24	be used for future studies to the CAS in	24	seroprotection rates against wild type
25	September '99." [As read] Right?	25	isolates were not about 95 percent?
	Page 91		Page 93
1	A. Yeah.	1	A. I don't recall other than what
2	A. Yeah.Q. This was a committee in which	2	A. I don't recall other than what it says on this document.
2 3	A. Yeah. Q. This was a committee in which you were the senior member?	2 3	A. I don't recall other than what it says on this document. Q. You can put that away.
2 3 4	A. Yeah. Q. This was a committee in which you were the senior member? A. Well, it's I don't recall	2 3 4	A. I don't recall other than what it says on this document. Q. You can put that away. MS. DYKSTRA: Are you through
2 3 4 5	A. Yeah. Q. This was a committee in which you were the senior member? A. Well, it's I don't recall I don't recall my exact membership on the	2 3 4 5	A. I don't recall other than what it says on this document. Q. You can put that away. MS. DYKSTRA: Are you through with Exhibit 3?
2 3 4 5 6	A. Yeah. Q. This was a committee in which you were the senior member? A. Well, it's I don't recall I don't recall my exact membership on the committee back in '99.	2 3 4 5 6	A. I don't recall other than what it says on this document. Q. You can put that away. MS. DYKSTRA: Are you through with Exhibit 3? MR. BEGLEITER: Yes, we're done
2 3 4 5 6 7	A. Yeah. Q. This was a committee in which you were the senior member? A. Well, it's I don't recall I don't recall my exact membership on the committee back in '99. Q. Are you saying that this is a	2 3 4 5 6 7	A. I don't recall other than what it says on this document. Q. You can put that away. MS. DYKSTRA: Are you through with Exhibit 3? MR. BEGLEITER: Yes, we're done with it.
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLI CONFIDENTIAL -		
	Page 94		Page 96
1	Q. And had he developed any other	1	Q. And what what would that
2	PRN assays, to your recollection?	2	equal in terms of the TCID50?
3	A. It was certainly within his	3	A. That would be 100,000.
4	level of expertise to have done that. I don't	4	Q. So that would increase from
5	recall which specific assays he may have	5	A. 20,000 to 100,000.
6	developed prior to this time.	6	Q. Tell me, sir, were you involved
7	Q. Do you know if he developed the	7	with that decision at all?
8	assay for the head-to-head Priorix versus MMR	1	A. I was not involved with that
9	II assay?	9	decision.
10	A. I do not recall.	10	Q. Do you know who made the
11	Q. Now, sir, do you know when Merck	11	A. Not that I recollect, of course.
12	started to develop the end expiry trial, about	12	Q. Do you know who was involved?
13	what year?	13	A. I do not know who was involved,
14	A. I don't recall directly. Again,	14	no.
15	on the basis of documents that I reviewed	15	Q. Did the filling to five log
16	recently, the question came up with regards to	16	raise any safety concerns in you?
17	whether or not 4.3 should reflect the end	17	A. They did not at the time. I
18	expiry value, so that would be roughly around	18	don't remember what my thoughts were obviously
19	the time that the consideration for it	19	you know, 20 years ago, but I would not have
20	properly came up, so that would be in 1999,	20	raised any safety concerns then and don't
21	2000, something along on those lines.	21	raise any safety concerns now. Again, the
22	Q. In 1999, was there a	22	decision was most likely than not taken with
23	withdrawn.	23	the concurrence of the agency.
24	Do you know what the word	24	Q. The amount of vaccine here goes
25	"overfill" means as related to the mumps	25	from 20,000 to 50,000, it quintuples. Right?
	Page 95		Page 97
1	vaccine?	1	A. 20,000 to 100,000.
2	vaccine? A. It's a standard terminology	2	A. 20,000 to 100,000. Q. 20,000, I'm sorry, to 100,000,
2 3	vaccine? A. It's a standard terminology within the industry. So what overfill means	2 3	A. 20,000 to 100,000. Q. 20,000, I'm sorry, to 100,000, quintuples. Do you know whether it raised any
2 3 4	vaccine? A. It's a standard terminology within the industry. So what overfill means is to add more into the unit, whether it be a	2 3 4	A. 20,000 to 100,000. Q. 20,000, I'm sorry, to 100,000, quintuples. Do you know whether it raised any concerns or not of you that to you whether or
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2 3 4 5 6	vaccine? A. It's a standard terminology within the industry. So what overfill means is to add more into the unit, whether it be a vial, a syringe, whatever the case happens to be, tied more into the unit than what would	2 3 4 5 6	A. 20,000 to 100,000. Q. 20,000, I'm sorry, to 100,000, quintuples. Do you know whether it raised any concerns or not of you that to you whether or not any safety tests were taken, field or clinical?
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25 (Pages 94 - 97)

212-279-9424

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

1 1	Page 98	1	Page 100
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	A. I don't understand your question.	1	Q. And you would have received it
	Q. Was there consideration of increasing the amount of virus by more than	$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	in the usual course of your employment with Merck?
3 4	five log?	4	A. I would have received it in the
5	A. Not to my knowledge.	5	usual course of my employment, of course.
6	MS. DYKSTRA: I think the court	6	
7	reporter got something incorrect on the	7	Q. You can put it aside. I'm not going to ask you any substantive questions
8	transcript. Do you mind if I just read	8	about it.
9	it to make sure?	9	So what's a warning letter from
10	MR. BEGLEITER: Sure, go ahead.	10	CBER?
11	MS. DYKSTRA: You asked him if	11	A. It's exactly what it says. It's
12	the fill to five log raised any safety	12	a warning letter from CBER in which the agency
13	concerns and you said they did not at	13	indicates specific deficiencies that it wishes
14	the time. I don't remember what my	14	to see corrected immediately. And it gives
15	thoughts were obviously, you know,	15	the recipient a relatively short period of
16	20 years ago. Again, the decision was	16	time to put together a correction plan that
17	most likely not taken with the	17	the agency would then need to certify.
18	concurrence of the agency or taken	18	Q. And what could happen if CBER is
19	with?	19	not satisfied with the correction plan?
20	THE WITNESS: No, taken with the	20	A. Again, it depends on what's the
21	concurrence of the agency.	21	nature of the warning letter. If the warning
22	MR. BEGLEITER: Okay. That's	22	letter reflects a manufacturing facility, they
23	fine. That's fair. That's how I heard	23	will close down a manufacturing facility. If
24	it.	24	it refers to a specific product, they can
25	MS. DYKSTRA: Thank you. Just	25	request withdraw of the product. It depends
	Page 99		Page 101
1	wanted to make sure it was clear.	1	on the details.
2	Thanks.	2	
2		4	
3	BY MR. BEGLEITER:	3	(Exhibit Emini-5, 2/9/01 Warning
4	Q. Sir, I'd like to show you a	1	(Exhibit Emini-5, 2/9/01 Warning letter, was marked for identification.)
		3	
4	Q. Sir, I'd like to show you a document with Bates number 00615147 through 174. I'm going to show it to you, but I'm	3 4	letter, was marked for identification.) BY MR. BEGLEITER:
4 5	Q. Sir, I'd like to show you a document with Bates number 00615147 through 174. I'm going to show it to you, but I'm telling you, I'm not going to ask you any	3 4 5	letter, was marked for identification.) BY MR. BEGLEITER: Q. Sir, again, I'm going to ask you
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26 (Pages 98 - 101)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

1 Q. Put it aside, sir. 2 Sir. do you know what a 3 validation protocol is? 4 A. Yes, sir. 5 Q. What's a validation protocol? 6 A. A validation protocol is, again, 7 it depends what the context is in which one is 8 using the terminology, but for an assay, let's 9 put it that way, for an assay validation 10 protocol is a protocol that one conducts to 11 validate the operational parameters of the 12 assay, the variability of the assay, the 13 variance of the assay, the reproducibility of 14 the assay, a statistical determination of how 15 one actually interprets the quantitative 19 values that the assay generates. It's a 17 statistically run and statistically predefined 19 protocol that one tose parameters are 19 established for the assay, the same of the assay, the variability of the assay, the variability of the assay wall dates the assay understance of the assay wall fication. 21 Terminology has changed since then. It's now 22 referred to as assay qualification. 23 Q. Were there validation assays for 24 Protocol 007? 25 MS. DYKSTRA: Objection. Form. 1 THE WITNESS: So, again, based 2 upon my review, as would have been the 3 case for any assay in support of a 2 clinical study, the assay would have 5 been validated, yes. 6 BY MR. BEGLEITER: 1 THE WITNESS: So, again, based 2 upon my review, as would have been the 3 case for any assay in support of a 2 clinical study, the assay would have 5 been validations for each assay. 11 Q. What is vaccine biometrics 12 research, what division of that — is that? 13 A. Not that I recall. 2 Would way the producibility of 14 the assay, the terminology. 15 MS. DYKSTRA: Exhibit 6. 16 WS. DYKSTRA: Exhibit 6. 17 MS. DYKSTRA: Exhibit 6. 18 MS. DYKSTRA: Exhibit 6. 18 MS. DYKSTRA: Exhibit 6. 19 WMR II. 00017036 to 0114. Give it 10 the court proper and give it to you. 10 (Exhibit Emini-6, FDA Response 10 to the inition of how of the proper and give it to you. 11 the wariance of the assay would have 12 to the inition look at a few pages. It bears 14 A. Not that I recall. 15 work of the w				
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27 (Pages 102 - 105)

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		_	
1 .	Page 106	1	Page 108
1	reduction neutralization?	1	me, yes.
2	A. Well, give me a second.	2	Q. Do you recall seeing this
3	Q. Take a second.	3	document?
4	MS. DYKSTRA: Take time if you	4	A. Again, subsequent to reviews of
5	need to look at the cover letter as	5	documents over the last period of time, I do
6	well. I'm not directing you to look at	6	recall receiving this document, the first page
7	anything, but take time to look at	7	which is the actual 483 document itself.
8	whatever time you need to make sure	8	Q. You saved me a question. A 483,
9	you're comfortable.	9	to be clear, is the sort of notice of
10	THE WITNESS: Yes, this does	10	deficiency that
11	appear to be the validation protocol	11	A. 483 is a notice of inspection
12	and the validation results for the	12	observations that the inspector wishes to
13	assay.	13	bring to your attention.
14	BY MR. BEGLEITER:	14	Q. And there was according to
15	Q. Going to the first page, this	15	the second page which you said you recall, the
16	appears to have been sent to CBER on March 12,	16	inspection occurred on what day?
17	2001.	17	A. The inspection occurred on
18	A. On the cover page it is	18	8/6/01, August 6, 2001.
19	March 12, 2001, yes.	19	Q. This e-mail was sent to you by
20	Q. Again, you don't recollect	20	Karen McKenney on August 7th, the next day?
21	whether you actually reviewed this before	21	A. Well, the memorandum is dated
22	you before it went to CBER?	22	August 6th. The e-mail is dated August 7th,
23	A. Not my recollection, no.	23	yes.
24	Q. You don't recall whether you	24	Q. And sir, I just want to you to
25	signed off on it?	25	take a look at number 1.
	Page 107		Page 109
1	A. I don't recall. It's timed. I	1	MS. DYKSTRA: On the 483?
2	don't recall.	2	THE WITNESS: On the 483?
3	Q. Okay. Fine.	3	BY MR. BEGLEITER:
4	MR. BEGLEITER: I'm going to	4	Q. I'll read it to you. Number 1
5	hand the court reporter Merck 00052249	5	says, "Raw data is being changed with no
		1 -	
6	through 53, ask her to mark it. What's	6	justification, for example," and then it
6 7	through 53, ask her to mark it. What's the number on this?	7	justification, for example," and then it gives a series of numbers which I'm not going
6 7 8	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7.	7 8	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding
6 7 8 9	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7.	7 8 9	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what
6 7 8 9 10	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7.	7 8 9 10	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to?
6 7 8 9 10 11	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7.	7 8 9 10 11	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was,
6 7 8 9 10 11 12	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7.	7 8 9 10 11 12	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of
6 7 8 9 10 11 12 13	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7. (Exhibit Emini-7, 8/7/01 E-mail with attachment, 00052249 - 00052253,	7 8 9 10 11 12 13	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the
6 7 8 9 10 11 12 13 14	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7.	7 8 9 10 11 12 13 14	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the inspector specifically actually in the end
6 7 8 9 10 11 12 13 14 15	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7. (Exhibit Emini-7, 8/7/01 E-mail with attachment, 00052249 - 00052253, was marked for identification.)	7 8 9 10 11 12 13 14 15	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the inspector specifically actually in the end wishes to have some explanation for. So if
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7. (Exhibit Emini-7, 8/7/01 E-mail with attachment, 00052249 - 00052253, was marked for identification.) BY MR. BEGLEITER: Q. You are permitted to look at the whole thing, but I'm only going to be asking you questions about the cover e-mail and what's behind the cover e-mail, 483.	7 8 9 10 11 12 13 14 15 16 17 18 19 20	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the inspector specifically actually in the end wishes to have some explanation for. So if the inspector was not able to find at the time that she conducted this inspection was that there were changes being made to the data related to whatever assay she was looking at, that did not have clear justification noted
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7. (Exhibit Emini-7, 8/7/01 E-mail with attachment, 00052249 - 00052253, was marked for identification.) BY MR. BEGLEITER: Q. You are permitted to look at the whole thing, but I'm only going to be asking you questions about the cover e-mail and what's behind the cover e-mail, 483. A. Okay.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the inspector specifically actually in the end wishes to have some explanation for. So if the inspector was not able to find at the time that she conducted this inspection was that there were changes being made to the data related to whatever assay she was looking at, that did not have clear justification noted when the changes were made.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7. (Exhibit Emini-7, 8/7/01 E-mail with attachment, 00052249 - 00052253, was marked for identification.) BY MR. BEGLEITER: Q. You are permitted to look at the whole thing, but I'm only going to be asking you questions about the cover e-mail and what's behind the cover e-mail, 483. A. Okay. Q. Now, the first question is, sir,	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the inspector specifically actually in the end wishes to have some explanation for. So if the inspector was not able to find at the time that she conducted this inspection was that there were changes being made to the data related to whatever assay she was looking at, that did not have clear justification noted when the changes were made. Q. And do you know Mr. Krahling who
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	through 53, ask her to mark it. What's the number on this? COURT REPORTER: 7. THE WITNESS: 7. MR. BEGLEITER: Okay. Emini-7. (Exhibit Emini-7, 8/7/01 E-mail with attachment, 00052249 - 00052253, was marked for identification.) BY MR. BEGLEITER: Q. You are permitted to look at the whole thing, but I'm only going to be asking you questions about the cover e-mail and what's behind the cover e-mail, 483. A. Okay. Q. Now, the first question is, sir, did you receive this document in the usual	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	justification, for example," and then it gives a series of numbers which I'm not going to read to you. Do you have an understanding sitting here today of what that meant, what that referred to? A. What that referred to was, again, remember 483 is a notice of observations that the agency or that the inspector specifically actually in the end wishes to have some explanation for. So if the inspector was not able to find at the time that she conducted this inspection was that there were changes being made to the data related to whatever assay she was looking at, that did not have clear justification noted when the changes were made. Q. And do you know Mr. Krahling who was sitting here
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	HIGHLI CONFIDENTIAL -	AI	TORNETS ETES ONET
	Page 110		Page 112
1	he warn you of this before August 7, 2001?	1	A. I signed that letter.
2	MS. DYKSTRA: Objection. Form.	2	Q. Your signature?
3	THE WITNESS: I have no	3	A. That is my signature.
4	recollection of any discussions with	4	Q. And, again, you can put this
5	Mr. Krahling related to this issue save	5	away, I have some questions to ask. I'm not
6	one. Again, this was as a result of	6	going to ask any questions about that
7	review of documents, and the document	7	document, at least right now.
8	that I saw that indicated that at some	8	Well, the purpose of this
9	point, and I don't remember what the	9	document was the purpose of this document,
10	date is, Mr. Krahling came to me to	10	was it to respond the 483 of August 6, 2001?
11	show me to express his concerns and	11	A. Right. The 483 was August 6th,
12	presumably show me some data on which	12	the response went back on August 20th.
13	he had his concerns.	13	Q. And tell me, sir, what did you
14	BY MR. BEGLEITER:	14	do between August 6th and August 20th that
15	Q. And was that concern that data	15	compiled information for you to respond to the
16	was being changed with no justification?	16	483?
17	A. I don't recall the nature of	17	A. Well, again, I have no direct
18	that concern.	18	recollection because of the period of time.
19	Q. You can put this away.	19	MS. DYKSTRA: I just caution you
20	Well, I'll ask you, did you work	20	not to disclose any communications with
21	on a response to 483? Did you review a	21	counsel related to the response or
22	response to the 483?	22	anything you did to generate the
23	A. Yes, I reviewed. Again, no	23	response, but otherwise, you can
24	direct recollection, but, again, based on	24	respond.
25	review of documents, I was involved in	25	THE WITNESS: Yes. No, that's
1	Page 111 responding to the 483 and reviewing the	1	Page 113
2	responses to the 483, yes.	2	fine. So the thank you very much. No, so the what I did is reflected
3	MR. BEGLEITER: I'll have the	3	right here in the responses. Worked
4	court reporter, please, mark this. I	4	with the team to pull together the
5	guess we're now up to 8, Emini-8. It's	5	responses that needed to be done.
6	a document bearing Bates numbers Merck	6	BY MR. BEGLEITER:
7	481 to 539. I'd like the witness to	7	
8		8	Q. So did you commence any kind of investigation of what happened?
9	look at it. It's being circulated to	9	
	other counsel.		
10	(E-1:1:4 E-::::: 0. 9/20/01 I -44-::	10	MS. DYKSTRA: Objection to the
11	(Exhibit Emini-8, 8/20/01 Letter	11	extent that that involves counsel. You
12	with attachment, 00481 - 00539, was	12	can answer yes and no and you can
13	marked for identification.)	13	discuss any other investigation.
14	DV MD DECLETED.	14	BY MR. BEGLEITER:
15	BY MR. BEGLEITER:	15	Q. Let me just I'll put a point
16	Q. Okay. And, sir, do you recognize	16	on this. I'm not going to ask you any
17	this document?	17	questions about what you may have said to
18	A. Yes. This would have been the	18	counsel or counsel to said to you. Okay?
19	formal response to the FDA to the four	19	A. Fair enough.
20	observations listed on the 483.	20	Q. However, let me ask you the
0.1	Q. And on page on the cover	21	question, did you consult with counsel after
21	1 0	~~	.1 400 ' 11 0
22	on the first sheet there's a letter. Is that	22	the 483 was received by you?
22 23	on the first sheet there's a letter. Is that right?	23	A. I consulted with counsel, but,
22	on the first sheet there's a letter. Is that		

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1	reviewed, I consulted with counsel immediately		A. That, I actually do not recollect.
2	prior actually to the receipt of the 483. And	2	Q. And do you recollect if counsel
3	consultation with counsel was in the context	3	was involved in drafting the response which
4	of	4	is I think it's Emini-9, the letter?
5	MS. DYKSTRA: Just to caution	5	A. Emini-8.
6	you not to disclose the content of	6	Q. Emini-8.
7	MR. BEGLEITER: Let him answer	7	A. Emini-8, yes. Normally counsel
8	the question.	8	would not have been involved in these
9	MS. DYKSTRA: You can say the	9	discussions. These are regulatory discussions.
10	time and the date, if you recall.	10	But, again, I have no direct recollection.
11	MR. BEGLEITER: Let him answer	11	Q. As far as you know, everything
12	the question.	12	in this document is correct, in Emini-8?
13	THE WITNESS: What I do recall	13	A. I signed it, yes, I believe it
14	was	14	is.
15	MS. DYKSTRA: Appropriately	15	Q. Now, sir, looking at Emini-8,
16	MR. BEGLEITER: I'm not asking	16	was that the final response regarding the 483
17	for any attorney-client communication.	17	or was there an additional response?
18	MS. DYKSTRA: He cannot disclose	18	A. I don't regarding the
19	any communications.	19	observations on the 483, this is the response.
20	BY MR. BEGLEITER:	20	I do not recall if there were subsequent
21	Q. I'm not asking for any communication		communications. Oftentimes there are. And,
22	between you. I asked you whether or not	22	in fact, I believe there probably are.
23	you consulted with	23	Q. Do you recall any teleconferences
24	A. Yes, I consulted with counsel.	24	with CBER regarding your response?
25	COURT REPORTER: Who am I	25	A. Not an exact recollection of the
25		25	
1	Page 115		Page 117
1	supposed to take?	1	teleconferences, per se, but, again, on the
2	BY MR. BEGLEITER:	2	basis of review of documents, there were
3	Q. I'm sorry. I'll ask the	3	teleconferences with CBER subsequent to this.
4	question again.	4	Q. You don't recollect anything
5	Did you consult I'll ask it a	5	regarding the substance of those teleconferences?
6	little differently.	6	A. Only on the basis of what I
7	Did you consult with counsel	7	reviewed.
8	after you received the 483?	8	Q. Well, what
9	A. I do not recollect that I	9	A. So on the basis of again, my
10	consulted with counsel after I received the	10	recollection, only on the basis of what I
11	483. Again, based on the review of documents	ſ	recently reviewed, those were clarified I
12	I believe that I consulted with counsel	12	don't recall the specific details, but they
13	immediately prior to the receipt of the 483.	13	reflected clarifying back and forth discussions
14	Q. Again, without telling me any	14	between the agency and the company of the
15	communication, why did you consult with	15	basis of the answers and to further clarify
16	counsel prior to receiving the 483?	16	whatever additional questions that the agency
17	A. Again, based on the review of	17	might have. It's a pretty standard practice.
18	documents, I consulted with counsel	18	Q. Do you recall who you spoke with
19	immediately after I met had with Mr. Krahling,	19	at the agency?
1		20	A. I don't recall even if I was
	and Mr. Krahling brought his concerns to my		
20	and Mr. Krahling brought his concerns to my attention.	21	present for that. The conversation would have
20 21	attention.	21 22	present for that. The conversation would have been held between our regulatory liaison and
20 21 22	attention. Q. I see. So you remember that,	22	been held between our regulatory liaison and
20 21 22 23	attention. Q. I see. So you remember that, but you don't remember whether or not you	22 23	been held between our regulatory liaison and the agency.
20 21 22	attention. Q. I see. So you remember that,	22	been held between our regulatory liaison and

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1	A. I know who she is. I don't	1	necessarily in terms of direct reporting
2	recall if I spoke with her.	2	relationship, but she had overall coordinating
3	Q. Just eliminated a document.	3	responsibilities. We'll go with that.
4	Sir, going back a little bit in	4	Q. And while you were in biologics,
5	time, sorry to be out of chronological order,	5	did you work with her?
6	do you recall, again, about when, what year	6	A. Yes, I did.
7	and when, what season the overfilling took	7	Q. Did you work with Dr. Scolnick?
8	place for the mumps vaccine?	8	A. Well, Dr. Scolnick was the
9	A. No, I don't.	9	president of the research laboratories.
10	Q. Do you recall Merck being	10	Q. Well, I'm saying you actually
11	requested by CBER to give the seroconversion	11	did things with him, discussed things with
12	rates that it was getting on Protocol 007 to	12	him?
13	CBER sometime in 1999?	13	A. Mostly in formal settings, yes.
14		14	
	MS. DYKSTRA: Objection. Form.		Q. I'm sorry, informal or formal?
15	THE WITNESS: I don't understand	15	A. Mostly in formal settings. MR.BEGLEITER: I'd like to show
16	the question. Sorry. Please, one more	16	
17	time?	17	you Merck 1898768 through 72.
18	BY MR. BEGLEITER:	18	
19	Q. CBER would from time to time ask	19	(Exhibit Emini-9, 10/31/99
20	you some results of some clinical trials,	20	E-mail with attachment, 01898768 -
21	testing, whatever. Right?	21	01898772, was marked for identification.)
22	MS. DYKSTRA: Objection to the	22	
23	form.	23	BY MR. BEGLEITER:
24	BY MR. BEGLEITER:	24	Q. We're calling it Emini-9.
25	Q. Isn't that true, in your	25	A. Okay.
	Page 119		Page 121
1	Page 119 experience?	1	Page 121 Q. Turning to page 69, 769, the
1 2		1 2	2
	experience?		Q. Turning to page 69, 769, the
2	experience? A. It depends on the nature of what's being discussed and what it is. I	2 3	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to
2 3	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end	2 3	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing
2 3 4	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end of a study before asking for any data from a	2 3 4	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to discussing the unanticipated low SCR for mumps
2 3 4 5	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end of a study before asking for any data from a study.	2 3 4 5	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to discussing the unanticipated low SCR for mumps with CBER, the results from sera from the head-to-head trial from MMR II and Priorix
2 3 4 5 6 7	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end of a study before asking for any data from a study. Q. Do you recall with regard to	2 3 4 5 6 7	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to discussing the unanticipated low SCR for mumps with CBER, the results from sera from the head-to-head trial from MMR II and Priorix will be reviewed to confirm that this low SCR
2 3 4 5 6 7 8	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end of a study before asking for any data from a study. Q. Do you recall with regard to Protocol 007, did they ask before the study?	2 3 4 5 6 7 8	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to discussing the unanticipated low SCR for mumps with CBER, the results from sera from the head-to-head trial from MMR II and Priorix will be reviewed to confirm that this low SCR is observed in both products."
2 3 4 5 6 7 8 9	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end of a study before asking for any data from a study. Q. Do you recall with regard to Protocol 007, did they ask before the study? A. I don't recall.	2 3 4 5 6 7	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to discussing the unanticipated low SCR for mumps with CBER, the results from sera from the head-to-head trial from MMR II and Priorix will be reviewed to confirm that this low SCR is observed in both products." Do you see that?
2 3 4 5 6 7 8 9	experience? A. It depends on the nature of what's being discussed and what it is. I mean, typically CBER would wait until the end of a study before asking for any data from a study. Q. Do you recall with regard to Protocol 007, did they ask before the study? A. I don't recall. Q. Now, what relationship, what	2 3 4 5 6 7 8 9	Q. Turning to page 69, 769, the bottom bullet point, "Mumps neutralizing antibody assay." Second sentence, "Prior to discussing the unanticipated low SCR for mumps with CBER, the results from sera from the head-to-head trial from MMR II and Priorix will be reviewed to confirm that this low SCR is observed in both products." Do you see that? A. Yes.
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1	discussion, the note was, from CBER,	1	A. That is correct.
2	that this was presumably from CBER,	2	Q. Again, the sentence I read to
3	certainly in agreement with CBER, that	3	you, why wait for the results of the
4	the seroconversion rate needed to be	4	head-to-head MMR II and Priorix before telling
5	assessed in a plaque reduction	5	CBER what the results the SCR results were
6	neutralization assay or a CPE-based	6	MS. DYKSTRA: Objection. Form.
7	assay, either way, with a wild type	7	THE WITNESS: The only reason
8	strain yielding, all right, yielding a	8	for doing that was to be able to
9	level of seroconversion that was	9	essentially have an independent
10	approximately 90 percent as noted in	10	verification that the primary driver
11	the first sentence because of the need	11	for the lower seroconversion that was
12	for sensitivity in the assay and	12	being observed, okay, was a function of
13	reflecting the known field efficacy of	13	the assay itself. In other words, if
14	the vaccine. What was occurring	14	you got two independent vaccines, both
15	apparently was that not apparently	15	of which elicit lower seroconversion
16		16	
	but for a fact, again, based upon	17	rates as measured using the Lo1 virus,
17	what's here, and I do recall this, what	l	one can and knowing that the field
18	was known, what was observed was that	18	efficacy data pretty much supports,
19	with different wild type strains or	19	does for a fact support that both
20	wild type isolates, rather, of the	20	vaccines are effective, then because
21	virus, seroconversion rates were	21	both are licensed vaccines in various
22	notably lower than 90 percent and,	22	parts of the world, then one can
23	therefore, the assay was not giving a	23	conclude that the assay that was being
24	set of results that was reflective of	24	developed using the Lo1 virus, was not
25	the vaccine's known efficacy, and,	25	fit for purpose for the intended reason
	Page 123		Page 125
1	therefore, could not be used for the	1	for the vaccine the assay was being
2	kind of comparison we were discussing	2	developed for the 007 study.
3	needed for the 007 study.	3	BY MR. BEGLEITER:
4	BY MR. BEGLEITER:	4	Q. So what you're saying here is
5	Q. Known efficacy referring to what	5	that because of the unanticipated low SCR for
6	was happening in the field?	6	MMR II, you wanted to have or Merck wanted to
7	A. Recurrent efficacy can only be	7	have the results for the head-to-head to
8	determined in the field.	8	buttress what it was doing?
9	O. Just straightening that out.	9	
9	Q. Just straightening that out. In the first sentence where it	9	MS. DYKSTRA: Objection.
10	In the first sentence where it	10	MS. DYKSTRA: Objection. BY MR. BEGLEITER:
10 11	In the first sentence where it says, "with JL as the test isolate," is	10 11	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results?
10 11 12	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn?	10 11 12	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I
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10 11 12 13 14	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the	10 11 12 13 14	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent
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10 11 12 13 14 15 16 17	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent.	10 11 12 13 14 15 16 17	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay
10 11 12 13 14 15 16 17 18	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent. Q. And also but for Lo1, do you	10 11 12 13 14 15 16 17 18	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay was to develop an assay that would measure an
10 11 12 13 14 15 16 17 18	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent. Q. And also but for Lo1, do you know what Lo1 stands for?	10 11 12 13 14 15 16 17 18 19	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay was to develop an assay that would measure an immunological response elicited by the vaccine
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10 11 12 13 14 15 16 17 18 19 20 21	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent. Q. And also but for Lo1, do you know what Lo1 stands for? A. Lo1 probably is the designation for another wild type virus test isolate.	10 11 12 13 14 15 16 17 18 19 20 21	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay was to develop an assay that would measure an immunological response elicited by the vaccine that would correlate with the known, the known established efficacy of the vaccine.
10 11 12 13 14 15 16 17 18 19 20 21 22	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent. Q. And also but for Lo1, do you know what Lo1 stands for? A. Lo1 probably is the designation for another wild type virus test isolate. Q. You don't remember what that is?	10 11 12 13 14 15 16 17 18 19 20 21 22	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay was to develop an assay that would measure an immunological response elicited by the vaccine that would correlate with the known, the known established efficacy of the vaccine. So here we have an assay using
10 11 12 13 14 15 16 17 18 19 20 21 22 23	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent. Q. And also but for Lo1, do you know what Lo1 stands for? A. Lo1 probably is the designation for another wild type virus test isolate. Q. You don't remember what that is? A. I don't remember exactly what it	10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay was to develop an assay that would measure an immunological response elicited by the vaccine that would correlate with the known, the known established efficacy of the vaccine. So here we have an assay using the Lo1 virus that was given a seroconversion
10 11 12 13 14 15 16 17 18 19 20 21 22	In the first sentence where it says, "with JL as the test isolate," is that Jeryl Lynn? A. I presume it is Jeryl Lynn, yes. Q. And using the clinical in the clinical testing, there was the seroconversion rates A. Was approximately 90 percent. Q. And also but for Lo1, do you know what Lo1 stands for? A. Lo1 probably is the designation for another wild type virus test isolate. Q. You don't remember what that is?	10 11 12 13 14 15 16 17 18 19 20 21 22	MS. DYKSTRA: Objection. BY MR. BEGLEITER: Q. To buttress the results? A. That's not what I said. What I said was by having the data from sera from children that had received an independent licensed and, therefore, efficacious vaccine, because remember I'm going to take a step back. The purpose for developing the assay was to develop an assay that would measure an immunological response elicited by the vaccine that would correlate with the known, the known established efficacy of the vaccine. So here we have an assay using

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1	reflected by that level. That would tend to	1	Q. Let me ask it a different way.
2	suggest that there is something not,	2	A. Let's be precise.
3	quote/unquote, correct about the assay in	3	Q. Let's ask it a different way.
4	terms of what it was reflecting that the	4	The test was being conducted to
5	vaccine was actually doing. By having data	5	see what the potency was at expiry. Isn't
6	from two from sera from children who	6	that right?
7	received independently two known efficacious	7	MS. DYKSTRA: Objection. Form.
8	vaccines, the fact that both vaccines elicited	8	THE WITNESS: The test was being
9	immune responses that gave rise to a result	9	conducted, which test, the study or the
10	that was roughly around 70 percent using the	10	clinical study?
11	Lo1 virus, allows you to firmly conclude that	11	BY MR. BEGLEITER:
12	and assay developed using the Lo1 virus is not	12	Q. 007.
13	fit for purpose and that it is incapable of	13	A. The clinical study was being
14	giving you the kind of sensitivity that is	14	conducted to generate data that would support
15	required to answer the question that was being	15	a vaccine potency level for mumps at the end
16	posed by the 007 trial.	16	of shelf life; so, therefore, the expiry
17	Q. If I believe you're saying	17	potency level.
18	that the efficacy in the field answers the	18	Q. But the conclusion you already
19	question as to the efficacy of the	19	had was that since it was efficacious in the
20	A. It is the only way to address	20	field, that no matter what that number was, it
21	efficacy.	21	was the vaccine was fit for purpose. Isn't
22	MS. DYKSTRA: Object to the	22	that what you're saying?
23	form.	23	MS. DYKSTRA: Objection.
24	BY MR. BEGLEITER:	24	THE WITNESS: The conclusion was
25	Q. And why have	25	that the vaccine that was being used
	Page 127		Page 129
1	MS. DYKSTRA: I objected to the	1	from the time the vaccine was licensed
2	form of the question.	2	up until the time that this entire
3	BY MR. BEGLEITER:	3	discussion occurred, which was late
4	Q. Then if your conclusion is	4	'90s, early 2000s, that the vaccine
5	because of what's happening in the field that	5	that was being used in the field was
6	the mumps virus is fit for purpose	6	indeed efficacious.
7	A. The vaccine.	7	BY MR. BEGLEITER:
8	Q. Excuse me, the mumps vaccine is	8	Q. And this study was designed to
9	fit for purpose as it stood, then why have	9	show that the vaccine was fit for purpose?
10	Protocol 007 at all?	10	A. No. The study was designed to
11	A. The purpose for Protocol 007 was	11	
12	to provide the data that would allow both the	12	support a number, a value for potency that
13	company and the agency to define an end expiry	13	could be placed in the label for determination
14	number that it could then place in the label.	14	of end expiry potency at the end of shelf
15	Q. And if that clinical study were	15	life.
16	to show a	16	Q. And why was end expiry potency
17	A. End expiry potency number.	17	important to CBER?
18	Q. If that clinical study was to	18	A. It was important for control
19	show that the potency had fallen below 90	19	purposes. And what I mean by control purposes
20	percent, wouldn't that be something of	20	is so that there is a consistency and you can
21	interest to the CBER?	21	determine a consistency at which point in
22	MS. DYKSTRA: Objection. Form.	22	terms of shelf life. So if over time, if a
22		22	montioulan botch of vocains t- 1
23	THE WITNESS: Repeat your	23	particular batch of vaccine were to lose
		23 24 25	particular batch of vaccine were to lose potency for whatever reason and were to drop below a given level, a given number which was

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Page 132 your end expiry potency, you could declare testing? 2 that, you know, there was loss of control 2 Well, according to this, the 3 potentially in the production of the vaccine 3 assays had been developed, that there was a 4 or in the storage of the vaccine. Doesn't 4 PRN assay and the CPE assay, apparently both 5 mean that the vaccine is no longer effective. 5 assays were being -- I'm reading what's in the That there was simply loss of control. 6 6 rest of the document, that were being done. 7 So the premise for this Protocol 7 And they were being developed, you know, 8 007 was that MMR/V, the mumps part of it at 8 probably with the concurrence, not probably least, was effective? 9 9 but for a fact, with the concurrence of the 10 10 Yes. agency using a wild type virus. And with a 11 MS. DYKSTRA: Objection to the 11 wild type virus, and, again, reading through the rest of the document, one of the ones that 12 form. 12 13 BY MR. BEGLEITER: 13 was used, probably the initial one that was 14 Q. Premise going in? 14 used was this Lo1 wild type virus. It was 15 MS. DYKSTRA: MMR/V wasn't in 15 giving seroconversion rates that were much 16 the study. lower than 90 percent, approximately 70 percent. 16 17 BY MR. BEGLEITER: 17 And that was not going to meet the agency's 18 Q. Excuse me, MMR II. 18 requirement for a sensitive enough test that 19 MMR II. 19 would allow you to answer the questions posed Α. 20 MMR II. Yes. 20 by 007. 21 A. That the mumps component --21 Q. Do you know if the agency was 22 we'll stick with the mumps component. That 22 told, if CBER was told about the low SCR for 23 the mumps component in MMR II --23 Lo1? 24 Q. Yes. 24 A. Based on documents that I 25 A. 25 -- was absolutely effective. reviewed, these were discussions that were Page 131 Page 133 1 And that's the premise going in? 1 going on in collaboration with the agency Q. 2 A. That is the observed fact. It's 2 because the agency very much wanted an assay 3 effective. 3 that would answer the question that would 4 And let's just -- while we're on 4 allow them to establish a value for end expiry 5 the subject, let's go to the first paragraph, 5 in the label. An SCR of 70 percent, all 6 MMR II end expiry. It says that -- first 6 right. So what we know is the following: We 7 sentence tells you how many people, how many 7 know that the vaccine is effective --8 subjects are enrolled. Skip that. Then it 8 Q. My question --9 says, "The primary study hypothesis of a..." 9 MS. DYKSTRA: Let him answer. 10 10 MR. BEGLEITER: He's not Seroconversion rate. 11 "...seroconversion rate equal to 11 answering my question. 12 or greater than 90 percent against wild type 12 THE WITNESS: I will get into 13 mumps...is unlikely to be met..." [as read] 13 the answer. Allow me to answer the 14 A. Right. 14 question, please. 15 15 Q. "...and therefore...should be What we know is that the vaccine revised either in terms of addressing the 16 is effective, it's been given to hypothesis or addressing the technical 17 children, to all the children in the 17 18 18 limitations of the assays used to date." study, and that the assay that had been 19 Α. Right. 19 developed using Lo1 was only yielding 20 Q. And this is in October 31, 1999. 20 an SCR of 70 percent. That would not 21 Right? 21 have been fit for purpose. That 22 22 Α. Right. indicates that the assay, the assay is 23 23 Do you know if by then there had not fit for purpose. It's not allowing 24 even -- that the PRN had actually been set up 24 you to determine whether or not -- it 25 to do any kind of assay work, any kind of was not allowing you to -- would not

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1	allow you, it would not prospectively	1	BY MR. BEGLEITER:
2	allow you to determine whether or not	2	Q. By the way, I don't know if I
3	there would be a difference in the	3	asked it. Did you receive this document in
4	seroconversion rate that would be	4	the usual course of your employment?
5	statistically acceptable among the	5	A. The document was let's see,
6	different, the three different potency	6	am I here? Yes, the document was sent to me
7	levels that were being tested in 007.	7	on October 31, 1999, and, therefore, I assume
8	So, therefore, the discussion with the	8	I did receive it.
9	agency was how can we modify the assay	9	MS. DYKSTRA: When is a good
10	that would give us an assay or assays	10	time to take a break? I don't know if
11	of sufficient sensitivity.	11	you want to go another time, we can
12	MR. BEGLEITER: Can you read the	12	break for lunch.
13	question back, please.	13	MR. BEGLEITER: Let me just see
14		14	what the latest one is. We can do it
15	(The court reporter read the	15	now.
16	pertinent part of the record.)	16	MS. DYKSTRA: Okay.
17		17	MR. BEGLEITER: Have it now.
18	BY MR. BEGLEITER:	18	MS. DYKSTRA: We'll come back.
19	Q. Do you know if they were told	19	MR. BEGLEITER: Come back and
20	specifically about what the low SCR was?	20	then we'll go to lunch.
21	A. I do not recall what the	21	MS. DYKSTRA: That's sounds
22	specific conversation was. What I do recall	22	fine.
23	was that there were ongoing conversations with	23	MR. BEGLEITER: Okay. Fine.
24	the agency to generate an assay with	24	VIDEOGRAPHER: The time is now
25	sufficient sensitivity.	25	12:16. Going off the video record.
	Page 135		Page 137
1	Q. But you don't recall whether or	1	
2	not somebody said, you know, we've done an	2	(A recess was taken.)
3	assay on Lo1 and the SCR is 70 to 75 percent?	3	·
4	A. What I do recall no, I don't	4	VIDEOGRAPHER: The time is now
5	recall that specific question.	5	12:31. We're back on the video record.
6	Q. That's my question. Okay.	6	BY MR. BEGLEITER:
7	A. That specific discussion.	7	Q. What would have what, if
8	Q. Now, in terms of whether CBER	8	anything, in the years '99, 2000, 2001 when
9	was going to be whether CBER was going to	9	you were with biologics, would have indicated
10	be told about the unanticipated low SCR, back		
10 11	be told about the unanticipated low SCR, back to the last paragraph on that page, when the	10 11	to you that there was a problem with the
10 11 12	to the last paragraph on that page, when the	10 11	to you that there was a problem with the efficacy of the vaccine?
11		10	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all.
11 12 13	to the last paragraph on that page, when the results from the head-to-head trial with	10 11 12 13	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field
11 12	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that	10 11 12	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different?
11 12 13 14	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall.	10 11 12 13 14	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field
11 12 13 14 15 16	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with	10 11 12 13 14 15	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER:
11 12 13 14 15	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall.	10 11 12 13 14 15 16	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way.
11 12 13 14 15 16 17	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall.	10 11 12 13 14 15 16 17	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means.
11 12 13 14 15 16 17 18	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall. Q. Isn't it a fact, sir, that the	10 11 12 13 14 15 16 17 18	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means. Q. On what basis you've said, I
11 12 13 14 15 16 17 18 19 20	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall. Q. Isn't it a fact, sir, that the three of you discussed that and came to a	10 11 12 13 14 15 16 17 18 19 20	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means. Q. On what basis you've said, I believe, you testified if I put words in
11 12 13 14 15 16 17 18 19 20 21	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall. Q. Isn't it a fact, sir, that the three of you discussed that and came to a conclusion this is what should be done?	10 11 12 13 14 15 16 17 18 19 20 21	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means. Q. On what basis you've said, I believe, you testified if I put words in your mouth, please correct me, I'm sure you
11 12 13 14 15 16 17 18 19 20 21 22	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall. Q. Isn't it a fact, sir, that the three of you discussed that and came to a	10 11 12 13 14 15 16 17 18 19 20 21 22	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means. Q. On what basis you've said, I believe, you testified if I put words in your mouth, please correct me, I'm sure you will.
11 12 13 14 15 16 17 18 19 20 21 22 23	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall. Q. Isn't it a fact, sir, that the three of you discussed that and came to a conclusion this is what should be done? MS. DYKSTRA: Objection to the form.	10 11 12 13 14 15 16 17 18 19 20 21 22 23	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means. Q. On what basis you've said, I believe, you testified if I put words in your mouth, please correct me, I'm sure you will. What is the basis on what
11 12 13 14 15 16 17 18 19 20 21 22	to the last paragraph on that page, when the results from the head-to-head trial with MMR II and Priorix was available. Was that discussed with Dr. Scolnick? A. I don't recall. Q. Was that discussed with Dr. Margolskee? A. I don't recall. Q. Isn't it a fact, sir, that the three of you discussed that and came to a conclusion this is what should be done? MS. DYKSTRA: Objection to the	10 11 12 13 14 15 16 17 18 19 20 21 22	to you that there was a problem with the efficacy of the vaccine? A. Nothing at all. Q. What if statistics in the field had been different? MS. DYKSTRA: Objection. Form. BY MR. BEGLEITER: Q. Well, do it this way. A. I don't know what that means. Q. On what basis you've said, I believe, you testified if I put words in your mouth, please correct me, I'm sure you will.

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Page 140 that the vaccine was effective? 1 BY MR. BEGLEITER: 2 A. Well, the original basis for the 2 Q. In that first paragraph again, 3 determination of the vaccine's efficacy or 3 "The primary study hypothesis of a SCR greater 4 efficaciousness is a controlled clinical 4 than or equal to 90 percent against wild type 5 5 mumps virus is unlikely to be met and study. So that was the controlled clinical therefore this should be revised either in 6 study that was performed that supported the original licensure of the vaccine back in 7 terms of addressing the hypothesis or 7 8 addressing the technical limitations of the 8 whenever it was, the '60s, the '70s. So that 9 assays used to date." [As read] 9 was the placebo-controlled study. 10 10 Your name is in this document. Subsequent to that, your 11 isn't it? 11 establishment of the -- one's determination of the continued effectiveness of the vaccine is 12 A. Yes. 13 that, you know, when the vaccine became widely 13 Q. What do you understand 14 "addressing the hypothesis" to mean? 14 used as a pediatric vaccine in this country, The hypothesis of the study, so 15 the mumps epidemics which tended to occur with 15 that would be the 007 study, and addressing 16 certain regularity completely disappeared and 16 17 the hypothesis of what the 007 study was 17 those epidemics have not recurred since. The 18 designed to do which was to provide data to only way in which that would have happened is 19 19 establish a number, potency number that could if the vaccine had, in fact, retained its 20 effectiveness. 20 be used for end expiry. And if the assay is 21 21 insufficiently sensitive to show statistical Would a sustained outbreak short 22 22 differences in terms of seroconversion rates, of an epidemic lead you to a different 23 23 conclusion? not effectiveness, seroconversion rates among 24 A. No, sustained outbreaks, the 24 the three levels that were being tested within 25 problem is there are a lot of variables 25 the study, one could not appropriately address Page 139 Page 141 associated with those. You don't know how 1 the hypothesis. many individuals were immunized, how, many 2 Q. And one way of addressing the 3 hypothesis was in the choice of the viral 3 individuals have not been immunized. Immunity 4 4 wains, goes away with time. It depends on how strain to be -- of the isolate to be assayed? 5 5 long -- I'm slowing down, my apologies. It A. Not to address the hypothesis depends on how long those individuals have 6 but the choice of the viral strain was 6 7 necessary to look at how one could devise an 7 been immunized. It depends on a number of 8 assay that would give sufficient sensitivity 8 factors which it's the only -- the only thing 9 9 that I personally would have taken as a clear as a measure of seroconversion. 10 indication of the loss of effectiveness of the And did that mean, going to the 11 vaccine, particularly given the fact that the 11 bottom paragraph, that Jeryl Lynn was a better 12 vaccine is used in practically every child, 12 choice for the assay than Lo1? 13 there are unfortunately children who are not 13 MS. DYKSTRA: Objection to the 14 immunized as we know, would be an actual 14 15 THE WITNESS: The low passage 15 sustained epidemic. 16 Q. Did you -- let's go back to this 16 Jeryl Lynn which was, as we discussed 17 document for a moment. 17 earlier, a representation of wild type 18 18 A. Which document? virus, was selected because this 19 O. This document, the one you had 19 particular strain, defined by both 20 before, I think it was 9. 20 passage and isolate, the Jeryl Lynn 21 21 A. Number 9? isolate, was apparently capable of 22 22 giving a much more sensitive O. It's 8. 23 23 Number 8? representation of seroconversion, yes. Α. 24 24 BY MR. BEGLEITER: MS. MAHENDRANATHAN: It's 9. 25 25 MR. BEGLEITER: 9 is right. Have you ever heard that the

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1	use anybody at CBER ever tell you that	1	group. So he was in not in my reporting
2	using the low passage Jeryl Lynn was for	2	relationship. He's a member of the vaccine
3	this assay was stacking the deck?	3	regulatory group who worked with Henrietta
4	MS. DYKSTRA: Objection. Form.	4	Ukwu who was the head of vaccine regulatory.
5	THE WITNESS: I do not recall	5	Q. Did you work with Dr. Chirgwin?
6	that. But what I do recall is that	6	A. Since he was a member of the
7	these discussions of selection of	7	regulatory group, as part of overall broad
8	that all of the discussions involving	8	collaboration of the vaccine research and
9	the actual design of the assays, both	9	development, yes, I did.
10	the plaque reduction neutralization	10	Q. Did you respect his opinion?
11	assay, the AIGENT assay and the	11	A. Yes, I did.
12	subsequent ELISA assay, were all	12	Q. I'm going to show you a
13	discussions that were held in	13	document, 626382 through 626384. As you look
14	collaboration with the agency and with	14	at it, the first page does not have any
15	the agency's concurrence.	15	e-mails to you. I'll save some time. So I'm
16	BY MR. BEGLEITER:	16	only going to be focusing on the e-mail on the
17	Q. Do you know if London-1 was	17	second page which I believe
18	tested using all three of the potencies?	18	
19	A. I do not recall.	19	(Exhibit Emini-10, E-mail
20	Q. So leaving aside the agency,	20	exchange, 00626382 - 00626384, was
21	there's a question I didn't ask you, but	21	marked for identification.)
22	you've said it, you're sure it happened and	$\begin{vmatrix} 21\\22\end{vmatrix}$	marked for identification.)
23	A. That I recall.	$\begin{vmatrix} 22\\23 \end{vmatrix}$	THE WITNESS: Sorry, please ask
24	Q. Can you tell me what day it	24	your question.
25	happened?	25	BY MR. BEGLEITER:
23	**	25	BT MR. DEGLETTER.
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1	A. I cannot tell you.	1	Q. I'm just letting you know I'm
2	Q. Who was there?	2	not going to you're not on the e-mails
3	A. No, I can't tell you because	3	beginning on the top third of the second page,
4	these were ongoing discussions with the agency.	4	so I'm not going to ask you any questions
5	Q. So you can't identify the people	5	about those e-mails. Okay?
6	at the agency. Maybe you can. Can you	6	A. Okay.
7	identify the people at the agency?	7	Q. But I will ask you about the
8	A. Not at this stage.	8	e-mail in which your name is in the cc. Do
9	Q. Let me finish. Can you identify	9	you see that?
10	the people at the agency that said this is the	10	A. Yes.
11	appropriate thing to do	11	Q. It's from Dr. Keith Chirgwin.
12	A. Not at this stage, no.	12	A. Yes.
13	Q using Jeryl Lynn virus?	13	Q. It's dated November 17, 1999.
14	A. No, I cannot identify the	14	See it? Okay. And let's talk about that,
15	individuals that were involved.	15	about that e-mail, that first paragraph.
16	Q. Or any document that says it?	16	A. Allow me time to read it,
17	A. I cannot at this point identify	17	please. Okay.
18	a document.	18	Q. In that paragraph can you tell
19	Q. Who is Keith Chirgwin, Dr. Keith	19	me what Dr. Chirgwin is addressing?
20	Chirgwin?	20	A. Well, Dr. Chirgwin is addressing
21	A. Dr. Keith Chirgwin was a member	21	the issue that we were discussing a moment
22	of the vaccine regulatory group.	22	ago, and that is whether or not there is
23	Q. So he was someone was he on a	23	relevance in the assay that is being
1-5		24	
24	par with you, below you, above you?	24	developed in support of the 007 study, whether
	par with you, below you, above you? A. Well, he was not within my	25	or not there is relevance to the use of wild

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Page 148 type strains of the virus. The argument he is What he's referring to -- what I refer to as 2 making is that when one uses different wild 2 an epidemic is a widespread sustained outbreak 3 type strains, not just the Lo1, there are 3 that would typically occur across all children 4 large differences that are seen in 4 of a given age who have received vaccine at 5 seroconversion rates. And since the sera that 5 the time that they were -- or received lots of are being tested are all the same sera, it 6 vaccine that were presumably no longer 7 would tend to suggest, not suggest, but 7 effective at the time that they hit that age 8 clearly shows that the differences are due to 8 when they would normally receive the vaccine. 9 9 the actual strains that are being used as the So these children would all grow up at the 10 indicator strains in the assay. 10 same time and then you would see an epidemic within that age band. That is a sustained 11 So, therefore, he makes the 11 12 conclusion that given that the vaccine 12 outbreak. We've not seen that with mumps. effectiveness is what it is observed to be, 13 Q. You're not trained in epidemiology, 14 very good vaccine effectiveness, since there 14 are you? 15 are no sustained outbreaks, that the assay 15 A. I am -- well, my training is 16 being developed with the different wild type 16 very broad and, in fact, in my current role, 17 strains giving not just low seroconversion 17 okay, I do field effectiveness studies, yes. 18 rates but a wide variation of seroconversion 18 You know what Dr. Chirgwin of 19 rates is an artifact, if you will, of the wild 19 sustained outbreaks is? 20 20 type strains being used, and, therefore, not A. Well, without having spoken to 21 reflective of the vaccine's effectiveness. 21 him, I interpret it the way I just mentioned. 22 22 He doesn't in this -- you Q. A couple of questions. First of 23 23 all, he has a different point of view, would haven't seen anywhere where he says a 24 that be fair to say, on the relevance of the 24 sustained outbreak is blumpity-blump? 25 sustained -- of sustained outbreaks? 25 MS. DYKSTRA: Objection to the Page 147 Page 149 1 MS. DYKSTRA: Objection. 1 form. 2 THE WITNESS: No, I would say 2 THE WITNESS: Of course not. 3 that that is, in fact, the same point 3 BY MR. BEGLEITER: 4 4 of view. Q. Okay. Fine. Well, I want to 5 5 BY MR. BEGLEITER: make sure we're on the same thing, may have 6 Q. Doesn't he say here, I'll read 6 missed it. 7 it, "...the low SCR with wild type does not 7 And then in the last sentence, correlate with the apparent field effectiveness 8 "If these arguments fail and CBER forces us to 9 of the vaccine and the low SCR with wild type 9 use wild type neutralization, then we will 10 10 has not resulted in sustained outbreaks, thus argue that 70 to 80 percent of SCR with Lo1 11 these low SCRs are not capturing the true 11 correlates with excellent field effectiveness 12 protective efficacy of the vaccine." [As read] 12 and that therefore this is an acceptable SCR." 13 A. That's exactly what I said 13 [As read] 14 before. 14 Do you see that? 15 15 Well, you drew a distinction, Yes. A. 16 did you not, between epidemics and sustained 16 Q. Do you agree with that? 17 outbreaks? 17 It's the only argument that one 18 A. Well, his definition of 18 can make. So if the agency is insisting that 19 sustained outbreaks, all right, and the way 19 the London-1 strain, which is what Lo1 20 he's defining it here is equivalent to my 20 apparently stands for, has to be used in the 21 definition of an epidemic. 21 assay because it is a wild type virus, we know 22 Q. How do you know that? 22 that the effectiveness of the vaccine is at a 23 23

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very high level, much higher than what would

be reflected in an assay using the Lo1 strain

which is on the order of, as noted here, 70 to

24

25

24

Well, because what he's

referring to is -- because an epidemiologist

would all refer to it as exactly the same way.

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1 -	HIGHLI CONFIDENTIAL -		
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1	80 percent, then the conclusion would be that	1	rates that could address the hypotheses
2	what you are measuring in the assay at a level	2	of the 007 trial.
3	of 70 to 80 percent using the Lo1 strain is a	3	BY MR. BEGLEITER:
4	reflection of the vaccine's known and observed	4	Q. Which included a 90 an equal
5	field effectiveness.	5	to or greater than 90 percent seroconversion
6	Q. And coming back to the premise	6	rate?
7	of what you just said, do you know what the	7	A. Which included a seroconversion
8	agency, what CBER was requiring in terms of	8	rate of 90 percent, at least a seroconversion
9	A. CBER was requiring	9	rate of 90 percent.
10	Q in terms of seroconversion	10	Q. What would a low seroconversion
11	rate?	11	rate have meant to shelf life
12	A. CBER was requiring an assay of	12	MS. DYKSTRA: Objection. Form.
13	sufficient sensitivity. And based on the	13	BY MR. BEGLEITER:
14	documents that I reviewed recently, they were	14	Q if anything?
15	requiring a level of sensitivity, of	15	A. Again, it's not what the
16	seroconversion rate of at least 90 percent as	16	seroconversion rate means to shelf life. It's
17	that would allow you a sufficient sensitivity	17	what the difference in seroconversion rates
18	to address the hypothesis that was being	18	might mean based upon a prespecified criterion when the results from the 007 trial would
19	addressed in the 007 trial.	19 20	
20	Q. The documents that I showed you	20	ultimately be evaluated and become available.
21	this morning?	$\begin{vmatrix} 21\\22\end{vmatrix}$	Q. This morning, I hope it's still
22 23	A. No, the documents that I reviewed with my counsel over the past several	23	morning, this morning you talked about how everything pharmaceutical decays over time?
24		24	A. Right.
25	days. Q. Do you know what the document	25	Q. And stabilizers is sometimes put
23		23	
1	Page 151 is?	1	Page 153
	18 ?		
1 7	A There were multiple documents	1	
2	A. There were multiple documents.	2	A. Correct.
3	I can't recall off the top of my head, but	2 3	A. Correct.Q to retard degradation?
3 4	I can't recall off the top of my head, but there were multiple documents that referred to	2 3 4	A. Correct.Q to retard degradation?A. Into any pharmaceutical product.
3 4 5	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient	2 3 4 5	A. Correct.Q to retard degradation?A. Into any pharmaceutical product.Right.
3 4 5 6	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents	2 3 4 5 6	 A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us,
3 4 5 6 7	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay	2 3 4 5 6 7	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log?
3 4 5 6	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent	2 3 4 5 6	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right.
3 4 5 6 7 8 9	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion.	2 3 4 5 6 7 8 9	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry
3 4 5 6 7 8 9 10	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion. Q. So the I think we'll get off	2 3 4 5 6 7 8 9	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry test was to see whether or not that would
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3 4 5 6 7 8 9 10 11 12	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion. Q. So the I think we'll get off the subject. Did Merck test the Protocol 007 serum samples against London-1?	2 3 4 5 6 7 8 9 10 11 12	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry test was to see whether or not that would be that it would meet, that the vaccine would meet CBER's requirements at the end of
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3 4 5 6 7 8 9 10 11 12 13 14 15	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion. Q. So the I think we'll get off the subject. Did Merck test the Protocol 007 serum samples against London-1? A. I don't recall if the tests against London-1 were done with the Protocol 007 serum samples or with samples from other studies.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry test was to see whether or not that would be that it would meet, that the vaccine would meet CBER's requirements at the end of expiry. Right? MS. DYKSTRA: Objection. Form. THE WITNESS: No. What it would mean no. So CBER established a
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion. Q. So the I think we'll get off the subject. Did Merck test the Protocol 007 serum samples against London-1? A. I don't recall if the tests against London-1 were done with the Protocol 007 serum samples or with samples from other studies. Q. So is it fair to say that in designing Protocol 007, that the assay that was chosen was an assay which gave Merck a likelihood of getting the seroconversion rate that CBER wanted?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry test was to see whether or not that would be that it would meet, that the vaccine would meet CBER's requirements at the end of expiry. Right? MS. DYKSTRA: Objection. Form. THE WITNESS: No. What it would mean no. So CBER established a requirement that the 4.3 potency value in the label, the vaccine's label should appropriately be considered to be, should be considered to be, this was CBER's declaration, should be
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion. Q. So the I think we'll get off the subject. Did Merck test the Protocol 007 serum samples against London-1? A. I don't recall if the tests against London-1 were done with the Protocol 007 serum samples or with samples from other studies. Q. So is it fair to say that in designing Protocol 007, that the assay that was chosen was an assay which gave Merck a likelihood of getting the seroconversion rate that CBER wanted? MS. DYKSTRA: Objection. Form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry test was to see whether or not that would be that it would meet, that the vaccine would meet CBER's requirements at the end of expiry. Right? MS. DYKSTRA: Objection. Form. THE WITNESS: No. What it would mean no. So CBER established a requirement that the 4.3 potency value in the label, the vaccine's label should appropriately be considered to be, should be considered to be the potency value at
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	I can't recall off the top of my head, but there were multiple documents that referred to the need of having an assay with sufficient sensitivity there were multiple documents that referred to the need to have an assay that demonstrated at least 90 percent seroconversion. Q. So the I think we'll get off the subject. Did Merck test the Protocol 007 serum samples against London-1? A. I don't recall if the tests against London-1 were done with the Protocol 007 serum samples or with samples from other studies. Q. So is it fair to say that in designing Protocol 007, that the assay that was chosen was an assay which gave Merck a likelihood of getting the seroconversion rate that CBER wanted? MS. DYKSTRA: Objection. Form. THE WITNESS: Both assays, the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Correct. Q to retard degradation? A. Into any pharmaceutical product. Right. Q. And we now know, you've told us, that there was a fill to 5.0 log? A. Right. Q. And the point of the end expiry test was to see whether or not that would be that it would meet, that the vaccine would meet CBER's requirements at the end of expiry. Right? MS. DYKSTRA: Objection. Form. THE WITNESS: No. What it would mean no. So CBER established a requirement that the 4.3 potency value in the label, the vaccine's label should appropriately be considered to be, should be considered to be, this was CBER's declaration, should be considered to be the potency value at the end of the vaccine's shelf life.

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1	Q. Who is Philip Bennett?	1	Q. And if the shelf life instead
2	A. I don't recall his exact	2	was, as you speculate is possible, you didn't
3	position within the company. He's not within	3	testify definite but it could be as much as
4	the company. Actually I don't recall exactly.	4	two years, you said?
5	Q. Did	5	A. It could be as much as two
6	A. I really don't.	6	years.
7	Q. Was there statisticians who	7	Q. That would be beyond the shelf
8	would review at Merck the results of clinical	8	life of the
9	trials?	9	A. No, that would be beyond
10	A. Any clinical trial is a	10	Q. Let me finish the sentence.
11	statistically driven study, yes. Yes.	11	beyond the shelf life intended?
12	Q. I'd like to show you this	12	A. None of this declares shelf
13	particular document which bears numbers	13	life. What this only says is that based on
14	MRK-0562218 and 19. Let me distribute it	14	statistical modeling, if I start at 5 and want
15	right now.	15	to end at 4.3 and I want to do that with a 95
16		16	percent probability, I probably should go no
17	(Exhibit Emini-11, 3/14/01	17	longer than 12 months.
18	E-mail with attachment, 0562218 &	18	Q. Now, if the expiry that CBER
19	0562219, was marked for identification.)	19	wanted could only be maintained for 12 months,
20		20	wouldn't that mean that a shelf life
21	THE WITNESS: Okay.	21	afterward, after 12 months well, what would
22	BY MR. BEGLEITER:	22	that mean to a shelf life that excuse me,
23	Q. You see on page 2, the second	23	withdraw the question.
24	page has a chart, a table. Do you see that?	24	If a determination was made by
25	A. Uh-huh.	25	Merck that 4.3 log 50 dose would only support
23		23	
1	Page 155	1	Page 157
1	Q. And this doctor makes the	1	12-month expiry using what would that mean
2	Q. And this doctor makes the following statement with regard to that table.	2	12-month expiry using what would that mean to shelf life, if anything?
2 3	Q. And this doctor makes the following statement with regard to that table.A. Right.	2 3	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form.
2 3 4	 Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss 	2 3 4	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring
2 3 4 5	 Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various 	2 3 4 5	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a
2 3 4 5 6	 Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." 	2 3 4 5 6	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination?
2 3 4 5 6 7	 Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." A. Right. 	2 3 4 5 6 7	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination? BY MR. BEGLEITER:
2 3 4 5 6 7 8	 Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." A. Right. Q. "Our expiry dating needs to be 	2 3 4 5 6 7 8	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination? BY MR. BEGLEITER: Q. No, I'm asking you as a general
2 3 4 5 6 7 8 9	Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." A. Right. Q. "Our expiry dating needs to be 12 months in order to provide 95 percent	2 3 4 5 6 7 8 9	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination? BY MR. BEGLEITER: Q. No, I'm asking you as a general question.
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2 3 4 5 6 7 8 9 10	Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." A. Right. Q. "Our expiry dating needs to be 12 months in order to provide 95 percent confidence that a lot released at 5.0 will be above 4.3 at expiry."	2 3 4 5 6 7 8 9 10 11	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination? BY MR. BEGLEITER: Q. No, I'm asking you as a general question. A. If a determination were made, well, so if the agreement, if there is an
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." A. Right. Q. "Our expiry dating needs to be 12 months in order to provide 95 percent confidence that a lot released at 5.0 will be above 4.3 at expiry." Do you see that? A. Yes. Q. What does that mean to you? A. That means by looking at the available stability data that was available to Phil Bennett at the time and then modeling that data on a statistical model, he comes to the conclusion that if we establish 4.3 as an expiry dating and you fill with a potency of 5, that there is that if you want to be guaranteed with a 95 percent probability, that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination? BY MR. BEGLEITER: Q. No, I'm asking you as a general question. A. If a determination were made, well, so if the agreement, if there is an agreement with the agency that the end expiry potency should be X, whatever the number is, and if a formal determination and a formal stability study shows that at a given time point you are highly likely to be below X, that does define your shelf life in general sense. Q. Let me ask you some questions and then maybe we'll go to lunch. Were you involved with hiring and firing people in your division?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. And this doctor makes the following statement with regard to that table. A. Right. Q. He says, "Following are the loss and variability estimates for mumps at various time points." A. Right. Q. "Our expiry dating needs to be 12 months in order to provide 95 percent confidence that a lot released at 5.0 will be above 4.3 at expiry." Do you see that? A. Yes. Q. What does that mean to you? A. That means by looking at the available stability data that was available to Phil Bennett at the time and then modeling that data on a statistical model, he comes to the conclusion that if we establish 4.3 as an expiry dating and you fill with a potency of 5, that there is that if you want to be guaranteed with a 95 percent probability, that you will be at the end of shelf life at 4.3	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	12-month expiry using what would that mean to shelf life, if anything? MS. DYKSTRA: Objection. Form. THE WITNESS: Are you referring specifically to this note as a determination? BY MR. BEGLEITER: Q. No, I'm asking you as a general question. A. If a determination were made, well, so if the agreement, if there is an agreement with the agency that the end expiry potency should be X, whatever the number is, and if a formal determination and a formal stability study shows that at a given time point you are highly likely to be below X, that does define your shelf life in general sense. Q. Let me ask you some questions and then maybe we'll go to lunch. Were you involved with hiring and firing people in your division? A. I did not hire and fire

40 (Pages 154 - 157)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLY CONFIDENTIAL -	111	TORNETS ETES OFTET
	Page 158		Page 160
1	Q. Was your signature necessary to	1	involved with the hiring one way or another of
2	hire someone?	2	Stephen Krahling?
3	MS. DYKSTRA: Objection.	3	A. It doesn't refresh my recollection
4	THE WITNESS: It depends on the	4	of the day that this was received, but I will
5	level of the individual that came in.	5	agree that this was sent to me, likely
6	BY MR. BEGLEITER:	6	received by me and that I likely may have read
7	Q. Let's say Mr. Krahling here.	7	it.
8	A. I don't recall what level he	8	Q. In the last paragraph on the
9	came in.	9	second page, "I therefore recommend offering
10	Q. How about terminating someone,	10	one of our remaining technical positions to
11	did you have a responsibility to sign off on a	11	Steve."
12	termination?	12	Do you see that?
13	MS. DYKSTRA: Objection.	13	A. Yes.
14	THE WITNESS: It depended on the	14	Q. And did you act on that
15	nature of the termination. But, again,	15	recommendation?
16	most terminations were handled directly	16	A. I don't recollect if I acted on
17	through HR and legal.	17	that recommendation directly or discussed it
18	BY MR. BEGLEITER:	18	with Dr. Shaw and allowed him to make the
19	Q. How about when Mr. Krahling left	19	final determination.
20	Merck, did you sign off on a document?	20	Q. Did you receive this document in
21	A. I have no recollection.	21	the usual course of your employment?
22	MS. DYKSTRA: Let him finish the	22	A. I will assume that I did because
23	question.	23	it was addressed to me.
24	THE WITNESS: I'm sorry.	24	Q. Do you have any reason why you
25	BY MR. BEGLEITER:	25	wouldn't have received it, you know of no
23	DI MIK. DEGLETTEK.		wouldn't have received it, you know of no
	Page 159		Page 161
1	Q. I'd like to show you withdrawn.	1	Page 161 reason?
2	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire	1 2	Page 161 reason? A. I know of no reason why I would
2 3	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling	1 2 3	Page 161 reason? A. I know of no reason why I would not have received it.
2 3 4	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary?	1 2 3 4	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as
2 3 4 5	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection,	1 2 3 4 5	Page 161 reason? A. I know of no reason why I would not have received it.
2 3 4 5 6	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my	1 2 3 4 5 6	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13.
2 3 4 5 6 7	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my approval would be necessary.	1 2 3 4 5 6 7	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13. (Exhibit Emini-13, Resignation
2 3 4 5 6 7 8	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my approval would be necessary. Q. Would he be consulting with you	1 2 3 4 5 6 7 8	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13. (Exhibit Emini-13, Resignation Authorization Form, 00582392, was
2 3 4 5 6 7 8 9	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my approval would be necessary. Q. Would he be consulting with you as to whether or not to hire someone?	1 2 3 4 5 6 7 8 9	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13. (Exhibit Emini-13, Resignation
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2 3 4 5 6 7 8 9 10 11 12 13	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my approval would be necessary. Q. Would he be consulting with you as to whether or not to hire someone? MS. DYKSTRA: Objection. THE WITNESS: The consultation would probably have been probably have been most likely with Dr. Shaw.	1 2 3 4 5 6 7 8 9 10 11 12 13	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13. (Exhibit Emini-13, Resignation Authorization Form, 00582392, was marked for identification.) BY MR. BEGLEITER: Q. Okay. Doctor, is your signature on this page?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my approval would be necessary. Q. Would he be consulting with you as to whether or not to hire someone? MS. DYKSTRA: Objection. THE WITNESS: The consultation would probably have been probably have been most likely with Dr. Shaw. BY MR. BEGLEITER: Q. Let's take a look at this.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	Page 161 reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13. (Exhibit Emini-13, Resignation Authorization Form, 00582392, was marked for identification.) BY MR. BEGLEITER: Q. Okay. Doctor, is your signature on this page? A. Yes, it is. Q. And you signed in the usual
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. I'd like to show you withdrawn. When Dr. Krah wanted to hire somebody, a virologist such as Stephen Krahling or someone else, was your approval necessary? A. I have no direct recollection, but it would be highly unlikely that my approval would be necessary. Q. Would he be consulting with you as to whether or not to hire someone? MS. DYKSTRA: Objection. THE WITNESS: The consultation would probably have been probably have been most likely with Dr. Shaw. BY MR. BEGLEITER: Q. Let's take a look at this. Merck 331424 to 33. This is Emini-12. (Exhibit Emini-12, 10/10/00 Memo, 00331424 - 00331433, was marked for identification.) THE WITNESS: Okay. BY MR. BEGLEITER:	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	reason? A. I know of no reason why I would not have received it. MR. BEGLEITER: Let's have it as Number 13. (Exhibit Emini-13, Resignation Authorization Form, 00582392, was marked for identification.) BY MR. BEGLEITER: Q. Okay. Doctor, is your signature on this page? A. Yes, it is. Q. And you signed in the usual course of your employment? A. Yes, I did. Q. And it's signed 12/20/01. Do you see that? A. Yes. Q. You indicated, I believe, a few minutes ago, again, if I got it wrong, please tell me, that you didn't sign off on every

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1	Page 162		Page 164
1	signed off on everyone's resignation. So I	1	Q. How about Frank Kennedy?
2	don't know I mean, this was obviously a	2	A. Frank Kennedy, I did see the
3	could have been a process that was in place	3	name when reviewing documents, but actually
4	which I have no recollection of at Merck at	4	have that's a recollection that hasn't even
5	the time that all resignations were signed off	5	come back. I don't recognize it at all.
6	by the appropriate HR person that was the	6	Q. How about Joan Wlochowski?
7	other signature on this and the head of the	7	A. First name, please?
8	department would have been me.	8	Q. Joan?
9	Q. That person is Robert Suter?	9	A. Joan. Joan Wlochowski.
10	A. From HR, yes.	10	Q. W-L-O-C-H-O-W
11	Q. And he wasn't a doctor?	11	A. Yes. Yes, I do recall. Yes, I
12	A. No.	12	do recall.
13	Q. Do you know what position	13	Q. We're talking together, it's
14	Mr. Suter held at HR?	14	going to drive her crazy.
15	A. The exact level of his position,	15	A. My apologies.
16	I don't know. But he was assigned as the	16	Q. Joan W-L-O-C-H-O-W-S-K-I?
17	senior HR person to the to my department.	17	A. Yes.
18	Q. How many was Steve Krahling's	18	Q. What do you recall about her?
19	title virologist, to your recollection?	19	A. Same thing. You know, same
20	A. I don't recollect the exact	20	level with Mr. Krahling and then with Mary
21	title.	21	Yagodich, you know, in the laboratory. The
22	Q. What were the titles of the	22	laboratory operational staff under Dr. Krah.
23	people who worked in who worked on Protocol	23	Q. How many people worked in how
24	007 with Dr	24	many professionals worked in the laboratory?
25	A. I don't recollect the exact	25	MS. DYKSTRA: Objection.
	Page 163		Page 165
1	titles. Too many companies in between and too	1	THE WITNESS: I believe there
2	many different titles.	2	were four or five.
3	Q. Do you have any recollection as	3	BY MR. BEGLEITER:
4	to who worked in that lab other than Dr. Krah	4	Q. Tell me, sir, do you know during
5	and Steve Krahling?	5	the time of Protocol 007 if any of the women
	and Sieve Riaming.	-	
	A Recollections only came back	6	
6	A. Recollections only came back	6	working in the lab were pregnant?
6 7	when reviewing documents over the past several	7	working in the lab were pregnant? A. I don't recall.
6 7 8	when reviewing documents over the past several months and seeing various names being present.	7 8	working in the lab were pregnant? A. I don't recall. Q. Was there a rule in the lab that
6 7 8 9	when reviewing documents over the past several months and seeing various names being present. Q. Okay. Let me just throw some	7 8 9	working in the lab were pregnant? A. I don't recall. Q. Was there a rule in the lab that pregnant women couldn't work near live viruses?
6 7 8 9 10	when reviewing documents over the past several months and seeing various names being present. Q. Okay. Let me just throw some names out and see if you recollect them. Mary	7 8 9 10	working in the lab were pregnant? A. I don't recall. Q. Was there a rule in the lab that pregnant women couldn't work near live viruses? A. That was a general rule,
6 7 8 9 10 11	when reviewing documents over the past several months and seeing various names being present. Q. Okay. Let me just throw some names out and see if you recollect them. Mary Yagodich?	7 8 9 10 11	working in the lab were pregnant? A. I don't recall. Q. Was there a rule in the lab that pregnant women couldn't work near live viruses? A. That was a general rule, absolutely. Still is.
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	when reviewing documents over the past several months and seeing various names being present. Q. Okay. Let me just throw some names out and see if you recollect them. Mary Yagodich? A. Yagodich I do recall, yes. Q. What was her what do you recall about her? A. I mean, to my recollection, under David Krah, so she was a member of David Krah's laboratory. My recollection is that practically everyone in the laboratory under David Krah had worked at the same level, but I can't attest to that being the fact. It could be, one could have been slightly higher, one below, I don't know.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	working in the lab were pregnant? A. I don't recall. Q. Was there a rule in the lab that pregnant women couldn't work near live viruses? A. That was a general rule, absolutely. Still is. Q. Let me see if I can refresh your memory. I'm going to show you Merck 14744 through 747. We'll mark this now as 13. MS. DYKSTRA: 14. MR. BEGLEITER: 14. (Exhibit Emini-14, 3/29/01 Memo, 00014744 - 00014747, was marked for identification.) THE WITNESS: Yes, I do recall

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	Page 166		Page 168
1	BY MR. BEGLEITER:	1	
2	Q. And did you receive this memo in	2	BY MR. BEGLEITER:
3	the usual course of your employment?	3	Q. We used them. Sorry. I
4	A. Yes, I did.	4	apologize. That should be stricken I believe.
5	Q. And does that indicate in the	5	Well, we'll leave it marked, we'll use it
6	second page that Mary is the	6	anyway, but not right now. I wanted to show
7	A. Mary Yagodich in seventh month	7	you something else.
8	of pregnancy.	8	A. Okay.
9	Q. That's as of March 29, 2001?	9	Q. This document would not indicate
10	A. Yes.	10	that Mr. Krahling was pregnant.
11	MS. DYKSTRA: Just for the	11	A. No, it would not.
12	record, I have two memos. Did you mean	12	Q. Jennifer Kriss, okay.
13	to give two memos?	13	MR. BEGLEITER: I'd like to have
14	MR. BEGLEITER: Are they both	14	marked 15719 to 15720.
15	Mary Yagodich?	15	
16	MS. DYKSTRA: They are both Mary	16	(Exhibit Emini-16, 3/29/01 Memo,
17	Yagodich.	17	00015719 & 00015720, was marked for
18	MR. BEGLEITER: I didn't mean to	18	identification.)
19	give you two but	19	
20	MS. DYKSTRA: They're different	20	BY MR. BEGLEITER:
21	memos, though.	21	Q. So this memo involves Jennifer
22	THE WITNESS: Yeah, they are	22	Kriss. Is that right?
23	different.	23	A. Yes, it does.
24	BY MR. BEGLEITER:	24	Q. And who was Jennifer Kriss, do
25	Q. The 746, I'll use that later.	25	you know?
	Page 167		Page 169
1	If you can hand that back to me, I appreciate	1	A. Jennifer Kriss I recall as being
2	it.	2	a member of the laboratory.
3	MS. DYKSTRA: Bob, can I have	3	Q. Dr. Krah's lab?
4	that copy back then, the one you're	4	A. Dr. Krah's laboratory.
5	using?	5	Q. This was sent to you in the
6	MR. BEGLEITER: Yes. It should	6	usual course of your employment?
7	be during the course of the year 2000.	7	A. Yes, it was.
8	That's how it should begin.	8	Q. Was she also pregnant?
9	MS. DYKSTRA: Ending in 14744 as	9	A. According to the memo, she was
10	the Bates number?	10	in the fifth month of her pregnancy, and it's
11	MR. BEGLEITER: Yes.	11	dated 29 March 2001.
12	MS. DYKSTRA: Thank you.	12	Q. Going to the previous one, which
13	BY MR. BEGLEITER:	13	was the one that was inadvertently marked
14	Q. You did receive this and	14	involving Stephen Krahling but dated the same
15	acknowledge that she was pregnant March 29,	15	day.
16	2001?	16	A. Yes.
17	A. That's what it says.	17	Q. Did you receive that in the
18	Q. And does this also refresh your	18	usual course of your employment?
19	recollection about forget it.	19	A. Yes, I did.
20	MR. BEGLEITER: Can you mark	20	Q. Now, all of these are dated
21	15702 to 03 as number 15, Emini-15?	21	March 29th?
22		22	A. Yes.
23	(Exhibit Emini-15, 3/29/01 Memo,	23	Q. Talk about Protocol 005. Is
1	00015702 & 00015703, was marked for	24	that what is were any of these people
24	00013702 & 00013703. Was marked for		
24 25	identification.)	25	working on Protocol 005?

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Page 172 A. Well, it refers to Protocol 005. by the agency with respect to end expiry, but 2 What I do not recall and don't know at the 2 I don't recollect the details of those 3 3 moment was whether or not Protocol 005 was the assessments. laboratory number for the assays that were 4 Q. Ms. Yagodich is in 14744. It 4 5 5 says, "In the middle of this activity we being done in support of the clinical study in Protocol 007. That, I don't recall. So we 6 received an FDA mandate to define an would need to look at what Protocol 005 end-expiry dose of mumps virus in MMR II." 7 8 8 actually refers to. Where are you? A. 9 9 The point being is that if you The middle of 14744. 10 10 look at any of those, can you tell whether or A. Right. not these people were working on Protocol 007? Sir, doesn't that refer to the 11 11 O. 12 A. Well, all of these refer to the 12 mandate which resulted in the Protocol 007? 13 neuts of the mumps neut assay, and in one case 13 It may, but I cannot, again, 14 it refers to 570 serum pairs were tested in 14 based on this language, make a direct 15 emergency response to CBER's citation during 15 determination. the MMD. But it doesn't say, I can't tell you 16 On the second sentence it refers 17 if it was 007 or something different. I 17 to "...an interim set of data in time for a 18 cannot tell from this. 18 projected meeting with the FDA." There was an 19 Q. You can't tell whether or not in 19 interim analysis that was performed in 007, so 20 20 this may refer to it. that first paragraph, I believe they're all --21 21 take a look at the one regarding Mary Q. I'll put it to you this way: 22 22 Yagodich, she was working on --This is Yagodich, going to the Krahling one, 23 A. This refers to two sets of 23 can you think of any other protocol other than 24 assessments, one was the development of an 24 007 in which this document would indicate he 25 25 assay that was then used to assess the sera in was working on? Page 171 Page 173 the head-to-head clinical study of MMR II and 1 MS. DYKSTRA: Objection. Form. 2 Priorix, as we discussed before. It does not 2 THE WITNESS: I cannot, no. 3 indicate whether or not that assay was 3 BY MR. BEGLEITER: 4 actually run in the laboratory here or just 4 Q. Same thing with Ms. Kriss, take 5 solely developed, which normally would have 5 a look at --You mean other than the 007? 6 been the case. The assay would have been run 6 A. 7 in a different laboratory. And then it also 7 Q. Other than 007. refers to data that needed to be generated to 8 Other than 007, from the 9 address a question that came up with respect 9 terminology in these memos, I can't conclude --10 to end expiry and shelf life to end expiry. 10 Q. I asked you another question. And that would be 007. Is that 11 Q. 11 Can you think of any other protocol --12 right? 12 A. No, I cannot. 13 I can't tell exactly from the 13 Q. Let me finish. 14 terminology used in this memo whether we're 14 Can you think of any other 15 referring specifically to 007 or to something 15 protocol that they could have been working on else. That, I don't recollect. other than 007? 16 16 17 17 Now, I thought I asked you A. It depends. It's the definition 18 before whether or not there were any other end 18 of working on that's causing me to hesitate. 19 expiry studies done other than 007 for mumps, 19 What do you mean by "working on," developing 20 and you said you knew of no others? 20 an assay or actually generating the clinical 21 A. I don't recollect that there 21 data using the assay? 22 were any -- well, that there were any specific 22 Q. The latter. 23 clinical studies that were done. There may 23 Generating the clinical data 24 have been assessment of sera to generate data 24 using the assay. The only one I am aware of in support of questions that may have come up

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_	Page 174		Page 176
1	Q. Now, in the years that you were	1	the assay, how is it accomplished? What would
2	at biologics and vaccines, how often did Merck	1	the virologist do to see if what the
3	outsource clinical trials approximately?	3	reaction was?
4	MS. DYKSTRA: Objection. Form.	4	A. I can't tell you what the exact
5	THE WITNESS: Outsource, sorry,	5	details were, but there were but there was
6	you need more specificity. What do you	6	clearly a standard operating procedure
7	mean by "outsource clinical trial"?	7	because, remember, the assay required to be
8	BY MR. BEGLEITER:	8	validated, so what was validated was defined
9	Q. Well, let me ask you this, go	9	by the standard operating procedure. So
10	right to the subject. Do you know who Dick	10	whether a validated assay, by definition,
11	Ward is?	11	doesn't matter where you run it and who runs
12	A. Yes, I know Dick Ward.	12	it, it will generate the same set of data.
13	Q. Who is Dick Ward?	13	Q. Well, are you saying in all
14	A. Dick Ward was a professor of	14	circumstances it would represent the it
15	virology. I don't know where he was at the	15	would result in the same set of data?
16	time. When I knew him he was at University o	f 16	A. Only if one could validate that
17	Cincinnati, if I remember correctly.	17	the laboratory that was run because in
18	Q. Do you know what hospital he was	18	addition to validating the assay, the
19	associated with?	19	laboratory needs to be validated as well.
20	A. I don't remember the exact title	20	Q. If you were to have if you
21	of the hospital.	21	were to hire, retain, I don't know what the
22	Q. Have you ever heard of the	22	right word is
23	Children's Hospital Medical Center in	23	A. Yes, I would validate the
24	Cincinnati?	24	laboratory.
25	A. Yes, I have certainly heard of	25	MS. DYKSTRA: Let him finish the
	Page 175		Page 177
1	it.	1	question.
1 2	it. Q. Is it a reputable hospital,	2	question. THE WITNESS: My apologies.
2 3	it. Q. Is it a reputable hospital, medical center?	2 3	question. THE WITNESS: My apologies. BY MR. BEGLEITER:
2 3 4	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes.	2 3 4	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the
2 3 4 5	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about	2 3 4 5	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to
2 3 4 5 6	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the	2 3 4 5 6	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory?
2 3 4 5 6 7	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial	2 3 4 5 6 7	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes.
2 3 4 5 6 7 8	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form.	2 3 4 5 6 7 8	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical
2 3 4 5 6 7 8 9	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER:	2 3 4 5 6 7 8 9	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual
2 3 4 5 6 7 8 9	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007?	2 3 4 5 6 7 8 9	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples.
2 3 4 5 6 7 8 9 10	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the	2 3 4 5 6 7 8 9 10 11	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the
2 3 4 5 6 7 8 9 10 11 12	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been	2 3 4 5 6 7 8 9 10 11 12	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet?
2 3 4 5 6 7 8 9 10 11 12 13	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the	2 3 4 5 6 7 8 9 10 11 12 13	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples
2 3 4 5 6 7 8 9 10 11 12 13 14	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to	2 3 4 5 6 7 8 9 10 11 12 13 14	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not
2 3 4 5 6 7 8 9 10 11 12 13 14 15	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay? A. Well, it is the assay that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you were comfortable that the assay as well as the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay? A. Well, it is the assay that the assays that are designed to generate the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you were comfortable that the assay as well as the facility had been appropriately validated.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay? A. Well, it is the assay that the assays that are designed to generate the data from the clinical studies. So in the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you were comfortable that the assay as well as the facility had been appropriately validated. Q. So nothing would go to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay? A. Well, it is the assay that the assays that are designed to generate the data from the clinical studies. So in the context of 007 that would have been the PRN	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you were comfortable that the assay as well as the facility had been appropriately validated. Q. So nothing would go to Dr. Ward's lab unless the facility itself was
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay? A. Well, it is the assay that the assays that are designed to generate the data from the clinical studies. So in the context of 007 that would have been the PRN assay and maybe possibly the ELISA. I don't	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you were comfortable that the assay as well as the facility had been appropriately validated. Q. So nothing would go to Dr. Ward's lab unless the facility itself was validated?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it. Q. Is it a reputable hospital, medical center? A. Well, yes, of course. Yes. Q. Was there any thought about outsourcing to Dr. Ward any part of the clinical trial MS. DYKSTRA: Objection to form. BY MR. BEGLEITER: Q of 007? A. It was not to outsource the clinical trial. It would have been outsourced would have been the conduct of the assays in support of the clinical trial, to generate the data from the clinical trial. Q. When you say "conduct of the assays," what are you referring to? What actual work is done to conduct the assay? A. Well, it is the assay that the assays that are designed to generate the data from the clinical studies. So in the context of 007 that would have been the PRN	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	question. THE WITNESS: My apologies. BY MR. BEGLEITER: Q. It would be validated before the any part of the clinical trial was sent to that laboratory? A. Yes. Q. You wouldn't have a clinical trial, if that's the right word, the actual A. Samples. Q samples in a place where the validation had not occurred yet? A. Well, you could have the samples in a place where the validation had not occurred yet. To actually run the assays using those samples to generate the data for the clinical trial purposes, typically, actually, you would not do that unless you were comfortable that the assay as well as the facility had been appropriately validated. Q. So nothing would go to Dr. Ward's lab unless the facility itself was

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	Page 178		Page 180
1	THE WITNESS: No. I don't	1	by many years.
2	recall if samples had been sent to	2	
3	Dr. Ward's laboratory, but, again, it	3	(Exhibit Emini-17, 2/26/09 Press
4	is not whether or not the samples were	4	release, was marked for identification.)
5	there, it's whether or not they would	5	
6	be running the assay.	6	BY MR. BEGLEITER:
7	BY MR. BEGLEITER:	7	Q. If you take a look at that, is
8	Q. So go back to something I asked	8	there any doubt in your mind that the Bill &
9	you before. Were you contemplating using	9	Melinda Gates Foundation would have given a
10	Dr. Ward's lab for any purpose regarding 007?	10	grant to the Children's Hospital of
11	A. Not that I recollect, other than	11	Cincinnati?
12	the review of the document showed that we were	12	MS. DYKSTRA: Objection.
13	clearly apparently contemplating the use of	13	THE WITNESS: Well, they did
14	Dr. Ward's laboratory as an additional	14	give a grant.
15	laboratory or as the laboratory that would run	15	BY MR. BEGLEITER:
16	the 007 samples.	16	Q. Okay. The place you're now
17	O. What documents were those?	17	working, that's a reputable institution?
18	A. Those were various documents and	18	A. An exceptionally reputable
19	memo that I reviewed. I cannot tell you the	19	institution.
20	specifics ones.	20	Q. And they wouldn't be giving
21	Q. You cannot because you don't	21	grants to people that weren't reputable?
22	remember or because you're	22	A. It depends on the nature of the
23	A. No, I don't remember. I just	23	work that needs to be done. Certainly
24	saw them and gave them back. I did not retain	24	reputable in the context for which the grant
25	anything.	25	was given, the answer is yes.
23		25	
1	Page 179	,	Page 181
1	Q. Now, did Dr. Ward himself have a	1	Q. Now, did you ever have a
2	Q. Now, did Dr. Ward himself have a good reputation?	2	Q. Now, did you ever have a discussion with Dr. Krah and Dr. Shaw as to
2 3	Q. Now, did Dr. Ward himself have a good reputation? A. Dr. Ward definitely had a good	2 3	Q. Now, did you ever have a discussion with Dr. Krah and Dr. Shaw as to whether or not they would have well, do one
2 3 4	Q. Now, did Dr. Ward himself have a good reputation? A. Dr. Ward definitely had a good reputation.	2 3 4	Q. Now, did you ever have a discussion with Dr. Krah and Dr. Shaw as to whether or not they would have well, do one at a time with Dr. Krah as to whether or
2 3 4 5	 Q. Now, did Dr. Ward himself have a good reputation? A. Dr. Ward definitely had a good reputation. Q. And did the hospital have a good 	2 3 4 5	Q. Now, did you ever have a discussion with Dr. Krah and Dr. Shaw as to whether or not they would have well, do one at a time with Dr. Krah as to whether or not he would have preferred to do the PRN or
2 3 4 5 6	Q. Now, did Dr. Ward himself have a good reputation? A. Dr. Ward definitely had a good reputation. Q. And did the hospital have a good reputation?	2 3 4 5 6	Q. Now, did you ever have a discussion with Dr. Krah and Dr. Shaw as to whether or not they would have well, do one at a time with Dr. Krah as to whether or not he would have preferred to do the PRN or have it outsourced?
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1 2 3 4	Page 182 MS. DYKSTRA: Objection. Form.		Page 184
2 3			
3		1	A. That would indicate that was a
	THE WITNESS: It doesn't matter.	2	tight capacity, so, therefore, it would be
4	What matters is whether or not the	3	have been, if appropriate, to send it to an
	validated assay can be run in a	4	outside laboratory to expand the capacity,
5	validated laboratory. It doesn't	5	yes.
6	matter if it's internal or external.	6	Q. We've already discussed, I hope
7	What usually drove the decision was	7	we remember this, that two of the members of
8	usually a capacity decision. Assuming	8	the staff, Mary Yagodich and Jennifer Kriss
9	that there was appropriate validation.	9	were pregnant and couldn't be near the live
10 E	BY MR. BEGLEITER:	10	vaccine.
11	Q. Capacity in what sense?	11	A. And could not be near the live
12	A. Capacity in that there are just	12	varicella.
1	so many people in a day and the facility is	13	Q. Right.
	only so large and there are a certain number	14	A. They could still work in the
	of samples that need to be run, so one can run	15	laboratory but not run the actual assays with
	them. Oftentimes a good reason for	16	the live virus.
	outsourcing an assay is because you need to	17	Q. Right. So that you assured to.
II.	have additional capacity to do it. But,	18	So weren't those reasons to outsource it,
	again, the critical aspect of it is that the	19	those reasons
	aboratory to whom you are outsourcing the	20	A. Any capacity.
	assay is appropriately validated and can	21	MS. DYKSTRA: Let him finish the
	demonstrate that it can run the assay the way	22	question so we can make sure the record
1	you would have run the assay.	23	is clear.
24	Q. Let's go back to 14.	24	THE WITNESS: Sorry.
25	A. 14?	25	MS. DYKSTRA: That's okay.
			•
1	Page 183	1	Page 185 BY MR. BEGLEITER:
1 2 li	Q. Yes, the Mary Yagodich. I'd	2	Q. So that was a reason to do it?
3	ike to read a sentence to you. A. Please.	3	A. Yes.
		4	
4 5 p	Q. The first sentence of the second	5	
6 B	paragraph. A. Please.	6	outsource. Right?
7		7	MS. DYKSTRA: Objection. THE WITNESS: The decision was
	Q. "The lab staff worked nights and	8	
II.	weekends across the Thanksgiving, Christmas	9	made not to outsource.
1	and New Year holidays in order to meet the	-	BY MR. BEGLEITER:
1	leadlines imposed on them."	10	Q. That decision was made by you,
11	A. Yes.	11	was it not?
12	Q. This is 2000 this memo is	12	MS. DYKSTRA: Objection.
	lated March 29, 2001?	13	THE WITNESS: I don't recall if
14	A. Yes.	14	I made that decision or not. However,
15	Q. "The plan for the remaining	15	in reading the memo, it was indicated
	amples had," Dr. Shaw emphasizes it.	16	that the reason why the decision, that
17	A. Yes.	17	was the next sentence after the
18	Q. "had been to send them to an	18	sentence that you note, not to
1.10	outside contract laboratory."	19	outsource it was concern that the
1	Do you see that?	20	outsourcing laboratory, which
20		21	presumably was Dr. Ward's laboratory
20 21	A. Yes.		presumably was Dr. Ward's laboratory,
20 21 22	Q. Was the conditions in the lab	22	was not capable of reproducing the
20 21 22 23 a	Q. Was the conditions in the lab among the workers having to work Thanksgiving	22 23	was not capable of reproducing the required precision that would be
20 21 22 23 at 24 at	Q. Was the conditions in the lab	22	was not capable of reproducing the

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Page 188 1 Where does it say capable? what he was referring to is the fact that the 2 A. Well, it just says --2 data generated using the samples that had been 3 It says not be able to 3 tested to date yielded values that were very Q. 4 reproduce. 4 tight with each other and, therefore, with a 5 5 very narrow confidence interval. When you see A. Well, I read it as capable. You 6 that, it is imperative that you be certain, 6 may read it as not being able to reproduce the particularly if you're going to a different 7 precision. So there was a concern obviously 8 laboratory, that the validation of that 8 that they could not reproduce the precision. 9 laboratory be very good because the precision 9 Q. Didn't we discuss like a half an 10 of the assay, which is the most difficult 10 hour ago that if the lab was validated, two labs validated the same way doing the same characteristic of an assay to control, is well 11 11 controlled, particularly for a biological 12 protocols would come up with the same results? 12 13 A. If the assay is validated, yeah. 13 assav. 14 Q. Are you speculating here this 14 If the assay and the laboratory are validated. 15 So there was obvious concern over the 15 afternoon that Dr. Ward's lab would not have validation of the laboratory. 16 had the proper validation? 16 17 17 A. What I am saying is that at the Q. Where does it say that? 18 MS. DYKSTRA: Objection. 18 time that this decision was made and given the 19 THE WITNESS: Where does it not 19 time constraints that were involved, that 20 20 say that? either there was a concern, that there was a 21 BY MR. BEGLEITER: 21 concern either based on observation or simply 22 based on principle, that Dr. Ward's lab might 22 Q. Okay. But where does it say it, 23 23 sir? not be able to run the assay in a way that 24 Well, it doesn't say. 24 would ensure the same level of required Α. 25 25 precision. MS. DYKSTRA: Objection. Page 187 Page 189 BY MR. BEGLEITER: 1 Q. Was the concern here also that 2 Q. Go ahead, I'm sorry. 2 could not -- that Dr. Ward's lab would not 3 Just slow down for a second. 3 replicate what Dr. Krah's lab was --4 Q. Okay. 4 A. No. 5 5 Tell me when you're ready. Ready. Q. -- coming up with?

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6 It doesn't say it, but in

7 reading the documents, the suggestion was, and again, I have no direct recollection, to not

9 to send it to Dr. Ward's laboratory either

- 10 because it had not yet been validated and
- 11 brought under time pressure to generate the
- 12
- data so, therefore, the decision was made to
- 13 keep it entirely internally and to deal the
- best that one could with the capacity issue,
- 15 which is what is reflected in these documents; or alternatively, to deal the best that we
- 17 could with the capacity issue because there 18 was concern over the quality of the data that 19 would be generated in Dr. Ward's laboratory.
 - What did you understand Dr. Shaw to mean when he said tightness of the data?
- 22 A. The precision of the data.
- 23 Well, I'm sorry. My apologies. I'll take
- 24 that back.

20

21

25 In the context of this memo,

- That's not what I said. That is not the concern. The concern is whether the assay could be run with sufficient precision so that one would be able to achieve a data set -- remember, this is a biological assay, biological assays are very difficult to run with appropriate precision. That one would be able to achieve a data set with tight enough confidence intervals that would allow you to address the hypothesis of the 007 study.
- Q. Have you seen any documents which say that Dr. Ward's lab was not capable of doing that?
- A. I have not seen any documents, but it is -- the decision is not based on data that would suggest that one is not capable of doing it. The decision is made on the basis of whether or not there are data that show that one is capable of doing it. So the absence of such data and given the time

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	Page 190		Page 192
1	constraints could very much have led someone	1	A. I don't recall if we actually
2	to make the decision not to transfer the assay	2	had a contract or not.
3	and to keep it internally.	3	Q. If there were such a contract,
4	Q. Which lab was able to achieve	4	would that indicate that there was some
5	the tight precision at Merck?	5	thought that Dr. Ward's lab was capable of
6	A. Well, again, it was from, again,	6	doing the kind of precision you're talking
7	reading that memo and Dr. Shaw's notation that		about?
8	the assay was run with the tight set	8	A. No, because contracts can be
9	of variant, and it was a validated assay, that	9	established prospectively with the supposition
10	we had what appeared to be reasonably good	10	that, you know, we'll actually execute the
11	precision around the assay.	11	contract and actually pay for the work and do
12	Q. By keeping it with Dr. Krah's	12	the work, you know, if we decide to use the
13	lab, you could ensure that what the result	13	individual. I've done contracts all the time
14	was going to be, couldn't you?	14	that indicate before I determine whether or
15	MS. DYKSTRA: Objection.	15	not I'm actually using somebody.
16	THE WITNESS: No, you could	16	MR. BEGLEITER: Let me show you
17	ensure that the	17	one document and we'll go to lunch.
18	MS. DYKSTRA: Misstates his	18	This is going to be 18.
19	testimony.	19	
20	THE WITNESS: assay would run	20	(Exhibit Emini-18, E-mail
21	consistently, could run with good	21	exchange, 00448867 & 00448868, was
22	accuracy and prescription, and would	22	marked for identification.)
23	allow you to generate data that you	23	
24	could then cross compare across the	24	BY MR. BEGLEITER:
25	three different arms of the study to	25	Q. So your name is not on this?
	Page 191		Page 193
1	address the hypothesis of the study.	1	A. No. Not in the top ones, no.
2	It is not to ensure that you would get	2	The one at the bottom.
3	a specific set of data coming out.	3	Q. It says, I had a long the one
4	BY MR. BEGLEITER:	4	Alan Shaw to David Krah, I'm going to ask you
5	Q. You're saying that Dr. Ward's	5	whether or not this has any recollection to
6	lab, as far as you can tell from reading this	6	you. Do you recollect this?
7	document, was incapable of doing that?	7	A. No, I don't.
8	MS. DYKSTRA: Objection. Again,	8	MS. DYKSTRA: Object. Let him
9	misstates testimony.	9	read through this.
10	THE WITNESS: No. I did not say	10	MR. BEGLEITER: Sure. Go ahead.
11	that he was incapable of doing it. I	11	I'm telling him what I'm going to ask
12	said there was uncertainty that it	12	him, that's all.
13	could be done. But by definition, that	13	MS. DYKSTRA: Understood.
14	uncertainty exists not just for	14	BY MR. BEGLEITER:
15	Dr. Ward but for every other high	15	Q. So the date on this e-mail, the
16	level, highly trained virologist on the	16	second one is November September 25, 2000.
17	planet unless you generate active data	17	If you'll recall the dates on the ones that
18	to show that you can maintain the same	18	was sent to you on the personal memos that you
19	accuracy and precision, which it is	19	saw were March 29, 2001. Do you see that?
20	very difficult across laboratories	20	A. Yes.
21	running biological assays. So it's not	21	Q. So they're six months?
22	specific for Dr. Ward.	22	A. Six months roughly.
23	BY MR. BEGLEITER:	23	Q. And would you agree, sir, that
24	Q. Do you know if Merck went so far	24	there were problems in the lab at the end of
25	as to have a contract with Dr. Ward's lab?	25	September 2000?
		1	-

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1			
1	Page 194 MC DVVCTD A. Objection	1	Page 196
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	MS. DYKSTRA: Objection. THE WITNESS: Well, what I read	1	BY MR. BEGLEITER:
3	·	2 3	Q. What do you think he meant by that?
4	in this memo, again, no direct recollection other than what I'm	3	A. What he was concerned about was
5	reading here, is that there was all	5	that he was getting frustrated over all the
6	of this relates to the fact that we	6	time and effort that was being spent in the
7	were talking about the potential for	7	laboratory around the mumps assay in support
8	hiring additional people power for the	8	of the 007 study. Because recall the
9	laboratory, additional personnel for	9	laboratory was originally set up to be a
10	the laboratory. There was some concern	10	research laboratory. They were working on
11	that a hiring freeze was going to be	11	varicella. There was a strong desire to pick
12	put into place by the company which	12	up work on an influenza vaccine program as you
13	happened on occasion all the time. And	13	can see is indicated here. And that the mumps
14	there was a discussion going back and	14	assay between the work that was required for
15	forth on this and I apparently had a	15	the development of the assay, to come up with
16	discussion with Alan Shaw noting that	16	an assay that would be suitable to address the
17	one of the things that we probably	17	hypothesis in 007 and then obviously was being
18	needed to have a careful look at in	18	contemplated at the time transferring the
19	David Krah's laboratory was the issue	19	assay to Dick Ward's laboratory so as to
20	of turnover within the laboratory.	20	alleviate his laboratory and actually having
21	BY MR. BEGLEITER:	21	to run the assays was part of the heavy
22	Q. In the third the fourth	22	workload that was ongoing in the lab.
23	paragraph beginning, "We had a discussion of	23	Q. So there was a capacity problem
24	what the coming workload would be for our	24	that was
25	group," do you see that sentence?	25	A. The same as we were saying
	Page 195		
1	A. Yes.	1	Page 197 before.
2	Q. And the "we" is you and Dr. Shaw?	2	Q. There was a capacity problem at
3	A. Yes.	3	the lab. Go ahead, answer.
4	Q. And "As I see it, the current	4	A. Yes, there was a capacity
5	major things are varicella support for Pharm	5	problem at the lab. My apologies.
6	R&D" What's that? Do you know what that	6	MR. BEGLEITER: Let's go to
7	is?	7	lunch.
8	A. That was support of the	8	VIDEOGRAPHER: The time is now
9	= =	9	1.20
1 -	Q. Chicken pox.		1:39.
10	A pharmaceutical research and	10	1:39.
-	A pharmaceutical research and	-	
10	A pharmaceutical research and developing, this was at the time that the	10	(A recess was taken.)
10 11	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the	10 11	
10 11 12	A pharmaceutical research and developing, this was at the time that the	10 11 12	(A recess was taken.)
10 11 12 13	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological	10 11 12 13	(A recess was taken.) VIDEOGRAPHER: The time is now
10 11 12 13 14	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be	10 11 12 13 14	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four.
10 11 12 13 14 15	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done.	10 11 12 13 14 15	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER:
10 11 12 13 14 15 16	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over	10 11 12 13 14 15 16	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor.
10 11 12 13 14 15 16 17	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over the next six to eight months"	10 11 12 13 14 15 16 17	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor. A. Hello.
10 11 12 13 14 15 16 17 18	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over the next six to eight months" Do you see that?	10 11 12 13 14 15 16 17 18	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor. A. Hello. Q. What is an SOP, standard
10 11 12 13 14 15 16 17 18	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over the next six to eight months" Do you see that? A. Yes. Eight months would include	10 11 12 13 14 15 16 17 18 19	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor. A. Hello. Q. What is an SOP, standard operating procedure?
10 11 12 13 14 15 16 17 18 19 20	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over the next six to eight months" Do you see that? A. Yes. Eight months would include March 29th.	10 11 12 13 14 15 16 17 18 19 20	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor. A. Hello. Q. What is an SOP, standard operating procedure? A. Standard operating procedure.
10 11 12 13 14 15 16 17 18 19 20 21	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over the next six to eight months" Do you see that? A. Yes. Eight months would include March 29th. Q. Transferring this I will say	10 11 12 13 14 15 16 17 18 19 20 21	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor. A. Hello. Q. What is an SOP, standard operating procedure? A. Standard operating procedure. Q. What is it in relation to what's
10 11 12 13 14 15 16 17 18 19 20 21 22	A pharmaceutical research and developing, this was at the time that the varicella vaccine was being developed so the laboratory was providing the biological support for that work. So that needed to be done. Q. "which should tail off over the next six to eight months" Do you see that? A. Yes. Eight months would include March 29th. Q. Transferring this I will say freaking, does that sound right to you?	10 11 12 13 14 15 16 17 18 19 20 21 22	(A recess was taken.) VIDEOGRAPHER: The time is now 2:36. This begins disc four. BY MR. BEGLEITER: Q. Good afternoon, Doctor. A. Hello. Q. What is an SOP, standard operating procedure? A. Standard operating procedure. Q. What is it in relation to what's in Protocol 007 or one of the other

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Page 200 things, but in the context of our ongoing 1 Do you have any recollection of 2 discussion here, it would be a standard 2 the preliminary subset? 3 operating procedure that describes the 3 A. I had no recollection from the 4 procedure for the conduct of a specific assay 4 time, no, only when reviewing documents. 5 and how to interpret the data from the assay, 5 This paragraph indicates that how to actually run the assay, how to do it, there were approximately 1,980 subjects 6 7 what you needed to control. 7 enrolled. Right? 8 8 Q. Among other things, did it sort Yes. A. 9 9 of set the rules for the assay? From the subset, this was a O. randomly selected subset of approximately 600 10 A. It depends what you define by 10 rules. What do you mean by rules? subjects, about 200 per group. Do you see 11 11 12 Q. How the assay is to be conducted. 12 that? 13 A. How the assay is to be 13 A. Right. 14 conducted. Yes, it is the procedure for 14 That doesn't ring a bell? Q. 15 operating the assay. 15 A. Other than what it says, no. 16 16 Q. It says, "Merck is still blinded - - -17 (Exhibit Emini-19, 11/13/00 17 to the treatment assignments." Is that --18 E-mail with attachment, 00009013 -18 Well, that's what normally would 19 19 we do when you do a subset analysis so you 00009034, was marked for identification.) 20 20 don't suffer a statistical penalty. 21 BY MR. BEGLEITER: 21 So in other words, when subset 22 Q. Could we hand Emini-19 to the 22 or the whole thing, blinding is required? 23 23 witness. It's docket number -- Bates-numbered So when you do a subset 24 MRK 9013 through 9034. 24 analysis, prior to having -- prior to having 25 25 analyzed the data to address the primary This is a rather long document. Page 199 Page 201 I'll just tell you you can read as much as you 1 endpoints of the study, right, so typically 2 want, I'm not stopping you, but I'll be 2 you would do this because this is a specific 3 talking about the first page, 9013. I'll be 3 immediate question that needs to be addressed, 4 asking you questions about that, and 9022. 4 as was the case here apparently, then you 5 5 Aside from that, I'm not going to ask any could do such a subset analysis. But what was 6 questions. Well, that's not true. And also 6 very critically important was to maintain the 7 page 9017. Those are the only three pages I'm 7 blind of the study so that the statistician 8 going to be making reference to. 8 and the other personnel involved in generating 9 9 A. Okay. the data, not involved in actually analyzing 10 10 So looking at the first page, the data for the final endpoints of the study, 11 9013, did you receive this document, including 11 are blinded to the treatment assignments. 12 the attachments, during the regular course of 12 Standard procedure. 13 your employment? 13 Q. A statistician in this case was 14 A. It was addressed to me as one of 14 not blinded -- was unblinded. You can't blind 15 the recipients of the e-mail. So yes, I did. 15 a statistician. Right? 16 It was received on November 13, A. No, you unblinded the statistician Q. 16 17 2000? 17 to do the subset analysis, but that would not 18 A. November 13, 2000. 18 the same statistician that did do the final 19 Q. Great. Now, if you can turn to 19 analysis. The final analysis statistician 20 page 9022. I'll ask you to read, you can read 20 would remain blinded. 21 it to yourself if you wish, a "Preliminary 21 Q. The sentence at the end of --Subset Analysis." The first paragraph and 22 what is a treatment assignment? 23 23 then I'm going to ask you some questions about A. The treatment assignment is 24 24 the preliminary subset. related to the three groups of the study. 25 A. Okay. Remember there are four potency levels --

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	Page 202		Page 204
1	excuse me, three potency levels?	1	Q. Yes.
2	Q. $4.9, 4.0, 3.7$, is that what you	2	A. No. The inspector came in the
3	said?	3	morning as being the senior person related to
4	A. Yes.	4	the area that she wanted to assess. I was
5	Q. And then at the end it says	5	handed what is known as a Form 482, which is
6	regardless of the end of the paragraph that	6	the announcement of the inspection. And then
7	begins the statistician not associated with	7	we made sure that we pulled together the
8	the conduct of the trial. In that paragraph	8	people who needed to be pulled together and
9	it says, regardless of the outcome of the	9	informed regulatory. Regulatory is
10	preliminary analysis, the sera from the remain	10	responsible for interacting with the inspector
11	set will be tested in a blinded fashion and	11	during the inspection. I retired and was not
12	all subject will be included in the final	12	called back until the inspection had been
13	analysis.	13	completed and the 483 had been prepared. To
14	A. That's correct.	14	my recollection, of course.
15	Q. That's looking forward beyond	15	MR. BEGLEITER: Have this
16	the preliminary subset into the final into	16	marked, please, as Number 20, I guess.
17	the completion of the assay?	17	Let me just announce it. This is a
18	A. Yes.	18	document Merck 8835 through 8839. It's
19	Q. Now, do you recall, looking at	19	a four-page document, if you could mark
20	the document, what the day of the unannounced		it.
21	inspection we talked about before? I could	21	
22	remind you but maybe you remember. Do you	22	(Exhibit Emini-20, E-mail
23	remember the inspection that resulted in the	23	string, 00008835 - 00008839, was marked
24	483?	24	for identification.)
25	A. Resulted in 483, yes.	25	
	Page 203		Page 205
1	Page 203 Q. You want to look at that just	1	BY MR. BEGLEITER:
1 2	Q. You want to look at that just you can fix the date, that's important.	1 2	BY MR. BEGLEITER: Q. My focus will be on your e-mail
1 2 3	Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do	1 2 3	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole
1 2 3 4	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was?	1 2 3 4	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string.
1 2 3 4 5	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8.	1 2 3 4 5	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay.
1 2 3 4 5 6	Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There	1 2 3 4 5 6	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you
1 2 3 4 5 6 7	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in	1 2 3 4 5 6 7	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails?
1 2 3 4 5 6 7 8	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it.	1 2 3 4 5 6 7 8	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am.
1 2 3 4 5 6 7 8 9	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER:	1 2 3 4 5 6 7 8	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as
1 2 3 4 5 6 7 8 9 10	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page?	1 2 3 4 5 6 7 8 9	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual
1 2 3 4 5 6 7 8 9 10 11	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring	1 2 3 4 5 6 7 8 9 10	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check
1 2 3 4 5 6 7 8 9 10 11 12	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page.	1 2 3 4 5 6 7 8 9 10 11 12	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see.
1 2 3 4 5 6 7 8 9 10 11 12 13	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483.	1 2 3 4 5 6 7 8 9 10 11 12 13	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time.
1 2 3 4 5 6 7 8 9 10 11 12 13 14	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes.	1 2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes. Q. I'm asking you to look at it to	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received. Q. Going to the first e-mail, I see
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes. Q. I'm asking you to look at it to confirm the date.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received. Q. Going to the first e-mail, I see this is to Anthony Ford-Hutchinson and Peter
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes. Q. I'm asking you to look at it to confirm the date. A. Confirm the date?	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received. Q. Going to the first e-mail, I see this is to Anthony Ford-Hutchinson and Peter Kim.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes. Q. I'm asking you to look at it to confirm the date. A. Confirm the date? Q. Of the inspection.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received. Q. Going to the first e-mail, I see this is to Anthony Ford-Hutchinson and Peter Kim. A. Yes.
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes. Q. I'm asking you to look at it to confirm the date. A. Confirm the date? Q. Of the inspection. A. That would have been August 6, 2001.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received. Q. Going to the first e-mail, I see this is to Anthony Ford-Hutchinson and Peter Kim. A. Yes. Q. With cc's to various people. These people, Hutchinson and Kim, I think you
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Page 203 Q. You want to look at that just you can fix the date, that's important. A. I have to dig through here. Do you remember which one it was? MS. DYKSTRA: Look at Exhibit 8. THE WITNESS: Exhibit 8. There was one that actually had the 483 in it. BY MR. BEGLEITER: Q. On the second page? A. That's the one you're referring to. That's the second page. Q. The handwritten 483. A. That would be 7. 7, yes. Q. I'm asking you to look at it to confirm the date. A. Confirm the date? Q. Of the inspection. A. That would have been August 6, 2001. Q. At the time of the inspection going on, was anybody giving you any updates as to what was going on, anybody reporting to	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. BEGLEITER: Q. My focus will be on your e-mail of August 7th, but you can read the whole thing. The first e-mail in the string. A. Okay. Q. And going to that did you are you the author of some of these e-mails? A. Yes, I am. Q. Did you receive all of them as part of your usual A. Let me see. Let me just check it to see. Q. Take your time. A. Yes, I either wrote or received. Q. Going to the first e-mail, I see this is to Anthony Ford-Hutchinson and Peter Kim. A. Yes. Q. With cc's to various people. These people, Hutchinson and Kim, I think you answered this morning you weren't sure who was there, whether they were both your report the person to whom you reported at the same
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Page 208 Kim was obviously there in the company since 1 note -- well, there was --2 they sent him the message as well. So I would 2 BY MR. BEGLEITER: 3 have been reporting to Tony Ford-Hutchinson 3 Q. Your counsel is right, that 4 who was, in turn, reporting to Peter Kim. 4 wasn't a good question. 5 Peter Kim was above him? 5 A. I know. Try it again. Was above him. And then, in 6 Is it your understanding that 6 turn, Peter Kim at that point since Ed 7 the correlation was important to the FDA? 8 Scolnick was still there, he had not yet 8 MS. DYKSTRA: Objection. Form. 9 9 retired, was reporting to Ed Scolnick. THE WITNESS: Correlation was 10 Q. Who was the president? 10 important only insofar as these were 11 A. Who was the president of the two independent measures of an immune 11 12 research laboratory, and Peter Kim eventually 12 response to the vaccine. If we were to 13 became president of the research laboratory 13 use both sets of data in order to 14 when Ed Scolnick retired. 14 compare the three different dose levels 15 Q. What was your purpose in writing 15 of the vaccine in 007, then a general 16 this e-mail, if you can recall? 16 correlation, didn't have to be perfect, 17 A. The purpose in writing the 17 but a general correlation would fall e-mail is as noted in the e-mail, we had 18 into the category of nice to have. received a Form 483 with inspection 19 BY MR. BEGLEITER: 20 20 O. It wasn't a correlation between observations from the FDA, and I felt it 21 appropriate to write a note to my supervisors 21 the neutralization in assay --22 22 indicating the four observations as were noted A. And the ELISA. 23 23 in the e-mail that the inspector had made on Q. -- and the ELISA was not 24 the Form 483. And to note to my opinion of 24 required? the nature of those observations and what we 25 25 A. It depends on what you mean by Page 209 were at least at that time contemplating to do 1 "correlation." It is an exact correlation? 2 subsequently. This was the day after the 2 Q. Well, you wrote the e-mail. 3 inspection. 3 What did you mean? 4 4 Q. And just some abbreviations So what I meant by "correlation" 5 5 here. GMP is? would be that in general if you're looking at 6 So GMP stands for good 6 a population of samples, right, not individual 7 manufacturing -- formerly stands for good 7 one-to-one samples, but you're looking at a manufacturing practices. The terminology is 8 population of samples, if the neutralization 9 also used generally to refer, at least at the 9 assay showed, let's say, 89 percent 10 10 time, to refer to appropriate defined seroconversion, plus or minus a certain procedures for conducts of -- for anything 11 11 variance, that the ELISA looking at the same 12 related to a potential product. So the term 12 population of samples would also show within 13 was used very generally, GMP. These days the 13 that variance an 89 percent seroconversion 14 term is much better defined. 14 within the variance established by the assay. 15 15 Q. In the last paragraph you talk Why did you inform the 16 about the correlation being excellent between 16 supervisors that you're writing this e-mail to 17 something and ELISA. Is the something the 17 of that fact? PRN? 18 18 A. Well, because the question that 19 The neut assay results and I 19 this one was referring to was observation or 20 presume that this was referring to the PRN, 20 what I was referring to as violation number 21 right, which was being run at the time. 21 one. Or which related to, and we can read it 22 Q. Was correlation something that 22 here, in that it potentially, that observation 23 was important to the FDA? 23 by the inspector potentially suggested that 24 MS. DYKSTRA: Objection. Form. 24 there might be an issue with the validity of 25 THE WITNESS: Correlation was a 25 the data because there had been changes that

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Page 212 were made to the spreadsheet that contained far as you're concerned? 2 the data but without noting the reason why the 2 A. The blinding is essential in change was made. That was the basis of the 3 order to be able to do that, right, because it 3 4 observation. So, therefore, that 4 is intended to avoid bias on the part of the 5 5 operator. automatically raises the issue to say are we 6 If you go to the next e-mail, certain that the data as they currently exist, 7 the one above it, also signed by you, you 7 or the data as they were originally derived, 8 say -- and what you say at the end is "The are they, in fact, reflecting the same 8 9 points in this note will be captured by Alan 9 conclusion. That's the observation. 10 10 Shaw in the draft of the responses of each of So, therefore, the resulting the individual notices of violation." 11 data, what we did is that we took the data, we 11 submitted it to the clinical statistical --12 Α. Yes. I'm reading directly from the memo. 13 Q. Do you see that? 14 A. 14 Correlated the neut assay results with that of Yes. an independently performed ELISA. The ELISA 15 Q. That's, again, you're referring was being performed independently. And as a 16 to 483 there? 17 A. Yes, the four individual points 17 result, I noted that the correlation was 18 made in 483. excellent suggesting that there were no global 19 problems. In other words, if changes were You can read it if you want, but 20 20 the point is that Alan Shaw was going to being made to the original data set that 21 respond? 21 radically changed the conclusion of that data 22 22 set, it might have a certain likelihood of A. Alan Shaw was going to work on 23 23 showing a miscorrelation with the making a draft of the responses. Who 24 independently performed ELISA. So this was 24 ultimately responded formally? Probably it 25 either came -- in this case it either came simply an initial indication of comfort taken Page 211 Page 213 1 from me or it came from someone in regulatory that there wasn't a global issue with the 2 in terms of the formal response. But the data. It was not to say that what was done 3 draft was being put together by Dr. Shaw. 3 was correct. It just that it was not a global 4 4 issue with the data. Q. I notice something in the 5 5 Q. The ELISA test, the ELISA test original message. and the neutralization assay, the ELISA assay 6 A. Which one? 6 7 The one at the bottom of 838 was 7 and neutralization assay, they're different Q. 8 not sent to Dr. Shaw. 8 assays. Right? 9 9 No, this was a message that was A. Completely different assays. 10 10 It also says it should be sent directly by me to my management. noted -- this in the last paragraph on page 11 11 The e-mail we were just talking 12 about where he says he's going to capture the 12 839, "It should be noted that all samples were tested, per protocol, with the lab personnel 13 points was also not sent to Dr. Shaw. blinded to sample identification." 14 A. Okay. 14 15 15 Q. As a matter of fact, none of Α. That is correct. 16 Q. What does that mean? 16 these e-mails were sent, except for one. 17 17 A. That means that the lab Except the reply that came back 18 personnel did not know whether or not the 18 from regulatory. sample came from our number one or number two 19 Q. Except for Dr. Ukwu? 20 20 A. Ukwu, right. or number three. In other words, it did not 21 Let's get to that. Okay. So know where the serum sample was taken and 22 weren't you talking to Dr. Shaw on the day of whether it was -- and which of the three dose 23 levels of the vaccine that the individual from 23 the inspection and the day after the 24 24 whom the sample was taken was inoculated with. inspection, the days you were --25 25 Q. Is that blinding important as Certainly the day after --

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Page 216 MS. DYKSTRA: Let him finish. 1 Q. No, no. You can recall that you 2 BY MR. BEGLEITER: 2 spoke to somebody but not remember what you 3 Q. Were you talking to Dr. Shaw on 3 said. 4 the date of the inspection and the day after 4 A. I know, but what I said, my 5 and then after that? 5 answer -- my apologies. My answer to your A. I do not recollect directly, but 6 question is, I have no recollection of a 6 7 I am certain based upon what we see here that 7 discussion, per se. 8 I was obviously in conversation with Dr. Shaw 8 Why not? O. 9 certainly the day after. And depending upon MS. DYKSTRA: Objection. 10 when the inspector left, I don't know if we 10 THE WITNESS: Because I don't conferred that afternoon of the inspection. 11 11 have one. 12 Everything you wrote in these 12 BY MR. BEGLEITER: 13 two e-mails you believed to be true? 13 Q. No, no, no. Why don't you 14 A. Yes. 14 have -- well, you're saying you could have had 15 a discussion with Dr. Krah but you just don't Q. Do you still believe them to be 15 16 true? 16 remember? 17 A. Based on what I see here, yes. 17 Well, yes, I could have had a 18 Well, based on anything. Do you 18 discussion with Dr. Krah, but I just don't 19 still believe them to be true? 19 remember. Yes. I literally don't remember. 20 A. Certainly I believe -- yes, I 20 Q. Okay. Now, take a look at Alan 21 believe them to be true. I have no evidence 21 Shaw's e-mail of August 8, 2001, at 9:36 p.m. 22 to the contrary that they're not true. 22 Which one is this? A. 23 23 Okay. You also didn't send any Q. That's the cover page. 24 of these e-mails to Dr. Krah. Isn't that 24 A. The cover page? 25 right? 25 The first page, 8835. The Q. Page 215 Page 217 1 MS. DYKSTRA: Objection. 1 bottom one on that page. 2 THE WITNESS: These are e-mails 2 A. Yeah. 3 that were intended for my immediate 3 Q. He suggests, "I would suggest 4 4 that people from your group...," meaning management. 5 5 BY MR. BEGLEITER: Henrietta Ukwu's group. Right? "...plus Kati 6 I understand that. But it was 6 Abraham fix a time with Dave Krah and Mary 7 Dr. Krah's lab was the one that was inspected. 7 Yagodich to make your audit." I'm not saying you should have, I'm just 8 A. Right. 9 saying the fact is you didn't send --9 O. What audit are you talking 10 A. I didn't send them, no. 10 about? 11 Q. Okay. Fine. 11 So, again, in reviewing the 12 A. No. 12 multiple back and forth communications that 13 Okay. And did you discuss with 13 occurred with the agency after this initial 14 Dr. Krah in the days after, the day of and the 14 inspection in the subsequent months, what days two or three days after the inspection clearly we conducted and then asked for was a 15 15 16 what happened in the inspection? 16 general audit. First of all, there were 17 A. I have no recollection of the 17 audits related to ensuring that what had been 18 actual discussions themselves. 18 observed by the inspector in the case of 19 Q. But did you recall actually 19 Dr. Krah's laboratory would result in -- first 20 speaking with him? 20 of all, would not result in any change to the 21 A. I have no recollection of the 21 interpretation of the data. That was 22 actual discussions themselves. So by 22 fundamentally critical, so we conducted that 23 23 assessment. We then also, you recall that definition, I don't have a recollection of 24 actually having spoken with him. Maybe we're 24 some of these observations were observations saying the same thing. related to operations in terms of how things

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	Page 218		Page 220
1	were operating in the laboratory. So we	1	recollection. Let's have a look.
2	conducted an audit to make certain that if	2	MR. BEGLEITER: I'd like to have
3	those operations were, in fact, not being	3	marked for identification Merck 52243.
4	conducted the way in which the inspector noted	4	It's a one page e-mail.
5	to us, that we would take appropriate	5	
6	corrective action to make sure that that was	6	(Exhibit Emini-21, 8/9/01
7	the case. And on top of all of that, we also	7	E-mail, 00052243, was marked for
8	went on in addition to looking specifically at	8	identification.)
9	Dr. Krah's laboratory, we also took the	9	
10	opportunity to conduct a broader audit across	10	BY MR. BEGLEITER:
11	all activities that were associated within the	11	Q. If you can read I'm only
12	organization that ran under standard operating	12	going to ask you about paragraph 1. You can
13	procedures to make sure the standard operating	13	read anything you want to read.
14	procedures were in place and that activities	14	A. This does not refer to sample
15	would be followed according to the appropriate	15	blinding. This refers to the blinding of the
16	standard operating procedures. Not an unusual		counting of the plaques on the plate. It's a
17	set of activities.	17	different situation than the one you were
18	Q. That resulted in the August 20th	18	talking about.
19	letter which number I don't have.	19	Q. Well, was it appropriate for
20	A. Which one is this now?	20	someone to be unblinded, for the head of the
21	MS. DYKSTRA: Exhibit 8.	21	lab to be unblinded?
22	BY MR. BEGLEITER:	22	A. For counter-qualification, yes,
23	Q. Exhibit 8.	23	that's perfectly acceptable.
24	A. Take a look to be certain. This	24	Q. Is that anywhere in the SOP?
25	was the initial response, if I remember	25	A. I don't recall if it was
	Page 219		Page 221
1	Page 219 correctly. Yes, it was. This was the initial	1	Page 221 specifically in the SOP, but typically someone
1 2	correctly. Yes, it was. This was the initial	1 2	specifically in the SOP, but typically someone
	correctly. Yes, it was. This was the initial response to the agency that I responded to		specifically in the SOP, but typically someone needs to be unblinded for a qualification to
2	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to	2	specifically in the SOP, but typically someone
2 3	correctly. Yes, it was. This was the initial response to the agency that I responded to	2 3	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were
2 3 4	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the	2 3 4	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals
2 3 4 5	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector.	2 3 4 5	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the
2 3 4 5 6	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector. Q. So were you under the impression	2 3 4 5 6	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the counters with the individual samples.
2 3 4 5 6 7	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector. Q. So were you under the impression when you wrote that letter	2 3 4 5 6 7	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the counters with the individual samples. Remember what the counters are doing, that
2 3 4 5 6 7 8	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector. Q. So were you under the impression when you wrote that letter A. Sorry, which letter, Number 8?	2 3 4 5 6 7 8	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the counters with the individual samples. Remember what the counters are doing, that this is individual counting of the plaques on
2 3 4 5 6 7 8 9	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector. Q. So were you under the impression when you wrote that letter A. Sorry, which letter, Number 8? Q. Number 8.	2 3 4 5 6 7 8 9	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the counters with the individual samples. Remember what the counters are doing, that this is individual counting of the plaques on the assay. So they were blinded to each
2 3 4 5 6 7 8 9	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector. Q. So were you under the impression when you wrote that letter A. Sorry, which letter, Number 8? Q. Number 8. A. Yes.	2 3 4 5 6 7 8 9	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the counters with the individual samples. Remember what the counters are doing, that this is individual counting of the plaques on the assay. So they were blinded to each other's results. He knew which ones were the
2 3 4 5 6 7 8 9 10 11	correctly. Yes, it was. This was the initial response to the agency that I responded to that addressed what we had done to reply to the observations that were made by the inspector. Q. So were you under the impression when you wrote that letter A. Sorry, which letter, Number 8? Q. Number 8. A. Yes. Q that the Protocol 007 had	2 3 4 5 6 7 8 9 10 11	specifically in the SOP, but typically someone needs to be unblinded for a qualification to be appropriately conducted. The individuals who were blinded were the individuals who were looking that were actually running the counters with the individual samples. Remember what the counters are doing, that this is individual counting of the plaques on the assay. So they were blinded to each other's results. He knew which ones were the actual value numbers because he was using, as
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Page 224 A. This would be the plates in 1 Q. I didn't -- I asked a question 2 which the assay was conducted, yes. 2 about blinding. I'm saying there was a 3 And his knowing what those 3 workbook printout. 4 plates showed in terms of plaques, that 4 A. Yes. 5 wouldn't bias him? 5 As a guide to check extra Q. 6 variables/single dilution positive samples? A. No. 6 7 MS. DYKSTRA: Objection. 7 A. Right. 8 THE WITNESS: It depends on what 8 So in other words, Dr. Krah knew 9 he was doing. In this particular case 9 what the single -- where the single -- which 10 he was doing counter-qualification. So 10 ones were in single dilution positive samples. 11 there is no bias associated with that. Is that right? 11 12 This was so that he could conduct an 12 A. Right. 13 independent assessment of the 13 Q. And that could tell him whether 14 variability that was occurring among 14 or not they were pre-positives or not. Isn't 15 three different potential readers. 15 that right? 16 Probably as a result of, you know, 16 A. No. I don't see how that would 17 having taken a careful look again to be possible. 17 18 determine what the variability of the 18 Q. You mean having a printout that 19 counting procedure was. 19 tells you what each plate, what the plates --20 BY MR. BEGLEITER: 20 A. It does not identify the sample. 21 Q. Did you inform supervisors who It's simply says these are the numbers that 21 22 you sent your e-mails to on the 7th and 8th 22 were counted. It does not identify from whom 23 that, in fact, that Dr. Krah had been 23 or from which individual the sample came from. unblinded on the counter-qualifications? 24 24 That was information that would only be 25 No, because it was not relevant 25 available to the blinded statistician. The Page 223 Page 225 to the overall inspection issue. 1 samples are blinded by code. 2 Q. Well, did you -- you had 2 Q. Then explain this to me. For 3 represented to your supervisors that, in fact, 3 the majority of the plates, the pen marks were there had been blinding? 4 left on the plate for initial recheck to see 4 5 5 Yes. if plaques were over or undercounted, i.e., 6 Q. Now, could the blinding, since 6 each pen mark -- was each pen mark associated 7 Dr. Krah would know the pre-positives, 7 with an identified plaque? post-positives, pre-negatives, would know 8 A. Right. 9 that -- would know who was what, wouldn't 9 And if there was a difference 10 that -- couldn't that bias the taker of the noted, the spots were removed and the plate 10 11 test? 11 was recounted. 12 A. No, it says here, if I read this 12 A. Right. correctly, it says, "...we are blinded for our 13 13 Is that appropriate to do, to counter qualification...for the rechecks of 14 remove the spots? the current assays that I have done. I have 15 MS. DYKSTRA: Objection. 15 not been blinded since I was using the 16 THE WITNESS: If you don't 17 workbook printout as a guide to check for 17 remove the spots, you can't recount 18 18 extravariable/single dilution positive because you won't be able to see the 19 samples." So he was checking to see if there 19 plaques so you have to remove the 20 were extra variable/single dilution positive 20 spots. 21 samples, the values that were being generated 21 BY MR. BEGLEITER: were the blinded values being -- were the 22 Who asked them to recount? 23 values that were being blindedly assessed by 23 MS. DYKSTRA: Objection. 24 the blinded counters. He was not changing any 24 THE WITNESS: I don't recall who 25 numbers there himself. specifically asked to do the

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Page 228 1 recounting. I don't recall who communications, so there were discussions that 2 specifically asked. I can tell you --2 were ongoing as normally would be the case 3 BY MR. BEGLEITER: 3 between regulatory and CBER as a result of the 4 Q. I take it from that that you 4 inspection. And part of the effort probably 5 have no recollection of asking him? 5 involved, based upon what I read here, a A. I have no recollection of asking 6 6 rechecking of the data and the actual counts 7 him personally to do the recount. that were done to determine if there was a 8 Q. You have no recollection of 8 complete -- if there was an issue in terms of 9 discussing with Dr. Shaw either? 9 following the SOP and if the numbers which had 10 A. I have no direct recollection of 10 been changed without explanation in that discussing it with Dr. Shaw. But this would original spreadsheet, if one does it again, 11 11 have been part of the procedure to assess the does one come up with the same set of 12 12 13 quality of the data. 13 conclusions. 14 Shouldn't the fact that there 14 Q. In Exhibit 7, which is the 483, was a recheck going on be something that 15 15 contains the 483, number 1 we already read, Dr. Shaw should have known? 16 raw data is being changed with no justification. 16 17 MS. DYKSTRA: Objection. 17 Right. 18 THE WITNESS: He may very well 18 For example. Okay. Q. 19 have known and probably did know it. I 19 No justification may mean that 20 just don't recall ever having --20 no justification was noted on the document, 21 20 years later having the conversation 21 not that there was no justification. Big 22 with him. 22 difference. 23 BY MR. BEGLEITER: 23 Q. And then two days later, three 24 Q. But it wasn't important enough 24 days later, August 9th, Dr. Krah says that he 25 to write an e-mail to you to tell you that it 25 was unblinded as to counter-qualifications. Page 227 Page 229 Do you think that something -- withdrawn. 1 was going on. Is that what you're saying? 1 2 MS. DYKSTRA: Objection. 2 Did you believe this was 3 Mischaracterizes his testimony. 3 something that should have been told to the 4 THE WITNESS: No. He just --4 FDA? 5 5 first of all, I don't recall if he did A. No. Because they're not 6 write me an e-mail because we haven't 6 correlated with each other. He was doing a 7 reviewed every single e-mail that went 7 counter-qualification which was to ascertain, 8 back and forth between myself and 8 since they were going to recount the plates 9 Dr. Shaw. But this activity was going 9 and the plates were apparently being recounted 10 on. It was undoubtedly part of the 10 by multiple individuals, so you go through this qualification process to see -- because 11 operational audit and reassessment of 11 12 the data since it was questioned in 12 remember, these are manual counts. They rely 13 terms of how the original data were 13 on human judgment. So, therefore, if analyst 14 generated or at least how they were 14 number one did it and analyst number two and 15 recorded, not necessarily generated but analyst number three, and they, according to 15 16 how they were recorded. That's 16 the memo, were all blinded to each other in perfectly standard. 17 17 terms of what they were actually counting, in 18 BY MR. BEGLEITER: other words, analyst number two was not 18 19 O. Was CBER told about the 19 looking over the shoulder of analyst number 20 rechecking --20 one. Everything was done blindly. So analyst 21 MS. DYKSTRA: Objection. 21 number one would do a set of counts, analyst 22 BY MR. BEGLEITER: 22 number two would do a set of counts and 23 23 -- by you? analyst number three would do a set of counts. 24 Not by me directly. My 24 They would sit there, okay, and then a third communications with CBER were formal 25 party, presumably a statistician, would sit

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1	down, look across the counts and determine,	1	unintended bias.
2	okay, so what are the actual counts and how	2	BY MR. BEGLEITER:
3	close are they in their actual counts. Now,	3	Q. What is done to avoid unintended
4	when one does that, there is sometimes and	4	bias?
5	this is a qualification effort that was	5	A. The blinding. The blinding is
6	ongoing, so these are qualifications.	6	done to avoid unintended bias.
7	Remember, this is like a validation. It's to	7	Q. And do you know sitting here
8	determine whether or not your eyes count X	8	today whether or not Dr. Krah had access to
9	number of plaques to my eyes also count X	9	the pre-positive samples?
10	number of plaques, if there is a big	10	MS. DYKSTRA: Objection.
11	difference between what you count and I count,	11	BY MR. BEGLEITER:
12	then we have an issue here. Whose numbers do	12	Q. Access to know which samples
13	we believe? Do we believe your numbers. Do	13	were pre-positive, I should say.
14		14	
	we believe my numbers. So, therefore, it		A. One pre-positive.
15	requires at that point to sit down, do some	15	Q. Yes.
16	training, do some assessments so as to	16	A. Please define pre-positive.
17	coordinate, if you will, how you interpret	17	Q. You don't know what it means?
18	what you see and how I interpret what I see.	18	A. No, I think I know what you're
19	You can only do that if then there's another	19	asking, but I'm not certain, so I'm asking you
20	party that really looks to see are there large	20	to be more precise, please.
21	variabilities. And that apparently is what	21	Q. I'll ask it a different way
22	Dr. Krah was doing. So what he's referring to	22	rather than get into an argument.
23	is the blinding of the blinded to the	23	What Dr. Krah was doing would
24	actual plate counting that was going on. This	24	allow him to know what the count was, what the
25	is not blinded blinding related to the	25	plaque count was per child. Isn't that right?
	Page 231		Page 233
1	designation of the actual samples being	1	MS. DYKSTRA: Objection.
2	tested.	2	THE WITNESS: That would not
3	Q. Could you tell from the counting	3	allow this would not allow him to
4	sheets which pre or post samples were	4	Irnovy that no
		1	know that, no.
5	associated with the specific trial?	5	BY MR. BEGLEITER:
		1	
5	associated with the specific trial?	5	BY MR. BEGLEITER:
5 6	associated with the specific trial? MS. DYKSTRA: Objection.	5 6	BY MR. BEGLEITER: Q. If he had a notebook that had
5 6 7	associated with the specific trial? MS. DYKSTRA: Objection. THE WITNESS: Well, by	5 6 7	BY MR. BEGLEITER: Q. If he had a notebook that had that information, he would already have known it. Correct? MS. DYKSTRA: Objection.
5 6 7 8	associated with the specific trial? MS. DYKSTRA: Objection. THE WITNESS: Well, by definition so one could make the	5 6 7 8	BY MR. BEGLEITER: Q. If he had a notebook that had that information, he would already have known it. Correct?
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5 6 7 8 9 10	associated with the specific trial? MS. DYKSTRA: Objection. THE WITNESS: Well, by definition so one could make the assumption that if, in fact, there was a high degree of neutralization,	5 6 7 8 9 10	BY MR. BEGLEITER: Q. If he had a notebook that had that information, he would already have known it. Correct? MS. DYKSTRA: Objection. THE WITNESS: Only if the
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Page 236 inspection, yes. might have been some inappropriate changing of 2 Q. Somewhat fairly close to the 2 data in Dr. Krah's lab? 3 unannounced inspection. Right? 3 A. The possibility always exists 4 A. Yes. 4 and when someone comes to me, and this has 5 Q. Didn't he tell you that there 5 been consistently true of anything I've always were -- what did he tell you about the way the done, comes to me with a -- we'll call it an 6 7 counts were being done in the lab? allegation that there might be something which 8 MS. DYKSTRA: Objection. 8 is improper, then one typically refers this to 9 THE WITNESS: So the only 9 an independent third party to do the 10 recollection I have of that, right, was assessment. What I can tell you and will tell 10 a notation in a document that I saw you is that I did refer this to legal counsel 11 11 12 over the last few days, right, that 12 in the company. 13 indicated that Mr. Krahling had shown 13 Q. Did you consider removing 14 me -- had shown me data suggesting that 14 Dr. Krah even temporarily from the laboratory? 15 there were changes being made to the 15 A. There was a -- I don't recall my 16 data, pretty much essentially what the 16 thoughts at the time but there would have been 17 inspector noted in the 483 report. no reason to do so until the third-party 17 18 That is the best of my recollection. 18 investigation would have been completed. Also 19 BY MR. BEGLEITER: 19 what I didn't recall, I really don't recall at 20 What document was that? 20 the time is whether or not there were actually O. 21 So this was a document, if I 21 activities still going on at the time. In 22 recall correctly, that was a document, it was 22 other words, additional assays going on at the 23 an e-mail largely redacted but with a 23 time. If there had been none going on, then 24 handwritten notation. 24 we would have stayed at status quo, stopped 25 O. What did the handwritten 25 everything and just waited for the independent Page 235 Page 237 notation say, if you recollect? assessment to be completed. 1 2 A. This was somebody who had 2 Q. Would that have been an 3 written to me or made a note of the fact that 3 appropriate thing to do? Mr. Krahling had shown me some data. I don't 4 4 MS. DYKSTRA: Objection. 5 recollect the exact terminology. 5 THE WITNESS: That would 6 Q. And who did Mr. Krahling accuse 6 normally being the appropriate thing to 7 of changing the data? 7 8 MS. DYKSTRA: Objection. 8 BY MR. BEGLEITER: 9 THE WITNESS: I do not recollect 9 O. You don't recall if that was 10 the details of the conversation. 10 done or not? 11 BY MR. BEGLEITER: 11 Α Well, what did occur -- what did 12 Q. Didn't Mr. Krahling accuse --12 occur was immediately thereafter, as it turned 13 withdrawn. 13 out, the inspector showed up, was within a few 14 Did Mr. Krahling make the days, the 483 was issued, the point was made 14 15 accusation that the changing of data was done directly on the 483. Therefore, what we 15 16 in Dr. Krah's lab? normally would have done independently of that 16 17 MS. DYKSTRA: Objection. Asked 17 anyway was just went on in response to this 18 and answered. 18 case, to the 483. THE WITNESS: I don't recall the 19 19 Q. You didn't directly ask Dr. Krah 20 details of the conversation. 20 about the allegation --21 BY MR. BEGLEITER: MS. DYKSTRA: Objection. 21 22 Q. By the time you received the 22 BY MR. BEGLEITER: 23 483 -- by the time you read the 483 and 23 Q. -- changing the date? 24 thought about it and did your e-mail the next 24 I am certain that we may have day, did you consider the fact that there 25 had some conversation related to it, but

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Page 240 normally once this is referred to a third happens, particularly when one is using human party for assessment, you allow the third judgment to count plaques, if you count it 3 party to conduct their assessment 3 multiple times, you're going to get 4 independently of any interaction with the 4 potentially multiply different sets of 5 third party because it would not have been 5 numbers. So that may, as he noted, introduce appropriate. 6 6 a bias. But as he noted from a statistical 7 Was Dr. Krah ever asked by 7 perspective, at least by eye, there were as 8 you -- who is the third party you're talking 8 many increases in numbers as there were 9 about here? Would that have been legal decreases in numbers. So when one does a 10 counsel? 10 statistical assessment in the end, it will 11 A. So the -- it was legal counsel 11 come out in the wash. 12 and -- may I? And then I had my --12 Q. And Dr. Krah to this very day 13 MS. DYKSTRA: Just legal 13 never told you about this rechecking? 14 14 MS. DYKSTRA: Objection. counsel. 15 THE WITNESS: Just legal 15 BY MR. BEGLEITER: 16 counsel. We'll leave it at that. 16 Q. Is that your testimony? 17 MS. DYKSTRA: Stop at that for 17 No, my testimony is I don't 18 privilege issues. 18 recollect having a discussion with Dr. Krah. 19 THE WITNESS: Privilege issues. 19 If there is even a possibility 20 20 BY MR. BEGLEITER: of introducing a bias, do you believe that the 21 Q. The very last sentence in that 21 FDA should have been informed of that paragraph, let me read -- there's two 22 22 possibility? 23 23 sentences. MS. DYKSTRA: Objection. 24 A. Please. 24 THE WITNESS: The FDA would 25 25 automatically have been informed when Q. "For the majority of the plates, Page 239 Page 241 1 they looked at the reanalysis in the pen marks were left on the plate for an initial recheck to see if plaques were over or 2 comparison with the initial assessment, 3 because the statistical assessment 3 under-counted (i.e., was each pen mark 4 4 associated with an identified plaque)..." would have indicated the presence of a 5 5 A. Right. statistical bias. So that happens ...and if there was a difference 6 automatically. Q. 7 BY MR. BEGLEITER: noted, the spots were removed from the -removed and the plate was recounted. Do you 8 Q. So you said "would have," but 9 you don't know? 9 see that? 10 10 A. Yes. If the statistical analysis, 11 In the next sentence Dr. Krah 11 and, again, subsequent -- looking at my reply to the agency, there was no indication of an 12 says something. "This may introduce a bias, 12 but the changes have been both up and down 13 inadvertent or advertent bias. 14 (although largely up due to missed counts)," 14 Q. This statistical analysis, do 15 you recall ever seeing this statistic analysis 15 the last word is in the parentheses. 16 What do you understand him by prepared by Dr. Krah somewhere in this lab? 17 17 A. Not by Dr. Krah. It would have saying that "this may introduce a bias"? 18 18 A. Well, by statistical definition, come from the statistical group. In fact, 19 every time you count something more than once, 19 it's probably embedded in the full reply to 20 there's a certain probability that you will 20 the agency and in subsequent discussions. 21 We talked before about there 21 introduce a bias. And that the criteria 22 being at least two kinds of validation. I'm that's used for counting the first time, and 23 23 even in one's own head, can be very different not giving it to you yet. 24 24 He's not going to give it to me. than the criteria that was done the second A. 25 Two kinds of validations, one time. So what then -- so then typically what Q.

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1	for the assay and one for the lab itself?	1	analyzing the assays?
2	A. Laboratory, yes.	2	A. Yes, but that was my requirement.
3	Q. Are there any other kinds that	3	That was the requirement, but it is not a
4	you're aware of?	4	formal requirement so let me explain. It
5	A. Well, validation both the	5	is not a formal requirement that validation or
6	terms validation and qualification are general	6	qualification be completed, be completed prior
7	terms. So they relate to any set of	7	to the actual conduct of the assay. It is a
8	activities in which there is a requirement for	8	requirement that it be completed prior to the
9	accuracy, precision and ability to interpret	9	analysis of the data from the assay. So if
10	the quantitative results, whether it be a	10	you develop an assay and you do not complete
11	laboratory, whether it be an individual,	11	the validation prior to actually running the
12	whether it be an assay. As an individual you	12	samples and you run the samples at risk
13	can be qualified and validated as well.	13	because you're doing the validation either
14	Q. Who did the validation for	14	afterwards or in parallel, it's your risk.
15	Protocol 007, the PRN part of the test?	15	Because once you run the samples, and if the
16	A. Well, the data for the	16	assay turns out not to be appropriately
17	validation would have been generated by the	17	validated following the validation protocol,
18	laboratory that developed the assay.	18	then you put the entire test and entire data
19	Q. Dr. Krah's laboratory?	19	set at risk.
20	A. That would have been Dr. Krah's	20	Q. Excuse me for one second.
21	laboratory, yes.	21	In the case of 007, was the
22	Q. Okay. And did CBER request the	22	validation experiments done by the same group,
23	validation results for the neutralization	23	same lab that was doing the assay, the PRN?
24	assays you were going to use?	24	MS. DYKSTRA: Objection.
25	A. I don't recall offhand, but I	25	THE WITNESS: I cannot recall
	,		
	Dog 242		Page 245
1	Page 243 would be very surprised if they had not	1	Page 245
1 2	would be very surprised if they had not	1 2	directly, but that would normally be
2	would be very surprised if they had not requested. It's a standard request from the	2	directly, but that would normally be the case.
2 3	would be very surprised if they had not requested. It's a standard request from the agency.	2 3	directly, but that would normally be the case. BY MR. BEGLEITER:
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Page 248 Typically what you would do is that you would, 1 both the lab running the assay and CBER would if laboratory A, in this case, the research 2 2 be the same. 3 laboratory were to develop the assay, then 3 Let me show you 682341 to 4 they would perform a validation. Terminology 4 682345. 5 used today is qualification. Means the same 5 6 thing. 6 (Exhibit Emini-22, List, 7 So they would normally perform 7 00682341 - 00682345, was marked for 8 it to determine the assays, as we said, 8 identification.) precision, accuracy, reproducibility. When an 9 10 assay that is a validated assay is then 10 MS. DYKSTRA: Do you have transferred from one laboratory to another 11 11 MS. MAHENDRANATHAN: Yes. laboratory, the assay is revalidated to make 12 sure that it behaves the way in which it 13 BY MR. BEGLEITER: 14 behaved when it was first developed. So you 14 Q. The only question I'm going to 15 would wind up basically revalidating the 15 have is what is this? Do you recognize this 16 laboratories. So what normally would have 16 type of document? 17 been done in this case is the research 17 A. Yes. What this document is, is laboratory would have developed the assay, a document in which the operator of the assay 18 would have qualified the assay, would have 19 will report their observations. 20 sent it to a testing laboratory, either 20 Q. And this is part and parcel of 21 internally or externally, and then the assay 21 actually doing the assay? would have been requalified in the context of 22 22 A. This is part and parcel of 23 that testing laboratory probably at the same 23 performing the assay, yes. 24 time that you would validate the laboratory 24 Q. Does it have a date on when this 25 itself. 25 was performed? Page 247 Page 249 1 Q. Wasn't -- didn't CBER want it --1 9th of February, 2001. 2 want to review and concur with the validation 2 And do you know when the 3 protocol before the testing? 3 validation protocol was given to --4 MS. DYKSTRA: Objection. 4 A. I don't recall. 5 5 THE WITNESS: Again, it is --Q. Let me finish the question. 6 the reason why I'm hesitating in 6 When the validation protocol was 7 answering your question is that that is 7 given to CBER? 8 not a formal requirement. CBER may ask 8 A. I apologize. 9 9 to view a validation protocol, a I do not recall. 10 10 validation data prior to the actual Q. I should point out on that 11 running of an assay. However, and this 11 document, 2341, at the bottom it says, "Mary Yagodich, December 12, 2000," at the bottom. 12 has happened to me on multiple 12 13 occasions, CBER will also say go right 13 Do you see that? 14 ahead, if you want to run the assay 14 A. It says, "December 12, 2000," at 15 prior to the time that we looked at the 15 the bottom. 16 validation, but you run it at your own 16 Right. Let me show you again Q. 17 17 Exhibit 6. You have that in front of you? risk. BY MR. BEGLEITER: 18 18 A. 6? 19 Q. Does CBER usually approve or 19 Q. Yeah. 20 concur with the validation? 20 Yes. A. 21 CBER would have to approve --21 And go to page 17080. O. 22 would have to concur that the validation was 22 A. 23 23 done correctly and that the numbers that were Q. And that shows -- what is this 24 24 document, that 17080? being reported from the assay, that the way in 25 which one would interpret those numbers by This is a document to Dr. Krah

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1	from the statistical analysis group that is	1	which the FDA, CBER were told that assays were
2	refers to the validation of the plaque	2	completed before the excuse me, the assays
3	reduction neutralization assay. And it refers	3	were conducted
4	to the validation results. Just bear with me	4	A. The assays
5	a second, let me go look. Yes, this refers to	5	Q. Let me start again.
6	the validation results, yes.	6	Do you recall from anyplace,
7	Q. Of the PRN?	7	whether it's a document, a conversation in
8	A. Of the PRN, plaque reduction	8	memory, that CBER was told that assays were
9	neutralization.	9	conducted prior to CBER receiving the
10	Q. If you go to the second page of	10	validation protocol for concurrence?
11	the exhibit, there's a letter.	11	A. I do not recall a direct
12	A. Of the overall exhibit, yes.	12	communication with CBER noting exactly what
13	Q. Yes, the whole entire exhibit.	13	you said, but it's self evident.
14	And that letter is dated March 12, 2001?	14	Q. Do you recall CBER being told
15	A. That is dated March 12, 2001.	15	when the individual assays were conducted?
16	Q. So it's some two months plus	16	MS. DYKSTRA: Objection.
17	after Exhibit 23 was prepared. Is that right?	17	THE WITNESS: I do not recall,
18	A. Exhibit 22.	18	but it's in the workbook, the dates.
19	Q. Exhibit 22 was prepared.	19	BY MR. BEGLEITER:
20	A. Yes.	20	Q. The workbook, you're referring
21	Q. And it's your statement that	21	to Exhibit 23?
22	that was perfectly okay?	22	A. Exhibit 22.
23	A. Yes.	23	Q. 22. Was the workbook given to
24	Q. But at the risk of Merck?	24	the FDA?
25	A. But it is at the risk of it	25	MS. DYKSTRA: Objection.
	Page 251		Page 253
1	is at the risk of the company. As, again,	1	THE WITNESS: I don't recall if
2			
	validation is required and accepted by the	2	the workbook was given to the FDA, but
3	validation is required and accepted by the agency prior to the time that the data that	2 3	the workbook was given to the FDA, but I do know that this was part of the
			I do know that this was part of the data, I presume, I don't know if it was
3	agency prior to the time that the data that	3	I do know that this was part of the
3 4	agency prior to the time that the data that you see here in Exhibit Number 22 can be analyzed by the statistician in the end. But the actual generation of the data, that occurs	3 4	I do know that this was part of the data, I presume, I don't know if it was
3 4 5	agency prior to the time that the data that you see here in Exhibit Number 22 can be analyzed by the statistician in the end. But the actual generation of the data, that occurs at your risk. So if you're not willing to	3 4 5	I do know that this was part of the data, I presume, I don't know if it was exactly this data, but part of the data
3 4 5 6	agency prior to the time that the data that you see here in Exhibit Number 22 can be analyzed by the statistician in the end. But the actual generation of the data, that occurs at your risk. So if you're not willing to take the risk, you wait until the validation	3 4 5 6	I do know that this was part of the data, I presume, I don't know if it was exactly this data, but part of the data that the FDA inspector came to observe
3 4 5 6 7	agency prior to the time that the data that you see here in Exhibit Number 22 can be analyzed by the statistician in the end. But the actual generation of the data, that occurs at your risk. So if you're not willing to take the risk, you wait until the validation is completed and accepted by the agency. If	3 4 5 6 7	I do know that this was part of the data, I presume, I don't know if it was exactly this data, but part of the data that the FDA inspector came to observe and upon which she noted the concern
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3 4 5 6 7 8 9 10	agency prior to the time that the data that you see here in Exhibit Number 22 can be analyzed by the statistician in the end. But the actual generation of the data, that occurs at your risk. So if you're not willing to take the risk, you wait until the validation is completed and accepted by the agency. If you believe that your assay is validate-able or qualifiable, means the same thing, then if	3 4 5 6 7 8 9	I do know that this was part of the data, I presume, I don't know if it was exactly this data, but part of the data that the FDA inspector came to observe and upon which she noted the concern over the apparent changes without written justification. BY MR. BEGLEITER: Q. That wasn't my question. My
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64 (Pages 250 - 253)

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	HIGHLY CONFIDENTIAL -		
1	Page 254		Page 256
1	A. I do not have a direct	1	Q. What page are you looking at,
2	recollection of such a communication.	2	the number at the bottom?
3	Q. I believe I asked you this	3	A. My apologies. I'm looking at
4	morning whether you signed any of the	4	page 17080.
5	validation protocols for PRN 007. Let's take	5	Q. Going back so when you signed
6	a look at 33 337307.	6	it, when you signed this document
7	I'm asking the reporter to mark	7	withdrawn.
8	for identification 337307 through 337313.	8	What does your signature on this
9	Tor identification 337307 through 337313.	9	document mean?
10	(Exhibit Emini-23, Plaque	10	MS. DYKSTRA: Exhibit 33. 23.
11	Reduction Neutralization Assay for	11	THE WITNESS: 23, that is
12	Mumps, 00337307 - 00337318, was marked	12	correct. It means that I am in
13	for identification.)	13	concurrence with the plan to conduct
	for identification.)	14	
14			the validation as indicated in the
15	BY MR. BEGLEITER:	15	documents, number 23.
16	Q. So what is this document?	16	BY MR. BEGLEITER:
17	A. This is allow me a moment,	17	Q. The plan to conduct the validation?
18	please. These are signature pages on the	18	A. The plan to yes. This is the
19	front end of the document related to Plaque	19	validation protocol. So Number 23 is the
20	Reduction Neutralization Assay, Analytical	20	protocol that describes how the validation
21	Validation Protocol Version 2. I don't know	21	will be conducted.
22	exactly which plaque reduction neutralization	22	Q. That's why if you turn to page
23	assay was being referred to here. This is the	23	315
24	AIGENT assay according to this document which	24	A. 15?
25	is the anti-IgG neutralization assay.	25	Q. Yeah. Let's say purpose. Let
	Page 255		Page 257
1	Q. This is the assay that we have	1	me read to you the sentence in the the
2	been discussing, yes, the PRN?	2	second sentence. The data rising from this
3	A. Yes.	3	validation study will be used to $1, 2, 3, 4$,
4	Q. And do you see your signature on	4	5, do you see that?
5	it? Well, do you see your signature on any of	5	A. Yes.
6	these sheets?	6	
7		0	O So that means it hadn't been
		7	Q. So that means it hadn't been
	A. Yes, I do.	7	done yet?
8	Q. And you signed it what day?	8	done yet? A. That is correct. This is the
8 9	Q. And you signed it what day?A. The 22nd of February 2001.	8 9	done yet? A. That is correct. This is the protocol for conducting
8 9 10	Q. And you signed it what day?A. The 22nd of February 2001.Q. And you had no comments?	8 9 10	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316,
8 9 10 11	Q. And you signed it what day?A. The 22nd of February 2001.Q. And you had no comments?A. I had specifically says none.	8 9 10 11	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments,"
8 9 10 11 12	 Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked 	8 9 10 11 12	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence,
8 9 10 11 12 13	 Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to 	8 9 10 11 12 13	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay
8 9 10 11 12 13 14	 Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to the being sent to CBER in March of 2000 	8 9 10 11 12 13 14	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay will be performed" And then the next
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8 9 10 11 12 13 14 15 16 17 18	Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to the being sent to CBER in March of 2000 March of 2001? Going back to that document. A. I need to go back, please. MS. DYKSTRA: Exhibit 6. BY MR. BEGLEITER:	8 9 10 11 12 13 14 15 16	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay will be performed" And then the next sentence, "The validation experiment will include" So this is all speaking in future tense? A. Yes, of course.
8 9 10 11 12 13 14 15 16 17	 Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to the being sent to CBER in March of 2000 March of 2001? Going back to that document. A. I need to go back, please. MS. DYKSTRA: Exhibit 6. BY MR. BEGLEITER: Q. Exhibit 6, the cover letter 	8 9 10 11 12 13 14 15 16 17	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay will be performed" And then the next sentence, "The validation experiment will include" So this is all speaking in future tense?
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8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to the being sent to CBER in March of 2000 March of 2001? Going back to that document. A. I need to go back, please. MS. DYKSTRA: Exhibit 6. BY MR. BEGLEITER: Q. Exhibit 6, the cover letter March 12th. A. The cover letter was March 12, 2001, yes. And the results of the validation 	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay will be performed" And then the next sentence, "The validation experiment will include" So this is all speaking in future tense? A. Yes, of course. Q. Do you know when it was completed? MS. DYKSTRA: Objection. Form.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to the being sent to CBER in March of 2000 March of 2001? Going back to that document. A. I need to go back, please. MS. DYKSTRA: Exhibit 6. BY MR. BEGLEITER: Q. Exhibit 6, the cover letter March 12th. A. The cover letter was March 12, 2001, yes. And the results of the validation were completed on February the memo from	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay will be performed" And then the next sentence, "The validation experiment will include" So this is all speaking in future tense? A. Yes, of course. Q. Do you know when it was completed? MS. DYKSTRA: Objection. Form. THE WITNESS: Well, the sorry.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 Q. And you signed it what day? A. The 22nd of February 2001. Q. And you had no comments? A. I had specifically says none. Q. So, sir, you'll notice we talked about the validation protocols being sent to the being sent to CBER in March of 2000 March of 2001? Going back to that document. A. I need to go back, please. MS. DYKSTRA: Exhibit 6. BY MR. BEGLEITER: Q. Exhibit 6, the cover letter March 12th. A. The cover letter was March 12, 2001, yes. And the results of the validation 	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	done yet? A. That is correct. This is the protocol for conducting Q. On page the next page, 316, at the bottom "Assay Validation Experiments," the second sentence the first sentence, "The plaque reduction neutralization assay will be performed" And then the next sentence, "The validation experiment will include" So this is all speaking in future tense? A. Yes, of course. Q. Do you know when it was completed? MS. DYKSTRA: Objection. Form. THE WITNESS: Well, the

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	HIGHLY CONFIDENTIAL -		1010,210,2120,01,21
	Page 258		Page 260
1	my only answer to that comes from	1	only thing that the signature page indicates
2	looking at the document in your Exhibit	2	is that there is approval, as long as no
3	Number 6 which was a response to the	3	comments are made by the individuals who sign.
4	agency and going to page 80 which was	4	That the validation protocol as written is
5	the data that was the completion of the	5	acceptable and can, in fact, be used to
6	validation assay dated approximately	6	validate the assay as described. Again, there
7	dated exactly seven days later, on	7	is also a risk factor associated with this
8	February 27, 2001.	8	because if it is approval after the validation
9	BY MR. BEGLEITER:	9	is actually if an issue is raised by any of
10	Q. On the document that you signed,	10	the individuals that were being asked to
11	is that a template or is that something that	11	review. If an issue was raised after the
12	was drafted just for this assay?	12	actual validation protocol is run, then one
13	MS. DYKSTRA: Objection. Form.	13	has to go back and one has to do it all over
14	THE WITNESS: I well, clear	14	again.
15	what's your question, sir, you were	15	Q. The document Number 23 has a box
16	referring to what? Are you referring	16	on the top, it says, "Initial Review," it's
17	to	17	bolded and there's a box.
18	BY MR. BEGLEITER:	18	A. Yes, I see it.
19	Q. The signature page.	19	Q. And then to the right of that
20	A. You're referring to the	20	there's "Final Review" in grayish letters.
21	signature page?	21	A. Yes.
22	Q. Yes.	22	Q. What is the initial review?
23	A. So we reference the signature	23	A. I don't recollect offhand what
24	page, well, it is specific for this assay	24	the difference between the initial review and
25	insofar as the names on the signature page are	25	final view. This is a four-page document, so
	meetar as the names on the signature page are		imai view. Tims is a rour page decament, se
	7. 450		D 044
1	Page 259	1	Page 261
1 2	present.	1 2	the initial review and final review would most
2	present. Q. Going back	2	the initial review and final review would most likely be exactly the same.
2 3	present. Q. Going back A. Because they were specific	2 3	the initial review and final review would most likely be exactly the same. Q. You're speculating now?
2 3 4	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting	2 3 4	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's
2 3 4 5	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships.	2 3 4 5	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward
2 3 4 5 6	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff	2 3 4 5 6	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review.
2 3 4 5 6 7	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff N/A. Do you know what that mean?	2 3 4 5 6 7	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review. Q. Do you know if you ever signed
2 3 4 5 6 7 8	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff N/A. Do you know what that mean? A. Jerry Sadoff was had	2 3 4 5 6 7 8	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review. Q. Do you know if you ever signed off on a, quote/unquote, final review?
2 3 4 5 6 7 8 9	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff N/A. Do you know what that mean? A. Jerry Sadoff was had responded. He was in the clinical research	2 3 4 5 6 7 8 9	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review. Q. Do you know if you ever signed off on a, quote/unquote, final review? A. I don't have any recollection.
2 3 4 5 6 7 8 9	present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff N/A. Do you know what that mean? A. Jerry Sadoff was had responded. He was in the clinical research group. N/A means he was not available.	2 3 4 5 6 7 8 9	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review. Q. Do you know if you ever signed off on a, quote/unquote, final review? A. I don't have any recollection. Q. If you take a look at page 7314,
2 3 4 5 6 7 8 9 10	Present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff N/A. Do you know what that mean? A. Jerry Sadoff was had responded. He was in the clinical research group. N/A means he was not available. Q. If he was listed on this	2 3 4 5 6 7 8 9 10	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review. Q. Do you know if you ever signed off on a, quote/unquote, final review? A. I don't have any recollection. Q. If you take a look at page 7314, the very bottom there's Karen Hencken's
2 3 4 5 6 7 8 9 10 11 12	Present. Q. Going back A. Because they were specific obviously to the laboratory and the reporting relationships. Q. Going to 23 it says Jerry Sadoff N/A. Do you know what that mean? A. Jerry Sadoff was had responded. He was in the clinical research group. N/A means he was not available. Q. If he was listed on this document for a signature, shouldn't his	2 3 4 5 6 7 8 9 10 11 12	the initial review and final review would most likely be exactly the same. Q. You're speculating now? A. I am totally speculating. It's a four-page document, pretty straightforward to review. Q. Do you know if you ever signed off on a, quote/unquote, final review? A. I don't have any recollection. Q. If you take a look at page 7314, the very bottom there's Karen Hencken's signature. I believe above the word "Comments"
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	HIGHLI CONFIDENTIAL -		
	Page 262		Page 264
1	data from a clinical study.	1	yes.
2	Q. Did you understand that the	2	Q. And did you ever sign any
3	validation protocol authorized the experiments	3	validation of Dr. Krah's lab and personnel to
4	to be conducted in a GLP compliant lab?	4	run a to run the clinical samples pursuant
5	MS. DYKSTRA: Objection.	5	to GCP?
6	THE WITNESS: All validation	6	A. Again, GCP does not refer to the
7 8	studies and all clinical assay studies	7 8	laboratory or to the laboratory operations.
9	are to be conducted in laboratories	9	What is being used in some of these documents
10	that follow good GLP refers to good laboratory practice, it means a	10	in a very loose fashion is the term GLP which refers to good laboratory practices. In
11	different thing today than it did then,	11	general what this refers, and this is typical
12	but	12	of all laboratories that run clinical assays,
13	BY MR. BEGLEITER:	13	is that they run a validated assay and that
14	Q. Yes. And, in fact, was Dr. Krah's	14	the laboratory's operations are run under
15	lab a GLP compliant lab?	15	specified standard operating procedures.
16	A. The laboratory the GLP	16	Q. Do you know if the personnel in
17	compliance required the presence of SOPs and	17	Dr. Krah's lab had been trained to perform
18	the requirement to follow SOPs, so my answer	18	assays under GMP or GCP?
19	to that question would be yes.	19	A. If the individuals followed the
20	Q. Is there a certification for	20	standard operating procedures and ran the
21	GLP?	21	validated assay in the way in which the assay
22	A. There is no formal certification	22	was defined by the SOP in a validated fashion,
23	as far as I'm aware for GLP.	23	that would have been acceptable.
24	Q. And a clinical trial involving	24	Q. But you don't know if, in fact,
25	clinical samples in children must be conducted	25	that occurred?
	Page 263		Page 265
1	according to a to good clinical practices.	1	A. If there was what, formal
2	Isn't that correct?	2	training?
3	MS. DYKSTRA: Objection.	3	Q. Yes.
4	THE WITNESS: The conduct of the	4	A. I do not recollect if there was
5	clinical trial has to be by good	5	formal training involved, but it is not a
6	clinical practices, yes, which are	6	•
7			requirement.
1	again, you know, clear specifications	7	Q. Well, I thought you said that it
8	in terms of what that means.	8	Q. Well, I thought you said that it was a requirement for a GLP?
9	in terms of what that means. BY MR. BEGLEITER:	8 9	Q. Well, I thought you said that it was a requirement for a GLP? A. That standard operating
9 10	in terms of what that means. BY MR. BEGLEITER: Q. Do you know if Dr. Krah's lab	8 9 10	Q. Well, I thought you said that it was a requirement for a GLP? A. That standard operating procedures be followed. Now, whether or not
9 10 11	in terms of what that means. BY MR. BEGLEITER: Q. Do you know if Dr. Krah's lab was a good clinical practices laboratory?	8 9 10 11	Q. Well, I thought you said that it was a requirement for a GLP? A. That standard operating procedures be followed. Now, whether or not one actually has a formal training for that or
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Page 266 Page 268 did you? wasn't completed and sent to CBER until 2 A. I did not, no. 2 March 12, 2001? 3 I'm asking, do you know who 3 MS. DYKSTRA: Objection. 4 Robin Mogg is? 4 THE WITNESS: Why it was not 5 I do not recall directly. I 5 sent? recognize the name, but I do not recall the 6 BY MR. BEGLEITER: 6 7 individual. 7 Q. Yes. 8 8 A. I can't tell you why it was not How about Joseph Antonello? 9 9 Joseph Antonello was a member of sent other than to say there was no requirement A. 10 the statistical group. 10 to send it. This document purports to give O. Well, it's about a seven-month 11 Q. 11 period from the first pediatric run until it 12 the dates of the asset runs, isn't that 12 13 correct, regarding -- purports to give the 13 goes to --14 dates of the asset runs? 14 I don't know what this pediatric A. 15 A. Of the assay runs. 15 run refers to. I really don't. The only 16 Q. Assay, I'm sorry. 16 thing that I can ascertain from this were the 17 A. Asset refers to something else. 17 validation runs that were run from -- the 18 MS. DYKSTRA: I'm sorry, Bob, is 18 so-called adult runs at the top that were run 19 there a question pending? 19 from the 18th of January to the 26th of 20 20 MR. BEGLEITER: I'm sorry, I February 2001. So that would have -- those 21 thought he was still looking at it. I 21 would have been runs that were run -- studies 22 think he is still looking at it. 22 that were run, you know, roughly at -- but 23 MS. DYKSTRA: I'm sorry, your 23 these are adult runs. So this refers to assay 24 question was? 24 runs. Whether or not they're directly related 25 MR. BEGLEITER: I'm showing him to the validation or not, I cannot tell from Page 267 Page 269 1 the document. Before I ask any 1 this. 2 question, I'm going to give him a 2 There's no question, though, 3 chance to look at it, the document. 3 that the validation could have been done prior 4 MS. DYKSTRA: Okay. I was 4 to when it was done? 5 asking whether there was a question 5 MS. DYKSTRA: Objection. Form. 6 pending. I wasn't sure. 6 THE WITNESS: Well, anything can 7 MR. BEGLEITER: There's no 7 be done at any time. 8 8 BY MR. BEGLEITER: question pending. 9 THE WITNESS: Okay. Thank you. 9 Q. That's true. What about -- I 10 10 BY MR. BEGLEITER: mean, the fact that we -- I showed you an 11 And does this show in Protocol 11 assay that was run in December. I'm trying to 007 the dates, at least, of some of the assay understand why maybe you -- you tell me that 12 12 13 runs? 13 it wasn't necessary --14 This shows the dates, if I read 14 A. It was not necessary. A. 15 Q. -- but I want to understand why 15 this correctly, it's pretty sparse, relates to the assay runs that were performed in the 16 it was that assays were done and then the 17 context of the assay validation. 17 validation went in? 18 Q. And the earliest for the 18 A. Well, when -- so I will give you 19 pediatrics were August 21, 2000. Is that 19 a hypothetical circumstance under which one 20 right? 20 would normally do that. Hypothetical 21 According to this, it would be 21 circumstances could be one in which an assay 22 for what it says here, August 21, 2000. But I 22 is developed. One is confident about the 23 23 don't know what that entry refers to. parameters of the assay. There is a time 24 24 Can you explain to me -- do you pressure of some sort to generate the data 25 have any explanation as to why the validation from the assay. Following the procedure of

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Page 272 performing a formal validation and then 1 constraint? 2 sending the data and then obtain concurrence 2 A. Specifically why there was any 3 to the agency prior to actually doing the run 3 kind of time constraint, in specific 4 takes time. Now, from a risk perspective, 4 discussions that I had recollect today, the 5 that's the least risky approach, because if 5 answer is no. there is a disagreement with the agency, then 6 Q. Now, you mentioned that there one has the opportunity to go back and modify 7 were -- I promised you we could break, so 8 the assay, redo the validation, whatever the 8 let's break. 9 VIDEOGRAPHER: The time is now 9 case happens to be. But once the assay 10 samples are run, the actual study samples are 10 4:02. We're going off the video 11 run, you can't go back and do it over again. 11 record. 12 So, therefore, you take a risk. 12 13 So if there's a time constraint 13 (A recess was taken.) 14 and I need to update it by a certain time, 14 VIDEOGRAPHER: The time is 4:17. 15 what one would do is to validate the assay in 15 We're back on the video record. 16 parallel, more or less in parallel with 16 17 running the actual clinical samples, it could 17 BY MR. BEGLEITER: be more or less, because it would be a little 18 Q. Doctor, was it generally bit before, it could be a little bit after. 19 understood at Merck -- withdrawn. 20 20 Your view that Merck could do The only point is you would not complete the 21 validation prior to actually generating data 21 the assay, test the assays and then do the 22 on the actual clinical samples. 22 validation, was that written somewhere? Is 23 Q. 23 Do you recall if there was a there any kind of rule for that that we can 24 time constraint with 007? 24 look at? Well, there were time constraints 25 25 A. Is there any written rule that Page 271 Page 273 related, but I don't know if they were related 1 I'm aware of? No. to this. There were time constraints 2 Q. So where do you get the idea 3 associated with generating data from that 3 that it's appropriate for -- it's permissible? 4 so-called interim analysis to have a look at 4 A. It's permissible. I mean, it's 5 5 the seroconversions that were present that -standard, it's standard practice. I've had 6 that the seroconversions that were elicited in 6 other examples, not necessarily when I was at 7 subjects who received vaccine of certainly the 7 Merck, but in my subsequent employment, I'll two lower potency values that were being 8 leave it at that, where we've done the same 9 assessed in the study. 9 thing, run assays at risk before there is 10 10 agreement with the agency on the validation. Because children had received vaccines below the 4.3 spec, is that what 11 11 Q. Shouldn't you have approved this 12 you're saying? 12 at risk running? 13 MS. DYKSTRA: Objection. Form. 13 MS. DYKSTRA: Objection. 14 THE WITNESS: Because there was 14 THE WITNESS: Not necessarily 15 a -- again, I do not recollect exactly, 15 formally approved it. I may have 16 but whatever it was there was a desire 16 approved it informally. I just simply 17 to generate data. I really don't 17 do not recollect. 18 18 recollect the discussions, but there 19 was a desire clearly to generate data 19 (Exhibit Emini-25, 1/4/02 E-mail 20 to assess the seroconversion as 20 with attachment, 00579518 - 00579521, 21 measured by the assay in those two 21 was marked for identification.) 22 lower potency values. 22 23 BY MR. BEGLEITER: 23 BY MR. BEGLEITER: 24 Q. You don't know sitting here 24 Q. I'm going to show you a document today why there was any kind of time 25 that's been marked Emini-25. It's Merck

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	Page 274		Page 276
1	579518 through 521. You'll find it an easy	1	derived from the clinical trial sera.
2	read. It's been mostly redacted.	2	BY MR. BEGLEITER:
3	A. Okay.	3	Q. If that were, in fact, done,
4	Q. First of all, did you receive	4	that would be a pretty serious scientific
5	this document in the usual course of your	5	violation?
6	employment with Merck?	6	MS. DYKSTRA: Objection.
7	A. If it was sent to me, I'm	7	THE WITNESS: That would be
8	looking for that right now.	8	probably something you consider to be
9	Q. Look at five lines from the top.	9	inappropriate, yes.
10	A. There's many names there. Yes,	10	BY MR. BEGLEITER:
11	there I am. So, therefore, the answer to your	11	Q. More than inappropriate. That
12	question is yes.	12	would be a violation of the ethics of
13	Q. And it says, "Attached are the	13	scientists?
14	minutes of the December 12 meeting of the	14	MS. DYKSTRA: Objection.
15	Critical Assay Subcommittee. Thanks Joan."	15	THE WITNESS: Well, ethics is a
16	[As read] Who is Joan Staub?	16	strong term. I would call it, I would
17	A. Joan Staub was she had	17	call it inappropriate and not something
18	multiple positions within the organization.	18	that one would normally do or should
19	So and she was in the, if I remember	19	normally do.
20	correctly, in the project management group, or	20	BY MR. BEGLEITER:
21	the program management group, whatever it was	21	Q. And did that happen?
22	called.	22	A. Not to my recollection. In
23	Q. Now, behind that is an e-mail	23	fact, that did not happen.
24	dated January 4, 2001. I won't ask you any	24	Q. You believe it didn't happen?
25	questions regarding this.	25	A. I believe that it didn't happen
	1 0 0		1 1
1	Page 275 A. Please don't.	1	Page 277
	Page 275 A. Please don't.	1	Page 277 for the reasons noted here.
1	Page 275 A. Please don't. Q. Turn to the second page.	1 2 3	Page 277 for the reasons noted here. Q. "We can document, using D.
1 2	Page 275 A. Please don't.	2	Page 277 for the reasons noted here. Q. "We can document, using D. Krah's," that's Dr. Krah, right,
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Page 280 So this would certainly not be 1 MS. DYKSTRA: Objection. 2 my perspective. 2 THE WITNESS: Okay. Yes. 3 Now, do you know what a summary 3 BY MR. BEGLEITER: 4 report is of a validation protocol? 4 Q. You know about that? 5 A. Exactly what it says. It is a 5 Well, it would be a standard Α report of the validation study that was done. 6 operation to be conducted but that refers to 6 7 Was one done for Protocol 007? the clinical investigator. The way he 8 A. I don't recall if -- well, there 8 described it specifically to the clinical 9 9 was a report -- there was a report that we investigator and the testing referred to there 10 noted in my reply to the CBER 483 from the 10 would be testing performed by the clinical statistical group, I believe that's what 11 investigator. 11 MR. BEGLEITER: Let's get this 12 you're referring to. 12 13 Q. Did you write that summary 13 one. 126340. Let's have it marked. It's 24. I'm asking the court reporter 14 report or did somebody else? 14 15 A. No. That would have been 15 to mark as an exhibit Merck 126340 16 written by the statistical group. 16 through Merck 126351. 17 Q. Is that Mr. Antonello's group? 17 18 A. That would have been 18 (Exhibit Emini-26, 2/5/02 Letter 19 Mr. Antonello's group. 19 with attachments, 00126340 - 00126351, 20 20 Q. Going back to 23, a document was marked for identification.) 21 that you signed at least on the second page of 21 BY MR. BEGLEITER: it, I just want to make sure I understand 22 22 23 23 this. The third sentence at the top, "It is Q. Your name is not in this 24 understood that these experiments will be 24 document. Are you familiar with the forms that are attached here? 25 performed in a GLP compliant laboratory to 25 Page 281 ensure the validity of the data." Okay. And 1 Allow me a moment. 2 was it your testimony that in order to be a 2 Q. Investigational New Drug Application. 3 GLP compliant laboratory you needed an SOP? 3 4 You needed to operate in the 4 That is your standard IND form 5 5 context of existing, approved and filed that goes with all correspondence associated 6 standard operating procedures, yes. And they 6 with an open IND, as was the case here. And 7 could relate to any one of a number of 7 then there's a form related to the statement 8 different factors in the laboratory. 8 of investigator. In this case it was a 9 9 Okay. Isn't GLP reserved for protocol amendment related -- I'm just reading testing in the experimental non-clinical 10 10 what's in the memo. And the note related to a 11 research arena? 11 new clinical investigator, new clinical side 12 A. The way the terminology is used 12 being brought on board, into the study. Q. To your knowledge, was a 1572 13 today, yes. It is used specifically to refer 13 14 to that. Back in the day, 20 years ago, the 14 form filled out for MMR II Protocol 007? terminology was used much more loosely. 15 MS. DYKSTRA: Objection. 15 16 Q. Do you know what Form 1572 is? 16 BY MR. BEGLEITER: 17 A. I don't recall off the top of my 17 Q. If you know. A. I don't know -- so this is a head, no. 18 18 19 Q. Is there a form that a principal 19 Form FDA 1572 but relating specifically to 20 investigator and the study sponsor are 20 this single investigator, April Palmer, MD. required to sign committing to conduct the 21 Notice on the front page it does study under accepted norms including GCP 22 make reference to Protocol 007. It gives the 23 compliance, not just with regard to the 23 title of it. 24 subjects but with all testing? Does that ring 24 Yes, that's right. And 25 25 a bell? presumably this form would have been filled

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1	out by all the other investigators involved in	1	Q. Was this a regular occurrence
2	the study as well.	2	where you would bring in entire labs, people
3	Q. And does this form contain a	3	and have discussions with them?
4	commitment that the study sponsors required	4	MS. DYKSTRA: Objection.
5	is committed to conduct the study under	5	THE WITNESS: It would not be an
6	accepted norms including good clinical	6	unusual occurrence.
7	practice compliance?	7	BY MR. BEGLEITER:
8	A. Would you, please, point that	8	Q. And was the lab in a different
9	out to me?	9	building from your office?
10	Q. Under "COMMITMENTS"?	10	A. I recollect that the laboratory
11	A. Yes.	11	was in the same building as my office. It
12	Q. "I agree to conduct the	12	would have been building 16.
13	study(ies) in accordance with the relevant,	13	Q. Did there come a time when you
14	current protocol(s) and will only make changes	14	met with them, with Dr. Krah's excuse me,
15	in a protocol after notifying the sponsor,	15	with the lab personnel in Dr. Krah's
16	except when necessary to protect the safety,	16	laboratory and advised them to follow
17	rights, or welfare of subjects."	17	Dr. Krah's orders?
18	Do you see that?	18	MS. DYKSTRA: Objection.
19	A. Yes, I do.	19	THE WITNESS: As I mentioned, I
20	Q. Are you familiar with 21 CFR	20	have no recollection of direct of
21	part 50?	21	any such meeting of any meeting,
22	A. I am not specifically familiar	22	period.
23	with the details of that particular part of	23	BY MR. BEGLEITER:
24	the CFR.	24	Q. Do you have any recollection of
25	Q. Move on.	25	discussing bonuses with any members of
23		23	•
1	Page 283	1	Page 285
1	A. Again, these are commitments	1	Dr. Krah's lab?
$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	that relate specifically by Dr. Palmer to	2	MS. DYKSTRA: Objection. Asked
	Dr. Palmer.	3	and answered.
4	Q. You mentioned a couple of times	4	THE WITNESS: I have no
5	you had a conversation with Steve Krahling	5	recollection.
6	before the unannounced inspection?	6	BY MR. BEGLEITER:
7	A. Again, not direct recollection	7	Q. Do you have any recollection of
8	of the conversations themselves, per se, but	8	discussing double bonuses with people in
9	upon review of documents.	9	Dr. Krah's lab?
10	Q. Now, we discussed before, I	10	A. That's the same question. I
11	don't know whether you agree or not, that	11	have no recollection.
12	there were some problems in the lab with	12	Q. Now, you saw documents where
13	personnel and the way the lab was being run.	13	Dr. Shaw advised you that people in Dr. Krah's
114	MS. DYKSTRA: Objection.	14	lab were working very hard
14	TILLE PROFESSION	1.5	A. Yes.
15	BY MR. BEGLEITER:	15	
15 16	Q. Actually in e-mails where there	16	Q including nights, weekends
15 16 17	Q. Actually in e-mails where there was some criticisms?	16 17	Q including nights, weekends and holidays?
15 16 17 18	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right.	16 17 18	Q including nights, weekends and holidays? A. Yes.
15 16 17 18 19	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some	16 17 18 19	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody,
15 16 17 18 19 20	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some criticism.	16 17 18 19 20	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody, whether it's the entire lab or just
15 16 17 18 19 20 21	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some criticism. Q. And did there come a time when	16 17 18 19	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody, whether it's the entire lab or just individuals, that there was a fall of 2001
15 16 17 18 19 20	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some criticism.	16 17 18 19 20	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody, whether it's the entire lab or just
15 16 17 18 19 20 21 22 23	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some criticism. Q. And did there come a time when	16 17 18 19 20 21	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody, whether it's the entire lab or just individuals, that there was a fall of 2001
15 16 17 18 19 20 21 22	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some criticism. Q. And did there come a time when you invited Dr. Krah's lab to come to your	16 17 18 19 20 21 22	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody, whether it's the entire lab or just individuals, that there was a fall of 2001 deadline to get Protocol 007 completed?
15 16 17 18 19 20 21 22 23	Q. Actually in e-mails where there was some criticisms? A. Yes, there was, that's right. You showed me e-mails where there was some criticism. Q. And did there come a time when you invited Dr. Krah's lab to come to your office to meet with them?	16 17 18 19 20 21 22 23	Q including nights, weekends and holidays? A. Yes. Q. Did you ever tell anybody, whether it's the entire lab or just individuals, that there was a fall of 2001 deadline to get Protocol 007 completed? MS. DYKSTRA: Objection.

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1	BY MR. BEGLEITER:	1	MS. DYKSTRA: Objection. Asked
2	Q. Whether you told them or not,	2	and answered. Go ahead, you can
3	was there any kind of deadline, whether	3	answer.
4	imposed by CBER or self imposed by Merck?	4	THE WITNESS: Thank you. Upon,
5	A. Well, again, based upon review	5	again, review of documents, I was shown
6	of the documents and overall what was	6	a memo that Mr. Krahling had written to
7	happening at the time, did it, in fact, appear	7	me concerning HR and personnel-related
8	to be a deadline, yes.	8	issues in the laboratory, or
9	Q. My question was, was it a	9	observations that he had that concerned
10	self-imposed deadline or was something that	10	him.
11	CBER wanted?	11	BY MR. BEGLEITER:
12	A. That I cannot answer because	12	Q. Who did you get the memo from?
13	that I really don't know the answer to. I	13	A. If I remember correctly, it was
14	don't know if it came out as a result of a	14	directly from Mr. Krahling.
15	discussion with CBER or if the company decided	15 16	Q. Who brought you the memo? A. Oh. I can't I don't recall.
16	that it needed to be self imposed for some reason.		- ,
17 18		17 18	It may have been sent by e-mail. It could
19		19	have been an e-mail actually. I don't even remember.
20	cause to get this thing, to get it done by a certain date?	20	Q. You mentioned Bob Suter. Did
21	MS. DYKSTRA: Objection.	21	you discuss Mr. Krahling with Bob Suter at any
22	THE WITNESS: You have to be	22	point?
23	more specific than that. Stress is	23	MS. DYKSTRA: Objection.
24	BY MR. BEGLEITER:	24	THE WITNESS: I may have.
25	Q. Do you recall what the deadline	25	Again, I cannot recollect the specific
		-	
1	Page 287		Page 289
	was to get Protocol 007 completed?	1	avant where I got down with Mr. Sutar
1 2	was to get Protocol 007 completed?	1	event where I sat down with Mr. Suter
2	A. Would I surmise it that the	2	to discuss Mr. Krahling.
2 3	A. Would I surmise it that the deadline no, I don't know what the exact	2 3	to discuss Mr. Krahling. BY MR. BEGLEITER:
2 3 4	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a	2 3 4	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski
2 3 4 5	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a	2 3 4 5	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter?
2 3 4 5 6	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a given day.	2 3 4 5 6	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter? A. I have no recollection of the
2 3 4 5 6 7	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a given day. Q. And you don't	2 3 4 5 6 7	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter? A. I have no recollection of the specific event.
2 3 4 5 6 7 8	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a given day. Q. And you don't A. I can't give you a specific date	2 3 4 5 6 7 8	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter? A. I have no recollection of the specific event. Q. How long had you worked
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2 3 4 5 6 7 8 9 10 11	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a given day. Q. And you don't A. I can't give you a specific date because I don't remember. Q. Can you give the reason why that was done at all? A. As I said, other than the it	2 3 4 5 6 7 8 9 10	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter? A. I have no recollection of the specific event. Q. How long had you worked withdrawn. Was Bob Suter, Mr. Suter assigned to your division? A. I recollect that Mr. Suter was
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a given day. Q. And you don't A. I can't give you a specific date because I don't remember. Q. Can you give the reason why that was done at all? A. As I said, other than the it was there, I don't recall the reason for it. Q. When did you first meet Steve Krahling? A. I gather, to the best of my current recollection, it would have been right after he joined the laboratory. Q. Did you visit the laboratory? A. I recall being in the laboratory on a couple of visits, but I cannot recall the context.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter? A. I have no recollection of the specific event. Q. How long had you worked withdrawn. Was Bob Suter, Mr. Suter assigned to your division? A. I recollect that Mr. Suter was the senior HR support person for my department, yes. Q. Did he set up a meeting between you and Mr. Krahling? A. As I said, I don't recollect having a specific discussion with Mr. Suter about Mr. Krahling. So I obviously have no specific recollection of such a meeting. Q. Well, the question wasn't asked about whether you had a conversation. You
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Would I surmise it that the deadline no, I don't know what the exact deadline was, but that there was certainly a date in order to be able to get results by a given day. Q. And you don't A. I can't give you a specific date because I don't remember. Q. Can you give the reason why that was done at all? A. As I said, other than the it was there, I don't recall the reason for it. Q. When did you first meet Steve Krahling? A. I gather, to the best of my current recollection, it would have been right after he joined the laboratory. Q. Did you visit the laboratory? A. I recall being in the laboratory on a couple of visits, but I cannot recall the context. Q. Did there come a time when	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	to discuss Mr. Krahling. BY MR. BEGLEITER: Q. Did you discuss Joan Wlochowski with Mr. Suter? A. I have no recollection of the specific event. Q. How long had you worked withdrawn. Was Bob Suter, Mr. Suter assigned to your division? A. I recollect that Mr. Suter was the senior HR support person for my department, yes. Q. Did he set up a meeting between you and Mr. Krahling? A. As I said, I don't recollect having a specific discussion with Mr. Suter about Mr. Krahling. So I obviously have no specific recollection of such a meeting. Q. Well, the question wasn't asked about whether you had a conversation. You said did he set it up. He could have set

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1	Q. Did he make a recommendation to	1	Q. I mean, did he come to your
2	you that there be a meeting between you and	2	office unannounced?
3	Mr. Krahling?	3	A. I don't have specific
4	MS. DYKSTRA: Objection.	4	recollection.
5	THE WITNESS: Again, I do not	5	Q. What did Mr. Krahling bring with
6	recall.	6	him to the meeting?
7	BY MR. BEGLEITER:	7	MS. DYKSTRA: Objection. Asked
8	Q. But you do recall there was a	8	and answered.
9	meeting	9	MR. BEGLEITER: No, he
10	MS. DYKSTRA: Objection.	10	BY MR. BEGLEITER:
11	BY MR. BEGLEITER:	11	Q. Go ahead.
12	Q with you and Mr. Krahling?	12	A. Only what was noted on the note
13	A. Upon review of the documents	13	that I reviewed, right, that he showed me some
14	there was a suggestion that there was a	14	information, some data. I don't remember the
15	meeting, yes.	15	exact terminology. So, again, I have no
16	Q. Which documents did you review	16	specific recollection of the nature of what I
17	that suggested that?	17	was shown.
18	A. There was if I remember	18	Q. How long did this meeting take?
19	correctly there was a document that was sent	19	A. I have no recollection of the
20	by to me by Mr. Suter actually. There was	20	meeting here, per se, so I can't tell you how
21	a notation on the document relating to the	21	long it took.
22	fact that Mr. Krahling had shown me, though I	22	Q. You don't recall the meeting but
23	don't know who made the notation, it was a	23	you're convinced that there was a meeting?
24	handwritten notation, Mr. Krahling had shown	24	A. Only because it is documented,
25	me data that caused him some concern.	25	the documents suggest that there was a meeting
	Page 291		Page 293
1	Page 291 O. Caused Mr. Suter some concern?	1	Page 293 and it led to an event afterwards, a follow
1 2	Q. Caused Mr. Suter some concern?		and it led to an event afterwards, a follow
	Q. Caused Mr. Suter some concern?A. Caused Mr. Krahling some concern.	1 2 3	and it led to an event afterwards, a follow up.
2	Q. Caused Mr. Suter some concern?A. Caused Mr. Krahling some concern.Q. Mr. Krahling. Okay.	2 3	and it led to an event afterwards, a follow up. Q. Did the document contain your
2 3 4	 Q. Caused Mr. Suter some concern? A. Caused Mr. Krahling some concern. Q. Mr. Krahling. Okay. Do you recall what the category 	2	and it led to an event afterwards, a follow up. Q. Did the document contain your version of a meeting with Mr. Krah?
2 3	Q. Caused Mr. Suter some concern?A. Caused Mr. Krahling some concern.Q. Mr. Krahling. Okay.	2 3 4	and it led to an event afterwards, a follow up. Q. Did the document contain your version of a meeting with Mr. Krah? A. This was a document sent to me,
2 3 4 5	Q. Caused Mr. Suter some concern? A. Caused Mr. Krahling some concern. Q. Mr. Krahling. Okay. Do you recall what the category of data was?	2 3 4 5	and it led to an event afterwards, a follow up. Q. Did the document contain your version of a meeting with Mr. Krah? A. This was a document sent to me, again if I recall correctly, from Mr. Suter.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Caused Mr. Suter some concern? A. Caused Mr. Krahling some concern. Q. Mr. Krahling. Okay. Do you recall what the category of data was? A. I do not recall the exact data that was or what was shown to me. Q. Was a meeting ultimately set up in your office? MS. DYKSTRA: Objection. THE WITNESS: Well, again, to my recollection, that was data that was shown to me, that was shown to me by Mr. Krahling. So this was the event that I was referring to earlier that then led to my contacting counsel. BY MR. BEGLEITER: Q. Was that meeting a scheduled meeting in the sense that it wasn't a surprise? MS. DYKSTRA: Objection. Form. THE WITNESS: I have no recollection. I don't have specific	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	and it led to an event afterwards, a follow up. Q. Did the document contain your version of a meeting with Mr. Krah? A. This was a document sent to me, again if I recall correctly, from Mr. Suter. Again, since I have no clear recollection of the meeting or what was seen, my only recollection is, in quotes, my recollection in quotes is what is in the document. Q. And from that document does it appear that that document contains your version of what happened at that meeting? A. I don't recollect the meeting so the answer to the question is I don't know. Q. Whether you recollect the meeting or not is not my question. My question is whether or not did it appear to contain your version of what happened sometime. Maybe meeting is the wrong word. A. Well, it was Mr. Suter's version of it because but, again, this was a

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	Page 294		Page 296
1	Q. What was the subject of the	1	Mr. Krahling?
2	memo?	2	A. No.
3	MS. DYKSTRA: Objection. Form.	3	Q. In terms of temporal terms
4	THE WITNESS: I don't recall the	4	between the time of when you went to seek
5	exact subject of the memo. I do recall	5	legal advice, we can fix can we fix the
6	that it was also a heavily-redacted	6	date on that? When did you seek legal advice?
7	memo. So obviously there were other	7	Again, I'm not asking for the legal advice. I
8	things in that there had nothing to do	8	want to know when you sought it.
9	with mumps.	9	A. It was obviously immediately
10	BY MR. BEGLEITER:	10	thereafter because the FDA inspection
11	Q. So you can't recall if there's a	11	occurred, if I remember correctly, it was only
12	meeting but there's a memo which talks	12	roughly a week, maybe two weeks thereafter. I
13	about	13	don't recall, so it was immediately
14	A. There having been one.	14	thereafter. So my seeking of legal advice
15	Q there having been one. Okay.	15	occurred between the time I spoke with
16	And did Mr. Krahling bring with him any	16	Mr. Krahling and the time that the FDA
17	counting sheets? I'm asking you	17	inspection occurred. I suspect very strongly
18	A. I don't recall.	18	it occurred almost immediately after
19	Q. Trying to refresh your memory.	19	Mr. Krahling came to me.
20	Did he bring with him any counting sheets?	20	Q. Did you suspect that Mr. Krahling
21	A. I don't recall.	21	was the cause of the inspection?
22	Q. Did he bring with you a mock	22	A. No. No. I mean, it did I
23	control plate?	23	make the connection at the time? No, I
24	A. I don't recall.	24	actually I remember very clearly in my own
25	Q. Did he bring with you any kind	25	mind, this I remember clearly, not making that
-		-	
1	Page 295	1	Page 297
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	of cell plate? A. I don't recall.	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	connection, interestingly enough. Q. You thought to yourself that
$\frac{2}{3}$	Q. Did Mr. Krahling ask you to	$\frac{2}{3}$	this is not because of Stephen Krahling?
4	- · · · · · · · · · · · · · · · · · · ·	4	MS. DYKSTRA: Objection. Say
5	examine the monolayer on the plate and tell him how many plaques he saw?	5	that again.
6	A. I don't recall. This is	6	BY MR. BEGLEITER:
		7	DI WIK. DEULEHEK.
7	17 years ago.		O Ilm turing to accountally
	O Do you recall what Mr. Krahling		Q. I'm trying to accurately
8	Q. Do you recall what Mr. Krahling	8	paraphrase what he said.
9	asserted that was do you recall what	8 9	paraphrase what he said. A. I remember clearly. The thought
9 10	asserted that was do you recall what Mr. Krahling asserted that was going on in the	8 9 10	paraphrase what he said. A. I remember clearly. The thought may have occurred to me, although, you know,
9 10 11	asserted that was do you recall what Mr. Krahling asserted that was going on in the lab which he thought was improper?	8 9 10 11	paraphrase what he said. A. I remember clearly. The thought may have occurred to me, although, you know, subsequent to that, but on that day that the
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Page 300 Q. I'm only asking about you. studies that they supported. What was 2 Prior to the unannounced visit on August 6, 2 unusual, if you want to use that terminology, 3 3 was the fact that we were running these 2001, how often had there been an unannounced 4 clinical assays in a laboratory, Dr. Krah's 4 visit to one of the labs under your 5 5 laboratory, that was originally designed to supervision? 6 support assay development, to support 6 A. Under my supervision? 7 research. But unannounced -- going back to 7 Q. Yes. 8 your previous question, unannounced agency 8 A. Never before. This was the 9 inspections related to any product, product 9 first time. 10 10 under development, product that was licensed Q. Was this a startling event for and produced, happens all the time. 11 you? 11 12 MS. DYKSTRA: Objection. 12 Let's go back a second. So it 13 THE WITNESS: Well, it was an 13 was unusual, to use a word I think you were 14 using, for the lab that developed the assay to 14 event that one remembers. That event I 15 remember clearly associated with that 15 actually do the assay testing, conduct the 16 one. Whether it would be startling, 16 assay? 17 Normally that would not be the 17 probably not because unannounced FDA 18 18 case, and as noted in one of the documents inspections of ongoing clinical studies 19 19 that you showed me earlier today, it was noted and/or of ongoing production facilities 20 20 in there that normally we would have are not unusual. It happens all the 21 21 transferred the assay onto a testing time because we had a laboratory under 22 22 laboratory. my supervision that was involved in the 23 23 conduct of a clinical assay in support Q. Typically? 24 of a clinical study and having an 24 A. Typically, Typically, usually. 25 25 We've already gone over why that unannounced inspection from the agency Q. Page 299 Page 301 1 was startling only because the agency 1 wasn't done. 2 showed up unannounced, but it was not 2 We've gone over why that wasn't, 3 an unusual event, if that was your 3 because there was time pressures. 4 question. 4 Did you see a lawyer after -- a 5 5 BY MR. BEGLEITER: Merck attorney, again I don't want to know 6 Q. Had you ever been -- had any 6 what he told you or you told him, but with 7 laboratory under your supervision ever before 7 regard to the unannounced visit, unannounced 8 been accused by the FDA of changing data? 8 inspection, did you seek advice? 9 MS. DYKSTRA: Objection. 9 I do not recollect. 10 10 THE WITNESS: No. But it O. Let me be clear. Going back a 11 never -- the opportunity for such an 11 second. You went to see a lawyer after you --12 accusation if it were ever to be made 12 after something happened with Steve Krahling, 13 never existed, but it existed with 13 whether it was a meeting or something else, 14 regard to a Protocol 007 only because 14 you're not sure. It was a meeting that is 15 15 recorded? there was the laboratory actually 16 running the assay. 16 A. It's a meeting that's recorded. 17 BY MR. BEGLEITER: 17 I don't recollect the specifics of the 18 Q. Which was a rare event. Who 18 meeting. 19 else would run the assay if not for the 19 Q. Did you at that point -- again, 20 laboratory? 20 before the announced visit, did you at that 21 A. It would be either an external 21 point consider terminating Mr. Krahling? 22 testing laboratory or another testing 22 Oh, I don't recollect at all 23 23 laboratory within the facility or a testing having ever thought that at that point. The 24 laboratory responsible for clinical assays 24 reason why I went to counsel was because in 25 over in the manufacturing division for the response to what Mr. Krahling presented to me

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Page 304 and I felt that I should bring it to counsel. 1 A. That was reporting the second meeting. 2 I'm going to leave it at that. 2 3 MS. DYKSTRA: Just caution you 3 Q. Right. What do that --4 not to get into privilege. 4 A. Or the second interaction. 5 MR. BEGLEITER: I'm not going to 5 O. What do you recall that memo 6 6 said about what Mr. Krahling had told you? ask him. 7 MS. DYKSTRA: I wasn't cautioning 7 Just what I said. There was a 8 you. I was cautioning the Doctor. 8 handwritten notation on the memo. It was a 9 9 THE WITNESS: She was yelling at wholly redacted memo. It was a handwritten 10 10 notation, and I don't know who wrote the me. BY MR. BEGLEITER: 11 notation. Again, just for clarity, I don't 11 know whether it was Mr. Suter or anybody else 12 Were you accompanied to counsel 12 who wrote the notation noting that 13 by Dr. Krah or Dr. Shaw or did you go 13 14 yourself? 14 Mr. Krahling had showed me, if I remember --15 I don't recall the specifics. 15 if I remember correctly, had showed me some Did you discuss Mr. Krahling's 16 Q. 16 information that caused concern, or that was 17 interaction with you with Dr. Krah? 17 concerning to Mr. Krahling. 18 A. Did I discuss -- with Dr. Krah. 18 Was there, after the unannounced 19 I don't recall. 19 inspection, did you commence any kind of 20 Q. How about with Dr. Shaw? 20 internal -- withdrawn. 21 I do not recall the specifics. 21 After that unannounced inspection, I don't recall. I don't recall if I had the 22 22 was there any internal investigation that was 23 23 meeting. I don't have the specifics of the conducted? 24 meeting. Again, it was 17 years ago. 24 A. Well, we conducted a full audit 25 And do you recall -- I'd like to 25 as noted in the response that went back to Page 303 Page 305 just make sure I know exactly what words, as 1 CBER approximately 20 days later. These are best you can remember, what you have -- what 2 all standard procedures that one follows to Mr. Krahling orally, in writing, whatever, 3 address the observations of the inspector. 3 4 communicated to you about what was going on in 4 And also oftentimes what one does is one goes 5 the lab. 5 beyond that to say, okay, so this is what the MS. DYKSTRA: Objection. Asked 6 inspector saw, therefore, we will address what 6 7 7 the inspector specifically saw. What we will and answered. THE WITNESS: Only by what was 8 also do is conduct a broader assessment to 8 9 9 make sure that even though the inspector in the memos that were shown me. There 10 10 was the original communication which, didn't shine a light on something else, that 11 as best as I can tell, was solely by 11 everything else is also operating the way it's supposed to operate. So it's not unusual to 12 memo, whether it was by memo or by 12 13 e-mail, whatever the case happens to 13 do that. 14 be, in which Mr. Krahling referred 14 Was there a witness' interview? Q. 15 MS. DYKSTRA: Objection. Form. 15 specifically to HR-related issues. It 16 was solely HR-related issues at that 16 THE WITNESS: I was not involved 17 17 in the overall audit so I can't tell point. And then sometime subsequent to 18 that, there was a subsequent meeting in 18 vou. 19 which whatever Mr. Krahling showed me, 19 BY MR. BEGLEITER: 20 and, again, I don't remember the 20 Q. I didn't ask you whether you 21 21 were involved. I asked you whether to your specifics of it, led me to approach 22 22 counsel. knowledge --23 23 BY MR. BEGLEITER: A. To my knowledge. 24 24 To your knowledge were witnesses Q. Does that memorandum that 25 Mr. Suter apparently put together -interviewed?

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1	A. I don't recollect.	1	not looking at individual lots. Sorry,
2	Q. Were you interviewed by anyone?	2	I don't understand your question.
3	A. I actually don't recollect.	3	BY MR. BEGLEITER:
4	Q. Again, I'm not asking what was	4	Q. There was a preliminary subset.
5	said to counsel. Wasn't what you said to	5	Is that correct?
6	counsel	6	A. There was an earlier subset
7	A. No. You're talking about the	7	looking at a subset of sera, yes.
8	post 483.	8	Q. And during the course of this
9	Q. No. I'm talking well, what	9	test, was MMD, did MMD do its own testing to
10	I'm asking I'm not going to ask what was	10	determine if there were lots that were below
11	said, but did your counsel interview you?	11	4.0?
12	A. I do	12	MS. DYKSTRA: Objection.
13	MS. DYKSTRA: Objection.	13	THE WITNESS: My apologies, but
14	THE WITNESS: But I don't recall.	14	you're talking about two different
15	BY MR. BEGLEITER:	15	things here which is confusing the
16	Q. Did you ever advise Mr. Krahling	16	question.
17	not to call the FDA about any problems he had	17	BY MR. BEGLEITER:
18	in the lab?	18	Q. Make it simple. With regard to
19	A. Not to my recollection.	19	in the 2000-2001 period, did MMD, Merck
20	MR. BEGLEITER: Take a break	20	Manufacturing Division, do any testing to see
21	now, and then I think we can I'm	21	if any of the lots that had been sent down
22	trying to see if I can wind it up. I'm	22	to for use had below 4.0, had a below 4.0
23	not promising.	23	spec?
24	VIDEOGRAPHER: Time is now 4:53.	24	MS. DYKSTRA: Objection.
25	We're going off the video record.	25	THE WITNESS: I do not know of
١.	Page 307		Page 309
1	(A	1	specific data from MMD. I would not
2	(A recess was taken.)		
	(11 100055 was taken.)	2	have seen it and I don't know.
3		3	BY MR. BEGLEITER:
3 4	VIDEOGRAPHER: The time is now	3 4	
3 4 5	VIDEOGRAPHER: The time is now 5:16. We're back on the video record.	3 4 5	BY MR. BEGLEITER: Q. Let's show it to you.
3 4 5 6	VIDEOGRAPHER: The time is now 5:16. We're back on the video record. BY MR. BEGLEITER:	3 4 5 6	BY MR. BEGLEITER: Q. Let's show it to you (Exhibit Emini-27, 2/26/01
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3 4 5 6 7 8	VIDEOGRAPHER: The time is now 5:16. We're back on the video record. BY MR. BEGLEITER: Q. Doctor, during the assay, the PRN assay in Protocol 007, did Dr. Krah's lab	3 4 5 6 7 8	BY MR. BEGLEITER: Q. Let's show it to you (Exhibit Emini-27, 2/26/01
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Page 312 paragraph, the first sentence, "We have been 1 BY MR. BEGLEITER: 2 assisting MMD in responding to CBER questions 2 O. It then says --3 re mumps end-expiry by performing an interim 3 A. It then says, Jerry, that would 4 analysis on 600 children participating in the 4 be Gerald Sadoff, and I feel 3.7 is medically 5 mumps end-expiry study (200 per group, studied 5 okay and would be defensible to the office of compliance. And based on the data, I would at mumps potencies of 4.9, 4.0 and 3.7)." 6 7 7 Do you see that? agree. 8 8 The last sentence of that Yes. 9 paragraph under "Ed" it says, the last two 9 That study, was that study part 10 of the Protocol 007? 10 sentences, "The less than 3.7 lots are of A. Yes. particular concern; the 3.7 to 4.0 lots are 11 11 likely defensible with some additional work." 12 Q. Now, did that study in the 12 13 preliminary subset indicate that lots below 13 And then it says, "All 106 lots are a compliance issue." 3.7 were not -- did not meet the requirements 14 14 15 15 of immunogenicity? Do you see that? A. Right. So I don't know what 16 MS. DYKSTRA: Objection. 16 17 THE WITNESS: No, that is not 17 the -- I believe the 106 lots are referring to 18 the result. The result is indicated 18 the lots that they believe at end expiry may 19 19 be below. It's unclear from what's written right here in the memo. It says in the 20 20 here. Maybe below that declared level which last paragraph on that first page, all 21 the way down at this bottom, it 21 the agency had declared at 4.3. The data, I'm 22 22 reading the penultimate sentence in the first describes the neut assays. It says, 23 23 "By the neutralization assays, ...and paragraph, the 3.7 to 4.0 lots are likely 24 end-expiry of 4.0...," remember this 24 defensible. And given the data at the end of 25 was one of the three levels that were 25 this page, I would agree, they are defensible Page 311 Page 313 because the data are not ostensibly different 1 tested in 007, "...meets CBER's 1 demand...," as was noted here, CBER's 2 2 between 4.0 and 3.7. 3 perspective criteria for 90 percent 3 The reason why the 3.7 lots are 4 seroconversion rate. So 4.0 is fine. 4 of particular concern, less than 3.7 lots are 5 5 While the 3.7 log titer misses, right, of particular concern is that there are no 6 with 88.2 percent seroconversion rate 6 data on the level of seroconversion that would 7 but a 95 percent confidence interval of 7 be -- that would occur because the study only 8 82.3 to 92.6. 8 went down to 3.7 lots, so what would happen at 9 Now, going back to our earlier 9 3.5, 3.4, any lower number, there are no data. 10 conversation from today, this is not an 10 So it's classic unknown lines. assessment of efficacy. Rather what But there was data at 3.7 and 11 11 O. 12 this is, is a measure of the ability of 12 4.0. Is that correct? 13 the vaccine at these three different 13 A. Right there, yes. 14 tested potency levels to elicit a 14 So I'm asking about the -- I'm talking about the lots which were between 4.0 15 measurable immune response as measured 15 16 by the assay. CBER obviously placed a 16 and 3.7. Those are the -- aren't those the 17 criterion around what they would accept 17 lots, 106 lots which are a compliance issue? 18 as given the assay of an acceptable 18 MS. DYKSTRA: Objection. 19 19 seroconversion rate, criterion that was THE WITNESS: The wording is 20 established on the basis of, I'm not 20 unclear, but it may refer that -- those 21 exactly certain what, but they 21 106 lots may refer to those lots 22 established it at 90 percent, that 22 between 3.7 and 4.0. 23 that's what they wanted to do, and they 23 BY MR. BEGLEITER: 24 did it. You will note that the 24 Q. You got this e-mail on 25 confidence interval crosses 90 percent. 25 February 23, 2001?

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	D 214		P 217
1	Page 314 A. Okay. Yes.	1	Page 316 the end expiry number, and remember the
2	Q. And did you do anything about	2	number had been established by the
3	that after learning that 106 lots may be a	3	agency at 4.3 initially simply because
4	compliant are a compliance issue?	4	it was simply the number that was in
5	A. That is a matter of regulatory	5	the original label that you showed me
6	discussion between the company and CBER.	6	this morning and therefore the agency
7	There was nothing for me to do.	7	said this should probably be the end
8	Q. Do you know how many doses there	8	expiry number, without there being any
9	are in 106 lots?	9	data supporting whether it should be
10	A. I don't know how many doses are	10	that number or a lower number or for
11	in a lot.	11	that matter a higher number, which is
12	Q. You weren't consulted on what to	12	why the 007 was being conducted, in
13	do with those 106 lots?	13	that sense a formal compliance
14	MS. DYKSTRA: Objection.	14	accepting 4.3 as representative of the
15	THE WITNESS: No, because I	15	end expiry number which is the way the
16	would not have been consulted. The	16	agency interpreted it in the initial
17	data are very clear and I would not	17	communications, then by definition,
18	disagree with the conclusions here.	18	they are these lots that are below 4.0,
19	The 106 lots, what we know from the 007	19	certainly below 4.3, are a potential
20	data from the initial analyses that	20	compliance issue, but not a medical
21	were done, is that at 3.7 the	21	issue.
22	seroconversion rate has a confidence	22	BY MR. BEGLEITER:
23	interval that crosses 90 percent. So	23	Q. If it was how do you know
24	statistically there is no difference in	24	that? How do you know it's not a medical
25	the seroconversion rate on a potency of	25	issue? How do you know what the consequences
	Page 315		Page 317
1	4 or a potency of 3.7, which is why	1	are withdrawn.
2	which is why there was the statement	2	How do you know what the
3	here saying that Jerry, who was in	3	conferences are of selling of using vaccine
4	medical at the time and Dorothy	4	below 4.1?
5	Margolskee together agreed that 3.7 is	5	A. Look at the data right here. So
6	medically acceptable and defensible,	6	what do we know. We know that the vaccine has
7	and she says it twice.	7	retained field effectiveness. So we know the
8	BY MR. BEGLEITER:	8	vaccine is effective even though there
9	Q. But I'm talking about the lots	9	clearly, as is noted here, 106 lots that are
10	between 3.7 and 4.0.	10	between 3.7 and 4.0, with that number of lots
11	A. That's the one I'm talking	11	with the number of doses probably involved in
12	about.	12	that number of lots, if this was ineffective
	Q. So there is no	13	vaccine, you would have had a large outbreak
13		11	
14	A. There are only I'm sorry.	14	of mumps. It was never seen.
14 15	A. There are only I'm sorry.Q. Do you know what the FDA was	15	So you have 106 lots that fall
14 15 16	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this?	15 16	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The
14 15 16 17	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection.	15 16 17	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that
14 15 16 17 18	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous	15 16 17 18	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis
14 15 16 17 18 19	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous communications I don't know personally	15 16 17 18 19	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis that the vaccine's effectiveness still exists.
14 15 16 17 18 19 20	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous communications I don't know personally whether or not the agency was informed	15 16 17 18 19 20	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis that the vaccine's effectiveness still exists. So now the question is where for control
14 15 16 17 18 19 20 21	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous communications I don't know personally whether or not the agency was informed but these were the kinds of things we	15 16 17 18 19 20 21	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis that the vaccine's effectiveness still exists. So now the question is where for control purposes do we put the end expiry number in
14 15 16 17 18 19 20 21 22	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous communications I don't know personally whether or not the agency was informed but these were the kinds of things we shared continuous communications	15 16 17 18 19 20 21 22	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis that the vaccine's effectiveness still exists. So now the question is where for control purposes do we put the end expiry number in the label.
14 15 16 17 18 19 20 21 22 23	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous communications I don't know personally whether or not the agency was informed but these were the kinds of things we shared continuous communications between the agency and the company.	15 16 17 18 19 20 21 22 23	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis that the vaccine's effectiveness still exists. So now the question is where for control purposes do we put the end expiry number in the label. So they're using seroconversion
14 15 16 17 18 19 20 21 22	A. There are only I'm sorry. Q. Do you know what the FDA was informed of this? MS. DYKSTRA: Objection. THE WITNESS: In continuous communications I don't know personally whether or not the agency was informed but these were the kinds of things we shared continuous communications	15 16 17 18 19 20 21 22	So you have 106 lots that fall between 3.7 and 4.0 field effectiveness. The agency was clearly comfortable with that conclusion because 007 is based on the basis that the vaccine's effectiveness still exists. So now the question is where for control purposes do we put the end expiry number in the label.

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1 3	3.7, so that would encompass these lots	1	don't know.
2 0	obviously between 3.7 and 4.0. All the way	2	BY MR. BEGLEITER:
3 (down to 3.7, the seroconversion, 95 percent	3	Q. Do you know that there have been
	confidence interval gave a rate that is	4	outbreaks over the last several years?
	statistically not different than the number	5	A. There have been, yes. But there
	observed at four logs.	6	have been outbreaks of other vaccines related
7	Q. If the label says 4.3, which it	7	to diseases as well. So there's nothing to
	did, we talked about that this morning.	8	conclude.
9	A. Right.	9	Q. You were in favor of using
10	Q. And at 4.0 to 3.7, there's an	10	antihuman IgG in Protocol 007 AIGENT PRN.
	understanding at Merck that these are	11	Right?
	there's a compliance issue with regard to	12	A. That was a conclusion that was
	those 106 lots. Right?	13	drawn between the company and the agency.
14	MS. DYKSTRA: Objection.	14	Q. I'm talking about you. That was
15	THE WITNESS: Relative to the	15	the question. You were in favor of it?
16	label.	16	MS. DYKSTRA: Objection.
	BY MR. BEGLEITER:	17	THE WITNESS: I was in favor of
18	Q. Yes, relative to the label.	18	it because of the nature of what the
19	A. Just be clear, compliance can	19	assay was being designed to do. And I
	mean many things.	20	recollect that even prior to the review
21	Q. So whether or not it's medically	21	of the documents, that the original
	or not medically a problem, let's assume it's	22	recommendation to use the anti-IgG
	not medically	23	actually came from the agency.
24	A. You	24	BY MR. BEGLEITER:
25	Q. It's probably medically, but	25	Q. Do you know what document that
	Page 319		Page 321
1	A. You can't say it's probably	1	is?
	medically, you don't know either.	2	A. No, I just have a recollection
3	Q. The lots were being sold as	3	of the event, that the recommendation came
	being compliant with the label, weren't they?	4	from the agency and within review of documents
5	MS. DYKSTRA: Objection.	5	I saw it as well, but I have an independent
6	THE WITNESS: The lots were	6	recollection.
7	being sold, I cannot answer that	7	Q. Were you present when the agency
8	question whether or not the supposition	8	said it was okay to use AIGENT?
9	was that they were compliant with the	9	A. I cannot tell you under which
10	label or whether the vaccine was	10	circumstance I was informed of that, but I do
11	considered to be effective. That is an	11	recollect discussions that's where that
12	assessment that is made not just by the	12	this was an agency-related recommendation.
13	company but by also by the FDA. The	13	Q. Sorry, that was a bad question.
14	FDA formally releases lots of the	14	I mean, were you present when the agency first
15	vaccine.	15	suggested that AIGENT be used?
	BY MR. BEGLEITER:	16	MS. DYKSTRA: Objection.
17	Q. Let's move on to AIGENT.	17	THE WITNESS: That the anti-IgG
18	You don't know what happened	18	be used in the assay?
	with those 106 lots, do you?	19	BY MR. BEGLEITER:
19	A. I do not.	- 20	O. KISHL.
19 v 20	A. I do not. O. Those 106 lots would have been	20 21	Q. Right. A. I do not recollect the
19 20 21	Q. Those 106 lots would have been	21	A. I do not recollect the
19 v 20 21 22 u	Q. Those 106 lots would have been used in the late '90s or early 2000s. Is that	21 22	A. I do not recollect the circumstance.
19 v 20 21 22 v 23 1	Q. Those 106 lots would have been used in the late '90s or early 2000s. Is that right?	21 22 23	A. I do not recollect the circumstance. Q. What was the purpose of using
19 v 20 21 22 u	Q. Those 106 lots would have been used in the late '90s or early 2000s. Is that	21 22	A. I do not recollect the circumstance.

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Page 324 increase the sensitivity of a virus Dorothy Margolskee? 2 neutralization assay when the virus 2 A. Yes. 3 neutralization assay is designed to 3 Q. So did she accurately relate 4 specifically measure virus neutralizing 4 that in her discussion with you, that somehow 5 antibody. 5 the neutralization assay is very artificial because the IgG -- was the IgG added? 6 So it makes the testing more 6 Q. 7 sensitive, is that it? 7 Well, very is a quantitative 8 8 term and I didn't write that, Dorothy A. It makes the testing more 9 9 sensitive. Margolskee wrote it, so I can't tell you what 10 Q. And is that a -- by adding the 10 the context in her mind was when she wrote it. antihuman IgG, is that an artificial way of I will agree, as I said a moment ago, that the 11 11 making the neutralization assays sensitive? assay, in all of its components is, 12 12 13 A. I will only answer that question 13 quote/unquote, artificial as it is designed to 14 in the context of the definition of the word 14 measure only what it is designed to measure. 15 artificial. The entire assay and all of its 15 So what did I mean by that? 16 components by definition are artificial to the 16 Answer the question because I 17 assay. 17 was going to ask you that. 18 How about very artificial? 18 So this assay was designed to Q. 19 MS. DYKSTRA: Objection. 19 measure virus neutralizing antibody. The THE WITNESS: That's a 20 20 effort was made to conduct the assay in such a 21 non-answerable question. 21 way that would give rise to a high level of 22 MR. BEGLEITER: I'd like to show sensitivity. So if you look at the three 22 23 23 different dose levels that were studied in the you a document marked Bates numbers 24 549462 through 470. Have it marked 24 007 study, the highest dose level was 4.9 25 Exhibit 28. 25 logs, so this is well above even the 4.3 that Page 323 Page 325 1 1 was listed in the original label of the 2 (Exhibit Emini-28, 2/26/01 2 vaccine. The reason why it was done at 4.9 3 E-mail with attachment, 00549462 -3 logs was that the argument is made that we 4 00549470, was marked for identification.) know probably it's highly likely that this is 4 5 5 clearly an effective potency level for the BY MR. BEGLEITER: 6 6 vaccine. Simply because going back to the 7 7 original studies that were done, the original Q. I'm going to focus on a 8 paragraph on page 471, the bolded paragraph 8 control studies done way back in 1960s with 9 towards the top. 9 the mumps vaccine, it was done at a potency 10 10 level, presumably at approximately 20,000, A. Okay. because that's what came in the label. So 4.9 11 Q. Is this a document that you 11 received in the usual course of your 12 12 is above the 4.3, more than a half log above, 13 employment at Merck? 13 more than a half log above. 14 A. Yes, it is. 14 So, therefore, the argument is 15 Q. Let me read the first sentence. 15 we would like to have an assay that measures 16 "In talking with Emilio, the neutralization 16 seroconversion at the 90 percent level for at 17 assay is very artificial because of the IgG 17 least that 4.9 log level that's being tested, 18 added; to avoid too many seropositives, very 18 right, because then we can benchmark what we 19 high initial dilutions were required." Do you 19 see at 4 and what we see at 3.7 using a very 20 think you're the Emilio referred to in this 20 sensitive assay. So the assay needed to be 21 sentence? 21 designed to have a sensitivity of 90 percent. 22 Since I was the only one with 22 Now, is what is being measured, 23 23 that name at the company at the time, I that immunological response that is being 24 24 measured, is that the actual immunological believe so, yes. 25 25 So this is a document written by basis for the vaccine's efficacy? That is not

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Page 328 known. Even to this day it is not known. But 1 Q. Okay. And the way of making it 2 it is considered to be a surrogate measure of 2 sensitive and the way of getting the results 3 the immunological response to the vaccine and 3 that CBER was looking for was to add the 4 therefore, a surrogate of effectiveness. But 4 anti-IgG and use the wild type Jeryl Lynn? 5 remember it's a surrogate. True effectiveness 5 MS. DYKSTRA: Objection. Form. THE WITNESS: With their can only be established out in the field. So, 6 therefore, what was done under these 7 concurrence because they wanted an 8 circumstances, the assays by definition is 8 assay that was sufficiently sensitive 9 9 to distinguish among the three artificial. So what was the first thing that 10 10 different potency levels being tested 11 was done? The first thing that was done was in 007. 11 BY MR. BEGLEITER: 12 to find a wild type strain that gave the 12 original assay a level that began to approach 13 Q. I'm going to show you three 14 90 percent. Hence the moving from the 14 documents, and the only purpose is for 15 London-1 strain to the low passage Jeryl Lynn 15 authentication. Identify whether you received 16 strain. So that was a change. It's designed 16 these documents in the usual course of your 17 to change the assay to reflect a certain 17 employment. I'm not going to ask you biological response that you want to measure 18 substantive questions. at a given level. The addition of the 19 A. Yes. 20 20 anti-IgG falls along the similar lines which 21 is an additional step that one put in to 21 (Exhibit Emini-29, E-mail 22 enhance the likelihood that you would see that 22 exchange, 00549497 & 00549498, was 23 virus neutralizing antibody responses. 23 marked for identification.) 24 So in the same sense that 24 25 switching to the low passage Jeryl Lynn strain 25 MS. DYKSTRA: Do you want to Page 327 Page 329 is artificial because it is a function of the 1 give me all three, maybe I can 2 assay, the same thing is true for the addition 2 stipulate to the authenticity? 3 of the anti-IgG. 3 MR. BEGLEITER: Well, if you 4 So it's a way of -- so it's 4 give them back to me, I'm not going to 5 another way of getting results that agree with 5 use it. I thought this was a document 6 what's going on in the field. Is that what 6 that had your name on it. I apologize. 7 7 If you could give it back to me, I'd you're saying? 8 A. It is another way of getting 8 appreciate it. 9 THE WITNESS: This one? results using, at a level of sensitivity that would allow you to distinguish any differences 10 MR. BEGLEITER: Yeah. Oh, I in the ability of the vaccine at the three 11 11 see. I see. 12 tested dose levels in 007 to elicit an 12 I'm sorry, we are going to use 13 immunological response as measured by the 13 it. We are going to use it, I'm sorry. 14 assay. 14 It's getting late in the afternoon. We 15 15 are going to use it. So this was all the -- the two Q. things you're talking about, the wild type, 16 BY MR. BEGLEITER: Jeryl Lynn being used over, let's say, the 17 Q. So I'd like you to take a look 17 18 London-1 and using antihuman IgG --18 at this, sir. Your name is not on it, but the 19 A. Right. 19 very first sentence -- this is, by the way, 20 Q. -- after the initial testing did 20 document 549497 through 498. The first line 21 not meet what CBER was looking for? 21 reads: I have given Emilio...60 cases -- 60 22 MS. DYKSTRA: Objection. 22 case numbers to re-test (the 42 failures plus 23 THE WITNESS: In terms of 23 17 marginal positives). 24 24 MS. DYKSTRA: Can we have a sensitivity. BY MR. BEGLEITER: 25 copy?

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	Page 330		Page 332
1	BY MR. BEGLEITER:	1	submissions?
2	Q. "I believe he will try to	2	A. To the best of my recollection,
3	re-test them with both ELISA (wild-type mumps)	3	the auditing responsibility is either with
4	and the wild-type neutral." [As read].	4	regulatory or a quality assurance group within
5	Are you the Emilio referred to	5	regulatory.
6	here?	6	Q. And what does auditing require?
7	A. I believe I am, yes.	7	A. Auditing typically requires
8	Q. Okay. Put it away.	8	any auditing typically requires that if you're
9	I'm going to give the court	9	reporting on numbers or statements of fact,
10	reporter Merck 68264 through 68271, ask her to	10	that there are data, that there are actual
11	mark it, please. 30.	11	original data sources that you can trace to.
12		12	Q. Who is actually did you audit
13	(Exhibit Emini-30, 11/10/00	13	submissions that Merck made to CBER about
14	E-mail with attachment, 00068264 -	14	Protocol 007?
15	00068271, was marked for identification.)	15	A. Did I audit?
16		16	Q. Yes.
17	BY MR. BEGLEITER:	17	A. No, I would not audit it. No,
18	Q. Sir, I'm just going to ask you	18	auditing is a very formal function.
19	on this document whether you received this in	19	Q. Did you ensure that quality
20	the usual course of your employment?	20	assurance audited Merck's submissions
21	A. Yes, I did.	21	regarding
22 23	Q. Put it away.	22 23	A. I don't recollect sorry. I
23	MR. BEGLEITER: If you guys give me five minutes, one last look and see	24	don't recollect if I specifically requested
25	if there's any more questions. Take a	25	auditing for on quality assurance for CBER submission, but that normally would have been
23		23	•
	Page 331		Page 333
1	short break.	1	done by the regulatory group.
2	VIDEOGRAPHER: The time is 5:46.	2	Q. Okay. So it was their prime
3	Going off the record.	3	responsibility, the regulatory group, not
4	(A recoss was taken)	5	yours?
5	(A recess was taken.)	6	A. CBER submission is a regulatory
6 7	VIDEOGRAPHER: The time is now	7	document and, therefore, it is the responsibility of the regulatory group.
8	5:50. We're back on the video record.	8	Q. Do you know if CBER was ever
9	BY MR. BEGLEITER:	9	sent audit results?
10	Q. Sir, isn't it true that every	10	MS. DYKSTRA: Objection.
11	submission that Merck sends to CBER must be		THE WITNESS: I would not know
12	audited	12	that.
13	MS. DYKSTRA: Objection.	13	BY MR. BEGLEITER:
	MD. DIROIM. OURCHOIL	14	Q. Talking about with regard to
14	BY MR. BEGLEITER:		
14 15	BY MR. BEGLEITER: Q as far as you know?	15	Protocol 007.
14 15 16	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's	15 16	Protocol 007. A. I am not aware.
14 15 16 17	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course.	15 16 17	Protocol 007. A. I am not aware. Q. What state do you reside in?
14 15 16 17 18	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER	15 16 17 18	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania.
14 15 16 17 18 19	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER submissions?	15 16 17 18 19	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania. Q. Do you plan on moving?
14 15 16 17 18	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER submissions? MS. DYKSTRA: One second. I	15 16 17 18	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania. Q. Do you plan on moving? A. Not by tomorrow I'm not, no. I
14 15 16 17 18 19 20 21	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER submissions? MS. DYKSTRA: One second. I don't think the Doctor has his	15 16 17 18 19 20	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania. Q. Do you plan on moving? A. Not by tomorrow I'm not, no. I mean, it's an open question. Do I ultimately
14 15 16 17 18 19 20	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER submissions? MS. DYKSTRA: One second. I	15 16 17 18 19 20 21	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania. Q. Do you plan on moving? A. Not by tomorrow I'm not, no. I mean, it's an open question. Do I ultimately plan on moving? I don't know.
14 15 16 17 18 19 20 21 22	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER submissions? MS. DYKSTRA: One second. I don't think the Doctor has his microphone on.	15 16 17 18 19 20 21 22	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania. Q. Do you plan on moving? A. Not by tomorrow I'm not, no. I mean, it's an open question. Do I ultimately plan on moving? I don't know. Q. I'm someone who doesn't like to
14 15 16 17 18 19 20 21 22 23	BY MR. BEGLEITER: Q as far as you know? A. As far as I know. That's standard practice, yes, of course. Q. Who is supposed to audit CBER submissions? MS. DYKSTRA: One second. I don't think the Doctor has his microphone on. BY MR. BEGLEITER:	15 16 17 18 19 20 21 22 23	Protocol 007. A. I am not aware. Q. What state do you reside in? A. The State of Pennsylvania. Q. Do you plan on moving? A. Not by tomorrow I'm not, no. I mean, it's an open question. Do I ultimately plan on moving? I don't know.

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1			
1 1	Page 334		Page 336
1	that to you if you need it.	1	different series that were tested. And for
2	MR. BEGLEITER: You'll agree to	2	the London-1 strain was approximately
3	provide it to me if I need it?	3	69 percent when averaged across the two serum
4	MS. DYKSTRA: If you need it.	4	series that were tested.
5	MR. BEGLEITER: Thank you. I	5	Q. What did Merck's practice, in
6	have no further questions.	6	your experience, in connection with the
7	Your witness.	7	development of 007 for Merck to be candid and
8	MS. DYKSTRA: Thank you.	8	transparent as it is here with the agency?
9		9	A. It was in my experience that
10	EXAMINATION	10	they were candid and transparent consistently
11		11	with the agency throughout all of the
12	BY MS. DYKSTRA:	12	discussions that we've been referencing today.
13	Q. Dr. Emini, I just have a couple	13	Q. You can put that document aside.
14	of clarifying questions based on your	14	I'm going to ask you to pull
15	testimony today.	15	back Exhibit 6. It was already marked
16	I'm going to mark as Emini-31, I	16	Exhibit 6. Focus your attention on page 1,
17	believe.	17	which is Bates label on the bottom is
18	A. 31.	18	17043. Again, this is a March 12, 2001,
19	 (Elikit Eini 21 12/1/00	19	letter from Merck to CBER. Correct?
20	(Exhibit Emini-31, 12/1/99	20	A. This is correct, yes.
21	Letter with attachment, 01201 - 01209,	21	Q. I just want to confirm, you had
22 23	was marked for identification.)	22 23	received questions during your questioning
23	BY MS. DYKSTRA:	24	around the company's use of passage 8 of the
25		25	Jeryl Lynn strain. Do you recall that?
23	Q. Dr. Emini, do you recall this	23	A. I don't have a specific
	Page 335		Page 337
1	is a December 1, 1999, letter that Merck	1	recollection of the discussion.
2	submitted to CBER. Correct?	2	Q. Do you recall the discussions
3	A. Yes. Yes, it is.	3	with Mr. Begleiter?
4	Q. Do you recall Mr. Begleiter asked you whether or not Merck disclosed to	4 5	A. Yes, I do, certainly.
- 5	asked you whether of not wierck disclosed to	,	
5		_	Q. Do you recall he asked you about
6	CBER the various seroconversion rates that	6	the use of the anti-IgG?
6 7	CBER the various seroconversion rates that Merck had obtained using different strains	6 7	the use of the anti-IgG? A. Yes, I do.
6 7 8	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus?	6 7 8	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your
6 7 8 9	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do.	6 7 8 9	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER
6 7 8 9 10	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of	6 7 8 9 10	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you
6 7 8 9 10 11	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is	6 7 8 9 10	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this
6 7 8 9 10 11 12	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says,	6 7 8 9 10 11 12	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck
6 7 8 9 10 11 12 13	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart?	6 7 8 9 10 11 12 13	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER
6 7 8 9 10 11 12 13 14	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to	6 7 8 9 10 11 12 13 14	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that
6 7 8 9 10 11 12 13 14 15	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who	6 7 8 9 10 11 12 13 14 15	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn
6 7 8 9 10 11 12 13 14 15 16	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay,	6 7 8 9 10 11 12 13 14 15 16	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007.
6 7 8 9 10 11 12 13 14 15 16 17	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl	6 7 8 9 10 11 12 13 14 15 16 17	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states
6 7 8 9 10 11 12 13 14 15 16 17 18	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain	6 7 8 9 10 11 12 13 14 15 16 17	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed
6 7 8 9 10 11 12 13 14 15 16 17 18 19	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain presumably and the London-1 strain as the	6 7 8 9 10 11 12 13 14 15 16 17 18	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed plaque-reduction neutralization assay,"
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain presumably and the London-1 strain as the target strains in the assay. And initial	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed plaque-reduction neutralization assay," although you've been referring to it as the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain presumably and the London-1 strain as the target strains in the assay. And initial results of the experiments as stated and as	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed plaque-reduction neutralization assay," although you've been referring to it as the PRN assay, "using a wild-type mumps strains
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain presumably and the London-1 strain as the target strains in the assay. And initial results of the experiments as stated and as shown on Table 2 suggested that the measured	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed plaque-reduction neutralization assay," although you've been referring to it as the PRN assay, "using a wild-type mumps strains has been optimized for use in the evaluation
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain presumably and the London-1 strain as the target strains in the assay. And initial results of the experiments as stated and as shown on Table 2 suggested that the measured seroconversion rate using the Jeryl Lynn	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed plaque-reduction neutralization assay," although you've been referring to it as the PRN assay, "using a wild-type mumps strains has been optimized for use in the evaluation of sera from the Mumps Expiry Trial," this
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	CBER the various seroconversion rates that Merck had obtained using different strains including the Lo1 strain of the virus? A. Yes, I do. Q. And if you look at page 2 of this document, can you explain to me what is referenced in the first paragraph that says, "Merck's experience" and Table 2, the chart? A. So the first paragraph refers to a pilot study that was sera from children who had been vaccinated with MMR II and assay, with assays that were either using the Jeryl Lynn strain, the low passage Jeryl Lynn strain presumably and the London-1 strain as the target strains in the assay. And initial results of the experiments as stated and as shown on Table 2 suggested that the measured	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the use of the anti-IgG? A. Yes, I do. Q. I just want to focus your attention on the first paragraph of the CBER submission. Let me know if this either you can read this to us or tell us whether this refreshes your recollection that Merck confirmed with CBER, number one, that CBER suggested the use of the anti-IgG, and that CBER agreed to use passage 8 of the Jeryl Lynn strain in 007. A. The first paragraph states clearly that "The newly developed plaque-reduction neutralization assay," although you've been referring to it as the PRN assay, "using a wild-type mumps strains has been optimized for use in the evaluation

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	Page 338		Page 340
1	we discussed previously.	1	Bennett and the second e-mail on the page is
2	Assay description and the	2	from Keith Chirgwin. Do you have that in
3	standard operating protocol procedure was	3	front of you?
4	submitted to CBER as background for the	4	A. This one?
5	November 29, 2000, conference. And as	5	Q. Emini-11.
6	suggested by CBER during the meeting held on	6	A. 11.
7	March 13th, the assay sensitivity for	7	Q. Might be
8	measurement of virus neutralizing antibody has	8	A. No, no. It's just getting a
9	been optimized by addition of the antihuman	9	little confused here. My apologies. Yes, 11.
10	IgG. It notes that the assay relies upon	10	Q. So you do you recall
11	immunostaining to reveal plaques since the	11	separate and apart from looking at the words
12	virus used in the assay is not ostensibly	12	on this document, do you recall discussions
13	cytopathic. And, therefore, also it's agreed	13	with Phil Bennett around his stability or any
14	with CBER during the March 13, 2000, meeting	14	stability modeling he may have done?
15	we have chosen the lowest available passage,	15	A. I do not have a specific
16	that would be passage 8.	16	recollection of discussions with Phil Bennett.
17	MR. BEGLEITER: You're reading	17	Q. In the context of determining
18	very quickly.	18	whether shelf life of the vaccine should be,
19	THE WITNESS: It's verbatim	19	how does the company determine that and wha
20	my apologies. I can read it again more	20	would they rely on at this point in time
21	slowly.	21	let me strike that.
22	So as I said, "As agreed with	22	You recall you had discussions
23	CBER," again, "during the	23	with Mr. Begleiter around CBER's
24	March 13, 2000, meeting, we have chosen	24	recommendation and approval to raise the
25	the lowest available passage	25	minimum release potency of the vaccine to 5.0
	Page 339		Page 341
1	(passage 8) of the Jeryl Lynn strain of	1	log10 TCID50. Correct?
2	mumps as being appropriately	2	A. Yes, I do.
3	representative of a wild-type mumps	3	Q. In connection with that increase
4	virus strain."	4	in potency, what would the company do to
5	BY MS. DYKSTRA:	5	determine the appropriate shelf life of the
6	Q. This paragraph in the submission	6	product?
7	to CBER is consistent with your recollection	7	A. Well, what would normally be
8	that CBER first suggested the use of antihuman	8 9	done in the context of an appropriate shelf
9	IgG and that they agreed that passage 8 of the		life is that one would conduct formal
10	Jeryl Lynn strain was appropriate for this	10	stability studies which is, I believe, what I
11	assay?	11 12	
12	A. It agrees with my recollection		would entail actual measurement of virus potency at different time points in realtime
13	of CBER's recommendation to use the antihuman	13	with in this case vaccine that had been stored
14	IgG to increase the sensitivity of the assay, again, for the reasons we discussed	15	at the accepted storage temperature of the
15	_	16	vaccine, which is 28 degrees Celsius.
16	previously. And with regarding I did not have a specific recollection of why the Jeryl	17	
17 18		18	Q. So is that similar to saying that the company would it would be
19	Lynn strain was chosen, but that was,	19	preferable or more reliable for the company to
20	recollection occurred, if you will, as a	20	rely on actual stability potency assay results
20	result of looking at documents over the past several days.	20	over time versus a stability model in
141		22	determining appropriate shelf life?
	() Thank you I'm going to also go		OCICIONIUS ADDIODUAIS SUST IIIS!
22	Q. Thank you. I'm going to also go		- 11 1
22 23	back and ask you to look at what was marked	23	MR. BEGLEITER: Object to the
22			- 11 1

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1 .	Page 342		Page 344
1	and the agency, yes.	1	departing just for this, it's the AEO
2	BY MS. DYKSTRA:	2	document? Thank you.
3	Q. Thank you. I wanted to just	3	BY MS. DYKSTRA:
4	clarify something that you had a question	4	Q. You said you thought they were
5	during your examination around whether or not	5	in quality assurance. Is that correct?
6	you recall where the ELISA assay was	6	A. I believe. I don't have an
7	conducted. Dr. Krah ran the PRN assay in your	7	exact recollection.
8	building. Correct?	8	Q. Can you just describe to me the
9	A. Yes, in his laboratory in my	9	type of memos these are and whether or not
10	building, in the building in which I had my	10	these are routine memos and the purpose of
11	office, yes.	11	this type of documentation of an FDA
12	Q. Do you recall that Merck also	12	inspection?
13	had a Wayne facility?	13	MR. BEGLEITER: Objection to the
14	A. Yes, I do.	14	form.
15	Q. Does that refresh your	15	THE WITNESS: So these are
16	recollection where the ELISA assay may have	16	routine memos that are that refer,
17	been conducted?	17	that provide information and also to
18	A. Again, based on documents that I	18	the file of what transpired in
19	was shown, yes, the Wayne facility by this	19	discussions that occurred during an FDA
20	time had been put into place and ELISA assay	20	inspection.
21	was performed there. The Wayne facility had	21	BY MS. DYKSTRA:
22	been put into place specifically to be a	22	Q. And are they what is the
23	physically separate facility for the conduct	23	purpose of them, of these memos?
24	of clinical assays, or assays in support of	24	A. The purpose of these memos is to
25	clinical studies.	25	provide a record of the nature of the
	D 242		•
1	Page 343 Q. If you could also pull back	1	Page 345 discussions, to provide a record of specific
2	Emini Exhibit 7.	2	documents that were provided to the agency or
3	A. Exhibit 7.		
		3	to the inspector at the inspector's request,
4	Q. It's an August 7, 2001, e-mail	3 4	to the inspector at the inspector's request, and to inform management of the relevant
4 5	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and	3 4 5	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired.
4 5 6	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen	3 4 5 6	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it
4 5 6 7	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth.	3 4 5 6 7	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of
4 5 6 7 8	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes.	3 4 5 6 7 8	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct?
4 5 6 7 8 9	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention	3 4 5 6 7 8 9	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes.
4 5 6 7 8 9 10	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo	3 4 5 6 7 8 9 10	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility
4 5 6 7 8 9 10 11	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA"	3 4 5 6 7 8 9 10 11	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to
4 5 6 7 8 9 10 11 12	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps	3 4 5 6 7 8 9 10 11 12	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the
4 5 6 7 8 9 10 11 12 13	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay."	3 4 5 6 7 8 9 10 11 12 13	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA?
4 5 6 7 8 9 10 11 12 13 14	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to
4 5 6 7 8 9 10 11 12 13 14 15	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who	3 4 5 6 7 8 9 10 11 12 13 14 15	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form.
4 5 6 7 8 9 10 11 12 13 14 15 16	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney,	3 4 5 6 7 8 9 10 11 12 13 14 15 16	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the
4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney, Pardue and Wadsworth, what department they're	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the responsibility of whomever was asked.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney, Pardue and Wadsworth, what department they're in? A. I recall Cathy Wadsworth, I believe that they were either in quality	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the responsibility of whomever was asked. What this memo indicates is that these copies were provided, whether they came directly from QA or they came from
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney, Pardue and Wadsworth, what department they're in? A. I recall Cathy Wadsworth, I believe that they were either in quality assurance or somehow involved with regulatory,	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the responsibility of whomever was asked. What this memo indicates is that these copies were provided, whether they came directly from QA or they came from someone else. But what the memo notes
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney, Pardue and Wadsworth, what department they're in? A. I recall Cathy Wadsworth, I believe that they were either in quality assurance or somehow involved with regulatory, but I'm not completely certain.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the responsibility of whomever was asked. What this memo indicates is that these copies were provided, whether they came directly from QA or they came from someone else. But what the memo notes is that all of these copies of these
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney, Pardue and Wadsworth, what department they're in? A. I recall Cathy Wadsworth, I believe that they were either in quality assurance or somehow involved with regulatory, but I'm not completely certain. MS. DYKSTRA: Can I pause just	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the responsibility of whomever was asked. What this memo indicates is that these copies were provided, whether they came directly from QA or they came from someone else. But what the memo notes is that all of these copies of these documents were provided to the
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. It's an August 7, 2001, e-mail from Karen McKenney which attaches the 483 and a memo dated August 6, 2001, from Karen McKenney, Kelly Pardue and Cathy Wadsworth. A. Yes. Q. I want to focus your attention on the second two pages which are the memo dated August 6, 2000, with the relined "FDA Inspection of Virus and Cell Biology for Mumps End Expiry Plaque Neutralization Assay." A. Yes. Q. Can you tell me, do you know who the people on the "from" line are, McKenney, Pardue and Wadsworth, what department they're in? A. I recall Cathy Wadsworth, I believe that they were either in quality assurance or somehow involved with regulatory, but I'm not completely certain.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to the inspector at the inspector's request, and to inform management of the relevant personnel of the nature of what transpired. Q. On the last page of the memo, it says, "COPIES PROVIDED," and a list of documents. Is that correct? A. Yes. Q. Would it be the responsibility of the people in QA who prepare this memo to include everything that was provided to the FDA? MR. BEGLEITER: Objection to form. THE WITNESS: It would be the responsibility of whomever was asked. What this memo indicates is that these copies were provided, whether they came directly from QA or they came from someone else. But what the memo notes is that all of these copies of these

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1	Page 346	1	Page 348
1	Q. Just a couple of more documents	1	concern is that there may be an issue of data
2	we'll look at briefly. If you can look at	$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	integrity or not, so we conducted the set of audits to show that that was not the case.
3 4	Emini what was marked Emini Exhibit 8,	4	
5	please. A. Yes.	5	But on top of that, and this is routinely done as well, which is to say let us make the
6	Q. That is an August 20, 2001,	6	assumption that the corrections, that refers
7	letter from you to CBER in response or	7	to those corrections that were made without
8	following the August 6th inspection. Correct?	8	justification, should not have been made. And
9	A. Correct.	9	what if one analyzes the data using the
10	Q. In this letter you have provided	10	original uncorrected data. And what does one
11	answers, and I want to focus your attention on	11	get. Does one actually see a substantial
12	page 1 of 3 under Observation number 1 which		difference either one way or the other. And
13	is document Bates-labeled 482.	13	what one is looking for, in fact, is a
14	A. I'm sorry, the page notation,	14	difference that might in some way favor the
15	yes. Thank you.	15	outcome of the study obviously. So that's
16	Q. And I want to focus your	16	what one looks for. But as we're seeing here,
17	MR. BEGLEITER: What page are	17	is that the overall seroconversion rates, in
18	you on?	18	fact, ostensibly didn't change. Overall
19	MS. DYKSTRA: I'm sorry. The	19	seroconversion rate on the analysis turned out
20	document labeled 482 at the bottom.	20	to be the original analysis with the
21	THE WITNESS: 482 at the bottom.	21	uncorrected data excuse me, with the
22	BY MS. DYKSTRA:	22	corrected data, the original analysis resulted
23	Q. I want to focus your attention	23	in the 92 percent seroconversion rate with a
24	on one, two, the third paragraph which begins,	24	95 percent confidence interval as noted
25	"We take seriously the issue of data integrity."	25	between 89.6 percent and 94.3 percent. By
	Page 347		B 040
			Page 349
1	A. Yes.	1	reanalysis where one goes back to the original
2	A. Yes.Q. You recall Mr. Begleiter asked	2	reanalysis where one goes back to the original numbers, the overall seroconversion rate was
2 3	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's	2 3	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of
2 3 4	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in	2 3 4	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that
2 3 4 5	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions?	2 3 4 5	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap
2 3 4 5 6	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do.	2 3 4 5 6	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals
2 3 4 5 6 7	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency	2 3 4 5 6 7	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and
2 3 4 5 6 7 8	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected	2 3 4 5 6 7 8	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't
2 3 4 5 6 7 8 9	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that?	2 3 4 5 6 7 8 9	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If
2 3 4 5 6 7 8 9	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that? A. Yes, I do.	2 3 4 5 6 7 8 9	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If anything, if one was looking to potentially
2 3 4 5 6 7 8 9 10 11	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that? A. Yes, I do. Q. Can you explain to me what this	2 3 4 5 6 7 8 9 10	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If anything, if one was looking to potentially raise the seroconversion level to a higher
2 3 4 5 6 7 8 9 10 11 12	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that? A. Yes, I do. Q. Can you explain to me what this paragraph means and how you interpret this or	2 3 4 5 6 7 8 9 10 11 12	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If anything, if one was looking to potentially raise the seroconversion level to a higher number, the effect of the corrections which
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that? A. Yes, I do. Q. Can you explain to me what this paragraph means and how you interpret this or what you recall of it? A. Well, the correction as referred to here would have been the correction that was noted by the inspector when the 483 was issued, the first observation of the inspector, that there were some data numbers that had been corrected but without there being a written justification for the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If anything, if one was looking to potentially raise the seroconversion level to a higher number, the effect of the corrections which were made which were not justified in the document actually lowered the seroconversion numbers. MS. DYKSTRA: I'm going to mark two more documents. I believe we're on Emini-32. (Exhibit Emini-32, 10/10/01
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that? A. Yes, I do. Q. Can you explain to me what this paragraph means and how you interpret this or what you recall of it? A. Well, the correction as referred to here would have been the correction that was noted by the inspector when the 483 was issued, the first observation of the inspector, that there were some data numbers that had been corrected but without there being a written justification for the correction. So that obviously opens the question as to why this was done and why was the correction made.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If anything, if one was looking to potentially raise the seroconversion level to a higher number, the effect of the corrections which were made which were not justified in the document actually lowered the seroconversion numbers. MS. DYKSTRA: I'm going to mark two more documents. I believe we're on Emini-32. (Exhibit Emini-32, 10/10/01 Letter, 01631027, was marked for identification.)
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. Yes. Q. You recall Mr. Begleiter asked you about Dr. Krah's and/or anyone else's counting or recounting of the assay plates in the PRN assay. Do you recall those questions? A. Yes, I do. Q. In this statement to the agency you relate an assessment of the uncorrected and corrected results. Do you see that? A. Yes, I do. Q. Can you explain to me what this paragraph means and how you interpret this or what you recall of it? A. Well, the correction as referred to here would have been the correction that was noted by the inspector when the 483 was issued, the first observation of the inspector, that there were some data numbers that had been corrected but without there being a written justification for the correction. So that obviously opens the question as to why this was done and why was the correction made. So part of the answer here, of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	reanalysis where one goes back to the original numbers, the overall seroconversion rate was 92.6 percent with a confidence interval of 90.2 percent to 95.1 percent. So what that indicates, given the significant overlap between among the two confidence intervals is that whatever changes were made and whatever the basis was, because it wasn't noted, did not change the results. If anything, if one was looking to potentially raise the seroconversion level to a higher number, the effect of the corrections which were made which were not justified in the document actually lowered the seroconversion numbers. MS. DYKSTRA: I'm going to mark two more documents. I believe we're on Emini-32. (Exhibit Emini-32, 10/10/01 Letter, 01631027, was marked for identification.) BY MS. DYKSTRA:
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Page 352 what's been marked as Emini-32, which is an 1 study? 2 October 10, 2001, letter from Manal Morsy to 2 A. Known negative samples and known Cathy Carbone at CBER, Bates-labeled 1631027. 3 3 positive samples, yes. I want to ask you whether or not, number one, 4 And known negative and known 4 Q. 5 5 positive mean what? this refreshes your recollection with respect to your questioning today around Dr. Ward at 6 A. These are samples where you know 7 all and/or -- just ask that. 7 that the known negatives do not contain the 8 Does this refresh your 8 antibody that you're measuring. They're known 9 recollection, this document with respect to 9 to that because you've assayed them many times what Dr. Ward's lab -- what role Dr. Ward's 10 10 in different tests. The known positive lab had in connection with 007? 11 11 samples are samples from individuals who have 12 A. According to this memo, the only 12 a range of antibody responses to what you're 13 immediate connection was that, as Dr. Shaw 13 measuring, which in this case is the mumps 14 explained in the reading now, the one, two, 14 virus. 15 three, four, fifth paragraph down, Dr. Shaw 15 Q. And known meaning based on other explained that the only positive and negative 16 assays, not Protocol 007? 17 17 controls sera samples were provided to A. Based on other assays. It is Dr. Ward. So these would typically be the 18 known that they should register as positive. samples that would be provided to do an 19 The objective of the doing the study is to see 20 20 what number came out and to correlate that initial assessment of the quality of the data 21 from the laboratory to determine whether or 21 number with the numbers obtained between the 22 not the results that Dr. Ward would obtain 22 two laboratories of Dr. Ward's and the 23 would be similar to the results that were 23 company. 24 obtained in the Merck laboratory. And as he 24 Q. I'm going to show you one last 25 25 notes, the results for the control samples, document which I've marked as Emini-33. Page 351 Page 353 which is what those were, are consistent with 1 2 the Merck results. Dr. Shaw explained that 2 (Exhibit Emini-33, 4/8/01 3 all the raw data from Mr. Ward's laboratory 3 Letter, 0000328 - 0000331, was marked 4 had been provided to Ms. Debra Bennett from 4 for identification.) 5 the agency during her last visit to the 5 6 research laboratories, and the specific data 6 BY MS. DYKSTRA: 7 7 were given the geometric mean titers for the Q. It's a little bit lengthy, two sera representing high and low value are 8 April 8, 2001, it looks like a letter to you 9 9 contained in the validation report which was signed by on page 4 Stephen Krahling, 10 also previously supplied to CBER. 10 Bates-labeled RELATOR_000033 looks like 8 --11 We believe this was probably, I 11 328, 329, 330, 331. Can you take a look at 12 believe, I believe that this was probably in this and let me know what you recall, if 12 13 response to a question from the agency as to 13 anything about this document or generally 14 whether or not there were potential or 14 about Mr. Krahling's complaints to you 15 15 significant differences between the values regarding HR issues in Dr. Krah's lab? that would have been generated in Dr. Ward's 16 So this is the document that I 17 17 laboratory as opposed to the Merck laboratory, reviewed prior to today and that I believe 18 Dr. Krah's laboratory and the results of the 18 referred to in my previous testimony that had 19 data that were presented or submitted to the 19 been shown to me and by which I recall that I 20 agency is that that was not the case. 20 did, in fact, receive this document from 21 21 The serum samples -- the sera Mr. Krahling in which Mr. Krahling documented 22 samples that were provided to Dr. Ward's lab 22 rather extensively his perspective that the, 23 were not the 007 clinical sera samples, but 23 call it, the HR environment within Dr. Krah's 24 control samples used to, I guess, validate the 24 laboratory was, in fact, in his opinion lab prior to actually running the clinical 25 problematic.

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	Page 354		Page 356
1	Q. And I see in the second	1	complaint at the end of July, that you would
2	paragraph he comments around highly personal	2	have contacted counsel?
3	relationships with female employees and	3	MR. BEGLEITER: Objection to the
4	personal gifts. Do you see that?	4	form.
5	A. Yes, I do.	5	THE WITNESS: As evidenced by my
6	Q. And in the third paragraph he	6	action that I took in contacting
7	raises issues around work schedules. Do you	7	counsel after the meeting that I had
8	see that?	8	with Mr. Krahling in which he showed me
9	A. Yes.	9	his concerns over the data, the answer
10	Q. And in the last paragraph,	10	to your question would be yes.
11	again, no vacation mandates and schedules?	11	BY MS. DYKSTRA:
12	A. Yes.	12	
13		13	Q. But other than that meeting, you
	Q. And we can go forward in the	l	don't have any recollection of Mr. Krahling
14	other paragraphs, just confirm that they also	14	raising to you anything other than HR
15	raise other HR-type concerns?	15	concerns?
16	A. All are HR environmental issues	16	A. I do not.
17	yes.	17	MS. DYKSTRA: I have no further
18	Q. Do you recall strike that.	18	questions.
19	You noted that you had seen a	19	MR. BEGLEITER: Can you give me
20	document that reflected that you met at some	20	a few minutes?
21	point in time just prior to the agency's FDA	21	MS. DYKSTRA: Sure.
22	483 inspection in August 2001, that you had	22	VIDEOGRAPHER: The time is 6:16.
23	met with Mr. Krahling where he raised an	23	Going off the video record.
24	allegation of something different than HR,	24	
25	something of concern to him?	25	(A recess was taken.)
	Page 355		Page 357
1	Page 355 A. Yes.	1	Page 357
1 2		1 2	Page 357 VIDEOGRAPHER: The time is now
	A. Yes.		
2	A. Yes. Q. You don't remember specifically	2	VIDEOGRAPHER: The time is now
2 3	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a	2 3	VIDEOGRAPHER: The time is now
2 3 4	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting?	2 3 4	VIDEOGRAPHER: The time is now 6:37. This begins tape six.
2 3 4 5	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR.	2 3 4 5	VIDEOGRAPHER: The time is now 6:37. This begins tape six.
2 3 4 5 6	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting	2 3 4 5 6	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER:
2 3 4 5 6 7	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling,	2 3 4 5 6 7 8	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn
2 3 4 5 6 7 8	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting	2 3 4 5 6 7	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER:
2 3 4 5 6 7 8 9	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel.	2 3 4 5 6 7 8 9	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43.
2 3 4 5 6 7 8 9 10	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes.	2 3 4 5 6 7 8 9 10 11	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go
2 3 4 5 6 7 8 9 10 11 12	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct?	2 3 4 5 6 7 8 9 10 11 12	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that
2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from?
2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was	2 3 4 5 6 7 8 9 10 11 12 13 14	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted	2 3 4 5 6 7 8 9 10 11 12 13 14 15	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in any way?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION FURTHER EXAMINATION OCCUPIED BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been optimized by addition of anti-human IgG."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in any way? A. Not to my recollection.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been optimized by addition of anti-human IgG." A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in any way? A. Not to my recollection. Q. Had he raised the complaint	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been optimized by addition of anti-human IgG." A. Yes. Q. So my question is, do you know
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in any way? A. Not to my recollection. Q. Had he raised the complaint around misconduct in the lab at any point in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been optimized by addition of anti-human IgG." A. Yes. Q. So my question is, do you know independent of this paragraph who at CBER made
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in any way? A. Not to my recollection. Q. Had he raised the complaint around misconduct in the lab at any point in time, is it fair to say that you would have	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been optimized by addition of anti-human IgG." A. Yes. Q. So my question is, do you know independent of this paragraph who at CBER made that suggestion supposedly?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. You don't remember specifically that meeting, but you remember seeing a document that referenced that meeting? A. That was a note from Mr. Suter to me from HR. Q. When you had that meeting referenced in that document with Mr. Krahling, you stated that you immediately contacted counsel. A. Yes. Q. Correct? A. Yes. Q. Other than that meeting that was referenced in the document where you contacted counsel, did Mr. Krahling ever raise to you any concerns regarding any fraud or misconduct, I'm distinguishing that from HR complaints, about the running of protocol in any way? A. Not to my recollection. Q. Had he raised the complaint around misconduct in the lab at any point in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	VIDEOGRAPHER: The time is now 6:37. This begins tape six. FURTHER EXAMINATION BY MR. BEGLEITER: Q. Doctor, I'd like you to turn back to Exhibit 6, page 17043. A. 43. Q. Yes. Actually if you go 17043. Do you know who wrote paragraph A that you read from? A. Who physically wrote it? No, I do not. Q. It says here, "As suggested by CBER during the meeting held on March 13, 2000, the assay's sensitivity for measurement of virus-neutralizing antibody has been optimized by addition of anti-human IgG." A. Yes. Q. So my question is, do you know independent of this paragraph who at CBER made

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	Page 358		Page 360
1	Q. Do you know whether CBER agrees	1	withdrawn. Let me just go on to the next one.
2	with the sentence?	2	Let's go to Exhibit 32. Do you
3	MS. DYKSTRA: Objection.	3	have that in front of you?
4	THE WITNESS: Well, it was	4	A. Yes, I do. Yes.
5	CBER's suggestion and recommendation,	5	Q. Is there anything in this letter
6	and then discussions were held	6	which explains to you why Dr. Ward's lab was
7	continuously with CBER. So CBER was	7	not used for Protocol 007?
8	certainly aware that this was	8	A. No, that was not the intent of
9	happening, and if they had a	9	this letter.
10	suggestion, they would have entered it.	10	Q. How do you know what the intent
11	BY MR. BEGLEITER:	11	was?
12	Q. Doctor, my question is, did you	12	A. Well, because I am inferring
13	know if the person who wrote this got it	13	the intent of this letter because what is
14	right?	14	being reported here is that using the control
15	MS. DYKSTRA: Objection.	15	sera, the data from Dr. Ward's laboratory were
16	THE WITNESS: By definition I	16	identical and were comparable, I'm looking for
17	cannot know that.	17	the exact word that was used here, to the data
18	BY MR. BEGLEITER:	18	from the Merck laboratory are consistent with
19		19	the Merck results was the terminology that was
20	Q. Thank you.A. By definition.	20	
	•	21	used. So the intent here presumably was to
21	Q. Let's go to Exhibit 31. That's		show that the two assays, you know, could be
22	the document you used to discuss the London-lisolate?		consistent. This was not a validation study,
23		23	this was just simply a determination looking
24	A. Yes.	24	for consistency.
25	Q. Do you know at what potencies	25	Q. So this would be a reason to
	Page 359		Page 361
1	the London-1 isolate was tested at?	1	corroborate the use of Dr. Ward's lab,
2	MS. DYKSTRA: Objection.	2	wouldn't it?
3	THE WITNESS: Please define	3	MS. DYKSTRA: Objection.
4	"potency."	4	THE WITNESS: It would be a
5	BY MR. BEGLEITER:	5	reason for stating that if one wanted
6	Q. If you don't understand the word	6	to well, no, again, this was not a
7	potency, I'm just going to go on to the next	7	formal validation. That would depend
8	question. You don't know what the word	8	on the validation of the assay in
9	"potency" means?	9	Dr. Ward's laboratory, and it would
10	A. I don't know what the potency	10	depend on the actual validation of the
11	means in context of your question. You said	11	laboratory itself.
12	at what potencies was it tested, are you	12	BY MR. BEGLEITER:
13	referring to the potency	13	Q. There are reasons why it
14	Q. In other words I understand.	14	would why you could or you couldn't, but
15	The 007 data was testing at three potencies,	15	I'm saying this letter isn't a negative to
16	were they not?	16	using Dr. Ward's lab?
17	A. At three potency levels, yes.	17	A. No, it is not directly a
	In the context of 007 study, yes. No, I do	18	negative.
18	• • • • • • • • • • • • • • • • • • • •	19	Q. Directly a negative?
18 19	not so to answer your question		- · · · · · · · · · · · · · · · · · · ·
	not so to answer your question Q. You do not know?	20	A. Directly a negative.
19 20	Q. You do not know?	l	, &
19 20 21	Q. You do not know?A. I do not know because I do not	20 21	Q. What do you mean "directly a
19 20 21 22	Q. You do not know?	20 21 22	Q. What do you mean "directly a negative"?
19 20 21 22 23	Q. You do not know? A. I do not know because I do not know what the serum series specifically refer to.	20 21 22 23	Q. What do you mean "directly a negative"? A. I'm sorry, directly meaning it
19 20 21 22	Q. You do not know? A. I do not know because I do not know what the serum series specifically refer	20 21 22	Q. What do you mean "directly a negative"?

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1 Q. Let's go to Exhibit 8. With 2 regard to 007, sir, do you know do you have 3 a definition of pre-positive? 4 A. Sorry, are you reading in a 5 specific place? 6 Q. I'm not reading anything. 7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 10 Q. Yes. 11 A. So my definition of a 12 pre-positive. Isn't that right? 2 MS. DYKSTRA: Objection. 3 THE WITNESS: So the use of terminology pre-positive in that regard, that is referring to an individual who you believe not to be en vaccinated, no record of vaccination or no record of natural exposure to the virus and yet when assay is run, there was an indication of antibody, plaque reduction neutralizing antibody present. 13 someone who had not received the vaccine or 14 had not been exposed to the virus in the 14 pre-positive. Isn't that right? 2 MS. DYKSTRA: Objection. 3 THE WITNESS: So the use of terminology pre-positive in that regard, that is referring to an individual who you believe not to be en vaccinated, no record of vaccination or no record of natural exposure to the virus and yet when assay is run, there was an indication of antibody, plaque reduction neutralizing antibody present. BY MR. BEGLEITER: Q. Okay. And the pre-positives	of the have
2 regard to 007, sir, do you know do you have 3 a definition of pre-positive? 4 A. Sorry, are you reading in a 5 specific place? 6 Q. I'm not reading anything. 7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 10 Q. Yes. 11 A. So my definition of a 12 pre-positive would be a serum sample from 13 someone who had not received the vaccine or 14 MS. DYKSTRA: Objection. 3 THE WITNESS: So the use of terminology pre-positive in that regard, that is referring to an individual who you believe not to be en vaccinated, no record of vaccination or no record of natural exposure to the virus and yet when assay is run, there was an indication of antibody, plaque reduction neutralizing antibody present. 18 MS. DYKSTRA: Objection. THE WITNESS: So the use of terminology pre-positive in that regard, that is referring to an individual who you believe not to be vaccinated, no record of vaccination or no record of natural exposure to the virus and yet when assay is run, there was an indication of antibody, plaque reduction neutralizing antibody present. BY MR. BEGLEITER:	of the have
3 a definition of pre-positive? 4 A. Sorry, are you reading in a 5 specific place? 5 regard, that is referring to an 6 Q. I'm not reading anything. 7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 10 Q. Yes. 11 A. So my definition of a 12 pre-positive would be a serum sample from 13 someone who had not received the vaccine or 14 terminology pre-positive in that 5 regard, that is referring to an 6 individual who you believe not to be en vaccinated, no record of 7 vaccination or no record of natural 8 exposure to the virus and yet when 10 assay is run, there was an indication 11 of antibody, plaque reduction 12 neutralizing antibody present. 13 BY MR. BEGLEITER:	of the have
4 A. Sorry, are you reading in a 5 specific place? 6 Q. I'm not reading anything. 7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 10 Q. Yes. 11 A. So my definition of a 12 pre-positive would be a serum sample from 13 someone who had not received the vaccine or 14 terminology pre-positive in that 15 regard, that is referring to an 16 individual who you believe not to be en vaccinated, no record of vaccination or no record of natural exposure to the virus and yet when 10 assay is run, there was an indication of antibody, plaque reduction 11 neutralizing antibody present. 12 BY MR. BEGLEITER:	have l n the
5 specific place? 6 Q. I'm not reading anything. 7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 10 Q. Yes. 11 A. So my definition of a 12 pre-positive would be a serum sample from 13 someone who had not received the vaccine or 15 regard, that is referring to an 16 individual who you believe not to a 17 been vaccinated, no record of a vaccination or no record of natural exposure to the virus and yet when assay is run, there was an indication of antibody, plaque reduction neutralizing antibody present. 16 Individual who you believe not to a regard, that is referring to an individual who you believe not to a regard, that is referring to an 17 been vaccinated, no record of a vaccination or no record of natural exposure to the virus and yet when a say is run, there was an indication of antibody, plaque reduction neutralizing antibody present. 18 Sy MR. BEGLEITER:	l n the
6 Q. I'm not reading anything. 7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 10 Q. Yes. 11 A. So my definition of a 12 pre-positive would be a serum sample from 13 someone who had not received the vaccine or 14 individual who you believe not to be en vaccinated, no record of a vaccination or no record of natural exposure to the virus and yet when assay is run, there was an indication of antibody, plaque reduction neutralizing antibody present. 15 BY MR. BEGLEITER:	l n the
7 A. Just a question, sorry. You 8 said Exhibit 8, my apologies. A definition of 9 a pre-positive? 9 exposure to the virus and yet when 10 Q. Yes. 10 assay is run, there was an indication of 11 pre-positive would be a serum sample from 12 pre-positive would be a serum sample from 13 someone who had not received the vaccine or 14 been vaccinated, no record of 8 vaccination or no record of 9 exposure to the virus and yet when 10 assay is run, there was an indication of antibody, plaque reduction 11 neutralizing antibody present. 12 BY MR. BEGLEITER:	l n the
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9 a pre-positive? 9 exposure to the virus and yet when 10 Q. Yes. 10 assay is run, there was an indication of a 11 of antibody, plaque reduction 12 pre-positive would be a serum sample from 12 neutralizing antibody present. 13 someone who had not received the vaccine or 13 BY MR. BEGLEITER:	n the
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13 someone who had not received the vaccine or 13 BY MR. BEGLEITER:	
14 had not been exposed to the views in the 14 O Okey And the pre-negitives	
	are
15 course of natural infection. 15 usually excluded from the testing. Isn'	t that
16 Q. Does pre-positive imply that 16 right?	
17 there is some, for example, some plaques in a 17 MS. DYKSTRA: Objection.	
18 cell plate that just a small number of plaques 18 THE WITNESS: It would dep	pend or
19 before withdrawn. 19 the level of the pre-positivity. If	
Does it imply that there are 20 you had such a pre-positive, you w	vould
21 some plaques in a cell plate before the 21 not be able, using the assay, to	
22 subject has before mumps has been 22 discern whether or not the individu	ual
23 introduced into the plate? 23 seroconverted subsequent to	
A. The plaques in a cell plate are 24 immunization because there was a	lready
25 a function of the indicator virus that one 25 antibody apparently present prior t	to
Page 363	
	Page 36
1 places in the cell plate. It does not refer 1 immunization.	Page 36
	Page 36
2 to the pre-positive sample, per se. 2 BY MR. BEGLEITER:	Page 36
2 to the pre-positive sample, per se. 2 BY MR. BEGLEITER: 3 Q. So pre-positive would be a 3 Q. Let's go back to Exhibit 8.	
2 to the pre-positive sample, per se. 3 Q. So pre-positive would be a 4 sample in which the child in this case would 4 I'll ask you whether or not there was an	ny
2 to the pre-positive sample, per se. 3 Q. So pre-positive would be a 4 sample in which the child in this case would 5 not have did not have mumps? 2 BY MR. BEGLEITER: 3 Q. Let's go back to Exhibit 8. 4 I'll ask you whether or not there was ar indication here that pre-positives were	ny
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92 (Pages 362 - 365)

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	Page 366		Page 368
1	corrected and what the nature of that	1	A. That would be the manufacturing
2	correction was and what that entailed,	2	division and the marketing division, not us.
3	so I can't answer the question. I	3	MR. BEGLEITER: Thank you.
4	don't know.	4	Thank you, Doctor.
5	BY MR. BEGLEITER:	5	MS. DYKSTRA: Thank you.
6	Q. Did you tell CBER of the impact	6	VIDEOGRAPHER: The time is 6:48.
7	on pre-positives?	7	This concludes the deposition of Emilio
8	MS. DYKSTRA: Objection. Form.	8	Emini.
9	THE WITNESS: I was not directly	9	
10	involved with any discussions with CBER	10	(Witness excused.)
11	around that question.	11	
12	BY MR. BEGLEITER:	12	(Deposition concluded at
13	Q. Who did this reanalysis that's	13	6:48 p.m.)
14	mentioned in this paragraph?	14	1 /
15	A. This reanalysis was performed by	15	
16	the statistical group, as it would have been	16	
17	performed.	17	
18	Q. So they didn't have the cell	18	
19	plates in front of them?	19	
20	MS. DYKSTRA: Objection.	20	
21	THE WITNESS: What they had in	21	
22		22	
23	front them were the two sets of data,	23	
	the original so-called uncorrected data		
24	and then the subsequent corrected data.	24	
25	BY MR. BEGLEITER:	25	
	Page 367		Page 369
1	Q. What this paragraph relies on is	1 2	CERTIFICATE
2	the integrity of that data?	3	
3	A. What this relies on are well,		I do hereby certify that I am a Notary
4	all analyses rely on the integrity of data by	4	Public in good standing, that the aforesaid
-	an analyses fely on the integrity of data by		
5	definition, yes.	5	testimony was taken before me, pursuant to notice, at the time and place indicated; that
6			testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the
	definition, yes.		testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the
6	definition, yes. Q. On Exhibit 8, again, did was		testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the
6 7	definition, yes. Q. On Exhibit 8, again, did was there ever a point at which undiluted IgG was added to the PRN test for Protocol 007?	6	testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my
6 7 8	definition, yes. Q. On Exhibit 8, again, did was there ever a point at which undiluted IgG was	6	testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription;
6 7 8 9	definition, yes. Q. On Exhibit 8, again, did was there ever a point at which undiluted IgG was added to the PRN test for Protocol 007? MS. DYKSTRA: Objection. THE WITNESS: I have no way of	6	testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness;
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	definition, yes. Q. On Exhibit 8, again, did was there ever a point at which undiluted IgG was added to the PRN test for Protocol 007? MS. DYKSTRA: Objection. THE WITNESS: I have no way of knowing that. BY MR. BEGLEITER: Q. You don't know? A. I don't know. Q. I do have a question, it's a follow up for today. Just one question. It's a yes or a no. Is there a way for Merck to determine who purchased 106 out of compliance lots? MS. DYKSTRA: Objection. Form. THE WITNESS: I would not know if there is a direct way of doing that.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof. WITNESS my hand and official seal this 19th day of June, 2017.
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	Page 370				Page 372
1	INSTRUCTIONS TO WITNESS	1		ERR	RATA SHEET
2	Please read your deposition over	2	IN RE-		ex rel. vs. MERCK
3	carefully and make any necessary corrections.	3		6/6/20	
4	You should state the reason in the appropriate	4		LINE	
5	space on the errata sheet for any corrections	5	THOE	LIIAL	CONNECTION / II VE READON
6	that are made.	6			
7	After doing so, please sign the errata	7			
8	sheet and date it.	8			
9	You are signing same subject to the	9			
10	changes you have noted on the errata sheet,	10			
11	which will be attached to your deposition.	11			
12	It is imperative that you return the	12			
13	original errata sheet to the deposing attorney	13			
14	within thirty (30) days of receipt of the	14			
15	deposition transcript by you. If you fail to	15			
16	do so, the deposition transcript may be deemed	16			
17	to be accurate and may be used in court.	17			
18	to or accornic and may or accornic	18			
19		19			
20		20			
21		21			
22		22			
23		23			
24		24			
25		25	(DATE)	DR. EMILIO EMINI
	Page 371		(,	
1	ACKNOWLEDGMENT OF DEPONENT				
2	Medito Wellboment of Bel oftent				
3	I have read the foregoing transcript of				
4	my deposition and except for any corrections or				
5	changes noted on the errata sheet, I hereby				
6	subscribe to the transcript as an accurate record				
7	of the statements made by me.				
8	or the statements made by me.				
9					
10	DR. EMILIO EMINI				
11					
12	SUBSCRIBED AND SWORN before and to me				
13	this day of				
14					
15					
16					
17	NOTARY PUBLIC				
18	THE TOBBLE				
19					
20	My Commission expires:				
21	, Commission expires.				
22					
23					
24					
25					
23					

94 (Pages 370 - 372)

10/25/2019 Declaration of G. Reilly EXHIBIT 116

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Page 1
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          IN THE UNITED STATES DISTRICT COURT
        FOR THE EASTERN DISTRICT OF PENNSYLVANIA
 2
 3
      UNITED STATES OF AMERICA : CIVIL ACTION
                            : NO. 2:10-04374 (CDJ)
      ex rel., STEPHEN A.
      KRAHLING and JOAN A.
 4
      WLOCHOWSKI,
 5
            Plaintiffs,
 6
            vs.
 7
      MERCK & CO., INC.,
            Defendant.
                                 : Master File No.
 8
      IN RE: MERCK MUMPS
                                 : 2:12-cv-03555 (CDJ)
 9
      VACCINE ANTITRUST
      LITIGATION
10
      THIS DOCUMENT RELATES TO: :
      ALL ACTIONS
11
12
13
                   ** CONFIDENTIAL **
14
15
                    December 22, 2016
16
17
          Videotaped deposition of FLORIAN
18
     SCHODEL, MD, taken at the offices of Spector
19
     Roseman Kodroff & Willis, 1818 Market Street,
20
     Suite 2500, Philadelphia, Pennsylvania 19103,
21
     beginning at 9:05 a.m., before LINDA
22
     ROSSI-RIOS, a Federally Approved RPR, CCR and
23
     Notary Public.
24
25
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                                                                                            INDEX
 1 APPEARANCES:
                                                                                     WITNESS
                                                                                                             PAGE
3
    On behalf of the Plaintiffs:
        SPECTOR ROSEMAN KODROFF & WILLIS, P.C.
                                                                                   FLORIAN SCHODEL, MD
        BY: JOHN A. MACORETTA, ESQUIRE
                                                                                    By Mr. Keller
            and
           DIANA J. ZINSER, ESQUIRE
                                                                                    By Mr. Macoretta
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        dzinser@srkw-law.com
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                                                                                   Schodel-2 LinkedIn profile
10
                                                                                11
       KELLER GROVER LLP
                                                                                   Schodel-3 Immunological Correlates 122
11
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                                                                                12
                                                                                          of Vaccine-Derived
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MRK-KRA01648951 - 1648956
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        212.350.2707
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19
                                                                                          MRK-KRA00549218 & 549219
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25
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                                                                      Page 3
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                                                                                          EXHIBITS (Cont'd.)
    APPEARANCES (cont'd.):
                                                                                 2 Schodel-10 E-mail chain,
                                                                                          MRK-KRA00561361 - 561365-00017
    On behalf of the Defendant:
 4
        VENABLE LLP
                                                                                   Schodel-11 10/19/01 Letter,
       BY: DINO S. SANGIAMO, ESQUIRE
                                                                                 4 MRK-KRA01469018 - 1469020
5 Schodel-12 4/25/02 E-mail with 30
                                                                                          attachment,
           DANIEL A. LOVELAND, JR., ESQUIRE
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        750 E. Pratt Street
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       dssangiamo@venable.com
       daloveland@venable.com
                                                                                   Schodel-14 E-mail chain with
                                                                                 10
                                                                                          attachments,
10
                                                                                          MRK-KRA00561199 - 561209
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                                                                                 11
       BY: THOMAS J. SULLIVAN, ESQUIRE
11
                                                                                   Schodel-15 E-mail chain,
                                                                                 12 MRK-KRA00791315 - 791319
13 Schodel-16 Excerpted document of 357
        1700 Market Street
       Philadelphia, PA 19103
12
                                                                                          Clinical Study Report,
MRK-KRA00001270 - 1466
        215.963.5146
13
       thomas.sullivan@morganlewis.com
                                                                                 15 Schodel-17 10/21/03 Memo,
14
                                                                                          MRK-KRA01638866 - 1639147
15
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   ALSO PRESENT:
                                                                                    Schodel-18 Supplemental Biologics 366
                                                                                 17
16
                                                                                          License Application,
                                                                                          MRK-KRA00000032 - 139
       STEPHEN KRAHLING
                                                                                 18
17
                                                                                   Schodel-19 Article draft,
18
       TIMOTHY K. HOWARD, ESQUIRE
                                                                                 19 MRK-KRA00032482 - 32519
20 Schodel-20 10/28/11 E-mail with
        Merck in-house counsel
                                                                                 attachment,
21 MRK-KRA00046402 - 46441
22 Schodel-21 E-mail chain, 37
19
20
21
                                                                                          MRK-KRA01481843 - 1481846
& 566614 - 566623
22
23
                                                                                24 Schodel-22 2/25/03 E-mail,
24
                                                                                          MRK-KRA00566606
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	D (D 0
1	Page 6 DEPOSITION SUPPORT INDEX	1	Page 8
2	DIRECTION TO WITNESS NOT TO ANSWER		MD MACODETTA, I-L. M.
3	Page Line	2	MR. MACORETTA: John Macoretta
4	21 24	3	from Spector Roseman for private
	22 24	4	plaintiffs as well.
5		5	MR. KRAHLING: Steve Krahling,
6		6	Relator for the United States of
7	DECLIFET FOR PRODUCTION OF POCUMENTS	7	America.
8	REQUEST FOR PRODUCTION OF DOCUMENTS Page Line	8	MR. HOWARD: Tim Howard for
10	(None)	9	Merck.
11	()	10	MR. SULLIVAN: Tom Sullivan from
12		11	Morgan Lewis for Merck.
13		12	MR. LOVELAND: Daniel Loveland
14		13	from Venable for Merck and Dr. Schodel.
	STIPULATIONS	14	MR. SANGIAMO: Dino Sangiamo
15	Dana Lina	15	from Venable for Merck and Dr. Schodel.
16	Page Line	16	VIDEOGRAPHER: Counsel on the
10	(None)	17	phone.
17	()	18	MR. BEGLEITER: Bob Begleiter,
18		19	plaintiffs.
19		20	VIDEOGRAPHER: The court
20	QUESTIONS MARKED	21	reporter is Linda Rossi of Veritext.
21	Page Line	22	Will the court reporter, please, swear
22 23	(None)	23	in the witness?
24		24	
25		25	
	Page 7		Page 9
1		1	FLORIAN SCHODEL, MD, after
2		2	having been duly sworn, was examined
3	VIDEOGRAPHER: We're now on the	3	and testified as follows:
4	record. My name is Russ Strain	4	VIDEOGRAPHER: Testimony can now
5	representing Veritext Legal Solutions.	5	proceed.
6	The date today is December 22,	6	
7	2016. The time is approximately	7	EXAMINATION
8	9:05 a.m. This deposition is being	8	
9	held at Spector Roseman, 1818 Market	9	BY MR. KELLER:
10	Street, Philadelphia, PA. The caption	10	Q. Dr. Schodel, can you state your
11	of this case is In Re: Merck Mumps		name for the record?
12	Vaccine Antitrust Litigation, filed in	12	A. My name is Florian Schodel.
13	the US District Court for the Eastern	13	Q. Have you ever been known by any
14	District of Pennsylvania, Case Number	14	other name?
15	2:12-cv-03555. The name of the	15	A. No.
16	witness is Dr. Florian Schodel, MD.	16	Q. Can you tell me your business
17	If counsel at this time will,	17	address?
18	please, introduce themselves for the	18	
19	record?	19	
			Q. Have you ever had your deposition
20	MR. KELLER: Sure. Jeffrey	20	taken before?
21	Keller from Keller Grover on behalf of	21	A. Not in a US court.
22	Relators.	22	Q. When you had your deposition
23	MS. ZINSER: Diana Zinser,	23	taken outside the US, when was that?
24	Spector Roseman Kodroff & Willis for plaintiffs.	24 25	A. I don't remember. A long time ago.
25			

1	Page 10	1	Page 12
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. I asked that. We'll go over	2	things so if you don't have a good
3	some of the	3	understanding or if you can't answer the
4	A. More than 20 years.	4	question except by guessing or estimating,
5	Q. Okay. We'll go over some of	5	please let us know. Is that fair?
6	the was that for one of your employers or	6	A. That's fair.
7	was that a personal matter?	7	Q. As you can tell, the court
8	A. No, personal matters.	8	reporter, again, takes down everything that we
9	Q. Let me go over some of the	9	say and it's helpful, though I don't think
10	ground rules to remind you. I'm sure your	10	we'll have a problem, is to not talk over each
11	counsel has sort of walked you through this,	11	other. Allow me to finish asking the
12	but it always helps to kind of go over it	12	question, though you're already probably going
13	before the deposition so it's fresh in your	13	to know what the rest of my question is when I
14	mind.	14	start it, I may pause in the middle as I try
15	You've your testimony today	15	to formulate a question, just give me the
16	is under oath under the penalty of perjury.	16	opportunity to finish the question before you
17	At the end of this deposition the court	17	answer. And I'll try to do the same thing
18	reporter is going to do a great job of writing	18	instead of asking you the next question before
19	down everything that you say, that I say and	19	you answer, fully answer, just so we get a
20	anybody else in the room says. You'll have a	20	nice clean record at the end of the day.
21	chance to review that and make any corrections	21	Because when the record comes out, it's going
22	that you think are appropriate, but I will	22	to have a question and an answer, and if we
23	remind you any changes you make to the	23	talk over each other, the question gets broken
24	transcript we'll be able to comment at trial.	24	up, because she just writes down whatever
25	Okay?	25	people are saying when they're saying it.
	Page 11		Page 13
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	A. Okay.	2	Dr. Schodel, do you have a
3	Q. Since the court reporter, though	3	personal lawyer?
4	she's amazing, can really only really	4	A. For this particular case?
5	capture words, though, she can't say if you	5	Q. Generally, overall.A. Not in the United States.
6	get up and ran out of the room, she'll write	7	
7	down witness ran out of the room. Try to		Q. Do you have an attorney for your
8	answer the questions with words, you know,	8 9	consulting firm?
9	instead of saying uh-huhs and uh-uhs, yes or		A. For my firm?
10	no would be we'll have a much cleaner	10	Q. Yes.
11	record if you could do that. Is that fair?	11	A. No.
12 13	A. No problem.	12	Q. Who is representing you today?
	Q. Great. I'm going to be asking		A. They already stated it. The
14	you questions and you're going to be answering	14	firm Venable.
15	the questions. If you don't understand my question, please let me know; otherwise, we're		Q. Is Morgan Lewis representing you today?
16		16 17	today?
17	all going to assume that you understood the		MR. SANGIAMO: That's
18 19	question. Is that fair? A. I will not answer a question I	18 19	Mr. Sullivan's firm as well.
20	can't understand so obviously I will ask you.	20	THE WITNESS: Are they?
21	Q. Perfect. As long as we have the	21	MR. SANGIAMO: Yes. THE WITNESS: They are
	same understanding.	21 22	THE WITNESS: They are. BY MR. KELLER:
122	same unucistanung.		
22	-	72	O Did you sign a rateinar
23	We don't want you to guess or	23	Q. Did you sign a retainer
	-	23 24 25	Q. Did you sign a retainer agreement with them? A. No, I did not.

4 (Pages 10 - 13)

	ELOI	Page 14		Page 16
1		RIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q.	Are you paying them any fees?	2	me and then I got in touch with Merck
3	A.	No, I do not.	3	which was maybe half a year ago, but I
4	Q.	Have they ever represented you	4	don't really remember.
5	in the pa		5	BY MR. KELLER:
6	A.	No, they have not.	6	Q. And when you somebody from
7	Q.	So they only represent you for	7	the plaintiff's side of this lawsuit contacted
8		oses of this lawsuit and your deposition	8	you. Correct?
9	today?		9	A. Contacted me. And they
10	A.	That's correct.	10	contacted me in a way that met that I
11	Q.	Yes?	11	thought it was a Merck lawyer because he did
12	A.	Yes.	12	not state in the beginning of the phone call
13	Q.	When did you first speak to your	13	who he was representing and started asking me
14	counsel	for the purposes of this deposition?	14	questions. And started asking whether I
15	A.	For the purposes of this	15	would be willing to appear as a witness in
16	deposition	on we spoke in the beginning of this	16	this case that I didn't know anything about.
17	week.		17	And it sounded very strange to me. So
18	Q.	Were they retained at the	18	finally, I asked whether he was representing
19	beginnin	g of this week?	19	Merck. He told me that he was not. And by
20	A.	No. A little earlier.	20	that time I told him that I would talk to
21	Q.	Do you know when earlier?	21	Merck and not continue this conversation.
22	A.	No.	22	Q. Do you recall so you called
23	Q.	Was it within the past month?	23	somebody at Merck. Did you call who did
24	Ä.	Yes, probably.	24	you call at Merck?
25	Q.	How many times have you spoken	25	A. To tell you the truth, I don't
		Page 15		Page 17
1	FLOF	RIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	to your c	counsel for the purposes of this	2	remember anymore. I don't I could
3	depositio	on?	3	probably try to I don't remember anymore.
4	Α.	Well, directly for the deposition,	4	But I tried to find somebody at Merck who was
5	we've on	lly spoken this week. We have a	5	responsible for, and then I eventually got to
6		discussion earlier.	6	the people who were dealing with this.
7	_	MR. SANGIAMO: Doctor, it's	7	Q. Did you speak to the legal
8	impo	ortant that you not disclose the	8	department at Merck?
9	_	ent of those prior discussions.	9	A. They eventually contacted me
10		our answer is okay but wait for	10	back, but they were not my first contact
11	-	Keller's next question.	11	because I wouldn't have known whom to call
12		KELLER:	12	there.
13	Q.	And you said you had a general	13	Q. The person who you spoke to at
14	-	on. I'm not going to ask you what you	14	Merck who wasn't one of Merck's lawyers, do
15		d, I just want to know when you	15	you recall what you discussed with them?
16		d this general discussion you had	16	A. No, I didn't actually discuss
17		this week, do you recall when that	17	anything other than I was contacted by a law
18	was?	and week, do you recan when that	18	firm in regards to a court case that Merck
19	A.	I don't recall exactly. I	19	seemed to be involved in and that I wanted
20		ok it up in my calendar, I had a lot	20	Merck to get in touch with me and figure out
21		ssions. I think my first knowledge	21	what needed to be done.
22		•	$\begin{vmatrix} 21\\22\end{vmatrix}$	
23		se was triggered by	$\begin{vmatrix} 22 \\ 23 \end{vmatrix}$, ,
		MR. SANGIAMO: I'm sorry, go	1	department at Merck reach out to you?
24 25	head		24 25	A. Yes.
43		THE WITNESS: somebody called	23	Q. Do you recall who that person

5 (Pages 14 - 17)

	Page 18		Page 20
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2 v	was?	2	A. Bloody detail. No, of course
3	A. Tia Clarke.	3	not.
4	Q. Can you spell the last name?	4	Q. Fair enough. And then you said
5	A. No. But I can try.	5	this week you spoke to your lawyers about
6 (C-L-A-R-K-E maybe. Could be K without an E.	6	preparation for this deposition. Correct?
7	Q. Fair enough. If you identify	7	A. Yes.
8 p	people's names, just for the court reporter's	8	Q. And when this week did you speak
_	sake, if you especially if they have a	9	to them?
	spelling that is difficult, it may be helpful	10	A. Monday.
	ust to spell it as you go. You're going to	11	Q. Monday.
-	have to do it eventually. She's going to ask	12	A. Was it Monday? Yeah.
	you anyway.	13	Q. Did you meet them in person or
14	A. In that case I simply don't	14	on the phone?
15 k	know. It's probably C-L-A-R-K-E.	15	A. Yes. Or was it Tuesday? I
16	Q. Close enough. Just so that we	16	don't know. I think I mean, I have a
17 h	nave even if it's phonetic, it's helpful to	17	lot had a lot of stuff on my plate this
	nave the names.	18	week. It may have been another day of the
19	And then you said that you do	19	week. Tuesday.
20 v	you recall how long you spoke to Ms. Clarke?	20	O. Your best recollection. I'm not
21	A. No, I think that was just an	21	going to hold you to Monday or Tuesday. So
	exchange of e-mails.	22	either Monday or Tuesday you met with them in
23	MR. SANGIAMO: Dr. Schodel, just	23	person. Do you recall how long you met with
24	make sure you just answer his	24	them?
25	question. His question was do you	25	A. Most of the day.
	Page 19		
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 2: FLORIAN SCHODEL, MD - CONFIDENTIAL
2	know how long you spoke to	2	Q. Most of the day. Did they show
3	THE WITNESS: I'm not even sure	3	you documents?
4	I spoke to her at all.	4	A. Yes.
	BY MR. KELLER:	5	Q. Do you recall how many documents?
6	Q. Do you recall how long did	6	A. No. Many.
	you speak to anybody in the legal department	7	Q. Many. Is many more than 10?
•	at Merck?	8	A. Yes.
9	A. No.	9	Q. Is it many more than 100?
10	Q. Did Merck refer you to one of	10	A. No.
	your lawyers that your that are	11	Q. More than 20?
	representing you here today?	12	A. Probably.
13	A. Yes, eventually.	13	Q. Less than 50?
14	Q. Then you said that you spoke to	14	A. I don't know.
	somebody other than this week, have you	15	
	spoken to anybody else at Merck regarding this	16	Q. And you reviewed those documents?A. Yes.
	awsuit?	17	Q. And did any of those documents
18	A. No.	18	help refresh your memory about what was in
19	Q. Have you spoken to anybody else	19	those documents?
	other than your lawyers regarding this lawsuit?	20	A. Yes.
20 0	A. Yeah, my wife. I told her that	21	Q. Do you recall which of those
		21 22	
77 I	had to spend the last days before Christmas	23	documents refreshed your memory as to what was in those documents?
23 g	giving a deposition.		
23 g 24	Q. Did you discuss with her any of the details?	24 25	MR. SANGIAMO: I'm going to interpose an objection. I'm going to

6 (Pages 18 - 21)

	Page 22		Page 24
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	instruct Dr. Schodel not to answer	2	(Exhibit Schodel-1, Curriculum
3	that question.	3	Vitae, was marked for identification.)
4]	BY MR. KELLER:	4	
5	Q. Are you going to follow your	5	BY MR. KELLER:
6	counsel's advice?	6	Q. Exhibit 1 is a document entitled
7	A. When you find out as you ask me	7	"CURRICULUM VITAE" which was produced this
8 a	about specific documents, which I do remember	8	morning by your counsel, Dr. Schodel. Is this
	and which I don't remember, I couldn't give	9	your CV?
	you a list off my head which ones I remember	10	A. Yes, it is.
•	or don't remember. But there were some	11	O. Is it current?
	some of them were e-mails that I had written	12	A. Yes, it is.
	and I had not remembered them if I hadn't	13	Q. Any reason to believe that the
	seen them.	14	information here is not accurate?
15	Q. Fair enough. Other than that	15	A. No.
16 f	full day that you met with your counsel in	16	Q. I just want to go over a couple
	preparation for this deposition, have you done	17	of things about your educational background.
	anything else in preparation for this	18	Can you just give me a quick summary of what
	deposition?	19	the degrees you have?
20	A. No. No.	20	A. Yeah, I have a degree in
21	Q. Did any of the documents that	21	medicine which is an earned doctorate. So I
	you looked at, did they surprise you in any	22	wrote a thesis in immunology. I have also an
	way?	23	earned doctorate in microbiology which is a
24	MR. SANGIAMO: Dr. Schodel, I'm	24	second doctorate in medical microbiology for
25	going to instruct you not to answer	25	which I wrote another thesis and I have
1	Page 23 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 25 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	that question. That's invading the	2	the it doesn't exist here, it's a
3	attorney/client privilege and work	3	habilitation which is a right to become a
4	product doctrine, legal doctrine. So	4	professor and teach.
5	I'm instructing you not to answer Mr.	5	Q. Can you describe for me what
6	Keller's question.	6	your understanding of an immunologist is?
	BY MR. KELLER:	7	A. An immunologist is somebody who
8	Q. Are you going to follow your	8	analyzes immune responses in living organisms.
	counsel's advice?	9	Q. That's what you're trained in?
10	A. Yes, I do.	10	A. That's one of the things I'm
11	Q. Was there anybody else present	11	trained in, yes.
	at that meeting either Monday or Tuesday that	12	Q. Do you consider yourself an
	weren't lawyers?	13	immunologist?
14	A. One more lawyer who is not here	14	A. No.
	right now.	15	Q. No?
16	Q. So they were all lawyers?	16	A. No, I consider myself a physician.
17	A. Yes.	17	Q. Have you ever used your
18	Q. There was nobody from Merck	18	immunology background as part of any of your
	present at that meeting?	19	job duties?
20	A. No.	20	A. Yes, of course.
21	MR. KELLER: Do we have Dr.	21	Q. Have you used your immunology
22	Schodel's CV? I'm going to mark as	22	background as part of your job duties at
23	Exhibit 1 a CV of Dr. Schodel that was	23	Merck?
24	produced to us this morning.	24	A. Yes.
	produced to us uns morning.	25	MR. KELLER: Let me mark as
25		/ . 1	VIK KELLEK: Lei me mark as

1	Page 26	1	Page 28
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Exhibit 2	2	yourself to have a good understanding of the
3		3	regulatory environment in the United States
4	(Exhibit Schodel-2, LinkedIn	4	for getting a vaccine license?
5	profile, was marked for identification.)	5	A. Yes.
6		6	Q. And that's one of the services
7	BY MR. KELLER:	7	you provide to your clients?
8	Q. Exhibit 2 is a document that we	8	A. Yes.
9	pulled down off of LinkedIn I'm sorry, that	9	Q. And that's part of your 30 years
10	we pulled in off of LinkedIn, which has a	10	of experience?
11	summary of some of your educational and work	11	A. Yeah.
12	background. Is the information on this	12	Q. When you say "clinical trials,"
13	document correct?	13	can you give me your understanding of what
14	A. I have to read it first.	14	clinical trials you're referring to?
15	Yes, it seems to be correct. I	15	A. Well, any clinical trial which
16	mean, I'm just referring to the summary. All	16	means any trial that puts a compound into
17	the other stuff, yeah.	17	humans and tests what happens, whether that's
18	Q. Sure. If there's something in	18	safety in Phase I, whether it's safety and
19	here as we if we go through this that you	19	immunogenicity or whether it is other
20	say that you see that's incorrect, feel	20	endpoints for the purpose of licensure.
21	free to let me know that.	21	Q. When you say "endpoints," what
22	In the first sentence it says	22	do you mean by "endpoints"?
23	that you have 20 years of large pharmaceutical	23	A. Endpoints are in the end what
24	biotech industry and academic experience of	24	you measure to determine whether something is
25	leading teams in the development of vaccines	25	safe or efficacious.
	Page 27		Page 29
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	and biologies. Is that correct?	2	Q. When you say "efficacious," what
3	A. Yes, only that by now it's	3	do you mean by "efficacious"?
4	probably longer.	4	A. Efficacious means that it
5	Q. How much longer is that?	5	prevents a disease.
6	A. It's about 30 years now.	6	Q. I apologize to have you define a
7	Q. 30 years, okay.	7	lot of these terms, they seem very rudimentary,
8	Your company that you founded,	8	I do that to make sure that we're all on the
9	what's the name of that company?	9	same page.
10	A. Philimmune.	10	A. Perfectly fine.
11	Q. What kind of consulting do you	11	Q. Have you ever done any work with
12	do at your company?	12	your consulting company for Merck?
13	A. I provide advice on developing	13	A. A single time I have, yes. A
14	biologics or vaccines primarily on the	14	single time I have.
15	clinical side, what kind of clinical trials	15	Q. So they're a client?
16	should be run to meet criteria for licensure	16	A. They're not a current client.
17	and how something works. I provide some	17	Q. Do you hope to do more work for
18	advice as to strategy on what compounds based	18	them in the future?
19	on data may be worth developing and what the	19	A. I can't speculate.
20	likely regulatory pathway would be for getting	20	Q. Would you like to do more work
21	them licensed in different jurisdictions.	21	for them in the future?
22	Q. Is one of those jurisdictions	22	A. I would like to do work for
23	the United States?	23	
23		24	anybody who needs me. Q. Including Merck. Correct?
24			
24 25	A. Yes. Q. So you have a you consider	25	A. Including Merck.

1	Page 30 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 32 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Let me go back to your Exhibit 2	2	something at a lower dose. But by
3	which is the your LinkedIn page. In the	3	that time the labeling philosophy had
4	second paragraph to the bottom it says,	4	changed or was about to change, hadn't
5	"Florian joined MRL in 1996" Do you see	5	quite changed yet, both from an FDA
6	that?	6	perspective and from a company
7	A. Yes.	7	perspective and from a company perspective. The old labels
8	Q. And MRL, what does that refer	8	originally just stated a number which
9	to?	9	was found to be efficacious in a
10	A. Merck Research Laboratories.	10	clinical trial, whatever that number
11	Qas Director of Clinical	11	was. Some of these numbers became
12	Vaccine Research leading EU vaccine clinical	12	compendial, by the way. Then over
13	trials in the clinical development of	13	time the understanding started to be
14	rotavirus, measles, mumps and rubella	14	that a vaccine needed to maintain that
15	vaccines. Do you see that?	15	number that was stated in the label
16	A. Yes.	16	throughout the shelf life. So that
17	O. What does EU stand for?	17	was a change. And because that was
18	A. The European Union.	18	not the case when mumps was originally
19	Q. Do you recall what clinical	19	licensed 40 years ago, Merck had to
20	trials you worked on during this time frame	20	make sure that whatever was in the
21	that you were working for Merck in Europe with	21	vaccine throughout shelf life
22	respect to the mumps vaccine?	22	maintained its efficacy. So that the
23	A. Those are several questions in	23	label statements would be as of the
24	one. With respect to the mumps vaccine, I	24	current understanding which had
25	don't remember any trial in the EU, although	25	changed.
1	Page 31 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 33 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	there might have been an EU arm so I don't	2	So Merck wasn't trying to sell
3	really remember details of the trials. I	3	anything different. It was always
4	know that there was a that the end expiry	4	selling the same thing. It was just
5	trial was being performed, but whether it was	5	providing additional actually being
6	performed in the EU, I don't remember.	6	quite diligent in providing additional
7	Q. And "the end expiry trial," can	7	information about the clinical
8	you describe what you mean by that?	8	behavior of the vaccine it was
9	A. That was a trial to determine	9	selling.
10	whether a lower dose of mumps at the end of	10	BY MR. KELLER:
11		11	Q. When you say "compendial," can
12	immune response as a higher titer obviously.	12	you describe what that means?
13	Q. So is the purpose to see whether	13	A. Yes. There are some compendia
14	or not if Merck sold the vaccine at a lower	14	that define concentrations or potencies of
15	dose, whether or not that would protect kids	15	certain things like the pharmacopeia. And in
16	in the same way that a higher dose would?	16	some cases they provide numbers for vaccines.
17	A. No, that's a	17	So, for example, in the European Union there
18	MR. SANGIAMO: Object to the	18	is a compendium that states essentially, I
19	form. You can answer.	19	don't know the exact text, but that states
20	THE WITNESS: I think that so	20	essentially that a mumps vaccine will have
21	you're sort of leading into something	21	3.7 logs of mumps virus.
22	which is not the premise is wrong.	22	Q. In that 3
23	It's not a matter of whether was Merck	23	A. So that becomes a rather
24	selling something that at a lower	24	than something that a company has tested,
25	dose. Merck wasn't planning to sell	25	that becomes a leading requirement for a

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1	Page 34	1	Page 36
2	FLORIAN SCHODEL, MD - CONFIDENTIAL vaccine to have that number in it.	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
3	Q. So in the US, do you recall it	3	plaque it's a plaque assay, so many units in there that when you put them in cell
	-	4	
5	being a higher number?	5	culture, they produce holes in the cell
6	A. I don't recall the US having a	6	culture which are counted as plaques.
	compendial statement at all.		Q. So when you say, "a plaque
7 8	Q. Do you recall that in the US	7 8	assay," are there different plaque assays? A. Yeah. There are all kinds of
9	that the label required that the mumps vaccine have a certain potency?	9	
		-	different assays to measure potency. They
10		10	could be fluorescent assays. They could
11	just said, understanding of what that meant	11	be it's just they're just measures to
12	had changed over time.	12	quantitate the amount of a live product.
13	Q. Gotcha. But it did have a	13	Q. So the plaque assay, is that a
14	certain potency?	14	plaque reduction neutralization assay?
15	A. Yes, but originally	15	A. No, that's the antibody assay.
16	MR. SANGIAMO: Dr. Schodel, make	16	MR. SANGIAMO: Object to form.
17	sure you let Mr. Keller finish his	17	You can answer.
18	question.	18	BY MR. KELLER:
19	I'm sorry. Could you restate	19	Q. So the plaque assay there is
20	your question, please, Jeff?	20	used for potency, is that it's just
21	MR. KELLER: Sure. Can you read	21	identifying how many viruses are in each dose.
22	it back?	22	Correct?
23		23	A. How many live viruses are in
24	(The court reporter read the	24	each dose. And it's not the assay is not
25	pertinent part of the record.)	25	as important as the I mean any assay could
1	Page 35		Page 37
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2		2	
3	BY MR. KELLER:	3	
4	Q. But you understood that the	4	8,
5	label in the United States did have a certain	5	criteria. But it's, of course, defined in
6	required potency for the vaccine?	6	defining documents. I don't remember exactly
7	MR. SANGIAMO: Object to the	7	what Merck did there.
8	form.	8	Q. So there's protocols that set
9	THE WITNESS: Yes.	9	for how these assays are run. Correct?
10	BY MR. KELLER:	10	A. Yes.
11	Q. And the question was whether or	11	Q. And those assays are validated
12	not that potency had to be not just at release	12	some
13	but also at the end expiry of the vaccine.	13	A. Yes.
14	Correct?	14	Q to a certain extent.
1.5	A TT1 4 '	1 ~	Correct?
15	A. That is correct.	15	
16	Q. When you say "potency," can you	16	MR. SANGIAMO: Object to the
16 17	Q. When you say "potency," can you define for me what you mean by "potency"?	16 17	MR. SANGIAMO: Object to the form.
16 17 18	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's	16 17 18	MR. SANGIAMO: Object to the form. BY MR. KELLER:
16 17 18 19	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's defined in the CFR, but potency in this	16 17 18 19	MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Let me strike the question.
16 17 18 19 20	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's defined in the CFR, but potency in this particular case means a certain quantity of	16 17 18 19 20	MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Let me strike the question. These assays, these potency
16 17 18 19 20 21	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's defined in the CFR, but potency in this particular case means a certain quantity of virus that leads to a biologic effect in an	16 17 18 19 20 21	MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Let me strike the question. These assays, these potency assays are validated. Correct?
16 17 18 19 20 21 22	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's defined in the CFR, but potency in this particular case means a certain quantity of virus that leads to a biologic effect in an in vitro assay. In that case it's a plaque	16 17 18 19 20 21 22	MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Let me strike the question. These assays, these potency assays are validated. Correct? A. Yes.
16 17 18 19 20 21 22 23	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's defined in the CFR, but potency in this particular case means a certain quantity of virus that leads to a biologic effect in an in vitro assay. In that case it's a plaque neutralizing reduction assay. So it a	16 17 18 19 20 21 22 23	MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Let me strike the question. These assays, these potency assays are validated. Correct? A. Yes. Q. Who does the validation?
16 17 18 19 20 21 22	Q. When you say "potency," can you define for me what you mean by "potency"? A. Potency is I mean, it's defined in the CFR, but potency in this particular case means a certain quantity of virus that leads to a biologic effect in an in vitro assay. In that case it's a plaque	16 17 18 19 20 21 22	MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Let me strike the question. These assays, these potency assays are validated. Correct? A. Yes.

Page 38 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 2 that validates the release assay. 2 you describe what you mean by that? 3 3 Q. You said that the label Well, because as that became 4 4 philosophy had changed at a certain point the requirement for new products, every new 5 5 during your tenure at Merck regarding the end product that would be licensed had to meet expiry versus whether or not, if I understand these kinds of expectations and, therefore, you correctly, the release potency would be there was always a discussion as to what the 8 8 the same or different from the end expiry data were to support these numbers. 9 9 potency. Correct? So this change that occurred, do 10 MR. SANGIAMO: Object to the 10 you recall when that change was? 11 form. 11 Not specifically. But I think BY MR. KELLER: 12 it evolved in the time period between 1990 13 and 2000 roughly, and then the years thereafter. Q. Do you understand my question? 13 14 The first part yes. The second 14 And so this change in the 15 part no. So the first part has a change. 15 requirement, do you recall Merck having any Yes, it has changed. It has nothing to do discussions that you became aware of with 17 with Merck. It has changed overall for the 17 respect to this requirement of having an end whole industry. The second part wasn't clear 18 expiry potency? 19 19 A. Yes. 20 Sure. When you say it's changed 20 Were you involved in those 21 for the whole industry, can you describe what 21 discussions directly with the FDA? 22 you mean by that? 22 A. No, not -- certainly not 23 Well, that in general the idea 23 initially. As specific protocols or filings 24 of how -- what the guarantee in the label had were discussed, I may have been part of some evolved and the science had evolved. I think 25 of those discussions. Page 39 Page 41 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 most labels were written 40, 50 years ago 2 2 Q. Were you involved in the end 3 with a description of the product that did expiry study that we talked about earlier? 4 not include either maximum release or minimum 4 Yes, on and off. 5 release potencies but just simply a number. 5 Q. Did you help develop original Q. And then that changed from a 6 protocols? 6 7 7 regulatory standpoint? Α. 8 A. It changed both from a 8 Do you know who developed 9 regulatory and from a company standpoint in original protocols? the sense that it was clarified what these 10 A. I know it on the biometric side 11 things mean. 11 but not the clinical side. 12 Who about on the biometric side? Q. So there is a clarification 12 13 13 Tim Schofield. At least that between -- you say clarified, clarified by 14 14 who? was my recollection. 15 A. Ultimately by the agencies. 15 Q. Do you recall -- what role did Q. 16 So in the case of the US, the 16 you play at all in this end expiry study? 17 17 FDA? Well, I was supervisor of the 18 18 physicians who were responsible for mumps Α. 19 Were you involved at all in any 19 where I was directly responsible for a short Q. 20 of the discussions with the FDA regarding this 20 time for anything that had to do with MMR or change in requiring a maximum and minimum 21 MMR/V. But that changed various times. So 22 potencies? 22 at times I had physicians report to me who 23 Not explicitly but implicitly, 23 were responsible for MMR or MMR/V. A. 24 24 And MMR/V, that's ProQuad. yes. Q. 25 25 Correct? When you say "implicitly," can

Page 42 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 2 ProQuad, yes. 2 then came back in November 2002 -- 2000, 3 3 Let me just sort of frame the sorry, and where you held executive director time frame on this. You said at some point 4 of vaccine integration through March of 2002. 5 5 your duties changed. You were a supervisor of Do you see that? folks, doctors that were responsible for 6 A. Yes. 7 7 MMR II. Correct? Q. What is vaccine integration? 8 8 MR. SANGIAMO: Mr. Keller, are Vaccine integration was a 9 9 you okay with Dr. Schodel looking at department at the time which was created in 10 his CV --10 anticipation of a number of vaccine filings, BY MR. KELLER: 11 11 quite a few, which made sure that the 12 Q. Absolutely. Whatever helps different departments of Merck collaborated 13 refresh your memory, that's fine. 13 in putting together the right data for the 14 A. That wouldn't give you the 14 filings. 15 information and I have to say that I don't 15 Q. Is that more focused on new remember the exact timing anymore because 16 vaccines versus existing vaccines? 17 that was -- in the time frame between the end 17 No, it was responsible for 18 of '96 when I started and roughly '98, I was 18 certain aspects of both. For example, we 19 on and off. I was assuming more 19 developed a way how to write the CTD in 20 responsibilities. MMR was certainly not the 20 electronic form. So it had various -- it had 21 focus of my work. It was much more rotavirus 21 a direct clinical team which was very small. 22 and a number of things and clinical trials in 22 And that was more focused on new things, but 23 Europe. But over time I got more of that 23 then it had a larger role across different 24 responsibility as well. 24 departments. 25 25 Let me just sort of back up so I When the formal reporting lines Page 43 Page 45 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 changed, I really don't remember. And then I 2 2 can understand what your actual duties were at 3 3 wasn't at Merck for about two years. And Merck and then we can sort of walk through. 4 when I came back -- I still worked for Merck 4 When you started in 1996 through 5 as a contractor or consultant but only on one 5 that 1998 time frame as a director of clinical approach, it had nothing to do with MMR. In vaccine research, what were your duties? We 6 6 7 that time period between '98 and 2000 I 7 can limit it really -- let me ask that 8 didn't work for Merck on the MMR. 8 generally. What were your duties generally? 9 Then when I came back, MMR was A. In general, I had a small group 10 initially not under me. I think it was still 10 that was responsible for the operational 11 under Jerry Sadoff. And it may have been 11 aspects of clinical trials in Europe. So 12 Scott Tyler or Mike Severino who were the 12 working with the CROs, working with the investigators, making sure that we had the responsible physicians not reporting to me. 13 14 14 And then at some point after 2000, maybe 2002 sites ready and so on. So more operational or so, 2001, 2002, I became formally 15 15 work. I was also the liaison to the 16 responsible for these vaccines. 16 17 joint venture with Sanofi Pasteur in Europe Q. So according to -- I'm looking 17 18 at your LinkedIn summary of your work 18 and sat on the clinical development team for experience. It has you starting at Merck 19 Hexavac which was a vaccine that we 20 Europe in 1996 through November of 1998. Were 20 co-developed with Sanofi at the time. That 21 you working in Europe or were you working in was a major part of my responsibilities, and 22 the United States? 22 I represented Merck on that team for clinical 23 A. Half and half. 23 issues. 24 And then in November 2000 -- and 24 Then in the US, as I mentioned you left for a company outside of Merck and 25 earlier, I was primarily responsible as a

1	Page 46 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 48 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	monitor for the new rotavirus vaccine, so I	2	think they were microneuts, but I don't
		3	
3	developed a clinical development plan for RotaTeq. And those were really the main		Q. Okay. Fair enough. What is the difference is the ELISA a functional assay?
4	•	5	·
5	responsibilities. That's what I spent most		A. No. It's a binding assay.
6	of my time on, between	6	Q. Binding assay. What do you mean
7	Q. So your role with respect to the	7 8	by "a binding assay"? A. Measures whether an antibody is
8	MMR vaccine was very limited during this time		A. Measures whether an antibody is bound to a substrate which could be a cell,
9	frame?	9	
10	A. At that time, my role was	10	could be an antigen that is fixed in the
11	limited, yes.	11	plate.
12	Q. The rotavirus vaccine, did you	12	Q. And so what is the an ELISA
13	conduct clinical studies with that vaccine?	13	assay, how is that reported in terms of
14	A. Yes. Yes.	14	reporting?
15	Q. What were the studies what	15	A. The ELISA assay reports, it has
16	were the assays that were run in that, with	16	a substance added to the test tube which by
17	that particular vaccine?	17	virtue of an enzyme is converted from one
18	A. Well, I mean, there were a	18	form to the other and then changes color.
19	number of ELISAs run to measure antibody	19	And that color change is measured. So if a
20	titers and functional assays to measure	20	lot of antibody is in there, the antibody is
21	neutralization of viruses as well.	21	tagged with an enzyme. A lot of enzyme in
22	Q. When you say a functional assay,	22	the tube and that enzyme causes a color
23	could you describe what you mean by a	23	change and the color change is measured.
24	functional assay?	24	Q. So your it's an optical test
25	A. A functional assay would be an	25	to identify a number of optical units. Is
	Page 47		Page 49
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	assay that is a neutralization assay that	2	that a fair way to say it?
3	basically mixes the virus with the antibodies	3	A. Yes, although most tests are
4	in a test tube and see whether the virus	4	optic because you have to look at them. So
5	activity on a cell log gets reduced.	5	when you count them, that's an optical test,
6	Q. So it either kills it or stops	6	too, in a way.
7	it from growing. Is that fair?	7	Q. Gotcha.
8	A. Yes. It could. Yes. Or stops	8	A. But this is one where you
9	it from entering a cell.	9	measure color change specifically. So the
10	Q. Gotcha. So in this, the	10	change of light absorption.
11	neutralizing assays that you did for the	11	Q. How is that reported?
12	rotavirus, was that a plaque reduction	12	A. Many different
13	neutralization assay?	13	MR. SANGIAMO: Jeff excuse
14	MR. SANGIAMO: Object to the	14	me. Jeff, you're saying how is that
15	form.	15	reported?
16	THE WITNESS: First of all, I	16	MR. KELLER: Yes.
17	didn't do these assays.	17	MR. SANGIAMO: Okay.
18	BY MR. KELLER:	18	THE WITNESS: It can be reported
19	Q. Fair enough.	19	just as an optic density change at a
20	A. So I was responsible for the	20	given dilution. That would be the
21	clinical part. And secondly	21	simplest form. It can be reported as
22	Q. Let me back up.	22	a titer, a titer being defined by
		23	certain criteria.
23	A. Secondly, there were different	23	certain criteria.
23 24	A. Secondly, there were different formats tried. I don't even remember anymore	24	BY MR. KELLER:

1	Page 50	1	Page 52
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	they usually typically report that as a seroconversion?	$\frac{2}{3}$	MR. SANGIAMO: Object to the
3			form. You can answer.
4	A. Those are two different	4	THE WITNESS: Yeah. You find a
5	concepts. Seroconversion means that a serum	5	collection of sera that by a
6	that previously was negative or lower by	6	comparator assay have been or by
7	defined measure becomes now higher in content	7	history have been known not to have
8	of antibody as measured by an ELISA or any	8	been exposed by whatever you're
9	other assay for that matter. So that's not	9	measuring. And you run your new assay
10	Q. That's a way to use ELISA	10	and you see how it classifies. It's a
11	utilize a test is to report	11	classification comparison if you want.
12	A. The ELISA test would be what	12	That's at least one way of doing it.
13	you measure. The seroconversion would be	13	There are other ways that you can use.
14	what you calculate out of that.	14	BY MR. KELLER:
15	Q. How would you determine when	15	Q. So that is that called a
16	you're calculating what you're measuring,	16	control?
17	whether or not it's a seroconversion or not?	17	A. No. No, it's not. A control
18	A. Well, you compare pre and post.	18	would be something that you run within the
19	So a seroconversion means that a serum that	19	assay to determine whether the particular
20	previously contained no or little antibody	20	assay run has actually worked the way you
21	contains now some antibody above a certain	21	predict it to work.
22	threshold. Or a serum that contained a	22	Q. And so the way to determine it
23	quantity of antibody in the first test now	23	by a factor, how does that work?
24	contains ten times more antibody. So it	24	MR. SANGIAMO: Object to the
25	contains more by some defined measure as any	25	form.
	Page 51		Page 53
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	FLORIAN SCHODEL, MD - CONFIDENTIAL which way you define that.	2	FLORIAN SCHODEL, MD - CONFIDENTIAL THE WITNESS: Well, the factor
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL which way you define that. Q. So either you can do it by a	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL THE WITNESS: Well, the factor is it depends on how you define it.
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL which way you define that. Q. So either you can do it by a fold factor or a cutoff. Is that correct?	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL THE WITNESS: Well, the factor is it depends on how you define it. There's many ways of defining a
2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL which way you define that. Q. So either you can do it by a fold factor or a cutoff. Is that correct? A. That is correct, yes.	2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL THE WITNESS: Well, the factor is it depends on how you define it. There's many ways of defining a factor. If you we're still talking
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL which way you define that. Q. So either you can do it by a fold factor or a cutoff. Is that correct? A. That is correct, yes. Q. And when you do it by a	2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL THE WITNESS: Well, the factor is it depends on how you define it. There's many ways of defining a factor. If you we're still talking about a serostatus cutoff factor.
2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL which way you define that. Q. So either you can do it by a fold factor or a cutoff. Is that correct? A. That is correct, yes. Q. And when you do it by a cutoff did you ever hear the term	2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL THE WITNESS: Well, the factor is it depends on how you define it. There's many ways of defining a factor. If you we're still talking about a serostatus cutoff factor. Right? Just to clarify the question.
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	Dec. 54		D 56
1	Page 54 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 56 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	experiments twofold is something that can	2	Q. Is one way to identify if the
3	generally reliably be pulled apart. A single	3	cutoff that's used to determine seroconversion
4		4	
	dilution is hard to tell apart and you make	5	in an ELISA assay to check it against a
5	an error, so it's too variable. Twofold is		fourfold analysis to see whether or not that
6	generally something that you can easily hold	6	cutoff is correct?
7	apart. In an era long gone in which most	7	MR. SANGIAMO: Object to the
8	assays were done by sero dilutions, the	8	form.
9	fourfold has become more and more a standard.	9	THE WITNESS: No. The two are
10	Even it's not a perfect standard but it is an	10	different concepts.
11	average standard that works reasonably well	11	BY MR. KELLER:
12	for that particular purpose. It's really an	12	Q. But they're both the two
13	old concept coming out of sero dilutions.	13	concepts are different ways of showing the
14	The other I think	14	same thing. Correct?
15	MR. SANGIAMO: I'm sorry,	15	A. Not exactly.
16	Doctor. Mr. Keller, what was your	16	MR. SANGIAMO: Object to the
17	last question?	17	form.
18	MR. KELLER: He wasn't done.	18	BY MR. KELLER:
19	Let him finish answering, then you can	19	Q. How is that how are they
20	go back and	20	different?
21	THE WITNESS: It was about the	21	A. One is an absolute number that
22	different ways of determining a factor	22	with a high likelihood differentiates a group
23	or the different factors. So one was	23	into two different states, positive or
24	the fourfold. The other one would be	24	negative or having antibodies or not having
25	one in which you determined the	25	antibodies. The other one is simply a
1	Page 55 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 57 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	variability of the assay and	2	measure derived from the presumed variability
3	determined a factor that clearly	3	of an assay saying you can likely
4	surpasses the variability of the assay	4	differentiate the two but they can be both
5	at a given quantity. And, therefore,	5	positive, for example. I mean, a fourfold
6	it's actually a better way of	6	rise could be something that's already
7	determining a factor in a way because	7	positive and becomes so they're really
8	it tells you, say, for example, your	8	different concepts.
9	assay is very has a very low	9	Q. When you talk about the absolute
10	standard deviation and you can easily	10	number, that's having a set serostatus cutoff
11	determine the twofold difference.	11	as a number. Correct?
12	Then a better cutoff would be whether	12	A. That's right.
13	something is changed by twofold from	13	Q. When you say a highly "a high
14	the start. You can easily imagine	14	likelihood," is there a percentage at which
15	that it depends on the units and it	15	you would expect that you'd have that
16	depends on the accuracy of the assay.	16	probability of it being the number that would
17	BY MR. KELLER:	17	most closely resemble let me strike that.
18		18	What do you mean by "a high
	Q. So doing a fourfold analysis is another way to determine if your cutoff is		· · · · · · · · · · · · · · · · · · ·
19		19	likelihood"? Is there a percentage
20	correct or not?	20	A. It depends on the circumstances.
21	MR. KELLER: Why don't you just	21	MR. SANGIAMO: Object to the
22	read the question back.	22	form.
23	Let me strike the question.	23	THE WITNESS: It depends on the
24	I'll say it over.	24	circumstances. It could be anything
25	BY MR. KELLER:	25	you predefine. I mean, you can

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2	define you can, for example,	2	industry standard for doing, you know,
3	predefine that you want to have a 95	3	immunogenicity testing with ELISA as to what
4	percent likelihood that a serum you	4	percentage you would want to see as a
5	stated within that example is	5	likelihood of the cutoff being correct?
6	seropositive rather than seronegative.	6	A. No.
7	You could define and have a 80 percent	7	Q. Is there a rule of thumb?
8	likelihood or a 50 percent likelihood.	8	MR. SANGIAMO: Object to the
9	Whatever you want to define. And the	9	form.
10	definitions then translate into what	10	THE WITNESS: I don't know.
11	your cutoff would be.	11	BY MR. KELLER:
12	BY MR. KELLER:	12	Q. If you're using an ELISA assay
13	Q. Gotcha.	13	that relies upon a serostatus cutoff that's
14	MR. SANGIAMO: Doctor, it would	14	being used for purposes of determining whether
15	be helpful if you just pause before	15	or not what you're testing will ultimately
16	you start to answer Mr. Keller's	16	protect somebody from getting sick in the
17	question. Give me a chance to	17	future based on that antigen, is there a
18	evaluate whether I need to object or	18	standard that comes to your mind or a
19	not.	19	percentage that comes to your mind that you'd
20	THE WITNESS: Okay.	20	like to see in terms of the accuracy of that
21	BY MR. KELLER:	21	serostatus cutoff?
22	Q. When you say that in those	22	MR. SANGIAMO: Object to the
23	numbers, the 95, 85 or 50 percent, are those	23	form.
24	are those typically written in a protocol	24	THE WITNESS: There are too many
25	or how are those determined? Are they	25	assumptions in your question. And let
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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	determined before you run the before you	2	me just deconstruct them one by one.
3	run the assay or is it something that you	3	BY MR. KELLER:
4	learn from running the assay?	4	Q. Sure.
5	MR. SANGIAMO: Object to the	5	A. So the first assumption is that
6	form.	6	the assay is directly correlated to
7	THE WITNESS: They could be	7	protection. I'm just leaving it there
8	either. It depends for what purposes	8	because you don't know that it in most cases.
9	you are defining them. If you have	9	The second one is that there is
10	already pre-established a serostatus	10	a given predetermined percentage that should
11	cutoff, for example, out of a	11	be one way or the other the way I understood
12	validation experiment and you've used	12	your assay. And that is it really also
13	whatever criteria you've used, you	13	depends on the circumstances.
14	could now run a prospective control of	14	Q. Let me ask you, if there's no
15	that serostatus cutoff with any given	15	correlate of let me back up. You say a
16	set of samples. With any given set of	16	correlation of protection. What do you mean
17	samples you would expect it to be a	17	by that?
18	little different and you could say,	18	A. A correlation of protection
19	okay, does this serostatus cutoff that	19	would be a measure by which you could
20	I have predefined in this new	20	predetermine whether somebody is protected or
21	experiment reliably differentiate the	21	has a very high likelihood of not acquiring a
21 22	negatives, the likely negatives from	21 22	disease. It's different from leave it at
23	- · · · · ·	23	
	the likely positives.		that.
24	BY MR. KELLER: Q. Is there a sort of an	24 25	Q. So if you said that's one of the criteria, whether or not there's a
25			

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Page 62 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 correlate of protection and the other was if 2 that blood sample. Correct? 3 there's a predetermined percentage that you're MR. SANGIAMO: Object to the 4 4 looking for. How are those two related, if form. 5 THE WITNESS: That's true for 5 they're related at all? 6 A. Well, if you have a very strong 6 any assay, yes. 7 correlate of protection, let's use the case 7 BY MR. KELLER: 8 Q. When you say "any assay," would 8 of hepatitis B for example where 10 million 9 international units is fairly well defined that be true for a plaque reduction 10 and accepted as a correlate, and then a 10 neutralization assay? 11 second premise would be that you know that a 11 In principle, yes. vaccine elicits a very high level of 12 Q. You said that -- you mentioned that there's very few correlates of protection protection with that correlate, then you want 13 13 14 to make sure that the accuracy at which you 14 that you're aware of. Can you identify if 15 determine it is also pretty high. So it's in 15 there's any correlates of protection in the the 90 and above percent range. That is, you 16 mumps, measles, rubella vaccine? 17 17 know, it depends on how reliable the assay is Yes, there is one for measles obviously because the correlate can't be very 18 which is not quite straightforward because it 19 was run in an assay format that is no longer precise if the assay to measure is not very 20 precise. And it depends on how well you know 20 run by anybody. And it has been differently 21 that the correlate actually really 21 transcribed into different numbers. But it's 22 correlates. Now, if there have been 22 the only one that has a very clear, 23 prospective randomized double blinded 23 established, recognized correlate. 24 efficacy trials in which a correlate has been 24 Q. So there's no clear established 25 25 clearly and unequivocally established, that's recognized correlate for mumps or rubella? Page 63 Page 65 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 2 sort of that best kind of data to have, A. No. 3 3 exists in very, very few disease. Where that Q. You say that when the -- for exists, you have a very high standard of 4 measles it's comparable because the assay 5 expectation on an assay that would mimic that 5 format has changed over time. What do you kind of a correlate. 6 mean by that? 6 7 7 Q. Gotcha. When you say -- when Well, that -- I don't recall 8 you talk about precision, what do you mean by 8 the exact way how this was established 9 9 precision, "precise"? originally, but I remember that it was 10 A. Well, there is a definition 10 established in a series of cases that were which I'm probably not able to exactly 11 11 linked to the preexistence of antibodies in 12 reproduce. 12 the serum of people who became cases. And 13 Your best understanding. 13 there was a cutoff established which was Q. 14 14 A. It means that the -- and I originally based on a neutralization assay and then translated into an ELISA. And there don't know the exact biometrically definition 15 of precision, but it means that the assay can is debate as to how that translation actually 17 reproducibly and accurately reflect the 17 was done and whether the ELISA number 18 analytical truth. 18 shouldn't be different from the number that 19 O. Of what you're testing? 19 is yet defined in a lot of literature. So 20 Of what you're testing. 20 there's -- some people reported 120 number 21 From the standpoint of an ELISA 21 and others reported 255. The 255, I think, 22 assay, you would want to have an ELISA assay 22 is better researched. 23 that's precise that it's only counting, for 23 Q. So when you say -- when you're 24 example, in the mumps case, mumps antibodies 24 comparing -- is what they did with that versus any other antibodies that may be in neutralizing assay when they compared it to

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	the ELISA assay, is that called did they	$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	be completely concordant because
3	correlate those two assays together? A. You could call that a		you're measuring different things. It depends on the circumstances how
5	A. You could call that a correlation, yes.	5	*
6	Q. Is there other ways to compare	6	important it is for your conclusion from that that they are exactly the
7	two assays to see if they get the same result?	7	same or not. It also depends on how
8	A. Yes, by what you just mentioned	8	variable they both are. For example,
9	previously, for example, by their power to	9	if you compare one relative variable
10	distinguish different groups, negatives and	10	or even fragile assay to one that's
11	positives. Do they distinguish the same	11	very well established and very robust,
12	groups, do they categorize them the same way.	12	you may find different correlations
13	Q. When they do that, is that	13	every time you do the correlation.
14	called a correlation analysis?	14	BY MR. KELLER:
15	MR. SANGIAMO: Object to the	15	Q. Gotcha. So when you're doing
16	form.	16	this concordance assay, you're looking at the
17	BY MR. KELLER:	17	result that are concordant and you're looking
18	Q. Or some other term?	18	at what's also the discordant. Correct?
19	A. I don't know whether what	19	A. That's correct.
20	specific term is really used for that.	20	MR. SANGIAMO: Object to the
21	Q. When you say that they're	21	form.
22	comparing the two groups, if the two groups	22	BY MR. KELLER:
23	can you describe that process, how you do	23	Q. Is there a standard way to
24	that?	24	describe those discordant rights as false
25	A. Well, if you have a group, say,	25	positives or false negatives? Do those terms
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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	of a given number of positives, a given	2	sound familiar to you?
3	number of negatives and they measure them in	3	MR. SANGIAMO: Object to the
4	the two assays and you put them in a 4-by-4	4	form.
5	table in which you see essentially how the	5	THE MUTNECO TI 4 11 41 4
6			THE WITNESS: That well, that
6	different assays classify them, you will see	6	·
7	different assays classify them, you will see those that are positive in both assays, that	l	is a way they are sometimes described, but that assumes that you know the
	different assays classify them, you will see those that are positive in both assays, that are negative in one and positive in the other	6	is a way they are sometimes described,
7	those that are positive in both assays, that	6 7	is a way they are sometimes described, but that assumes that you know the
7 8	those that are positive in both assays, that are negative in one and positive in the other	6 7 8	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here
7 8 9	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you	6 7 8 9	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just
7 8 9 10	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a	6 7 8 9 10	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find
7 8 9 10 11	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation	6 7 8 9 10 11	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's
7 8 9 10 11 12	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing.	6 7 8 9 10 11 12	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily
7 8 9 10 11 12 13	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing,	6 7 8 9 10 11 12 13	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or
7 8 9 10 11 12 13 14	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information	6 7 8 9 10 11 12 13 14	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive.
7 8 9 10 11 12 13 14 15	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent	6 7 8 9 10 11 12 13 14 15	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER:
7 8 9 10 11 12 13 14 15 16	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up?	6 7 8 9 10 11 12 13 14 15 16	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a
7 8 9 10 11 12 13 14 15 16 17 18	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the	6 7 8 9 10 11 12 13 14 15 16 17	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the
7 8 9 10 11 12 13 14 15 16 17 18 19 20	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: All assays are artifactual. They're all a specific	6 7 8 9 10 11 12 13 14 15 16 17	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the truth and the other one for the experiment,
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: All assays are artifactual. They're all a specific creation of measures to approximate,	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the truth and the other one for the experiment, then, yes, you can use those terms. Q. So in the case where you're in the measles context, you are the folks in
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: All assays are artifactual. They're all a specific creation of measures to approximate, to approximate the true biological	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the truth and the other one for the experiment, then, yes, you can use those terms. Q. So in the case where you're in the measles context, you are the folks in those assays were doing a concordance analysis
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: All assays are artifactual. They're all a specific creation of measures to approximate, to approximate the true biological nature of what you're measuring. So	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the truth and the other one for the experiment, then, yes, you can use those terms. Q. So in the case where you're in the measles context, you are the folks in those assays were doing a concordance analysis between a neutralizing assay and an ELISA
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: All assays are artifactual. They're all a specific creation of measures to approximate, to approximate the true biological nature of what you're measuring. So you're measuring two different assay	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the truth and the other one for the experiment, then, yes, you can use those terms. Q. So in the case where you're in the measles context, you are the folks in those assays were doing a concordance analysis between a neutralizing assay and an ELISA assay. Is that correct?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	those that are positive in both assays, that are negative in one and positive in the other or negative in both assays. And then you can it's more I would call that a concordance testing rather than a correlation testing. Q. And those concordance testing, how important is that that the information match up and how important is it to the extent they don't match up? MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: All assays are artifactual. They're all a specific creation of measures to approximate, to approximate the true biological nature of what you're measuring. So	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	is a way they are sometimes described, but that assumes that you know the truth, which is sometimes neither here nor there. Sometimes they're just simply different and you have to find out why they're different if it's important. But it doesn't necessarily mean that there's a false negative or a false positive. BY MR. KELLER: Q. Is there a A. But if you take one for the truth and the other one for the experiment, then, yes, you can use those terms. Q. So in the case where you're in the measles context, you are the folks in those assays were doing a concordance analysis between a neutralizing assay and an ELISA

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2	that. I'm not sure what they ever did. I	2	MR. KELLER: Hey, Bob, it's
3	just found that in some of the papers that	3	Jeff. I'm just going to put the
4	were written relatively shortly after the	4	microphone closer the Polycom
5	observation, that there was a certain titer	5	closer to you to the witness so you
6	that correlated with a low likelihood of	6	can hear. Let's carry on.
7	becoming a measles case, all of a sudden that switched to ELISA titers and the ELISA titers	7	BY MR. KELLER:
8		8	Q. You said that typically you're
9	may or may not have been really the same	9	looking the regulatory folks are looking
10	numbers. So I think this is not a formal	10	for noninferiority. Can you define what you mean by that?
11	concordance testing, at least I'm not aware	11	<u> </u>
12	of it. It is more an error in transcription.	12	A. Yeah. Noninferiority would be
13 14	Q. I see. A. And then later on actually the	13 14	noninferiority of say, for example, a seroconversion rate. And if a vaccine A has
	9		a seroconversion rate of X and vaccine B
15	255 was based on a to the best knowledge at the time an effort to correlate the ELISA	15	
16	as it was then run with the old data in the	16	which contains supposedly the same components
17 18		17 18	or is supposed to elicit the same protection
19	literature.	19	as a seroconversion rate; B, the noninferiority would be defined by immunizing
20	Q. And that correlation, how is that correlation used for purposes of from	20	people, measuring the antibodies, creating
20	a regulatory standpoint?	$\begin{vmatrix} 20 \\ 21 \end{vmatrix}$	the difference between the seroconversion
22	A. I don't know exactly. Because	$\begin{vmatrix} 21\\22\end{vmatrix}$	rates and building a confidence interval
23	just to remind you, the basis of licensure	$\begin{vmatrix} 22 \\ 23 \end{vmatrix}$	around the differences in seroconversion rate
23	for these vaccines is generally	24	and postulating that. That is not greater
25	noninferiority which is not an absolute	25	than a given number. For example, 10 percent
23	<u> </u>	23	
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2	cutoff alone. So how was it used for	2	or 5 percent, whatever is appropriate. That
3	regulatory purposes, I don't think it was	3	would often be the criterion for declaring
4	regulatory purposes, r don't timik it was	4	that something is noninferior and an
5	(Interruption.)	5	extension of that similar, even though what's
6		6	really being tested is not inferiority, that
7	MR. SANGIAMO: Mr. Keller, if	7	could apply to concomitant use in which you
8	anyone enters the conference, they	8	give it with another vaccine or it could
9	ought to say who they are, but I would	9	sometimes, more rarely, but sometimes also
10	also appreciate if people not enter	10	apply to the de novo licensure of the
11	and then leave. And perhaps if anyone	11	vaccine.
12	wants to enter, they can contact	12	Q. When you're talking about you
13	someone here find out when there's a	13	mentioned a 4-by-4 table as part of a
14	break and they can enter during a	14	concordance analysis. Can you define what you
15	break and announce themselves at that	15	mean by that?
16	time.	16	A. Just a table that classifies
17	MR. BEGLEITER: I'll do that.	17	the positives by one assay, the positives by
18	The reason why I got cut off, I don't	18	the other assay, the negatives by one assay,
19	think the witness is speaking into a	19	the negatives by the other assay and how that
20	microphone, not being picked up by the	20	overlaps.
21	microphone. I was trying to see if I	21	Q. And how are those for
22	could get a better way of hearing. I	22	purposes of comparing, for example, an ELISA
23	apologize for the disruption. I would	23	to a plaque reduction neutralization assay,
24	ask that maybe he speak a little	24	how would you is that a typical form you
25	louder.	25	would expect to see in a concordance analysis
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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	of those two assays?	2	A. Yes. Yes.
3	MR. SANGIAMO: Object to the	3	Q. So you've seen a concordance
4	form.	4	analysis comparing a plaque reduction
5	THE WITNESS: Yes, something	5	neutralization assay and an ELISA assay?
6	like that. You would find some kind	6	A. Yes.
7	of an analysis that would tell you to	7	Q. Do you recall seeing a 4-by-4
8	which extent the assays not so much	8	chart for that?
9	measure the same thing as classify	9	A. Yes, I think I do, but I don't
10	people the same way, which is	10	remember the details.
11	concordance.	11	Q. In that assay, do you recall
12	BY MR. KELLER:	12	why would the percentages of discordant
13	Q. So when they classify the same	13	results in that assay be important?
14	way or they discord it in the way they	14	MR. SANGIAMO: Object to the
15	classify things, have you ever worked on a	15	form.
16	concordance assay between a plaque reduction	16	THE WITNESS: Well, because they
17	neutralization and an ELISA in your	17	give you a general idea whether the
18	MR. SANGIAMO: Object to the	18	classification is the same.
19	form.	19	BY MR. KELLER:
20	BY MR. KELLER:	20	Q. When you say "the classification,"
21	Q professional experience over	21	what do you mean by classification?
22	30 years?	22	A. Of positives and negatives in
23	A. I have not really run the assay	23	the assay.
24	lab, so I have not worked on any concordance	24	MR. SANGIAMO: Jeff, we've been
25	assays. I have, of course, seen them.	25	going about an hour and ten minutes.
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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. When you say you've seen them,	2	If you reach a good breaking point
3	can you describe how you came about to see	3	MR. KELLER: We can take a break.
4	them? Let me just strike that.	4	VIDEOGRAPHER: Off the record at
5	What do you mean by see them?	5	10:13. This will end disc number one.
6	A. I've seen the results of	6	
7	whatever the lab did to provide the data and	7	(A recess was taken.)
8	then I sometimes try to understand them.	8	
_			
9	Q. And these 4-by-4 tables, how are	9	VIDEOGRAPHER: Back on the
9 10	Q. And these 4-by-4 tables, how are they useful?	10	VIDEOGRAPHER: Back on the record at 10:25. Beginning of disc
-		-	
10	they useful?	10	record at 10:25. Beginning of disc
10 11	they useful? A. Well, they tell you what	10 11	record at 10:25. Beginning of disc number two.
10 11 12	they useful? A. Well, they tell you what percentage of results are the same and what	10 11 12	record at 10:25. Beginning of disc number two. BY MR. KELLER:
10 11 12 13	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are	10 11 12 13	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from
10 11 12 13 14	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a	10 11 12 13 14	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical
10 11 12 13 14 15	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you	10 11 12 13 14 15	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive
10 11 12 13 14 15 16	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you find out whether an assay, two assays	10 11 12 13 14 15 16	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive director of vaccine integration, did you
10 11 12 13 14 15 16 17	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you find out whether an assay, two assays classify things the same way. You would not expect them generally to do that exactly. In	10 11 12 13 14 15 16 17	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive director of vaccine integration, did you physically move to the United States?
10 11 12 13 14 15 16 17 18	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you find out whether an assay, two assays classify things the same way. You would not	10 11 12 13 14 15 16 17 18	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive director of vaccine integration, did you physically move to the United States? A. Yes.
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10 11 12 13 14 15 16 17 18 19 20 21	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you find out whether an assay, two assays classify things the same way. You would not expect them generally to do that exactly. In some cases they do it pretty well and other cases not so much. Q. And for the ones that you've reviewed with regard to a plaque reduction	10 11 12 13 14 15 16 17 18 19 20 21	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive director of vaccine integration, did you physically move to the United States? A. Yes. Q. And that was in November of 2000, around there? A. Yes. Q. And when you and you
10 11 12 13 14 15 16 17 18 19 20 21 22 23	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you find out whether an assay, two assays classify things the same way. You would not expect them generally to do that exactly. In some cases they do it pretty well and other cases not so much. Q. And for the ones that you've reviewed with regard to a plaque reduction neutralization assay and an ELISA, have you	10 11 12 13 14 15 16 17 18 19 20 21 22 23	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive director of vaccine integration, did you physically move to the United States? A. Yes. Q. And that was in November of 2000, around there? A. Yes. Q. And when you and you testified earlier that your job duties didn't
10 11 12 13 14 15 16 17 18 19 20 21 22	they useful? A. Well, they tell you what percentage of results are the same and what results are different, what percentage are different in a classification assay, in a classification exercise I should say. So you find out whether an assay, two assays classify things the same way. You would not expect them generally to do that exactly. In some cases they do it pretty well and other cases not so much. Q. And for the ones that you've reviewed with regard to a plaque reduction	10 11 12 13 14 15 16 17 18 19 20 21 22	record at 10:25. Beginning of disc number two. BY MR. KELLER: Q. Dr. Schodel, when you moved from the clinical the director of clinical vaccine research in Europe to the executive director of vaccine integration, did you physically move to the United States? A. Yes. Q. And that was in November of 2000, around there? A. Yes. Q. And when you and you

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	from the executive director of vaccine	2	came to the US in this executive director of
3	integration to executive director of biologics	3	vaccine integration position, did you stop
4	in vaccine clinical research. Is that	4	having responsibilities with regard to vaccine
5	correct?	5	clinical research?
6	MR. SANGIAMO: Object to the form.	6	A. No. I still had responsibility for vaccine clinical research but primarily
8	THE WITNESS: I don't think I	8	at that particular time, initially, primarily
9	said that.	9	on varicella-containing vaccines.
10	BY MR. KELLER:	10	Q. That was part of the ProQuad
11	Q. Let me ask you the question.	11	application?
12	Did your duties change when you changed	12	A. ProQuad, Zostavax, yes. And
13	positions?	13	varicella itself, Varivax.
14	A. When I came to the US, I	14	Q. You said that you worked for the
15	yes, my duties did change. I no longer had	15	joint venture in Europe for some of the did
16	the EU clinical trials. I still was involved	16	you work on the joint venture in getting the
17	with the joint venture but much less	17	MMR vaccine approved in Europe?
18	frequently. And I had this vaccine	18	A. Certainly not the initial
19	integration role that I described to you	19	approval because that had been approved way
20	previously, which I did not have before.	20	before I came. But in subsequent approvals I
21	Q. You also testified that you had	21	may have occasionally been a part of the
22	some role with respect to the end expiry study	22	discussions with the joint venture. Most
23	for the mumps vaccine. Correct?	23	likely because I was on the oversight
24	A. Did I have a role? No, I did	24	committee, so called JDVMC.
25	not have a direct role in that study at all.	25	Q. And so the are you aware that
	Page 79		Page 81
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	I have not designed it. So, no, I did not	2	Merck ultimately changed its label with regard
3	have a direct role. But some of the people	3	to its end expiry potency?
4	at points reporting to me had a direct role.	4	A. Yes.
5	Q. And then they would report to	5	Q. Okay. Do you know whether or
6	you what was happening with that study?	6	not they changed a label with regard to its
7	A. Among other studies, yes.	7	end expiry potency in Europe as well?
8	Q. With particular to that end	8	A. I don't remember. But there is
9	expiry study, did they ask you for any of your	9	a compendial specification in Europe.
10	advice?	10	Q. In that compendia, do you know
11	A. In all probability, yes.	11	if that was changed similar to what was done
12	Q. And did you review any	12	in the US in terms of end expiry potency?
13	documentation related to that study?	13	A. Not to my knowledge.
14	A. Probably, yes.	14	Q. Do you recall submitting
15	Q. Did you have any did you have	15	the results of Protocol 007 let me strike
16	any role whatsoever before you moved from	16	that.
17	Europe to the United States on that end expiry	17	The end expiry study we're
18	study?	18	talking about, you understand to be Protocol
19	A. I have a vague recollection	19	007. Correct?
20	of as a direct role, no. I have a vague	20	A. Yes.
21	recollection of discussions during the time I was in Europe for Merck but not in the	21 22	Q. When I say "Protocol 007," you understand that to be the end expiry study.
22	was in Europe for wierek but not in the		
22		22	Correct?
23	interim periods. Neither information nor any	23	Correct?
		23 24 25	Correct? A. Yes. Q. So Protocol 007, do you know if

	Page 82		Page 84
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
	hat was ever submitted to the EMA for	2	Q. And you understand that Protocol
	ourposes of changing the label?	3	007 had reported on two different assays.
4	A. You have two parts of the	4	Correct?
	question.	5	A. Yes. Correct.
6	Q. Let me start over. I'll make it	6	Q. One assay was the ELISA?
	simpler.	7	A. Yes.
8	Do you know if Protocol 007 was	8	Q. The other assay was a plaque
	ever reported to the EMA?	9	reduction neutralization assay?
10	A. It would have been reported,	10	A. Yes.
	ves.	11	Q. That PRN when I say PRN, you
12	Q. Why would it have been reported?	12	understand that to be plaque reduction
13	A. Because there is a general I	13	neutralization assay?
	hink it might even be a law that the or	14	A. Yes.
	at least there's guidance that any clinical	15	Q. That PRN assay had been
	studies with licensed vaccines have to be	16	modified. Are you aware of how the assay was
	eported.	17	modified?
18	Q. Do you know what the CDC is?	18	MR. SANGIAMO: Object to the
19	A. Excuse me?	19	form.
20	Q. The CDC?	20	THE WITNESS: Not in all detail,
21	A. Yes, I do know what the CDC is.	21	but I do remember that the FDA had
22	Q. Did you have any did you ever	22	urged Merck to run an assay that was
	nave any communication with the CDC?	23	different in format than the assay
24	A. Yes.	24	they were at that time running.
25	Q. In what context?	25	BY MR. KELLER:
	Page 83		Daga 95
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 85 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	A. For example, the ACIP.	2	Q. In this were you at that
3	Q. Did you ever speak in front of	3	meeting when that was discussed?
4 tl	he ACIP?	4	MR. SANGIAMO: Object to the
5	A. Yes, I have asked questions	5	form.
6 tl	here for sure.	6	THE WITNESS: I don't remember.
7	Q. In regard to the MMR vaccine?	7	BY MR. KELLER:
8	A. No, I don't think so.	8	Q. You say that the assay was
9	Q. Did you ever have any	9	modified. Do you remember whether or not it
10 c	conversations with the CDC regarding Protocol	10	was modified with the use of rabbit anti-IgG,
	007?	11	antihuman strike that.
12	A. No, I don't remember that	12	Do you recall whether the PRN
	either.	13	assay that was modified was modified with the
14	Q. Do you recall Merck ever	14	use of adding rabbit human IgG?
	eporting the results of Protocol 007 to the	15	A. That is my understanding now,
	CDC?	16	but I didn't remember that quite frankly. I
17	A. They were published, so I guess	17	wasn't sure whether it was that or a
	hat certainly they certainly could have	18	complement anti-IgG.
	ead them. Whether they were independently	19	Q. And complement is different from
	eported to the CDC, I wouldn't see why, but	20	rabbit anti-IgG?
	don't know.	21	A. Yes, it is. Yes, it is.
22	Q. Where were the results of the	22	Q. Have you ever heard of anybody
	Protocol 007 published?	23	using rabbit antihuman IgG in a plaque
24	A. I don't remember, but it's I	24	reduction neutralization assay?
	hink they were published.	25	A. Yes.
(positioned.		

22 (Pages 82 - 85)

	D 0/		D 00
1	Page 86 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 88 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Where did you hear that from?	2	Q. Is it based on your 30 years'
3	A. It's in the scientific literature.	3	experience working with clinical studies
4	Q. When was that literature	4	including plaque reduction neutralization
5	written?	5	assays and ELISA assays?
6	A. It's old. I think it comes out	6	MR. SANGIAMO: Object to the
7	of NIH or FDA. I don't remember anymore.	7	form.
8	Q. That was done in the early '70s.	8	BY MR. KELLER:
9	Does that make	9	Q. We're entitled to your best
10	A. Probably right.	10	understanding.
11	Q. Do you recall any had Merck	11	MR. SANGIAMO: But not speculation.
12	ever used this method of using a rabbit	12	Right?
13	antihuman IgG?	13	BY MR. KELLER:
14	A. I don't know.	14	Q. Not speculation.
15	Q. You don't know. Have you ever	15	A. Well, I couldn't offer anything
16	seen any other manufacturer use it?	16	but speculation because at the end of the day
17	A. I have been told that it has	17	I have not run any assays with the addition
18	been used by other manufacturers, but I don't	18	or without the addition of IgG. So I
19	remember seeing it.	19	wouldn't know the effect.
20	Q. Who told you that?	20	Q. Let me ask you differently. Do
21	A. I don't remember.	21	you recall any discussions do you recall
22	Q. Was it GlaxoSmithKline in their	22	reviewing any documentation at Merck that
23	MMR vaccine that they used rabbit anti-IgG?	23	criticized the use of the rabbit anti-IgG in
24	A. I think they did, yes, but I'm	24	that assay?
25	not sure.	25	A. No, not specifically.
	Page 87		Page 89
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Do you know how when did you	2	Q. Do you recall any you say
2			
3	learn about this?	3	
4	learn about this? A. I don't know. I mean, it could	3 4	not what about generally?
	A. I don't know. I mean, it could		not what about generally? A. Well, what do you mean with
4	A. I don't know. I mean, it could have been through a publication, it could	4	not what about generally? A. Well, what do you mean with generally? I mean
4 5	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay.	4 5	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that
4 5 6	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to	4 5 6	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally
4 5 6 7	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use	4 5 6 7	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering
4 5 6 7 8	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to	4 5 6 7 8	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally
4 5 6 7 8 9	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction	4 5 6 7 8 9	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall
4 5 6 7 8 9 10	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay?	4 5 6 7 8 9 10	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit
4 5 6 7 8 9 10 11	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No.	4 5 6 7 8 9 10 11	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not.
4 5 6 7 8 9 10 11 12	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever	4 5 6 7 8 9 10 11 12	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just
4 5 6 7 8 9 10 11 12 13	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the	4 5 6 7 8 9 10 11 12 13	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know
4 5 6 7 8 9 10 11 12 13 14	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007?	4 5 6 7 8 9 10 11 12 13 14	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity.
4 5 6 7 8 9 10 11 12 13 14 15	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes.	4 5 6 7 8 9 10 11 12 13 14 15	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on
4 5 6 7 8 9 10 11 12 13 14 15 16	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the analysis of what impact the rabbit antihuman	4 5 6 7 8 9 10 11 12 13 14 15 16	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall
4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the	4 5 6 7 8 9 10 11 12 13 14 15 16 17	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall specifically the use of anti-IgG? No. In
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the analysis of what impact the rabbit antihuman IgG had on that assay?	4 5 6 7 8 9 10 11 12 13 14 15 16 17	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall specifically the use of anti-IgG? No. In fact, I didn't even remember it until
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the analysis of what impact the rabbit antihuman IgG had on that assay? A. No.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall specifically the use of anti-IgG? No. In fact, I didn't even remember it until recently.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the analysis of what impact the rabbit antihuman IgG had on that assay? A. No. Q. Are you familiar what effect the	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall specifically the use of anti-IgG? No. In fact, I didn't even remember it until recently. Q. Gotcha. Do you recall ever
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the analysis of what impact the rabbit antihuman IgG had on that assay? A. No. Q. Are you familiar what effect the rabbit antihuman IgG does have on neutralization? A. Not in detail.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall specifically the use of anti-IgG? No. In fact, I didn't even remember it until recently. Q. Gotcha. Do you recall ever seeing any having any discussions at Merck where they where somebody criticized the
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I don't know. I mean, it could have been through a publication, it could have been through hearsay. Q. Do you recall ever speaking to somebody at GlaxoSmithKline regarding the use of rabbit anti-IgG in a plaque reduction neutralization assay? A. No. Q. Have you ever did you ever look at the validation documents regarding the PRN assay in Protocol 007? A. The Merck one, yes. Q. Do you recall reviewing the analysis of what impact the rabbit antihuman IgG had on that assay? A. No. Q. Are you familiar what effect the rabbit antihuman IgG does have on neutralization? A. Not in detail.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	not what about generally? A. Well, what do you mean with generally? I mean Q. Do you recall any documents that generally A. I said I was answering specifically your question whether I recall any documentation on the use of rabbit anti-IgG. And, no, I do not. Q. You said specifically. I just want to know A. That was the specificity. Not I mean, do I recall assays on discussions on PRN, yes. Do I recall specifically the use of anti-IgG? No. In fact, I didn't even remember it until recently. Q. Gotcha. Do you recall ever seeing any having any discussions at Merck

1	Page 90 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 92 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. And do you recall any discussions	2	other in other words, if you run it
3	about the use of rabbit anti-IgG, its effect	3	several times, do you get the same value, is
4	on the PRN assay?	4	it does it have a high standard deviation
5	A. No.	5	or not.
6	Q. You said that you reviewed some	6	Q. How would the rabbit antihuman
7	information, scientific information that was	7	IgG affect the robustness?
8	published a long time ago regarding the use of	8	A. It's a biologic reagent, so one
9	rabbit anti-IgG in a plaque reduction	9	of the ways it would potentially affect it is
10	neutralization assay. Do you recall gaining	10	that it could vary over time.
11	any understanding other than that publication?	11	Q. Would it have any impact on
12	MR. SANGIAMO: Object to the	12	do you understand the term "specificity"?
13	form.	13	A. Yes, I do.
14	BY MR. KELLER:	14	Q. And with respect to specificity,
15	Q. Do you understand my question?	15	is do you understand the term as it's to be
16	A. I'm not sure I'm not sure if	16	used in a PRN assay?
17	I do.	17	A. Yes.
18	Q. I'll rephrase it then. Other	18	Q. What's your understanding of
19	than the review of that early scientific paper	19	specificity with respect to
20	that you testified to earlier regarding the	20	A. It's the ability to distinguish
21	use of rabbit anti-IgG in a plaque in a PRN	21	between a signal that is caused by what you
22	assay, do you recall gaining any understanding	22	want to measure, antiviral immune response as
23	other than that paper from any other source?	23	opposed to something else, something that is
24	MR. SANGIAMO: Object to the	24	in the serum, something that could be against
25	form.	25	another virus or whatever.
	Page 91		Page 93
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	THE WITNESS: As I said, I	2	Q. So specificity for a plaque
3	specifically did not have I don't	3	reduction neutralization assay, you would be
4	remember having specific discussions	4	looking at whether or not the neutralization
5	about the use or nonuse of rabbit IgG	5	was caused by something other than the in
6	in the assay, I mean, as opposed to	6	the case of the mumps assay, the mumps vaccine
7	the assay.	7	versus some other let me start that over.
8	BY MR. KELLER:	8	In the case of a plaque
9	Q. Based on your 30 years'	9	reduction neutralization assay, when you look
10	experience in running and overseeing clinical	10	at specificity, if you're testing mumps, you'd
11	studies, do you have an understanding how the	11	want to make sure that the neutralization was
12	use of rabbit antihuman IgG would affect a	12	caused by the mumps vaccine as compared to
13	plaque reduction neutralization assay?	13	some other antibody or any other effect.
14	A. Well, in a general sense,	14	Correct?
15	adding a factor to an assay might increase	15	MR. SANGIAMO: Object to the
16	its sensitivity. It might decrease its	16	form.
17	robustness or increase it. So it could go	17	THE WITNESS: That's true for
18	either way.	18	any assay. You always want to make
19	Q. When you say "sensitivity," what	19	sure that you're actually measure what
20	do you mean by that?	20	you want to measure and not something
21	A. It's the ability to pick up	21	that is influenced by something else.
<u> </u>		22	It could be influenced by serum alone
22	small amounts of antibody from a background.	22	it could be illitacticed by scrain alone
	small amounts of antibody from a background. Q. Gotcha. And when you say	23	or by other viruses or by schmutz. I
22			-

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	Page 94		Page 9
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAI
2	measuring, you want to make sure that	2	007?
3	you reliably measure what you want to	3	A. As any reagents in an assay, it
4	measure.	4	likely would have an impact on specificity.
5	BY MR. KELLER:	5	Q. But you're not aware of Merck
6	Q. So in a plaque reduction	6	ever analyzing what that impact was?
7	neutralization like, for example, in	7	A. No. And I certainly don't know
8	Protocol 007 when they did a plaque reduction	8	if they have done it. I just don't know.
9	neutralization assay using the mumps vaccine,	9	Q. You just don't recall?
10	when they do you know whether or not they	10	A. No, I well, yeah, I don't
11	validated and tested whether or not that assay	11	recall it, I don't know.
12	was specific and what percentage of	12	Q. Would you
13	specificity it had?	13	A. I mean, it's possible that
14	A. I do not remember that the	14	they've done it and they haven't told me.
15	percentage of specificity was specifically	15	It's always possible that I forgot it, but I
16	analyzed in the validation protocol. I do	16	don't know.
17	remember that the assay was validated and the	17	Q. Would you be surprised with the
18	validation was accepted by the FDA.	18	use of the rabbit antihuman IgG that they
19	Q. Do you know whether or not do	19	wouldn't have tested this specificity
20	you recall any discussions at Merck regarding	20	MR. SANGIAMO: Object to the
21	the specificity of the of Protocol 007's	21	form.
22	PRN assay?	22	BY MR. KELLER:
23	A. Vaguely. As with any assay,	23	Q since you're adding that into
24	you would have you would have potentially	24	a into the test that you're doing?
25	specificity issues.	25	MR. SANGIAMO: Object to the
	Page 95		Page 9'
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAI
2	Q. Do you recall if there were	2	form.
3	specificity issues with this particular PRN	3	THE WITNESS: Would I be
4	assay in Protocol 007?	4	surprised? I think as part of the
5	A. Well, I don't know that the	5	as part of the assay analysis, it
6	specificity, as I said, has ever been	6	might be reasonable to do it. I would
7	analyzed, so I can't tell you for sure.	7	not be too surprised if that
8	Q. Do you recall there ever	8	particular analysis had not been done.
9	Merck ever doing any analysis as to whether or	9	BY MR. KELLER:
10	not the use of the rabbit antihuman IgG had	10	Q. Have you, as part of your
11	any impact on the specificity of the PRN assay	11	research in looking strike that.
12	in Protocol 007?	12	Do you recall there being any
13	A. No, I do not.	13	discussion at Merck that the use of the rabbit
14	Q. Do you ever have an opinion	14	antihuman IgG had a significant fold increase
15	yourself about that?	15	in the neutralization of that assay?
16	A. It would be speculation because	16	A. Well, again, I've already said
17	I wouldn't have a comparison so I wouldn't	17	that several times. I don't I do remember
18	know what specificity to expect in comparison	18	that Merck, under guidance from the FDA,
10	because the analysis hasn't been done, so I	19	tried to make particularly sensitive assay,
19		20	but I don't remember any discussion as to the
19	really can't tell you.		IgG.
19 20	Q. I see. Do you have any, based	21	igo.
19 20		21 22	Q. Sure.
19 20 21	Q. I see. Do you have any, based		-
19 20 21 22	Q. I see. Do you have any, based on your 30 years of experience, have any	22	Q. Sure.

1	Page 98	1	Page 100
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. In your 30 years of experience,	2	assays in the past, you've overseen those
3	would it be a concern to you if the use of	3	assays used in other context. Correct?
4	rabbit antihuman IgG would increase the	4	A. No, not correct.
5	neutralization by a hundredfold?	5	Q. You've never reviewed the
6	MR. SANGIAMO: Object to the	6	protocols of the plaque reduction neutralization
7	form.	7	assay before?
8	THE WITNESS: No, because all	8	A. They were not run in my lab. I
9	the assays are relative and have to be	9	have I mean, in the course of my life,
10	validated in and by themselves. I	10	I've seen protocols. I've seen validation
11	mean, a hundredfold increase of	11	protocols and I've seen validation results.
12	something, you know, PCR assays are	12	But and I've read them. But I wasn't the
13	sometimes a lot more sensitive than	13	one who wrote them or put them in place.
14	other assays, but it might have less	14	Q. Gotcha. And as part of your
15	specificity because it's easier prone	15	consulting duties since you left Merck, have
16	to contamination. So in principle,	16	you ever discussed with one of your clients
17	no.	17	these are the plaque reduction neutralization
18	BY MR. KELLER:	18	assays?
19	Q. So would you expect when Merck	19	A. With several, yes.
20	validated the PRN assay with the antihuman	20	Q. Did you review those protocols?
21	IgG, that they would have somehow tried to	21	A. No, not in detail. In general.
22	control for that affect on specificity?	22	My advice is usually more strategic.
23	MR. SANGIAMO: Object to the	23	Q. In any of the plaque reduction
24	form.	24	neutralization assays, protocols or
25	THE WITNESS: Well, you're	25	discussions that you've had in your 30 years
	Page 99		Page 101
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	assuming that they have analyzed and	2	of experience, have you ever discussed whether
3	indeed and that specificity and	3	or not to use a mock serum control versus a
4	then they would have to control for it	4	serum control?
5	because it wasn't what was expected.	5	A. Yes.
6	So there's too many assumptions in	6	Q. What is the difference, reason
7	there.	7	why you'd use one or the other?
8	BY MR. KELLER:	8	A. In fact, I've discussed using
9	Q. Gotcha. Let me ask you	9	various kinds of mock serum or serum
10	differently then. Do you know whether or not	10	controls. They all have their pros and cons.
11	Merck used a serum negative control versus a	11	A none negative serum control has the
12	mock control in their PRN assay in Protocol	12	advantage that it is in the right matrix
13	007?	13	serum that you want to measure in, but it
14	A. No.	14	doesn't necessarily represent all sera. A
15	Q. Do you know what difference that	15	mock depleted serum control in which the
16	would make with respect to the use of rabbit	16	specific antibody has been depleted by
17	anti-IgG in terms of determining whether or	17	absorption has the advantage that you're
18	not the use of that addition would change the	18	measuring in a matrix in which it would
19	specificity of the vaccine of the assay?	19	normally be the analyte but it has been
20	MR. SANGIAMO: Object to the	20	artificially removed. It's also artificial
21	form.	21	but it has some other advantages. Then there
22	THE WITNESS: No, I don't.	22	are other mock controls which appear to mimic
23	BY MR. KELLER:	23	the composition of serum without being serum
24	Q. When you have overseen the	24	themselves, for example, by adding albumin
25	running of plaque reduction neutralization	25	and other things. They have the advantage
		1	

26 (Pages 98 - 101)

1	Page 102	1	Page 104
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	that they're highly reproducible. But the	2	on it depends on whether it's a
3	disadvantage that they're not as close to all	3	monoclonal antibody or polyclonal
4	the kinds of things we do know in serum.	4	serum, it will bind to different
5	So there's all kinds of	5	things on immunoglobulin G.
6	different ways of creating these controls.	6	BY MR. KELLER:
7	I've seen many of them applied. I don't	7	Q. Does it also bind to other
8	recall any major problems with any of them as	8	antibodies?
9	such other than that with any of these	9	A. That's not something that I can
10	controls containing serum, it's difficult to	10	answer in general because it depends on how
11	figure out exactly what you have to control	11	it's been made and how it's been absorbed.
12	for because sera are variable. In other	12	So if depending on whether it is made with
13	words, you have one control, but you can't	13	IgG as the immunizing principle and it's not
14	control for all the things that are in sera	14	cross absorbed, it might bind to other
15	other than specific antibodies.	15	antibodies or not. It really depends on what
16	Classic one is that, for	16	it is.
17	example, if a serum is bloody, you generally	17	Q. What human antibodies have IgG
18	don't use it because it has live erythrocytes	18	in it, what percentage, if you know?
19	in it. That influences some assays, not	19	A. It's the predominant antibody
20	others. So that's a wide field. They have	20	in serum.
21	to be appropriate for the assay. It doesn't	21	Q. So antihuman IgG would bind
22	necessarily mean that one is better than the	22	let me back up for a second. Let me come back
23	other.	23	to that in a minute. Let's keep pushing
24	Q. Let me ask you a question about	24	forward. Let me ask you a couple of
25	that in a little more detail. Do you have any	25	questions.
	Page 103		Page 105
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	understanding as to how rabbit antihuman IgG	2	In a PRN assay, you've testified
3	would interact with serum that may have other	3	that specificity is important to make to
4	antibodies in it?	4	make sure that the neutralization that you're
_			make sure that the neutranzation that you're
5	A. No, I don't.	5	
6		5 6	getting in that assay is actually caused by
6	Q. You don't. Do you recall any		
6 7	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit	6	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct.
6	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum?	6 7	getting in that assay is actually caused by the antigen that you're testing for. Correct?
6 7 8 9	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any	6 7 8	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form.
6 7 8 9 10	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG.	6 7 8 9 10	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER:
6 7 8 9 10 11	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough.	6 7 8 9 10 11	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule
6 7 8 9 10 11 12	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question	6 7 8 9 10 11 12	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque
6 7 8 9 10 11 12 13	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about	6 7 8 9 10 11 12 13	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what
6 7 8 9 10 11 12 13 14	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see	6 7 8 9 10 11 12 13 14	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity?
6 7 8 9 10 11 12 13 14 15	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the	6 7 8 9 10 11 12 13 14 15	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No.
6 7 8 9 10 11 12 13 14 15 16	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected	6 7 8 9 10 11 12 13 14 15 16	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent
6 7 8 9 10 11 12 13 14 15 16 17	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry.	6 7 8 9 10 11 12 13 14 15 16 17	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was
6 7 8 9 10 11 12 13 14 15 16 17 18	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry. Q. Let me ask you a question a	6 7 8 9 10 11 12 13 14 15 16 17	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was neutralizing wasn't the antigen you were
6 7 8 9 10 11 12 13 14 15 16 17 18	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry. Q. Let me ask you a question a little more scientific. What does antihuman	6 7 8 9 10 11 12 13 14 15 16 17 18	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was neutralizing wasn't the antigen you were testing, that would be a concern, wouldn't
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry. Q. Let me ask you a question a little more scientific. What does antihuman IgG bind to?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was neutralizing wasn't the antigen you were testing, that would be a concern, wouldn't that?
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry. Q. Let me ask you a question a little more scientific. What does antihuman IgG bind to? MR. SANGIAMO: Object to the	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was neutralizing wasn't the antigen you were testing, that would be a concern, wouldn't that? MR. SANGIAMO: Object to the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry. Q. Let me ask you a question a little more scientific. What does antihuman IgG bind to? MR. SANGIAMO: Object to the form.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was neutralizing wasn't the antigen you were testing, that would be a concern, wouldn't that? MR. SANGIAMO: Object to the form.
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You don't. Do you recall any discussion at Merck regarding how the rabbit antihuman IgG would interact with serum? A. I simply don't recall any discussions with rabbit anti-IgG. Q. Fair enough. Fair enough. Let me ask you a question about A. By the way, it's because I see the transcription, it's rabbit as in the animal, not rabid as in the infected sorry. Q. Let me ask you a question a little more scientific. What does antihuman IgG bind to? MR. SANGIAMO: Object to the form.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	getting in that assay is actually caused by the antigen that you're testing for. Correct? A. That's correct. MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. So is there a standard or a rule of thumb that you're aware of for plaque reduction neutralization assays as to what you'd want to see in terms of specificity? A. No. No. Q. If there was only 10 percent specific, so 90 percent of what it was neutralizing wasn't the antigen you were testing, that would be a concern, wouldn't that? MR. SANGIAMO: Object to the form.

1	Page 106	1	Page 108
2	FLORIAN SCHODEL, MD - CONFIDENTIAL make sure that the 10 percent are	$\frac{1}{2}$	FLORIAN SCHODEL, MD - CONFIDENTIAL identified as seroconversion?
3	-	3	
	always the same 10 percent. But	_	A. That's more the sensitivity
4	that's a bit of an extreme example.	4	that would impact that rather than the
5	BY MR. KELLER:	5	specificity, as long as the specificity is
6	Q. Well, in the Protocol 007 PRN,	6	always kept at the same level.
7	they are reporting in seroconversion,	7	Q. Right. But if you're test if
8	correct let me strike that.	8	the purpose of Protocol 007 let me ask you,
9	For Protocol 007, do you know	9	was the endpoint of Protocol 007 was to
10	what the endpoint was for the PRN assay?	10	test to identify a seroconversion rate.
11	A. It was I don't have a	11	Correct?
12	perfect recollection. I think it was the	12	A. The endpoint was to make sure
13	seroconversion rate, and the major endpoint	13	that the lower titered cells would have at
14	that I remember, because that's why the	14	least as good as be noninferior to the
15	protocol was done, was the comparison of the	15	marketed control.
16	seroconversion rates between the different	16	Q. But my question is, if the
17	lower titered cells	17	seroconversion rates that are being tested, if
18	Q. So how would specificity	18	that assay is has a specificity that is
19	A to the control.	19	low, let's use 50 percent as a number, it's in
20	Q. Strike that. Strike that.	20	the middle, if 50 percent of the if the
21	How would specificity affect	21	assay is only 50 percent specific, that means
22	seroconversion rates in this particular	22	50 percent of the neutralizing
23	Protocol 007 PRN assay?	23	neutralization that occurs is based on something
24	A. That's a really interesting	24	other than the mumps vaccine. Correct?
25	question. I can't really answer it, but it	25	MR. SANGIAMO: Object to the
	Page 107		Page 109
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	would certainly not affect the comparison	2	form.
3	because you would expect the specificity to	3	THE WITNESS: You have to see
4	be always the same. Since the major point	4	that in the design. So I don't know
5	was the comparison, it wouldn't really affect	5	how a low specificity would affect the
6	the major point of the trial.	6	seroconversion rates because that's
7	Q. Well, in Protocol 007 they	7	more determined by the sensitivities I
8	tested the market product potency.	8	said. And as long as the specificity
9	A. Right.	9	is the same in all three cells, you
10	Q. Correct?	10	would still have a valid comparison of
11	A. Right.	11	whether they were noninferior.
12	Q. They tested the intermediate	12	So here in the design and in the
13	potency?	13	question of this protocol, I'm not
14	A. Right.	14	concerned about the absolute
15	Q. And low potency. Correct?	15	seroconversion rate. I'm concerned
16	A. Right.	16	about which does it fall off
17	Q. So do you recall there being a	17	somewhere. If you give less than you
18	concern that in testing Protocol 007 through a	18	normally give, would that make it less
19	PRN assay, that the seroconversion rate that	19	potent. It's a different comparison,
20	reported would possibly impact the label for	20	therefore, specificity doesn't in my
21	the seroconversion reported in the label?	21	mind directly influence it.
22	A. No.	22	BY MR. KELLER:
23		23	
24	Q. So is it fair to say that the specificity of in the Protocol 007's PRN	24	Q. I see. But it does directly influence whether or not that seroconversion
25	assay could impact the percentage that's	25	number would let me ask you a question.
25	assay could impact the percentage that's	23	number would let me ask you a question.

	Page 110		Page 112
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	In the original Hilleman assays	2	assay and protection from disease, then would
3	that were conducted where they approved the	3	specificity matter in that assay?
4	mumps vaccine, these used seroconversion as a	4	MR. SANGIAMO: Object to the
5	means to show how well the vaccine would work	5	form.
6	in protecting kids from getting sick from the	6	THE WITNESS: That's too
7	disease. Correct?	7	absolute a question. In other words,
8	A. Well, it was sort of the other	8	in a comparison it still wouldn't
9	way around. They had at that time because	9	matter. In a comparison of two things
10	mumps was frequent, still the luxury of doing	10	that are different and used as just
11	controlled studies in the population that was	11	for the sake of the comparison. So
12	exposed to mumps, and primarily what they	12	for the purposes of 007 that wouldn't
13	measured was whether the vaccine would	13	matter.
14	prevent cases of mumps or not. Sorry. And	14	BY MR. KELLER:
15	then, of course, they also measured	15	Q. Would it be something that would
16	immunogenicity, and it turned out that the	16	be important for a regulator to know?
17	seroconversion was probably even	17	MR. SANGIAMO: Object to the
18	underestimating the level of protection that	18	form.
19	they saw. But there was never a clear	19	
20	correlate established between the two.	20	THE WITNESS: If the regulator wanted to ask that question, obviously
21	Q. So if Merck do you know	21	it would be important for them to
22	whether or not Merck ever represented let	22	know, but that's not a question that I
23	me strike that.	23	remember ever having been asked.
24	So your just so I'm clear,	24	BY MR. KELLER:
25	your testimony is that specificity wouldn't	25	
23		23	Q. You don't think it's important
1	Page 111 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 113 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	matter in this particular assay because you're	2	whether or not when you're looking at
3	only testing whether or not the lower doses	3	something that's correlated to immunity,
4	matched seroconversion in the higher doses.	4	correlated to protection of a disease by a
5	Correct?	5	vaccine, whether or not in a plaque reduction
6	A. It wouldn't matter for the	6	neutralization assay, in fact, that a
7	outcome of the study, yes.	7	percentage of what's being neutralized that is
8	Q. I see. Would it matter if the	8	used to report seroconversion was based on
9	outcome was determine whether or not the kids	9	something other than the vaccine?
10	would get be protected by the vaccine?	10	MR. SANGIAMO: Object to the
10		11	form.
11		11	ioiii.
11		12	THE WITNESS. I don't understand
12	the question of the study. And secondly, no,	12	THE WITNESS: I don't understand
12 13	the question of the study. And secondly, no, because an assay in itself does not does	13	your question.
12 13 14	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been	13 14	your question. BY MR. KELLER:
12 13 14 15	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty	13 14 15	your question. BY MR. KELLER: Q. Sure. I'll back up a second,
12 13 14 15 16	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the	13 14 15 16	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you.
12 13 14 15 16 17	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate	13 14 15 16 17	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is
12 13 14 15 16 17 18	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it	13 14 15 16 17 18	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that.
12 13 14 15 16 17 18 19	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it has not been established is that there is not	13 14 15 16 17 18 19	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that. Is specificity was
12 13 14 15 16 17 18 19 20	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it has not been established is that there is not a known titer at which you have absolutely no	13 14 15 16 17 18 19 20	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that. Is specificity was specificity irrelevant in Protocol 007, the
12 13 14 15 16 17 18 19 20 21	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it has not been established is that there is not a known titer at which you have absolutely no certainty of absolutely no chance of	13 14 15 16 17 18 19 20 21	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that. Is specificity was specificity irrelevant in Protocol 007, the PRN assay?
12 13 14 15 16 17 18 19 20 21 22	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it has not been established is that there is not a known titer at which you have absolutely no certainty of absolutely no chance of getting mumps. You can have antibodies and	13 14 15 16 17 18 19 20 21 22	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that. Is specificity was specificity irrelevant in Protocol 007, the PRN assay? A. Largely, yes, because it's a
12 13 14 15 16 17 18 19 20 21 22 23	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it has not been established is that there is not a known titer at which you have absolutely no certainty of absolutely no chance of getting mumps. You can have antibodies and you can still get mumps.	13 14 15 16 17 18 19 20 21 22 23	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that. Is specificity was specificity irrelevant in Protocol 007, the PRN assay? A. Largely, yes, because it's a comparison. So the absolute and I don't
12 13 14 15 16 17 18 19 20 21 22	the question of the study. And secondly, no, because an assay in itself does not does not especially if no correlate has been established, does not give you a certainty that you're protected or not. That's the difficulty with something where no correlate has been established. One of the reasons it has not been established is that there is not a known titer at which you have absolutely no certainty of absolutely no chance of getting mumps. You can have antibodies and	13 14 15 16 17 18 19 20 21 22	your question. BY MR. KELLER: Q. Sure. I'll back up a second, try to break it down for you. Your testimony specificity is irrelevant let me strike that. Is specificity was specificity irrelevant in Protocol 007, the PRN assay? A. Largely, yes, because it's a

Page 114 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 comparative nature of the study, it was not a 2 it was. So I don't see how 3 3 study to predict the likelihood of cases of specificity would be -- would enter 4 4 mumps occurring but a study to compare into the label. 5 BY MR. KELLER: 5 different potencies of mumps. For that 6 particular purpose it was irrelevant. 6 Q. Do you recall there being any Do you know whether or not Merck 7 discussions at the time that you were at Merck 8 ever represented that its Protocol 007 study 8 where there was a concern that if Merck was correlated to protecting kids from getting 9 reported seroconversion rates lower than what 10 sick? 10 was reported in its label, that it would have 11 A. No, I don't remember that. And 11 to reduce or change its label to reflect those 12 I -- no, I don't. 12 new results? 13 Q. Would that change your testimony 13 A. I don't remember a discussion 14 as to whether or not specificity of the PRN 14 exactly around those lines, but I do remember 15 assay was relevant? 15 -- and I don't remember whether I heard them 16 MR. SANGIAMO: Object to the 16 myself or heard of them, discussions with the 17 form. 17 FDA where the FDA expressed a desire that the 18 THE WITNESS: No, it would not. seroconversion rates in the label be 19 BY MR. KELLER: 19 reflected by an assay that was run to test 20 20 O. Still not? the vaccine. A. It would not because the same 21 21 O. Let me sort of break this down a 22 22 little bit. If your -- if the assay was -- if lack of specificity would be true for all --23 would be true for all cells. In other words, 23 you had to report the seroconversion rate that 24 if they behaved the same, there's no reason 24 was reported in the Protocol 007 in its label 25 25 to expect that they would correlate as -- would that affect your analysis as to Page 115 Page 117 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 differently with the likelihood of getting 2 whether or not the specificity of what was 3 3 neutralized would have been relevant for that disease 4 So in other words, even if the 4 analysis? 5 assay wasn't perfect, as no assay is, if they 5 A. No. I don't really -- I don't were the same in all three cells, even if really see the connection. I mean, what 7 7 there was a correlation, the correlation you're talking about is more sensitivity than 8 would still be the same for all three cells. 8 specificity. 9 9 O. Well, let me break it down into It doesn't matter. So the concept is different. 10 Q. If Merck was conducting -- let 10 smaller bits. You testified earlier that me strike that. 11 11 specificity in a plaque reduction 12 If the PRN assay was going to be neutralization assay is identifying whether or 12 13 used to set what the seroconversion rate was not the neutralization that occurs happens 13 14 14 for the label, for that purpose, would that from the antigen you're testing. Correct? have -- would the specificity have -- be 15 A. That's correct. 16 important for that analysis? 16 And if a percentage of that 17 MR. SANGIAMO: Object to the 17 neutralization comes from something other than 18 form. 18 the antigen, that means -- that's what 19 THE WITNESS: I can't really 19 specificity is discussing. If it's 50 percent 20 20 answer that question. I mean, the specific, 50 percent of what's being 21 reported number in the label is a 21 neutralized is caused by the antigen being 22 number given -- that was an assay tested and 50 percent is being caused by 23 result at a given time when the 23 something else. Correct? 24 vaccine was licensed. And at that 24 Yeah, that's correct. Α. 25 time it was truly reported as whatever 25 Q. And so --

1	Page 118 ELODIAN SCHODEL MD. CONFIDENTIAL	1	Page 120
2	FLORIAN SCHODEL, MD - CONFIDENTIAL A. But we don't have an analysis	2	FLORIAN SCHODEL, MD - CONFIDENTIAL a pre-titer of 1 to 4. And the pre-titer of
3	A. But we don't have an analysis that the	3	1 to 4, assuming that everything is linear,
<i>3</i>		4	
-	Q. Let me just kind of go through		would go to half of 1 to 256 or 128. That
5	this so I understand it.	5	would still be a seroconversion. So it
6	And so if	6	would in that case it would have no impact
7	MR. SANGIAMO: Wait a minute,	7	whatsoever.
8	Jeff. He was let him finish with	8	Q. But in the case where the
9	his answer.	9	A. So you're making a wrong
10	BY MR. KELLER:	10	assumption. Your assumption, and I'm not
11	Q. Are you done?	11	quite sure where that happens, but that
12	A. No, I wasn't. We don't have an	12	example should make it clear to you that even
13	analysis that suggests that the assay had a	13	an assay in which not all the reported
14	50 percent specificity to start with.	14	numbers come from the specific part of the
15	Q. Assume it did for the purpose of	15	assay but there is also contribution of a
16	this discussion. And so in that situation,	16	nonspecific part can still be highly
17	what effect does neutralization have on the	17	sensitive and sufficiently specific to report
18	reporting of seroconversions in a plaque	18	a seroconversion rate.
19	reduction neutralization assay?	19	Q. So what happens when the numbers
20	MR. SANGIAMO: Object to the	20	are compressed, you know, you're looking at
21	form.	21	around that seroconversion cutoff, you have
22	THE WITNESS: I'm not sure I	22	numbers that are much closer to the cutoff,
23	understand. What effect does	23	that 50 percent criteria?
24	neutral	24	MR. SANGIAMO: Object to the
25	BY MR. KELLER:	25	form.
	Page 119		Page 121
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Yeah, when a plaque reduction	2	THE WITNESS: Well, again,
3	neutralization assay reports in a	3	that's making too many assumptions.
4	seroconversion, it's reporting the number of	4	Then they would also be if
5	plaques that have been that are identified	5	everything was linear, they would also
6	in a dish. Correct?	6	be still linear. It would still be in
7	A. Yes.	7	the same direction.
8	Q. And so what the plaque reduction	8	MR. SANGIAMO: Sorry. Let me
9	neutralization assay is doing, it's looking at	9	MR. KELLER: Just so I'm clear,
10	a dish prevaccination and comparing that to a	10	let me
11	dish postvaccination after a certain period of	11	MR. SANGIAMO: No, no, no. I've
		12	been letting this go for a while.
12	time. Correct?	12	
	A. Right.	13	You're asking Dr. Schodel is not
12			6 6
12 13	A. Right.Q. So if the neutralization that	13	You're asking Dr. Schodel is not
12 13 14	A. Right.Q. So if the neutralization thatoccurs is caused by 50 percent something other	13 14	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact
12 13 14 15	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that	13 14 15	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of
12 13 14 15 16 17	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate	13 14 15 16 17	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's
12 13 14 15 16	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it?	13 14 15 16	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it
12 13 14 15 16 17 18 19	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it? A. It depends on the circumstances.	13 14 15 16 17 18 19	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it go. I think we're getting close to
12 13 14 15 16 17 18 19 20	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it? A. It depends on the circumstances. You have to just to give you an example,	13 14 15 16 17 18 19 20	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it go. I think we're getting close to the time where it's time to start
12 13 14 15 16 17 18 19 20 21	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it? A. It depends on the circumstances. You have to just to give you an example, if you have to stay with this kind of a	13 14 15 16 17 18 19 20 21	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it go. I think we're getting close to the time where it's time to start moving on.
12 13 14 15 16 17 18 19 20 21 22	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it? A. It depends on the circumstances. You have to just to give you an example, if you have to stay with this kind of a general assumption, if you have a pre-titer	13 14 15 16 17 18 19 20 21 22	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it go. I think we're getting close to the time where it's time to start moving on. BY MR. KELLER:
12 13 14 15 16 17 18 19 20 21 22 23	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it? A. It depends on the circumstances. You have to just to give you an example, if you have to stay with this kind of a general assumption, if you have a pre-titer of say 1 to 8, and then you have a post titer	13 14 15 16 17 18 19 20 21 22 23	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it go. I think we're getting close to the time where it's time to start moving on. BY MR. KELLER: Q. Just so I'm clear, Dr. Schodel,
12 13 14 15 16 17 18 19 20 21 22	A. Right. Q. So if the neutralization that occurs is caused by 50 percent something other than the antigen that you're testing, that could have an impact on an overstate seroconversion, couldn't it? A. It depends on the circumstances. You have to just to give you an example, if you have to stay with this kind of a general assumption, if you have a pre-titer	13 14 15 16 17 18 19 20 21 22	You're asking Dr. Schodel is not being presented as an expert witness in this case. He's here as a fact witness. You're asking a whole lot of hypothetical questions. He's answering them, I've been letting it go. I think we're getting close to the time where it's time to start moving on. BY MR. KELLER:

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	MR. SANGIAMO: Objection. Asked	2	Q. When you wrote that, did you
3	and answered.	3	believe that statement to be correct?
4	THE WITNESS: No, that's not	4	A. Yes, I still think it's correct.
5	exactly what I said. I said that for	5	Q. Under "Terminology" you write in
6		6	·
7	the degree of specificity, as long as it was the same or similar was		the third paragraph, "I'd suggest that the
8		7 8	term immunological correlate of protection is reserved for such correlates where immune
9	irrelevant for the primary endpoint,	9	
	the analysis of the comparison.	-	measures in a validated assay have been shown
10	MR. KELLER: Let's do this,	10	to correlate with protection from infection
11	let's let me mark as Exhibit 3	11	and/or disease in controlled trials in a
12		12	statistically meaningful manner."
13	(Exhibit Schodel-3, Immunological	13	Do you see that?
14	Correlates of Vaccine-Derived Protection	14	A. Yes.
15	Fondation Mèrieux Conference Center	15	Q. Do you believe that statement to
16	'Les Pensières' Veyrier-Du-Lac, France	16	be true?
17	article, was marked for identification.)	17	A. Yes.
18		18	Q. So correlates of protection,
19	BY MR. KELLER:	19	that's an important let me strike that.
20	Q. This is a document, an article	20	Typically you look at a
21	written by you, Dr. Schodel, "Immunological	21	correlate of protection in a situation where
22	Correlates of Vaccine-Derived Protection,"	22	you can't do a clinical study because of
23	and then it appears that this was presented at	23	ethical reasons. Correct?
24	a conference in France. And I will not even	24	A. If one is available. You
25	try to give the rest of the title in French.	25	typically look at a correlate of protection
	Page 123		Page 12:
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	But do you recall comparing this?	2	where a correlate of protection has been
3	A. Yeah, this was basically a	3	established. Sometimes you have to do it
4	summary of that meeting.	4	without one because there hasn't been one
5	Q. Dr. Plotkin gave a lecture about	5	established.
6	correlates and surrogates. Correct?	6	Q. So as you it's your testimony
7	A. Uh-huh.	7	earlier that for MMR the only correlates of
,	71. On hom.		carner that for white the only correlates or
8	O Do you recall that particular	R	<u>-</u>
8	Q. Do you recall that particular	8	protection that you're aware of is with
9	seminar?	9	protection that you're aware of is with measles. Correct?
9 10	seminar? A. I've heard him not that	9 10	protection that you're aware of is with measles. Correct? A. That's the best established.
9 10 11	seminar? A. I've heard him not that particular one, but I've heard Stanley speak	9 10 11	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some
9 10 11 12	seminar? A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes.	9 10 11 12	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues.
9 10 11 12 13	seminar? A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write,	9 10 11 12 13	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of
9 10 11 12 13 14	seminar? A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not	9 10 11 12 13 14	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the
9 10 11 12 13 14 15	seminar? A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo	9 10 11 12 13 14 15	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness?
9 10 11 12 13 14 15 16	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy.	9 10 11 12 13 14 15 16	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No.
9 10 11 12 13 14 15 16 17	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced	9 10 11 12 13 14 15 16 17	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference?
9 10 11 12 13 14 15 16 17 18	seminar? A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced protection have an important role in the	9 10 11 12 13 14 15 16 17 18	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference? A. Well, effectiveness is a
9 10 11 12 13 14 15 16 17 18	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced protection have an important role in the discovery, development and life cycle	9 10 11 12 13 14 15 16 17 18	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference? A. Well, effectiveness is a concept which combines real world exposure to
9 10 11 12 13 14 15 16 17 18	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced protection have an important role in the discovery, development and life cycle management of vaccines (for example changes in	9 10 11 12 13 14 15 16 17 18	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference? A. Well, effectiveness is a
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9 10 11 12 13 14 15 16 17 18 19 20	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced protection have an important role in the discovery, development and life cycle management of vaccines (for example changes in	9 10 11 12 13 14 15 16 17 18 19 20	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference? A. Well, effectiveness is a concept which combines real world exposure to a drug or a vaccine and outcomes that are
9 10 11 12 13 14 15 16 17 18 19 20 21	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced protection have an important role in the discovery, development and life cycle management of vaccines (for example changes in the manufacturing process, concomitant use	9 10 11 12 13 14 15 16 17 18 19 20 21	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference? A. Well, effectiveness is a concept which combines real world exposure to a drug or a vaccine and outcomes that are observed. It is usually not prospective, it
9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I've heard him not that particular one, but I've heard Stanley speak many times about correlates, yes. Q. In this introduction you write, "It is often not feasible and occasionally not ethically justifiable to run placebo controlled clinical trials for efficacy. Hence, correlates of vaccine induced protection have an important role in the discovery, development and life cycle management of vaccines (for example changes in the manufacturing process, concomitant use with vaccines, extension of the age range of	9 10 11 12 13 14 15 16 17 18 19 20 21 22	protection that you're aware of is with measles. Correct? A. That's the best established. Even that, as I pointed out, there are some issues. Q. When you say "correlate of protection," do you mean that is that the same as correlate of effectiveness? A. No. Q. What's the difference? A. Well, effectiveness is a concept which combines real world exposure to a drug or a vaccine and outcomes that are observed. It is usually not prospective, it can be prospective and the controls are not

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	for opposed to people who are not vaccinated.	2	Q. Would that surprise you as well?
3	But there are many other factors why people	3	A. Well, depends on who made that
4	aren't vaccinated, and so the groups are	4	statement.
5	hardly ever exactly identical. So	5	Q. If Merck made that statement.
6	effectiveness is much less precise measure of	6	A. Somewhat. It's not an efficacy
7	whether a vaccine as such works or is	7	study.
8	efficacious than efficacy. It is on the	8	Q. Did you ever make that statement?
9	other hand by some felt to be a measure of	9	A. I don't remember it, no.
10	real life usefulness. But it has many, many	10	Q. Did you ever make the statement
11	factors that go beyond any of the things	11	that Protocol 007 was a correlate of vaccine
12	we've discussed here.	12	effectiveness?
13	Q. So have you ever seen the term	13	A. I don't think so.
14	correlate with efficacy?	14	MR. SANGIAMO: Object to the
15	A. Yes.	15	form.
16	Q. And what does that mean based on	16	BY MR. KELLER:
17	your understanding?	17	Q. You would be surprised if you
18	A. Well, that means that a	18	did?
19	laboratory measure can predict whether	19	A. I would be surprised if I did.
20	somebody is protected or not. In that	20	O. Because correlates of vaccine
21	regard, measuring that laboratory measure can	21	effectiveness and correlates of vaccine
22	help you ascertain whether a drug vaccine,	22	efficacy, those are two different ways that
23	whatever else will likely protect or not	23	show that a vaccine actually protect the kids
24	likely protect or not protect against the	24	from getting sick. Correct?
25	disease. But that's measured in an efficacy	25	A. In the efficacy, yes, that's
	*		· · ·
1	Page 127 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 129 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	setting. Efficacy means that you have a	2	clearly primarily the vaccine. In the
3	well-defined randomized controlled trial with	3	effectiveness it is societal factors other
4	enough endpoints and it's all set up in the	4	than the vaccine as well so it's not as
5	right way.	5	direct a measure of the vaccine.
6	Q. Are you aware of whether or not	6	Q. Would you consider if somebody
	Protocol 007 was ever described as a correlate	7	made the statement that both of those existed
7			
8	of vaccine effectiveness?	8	with Protocol 007, that that would be
9	A. No	9	considered a correlative with protection?
10	MR. SANGIAMO: Object to the	10	MR. SANGIAMO: Object to the
11	form.	11	form.
12	THE WITNESS: I'm not aware	12	THE WITNESS: No. It was not
13	of that.	13	set up to do, to measure efficacy or
14	BY MR. KELLER:	14	effectiveness. I mean, MMR is a
15	Q. Did you ever	15	highly efficacious and effective
16	A. If it had been described that	16	vaccine but the measure for that is
17	way, I might be a bit surprised.	17	different.
18	Q. Are you aware of Protocol 007	18	MR. KELLER: Let me mark as
19	ever being described as a correlate of vaccine	19	Exhibit 4.
20	efficacy?	20	
21	MR. SANGIAMO: Object to the	21	(Exhibit Schodel-4, E-mail string,
∠ 1	form.	22	Bates MRK-KRA01648951 - 01648956, was
22			
	THE WITNESS: No, I'm not aware	23	marked for identification.)
22		23 24	marked for identification.)

1	Page 130	1	Page 132
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Exhibit 4 is a document that	2	Q. And Barry Garfinkle?
3	bears Bates stamp numbers KRA01649851 through	3	A. Henrietta was on the clinical
4	956, and it's a series of e-mails.	4	side, Barry was on the manufacturing side.
5	Doctor, if you could take a	5	He was the quality person of it. I don't
6	moment to review the e-mails, it will save us	6	know whether he was regulatory or quality for
7	time rather than me trying to read this stuff	7	vaccines on the manufacturing side.
8	into the record. Just take a moment. Let me	8	Q. Here Joan Staub is saying,
9	know when you're done.	9	"Henrietta/Barry, The suggestion from the MMR
10	MR. SANGIAMO: It's a long	10	Competitive Defense Task Force was to actually
11	e-mail thread, Jeff. No expectation	11	run a clinical trial with Mu at expiry since
12	he would have been done already.	12	SB will be filing in Germany and is expected
13	MR. KELLER: I understand.	13	to come on the market in 1998."
14	THE WITNESS: I think I have	14	Do you see that?
15	a I will see whether I may need to	15	A. Yes.
16	go back because there's a lot of stuff	16	Q. This MMR competitive defense
17	in there.	17	task force, were you a member of that?
18	BY MR. KELLER:	18	A. I don't remember that.
19	Q. That's okay. I just wanted to	19	Q. Do you remember what that task
20	have you so you have an understanding of	20	force job was or role or purpose?
21	sort the context of this e-mail. This	21	A. Probably to make sure that MMR
22	e-mail there's a series of e-mails that	22	meets all criteria and can stay on the
23	were written before it was before you were	23	market. Remain competitive. I don't know.
24	e-mailed as part of this e-mail chain and	24	Q. Do you recall there ever
25	instead of me going through everything that	25	being do you recall ever seeing any
	Page 131		Page 133
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	happened before the e-mails came to you, I	2	documentation from this task force?
3	thought it was helpful to have you review it.	3	A. I'm not seeing one right here
4	But if you look on the third	4	apparently. So that's the last time that I
5	page, which is 1648953, there's an e-mail from	5	remember one. I didn't even know the thing
6	Joan Staub on June 19, 1997, to Henrietta Ukwu	6	existed.
7	and Barry Garfinkle and there's a series of	7	Q. Fair enough. Was it during
8	other people on this e-mail including David	8	the time that you were at Merck, was it
9	Krah, Alan Shaw, Jerry Sadoff. And this is	9	Merck's practice before meetings of its
10	regarding mumps issues. In here this e-mail,	10	committees that it would send out an agenda in
11	though you're not on this, it's in the chain	11	a background paper what was to be discussed at
12	of e-mails that was ultimately sent to you,	12	that meeting?
13	there's a statement that says Henrietta let	13	MR. SANGIAMO: Object to the
14	me back up for a second.	14	form.
15	Who is Joan Staub?	15	THE WITNESS: I don't know
16	A. Joan Staub was a project	16	whether I can make a general statement
17	manager at Merck.	17	like that. There were all kinds of
18	Q. Was she a project manager on	18	general meetings. Some meetings were
19	MMR II, if you recall?	19	very formalized, and, yes, that was
20	A. I don't remember. But since	20	done. Other meetings were very
21	she's sending these e-mails, she had probably	21	informal and, no, that was not done.
22	some project management responsibilities.	22	BY MR. KELLER:
23	Q. Who is Henrietta Ukwu?	23	Q. In this e-mail when it says Mu,
24	A. Henrietta Ukwu at the time was	24	you understand that to be mumps. Correct?
25	the regulatory person for vaccines at Merck.	25	A. No, it's MMR. Mu, yes. Mu is
120	and regulatory person for vaccines at wiciek.	23	11. 110, 10 1111111. 111u, yes. 111u is

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1	Page 134		Page 136
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	mumps. Yeah. Okay.	2	to figure out what to do.
3	Q. And SB, that's Smith	3	BY MR. KELLER:
4	A. Smith Beecham probably, yeah,	4	Q. When you say not meet the
5	sure.	5	criteria of the study, end up with a
6	Q. And that's Glaxo Smith today.	6	seroconversion rate lower than what was in the
7	Correct?	7	label?
8	A. Yeah. Yeah.	8	A. No. It could be all kinds of
9	Q. Do you know whether or not so	9	things. I mean studies, clinical studies
10	here there is a discussion here about running	10	have their problems. You could not have
11	a clinical trial with mumps at expiry. Do you	11	enough participants or valid assay points to
12	see that?	12	make any statement.
13	A. Uh-huh.	13	Q. Sure. If you look on page 2,
14	Q. Do you recall giving an opinion	14	there's an e-mail on the 27th of June, 1997
15	about what that clinical trial would look like	15	from a Joline Fontaine to you, Dr. Schodel.
16	during this time frame? I know it's a long	16	Do you see that?
17	time ago.	17	A. Uh-huh. Which one is this?
18	A. No, I don't specifically	18	This here. Where is it?
19	remember this one. But, you know, there's	19	Q. It's on
20	a in general, there's always a debate if	20	A. She said, "what do you think of
21	you want to know whether something works at	21	the studies proposed below?"
22	end expiry as to whether how you should do	22	Q. Correct. Who is Joline
23	that. And I if somebody had asked me an	23	Fontaine?
24	opinion on how to do that, I would certainly	24	A. I'm not 100 percent sure, but
25	have weighed the pros and cons of doing	25	she may have been another Merck employee. I
	Page 135		Page 137
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	dilutions over aging over various other	2	do remember the name, but what her exact
3	things.	3	function was, I don't remember.
4	Q. Gotcha. Here in the last	4	Q. Sure. In here you in the
5	sentence to Ms. Staub's e-mail, she has, "Any	5	e-mail that came after that where you
6	downsides to thisother than the obvious?"	6	responded on June 30, 1997, you say here, Dear
_	D		
7	Do you see that? Do you understand what she	7	Joline, If we decide to address the at expiry
8	meant as to what the obvious downsides were?	7 8	Joline, If we decide to address the at expiry mumps titer versus immunogenicity issues by
			* *
8	meant as to what the obvious downsides were?	8	mumps titer versus immunogenicity issues by
8 9	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls	8 9	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not
8 9 10	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation.	8 9 10	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks;
8 9 10 11	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I	8 9 10 11	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that
8 9 10 11 12	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that	8 9 10 11 12	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles
8 9 10 11 12 13	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time.	8 9 10 11 12 13	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in
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8 9 10 11 12 13 14 15	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time. BY MR. KELLER: Q. Okay. Do you recall	8 9 10 11 12 13 14 15	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in interference. Do you see that?
8 9 10 11 12 13 14 15 16	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time. BY MR. KELLER: Q. Okay. Do you recall A. It's not obvious to me. Q understanding what the obvious downsides would be of running an end	8 9 10 11 12 13 14 15 16	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in interference. Do you see that? A. Uh-huh. Q. What were you talking about? Do you recall writing this e-mail?
8 9 10 11 12 13 14 15 16 17	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time. BY MR. KELLER: Q. Okay. Do you recall A. It's not obvious to me. Q understanding what the	8 9 10 11 12 13 14 15 16 17	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in interference. Do you see that? A. Uh-huh. Q. What were you talking about? Do
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8 9 10 11 12 13 14 15 16 17 18 19 20	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time. BY MR. KELLER: Q. Okay. Do you recall A. It's not obvious to me. Q understanding what the obvious downsides would be of running an end expiry study of mumps? MR. SANGIAMO: Object to the	8 9 10 11 12 13 14 15 16 17 18 19 20	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in interference. Do you see that? A. Uh-huh. Q. What were you talking about? Do you recall writing this e-mail? MR. SANGIAMO: Mr. Keller, I'll just ask you to let him read the rest
8 9 10 11 12 13 14 15 16 17 18 19 20 21	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time. BY MR. KELLER: Q. Okay. Do you recall A. It's not obvious to me. Q understanding what the obvious downsides would be of running an end expiry study of mumps? MR. SANGIAMO: Object to the form.	8 9 10 11 12 13 14 15 16 17 18 19 20 21	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in interference. Do you see that? A. Uh-huh. Q. What were you talking about? Do you recall writing this e-mail? MR. SANGIAMO: Mr. Keller, I'll just ask you to let him read the rest of that e-mail if he has not read it
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	meant as to what the obvious downsides were? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: I have no I have no idea what Joan thought at that time. BY MR. KELLER: Q. Okay. Do you recall A. It's not obvious to me. Q understanding what the obvious downsides would be of running an end expiry study of mumps? MR. SANGIAMO: Object to the form. THE WITNESS: The first thing it	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	mumps titer versus immunogenicity issues by clinical trials, I think we should A, not compare to at release for the obvious risks; and B, not titrate the virus, because that risks to change the ratio of mumps and measles and rubella with possible ensuing changes in interference. Do you see that? A. Uh-huh. Q. What were you talking about? Do you recall writing this e-mail? MR. SANGIAMO: Mr. Keller, I'll just ask you to let him read the rest of that e-mail if he has not read it already.

Page 138 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 MR. SANGIAMO: The question is, 2 There's a lot of publications on that. 3 3 do you recall writing the e-mail? So if you were to hold THE WITNESS: I don't, but I can 4 4 everything the same but change one of the 5 5 certainly recall if I reread this components, you actually change the whole. 6 again my kind of argumentation here. So you're no longer comparing the same 7 BY MR. KELLER: vaccine. It's not a good way of determining 8 the end expiry. So that's one of the Q. Sure. Take whatever time you 8 9 need. Let me ask you the question, then you 9 factors. 10 10 can see if you can answer it, if you have to Let me think about what the reread it. 11 11 other factors were. The other factor is the 12 What did you mean when you uncertainty of actually knowing exactly what 13 decided to address that expiry mumps titers 13 titer of what you have in there because every 14 versus immunogenicity issue? 14 release assay has variability. And I 15 MR. SANGIAMO: You should read 15 remember one thing that when this was finally 16 the remainder of the e-mail. 16 done, which I was not part of, the -- Merck 17 BY MR. KELLER: 17 put in a heroic effort to actually determine Q. Or is that versus or is that as? 18 the exact titers of the mumps component in 19 19 It's confusing to me. the MMR that it had specifically created for 20 A. So there are two -- there are 20 the trial to compare, as you said before, the 21 at least two issues in trying to post hoc 21 medium dose and lower dose to the normal 22 22 release dose. That was very important determine an end expiry titer. Some are 23 linked to the -- well, it's at least three. 23 because if you just pick a lot that's 24 Some are linked to the general risk of 24 somewhere sitting in your refrigerator and 25 25 running clinical trials and some are linked that had been analyzed, because they analyze Page 139 Page 141 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL to the -- to what you compare it to. And 2 the release assays, happen when the lots are 3 obviously many vaccines, if you compare them made, so, you know, they may have been 4 at the high titer, they have -- initially, 4 analyzed, I don't know, two years ago. The will have a higher immunogenicity at release 5 way the assay ran then, you may have a number 6 which I'm not sure is actually true for 6 that is not contemporaneous and it does not 7 7 mumps. I don't think it is. But for reflect the truth of the comparison. Again, 8 varicella, for example, it's very well known. 8 we're talking about comparisons. The 9 9 So if you compare, if you compare the comparisons is what really matters. So I was release, the release titers and they're very 10 also nervous that if you -- in this e-mail, 11 high to the end expiry titers which are 11 that if you were to construct something like 12 lower, you will see a difference which is 12 that and not come up with a format of testing 13 fine, but it's a real difference. 13 that really increased the variability --14 14 The second one is how do you decreased the variability of the release 15 actually prepare such a material. And the 15 assays, that not only would you create an 16 third one is how do you measure it. And that 16 artificial situation, you would potentially 17 goes both for the product side and for the 17 amplify it by the uncertainty that is 18 clinical side. So in the preparation, we've 18 inherent in every assay and in every assay 19 always made MMR pretty much the same way. 19 depending on the form that it's run. 20 20 Q. Why wouldn't you want to have an It's the same kind of cell culture, it's the 21 same kind of harvest site, it's the same way 21 artificial situation? 22 of blending the viruses. Those viruses are 22 A. Why would I not want to? 23 not innocuous to each other. They do stuff 23 Because it wouldn't reflect what I put out on 24 to each other when you mix them. We 24 the market. And I have been putting out in certainly found that out when we did ProQuad. the market for 40 years. It wouldn't reflect

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Page 142 Page 144 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 2 the safety, effectiveness and efficacy record 2 So what I was thinking of is simply the 3 3 of the vaccine. It would be something impact of time on regulatory expectations. I 4 completely contrived. 4 mean, we have a lot of -- these are old 5 5 Q. So you wanted to make sure when products, they've been extremely successful 6 you -- when they were -- if you were going to 6 in the market. They've been very safe, do this end expiry study with different they've been given to hundreds of millions of 8 potencies, that the potencies that you were people and they've worked. We have a low, testing with were as accurate as possible to 9 very, very low burden of disease in this 10 that potency that --10 country because we use this, different to 11 A. On one hand as accurate as 11 almost everywhere else in the world. So the possible and on the other hand reflecting the 12 12 last thing you want to do is now store it. A material that's actually out there on the set of comparisons with such a record and 13 13 14 market, not something that is just made up in 14 distract from that record by running 15 the lab and then put into people. 15 something which is not ideally controlled and 16 Q. Gotcha. So in this e-mail you 16 very different from what was done in 17 talk about the obvious risk, is that the 17 1960-something. However, standards have obvious risk you were talking about? 18 evolved. That was the reference here to the 19 A. Yeah. 19 regulatory agency. So you have to come up 20 Was there a concern that the 20 with something which works. 21 results, if you ran this assay, would be lower 21 O. So the fact that when Maurice 22 than what was identified in the label? 22 Hilleman did the original studies back in the 23 A. No. This was not -- I'm not 23 1960s, there's a expectation, at least a 24 dealing with the label here. I'm just 24 regulatory expectation, that current modern 25 25 dealing with comparisons. So there was no assays would be used for these types of tests. Page 143 Page 145 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL concern about the label. The concern was 2 Correct? simply that this would not reflect the 3 MR. SANGIAMO: Object to the 3 4 situation that we wanted to test. 4 form. 5 Q. Here you write, The trial should 5 THE WITNESS: Yes, of course, only compare seroconversion rates to 6 but -- they were modern, but, you 6 7 7 acceptable historical seroconversion data know, I was modern in 1956. 8 after immunization with lots at expiry, thus 8 BY MR. KELLER: 9 9 So in 1997, modern for 1997. making sure that even lower titers meet the O. standards (the problem here is whether the 10 Correct? 11 assays our lab are willing to run are 11 Α Yeah. generally accepted by the agencies or the 12 MR. SANGIAMO: Jeff, we've been 12 scientific public at large, short of 13 going about an hour and ten minutes. 14 14 publications I have my doubts). Are you at or close to a breaking 15 point? What assays were you talking 15 about? MR. KELLER: Let me just finish 16 16 17 17 Well, so that's the first set this document and then we can move on 18 of assays on the product which to make sure 18 from there. 19 that they're accurately reflecting what's on 19 BY MR. KELLER: 20 20 the product. Then the other one is that the Q. This concern you talked about 21 assays that are -- whether that's the ELISA 21 here, the changes in interference, was there 22 or the PRN, that are currently run are up to interference with the ratio of virus in the 23 snuff by the standards of when this happened. 23 MMR II vaccine between the different antigens? 24 Not assays that were run in 1970 or 1965 when 24 MR. SANGIAMO: Object to the Maurice did his original licensure of MMR. 25 form.

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	THE WITNESS: I don't know. I	2	6:39 p.m. Mr. Chirgwin writes
3	was there was a theoretical	3	A. Where is this? So this is from
4	concern.	4	me to or is this from no, this is
5	BY MR. KELLER:	5	Q. From Keith Chirgwin. You got
6	Q. Have you ever seen any	6	it. To you and Ms. Fontaine. Do you see
7	documentation that talks about let me	7	that, June 30th?
8	strike that.	8	A. This is from me to
9	When you were working on the	9	Q. No, from Keith Chirgwin to you.
10	ProQuad licensing applications, did was	10	A. There's something wrong.
11	there any discussion about interference	11	MR. SANGIAMO: It says from.
12	between the mumps, rubella and measles	12	BY MR. KELLER:
13	antigens in the ProQuad?	13	
14	A. No, varicella.	14	Q. From Keith Chirgwin. I'll go through that in a second. It's a weird
15	Q. It was varicella?	15	e-mail.
16	A. Yes. So that, of course and	16	
	,		8 8
17	that's published that that interference had	17	because this is a message I sent to Keith
18	led to the very long half towards ProQuad	18	obviously from the text.
19	licensure because the viruses had to be	19	Q. Right.
20	appropriately re-titrated. It didn't change	20	A. But
21	the MMR component but it did change the	21	Q. Looks like he's cutting and
22	varicella component.	22	pasting into his e-mail.
23	Q. Do you recall any discussion at	23	A. Maybe he wrote it and just I
24	Merck that there's interference between	24	don't know. I'll have to read it and see.
25	measles and higher the amount of measles	25	Q. It looks like Mr. Chirgwin had
1	Page 147		Page 149
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	that's added in a dose, the lower the potency	2	taken something that you had written
3	of the mumps?	3	previously, though it's not in any e-mails
4	A. No, I do not. As I said, the	4	that we've been able to find, and then
5	example I just gave you is the ProQuad	5	responded below that. I was wondering if you
6	example, that one I knew about, but not what	6	look at the part that's attributed to you,
7	you're saying.	7	Dr. Schodel, do you recall writing this
8	Q. You weren't aware of that?	8	particular section?
9	A. No. Or at least I don't	9	A. I have certainly not written
10	remember it.	10	this. This is not something I would write.
11	Q. If you look on the next e-mail	11	It's just not my style of writing and I don't
12	from Keith Chirgwin to you and Ms. Fontaine,	12	remember this. So this is something that he
	who is Keith Chirgwin?	13	pasted in there. In my
13		14	Q. In here it appears that either
14	A. Keith Chirgwin was in the		
14 15	regulatory group. I don't know what his role	15	he wrote it or where he got this information,
14			he wrote it or where he got this information, he says this e-mail says, What worries me
14 15	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head	15	he says this e-mail says, What worries me is there is no clearly defined standards and
14 15 16	regulatory group. I don't know what his role was at that time, but he eventually basically	15 16	he says this e-mail says, What worries me is there is no clearly defined standards and we may be waking sleeping dogs up as they say
14 15 16 17	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head	15 16 17	he says this e-mail says, What worries me is there is no clearly defined standards and
14 15 16 17 18	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head of vaccine regulatory.	15 16 17 18	he says this e-mail says, What worries me is there is no clearly defined standards and we may be waking sleeping dogs up as they say
14 15 16 17 18 19	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head of vaccine regulatory. Q. If you see in the middle of	15 16 17 18 19	he says this e-mail says, What worries me is there is no clearly defined standards and we may be waking sleeping dogs up as they say (especially since I get no clear picture of
14 15 16 17 18 19 20	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head of vaccine regulatory. Q. If you see in the middle of Mr. Chirgwin's e-mail	15 16 17 18 19 20	he says this e-mail says, What worries me is there is no clearly defined standards and we may be waking sleeping dogs up as they say (especially since I get no clear picture of whether our assays are generally acceptable.
14 15 16 17 18 19 20 21	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head of vaccine regulatory. Q. If you see in the middle of Mr. Chirgwin's e-mail A. Which one is that, on the first	15 16 17 18 19 20 21	he says this e-mail says, What worries me is there is no clearly defined standards and we may be waking sleeping dogs up as they say (especially since I get no clear picture of whether our assays are generally acceptable. I get a wide spectrum of answers to the
14 15 16 17 18 19 20 21 22	regulatory group. I don't know what his role was at that time, but he eventually basically succeeded Henrietta Ukwu and became the head of vaccine regulatory. Q. If you see in the middle of Mr. Chirgwin's e-mail A. Which one is that, on the first page?	15 16 17 18 19 20 21 22	he says this e-mail says, What worries me is there is no clearly defined standards and we may be waking sleeping dogs up as they say (especially since I get no clear picture of whether our assays are generally acceptable. I get a wide spectrum of answers to the acceptability of ELISAs only).

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1	Page 150	1	Page 152
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	discussion with respect to doing an end expiry	2	is or is not acceptable to regulatory
3	study in this time frame, that Merck wanted to	3	agencies. By that time there was
4	use just an ELISA assay for its end expiry	4	still a strong desire by at least the
5	study?	5	FDA to see virus neutralizing titers,
6	A. I don't remember that. I don't	6	functional assay titers for this
7	think I've written that, so but on the	7	particular virus. That is not and
8	other hand, I it's a reasonable question	8	so they are not opposites. I mean,
9	as to whether the ELISA alone would be	9	the it does not mean that the ELISA
10	acceptable and reasonable. That question	10	is not more reliable and better
11	Q. Why would that be a reasonable	11	standardized. It is simply that the
12	A. Well, the ELISA is a much	12	expectations may have been different
13	better controlled assay than the PRN. By its	13	at that time.
14	nature it can be. So it's just a more	14	BY MR. KELLER:
15	reliable assay.	15	Q. Well, an ELISA assay only counts
16	Q. So the here the opposite is	16	antibodies. Correct?
17	the concern is that whether the acceptability	17	A. Yes, it does.
18	of ELISA alone versus some other assay. So	18	Q. It doesn't count whether or not
19	why would that	19	those antibodies protect the kid from getting
20	A. Well, there was a	20	sick?
21	MR. SANGIAMO: Object to the	21	MR. SANGIAMO: You have to let
22	form. Actually, Jeff, did you finish	22	him finish his answers. He didn't
23	your question? You said so here the	23	just now.
24	opposite is the concern is that	24	THE WITNESS: But it does detect
25	whether in the acceptability of ELISA	25	antibodies reliably.
	Page 151		Page 153
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	alone	2	MR. KELLER: Let's take a break.
3	MR. KELLER: I'll rephrase it.	3	VIDEOGRAPHER: Off the record at
4	Let me strike it.	4	11:41. This will end disc number two.
5	MR. SANGIAMO: Thank you.	5	
6	BY MR. KELLER:	6	(A recess was taken.)
7	Q. From the wording of this e-mail	7	
8	it appears to me the opposite, that there was	8	VIDEOGRAPHER: Back on the
9	a concern that there wouldn't be an acceptance	9	record 11:55. Beginning of disc
10	to the use of ELISA alone, and I'm asking you	10	number three.
11	whether or not what you understand that to	11	MR. KELLER: For the record I'd
12	mean?	12	like to mark as Exhibit 5 a document.
13	A. So those are not opposites.	13	
14	MR. SANGIAMO: Object. I'm	14	(Exhibit Schodel-5, 2/23/01
15	sorry, Doctor. Objection. You're	15	E-mail with attachment, Bates
16	asking what the author meant, or are	16	MRK-KRA00549510 - 00549535, was marked
17	you asking his interpretation of those	17	for identification.)
18	words?	18	
19	MR. KELLER: His interpretation,	19	MR. KELLER: For the record,
20	yes.	20	Exhibit 5 is a document that bears
21	MR. SANGIAMO: His interpretation.	21	Bates stamp number KRA 549510 through
22	THE WITNESS: So let's first	22	535. There is some documents in the
23	talk about acceptability. Acceptability	23	middle that aren't Bates numbered but
24 25	would mean acceptability to regulatory	24 25	they are Bates numbered in the way
23	agencies. I can't speculate on what	23	they are produced to us, we just

١.	Page 154		Page 156
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	couldn't print them out with Bates numbers. So 549518 oh, I wasn't	$\frac{2}{3}$	A. Uh-huh. O. Who is that?
4	able to do it. Which is just the	4	
5	attachments to this e-mail. So I will	5	A. Doug at the time was the head of clinical.
6	represent to you they are Bates	6	O. Clinical?
7	numbered in there. Are there Bates	7	A. Yeah.
8	numbers in yours?	8	Q. Clinical research?
9	MS. ZINSER: Yes.	9	A. Clinical research within MRL.
10	MR. KELLER: Good, good, good.	10	So he was reporting to Ed.
11	Strike my last statement.	11	Q. And was it typical to send
12	BY MR. KELLER:	12	e-mails to Ed Skolnick during this time frame,
13	Q. Exhibit 5 is a document that	13	once the information was important?
14	bears Bates numbers KRA 549510 through 535.	14	MR. SANGIAMO: Object to the
15	And I will ask you, Dr. Schodel, you are	15	form. Calls for speculation.
16	identified as receiving this document and its	16	THE WITNESS: I'd have to
17	attachments on February 26, 2001, from Dorothy	17	speculate. Of course. I mean, he was
18	Margolskee. I'll ask you, do you recall	18	somebody who took a lot of interest in
19	receiving this e-mail and the attachments?	19	details.
20	A. No, but I probably received it	20	BY MR. KELLER:
21	if it says so.	21	Q. And here it was cc'd to Jerry
22	Q. Do you have any reason to	22	Sadoff, Henrietta Ukwu, Emilio Emini, Keith
23	believe that you didn't receive it?	23	Chirgwin, Michael DeAngelo Michael Angelo
24	A. No.	24	and Michael King. Who is Emilio Emini?
25	Q. Do you have any reason to	25	A. Emilio Emini was the head of
	Page 155		Page 157
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	believe that you didn't review the attachments?	2	the basic research group.
3	A. No. I think I probably read	3	Q. Was his group
4	them.	4	A. In MRL.
5	Q. In the attaching e-mails from	5	Q the one running Protocol 007?
6	Dorothy Margolskee who is Dorothy	6	A. No, his group was the one that
7	Margolskee during this time frame, what was	7	was running the neutralization assay.
8	her position?	8	Q. So his group was
9	A. Dorothy was still my boss at	9	A. And possibly the ELISA as well.
10	the time. She I can't tell you what her	10	Pretty certain the ELISA as well.
11	exact title was but she had essentially all	11	Q. So his team was the one actually
12	of vaccine development on the MRL side under	12	running the assays that were part of Protocol
13	her.	13	007?
14	Q. Was she on the manufacturing	14	A. Not the assays on the protocol
15	side or the laboratory side?	15	side on the product side, but the assays on the clinical side.
16 17	A. The laboratory side.Q. This e-mail on February 23,	16 17	
18	Q. This e-mail on February 23, 2001, was sent to an Edward Skolnick. Who is	18	Q. Correct. For part of Protocol 007, they were doing the PRN assay testing.
19	Edward Skolnick in this time frame?	19	Correct?
20	A. Ed Skolnick was the head of	20	A. Yes.
21	MRL.	21	Q. They were doing the ELISA
22	Q. Was he the president of MRL?	22	testing as well?
23	A. Yes.	23	A. Yes.
24	Q. Also cc'd do you know who	24	Q. So it was running in the labs
25	Douglas Greene was?	25	that he controlled?

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	D 150		P 160
1	Page 158 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 160 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	A. Yes.	2	that the lab doesn't know what group
3	Q. Who is Michael Angelo?	3	it belongs to to avoid any potential
4	A. Michael Angelo was in	4	bias.
5	manufacturing. I don't know what his exact	5	BY MR. KELLER:
6	role was, but I think quality.	6	
7		7	
8	Q. What about Michael King?A. Also manufacturing.	8	A. You're I mean, are you assuming that the lab was unblinded to the
9	Q. In the first paragraph,	9	individual assays? There's nothing would
10	Ms. Margolskee writes to Mr. Skolnick, "We	10	suggest that.
11	have been assisting MMD in responding to CBER	11	
12		12	· ·
13	questions re mumps end-expiry by performing an	13	the preliminary subset analysis was run, that the lab was not unblinded to the results of
	interim analysis on 600 children participating	14	
14	in the mumps end-expiry study (200 per groups, studied at mumps potencies of 4.9, 4.0 and	15	that assay?
15	3.7)."	16	MR. SANGIAMO: Objection.
16 17		17	THE WITNESS: What do you mean
18	Do you see that? A. Yes.	18	with unblinding? I mean, unblinding would so the lab was, of course,
19	Q. Do you recall Merck conducting a	19	not blinded to the results of the
20 21	preliminary subset analysis of Protocol 007's	20 21	assays they run because they run the
22	PRN assay? A. Yes.	$\begin{vmatrix} 21\\22\end{vmatrix}$	assay and they report the data. But they would not know who the sera comes
			•
23 24	Q. Do you know why it ran that	23 24	from. So that's the important part.
25	assay did a preliminary look at the results?	25	They wouldn't know whether it comes
23		23	from one group or the other group as
1	Page 159 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 161 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	A. I'm not sure, but it may have	2	well. And the analysis is done by
3	been due to CBER questions.	3	statisticians so it's not the lab who
4	Q. Was it common to unblind a study	4	does the analysis.
5	in the middle of it to take a look at the	5	BY MR. KELLER:
6	results of a subset?	6	Q. You said the reason that you
7	A. This is making an assumption.	7	would do blinding was to protect against bias.
8	I don't know how much unblinding was done.	8	Correct?
9	Unblinding had all kinds of different levels	9	A. Right.
10	of detail.	10	Q. And so you said that for the
11	Q. Why	11	plaque reduction neutralization assay it was
12	A. Interim analysis would be run	12	important to blind the folks doing the assays
13	based on the data then available. And it	13	as to the different potency groups. Correct?
14	could be done in a blinded or in an unblinded	14	MR. SANGIAMO: Objection.
15	fashion. And it could be group unblinded or	15	THE WITNESS: Yeah.
16	individual unblinded. So there's all kinds	16	MR. SANGIAMO: Are you asking
17	of details. I don't know what the details	17	him about questions about decisions
18	are here.	18	that were made about Protocol 007 and
19	Q. Do you why are assays	19	the running of the assay in Protocol
20	blinded strike that.	20	007
21	Why would a plaque reduction	21	MR. KELLER: I'm asking
22	neutralization assay be blinded?	22	questions about
23	MR. SANGIAMO: Object to form.	23	MR. SANGIAMO: or are you
24	THE WITNESS: Every assay would	24	asking in general let me finish my
∠+	* *	25	question. Are you asking for general
25	be blinded in the lab to make sure	/ ·	

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. 1	Page 162	1	Page 164
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	expert testimony or are you asking	2	Q. What are the benefits of
3	for	3	blinding the prevaccination versus the
4	MR. KELLER: Dino, you can	4	postvaccination
5	object and that's it. Speaking	5	MR. SANGIAMO: Object to the
6	commentaries are not appropriate.	6	form.
7	MR. SANGIAMO: Well, I've let	7	BY MR. KELLER:
8	you go a long time with these	8	Q based only your experience?
9	hypothetical questions. I think at a	9	MR. SANGIAMO: Object to form.
10	minimum you need to clarify for the	10	THE WITNESS: I'm not sure there
11	witness	11	are any.
12	MR. KELLER: Instruct the	12	BY MR. KELLER:
13	witness not to answer then. Stay out	13	Q. Somebody running the assays for
14	of my deposition, Dino.	14	a plaque reduction neutralization, the
15	MR. SANGIAMO: I think you need	15	prevaccination serum you'd expect to see a
16	to make it clear what you're asking.	16	whole lot of plaque in those samples. Correct?
17	BY MR. KELLER:	17	A. Yes, that's correct.
18	Q. Dr. Schodel, are you aware of	18	Q. And in the postvaccination group
19	how Protocol 007 was blinded?	19	you would expect to see fewer plaques. Correct?
20	A. No.	20	MR. SANGIAMO: Object to the
21	Q. For plaque reduction neutralization	21	form.
22	assay would you expect, based on your 30 years	22	THE WITNESS: That's correct.
23	of experience and participating with these	23	BY MR. KELLER:
24	protocols, that the groups of the three	24	Q. So if the person counting the
25	different potencies would have been blinded to	25	assays or counting the plaques to determine
	Page 163		Page 165
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	the people doing the assays?	2	how many are in each of those dishes, if they
3	MR. SANGIAMO: Object to the	3	know it's a prevaccination versus a
4	form.	4	postvaccination, that could introduce bias
5	THE WITNESS: Like any other	5	into their counting, couldn't it?
6	assay that goes into the lab that	6	MR. SANGIAMO: Object to the
7	would be blinded. Priority blinded	7	form.
8	studies are generally given blinded	8	THE WITNESS: Depends on how
9	into the lab.	9	it's otherwise controlled.
10	BY MR. KELLER:	10	BY MR. KELLER:
11	Q. Would you have expected there to	11	Q. How else could it be otherwise
12	be blinding as to whether or not it was a pre	12	controlled to prevent bias?
13	or postvaccination sample?	13	A. By an SOP.
14	MR. SANGIAMO: Object to the	14	Q. So how would an SOP prevent bias
15	form.	15	if the person counting the plaques know which
16	THE WITNESS: Not necessarily.	16	ones are the prevaccination serum and which
17	Because of the timing as to when the	17	are postvaccination?
18	assays are run. If they're run	18	A. They don't know.
19	parallelized, they may have been	19	MR. SANGIAMO: Object to the
20	blinded. If they're run as they come	20	form.
1	in, they would not have been blinded	21	THE WITNESS: They don't know
21	because they come in at a certain	22	that. They can only speculate on it
21 22	because they come in at a certain		J J 1
	time, not perfectly blinded, but they	23	because they're not told that this is
22		23 24	

	D 1//		D 160
1	Page 166 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 168 FLORIAN SCHODEL, MD - CONFIDENTIAL
2		2	physically nor I have no idea about these
3	postvaccination sample with a low	3	2 7 7
	titer or a prevaccination titer		things.
4	prevaccination sample with a high	5	Q. Do you know who David Krah is?
5	titer, which also exists. So they		A. Yes, I know David.
6	simply wouldn't know.	6	Q. What is your opinion of David
7	BY MR. KELLER:	7	Krah?
8	Q. Is that from your personal	8	MR. SANGIAMO: Mr. Keller,
9	knowledge or are you just or is that a	9	you're not letting him finish his
10	general statement?	10	answers.
11	MR. SANGIAMO: Object to the	11	THE WITNESS: Highly qualified
12	form.	12	scientist, very personable.
13	THE WITNESS: I don't know	13	BY MR. KELLER:
14	exactly what the lab did in this	14	Q. Did you ever hear of anybody
15	particular case, but it's	15	calling him a fraud?
16	BY MR. KELLER:	16	A. No.
17	Q. If the folks running the lab	17	Q. Did you hear anybody stating
18	were knew which samples were prevaccination	18	that he committed fraud in a clinical study?
19	serum and postvaccination serum and were	19	A. No.
20	running whether or not they were	20	Q. That would surprise you?
21	seroconverting as the assay was going on,	21	A. Yes.
22	would that cause you concern from a bias	22	Q. Did you ever see the preliminary
23	standpoint?	23	results from Protocol 007, this interim
24	MR. SANGIAMO: Objection.	24	analysis of 600 kids?
25	THE WITNESS: That's making too	25	A. Well, according to the e-mail I
	Page 167		Page 169
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	many assumptions. They don't	2	did. I'd have to say that I didn't it was
3	generally know and I don't see the	3	not in the front of my mind for the last
4	interest they would have in the lab to	4	Q. Gotcha. So let me direct your
5	have any impact on that. I mean, all	5	attention
6	they do is count holes and record	6	A almost 20 years.
7	them. And they have to actually	7	Q to 549517.
8	the plates that are counted are kept.	8	MR. SANGIAMO: Jeff, you got to
9	So if they were to count wrong, yet	9	let him finish. You know you're doing
10	another control because you can go	10	it. You got to let him finish.
11		11	
11	back and count again.	11	THE WITNESS: It's okay.
12	back and count again. BY MR. KELLER:	12	
	BY MR. KELLER:		THE WITNESS: It's okay. MR. SANGIAMO: She got it. She got the additional testimony.
12 13	BY MR. KELLER: Q. That's the reason why you count	12	MR. SANGIAMO: She got it. She
12 13 14	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a	12 13	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER:
12 13 14 15	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control?	12 13 14	MR. SANGIAMO: She got it. She got the additional testimony.
12 13 14	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a	12 13 14 15	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention
12 13 14 15 16 17	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form.	12 13 14 15 16 17	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517.
12 13 14 15 16 17 18	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle.	12 13 14 15 16 17 18	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that?
12 13 14 15 16 17 18 19	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle. BY MR. KELLER:	12 13 14 15 16 17 18 19	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that? A. Okay.
12 13 14 15 16 17 18 19 20	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle. BY MR. KELLER: Q. Are you aware of	12 13 14 15 16 17 18 19 20	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that? A. Okay. Q. And are these the preliminary
12 13 14 15 16 17 18 19 20 21	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle. BY MR. KELLER: Q. Are you aware of A. Or take a photograph.	12 13 14 15 16 17 18 19 20 21	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that? A. Okay. Q. And are these the preliminary results of Protocol 007 of those 600 kids?
12 13 14 15 16 17 18 19 20 21 22	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle. BY MR. KELLER: Q. Are you aware of A. Or take a photograph. Q. Are you aware of anybody	12 13 14 15 16 17 18 19 20 21 22	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that? A. Okay. Q. And are these the preliminary results of Protocol 007 of those 600 kids? MR. SANGIAMO: Objection.
12 13 14 15 16 17 18 19 20 21 22 23	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle. BY MR. KELLER: Q. Are you aware of A. Or take a photograph. Q. Are you aware of anybody destroying the plates in Protocol 007 before	12 13 14 15 16 17 18 19 20 21 22 23	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that? A. Okay. Q. And are these the preliminary results of Protocol 007 of those 600 kids? MR. SANGIAMO: Objection. Answer if you know, Dr. Schodel.
12 13 14 15 16 17 18 19 20 21 22	BY MR. KELLER: Q. That's the reason why you count the plates, so that they could be used as a quality control? MR. SANGIAMO: Object to the form. THE WITNESS: In principle. BY MR. KELLER: Q. Are you aware of A. Or take a photograph. Q. Are you aware of anybody	12 13 14 15 16 17 18 19 20 21 22	MR. SANGIAMO: She got it. She got the additional testimony. BY MR. KELLER: Q. So let me direct your attention to 549517. A. 549517. Q. Do you see that? A. Okay. Q. And are these the preliminary results of Protocol 007 of those 600 kids? MR. SANGIAMO: Objection.

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	the preliminary subset analysis.	2	do you want to know?
3	BY MR. KELLER:	3	BY MR. KELLER:
4	Q. Here under the topic it says,	4	Q. What does this document represent
5	Jon Hartzel biometrician vaccine, do you know	5	to you? What is it reporting?
6	who Jon Hartzel is?	6	A. It looks like a table.
7	A. Yes. I do.	7	
8		8	Q. Is it reporting by potency group
	Q. Is it your understanding that		4.9, 4.0 and 3.7 for each of the subjects
9	Mr. Hartzel is the one that ran this analysis?	9	identifying the titers and whether or not they
10	A. The statistical analysis, yes.	10	seroconverted for the preliminary subset
11	Q. And who did Mr. Hartzel work for	11	analysis of Protocol 007?
12	at Merck Research Labs during this time frame?	12	A. I don't see the grouping here.
13	A. He works for Merck Research	13	What I do see is serostatus attributions. It
14	Labs.	14	has the report. It has that here.
15	Q. Do you know who he reported to?	15	Q. So this is the unblinded results
16	A. Probably I don't really	16	of the preliminary subset analysis. Is that
17	know. Probably Joe Heyse.	17	correct?
18	Q. And do you know who Joe Heyse	18	A. It's at least partly unblinded.
19	reported to?	19	It's unblinded by group allocation.
20	A. Ultimately Doug Greene, I	20	Q. And it identifies each kid that
21	think. But, again, I'm not sure. So the	21	was tested by their titers and whether or not
22	better answer would be I don't know.	22	they seroconverted. Correct?
23	Q. Let me direct your attention to	23	MR. SANGIAMO: Objection.
24	page 549519, and tell me if you	24	Answer if you know.
25	A. 549	25	THE WITNESS: It doesn't
	Page 171		Page 173
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. 519. This is a group of	2	identify them. It just lists their
3	documents	3	values in a row. That's different
4	A. 518 here.	4	from identifying them because it
5	Q through 535 entitled, "MMRII	5	doesn't give an identifier to which
6	007 Subset Analysis PRN Assay Listing for	6	kid that might be.
7	Subjects Initially Seronegative."	7	BY MR. KELLER:
8	Do you see that?	8	Q. Right. It identifies the
9	A. No. Okay. Here we go.	9	results for those approximately 600 kids.
10	Q. What do you understand this	10	Correct?
11	document to be?	11	A. As far as I can tell, it
12	MR. SANGIAMO: For the record, I	12	identifies the results in these two assays
13	don't think Dr. Schodel has been given	13	here.
14	the chance to read the cover e-mail.	14	
15	So I want that noted before he answers		
16	the question.	15 16	prevaccination titer and the postvaccination titer. Correct?
	-	l	
17	BY MR. KELLER:	17	A. Yes, that's true.
	Q. This was attached to the e-mail	18	Q. It also identified whether or
18	41-4	19	not the child seroconverted. Correct?
18 19	that you receive. Correct?		 A. I assume so because it says
18 19 20	MR. SANGIAMO: In 2001.	20	
18 19 20 21	MR. SANGIAMO: In 2001. THE WITNESS: In 2001 and it has	21	sero is probably not in one, but I have to
18 19 20 21 22	MR. SANGIAMO: In 2001. THE WITNESS: In 2001 and it has a lot of pages. So let me at least	21 22	sero is probably not in one, but I have to speculate because it doesn't say that here.
18 19 20 21 22 23	MR. SANGIAMO: In 2001. THE WITNESS: In 2001 and it has a lot of pages. So let me at least get to the page before I tell you	21 22 23	sero is probably not in one, but I have to speculate because it doesn't say that here. Q. Do you know whether or not these
18 19 20 21 22	MR. SANGIAMO: In 2001. THE WITNESS: In 2001 and it has a lot of pages. So let me at least	21 22	sero is probably not in one, but I have to speculate because it doesn't say that here.

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1	Page 174	1	Page 176
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	this e-mail?	2	represent log potency. Correct?
3	A. They would appear to have been	3	A. Yes.
4	because unless something else was attached to	4	Q. The less than 3.7 lots are of
5	the e-mail sent to me.	5	particular concern; the 3.7 to 4.0 lots are
6	Q. So this was also provided to	6	likely defensible with some additional work.
7	Emilio Emini who was head of the lab that was	7	106 lots are a compliance issue.
8	running the PRN assay?	8	Do you see that?
9	A. That's correct.	9	A. Uh-huh.
10	Q. If you go to the first page of	10	Q. Do you recall at this time frame
11	the e-mail that was sent to Mr. Skolnick and	11	that the end expiry potency was 4.3 log?
12	forwarded on to you, Doctor, Emilio goes on	12	A. No, I don't.
13	and says, On the basis of this analysis and	13	Q. Do you understand what is
14	what is currently calculated by MMD as mump	14	understood what is meant here by "a
15	stability in MMR-II (obtained from analyses of	15	compliance issue"?
16	recent MMD stability lots since the summer of	16	A. Well, compliance issue might be
17	1998), there are MMD "lots in question" that	17	that if Merck had data that the lot did not
18	have been released in the past 2 years.	18	meet the then expectations of the FDA in
19	Do you see that?	19	terms of potency through shelf life, that
20	A. Yes.	20	lots would have to be recalled.
21	Q. And so do you know what they're	21	Q. So do you recall there being a
22	referring to as this recent stability, MMD	22	discussion at Merck during this time frame
23	stability, do you recall there being a	23	about recalling those 106 lots for being below
24	stability analysis of these lots since 1998 to	24	the end expiry requirement in this letter?
25	current?	25	A. I don't recall that. That's
	Page 175		Page 177
1	Page 175 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
1 2	_	1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the
	FLORIAN SCHODEL, MD - CONFIDENTIAL		FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability
2	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall	2	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any
2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is	2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these
2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability.	2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any
2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER:	2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to
2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at	2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall.
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what
2 3 4 5 6 7 8 9 10 11	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability?	2 3 4 5 6 7 8 9 10 11	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal
2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a	2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be
2 3 4 5 6 7 8 9 10 11 12 13	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a regulated product manufacturing is that you	2 3 4 5 6 7 8 9 10 11 12 13	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be recalled, if you know
2 3 4 5 6 7 8 9 10 11 12 13	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a regulated product manufacturing is that you put a certain sample of lots on stability,	2 3 4 5 6 7 8 9 10 11 12 13	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be recalled, if you know MR. SANGIAMO: Object to the
2 3 4 5 6 7 8 9 10 11 12 13 14 15	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a regulated product manufacturing is that you put a certain sample of lots on stability, routine stability testing and you determine	2 3 4 5 6 7 8 9 10 11 12 13 14 15	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be recalled, if you know MR. SANGIAMO: Object to the form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a regulated product manufacturing is that you put a certain sample of lots on stability, routine stability testing and you determine whether they maintain stability through shelf	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be recalled, if you know MR. SANGIAMO: Object to the form. BY MR. KELLER:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a regulated product manufacturing is that you put a certain sample of lots on stability, routine stability testing and you determine whether they maintain stability through shelf life. The analysis of that which takes into	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be recalled, if you know MR. SANGIAMO: Object to the form. BY MR. KELLER: Q during this time frame?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall that one specifically, but there is always lots on stability. BY MR. KELLER: Q. So what is Merck looking at when you say lots are on stability, what do you understand that Merck is looking at with regard to testing lots on stability? A. Well, it's a part of a regulated product manufacturing is that you put a certain sample of lots on stability, routine stability testing and you determine whether they maintain stability through shelf life. The analysis of that which takes into account the totality of the data will tell you whether it does or does not meet the stability criteria. Q. So here it says, "These lots may still be in circulation with 24 month end-expirythat fall below 3.7 (6 lots) or	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL something you would have to ask the manufacturing guys. But in all probability there was a discussion that's referenced here as whether these lots are whether these are just individual outliers without any significance or whether they are a reason to recall. Q. So if a lot is released below the end expiry specification, under what circumstances would regulations, federal regulators FDA require those lots to be recalled, if you know MR. SANGIAMO: Object to the form. BY MR. KELLER: Q during this time frame? MR. SANGIAMO: As he said, answer if you know. And object to form. THE WITNESS: Yeah, it's not an absolute, there's not an absolute
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	Page 178		Page 180
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	They were released under	2	compliance issues, yes. It's a lose term.
3	specifications. And at the time the	3	It doesn't mean all that much.
4	end expiry rules were evolving.	4	Q. It doesn't mean all that much,
5	Individual time points of the	5	compliance?
6	stability study because of the	6	A. Well, it means that there is
7	variability of the assay can always	7	that obviously compliance means compliance
8	fall under specifications. And the	8	with all relevant rules and regulations. And
9	model is a model. There would have to	9	so there's a wide spectrum of things that
10	be additional research being done in	10	compliance issue can mean. It can mean that
11	the lab in manufacturing to determine	11	you need additional data to figure out
12	whether the actual lots were actually	12	whether you're in compliance with rules and
13	meeting expectations or not, and then	13	regulations or it can mean that you've
14	there would have been to be a	14	discovered that something is outside of rules
15	discussion as to what, if they weren't	15	and regulation and then you act upon it.
16	meeting expectations, what that would	16	Q. Do you know whether or not Merck
17	mean and whether it would be better	17	ever reported these 106 lots that are
18	for the vaccinees to go through a	18	compliance issue to the FDA?
19	recall and revaccination or whether it	19	MR. SANGIAMO: Objection. Calls
20	was whether there were enough data	20	for speculation.
21	to defend the product as it was	21	THE WITNESS: I do not know.
22	released.	22	BY MR. KELLER:
23	BY MR. KELLER:	23	O. If Merck's 106 lots were out of
24	O. Was there a when an issue	24	compliance with the specification, would you
	like this would come up where the product	25	have expected Merck to have disclosed that to
1	Page 179 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 181 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	would be do you understand the term "out of	2	the FDA?
3	specification"?	3	MR. SANGIAMO: Objection.
4	A. Yes.	4	THE WITNESS: I don't know
5	Q. What is that what's your	5	whether they were out of compliance,
6	understanding of that term as used at Merck?	6	and as I said. I don't know.
7	MR. SANGIAMO: Object to the	7	BY MR. KELLER:
8	form.	8	Q. At the time of Protocol 007 they
9	THE WITNESS: Well, it	9	were doing testing, they were testing three
10	MR. SANGIAMO: Object to the	10	different potencies, correct, 4.9, 4.0 and
11	form. You can answer.	11	3.7? Correct?
12		12	A. That's correct.
13	THE WITNESS: It in general	13	
13	means that a product at some point		
	doesn't meet the expected specifications.	14	released the dose was released to the
15 16	BY MR. KELLER:	15 16	market. Correct? A. That's correct.
	Q. That could be the end expiry		
17	specification?	17	Q. And the 4.0 and 3.7 were below
18	A. If that end expiry	18	what that current end expiry was that they're
19	specification is formally set and if it	19	required to comply with. They were trying
20	yes, then theoretically it could be that.	20	to back up.
21	Q. Have you ever seen the term	21	Protocol 007, purpose of
22	"compliance issue" used at Merck before other	22	Protocol 007 was to lower the end expiry
23	than in this document?	23	dosage that was identified in the label.
24	A. Yeah. In all pharmaceutical	24	Correct?
25	companies you talk about sometimes about	25	A. I don't recall I don't

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	Page 182		Page 184
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	recall it with that precision. I think it	2	respect to the statement "medically ok"? What
3	was a quite substantial effort to establish	3	are they looking at here with respect to these
4	the data for a scientifically supported end	4	106 lots and whether or not they're medically
5	expiry label in the label. With the changes	5	okay? Do you have an understanding?
6	in labeling philosophy, that we have	6	MR. SANGIAMO: Objection. Calls
7	discussed initially when we started this	7	for speculation. I also want to note
8	interview.	8	he's still not given a chance to read
9	Q. If you look on under the	9	this document.
10	"First, the neuts data," neuts, that means,	10	THE WITNESS: I really don't
11	that represents is that do you	11	know what they meant precisely. It's
12	understand it to mean the neutralization data	12	a pretty loose term. As you know, the
13	from the preliminary subset analysis of	13	compendial specifications in the EU is
14	Protocol 007?	14	3.7. It's also pretty clear when you
15	A. Yeah.	15	look at the data, that even though the
16	Q. In the second bullet point it	16	number seems to be lower than the ones
17	says, "By the neutralization assay, an MMR-II	17	for 4.0 and 4.9, it's still a pretty
18	mumps end-expiry of 4.0 meets CBER's demand	18	high number of seroconversions. So
19	for a 90% seroconversion rate floor"	19	there's not a reason to assume
20	Do you see that?	20	since there is not direct correlation
21	A. Yes.	21	between titers and protection, there's
22	Q. Did you understand that CBER was	22	no reason to assume that it would be
23	requiring a 90 percent seroconversion rate	23	clinically less efficacious.
24	floor?	24	BY MR. KELLER:
25	A. Unfortunately I don't remember	25	Q. So then what is the purpose of
	Page 183		Page 185
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	that MMR, but	2	having doing an analysis of seroconversion
3	Qwhile the 3.7 log titer	3	if let me strike that.
4	misses (88.2 percent seroconversion, with 95	4	So is it your testimony that it
5	percent CI of 82.3 to 92.6 percent).	5	may be medically okay for kids who got
6	Do you see that?	6	vaccines that had end expiries below, in this
7	A. Yes.	7	case, 4.0 and because the seroconversion rate
8	Q. CI, that's what do you	8	was close to the 4.0 and the 4.9?
9	understand CI to represent?	9	MR. SANGIAMO: Object to the
10	A. Confidence interval.	10	form.
11	Q. 95 percent confidence interval,	11	THE WITNESS: That was not the
12	that was the criteria upon which you this	12	totality of my argument but a part of
13	document identifies Protocol 007, the criteria	13	it. I would say that it would still
14	that was being required by the FDA?	14	be provide a substantial level of
15	A. Yes.	15	protection against all components in
16	Q. Here it says, (Jerry and I feel	16	the vaccine.
17	3.7 is medically okay and may be defensible to	17	BY MR. KELLER:
18	the Office of Compliance; see below). Lots	18	Q. Well, here Merck is CBER is
19	which have 24 months end expiry titers	19	demanding a 90 percent seroconversion floor
20	below lower than 3.7 lots would not have	20	for purposes of Protocol 007. Do you see
21 22	data from this study to support the	21 22	that?
44	shelf-life.	1	A. That's what I read here, yes.
	Do you goo that?	100	O Do vou know why ED 44 00
23	Do you see that?	23	Q. Do you know why FDA set 90
	Do you see that? A. Yes. Q. What is your understanding with	23 24 25	Q. Do you know why FDA set 90 percent as a seroconversion floor? A. I can't speculate as to why the

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	D 107		D 100
1	Page 186 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 188 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	FDA set 90 percent as an absolute number	2	subset of Protocol 007, the 4.9 dose group had
3	floor.	3	a seroconversion rate of 94 percent,
4		4	94.1 percent and the 3.7 group had a
5		5	seroconversion rate of 88.2 percent, and that
	Merck it looks it appears to me from reviewing the parts that we've gone over, that		-
6		6	those are highly or so close in number that
7	Merck is using as its defense of whether or	7	all that matters is how those numbers compare
8	not the lots that have been released at below	8	to each other and not the actual results of
9	4.0 and at 3 between 3.7 and 4.0 are	9	whether or not they let me strike that.
10	relying upon the data from the preliminary	10	That's a terrible question.
11	subset of Protocol 007. Correct?	11	How do you understand you
12	MR. SANGIAMO: You mean this one	12	testified that they're comparing they're
13	bullet point that I'm reading?	13	using it to compare how the different groups
14	MR. KELLER: Yes.	14	performed to justify that these lots released
15	THE WITNESS: I don't think that	15	at end expiry of 3.7 are medically okay. Can
16	that's the entire argument. And I	16	you explain that to me a little more detail?
17	don't know the entire argument. What	17	I'm not sure I understand it.
18	you see here, to the extent that I	18	MR. SANGIAMO: Object to the
19	remember this, is an effort to use the	19	form.
20	data as data supporting the argument.	20	THE WITNESS: So I would see
21	But it doesn't mean that that's what	21	this very differently. This is
22	Merck relied on for anything.	22	testing them in a clinical trial is
23	BY MR. KELLER:	23	more an exercise of willingness to
24	Q. But it appears that there as	24	provide data on a future end expiry
25	at least one data point to determine whether	25	dose that will be written into the
	Page 187		Page 189
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	or not these lots are medically okay and	2	appropriate manufacturing
3	defensible with the Office of Compliance	3	documentation. It the trial was
4	let me strike that.	4	not run with the intent of justifying
5	The Office of Compliance, that's	5	anything in that regard.
6	the FDA. Correct?	6	So when you then look at the
7	A. I don't know. It's not this	7	data, you see that actually all three
8	is a strange term. I don't really know what	8	groups provide very respectable
9	that is. It's probably an office within the	9	seroconversion rates, and it would
10	FDA, but I'd have to speculate.	10	probably be hard to tell them
11	Q. So is it fair to say that at	11	statistically apart even though they
12	least for this part of the argument, analysis	12	appear different which often deceives
13	for whether or not these lots are medically	13	the eye because you see a number, it
		l .	
14	okay, Merck is relying upon this preliminary	14	is a different number. But if you
15	subset results of Protocol 007?	15	look at the confidence intervals,
16	A. I would not word it that way.	16	they're overlapping. So I'm not sure
17	I think Merck is looking at the subset	17	that even just looking at this little
18	analysis to provide current data as to how	18	fragment, which is not even the
19	the vaccines are behaving relative to each	19	complete study, it's incomplete
20	other. It does not entirely rely on anything	20	numbers, you would be able to tell
21	in that study to say that the lots are okay,	21	them apart. So they're all behaving
22	or not okay for that matter.	22	fairly well. Which provides
23	Q. I see. And so you say how they	23	additional information that's relevant
24	behaved together. So what your is it your	24	to the question as to whether low
25	position that because in Merck's preliminary	25	titered or lower titered lots might

1	Page 190	1	Page 192
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	be clinically acceptable doesn't mean		A. I think you gave the answer
3	that that's what you would use in your	3	into your relatively convoluted question
4	label because you have an excess of	4	yourself. I'm not sure I can even follow it
5	caution, you make sure that you're	5	entirely. But the answer was at the end when
6	always above a certain threshold. But	6	you said that they were all similar. That
7	actually what this provides to me is	7	basically tells you that sensitivity of the
8	reassurance that even a somewhat lower	8	assay is not the major factor in determining
9	titered vaccine is still performing	9	whether these lots are different or not.
10	quite well.	10	Q. Well, the 3.7 that's derived was
11	BY MR. KELLER:	11	derived in a different assay. That was
12	Q. And in you're relying upon the	12	derived from a potency assay, not a plaque
13	seroconversion rate for that?	13	reduction neutralization assay.
14	A. No, I look at the whole thing.	14	A. Yeah, but when they're put in
15	I look at the titers and the seroconversion	15	people, they behave relatively similar. It
16	rate. And I don't have the ELISA titers in	16	doesn't matter whether I have a number here
17	front of me unfortunately, which are even	17	of 70 percent seroconversion or 90 percent
18	more important because the ELISA has less	18	seroconversion and a titer that's slightly
19	variability. And I don't have the complete	19	lower or higher. I compare the three cells.
20	analysis. So you're talking about an interim	20	And if the confidence intervals overlap, I
21	analysis. But in the meantime, the complete	21	tell you I can't tell them apart which means
22	data would be much more helpful to actually	22	they're all potent in the clinic. The
23	look at the complete data set rather than	23	absolute numbers don't tell me anything.
24	just an interim set. That was just what was	24	Q. So it's your view that
25	known at the time.	25	seroconversion is irrelevant for purposes of
	Page 191		Page 193
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. I see. I apologize if I'm a bit	2	analyzing what happened in Protocol 007
3	confused. Let me ask you this question: If	3	A. No.
4	here Merck is relying upon the seroconversion	4	Q the PRN assay?
5	numbers of the preliminary subset as support	5	A. That's not what I said. And
6	and comfort that doses that have an end expiry	6	you're trying to lead me into saying
7	of 3.7 would be medically okay when you	7	something which I absolutely did not say. I
8	testified earlier that the Merck never	8	did not say that seroconversion was not
9	tested the specificity of its plaque reduction	9	important. I said that it is similar between
10	neutralization assay that you're aware of.	10	the groups. It is not important for
11	MR. SANGIAMO: Object to the	11	predicting efficacy. That's what I said.
12	form. Actually there's no question	12	MR. SANGIAMO: Jeff, it's 12:32.
13	yet. Is there a question?	13	MR. KELLER: That's fine.
14	BY MR. KELLER:	14	VIDEOGRAPHER: Off the record at
15	Q. My question is, if the	15	12:32.
16	specificity of these plaque reduction	16	
17	neutralization assays was low, wouldn't that	17	(A recess was taken.)
18	affect the seroconversion rates that were	18	
19	reported across all three dosage ranges?	19	VIDEOGRAPHER: Back on the
20	MR. SANGIAMO: Object to the	20	record at 1:29.
21	form.	21	BY MR. KELLER:
22	BY MR. KELLER:	22	Q. Doctor, can you put Exhibit 5
23	Q. And underestimate seroconversion	23	back in front of you? Let me direct your
24	overestimate I'm sorry, overestimate	24	attention to 549511. In the middle of the
25	seroconversion?	25	page it says, "Background/Impact Assessment"
24	overestimate I'm sorry, overestimate	24	attention to 549511. In the middle of the

1	Page 194	1	Page 196
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL A. Wait. Wait a second. 5495	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
$\frac{2}{3}$		$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	Q. Do you recall there being
			discussions of the 1.0 log loss over 24 months
4 5	A. Okay.	4	to be at issue with Merck's complying with its
-	Q. It's the second page of the	5	end expiry specifications of its label for the
6	document.	6	mumps component?
7	In the middle of the document it	7	A. Not that specifically.
8	says, "Background/Impact Assessment on	8	Q. You just generally recall that?
9	Marketed Product." Do you see that?	9	A. I generally recall that when
10	A. Uh-huh.	10	there were data like the ones that are
11	Q. In the middle bullet point it	11	suggested initially of lots on stability not
12	says, In the meantime, there has been	12	being above a certain titer that there was
13	continuing discussions with CBER re mumps end	13	sometimes a discussion about that. I don't
14	expiry titers. In response to recent CBER	14	remember any detailed discussion about the
15	inspection from the Office of Compliance to	15	modeling piece.
16	MMD, manufactured mumps stability data was	16	Q. Do you recall any discussion
17	re-examined. In that analysis, it appears	17	about anybody who criticized the model that
18	that mumps stability has been somewhat less	18	Merck was using at Merck within Merck's
19	(i.e. around .2 logs faster over a 24 months	19	employees that calculated this projected 1.0
20	period; a total of around 1.0 log lost over	20	log loss at 24 months?
21	24 months) for lots manufactured at least	21	MR. SANGIAMO: Objection. Form.
22	since the summer of 1998.	22	THE WITNESS: No.
23	Do you see that?	23	BY MR. KELLER:
24	A. Yes.	24	Q. If you go back to the document,
25	Q. Were you aware that based on	25	the second bullet point it says, "Given this
	Page 195		Page 197
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Merck's then current mumps stability models,	2	new analysis, lots manufactured since1999
3	that it was projecting an approximate 1.0 log	3	are still fine with the overfill and 24 month
4	loss over the shelf life of its product?	4	end-expiry titers projected at or above 4.0."
5	MR. SANGIAMO: Object to the	5	Do you see that?
6	form.	6	A. Yes.
7	THE WITNESS: I may have been	7	Q. Do you recall what they're
8	aware of it. As you know, I didn't	8	talking about for the overfill?
9	work in manufacturing, so this wasn't	9	MR. SANGIAMO: Objection. Calls
10	exactly my line of business.	10	for speculation.
11	BY MR. KELLER:	11	THE WITNESS: I can read this
12	Q. Do you recall any discussion at	12	and tell you what an overfill would
13	Merck regarding the stability models that	13	be, but I'm not sure I don't
14	projected a one log loss over 24 months?	14	remember the details.
15	A. Not in any detail.	15	BY MR. KELLER:
16	Q. What generally do you understand	16	Q. What's your understanding of an
10	those conversations to take place?	17	overfill?
17	mose conversations to take prace:	10	A. Overfill would be that you fill
	MR. SANGIAMO: Objection.	18	
17	-	18	in more vaccine than you have previously at
17 18	MR. SANGIAMO: Objection.	1	
17 18 19	MR. SANGIAMO: Objection. THE WITNESS: I was not involved	19	in more vaccine than you have previously at
17 18 19 20	MR. SANGIAMO: Objection. THE WITNESS: I was not involved in the modeling exercises so I	19 20	in more vaccine than you have previously at least by that assay.
17 18 19 20 21	MR. SANGIAMO: Objection. THE WITNESS: I was not involved in the modeling exercises so I wouldn't it wouldn't have been	19 20 21	in more vaccine than you have previously at least by that assay. Q. Do you recall that in September
17 18 19 20 21 22	MR. SANGIAMO: Objection. THE WITNESS: I was not involved in the modeling exercises so I wouldn't it wouldn't have been discussed with me. I mean, what would	19 20 21 22	in more vaccine than you have previously at least by that assay. Q. Do you recall that in September of 1999 Merck and CBER or CBER required and
17 18 19 20 21 22 23	MR. SANGIAMO: Objection. THE WITNESS: I was not involved in the modeling exercises so I wouldn't it wouldn't have been discussed with me. I mean, what would have been discussed with me is more	19 20 21 22 23	in more vaccine than you have previously at least by that assay. Q. Do you recall that in September of 1999 Merck and CBER or CBER required and Merck agreed to overfill its minimum release

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7 8 t 9 f 10 1 11 v 12 4 13 a 14	Page 198 FLORIAN SCHODEL, MD - CONFIDENTIAL form. THE WITNESS: Not in that detail but now that you know, this makes sense in the context. BY MR. KELLER: Q. So in the last bullet point on this page it says, Unfortunately, with the faster mumps potency loss rates seen since at	1 2 3 4 5 6 7	Page 200 FLORIAN SCHODEL, MD - CONFIDENTIAL decision whether or not 3.7 would be medically okay during this time frame? A. Well, Jerry Sadoff was probably and Dorothy Margolskee were
2 3 4 5 6 H 7 8 t 9 f 10 l 11 v 12 4 13 a 14	form. THE WITNESS: Not in that detail but now that you know, this makes sense in the context. BY MR. KELLER: Q. So in the last bullet point on this page it says, Unfortunately, with the	2 3 4 5 6	decision whether or not 3.7 would be medically okay during this time frame? A. Well, Jerry Sadoff was
3 4 5 6 F 7 8 t 9 f 10 1 11 v 12 4 13 a 14	THE WITNESS: Not in that detail but now that you know, this makes sense in the context. BY MR. KELLER: Q. So in the last bullet point on this page it says, Unfortunately, with the	3 4 5 6	okay during this time frame? A. Well, Jerry Sadoff was
4 5 6 F 7 8 t 9 f 10 1 11 v 12 4 13 a 14	but now that you know, this makes sense in the context. BY MR. KELLER: Q. So in the last bullet point on this page it says, Unfortunately, with the	4 5 6	A. Well, Jerry Sadoff was
5 6 F 7 8 tt 9 ft 10 Ft 11 vt 12 4 13 a 14	sense in the context. BY MR. KELLER: Q. So in the last bullet point on this page it says, Unfortunately, with the	5 6	
6 H 7 8 t 9 f 10 l 11 v 12 4 13 a 14	BY MR. KELLER: Q. So in the last bullet point on this page it says, Unfortunately, with the	6	
7 8 t 9 f 10 1 11 v 12 4 13 a 14	Q. So in the last bullet point on this page it says, Unfortunately, with the		probably making the assessment as they said
8 t 9 f 10 l 11 v 12 4 13 a 14	this page it says, Unfortunately, with the	/	here.
9 f 10 l 11 v 12 4 13 a 14		8	Q. Here back on 549512, in the
10 1 11 v 12 4 13 a 14	laster mumps potency loss rates seem since at	9	case "In case you want the details,
11 v 12 4 13 a 14	least summer of 1998, there are released lots	10	Attachment #4 is a line listing of the lots -
12 4 13 a 14	which, at 24 months, are projected to be below	11	note column 5, which is the release dose per
13 a	4.0 (100 lots) or 3.7 (6 lots). This will be	12	lot"
14	a compliance issue with the Agency.	13	A. Where are we here?
	Do you see that?	14	Q. On page 3 of the document which
15	A. Yes, I see that.	15	is 549512.
16	Q. Do you understand that to mean	16	A. Page 3, okay. And where?
	the agency is the FDA?	17	Q. Just where I left off reading.
18	A. It could have referred to the	18	I'm just reading the next
	FDA or to other agencies as well.	19	A. Again.
20	Q. During this time frame, did you	20	Q. In case you want the details,
	understand that the at this time the label	21	Attachment 4 is a line listing of the lots -
	required that at end expiry there would be 4.3	22	note column 5, which is the release dose per
	log?	23	lot and assume a 1 around a 1.1 log fall
24	A. I think this was just this	24	over 24 months. Do you see that?
	was still in the I don't remember exactly	25	A. Yeah, I see that.
	Page 199		Page 201
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2 v	whether at this time the label was already	2	Q. If you go to 549518 of this
	defined as an end expiry label as it was	3	document, it actually doesn't have a Bates
	later on understood to be, whether it was a	4	number on it, but when we printed it out, the
5 r	release label essentially.	5	Excel printed with a number. This was also
6	Q. Do you remember at some point	6	part of that document. It's a document
7 t	the end expiry log being set at 4.3?	7	entitled: "Total Doses on Low Mumps Titer
8	A. I'm not I'm a bit murky on	8	Lots within Expiry." Do you see that?
9 t	the details here. It probably was, but	9	A. Uh-huh.
10 I	I'm	10	Q. Here it says that US Doses
11	Q. If when this says when	11	Distributed in 2002 has 12,765,787. Do you
12 t	this e-mail that was sent to the president of	12	see that?
13 N	Merck in February of 2001 says this will be a	13	A. Yes, I see that.
14 c	compliance issue with the agency, who at Merck	14	MR. SANGIAMO: In 2000.
15 v	would decide whether or not to disclose this	15	BY MR. KELLER:
16 i	information to the agency?	16	Q. In 2000, right.
17	MR. SANGIAMO: Object to the	17	Is it fair to say that based on
18	form.	18	this attachment that what they're identifying
19	THE WITNESS: That's not my	19	here is the number of doses released in the US
20	responsibility. I didn't know.	20	that had low potency below the 4.0 spec?
21 I	BY MR. KELLER:	21	MR. SANGIAMO: Object to the
22	Q. In this document they're talking	22	form.
	about whether or not 3.7 will be medically	23	THE WITNESS: No, I can't really
	okay and maybe defensible with the Office of	24	see that here. It says, "Total Doses
25 (Compliance. Do you know who would make the	25	on Low Mumps Titer Lot within Expiry."

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	Page 202		Page 204
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	So they would have been within expiry.	2	A. That obviously was her opinion.
3	I'm not sure this is not there's	3	Q. But you don't recall any
4	not sufficient labeling here for me to	4	discussion about a compliance issue of tens of
5	tell what these are.	5	millions of doses below end expiry projections
6	BY MR. KELLER:	6	that were made by this model?
7	Q. Fair enough. If you look at the	7	A. Not as you word it. I do
8	rest of the spreadsheet that's attached it	8	recall a discussion about mumps potency and I
9	identifies for each lot, lot number, release	9	do recall that there were discussions with
10	potency, expiry potency, package number, and	10	the agency as well, but I certainly don't
11	at the back of it it will identify the number	11	recall that anybody said certainly the
12	of lots that have been released for each	12	agency would be the one to tell us that there
13	number of doses in each lot. Do you see that?	13	were X number, million number of doses that
14	A. Well, I'm not familiar with	14	were out of compliance or released at the
15	these kinds of tables, so I I can see	15	wrong titer.
16	what's labeled here. This is not	16	Q. When you say that there was
17	Q. Do you recall	17	discussions about mumps potency with the
18	A. There's a line total doses here	18	agency, were you involved in those discussions?
19	but there's nothing in it.	19	A. Probably not, certainly not as
20	Q. That's after the first page. I	20	far as they concerned involved manufacturing
21	can represent to you without going back and	21	issues.
22	adding them up	22	Q. Were you involved in any
23	A. This is not this is	23	discussions where there was a discussion as to
24	obviously spread out over several pages and does not these are not labeled. So it's	24	what to tell CBER about these 106 doses at 4.0
25	does not these are not labeled. So it's	25	and lower?
1	Page 203	1	Page 205
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and	2	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form.
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related.	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean
2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do	2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have
2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any	2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them.
2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million	2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER:
2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the	2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry?	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots?
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said
2 3 4 5 6 7 8 9 10	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so	2 3 4 5 6 7 8 9 10 11	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility.
2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was	2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you
2 3 4 5 6 7 8 9 10 11 12 13	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything.	2 3 4 5 6 7 8 9 10 11 12 13	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or
2 3 4 5 6 7 8 9 10 11 12 13 14	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if	2 3 4 5 6 7 8 9 10 11 12 13 14	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below	2 3 4 5 6 7 8 9 10 11 12 13 14 15	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's very different. That's a model is a model is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's a model is a model.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's a model is a model. Q. Okay. Here Dorothy Margolskee,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were below 4.3?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's very different. That's a model is a model. Q. Okay. Here Dorothy Margolskee, she's a fairly senior executive at Merck.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were below 4.3? A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's very different. That's a model is a model. Q. Okay. Here Dorothy Margolskee, she's a fairly senior executive at Merck. Correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were below 4.3? A. No. Q. Do you recall any discussion
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's very different. That's a model is a model. Q. Okay. Here Dorothy Margolskee, she's a fairly senior executive at Merck. Correct? A. Very senior.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were below 4.3? A. No. Q. Do you recall any discussion about 227 lots with respect to anything?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's very different. That's a model is a model. Q. Okay. Here Dorothy Margolskee, she's a fairly senior executive at Merck. Correct? A. Very senior. Q. Very senior. So she's	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were below 4.3? A. No. Q. Do you recall any discussion about 227 lots with respect to anything? A. The number doesn't strike a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL package doses, but I'd have to go back and forth and relate them to something, if they're even related. Q. Let me ask you a question. Do you recall during this time frame any discussion about there being 10 or 12 million doses that fell below the specification in the label for end expiry? A. Well, that's a lot of assumptions. So what we're talking about so far was a model, a stability model. It was not saying that the doses fell below anything. Q. Well, it's projecting that if doses would fall below A. That's very different. That's very different. That's very different. That's a model is a model. Q. Okay. Here Dorothy Margolskee, she's a fairly senior executive at Merck. Correct? A. Very senior.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL MR. SANGIAMO: Object to the form. THE WITNESS: What do you mean with what to tell CBER? We would have shared data with them. BY MR. KELLER: Q. Did Merck tell CBER about these 106 lots? A. How am I to know? As I said before, that was not my responsibility. Q. I understand that. Do you recall any discussions regarding whether or not to tell CBER about these 106 lots? A. No, I do not. That was also not my responsibility. Q. Okay. Fair enough. Do you recall any discussion about 227 lots that were below 4.3? A. No. Q. Do you recall any discussion about 227 lots with respect to anything?

52 (Pages 202 - 205)

1	Page 206	1	Page 208
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL next exhibit as Exhibit 5.	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
			Antonello, who is that?
3	MR. SANGIAMO: 5?	3	A. He was working in his group.
4	MR. KELLER: 6. I'm sorry.	4	He was also biometrician. Also not somebody
5	Strike that.	5	who dealt with clinical statistics, but
6	Let me mark this next exhibit as	6	somebody who would work with the lab to
7	Exhibit 6.	7	validate assays and so on.
8	 (E.132.01, 11.6.E., 3)	8	Q. Did Mr. Hartzel and Mr. Antonello
9	(Exhibit Schodel-6, E-mail	9	work together?
10	chain, Bates MRK-KRA00549497 &	10	A. I think actually Jonathan
11	00549498, was marked for identification.)	11	Hartzel was in the clinical statistics group,
12		12	to which exact I mean, I was not in either
13	BY MR. KELLER:	13	of these two groups, so they may have worked
14	Q. For the record, Exhibit 6 is a	14	together or not, I don't know.
15	document that bears Bates stamp number	15	MR. SANGIAMO: Jeff, these guys
16	KRA 549497 through 498. It's a series of	16	are both doctors.
17	e-mails. I'll direct your attention to the	17	MR. KELLER: Sure.
18	e-mail that starts at the bottom of 5497	18	BY MR. KELLER:
19	549497 and runs on to the second page at 498.	19	Q. Dr. Hartzel, he's the one that
20	This one is from Timothy Schofield to Dorothy	20	was who worked on the planning subset data,
21	Margolskee, and it's talking about the "Low	21	correct, the unblinded subset data for
22	Months Target Lots within Expiry."	22	Protocol 007?
23	A. Note that I was not copied on	23	A. I don't know that for sure. He
24	this e-mail.	24	may have been the statistician associated to
25	Q. Right, I see that. The e-mail	25	the study all of the sudden but whether he
	Page 207		Page 209
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	above that is from you. Do you see that?	2	has actually worked on that set of data other
3	A. That's right.	3	than summarize it, I don't know. There may
4	Q. Here it appears that you were	4	have been other people in the background who
5	responding to the e-mail that was below. So		1 1 '. T 1' 1 1 1'
-		5	worked on it. I did you're asking me
6	it looks like if you look at the February 22,	5 6	things that I wouldn't know.
			· · · · · · · · · · · · · · · · · · ·
6	it looks like if you look at the February 22,	6	things that I wouldn't know.
6 7	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee,	6 7	things that I wouldn't know. Q. Sure. In here, in this e-mail
6 7 8	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about	6 7 8	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says,
6 7 8 9	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that?	6 7 8 9	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working
6 7 8 9 10	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just	6 7 8 9 10	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas:
6 7 8 9 10 11	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand.	6 7 8 9 10 11	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello
6 7 8 9 10 11 12	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you	6 7 8 9 10 11 12	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation
6 7 8 9 10 11 12 13	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me.	6 7 8 9 10 11 12 13	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that?
6 7 8 9 10 11 12 13 14	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was	6 7 8 9 10 11 12 13 14	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah.
6 7 8 9 10 11 12 13 14 15	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position?	6 7 8 9 10 11 12 13 14 15	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is
6 7 8 9 10 11 12 13 14 15 16	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics	6 7 8 9 10 11 12 13 14 15 16	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007?
6 7 8 9 10 11 12 13 14 15 16 17	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time.	6 7 8 9 10 11 12 13 14 15 16 17	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't.
6 7 8 9 10 11 12 13 14 15 16 17 18	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time. Q. He was a statistician?	6 7 8 9 10 11 12 13 14 15 16 17	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't. Q. You don't know? A. You're telling me now.
6 7 8 9 10 11 12 13 14 15 16 17 18 19	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time. Q. He was a statistician? A. Yes.	6 7 8 9 10 11 12 13 14 15 16 17 18	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't. Q. You don't know? A. You're telling me now. Q. He suggested that we look at the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time. Q. He was a statistician? A. Yes. Q. And Jonathan also? A. Not a clinical statistician. A	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't. Q. You don't know? A. You're telling me now. Q. He suggested that we look at the dilution response profiles to see if the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time. Q. He was a statistician? A. Yes. Q. And Jonathan also? A. Not a clinical statistician. A biometrics person. So he was dealing with	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't. Q. You don't know? A. You're telling me now. Q. He suggested that we look at the dilution response profiles to see if the negatives were "marginal," or strictly flat.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time. Q. He was a statistician? A. Yes. Q. And Jonathan also? A. Not a clinical statistician. A	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't. Q. You don't know? A. You're telling me now. Q. He suggested that we look at the dilution response profiles to see if the negatives were "marginal," or strictly flat. In addition, it could be interesting to see
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	it looks like if you look at the February 22, 2001, e-mail from Mr. Schofield to Margolskee, it was subsequently forwarded to you about 40 minutes later. Do you see that? A. Okay. Now I get it. I just didn't understand. Q. Fair enough. I'm glad you pointed that out to me. If you look at Mr who was Mr. Schofield again, what was his position? A. He was the head of biometrics at the time. Q. He was a statistician? A. Yes. Q. And Jonathan also? A. Not a clinical statistician. A biometrics person. So he was dealing with not clinical issues but manufacturing issues,	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	things that I wouldn't know. Q. Sure. In here, in this e-mail from Schofield to Margolskee, Schofield says, "Dorothy, Here's the spreadsheet I was working from. A couple ideas: "1. I spoke with Joe Antonello who is doing the evaluation of the validation data" Do you see that? A. Yeah. Q. Do you understand that this is the validation data for Protocol 007? A. No, I didn't. Q. You don't know? A. You're telling me now. Q. He suggested that we look at the dilution response profiles to see if the negatives were "marginal," or strictly flat.

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Case: 23-2553 Document: 42 Page: 245 Date Filed: 11/01/2023

Page 212 Page 210 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL Do you see that? 2 2 I'm not sure what he means with 3 3 A. Yes. failures here, whether those are failures O. He's talking about a 4 that are failures because they are -- don't 5 5 neutralization assay. Correct? yield useful values or they're failures 6 A. It would seem from here, 6 because they were wrongly classified, I'm not 7 because he mentions 40 percent neutralization, 7 so sure. 8 8 but out of context I wouldn't know. Sure. If you look at the e-mail 9 Q. Fair enough. Number 2 he says, 9 from you the same day, only an hour and a half 10 "Would there be a better probability of 10 later, again, cc'ing Hartzel, and in here you write, "Dear Tim, I think esp. 2 would be 11 success in retesting the failures (and some 11 12 marginal positives) in the wild type neut." useful...." Esp. means especially 2? 13 Do you see that? 13 A. Yes. 14 A. Yes. 14 Q. What did you mean by "esp"? 15 Q. The wild-type neut, that's 15 A. 16 Protocol 007's PRN assay. Correct? 16 Q. So here you're saying retesting 17 of the failures would be useful. Correct? A. Uh-huh. I mean, this is a bit 17 18 A. Well, no. What I'm saying --18 of jargon, so I -- in seeing the name, that's what I would expect, but I'm not sure. I 19 yes and no. So what I'm saying really is it 20 don't know what he refers to exactly because 20 would be useful to have more data, more valid 21 he can do a wild-type neut with any wild-type 21 data. I'm making an argument that if you 22 mump strain. 22 have a postimmunization -- a preimmunization 23 So when they're talking about 23 titer that seems higher than the 24 better probability of success in retesting 24 preimmunization titer -- the other way 25 25 that failures, how would you get a better around. The preimmunization titer that seems Page 211 Page 213 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 probability of success by retesting failures 2 higher than the postimmunization titer, 3 3 in a wild-type plaque reduction neutralization there's something funny going on. If you 4 assay? 4 don't have data, you're actually -- you 5 MR. SANGIAMO: Objection. 5 should retest and figure out whether there 6 THE WITNESS: Well, failures in 6 was something wrong. 7 7 this context here, you know, means Q. I see. 8 failures of performing in the assay so 8 But, of course, you wouldn't do 9 they are not -- so you don't have a a retest just on those. Just the advantage 10 valid data point for this particular of doing a retest is that it would also 11 sera which is, of course frustrating. 11 include those where you -- where something 12 They humanize people. They are sera. biologically not plausible is happening. 12 13 They've been analyzed, but for 13 Q. So would you not test vaccine 14 14 failures in a PRN assay? Why don't you just -whatever reason the control was wrong, 15 the cells were old, something else 15 I'm still not sure whether 16 didn't work, so they're failures, test we're talking about vaccine failures or not. 17 failures. Now the question is what 17 Nobody says vaccine failures. 18 are the values in these sera and you 18 Q. Let's go to the next e-mail from 19 can --19 Jonathan Hartzel to you, Dr. Schodel, which 20 20 happened about two minutes later. It says, BY MR. KELLER: 21 Q. You say the controls, do you this is from Hartzel, "I have given Emilio...." and that's Emilio Emini. Correct? 22 recall there being any discussion about 22 23 testing the failures in the preliminary subset 23 A. Uh-huh. 24 of Protocol 007, the ones that didn't 24 He's running the lab that's seroconvert? 25 running Protocol 007. Correct?

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	Page 214		Page 216
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 216 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	MR. SANGIAMO: Object to the	2	Q. So let me just direct your
3	form.	3	attention to back to Exhibit 5, which is
4	THE WITNESS: He was in charge	4	the Margolskee e-mail. And an attachment at
5	of the lab.	5	549517, which is the preliminary subset
6	BY MR. KELLER:	6	summary that Jonathan Hartzel is identified
7		7	
	•	8	on. Do you see that? A. Yes.
8	(the 42 failures and 17 marginal positives).	9	
9	Do you see that?		Q. Now, if you look at the
10	A. Yes, I see that.	10	seroconversion failures from the 4.9, the 4.0,
11	Q. I believe he will try to retest	11	the 3.7, you'll see that there's ten failures
12	them in both the ELISA (the wild-type mumps)	12	of the 4.9, there's 12 failures
13	and the wild-type neut.	13	A. Wait a second. Where do I see
14	Do you see that?	14	those?
15	A. Yes, I see that.	15	Q. Looking at the percentages of
16	Q. Those are the two arms of	16	seroconversion, 159 over 169, 167 over 179,
17	Protocol 007. Correct?	17	149 over 169. That's how they're calculating
18	MR. SANGIAMO: Object to the	18	seroconversion, the total number by what
19	form.	19	percentage of those seroconverted. Correct?
20	THE WITNESS: I don't really	20	MR. SANGIAMO: Object to the
21	know what these failures refer to	21	form. Dr. Schodel, do you see the
22	here, whether they're failures in the	22	data to which Mr. Keller is referring?
23	overall protocol that could be	23	THE WITNESS: I see the data,
24	including the control arm or whether	24	but there's you're making an
25	they would be any of the cells. This	25	assumption that I don't know which
	Page 215		Page 217
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	is just an assay issue. You have	2	ones are test failure. What I do see
3	serum samples in there which are low	3	here is the response rates that are
4	and sometimes look like they can't	4	indicated here.
5	easily be interpreted, like the ones	5	BY MR. KELLER:
6	below which have been higher before	6	Q. Right. So there's 169 kids in
7	they get immunized and then they're	7	the 4.9, 159 of those seroconverted. Right?
8	lower, which is sort of strange. So	8	A. 159 of 169, that's right, yeah.
9	you wonder what's going on.	9	Q. If you actually run the number,
10	BY MR. KELLER:	10	that's 94.1 percent. Does that make sense?
11	Q. So during the middle of this	11	A. Yeah, that makes sense.
12	protocol, you're having the lab go back and	12	Q. So if you look at the failures,
13	retest results from the protocol, whether	13	159 out of 169, 10 kids didn't seroconvert for
	111111 135416 Irom the protocol, whether	14	4.9, 12 didn't seroconvert for 4.0 and 20
14	they're control failures or vaccine failures		1.2, 12 didn't seroconvert for 4.0 and 20
14 15	they're control failures or vaccine failures,		didn't seroconvert for 3.7. Do you see that?
15	but you're retesting data that's	15	didn't seroconvert for 3.7. Do you see that? $\Delta = \mathbf{V}_{\text{es}}$
15 16	but you're retesting data that's A. I'm not having anybody do	15 16	A. Yes.
15 16 17	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I	15 16 17	A. Yes.Q. That adds up to 42, doesn't it,
15 16 17 18	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of	15 16 17 18	A. Yes. Q. That adds up to 42, doesn't it, sir?
15 16 17 18 19	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of data I would like to see. So in other words,	15 16 17 18 19	A. Yes. Q. That adds up to 42, doesn't it, sir? A. Yeah, it would.
15 16 17 18 19 20	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of data I would like to see. So in other words, where it would be useful to get data now I	15 16 17 18 19 20	A. Yes. Q. That adds up to 42, doesn't it, sir? A. Yeah, it would. Q. So does that help you to
15 16 17 18 19 20 21	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of data I would like to see. So in other words, where it would be useful to get data now I you know, you can't just willy-nilly retest	15 16 17 18 19 20 21	A. Yes. Q. That adds up to 42, doesn't it, sir? A. Yeah, it would. Q. So does that help you to understand the 42 failures that are listed
15 16 17 18 19 20 21 22	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of data I would like to see. So in other words, where it would be useful to get data now I you know, you can't just willy-nilly retest stuff. So there has to be some protocol	15 16 17 18 19 20 21 22	A. Yes. Q. That adds up to 42, doesn't it, sir? A. Yeah, it would. Q. So does that help you to understand the 42 failures that are listed here that were given to the research lab
15 16 17 18 19 20 21 22 23	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of data I would like to see. So in other words, where it would be useful to get data now I you know, you can't just willy-nilly retest stuff. So there has to be some protocol followed, and that's the lab's problem, not	15 16 17 18 19 20 21 22 23	A. Yes. Q. That adds up to 42, doesn't it, sir? A. Yeah, it would. Q. So does that help you to understand the 42 failures that are listed here that were given to the research lab that's doing Protocol 007 to retest the 42
15 16 17 18 19 20 21 22	but you're retesting data that's A. I'm not having anybody do anything. I did not direct anything or I just expressed an opinion as to what kind of data I would like to see. So in other words, where it would be useful to get data now I you know, you can't just willy-nilly retest stuff. So there has to be some protocol	15 16 17 18 19 20 21 22	A. Yes. Q. That adds up to 42, doesn't it, sir? A. Yeah, it would. Q. So does that help you to understand the 42 failures that are listed here that were given to the research lab

1	Page 218	1	Page 220
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	positives. I hadn't made that connection,	2	for speculation.
3	but it may explain it.	3	THE WITNESS: I don't know that
4	Q. Why would you test in the middle	4	from the e-mail. It was obviously
5	of an assay let me back up a second.	5	discussed. But whether they did it, I
6	If the assay had not been	6	don't know.
7	completely validated at this point, based on	7	
8	your supervising clinical studies throughout	8	(Exhibit Schodel-7, 3/1/01
9	your 30-year career, what justification could	9	E-mail, Bates MRK-KRA00549218 &
10	be done for going back and testing the	10	00549219, was marked for identification.)
11	failures	11	
12	MR. SANGIAMO: Object to the	12	BY MR. KELLER:
13	form. Calls for speculation.	13	Q. For the record, I've marked as
14	MR. KELLER: I'm not done, Dino.	14	Exhibit 7 a document that has previously been
15	BY MR. KELLER:	15	marked by Morsy
16	Q for testing the failures in	16	MR. SANGIAMO: Exhibit 12.
17	the middle of a clinical study before you	17	BY MR. KELLER:
18	validated the study?	18	Q Exhibit 12 which bears Bates
19	MR. SANGIAMO: Object to the	19	stamp number KRA 549218 through 219. Doctor,
20	form. Calls for speculation.	20	I'd like you to take a minute to look at this
21	THE WITNESS: There's a lot of	21	and see if you recall receiving this e-mail.
22	inherent assumptions in there. First	22	I'll represent that you're on one of the
23	of all, what does validating the study	23	listed.
24	mean?	24	A. I'm obviously copied on that.
25	BY MR. KELLER:	25	I was you know, it's an invitation for a
	Page 219		Page 221
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Validating the protocol of	2	meeting. So I since I'm copied on it, I
3	Protocol 007 for the PRN assay	3	probably received it and I probably I
4	A. How would you do that?	4	don't remember this meeting at all. This was
5	Q. Don't they validate those assays	5	a few years ago.
6	before they run them?	6	Q. That's fair. This was an e-mail
7	A. That's not the protocol.	7	dated March 1, 2001, from Keith Chirgwin to a
8	That's the assay. The assay, I believe, was	8	whole host of people including yourself.
9	validated.	9	Correct?
10	Q. Was it validated before the	10	A. Yes.
11	assay was started?	11	Q. The topic was "URGENT Mumps
12	A. I would assume so, but I don't	12	expiry - Tomorrow's Teleconference." Do you
13	know.	13	see that?
14	Q. Is that typically done?	14	A. Yes.
15	MR. SANGIAMO: Object to the	15	Q. In the first there's a point
16	form.	16	that says number "1-Preparation for RMC
17	THE WITNESS: You're asking me	17	discussion on March 8." Do you see that?
18	to speculate about what the lab did.	18	A. Yes, I see it.
19	It was not my responsibility.	19	Q. Do you know what RMC is?
20	BY MR. KELLER:	20	A. I don't remember that acronym
21	Q. Sure. But is it fair to say	21	anymore. It was some research management
22	that in February 22nd, 2001, the lab was going	22	committee or something, but I'm making this
23	back and retesting the failures from the	23	up because I'm not sure what it means.
24	seroconverting failures of Protocol 007?	24	There's a lot of acronyms at Merck.
	MR. SANGIAMO: Objection. Calls	25	
25	MR. SANGIAMO: Objection. Cans	43	Q. Do you know what a recall

56 (Pages 218 - 221)

1	Page 222	1	Page 224
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	committee meeting is? A. Huh?	2	And under 6 it says you, Dr. Schodel.
		3	Do you see that? A. Yes.
4 5	Q. A recall committee meeting is?	5	
l	A. This is I don't think this	-	Q. Number 2 it says, "plans for
6	is a recall meeting. But I don't know.	6	assessment and possible need for rescue."
7	Q. Fair enough.	7	What did you mean by that? What do you
8	A. Recall meeting? I don't know.	8	understand that to mean?
9	I don't think so.	9	MR. SANGIAMO: Objection.
10	Q. I'm just asking if you	10	THE WITNESS: I have no idea.
11	A. No.	11	MR. SANGIAMO: The question is
12	Q. Number 2 says, "Preparation for	12	what do you understand that to mean?
13	CBER stability discussion later this month."	13	MR. KELLER: Yes.
14	Do you see that?	14	THE WITNESS: Assessment I
15	A. Yes.	15	mean, rescue would mean revaccination,
16	Q. Under "Agenda" it says, "MMD:	16	I guess, if there was any rescue
17	Follow-up discussion with CBER - lots out of	17	needed, but I don't know what was
18	compliance." Do you see that?	18	meant here.
19	A. Yes.	19	BY MR. KELLER:
20	Q. It has Roberta McKee, Mike King	20	Q. You don't know. Okay. Fair
21	and Mike Angelo. Do you see that?	21	enough.
22	A. Yes.	22	MR. KELLER: Mark Exhibit 8.
23	Q. Were those the people responsible	23	
24	for determining whether or not to disclose the	24	(Exhibit Schodel-8, PowerPoint
25	lots out of compliance issue that we talked	25	presentation, Bates MRK-CHA00086318,
	Page 223		Page 225
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	about?	2	was marked for identification.)
3	A. As I said before, I don't know	3	
4	who was responsible, if there was a	4	BY MR. KELLER:
5	responsibility indeed. Roberta McKee was in	5	Q. For the record, Exhibit 8 is a
6	regulatory on the CMC side, so on the	6	document that bears Bates stamp number 86318,
7	manufacturing side, and Mike King was	7	and it's a three-page presentation document.
8	manufacturing, and Mike Angelo was in quality	8	And I'll tell you from the metadata produced,
9	control and manufacturing as well.	9	this is dated March 3, 2001. And my note
10	Q. These lots out of compliance,	10	identifies this as being used at the 3/8
11	since this is contemporaneous with the memo	11	teleconference.
12	that Ms. Margolskee is it Dr. Margolskee?	12	A. Is that the entire presentation?
13	MR. SANGIAMO: Dr. Margolskee.	13	Q. Yes. Can you tell me if you
14	BY MR. KELLER:	14	recall ever seeing this presentation before?
15	Q. Dr. Margolskee sent to the	15	MR. SANGIAMO: Dr. Schodel, you
16	president of Merck as well as a bunch of other	16	don't have to accept Mr. Keller's
17	folks, do you understand that to be the same	17	representation that he just made to
18	106 lots she was talking about?	18	you about being the entire
19	A. I don't know.	19	presentation and the date. I'm not
20	Q. You don't know. If you look on	20	saying he's wrong, but you don't have
21	the next page under "Clinical," number 1 it	21	to accept it.
	says, "Clinical support for end of shelf life	22	MR. KELLER: Are you saying the
122		23	metadata is false?
22	titers " Do you see that"		
23	titers." Do you see that?		
	A. Yes. Q. Under 5 it says, "Jerry Sadoff."	24 25	MR. SANGIAMO: No, I'm not saying that it is false. I haven't

	Page 226	1	Page 228
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	seen the metadata. Sitting here right	2	A. I see that.
3	now, I can't I don't know what the	3	Q. That data, that's Protocol 007
4	metadata says.	4	with a release with a potency below 4.3,
5	THE WITNESS: I don't remember	5	either 4.0 or 3.7. Correct?
6	the details, but I can read it, of	6	A. I'm not sure entirely because
7	course.	7	this is a different time here. This was
8	BY MR. KELLER:	8	when did this happen? I mean
9	Q. Sure. Focus on the first page.	9	Q. The date on the document says
10	A. Okay.	10	the metadata which is the computerized
11	Q. Stability data do not support	11	data that comes
12	current end of shelf life (4.3 log). Do you	12	A. We're talking about 2001.
13	see that?	13	Q. Yes.
14	A. I see that.	14	A. Which was when that protocol
15	Q. Does this help refresh your	15	was being run. Right?
16	memory at the time of this presentation that	16	Q. Correct.
17	the shelf life label claim was 4.3 log?	17	A. So it's not it wasn't
18	A. That's what is stated here.	18	planned for that purpose.
19	Q. Do you recall there being a	19	Q. But was it used for that purpose?
20	meeting that discussed that the stability data	20	MR. SANGIAMO: Object to the
21	did not support the current end of shelf life	21	form.
22	label claim of 4.3?	22	BY MR. KELLER:
23	MR. SANGIAMO: Objection.	23	Q. Let me back up. What was the
24	THE WITNESS: I now remember	24	purpose of you say it wasn't planned for
25	that I was in a meeting with this	25	the purpose. What was the purpose Protocol
	Page 227		Page 229
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 229 FLORIAN SCHODEL, MD - CONFIDENTIAL
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL topic because you just showed me the	2	5
	FLORIAN SCHODEL, MD - CONFIDENTIAL		FLORIAN SCHODEL, MD - CONFIDENTIAL 007? A. I said that before. It was to
2	FLORIAN SCHODEL, MD - CONFIDENTIAL topic because you just showed me the	2	FLORIAN SCHODEL, MD - CONFIDENTIAL 007? A. I said that before. It was to provide clinical data to support what now had
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL topic because you just showed me the agenda so, yes, I do, I can read. BY MR. KELLER: Q. Do you recall any discussion	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL 007? A. I said that before. It was to provide clinical data to support what now had changed in the labeling expectations, a
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL topic because you just showed me the agenda so, yes, I do, I can read. BY MR. KELLER: Q. Do you recall any discussion that happened at that meeting?	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL 007? A. I said that before. It was to provide clinical data to support what now had changed in the labeling expectations, a scientifically supported end expiry number.
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	D 220		D 222
1	Page 230	1	Page 232 FLORIAN SCHODEL, MD - CONFIDENTIAL
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	·
2	was run, because quite obviously I mean,		and negative," is that for purposes of the
3	this happened in 2001, the protocol was	3	ELISA assay used in Protocol 007, used to
4	already under way, so it was not planned or	4	determine whether or not the results are
5	designed for this particular purpose.	5	treated as a seroconversion?
6	Q. But it certainly increased the	6	A. Yeah, it would be for the
7	importance of that protocol having a reduced	7	purpose of a seroconversion and to determine
8	potency from 4.3 to either 4.0 or 3.7. Correct?	8	whether somebody has preexisting antibodies
9	MR. SANGIAMO: Object to the	9	or postvaccination antibodies. The two are
10	form.	10	linked, of course.
11	THE WITNESS: At least	11	Q. You talked earlier, there's two
12	temporarily, yes, because now there	12	ways to analyze ELISA assays. One was by
13	were data that could be supplied	13	using a fixed cutoff and the other one was
14	which and often not available in	14	using a fold criteria?
15	these kinds of situations.	15	A. Right.
16		16	Q. Fourfold criteria?
17	(Exhibit Schodel-9, 9/28/01 E-mail	17	A. Right.
18	with attachment, Bates MRK-KRA00561416	18	Q. So is it fair let me just
19	- 00561421, was marked for identification.)	19	kind of go through this e-mail. Here the
20		20	subject is CBER background ELISA. During the
21	BY MR. KELLER:	21	CAS strike that.
22	Q. Let me mark as Exhibit 9 a	22	"During CAS and at some
23	document bearing Bates stamp number 561416	23	follow-up meeting, some additional clinical
24	through 21. And here there is a it's an	24	information was request to address some areas
25	e-mail with an attachment. The e-mail is from	25	of concern."
	Page 231		Page 233
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL Jonathan Hartzel to a laundry list of folks including you, Dr. Schodel. Can you tell me, if you take a minute to take a look at this and tell me if you recognize the e-mail and the attachment as well? A. There's a lot of information in here, so while I can quickly read it, it doesn't mean that I'll be able to answer to all details. Q. Do you recall seeing this e-mail and attachment? A. Not this specific one, but I do remember that a discussion about the ELISA cutoff at some point happened. Q. That discussion about the ELISA cutoff, we're talking about the cutoff of the wild-type ELISA assay used in Protocol 007? A. Uh-huh. Q. What is a cutoff? A. A cutoff is a number that with reasonable certainty distinguishes between	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL The CAS, that's the clinical assay subteam committee. Correct? A. I think so, yeah. Q. Were you a member of that? A. Yes. Q. Were you the head of that committee? A. At some point, yes. Q. During this period A. Or co-chair anyway. Q. During the September of 2001 were you the co-chair or head of this committee? A. Probably. Not so good with the time exactly. Q. What was the purpose of this committee? A. Was to review the status. The major purpose was an operational one. It was to make sure that we actually could do the assays that we needed to be done in time. So we had a lot of assay throughput because of

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	D 224		p. 226
1	Page 234 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 236 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	not being done in time. We had to come up	2	used.
3	with a better way to manage that. That was	3	So we had similar discussions
4	the major purpose why we started this	4	about a number of assays. So the concern was
5	committee and then we on occasion also looked	5	whether we could come to a common
6	at specific questions around the assays as	6	understanding. In order to do that, we had
7	they concerned any one of the participants,	7	to look at the data. That's not something
8	whether that was clinical or regulatory or	8	that was not shared with CBER because it
9	the lab.	9	wouldn't have been shared with CBER. In
10	Q. So do you recall a discussion at	10	fact, the e-mail below tells you that it has
11	the clinical assay subcommittee regarding the	11	actually been faxed to CBER. So data
12	setting of what standard would be used to	12	was faxed to CBER
13	determine a seroconversion with the ELISA	13	O. That's a different that
14	assay used in Protocol 007?	14	attached something different.
15	A. No. I do vaguely remember that	15	MR. SANGIAMO: Mr. Keller, you
16	the discussion that is represented here	16	got to let him finish his answers.
17	happened that it was set, and that I don't	17	MR. KELLER: Sure.
18	think we had pre-discussed how to set it in	18	MR. SANGIAMO: So what's the
19	that particular committee. At least I don't	19	pending question?
20	remember it. And that CBER wanted more	20	THE WITNESS: But the value of
21	information about its behavior in classifying	21	the I mean the data themselves
22	sera and that information was provided. Then	22	would have been discussed internally
23	the information that was available was	23	before they were sent off. Besides
24	discussed obviously as it is attached here.	24	these are these are this is all
25	Q. So here in these the second	25	based on just assay data that have not
	Page 235		Page 237
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	these areas where it says, "to address some	2	been cleaned or screened so they would
3	areas of concern," it says, "This information	3	never been used for clinical
4	was not to be sent to CBER, but was for our	4	submission. They would not be they
5	own understanding." Do you see that?	5	would not send to an agency data you
6	A. Yeah.	6	do not consider final data because
7	Q. So was that typical at Merck, to	7	they have not been cleaned or
8	discuss information that would be a concern	8	screened. That would be actually not
9	and not provide that information to CBER?	9	in compliance. So why should they be
10	A. There was nothing to provide to	10	shared with CBER. There's no reason
11	CBER because the area of concern is the	11	to.
12	debate that was ongoing at CBER at the time	12	Now I have to share something
13	as well as to whether an absolute cutoff was	13	with you. I need a break.
14	okay or whether you should apply fourfold	14	MR. KELLER: Sure.
15	criteria and all kinds of permutations in	15	VIDEOGRAPHER: Off the record at
16	between which can cause more confusions than	16	2:11. This will end disc number
17	anything else. The same discussion about	17	three.
18	Varicella and about other assay. I don't	18	
19	recall any specific issue with mumps. And,	19	(A recess was taken.)
20	of course, in addressing these kinds of in	20	
21	CBER there were two schools of thought.	21	VIDEOGRAPHER: Back on the
22	There were those who wanted to have fourfold	22	record at 2:19. Beginning of disc
23	criteria and those who were okay with the	23	number four.
24	cutoff and had been taking part in these	24	BY MR. KELLER:
25	cutoff discussions and how they were to be	25	Q. Dr. Schodel, if you look on the

Page 238 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 e-mail that you received attaching this Mu 2 regarding the setting of the serostatus cutoff 3 3 Dist plus Mu Me Pre-Pos Rates.doc, it says, at a range between 10 and 40? 4 Attached is a memo which contains information A. No. 5 5 on the distribution of 6 week mumps titers Do you recall there being any based on mumps wild-type ELISA assay (with 6 discussion about the serostatus cutoff of 10 7 special interest in those falling between 10 7 being too low? 8 and 40). 8 A. No. 9 9 Do you recall discussions Do you recall there being any 10 regarding whether or not setting the 10 concern that CBER would want to see a higher serostatus cutoff for the ELISA arm of 11 serostatus cutoff? Protocol 007 as to whether or not the A. No, not in this particular way. 12 12 13 serostatus cutoff should be set between those You have to go back to what we discussed 13 14 ranges of 10 and 40? 14 before which is the mixing of these two 15 MR. SANGIAMO: Object to the 15 16 16 Q. Gotcha. So at this point in form. 17 THE WITNESS: I do not recollect 17 time there hadn't been a determination as to 18 such discussions. what criteria would be used, whether the 19 BY MR. KELLER: serostatus cutoff, a fixed cutoff or one 20 Q. Do you know -- so you don't know 20 with -- that's based on a fourfold criteria. 21 the special interest in those fall in between 21 Correct? 22 those 10 and 40 range? 22 No. It had been determined A. 23 No, you asked me a different 23 that a serostatus cutoff would be used. So a 24 question. So ask the question again. fixed cutoff. That is what was submitted to 25 Sure. Do you recall -- so you 25 CBER and what was -- how the assay was run. Page 239 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 2 don't recall what the special interest CBER on the other hand, was apparently still 3 identified in this particular e-mail the struggling with the concept and some people writer had with respect to the cutoff arm 4 wanted, in addition, to apply a fold rise 5 between 10 and 40? 5 criteria. That message was the serostatus 6 MR. SANGIAMO: Object to the 6 cutoff because now you have to figure out 7 7 form. what would that mean in terms of THE WITNESS: I can deduce it 8 classification because you're not changing 9 from the rest of the e-mail. So could your serostatus cutoff but you're adding a 10 you. It goes back to this discussion different criterion and it changes how you 11 of whether a fourfold rise is 11 classify things. 12 important or it should be applied on 12 Q. So if you hit a serostatus 13 top of a serostatus cutoff. Because cutoff of -- if you set it at, for example, 14 ten, there was a concern that you'd also have these things were not completely 14 15 worked out by the time of this 15 a fourfold increase between the pre and the 16 meeting, we had to take into account 16 post? 17 17 what would happen if a fold rise would A. That's right. And if you were 18 apply even though the serostatus 18 to do that, then obviously you would lose 19 cutoff in our eyes was the right thing 19 quite a bit of the population that fall in 20 20 to do. between these two because you could no longer 21 BY MR. KELLER: 21 determine whether they were seroconverting. 22 Q. I see. Was there a concern, do 22 So that would change the population in your 23 you recall -- you said that you're deducing 23 trial. 24 from that. Do you recall any specific 24 And the people that were leaning conversations at Merck during this time frame 25 towards doing a fourfold analysis were the

1	Page 242	1	Page 244
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL folks at CBER. Correct?	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
		2	whether or not it can protect a kid from
3	A. It came back several times from	3	getting the kid has more
4	CBER. I think it's more I don't know	4	A. There is no absolute cutoff
5	exactly who it was, but I think it's more the	5	that the would protect anybody. Even a
6	old school thought of because that's what	6	higher titer wouldn't necessarily protect
7	we've done all the time. And then eventually	7	them.
8	it changed.	8	Q. So the cutoff is not tied to
9	Q. Let's turn your attention to the	9	whether or not for this ELISA assay,
10	attachment to this e-mail which is 561418.	10	whether or not it will protect kids from
11	A. Yes.	11	getting mumps. Right?
12	Q. Here it says, "Distribution of	12	A. No. No.
13	6-week Mumps Titers Using the Mumps Wild-type	13	Q. Subjects who have titers of than
14	ELISA Assay." Do you see that?	14	less than 10 Ab units are considered negative.
15	A. Yes.	15	Do you see that?
16	Q. This wasn't attached to CBER.	16	A. Yes.
17	Correct?	17	Q. So those folks, if you have a 10
18	A. I don't know	18	Ab cutoff if you had if the results of
19	MR. SANGIAMO: Object to the	19	this assay were below 10 Ab, that would be a
20	form.	20	seroconversion failure. Right?
21	THE WITNESS: whether it was	21	MR. SANGIAMO: Object to the
22	attached to CBER, so I couldn't tell	22	form.
23	you.	23	THE WITNESS: No. If you have a
24	BY MR. KELLER:	24	titer initially of 8 and you have 200
25	Q. It's not in the listing of the	25	afterwards, that's a seroconversion.
	Page 243		Page 245
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	e-mail that's below	2	If you have a titer initially of 12
3	A. As it states in this e-mail	3	and you now have a titer of 8, that's
4	here, these are uncleaned and screened data	4	not a seroconversion.
5	so they would not be submitted as such to	5	BY MR. KELLER:
6	CBER.	6	Q. That's a pre-positive?
7	Q. Here it says, "M-M-R® II	7	A. That's where a problem
8	Protocol 007 and ProQuad® Protocol 012 are	8	potentially could be. Or if you have a titer
9	currently the only studies in which the new	9	of 8 and 8, that's also not a seroconversion.
10	mumps wild-type ELISA assay has been performed.	10	But anything goes from below 10 or above 10
11	Do you see that?	11	is a seroconversion.
12	A. Uh-huh.	12	Q. Gotcha. And that's what
13	Q. These were a new assay.	13	you're converting the blood is converting
14	Correct?	14	from one state to another. Correct?
15	A. Yes.	15	A. That's right. That's why it's
16	Q. "For this assay the seroprotective	16	a classification, it's a little different
17	level is defined to be 10 Ab units."	17	from the fourfold criteria.
18	Do you see that?	18	Q. So here in this document it
19	A. Yes.	19	says, There is some concern that CBER may
20	Q. When it says "seroprotective,"	20	require a fold rise in titers (from
21	what do you understand that to mean?	21	pre-negative to postvaccination) in order to
22	A. Well, that's actually a little	22	demonstrate that seroconversion has occurred.
23	bit of mislabeling. It's the seropositive	23	So that a subject who has a prevaccination
24	level.	24	titer of 9.9 and a postvaccination titer of
25	Q. I see. So it's not identifying	25	10.1 (the difference being within the
20	Z. 1500. So it's not identifying		13.1 (ale difference being within the

1	Page 246	1	Page 248
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	variability of the assay) would not be	2	general I think when such requests came in,
3	considered a seroconverter.	3	we would do an analysis of what it would do to the results. But there is an additional
4 5	Do you see that? A. That's correct.	5	difficulty with that. It's not just that it
6	Q. But for the end result was that	6	changes the results. It also changes the
7	a fourfold analysis wasn't done. Correct?	7	population that you identify because now
8	A. No.	8	everybody who is between 10 and 40 falls out.
9	Q. So under Merck's analysis, if	9	So there's a number of things, number of
10	their prevaccination titer and their wild-type	10	consequences to consider. So all the people
11	ELISA assay was 9.9 and postvaccination titer	11	who actually have responded but at a lower
12	was 10.1, that would be a seroconverter?	12	rate are no longer considered. Not that
13	A. Yes.	13	that's it's not a big population here,
14	Q. When it says that is the	14	but
15	difference being "the difference being	15	Q. But isn't the purpose of setting
16	within the variability of the assay," is	16	the here it says seroprotective level, but
17	that does that mean that those results	17	the serostatus cutoff is to identify some
18	could switch each time you ran the assay?	18	immunological response in the blood to the
19	A. That's right. But, of course,	19	antibodies that would lead to a conclusion
20	they do that in both ways, because it's the	20	that the kid will be protected from getting
21	variability of the assay. So you will also	21	the mumps virus?
22	have people who are pre-positives. In other	22	MR. SANGIAMO: Object to the
23	words, they're not considered, and then they	23	form.
24	become seronegative.	24	THE WITNESS: Those are two
25	Q. If the analysis show that they	25	different concepts. First of all, the
	Page 247		Page 249
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	were all going in one direction, would that	2	primary and most important part is
3	cause you concern?	3	that you said a cutoff in a way that
4	MR. SANGIAMO: Objection to the	4	it relatively reliably and repeatedly
5	form.	5	allows you to distinguish between two
6	BY MR. KELLER:	6	different populations, those that have
7	Q. Like the variability, if, you	7	seroconverted and those that have not
8	know, instead of being balancing out the	8	seroconverted. The question as to
9	disgruntle results balancing out	9	whether that's related to protection
10	A. It's a theoretical question.	10	or not is not one that entered here at
11	In any assay if everything goes in one	11	all because there is no efficacy study
12	direction, you would try to analyze why that	12	attached to it.
13	is. It doesn't necessarily mean it's wrong.	13	BY MR. KELLER:
14	There could be reasons for it. But it's	14	Q. Right. CBER didn't require any
15	something that you want to look at. But it	15	sort of analysis to sort of link the
16	doesn't apply here.	16	serostatus cutoff to something that relates to
17	MR. SANGIAMO: Objection to the	17	the vaccine at that level protecting the kid
18	form of that last question. Thank	18	from getting sick?
10	=	19	MR. SANGIAMO: Object to the
19	you.		
	you. BY MR. KELLER:	20	form.
19	•	20 21	form. THE WITNESS: There is no
19 20	BY MR. KELLER:		
19 20 21	BY MR. KELLER: Q. Do you recall doing any analysis	21	THE WITNESS: There is no
19 20 21 22	BY MR. KELLER: Q. Do you recall doing any analysis as to the results of Protocol 007 to see	21 22	THE WITNESS: There is no efficacy trial that that could have

1	Page 250	1	Page 252
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL of acquiring mumps.	$\frac{1}{2}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
$\frac{2}{3}$	BY MR. KELLER:	$\frac{2}{3}$	other institutions, that different mumps
4		4	strains react differently in the neuts assay. So if you use a different strain and if you
5	Q. What's your basis for that?	5	use different conditions, you can see
_	A. Epidemiology, look at the	6	seroconversion rates that are different with
6	curves. There's almost no mumps in the United States.		
7 8	0	7 8	the same set of sera. It has nothing to do with Merck. That's just a general fact of
9	Q. How do you explain the outbreaks that occurred in 2006, 2009 and currently?	9	
10		10	the neutralization assay.
11	A. It's not perfect protection but it's a protection that has reduced the level	11	Q. Who do you recall speaking with at NIH?
12	by several hundred folds.	12	
13		13	,
		14	
14	is not performing as well as it did in the		A. Oh, I don't know.
15	past?	15	Q. Last year? A. No, no.
16	A. No, I don't have to admit that at all.	16	
17 18		17 18	Q. 20 years ago?
19	Q. You think it works perfectly the same as it did back when Dr. Hilleman ran		A. It was certainly more around the time of the of an outbreak probably or
		19 20	an investigation into an outbreak.
20 21	those assays? A. Yes, I do.	21	Q. So in the 2006, 2009?
$\begin{vmatrix} 21\\22\end{vmatrix}$	Q. Do you sit here today and think	$\begin{vmatrix} 21\\22\end{vmatrix}$	
23	that the vaccine protects 96 percent of the	$\begin{vmatrix} 22\\23 \end{vmatrix}$	A. Yeah, that may be the right time.
24	kids who get the vaccine?	24	Q. In regards to 2006 or 2009?
25	A. That's I don't know that	25	A. No, I don't. I said 2009
1	Page 251 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 253 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	exact number. But it certainly whatever	2	certainly not.
3	the number was then, which has some	3	Q. Sometime around 2006?
4	uncertainty around it, too, because of how	4	A. Yeah.
5	the trials were run, I would consider under	5	O. Were these studies ever
6	the same circumstances that to be still the	6	conducted by Merck or studies conducted by
7	same.	7	CBER?
8	Q. I see. Have you seen any	8	A. What do you mean by "these
9	studies conducted by Merck that showed that	9	studies"?
10	the vaccine performed significantly lower than	10	Q. These discussions you talked
10			
		11	about, were those studies
11 12	96 percent	11 12	about, were those studies A. Well, at the time
11	96 percent A. That the vaccine performance		A. Well, at the time
11 12	96 percent	12	
11 12 13	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that.	12 13	A. Well, at the timeMR. SANGIAMO: Just a minute,Dr. Schodel, let Jeff finish his
11 12 13 14	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays	12 13 14	A. Well, at the time MR. SANGIAMO: Just a minute,
11 12 13 14 15 16	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps	12 13 14 15	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER:
11 12 13 14 15	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization	12 13 14 15 16	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER:
11 12 13 14 15 16 17	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be	12 13 14 15 16 17	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different
11 12 13 14 15 16 17 18	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be below 80 percent?	12 13 14 15 16 17 18	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different seroconversion rates based on a plaque
11 12 13 14 15 16 17 18 19	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be below 80 percent? A. Not a formal study, no.	12 13 14 15 16 17 18 19	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different seroconversion rates based on a plaque reduction neutralization assay, were these
11 12 13 14 15 16 17 18 19 20	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be below 80 percent? A. Not a formal study, no. Q. If it's not a formal study, then	12 13 14 15 16 17 18 19 20	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different seroconversion rates based on a plaque reduction neutralization assay, were these assays that you discussed, were these run by
11 12 13 14 15 16 17 18 19 20 21	96 percent A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be below 80 percent? A. Not a formal study, no.	12 13 14 15 16 17 18 19 20 21	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different seroconversion rates based on a plaque reduction neutralization assay, were these assays that you discussed, were these run by Merck or were they run by somebody else
11 12 13 14 15 16 17 18 19 20 21 22	A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be below 80 percent? A. Not a formal study, no. Q. If it's not a formal study, then what kind of study did you see?	12 13 14 15 16 17 18 19 20 21 22	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different seroconversion rates based on a plaque reduction neutralization assay, were these assays that you discussed, were these run by
11 12 13 14 15 16 17 18 19 20 21 22 23	A. That the vaccine performance Q by neutralizing studies? Let me strike that. Have you ever seen any assays conducted at Merck with respect to the mumps vaccine by a plaque reduction neutralization assay that showed the seroconversion to be below 80 percent? A. Not a formal study, no. Q. If it's not a formal study, then what kind of study did you see? A. I remember that both from	12 13 14 15 16 17 18 19 20 21 22 23	A. Well, at the time MR. SANGIAMO: Just a minute, Dr. Schodel, let Jeff finish his question. BY MR. KELLER: Q. These studies, these conclusions that different viruses will have different seroconversion rates based on a plaque reduction neutralization assay, were these assays that you discussed, were these run by Merck or were they run by somebody else MR. SANGIAMO: Object to the

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1	Page 254 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 256 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q when you talked to Mr. Rubin,	2	be an argument. But then you would get into
3	Dr. Rubin?	3	the other problem that you misclassify people
			who are actually seropositive into being
4	A. I think both at Merck and at	4	
5	the NIH there were mumps neutralizing assays	5	seronegative. So it's a decision that has to
6	performed with different strains. At the	6	do with the classifications. And you would
7	time there was a question as to whether	7	change whom you call positive and whom you
8	outbreaks might be due to strains with	8	call negative.
9	different characteristics, different genetic	9	Q. I'm just trying to understand
10	sequences, different virulents. So various	10	how you set a cutoff, serostatus cutoff. If
11	labs tried to figure out what the basis of	11	it's not linked to whether or not it protects
12	these apparently high out attack rates in	12	the kid, then what are you linking that cutoff
13	certain populations were. And in the context	13	at? It seems arbitrary.
14	of that other strains were tried as well.	14	MR. SANGIAMO: Object to what
15	Q. Do you know which strains were	15	is your question?
16	tried?	16	BY MR. KELLER:
17	A. No, no idea.	17	Q. Is that cutoff, is it arbitrary
18	Q. Let me direct your attention	18	if it's not set to some ability to protect a
19	back to Exhibit 9 in the attachment 561418.	19	kid, if you're going to use an assay that
20	Here it says in the second paragraph, "Due to	20	reports in seroconversion, and that
21	the characteristics of the mumps wild-type	21	seroconversion is based on a static cutoff,
22	assay, it will be very difficult to accurately	22	and that cutoff is not set to anything as to
23	read titers below 10 Ab units."	23	whether or not it's going to protect a kid
24	Do you see that?	24	from getting sick, I'm just trying to
25	A. Yes.	25	understand, how do you set the cutoff? What's
	Page 255		Page 257
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. If the serostatus cutoff is set	2	the basis for setting it?
3	at 10, is there a concern that that assay	3	MR. SANGIAMO: Object to the
4	can't read below 10?	4	form.
5	A. Well, there is a concern if you	5	THE WITNESS: I think I said
6	apply a fourfold criterion. Because in order	6	that several times. The basis is a
7	to apply a fourfold criterion with a 10	7	simple classification of positives and
8	cutoff, you need to be able to read down to	8	negatives. You can set it at
9	2.5 accurately. That may not be possible,	9	different points and you will have
10	technically not be possible.	10	different classifications. And they
11	Q. Well, that's a question of	11	have they inherently have different
12	dilution, isn't it?	12	errors relative to the assay and
13	A. No, it's a question of the	13	potentially relative to outcomes. But
14	sensitivity of the assay. You can dilute as	14	this particular assay and the outcomes
15	much as you want. As you dilute, you also	15	are not linked in any meaningful
16	dilute the antibody. You may get rid of some	16	manner. So I can't say that on
17	background, but you don't necessarily gain	17	protection rates because I don't know
18	sensitivity.	18	what they are. And besides, it's been
19	Q. I see. So wouldn't that be an	19	observed in mumps that there isn't an
20	-	l	_
1	argument for increasing the cutoff?	20	absolute cutoff for protection,
21	A. As I said before, you can't see	21	otherwise we probably would have
22	these things in isolation. Yes, if you	22	cutoffs. In other words, there is not
23	wanted to use a fourfold criterion which I	23	a titer that you're completely
24	think would be inappropriate for this kind of	24	reliably protected.
25	an assay by today's standards, then it would	25	BY MR. KELLER:

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. So these errors that you're	2	required a 4-fold rise in titers (defined as
3	talking about, are these at all related to	3	less than 10 to greater than equal to 40), the
4	let me strike that.	4	seroconversion rate for these studies would
5	What do you mean by "errors"?	5	range from 80.9 percent to 85.2 percent.
6	You just referred to the errors in the	6	Do you see that?
7	classifications.	7	A. Yes.
8	A. Well, errors in classification	8	Q. That range is based on the
9	would be if you had a crystal ball and you	9	different potencies in the protocol for the
10	could tell the absolute truth of who has an	10	wild-type ELISA. Correct?
11	antibody and who doesn't have an antibody	11	A. Well, I assume that. I don't
12	even below the detection limit of an assay,	12	know that for sure. It could also be a
13	which, of course, you can't, then you would	13	different analysis that he performed. I
14	falsely classify some by one cutoff and	14	mean, it's clear the more people you exclude
15	others by another cutoff. But you don't	15	from the analysis, the more you change the
16	since you need a third, as they say in	16	outcome.
17	philosophy, tertium non datur, there is no	17	O. I see. So was that one of the
18	third to compare it to. So you don't have an	18	concerns that they're talking about here, is
19	absolute measure and therefore, the there	19	that if CBER required this fourfold rise, that
20	is always a degree of arbitrariness to	20	the seroconversion rate would, in fact, be
21	setting a serostatus cutoff, to use your own	21	lower than reported with the fixed 10 Ab
22	words. However, it is based on some	22	cutoff?
23	scientific principles which is you can	23	MR. SANGIAMO: Objection.
24	reliably distinguish seronegatives and	24	THE WITNESS: I can't speculate
25	seropositives and you can reliably	25	as to that. That would have been a
1	Page 259 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 261 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	distinguish those who will respond and those	2	consequence of what we thought at the
3	who will not respond. And that's good enough	3	time was not the right thing to do. I
4	for this kind of an assay.	4	think CBER concurred in the end.
5	Q. I see. Here in this memo, they	5	MR. KELLER: Let's mark this
6	state, "the difference being within the	6	next exhibit as Exhibit 10.
7	variability of the assay." If the variability	7	
8	of the assay falls below if you set it at	8	(Exhibit Schodel-10, E-mail chain,
9	10, the variability can run below 10, then you	9	Bates MRK-KRA00561361 - 00561365-00017
10	may have assays that have errors around that	10	was marked for identification.)
11	variability?	11	was marked for identification.)
12	MR. SANGIAMO: Objection to	12	BY MR. KELLER:
13	form.	13	Q. For the record, Exhibit 10 is a
14	THE WITNESS: That would be true	14	document that bears Bates stamp number 561361
15	for any cutoff in any form of	15	through 561365 which includes a PowerPoint
16	seroconversion rate you apply because	16	presentation at 561365 through there's 17
17	there's always an error around any	17	pages of this presentation.
1/	cutoff and any criterion and you will	18	A. I have two different ones here.
18	Catori and any criterion and you will	19	Q. One is I'm sorry. Let's pull
18	always have comething that falls	17	
19	always have something that falls	20	
19 20	within the error. The art is to be	20	the one of them. The 19058 you can just get
19 20 21	within the error. The art is to be reasonably outside of the error with	21	rid of. It's the same document. We
19 20 21 22	within the error. The art is to be reasonably outside of the error with the majority of your samples.	21 22	rid of. It's the same document. We previously marked 19085 in Morsy as
19 20 21 22 23	within the error. The art is to be reasonably outside of the error with the majority of your samples. BY MR. KELLER:	21 22 23	rid of. It's the same document. We previously marked 19085 in Morsy as Exhibit 20. I'm going to use this copy
19 20 21 22	within the error. The art is to be reasonably outside of the error with the majority of your samples.	21 22	rid of. It's the same document. We previously marked 19085 in Morsy as

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	Page 262		Page 264
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	MR. SANGIAMO: Actually it	2	Q. Let me direct your attention, do
3	doesn't. 19085 that's out of play	3	you recall the CRRC, that's the Clinical
4	right now.	4	Regulatory Review Committee. Correct?
5	MR. KELLER: That's out of play.	5	A. I don't know the exact acronym,
6	I'm just for the record, that	6	but something like that, yes.
7	document was used in Schodel [sic] and	7	Q. Were you a member of that
8	it's the same presentation but this	8	committee?
9	one was attached to an e-mail that	9	A. I don't think I was a member of
10	went to Dr. Schodel.	10	that as a core member. I was probably called
11	BY MR. KELLER:	11	in on occasion.
12	Q. So for the record, on	12	Q. Why would you be brought in on
13	January 18, 2002, there is a doc subject of	13	occasion?
14	this e-mail is CRRC Agenda - 22 January, 2002.	14	A. Well, if there were things
15	And, Dr. Schodel, you received this and was	15	discussed that were related to something I
16	sent by Dr. Chirgwin. Do you see that?	16	was responsible for. I mean, I was not
17	A. Yes.	17	responsible for all of clinical research or
18	Q. Can you take a minute and look	18	regulatory at Merck.
19	at this presentation and tell me if you recall	19	Q. Were you responsible for any
20	seeing this presentation? I'm not going to	20	aspect of Protocol 007?
21	ask you about every page, but you're welcome	21	A. No.
22	to look at it.	22	Q. So you don't know why you were
23	A. Okay.	23	called in?
24	Q. If you look on the e-mails that	24	A. Well, because I was I mean,
25	attach this particular PowerPoint, there's an	25	it wasn't only Protocol 007. Some of the
	Page 263		Page 265
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	e-mail from Jeffrey C-H-O-D-A-K-E-W-I-T-Z to	2	people who were running Protocol 007 by that
3	you as well as a bunch of other folks	3	time probably reported to me and I was, as
4	including Emilio Emini and it's talking about	4	you have noted before, on the clinical assay
5	the CRRC agenda. Here it says, Have you seen	5	subteam which is a subteam of the BPC.
6	draft overheads for the mumps assay issue?	6	Q. So you have expertise in the
7	Has the variability of the current status or	7	area of assays. Correct?
8	contingency of extended commitment to 4.3 been	8	A. Yes.
9	discussed addressed by MMD	9	Q. Let me direct your attention to
10	A. Sorry, viability.	10	slide 3 at 561365. And here talks of "Mumps
11	Q. Sorry. Viability. "Has the	11	Expiry Background Chronology of Events." Here
12	viability of the current status or contingency	12	it says, "1997 Clarification that labeled
13	of extended commitment to 4.3 been addressed	13	potencies must reflect end of shelf life claim
14	by MMD?"	14	(not minimal release)."
15	And then you responded, "Dear	15	Do you see that?
16	Jeff, I asked Joye and Alan yesterday and they	16	A. Yes.
17	assured me that Keith would present. I have	17	Q. Does that refresh your memory
18	not seen any overheads yet?"	18	that in 1997 is when that clarification
19	Then Chirgwin sent you the	19	occurred for mumps
20	overheads. Does that refresh your memory,	20	A. Yeah. I mean, that's what it
21	that you actually received these?	21	states here. I mentioned that several times,
22	A. Yeah.	22	that I didn't know anymore when it occurred
23	Q. Do you have any reason to	23	but that that particular clarification and
24	believe that you didn't receive this document?	24	the ensuing discussions ultimately led to the
25	A. No.	25	Protocol 007, not the modeling on stability
/ 1			1 10 10 00 1 , mot the incurring on statinty

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Page 266 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 that you referred to later. 2 form 3 THE WITNESS: I'm not sure what 3 Q. So it's your understanding that 4 as of 1997, CBER required that Merck's end of 4 that exactly refers to, what was 5 5 expiry shelf life have a minimum of what was validated, whether it was the assay or identified in the label at that point, not 6 something else. You have to see that 7 just release. Correct? 7 this was obviously an ongoing 8 8 A. I think that was the first time discussion with CBER and there may 9 9 when CBER formally informed Merck that that have been very specific CBER requests 10 was how their understanding of the labels had 10 that were honored by Merck. And that 11 evolved. And then there was a discussion 11 would supersede whatever normal ensuing so that it wasn't a one-time event as 12 procedure Merck had in place. 13 13 far as I remember. But, yes, at that point BY MR. KELLER: 14 in time CBER apparently shared its change of 14 Q. Is that typical for validating 15 view. 15 studies, to have them be validated 16 If you look on the next page, 16 concurrently with the running of the study? Q. September 1999 "Chronology of Events Mumps 17 17 A. It depends on -- it depends on Overfill." It says, Ongoing CBER concerns 18 the phase in which the study is done and what about misbranding result in general -- in 19 its purpose is. Very typical for Phase I and 20 agreement to increase the minimum release spec 20 Phase 2 studies. 21 for mumps from 4.3 to 5.0. Do you see that? 21 Q. This was Phase 3 study, though, 22 22 A. Yes. correct, Protocol 007? 23 Q. If you look on the next page, 23 A. No, it's not. No, it's not. 24 "Concerns about Stability," in August of 2000 24 This was not. This was probably a Phase 4 25 "Concerns raised regarding compliance with 25 study or a Phase 5 study. It was something Page 267 Page 269 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 that was negotiated with CBER. CBER knew 2 stability monitoring during FDA inspection." 2 3 3 Do you see that? very well what assays were available and were 4 A. Yes. 4 not available and what had to be developed 5 Q. Do you recall the inspection 5 because they even influenced which assays had that occurred in August of 2000 regarding 6 6 to be selected. 7 7 mumps stability? Q. So is it your testimony that you 8 A. No. Only some of the 8 knew -- that CBER -- is it your testimony that 9 discussions afterwards that you just shared 9 CBER knew that Merck was validating the assay 10 with me again. 10 while it was conducting it? 11 Q. Do you recall there being a 11 A. That, I don't know. I simply 12 concern that Merck's then current product was 12 wouldn't know. But it is my testimony that 13 out of specification with its end expiry CBER had a major role in deciding on this IgG 13 14 claims? 14 assay that you mentioned earlier. 15 A. No, I don't recall that until 15 Q. Why do you say that? 16 the dates when you showed me the --16 A. Because it came out of CBER. 17 Q. If you see at the bottom it says 17 It was CBER who suggested that assay in the 18 December of 2000. The "Expiry trial sera 18 first place. 19 began to be assayed; validations studies 19 How do you know they suggested Q. 20 20 it? conducted in parallel." Do you see that? Uh-huh. 21 21 A. That was what I always heard. 22 So while they were analyzing the 22 Who did you hear that from? 23 Protocol 007 data, they were at the same time 23 Probably from CBER as well as 24 validating those same studies? 24 from Merck people. I don't remember who 25 MR. SANGIAMO: Object to the specifically told me. But this is an ongoing

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Page 270 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 discussion. It was an ongoing discussion. 2 are you just --3 3 What was the ongoing discussion? A. No. 4 4 I don't know the details Q. -- summarizing? 5 Well, I -- it was mentioned in 5 anymore. Just what I remember is that this Α. particular assay format was suggested by CBER. 6 some of the mails that you showed me. Q. Do you know whether or not Merck 7 Q. But you don't recall. Let me --8 8 do you recall any discussion that Merck used had brought it up to CBER first and asked if 9 they could use it? 9 the results of Protocol 007's PRN assay to 10 A. No, I don't know that. 10 prevent CBER from recalling the product that was out on the market below 4.3 end expiry? 11 Q. Do you know whether or not CBER 11 required that to use the rabbit anti-IgG, that 12 A. I do not. it would have to properly validate that assay 13 13 You don't know. If you look on 14 before it was used? 14 the last date in this chronology, December 15 A. You'd have to ask Kathy Carbone 15 '01, "CBER indicates that compliance concerns 16 since she would know that better than I. I may preclude using the mumps PRN data." 17 17 don't know. Do you see that? 18 Yes, I see that. 18 Q. Let me direct your attention to 19 19 slide 6 which is the chronology of events for Do you know what the compliance 20 preliminary results of expiry trial. Do you 20 concerns were? 21 see that? 21 A. Vaguely. I remember that there 22 22 A. Yes. was an FDA inspection of the lab that ran the 23 Q. Here it says February '01, 23 assay as opposed to manufacturing. And then 24 "Subset analysis indicates that 4.0 log (but 24 that in that particular -- I wasn't in the 25 25 not 3.7...) dose will likely be acceptable." lab so I can't tell you all the details, but Page 271 Page 273 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 Do you see that? 2 there seemed to be compliance concerns 3 A. 3 Yes. primary around documentation of the results, 4 Then in March it says, "Subset 4 whether they were signed off and whether they 5 analysis results included in response to FDA 5 had the right format and so on. Which is not warning letter regarding compliance with atypical for a research laboratory. That may 6 7 7 expiry potency claim." be what CBER says here, but I can't speak for 8 Do you see that? 8 CBER. 9 9 Yes. Q. Were you involved at all in 10 So is it fair to say that Merck 10 responding to CBER with regard to those 11 was using the preliminary subset analysis as 11 compliance issues? A. No. Certainly not directly 12 proof that the vaccine worked below 4.3 log at 12 13 13 because I wasn't in the lab. I didn't even end expiry? 14 14 MR. SANGIAMO: Object to the know what the exact compliance issues were. 15 form. 15 Q. Do you recall there being any THE WITNESS: I think that's an 16 16 issues about Merck retesting samples without 17 over interpretation. I think in 17 written justification? 18 discussions with CBER at the time 18 Not specifically, no. 19 Merck agreed to provide whatever data 19 Q. Let me direct your attention to 20 were available, and CBER probably 20 slide 10 of this presentation that was made to 21 asked to provide any data that were 21 the clinical regulatory review committee on 22 available. So Merck provided the 22 January 22, 2002. 23 23 MR. SANGIAMO: I'm going to data. 24 BY MR. KELLER: 24 object to the preamble. 25 Q. Do you know that for a fact or 25 BY MR. KELLER:

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1	Page 274	1	Page 276
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
3	Q. It says, "Current Status." A. Wait, wait, wait, Wait a	$\frac{2}{3}$	filing BPDR reports to CBER? A. No. Unless they contained
4	A. Wait, wait, wait. Wait a second. What's this here? This is this	4	clinical data and they would have asked me
5	is okay. That's the presentation. Okay.	5	•
		6	for clinical data. But not in the filing at all.
6	So you're just referring to that presentation which was likely presented at the CRRC.	7	
8	Q. Yes. Do you have any reason to	8	Q. Do you know if Merck ever submitted a BPDR for those 106 lots?
9	believe that it wasn't presented at that	9	A. No.
10	meeting?	10	
11	A. Well, no. I don't have any	11	Q. You don't know, okay. Can you see the last on
12	reason to believe that a presentation wasn't	12	page on slide 14, "Mumps Expiry Issue Path
13	presented at that meeting, but this is the	13	Forward?"
14	attachment of the e-mail that came with the	14	"Strategies for ensuring
15	invitation which you gave me. So is it	15	compliance if expiry trial data cannot be
16	exactly the same presentation that was given	16	used."
17	or not, I don't know, I would expect it to	17	Do you see that?
18	be.	18	A. Yes.
19	Q. It's the one that you got,	19	Q. Do you recall any discussion at
20	though. Correct?	20	Merck regarding the failure of Protocol 007's
21	A. It's the one I got. I'm just	21	PRN assay reaching the conclusions that were
22	objecting to the additional premises that I	22	required as part of the end points?
23	know what was actually presented there and	23	MR. SANGIAMO: Object to the
24	can reconstruct it out of my memory 15 years	24	form.
25	later.	25	THE WITNESS: The only thing I
1	Page 275 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 277 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. But you have no reason to	2	remember was what is listed here on
3	believe that it wasn't provided?	3	the slide that we looked at before
4	A. No, I have no reason to believe	4	where that CBER indicated that
5	anything.	5	there might be compliance issues. I
6	Q. Sure. If you look at slide 10	6	don't know what they are and I can't
7	under "Current Status," it says, Response to	7	speculate what exactly they were. And
8	CBER comments on mumps PRN assay submitted	8	then the fallback would have been to
9	January 21, 2002.	9	use the ELISA.
10	In the third bullet point it	10	BY MR. KELLER:
11	says, "Products still not compliant with	11	Q. And so the path forward here, do
12	labeled mumps potency 95% lower bound of	12	you recall any discussion about the path
13	potencies through end of shelf life is 4.0	13	forward let me strike that.
14	log.	14	The term "path forward," is that
15	"However, subset analysis	15	a term used at Merck that you've seen in the
16	suggests that 4.0 log (but not 3.7 log) mumps	16	past?
17	dose will likely be acceptable."	17	A. I've seen it used in many
18	Each time a log tests below 4.3,	18	places, yes. Including Merck.
19	MMD must file a Biologic Product Deviation	19	Q. What does that mean to you?
20	Report to CBER detailing results of	20	A. Something that goes in a
21	investigation and medical impact (estimate	21	direction in time probably. Instead of
22	around 6 to 10 a year).	22	backward.
23	Do you see that?	23	Q. So it's projecting the future,
24	A. Yes.	24	how to get to a future result. Correct?
25	Q. Were you involved at all in MMD	25	A. Probably, yes.

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Page 278 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 Q. And here number 2 it says, 2 more mumps virus or any other live virus for 3 3 "Reduce 90% lower bound for stability losses." that matter, if you don't have data to 4 Do you have any idea what they're talking 4 support that it's a --5 5 about there? What kind of data would you look 6 6 A. No. That's a manufacturing 7 issue. I wouldn't be involved in the 7 A. Well, that's the difficulty. 8 8 discussions of how they ran their stability You would be particularly -- you would be 9 models. particularly concerned about the very rare 10 Q. Do you recall any discussion 10 events like aseptic meningitis and that -about the next statement, "Reduce shelf-life 11 11 this particular mumps vaccine does not have 12 to 13 months - not considered feasible"? 12 associated with it, which is the reason it's 13 A. No. 13 used in the United States as opposed to the 14 Do you recall any discussion at 14 virology strains. But those events are so 15 Merck that it's one log loss projections from 15 rare that they cannot be practically measured its then current stability model projected and that's where the feasibility comes in. I 17 that the shelf life would be below 12 months? 17 don't know whether they were -- I mean, you 18 A. Not specifically, no. I 18 know, that's only on the safety side. 19 remember what you showed me, that there was a 19 Q. Were you involved at all with 20 model anyway that predicted potential one log 20 the prior overfill where they increased the losses, but I don't remember a discussion of 21 21 amount of mumps they put into every virus in 22 a shorter shelf life. 22 23 Q. Do you recall any discussion 23 I don't really -- in 1991? Α. 24 about one log loss converted to a shelf life 24 Q. 1999. 25 1999. of 12 months or lower? A. Page 279 Page 281 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 2 O. The overfill. A. No. 3 3 No, I don't remember that. Q. Do you --A. 4 MR. SANGIAMO: I think he 4 Also 1999 I wasn't at Merck, so I wouldn't 5 answered, Jeff. 5 have been either informed or involved. 6 THE WITNESS: I said no. 6 Q. Here it says, "Improvement in 7 7 BY MR. KELLER: stabilizer (urea)." Do you see that? 8 8 A. Yes. O. I'm sorry. 9 9 A. Was too simple an answer. You Q. Do you recall any discussion 10 don't take no? 10 about actually changing the MMR II product by 11 No, yeses are all fine. 11 changing the stabilizer in it to help improve 12 Here it says, "Increase in its stability over 24 months? 12 release titer - safety concerns." Is there 13 A. Well, I don't remember any 13 14 14 here a discussion -- do you recall a discussions in this particular context. I discussion about increasing the overfill in remember them in very different context with 16 order to improve? the WHO but not necessarily even led by 17 A. Where do you have that here? 17 Merck. So I -- for this purpose, no, I don't 18 Number 2. 18 remember it. 19 In a theoretical way I do not 19 Q. Do you recall -- and the last 20 specifically, but I would certainly have been 20 one says, "Improvement in assay variability -one who would have objected to doing that 21 limited room for further improvement." 22 without data. 22 Do you see that? 23 23 Q. I see. Why would you have Yes. 24 objected to that without data? 24 That's talking about the 25 A. Well, you can't just fill in stability model. Correct?

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1	Page 282	1	Page 284
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
	MR. SANGIAMO: Object to the	3	THE WITNESS: It wasn't actually
3	form.		a suggestion. It was I was expressing what kind of data I would like to see
4	THE WITNESS: I don't know. You	4	
5	expect me to speculate, but I think	5	as a clinician.
6	it's probably, I think, to the	6	BY MR. KELLER:
7	stability model.	7	Q. I see. Here it says under
8	BY MR. KELLER:	8	"Concerns," "Recounts were made, dated, and
9	Q. Do you recall any discussion	9	signed, but not justified, on the raw data
10	about Merck trying to improve the assay	10	sheets."
11	variability of its stability model?	11	Do you see that?
12	A. No, I don't, but I think that's	12	A. Yes.
13	a logical thing that one would consider.	13	Q. Do you recall any discussion at
14	Q. I'm sorry?	14	Merck regarding the justification for changing
15	A. It's a logical thing to	15	data without changing data without
16	consider, but I don't remember any specific	16	justification?
17	discussion. Mind you this is manufacturing	17	A. It doesn't say here that data
18	so it wouldn't be my	18	were changed. All it says is that the
19	Q. Sure. Let me have you turn to	19	recounts were made. That doesn't mean that
20	the next page at 16, and it's "GMP Compliance	20	any data was changed. It just means that the
21	Issues Recounting of Test Wells." What does	21	same plaques were counted again and it was
22	GMP mean?	22	probably dated and signed and recorded. So
23	A. Good manufacturing practice.	23	it doesn't change data. It just counts them
24	Q. Under "Background" in the second	24	again.
25	bullet point says, Spreadsheet developed	25	Q. You don't recall any discussion
	Page 283		Page 285
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	during preliminary during testing and	2	about data being changed?
3	preliminary subset included flags for	3	A. No.
4	statistical and operational acceptance	4	Q. Here it says the "Rules
5	criteria triggered recounts and retests.	5	developed/implemented after starting to assay
6	Do you see that?	6	the expiry trial sera."
7	A. Uh-huh.	7	Do you see that?
8	Q. Do you recall any discussion	8	A. I see that.
9	you talked about generally that there was a	9	Q. What do you understand that to
10	compliance issue in the lab. This retesting,	10	mean?
11	do you know whether or not Merck actually went	11	A. Well, I don't know what rules
12	back and retested vaccine failures?	12	it applies to. Maybe rules on recounts or
13	A. No, I do not.	13	rules on other things, documentations. So it
		1 1 1	de agult maelly maen much if I tall you what I
14	MR. SANGIAMO: Object to the	14	doesn't really mean much if I tell you what I
	form.	15	think of it because it depends on what it is.
14	_	l	think of it because it depends on what it is. Q. Sure. Let's go to the next
14 15	form.	15	think of it because it depends on what it is.
14 15 16	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But	15 16	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts
14 15 16 17	form. THE WITNESS: I do not. What I remember is what I told you, that	15 16 17	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on
14 15 16 17 18	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But	15 16 17 18	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts
14 15 16 17 18 19	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But that was pretty general. I don't	15 16 17 18 19	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts involved pre-vaccination sero which were
14 15 16 17 18 19 20	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But that was pretty general. I don't remember the details.	15 16 17 18 19 20	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts involved pre-vaccination sero which were positive at one dilution only."
14 15 16 17 18 19 20 21	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But that was pretty general. I don't remember the details. BY MR. KELLER:	15 16 17 18 19 20 21	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts involved pre-vaccination sero which were positive at one dilution only." Do you see that?
14 15 16 17 18 19 20 21 22	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But that was pretty general. I don't remember the details. BY MR. KELLER: Q. You don't know if they followed	15 16 17 18 19 20 21 22	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts involved pre-vaccination sero which were positive at one dilution only." Do you see that? A. Uh-huh.
14 15 16 17 18 19 20 21 22 23	form. THE WITNESS: I do not. What I remember is what I told you, that there were documentation issues. But that was pretty general. I don't remember the details. BY MR. KELLER: Q. You don't know if they followed your suggestion of retesting the vaccine	15 16 17 18 19 20 21 22 23	think of it because it depends on what it is. Q. Sure. Let's go to the next page, "Impact of Recounts." Here it says on the first bullet point, "Majority of recounts involved pre-vaccination sero which were positive at one dilution only." Do you see that? A. Uh-huh. Q. Do you understand what that

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1	Page 286	1	Page 288
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	but I don't know whether that is just because	2	THE WITNESS: No, that's
3	of how the sera they recounted happened to	3	incorrect. If the statement says that
4	be, whether it was a choice. I didn't even	4	they had been missed, it means that
5	know that there was a recount, so leave alone	5	not that they were added, but that
6	whether the	6	they hadn't been seen before. It
7	Q. Can you think of any clinical	7	means in the first count you see maybe
8	MR. SANGIAMO: Jeff.	8	ten plaques and you let somebody look
9	THE WITNESS: Leave alone	9	again and they find 15 plaques.
10	whether there was any deliberate	10	BY MR. KELLER:
11	selection.	11	Q. So if they're only finding
12	BY MR. KELLER:	12	plaques that had been missed, that's one
13	Q. I see. Can you think of any	13	direction. Correct?
14	reason to recount only one data set that's	14	A. No. It's one direction on that
15	one that's positive one dilution?	15	specific plate, but it's not necessarily one
16	MR. SANGIAMO: Objection.	16	direction in the assay, because it may move
17	THE WITNESS: I can think of	17	them in either direction depending on what
18	reasons to recount any data set. If	18	the dilution is that you test. It's not
19	you see a valid reason why it might	19	unidirectional in terms of outcome, it's only
20	have been counted wrongly, you recount	20	unidirectional in terms of the physical
21	it.	21	measuring object that you have.
22	BY MR. KELLER:	22	Q. But if it was unidirectional as
23	Q. Would you recount all data or do	23	to outcome, would that cause you concern?
24	you just recount a certain subset of data?	24	MR. SANGIAMO: Objection.
25	MR. SANGIAMO: Objection.	25	THE WITNESS: Potentially. But
	Page 287		Page 289
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	THE WITNESS: In general it	2	that's not what is described here.
3	depends on what the error is. So in	3	Obviously if you look at any if you
4	principle I would probably recount all	4	look at a measure for which you have
5	data if they were all the same. If,	5	more likelihood of making an error,
6	however, there are something there	6	you would be more likely to repeat it
7	are something some specific	7	because your measure is not as good.
8	characteristics, for example, that	8	BY MR. KELLER:
9	something is particularly hard to see	9	Q. In the next bullet point says,
10	or you're not worried about the ones	10	"Recounts resulted in pre-vaccination sero
11	that are in the middle of a	11	becoming negative and therefore valid for
12	distribution but you may be worried	12	inclusion in pre-protocol analysis (subjects
13	about the ones if you have a dish	13	included in analysis increased from 449 to
14	that's full of plaques, if you get too	14	514)."
15	many points, they're hard to count.	15	Do you see that?
16	If you have too little, they're may be	16	A. Yeah.
17	hard to recognize. So there may be	17	Q. So by changing recounting
18	reasons why something recounted	18	these specific results at one dilution, missed
19	because the error is higher. But I	19	plaques were recounted and had the result
20	don't know what the case here is.	20	of for just the pre-positives, converting
21	BY MR. KELLER:	21	pre-positives to pre-negatives 65 of these
22	Q. Here it says, "Recounts showed	22	samples. Is that fair statement there?
23	that plaques had been missed." So they added	23	MR. SANGIAMO: Object to the
24	more plaques. Is that correct?	24	form.
25	MR. SANGIAMO: Objection.	25	THE WITNESS: Well, that's what
4.)	wik. Sandiawo. Objection.	45	THE WITHESS. WEIL, mand what

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	it seems to say here.	2	discussing adding the rabbit IgG at all leave
3	BY MR. KELLER:	3	alone its impacts.
4	Q. So if the results of recounting	4	Now would be a really good time
5	appear to occur in one direction and change	5	to take another break.
6	results, would that cause you to have concern	6	Q. Sure.
7	with how the assay was conducted?	7	A. I'm sorry, but I'm getting
8	A. Not necessarily. It depends on	8	older.
9	again what it's due to. I mean, something	9	O. That's fine.
10	that's hard to see you would miss more often	10	VIDEOGRAPHER: Off the record
11	than something that's easy to see. If you	11	3:10. This will end disc number four.
12	have titers of several hundreds, you know	12	
13	that the blades are black, doesn't matter	13	(A recess was taken.)
14	whether they're 449 or 451.	14	
15	Q. I see. So in this case we're	15	VIDEOGRAPHER: Back on the
16	talking about	16	record at 3:17. Beginning of disc
17	A. Then you have to look when	17	number five.
18	you talk about impact, you have to look at	18	MR. KELLER: I'd like to mark as
19	does that really change the result, not just	19	Exhibit 11.
20	the classification.	20	
21	Q. Well, pre-positives mean that	21	(Exhibit Schodel-11, 10/19/01
22	those kids are not included in the assay,	22	Letter, Bates MRK-KRA01469018 -
23	correct, for the plaque reduction	23	01469020, was marked for identification.)
24	neutralization assay?	24	
25	A. They're not included in	25	BY MR. KELLER:
	Page 291		Page 293
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	they're included in the assay, but they're	2	Q. Exhibit 11 is a document that
3	not counted as seroconverters. So you have	3	bears Bates stamp number 1469018 through 020.
4	to look at the end when you compare the	4	And it's a document dated October 19, 2001,
5	end results with corrected and uncorrected	5	from Manal Morsy to Henrietta Ukwu regarding
6	results, whether there is any impact on this	6	CBER teleconference (October 16, 2001):
7	correction in terms of the outcome.	7	Mumps Measles, Mumps and Rubella ELISAs.
8	Otherwise, you're talking about something	8	I'll say, Dr. Schodel, you are identified on
9	which is not very useful.	9	the cc as well as identified as participating
			the cc as well as identified as participating in this meeting with CBER on this date. Can
9	which is not very useful.	9	
9 10	which is not very useful. Q. Do you recall any discussion at	9	in this meeting with CBER on this date. Can
9 10 11	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG	9 10 11	in this meeting with CBER on this date. Can you tell me if you can take a minute to
9 10 11 12	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization	9 10 11 12	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you
9 10 11 12 13	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives	9 10 11 12 13	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I
9 10 11 12 13 14	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert	9 10 11 12 13 14	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on
9 10 11 12 13 14 15	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No.	9 10 11 12 13 14 15	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001?
9 10 11 12 13 14 15 16	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre	9 10 11 12 13 14 15 16	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay.
9 10 11 12 13 14 15 16 17	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre strike that.	9 10 11 12 13 14 15 16 17	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay. Q. Do you recall participating in
9 10 11 12 13 14 15 16 17 18	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre strike that. Do you recall any discussion at	9 10 11 12 13 14 15 16 17 18	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay. Q. Do you recall participating in this teleconference?
9 10 11 12 13 14 15 16 17 18 19	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre strike that. Do you recall any discussion at Merck regarding the use of rabbit anti-IgG in	9 10 11 12 13 14 15 16 17 18	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay. Q. Do you recall participating in this teleconference? A. Honestly I don't, but I read
9 10 11 12 13 14 15 16 17 18 19 20	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre strike that. Do you recall any discussion at Merck regarding the use of rabbit anti-IgG in the plaque reduction neutralizing assay in	9 10 11 12 13 14 15 16 17 18 19 20	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay. Q. Do you recall participating in this teleconference? A. Honestly I don't, but I read I glanced over the meeting minutes.
9 10 11 12 13 14 15 16 17 18 19 20 21	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre strike that. Do you recall any discussion at Merck regarding the use of rabbit anti-IgG in the plaque reduction neutralizing assay in Protocol 007 that had an impact on the	9 10 11 12 13 14 15 16 17 18 19 20 21	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay. Q. Do you recall participating in this teleconference? A. Honestly I don't, but I read I glanced over the meeting minutes. Q. Do you have any reason to
9 10 11 12 13 14 15 16 17 18 19 20 21 22	which is not very useful. Q. Do you recall any discussion at Merck regarding the impact of rabbit anti-IgG had on the plaque reduction neutralization assay in that it increased the pre-positives as well as increased the seroconvert A. No. Q for neutralize the pre strike that. Do you recall any discussion at Merck regarding the use of rabbit anti-IgG in the plaque reduction neutralizing assay in Protocol 007 that had an impact on the pre-positives, that increased the number of	9 10 11 12 13 14 15 16 17 18 19 20 21 22	in this meeting with CBER on this date. Can you tell me if you can take a minute to look at this document and tell me if you recall participating in this teleconference, I mean this meeting on this teleconference on October 16, 2001? A. Okay. Q. Do you recall participating in this teleconference? A. Honestly I don't, but I read I glanced over the meeting minutes. Q. Do you have any reason to believe that you didn't attend this meeting?

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	Page 294		Page 290
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAI
2	accurate?	2	true difference of two samples measuring 9 and
3	A. No.	3	10 Ab ELISA units and the inherent variability
4	Q. Were these meeting minutes	4	of the assay. CBER reminded Merck of their
5	generated by Merck in its ordinary course of	5	position regarding a threshold versus a 4 fold
6	its business?	6	increase for Varicella gpELISA where a 4 fold
7	A. I suspect so.	7	rise is required for assignment of
8	Q. Do you know whether or not these	8	seroconversion (i.e. less than equal to 1.25
9	meeting minutes would be provided to CBER?	9	pre to greater than equal 5 post).
10	A. They would be.	10	Do you see that?
11	Q. If you look at this teleconference	11	A. I see that.
12	that occurred on October 16, 2001	12	Q. So that exact or that very
13	A. 19. You've got 16.	13	similar example that's being raised at this
14	O. The date of this memo is three	14	meeting had already been discussed internally
	days later. It identifies the CBER	15	at Merck
15	•		
16	participants as Kathy Carbone, Dr. Steven	16	MR. SANGIAMO: Objection.
17	Rubin, Dr. Henry Hsu and Dr I mean, and	17	BY MR. KELLER:
18	Ms. Luba Vujcic. Do you see that?	18	Q in Exhibit 9. Do you
19	A. Uh-huh.	19	remember that?
20	Q. Those were the folks that were	20	MR. SANGIAMO: Object to the
21	typically working on the Protocol 007 assays	21	form.
22	at CBER, the primary contacts for Merck?	22	THE WITNESS: Well, it's
23	A. I don't know who else was	23	you're making assumptions here. It's
24	working on that particular protocol, but	24	not the exact same issue. It's the
25	certainly I've seen their names in	25	same approach of requiring in addition
	Page 295		Page 29
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAI
2	association with the protocol.	2	to a seroprotection cutoff, also a
3	Q. Let me have you turn your	3	fourfold rise criterion. But it's not
4	attention to page 2, 1469019 under "Summary of	4	the same assay, it's not the same
5	discussion." Under the "Wild type mumps ELISA	5	variability and it's not the same
6	cutoff."	6	numbers.
7	Do you see that?	7	BY MR. KELLER:
8	A. Yes.	8	Q. So there's at this point CBER
9	Q. That's the ELISA arm of Protocol	9	is still considering whether or not it was
10	007. Correct?	10	going to require Merck to do a fold increase
11	A. Well, that's the assay used in	11	to set the serostatus cutoff for its ELISA
12	Protocol 007, but it is also the	12	assay. Correct?
13	discussion here is about not so much only	13	A. That is correct.
14	Protocol 007 but whether the ELISA cutoff was	14	Q. If you look on the next page, in
15	set right apparently.	15	the middle one, two, three, four, five
16	Q. Because that was going to be	16	bullet points five paragraphs down it says,
17	used with respect for gaining approval of	17	"It should be noted that if the question about
18	ProQuad, too. Correct?	18	justification and relevance of the mumps ELISA
19	A. That's correct.	19	cutoff could be addressed (i.e. by correlating
20	Q. So if you look in the second	20	to PRN), then a 4 fold criterion would not be
21	bullet point on 1469019 it says, "Assay	21	necessary. If, however there continues to be
22	variability and true seroconversion around the	22	uncertainty about the biological/clinical
23	cutoff:"	23	relevance of the cutoff, it is expected that
24	CBER requested clarification on	24	CBER would require a 4 foldcriterion, as
	CDER requested clarification on	∠+	CDER WOULD require a + 1010CHETIOH, as
25	how we would be able to distinction between a	25	that would be necessary to demonstrate

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Page 298 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 significant response to the vaccine. This 2 right around that cutoff could be applied for 3 3 reasoning would parallel that which is used these as well regardless of whether there is 4 for measles and rubella ELISAs. CBER did not 4 a correlation or not. 5 5 require a fold rise in these assays because Why would CBER -- what was the measles and rubella ELISAs employ a recognized 6 discussion in this meeting that CBER was 7 reference standard for seroprotection." requesting that Merck correlate that Do you see that? 8 8 serostatus cutoff to the PRN? 9 9 Yes. A. I don't speculate on CBER's 10 Q. So is it fair to say that if 10 intent. Merck did not correlate its PRN assay to its 11 11 Q. You understood that's what CBER ELISA assay to justify its static cutoff, it 12 was asking for? was going to be required to do a fourfold 13 A. It was one of the issues they 13 14 criterion? 14 requested, and that was -- it was up to CBER 15 MR. SANGIAMO: Objection. Calls 15 to request it without justifying it. 16 for speculation. 16 Q. I see. Did Merck correlate its 17 THE WITNESS: I think that's 17 serostatus cutoff to the PRN assay? 18 18 speculation. The -- that's the fear A. Since CBER requested it, they 19 expressed by the person who wrote 19 would have probably done it. 20 this, but that is not what CBER has 20 Q. Did you ever see that data? I don't remember it in detail. 21 stated. 21 22 BY MR. KELLER: 22 but I may have seen it. 23 Q. Isn't this sent to CBER? 23 Q. Do you know whether or not that 24 A. It is sent to CBER but it does was ever submitted? You don't know if it was 25 25 ever submitted to CBER? not reflect only CBER's position. It Page 299 Page 301 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 reflects a discussion. 2 No, I don't know that. Q. I see. So --3 3 Q. But you do know that the 4 A. It was not sent to us by CBER 4 fourfold criteria was not required for 5 saying this is what you have to do. This is 5 purposes of the wild-type ELISA that was used what will happen if you don't do it. So this 6 and not just Protocol 007 but used for 7 7 is a lot of speculation that you're asking me approval of ProQuad's BLA? 8 8 for. I do know that. Α. 9 9 Sorry. This is a discussion O. They didn't require the fourfold 10 that Merck had with CBER where CBER was 10 criteria? 11 communicating what it expected, though. 11 No, they did not. But the 12 Correct? 12 reason why they did not may be different. 13 Yes, but the criteria are -- so 13 There are other -- if you read through the 14 CBER expected additional information which 14 whole document, you find, for example, it is was provided. And it also recognized that 15 actually -- it turns out that the ELISA is there are constraints in the assay. It also more conservative in assigning seropositivity 17 recognized that in other assays like rubella 17 and seronegativity. So CBER may have had 18 and measles, this kind of a criterion was not 18 other reasons than simply the correlation for 19 applied. 19 allowing the ELISA to go forward with a 20 20 fourfold -- without a fourfold rise. Q. Because there there was some 21 reference standard for seroprotection at that 21 MR. KELLER: Can I get that 22 serostatus cutoff. Correct? 22 answer back? I'm sorry. 23 A. That is correct. But not the 23 24 only reason because the same argument that 24 (The court reporter read the you made before that if something is variable 25 pertinent part of the record.)

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1	Page 302 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 304 FLORIAN SCHODEL, MD - CONFIDENTIAL
$\frac{1}{2}$	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\frac{1}{2}$	A. No. CBER wanted to see some
3	BY MR. KELLER:	3	type of correlation going into that meeting.
4			
5	Q. What would those reasons have been?	5	Taking all that together, I don't want to
-			speculate, but reading what CBER said, I'm
6	A. They're listed in here somewhere.	6	not so sure that they were as interested
7	MR. SANGIAMO: Object to that	7 8	anymore.
8	question as calling for speculation. BY MR. KELLER:	9	Q. I see. Let's find out.
9		_	A. And they still wanted it to be
10	Q. You can answer.	10	shown. Whether the data mattered, I don't
11	A. I can't speculate on what CBER	11	want to speculate on that.
12	wanted, but the assay let me see where it	12	Q. I see. But they wanted to see
13	was. I just read something here. Actually	13	that data?
14	it speaks directly to what CBER said, so I	14	A. Obviously.
15	don't have to speculate. You can actually	15	MR. KELLER: Let me mark as
16	read what CBER said. It's the last paragraph	16	Exhibit 12.
17	on the second page. It says, "CBER pointed	17	
18	out that a correlation rate of 92% was low,	18	(Exhibit Schodel-12, 4/25/02
19	particularly when related to the expected	19	E-mail with attachment, Bates
20	criteria for success in terms of	20	MRK-KRA00544512 - 00544538, 00544540 -
21	seroconversion rate (5% delta, 90% floor),	21	00544543, was marked for identification.)
22	but noted that the ELISA seemed to be more	22	
23	conservative than the PRN in assignment of	23	BY MR. KELLER:
24	low sero-positives."	24	Q. For the record, Exhibit 12 is a
25	So that was CBER's opinion.	25	document that bears Bates stamp number 544296
	Page 303		Page 305
	9		1 age 303
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in	2	6
	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here.		FLORIAN SCHODEL, MD - CONFIDENTIAL
2	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have	2	FLORIAN SCHODEL, MD - CONFIDENTIAL through
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here.	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one.
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what
2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN assay was more variable at assigning low	2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one.
2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN	2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one. (A discussion off the record
2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN assay was more variable at assigning low seropositives? A. The PRN assay was probably more	2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one (A discussion off the record
2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN assay was more variable at assigning low seropositives?	2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one. (A discussion off the record occurred.)
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN assay was more variable at assigning low seropositives? A. The PRN assay was probably more variable full stop as PRN assays are known to be. Q. I see. A. And it goes on also as stated by CBER, "It was pointed out to CBER that although this was true for pre-vaccination samples, results of this limited data set show that in case of post-vaccination sera, the ELISA was more sensitive than the PRN in assigning high titers," which also helps in the distinction. Q. But taking all that together, CBER wanted to see some sort of correlation between the PRN assay and the serostatus	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one. (A discussion off the record occurred.) MR. KELLER: I'm sorry. Just mark this one the next one. Mark this one as 13. (Exhibit Schodel-13, 5/7/02 E-mail with attachment, Bates MRK-KRA00544296 - 00544324, was marked for identification.) THE WITNESS: Disregard 12 at this point. BY MR. KELLER: Q. Just set it aside for now. Start with 13. Let me mark Exhibit 13 Bates
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL And that is obviously a major factor in making a decision. And they stated it here. So that's not a speculation, it's you have it in writing here. Q. So your statement is that PRN assay was more variable at assigning low seropositives? A. The PRN assay was probably more variable full stop as PRN assays are known to be. Q. I see. A. And it goes on also as stated by CBER, "It was pointed out to CBER that although this was true for pre-vaccination samples, results of this limited data set show that in case of post-vaccination sera, the ELISA was more sensitive than the PRN in assigning high titers," which also helps in the distinction. Q. But taking all that together, CBER wanted to see some sort of correlation	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL through MR. SANGIAMO: That's not what you gave us. Wrong one. (A discussion off the record occurred.) MR. KELLER: I'm sorry. Just mark this one the next one. Mark this one as 13. (Exhibit Schodel-13, 5/7/02 E-mail with attachment, Bates MRK-KRA00544296 - 00544324, was marked for identification.) THE WITNESS: Disregard 12 at this point. BY MR. KELLER: Q. Just set it aside for now. Start with 13. Let me mark Exhibit 13 Bates number 544296 through 331836. Wait. Whoa

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Appx4669

Page 306 Page 308 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 Let me mark Exhibit 13 Bates 2 3 3 number 544296 through 544324. And for the If you look further, Chirgwin 4 record, Exhibit 13 is a document, an e-mail 4 says, "I agree that CBER did not specifically 5 from Keith Chirgwin to Dr. Schodel regarding 5 indicate that we would be required to draft document mumps cutoff, and attaches a 6 demonstrate concordance. However in reviewing 7 series of exhibits. This e-mail is dated the meeting minutes from last October 8 8 May 7, 2002. And if you could take a look at (attached below), it is...clear that they are this for a minute, Doctor, and tell me, if you 9 going to look closely at how sera with values 10 recall receiving this e-mail. 10 around the cutoff are classified in the two 11 A. I don't recall receiving this 11 assays." Do you see that? 12 specific e-mail, but I mean, it's along the 12 13 13 Α. Yes. 14 Do you have any reason to 14 In this October, do you believe 15 believe you didn't receive it? 15 that's referring back to that October 16, 16 A. No. 16 2001, meeting or teleconference where the 17 Any reason to believe you didn't 17 serostatus cutoff was discussed? receive the attachments to it? 18 18 A. I assume so. 19 19 Q. At least -- and he goes on to A. No. 20 In this e-mail from Mr. -- from 20 say, "At least based on October's discussion, 21 Dr. Chirgwin he writes, Florian, This is the 21 if we are unable to provide sufficient reassurance about the clinical relevance of 22 latest version of the mumps cutoff CBER 22 23 response from Joe. As per the previous e-mail 23 the ELISA cutoff (which in Kathy's mind means 24 message, it appears that things have gotten 24 linking this to the PRN) then we may end up 25 25 stuck with regard to the table that Joe with some type of a fold-rise criterion which Page 307 Page 309 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 presented at the VAC several weeks ago showing 2 I assume we would rather avoid if possible." 3 the breakdown by ELISA strata of the Do you see that? 4 discordant PRN negative/ELISA positive sera. 4 A. Yes. 5 Do you see that? 5 O. So there was a concern that if 6 Yes. 6 Merck provided CBER certain data, that they A. 7 7 Q. That's the vaccine assay would increase the ELISA cutoff. Is that what 8 committee. Correct? 8 this document is saying? 9 9 A. Uh-huh. A. That's what it seems to say 10 That's the committee that you 10 here. 11 were either the co-chair or a member? 11 So Joe, that's Joe Antonello, 12 A. Yes. 12 correct, he's a statistician? 13 It goes on to say that the large 13 A. I assume that if it's not Joe 14 14 majority of these discordants had ELISA titers Heyse, it must be Joe Antonello. 15 less than 40 and one concern is that Q. See below that there's a presenting the data in this fashion may prompt reference, it says, "Joe I removed tables 6 c 17 CBER to request that the ELISA cutoff be 17 and 6 d and information referring to them from 18 raised. 18 the 007 ELISA and PRN comparison document 19 Do you see that? 19 (Attachment 2)...," and he says, "...too 20 20 A. Yes. distracting." Do you see that? 21 Q. Do you recall discussions 21 A. Yes. 22 regarding the removal of certain tables in 22 Q. Let me have you draw attention 23 response to CBER regarding the cutoff that 23 to Exhibit 12 that we had just marked 24 there was a concern that that data would lead 24 previously. On the e-mail on 544512, there's CBER to increase the cutoff? a couple documents attached to it. And

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	D 440		
1	Page 310	1	Page 312
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Attachment 1 on 55 544514 is a the		number of discrepant paired sera in ELISA and
3	Table 6c and 6d that the previous or the	3	PRN relative to what is expected per assay
4	that was identified as being removed. Have	4	variability in the STD range."
5	you ever seen this table before?	5	Do you see that?
6	MR. SANGIAMO: Object to your	6	A. Yes.
7	preamble. What is your question,	7	Q. STD, is that standard deviation?
8	whether he has seen the table at	8	Do you understand that to be standard
9	544514?	9	deviation?
10	MR. KELLER: Yes.	10	A. I'm not exactly sure what STD
11	MR. SANGIAMO: Okay.	11	stands for here.
12	THE WITNESS: I would have	12	Q. Do you have any reason to
13	probably seen it as an attachment of	13	believe that you didn't receive this e-mail?
14	this e-mail provided I mean,	14	A. No. Just, you know, I'm copied
15	provided I read the details of all	15	as are others.
16	these e-mails because I was not the	16	Q. Sure. It goes on to say, "I
17	primary person responsible anymore.	17	understand that at 1 STD and 2 STD
18	BY MR. KELLER:	18	discrepancies observed fall within expected %
19	Q. You see that you were cc'd on	19	but at 3STD we have more discrepancies than
20	this e-mail.	20	what can be explained by just assay
21	A. Yeah. I was cc'd on a lot of	21	variability"
22	e-mail, 200 or 300 a day.	22	Do you see that?
23	Q. This was sent to Joseph	23	A. Yes.
24	Antonello. Do you see that?	24	Q. Do you understand why that would
25	A. Yes.	25	be important?
	Page 311		Page 313
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. And Jonathan Hartzel?	2	MR. SANGIAMO: Object to the
3	A. Yes, yes, yes.	3	form.
4	Q. And David Krah?	4	THE WITNESS: No.
5	A. Yeah.	5	BY MR. KELLER:
6	O. And Alan Shaw? Those were the	6	Q. It goes on to say, "Joe, also
7	folks that were working on Protocol 007.	7	please confirm that the attachments enclosed
8	Correct?	8	are in fact the audited documents (I have
9	A. Dave was working in Alan's lab,	9	deleted as you know tables 6c and 6d and their
10	yes.	10	corresponding text from attachment 2 - I have
11	Q. And Alan reported to Emini?	11	attached the tables and text deleted for your
12	A. Yes.	12	reference - which I would like to replace as
13	Q. And David Krah reported to	13	we discussed with a table showing
14	Emini?	14	discrepancies within std ranges instead of
15	A. To Alan Shaw.	15	cutoffs)"
16		16	
	Q. And here Manal Morsy, she was the regulatory liaison at this time frame,	17	Do you see that? A. Uh-huh.
17 18	wasn't she?	18	
		1	Q. So if you look on 544514, table
19	A. I believe so, yes.	19	6c and 6d, is this a 4-by-4 table that you
20	Q. And here she writes Joe, Jon,	20	discussed earlier?
	Luwy, Alan and Dave:	21	A. It's a little bit of a
21	HDI 1 1 1	22	different format. But it's a classification
22	"Please review the documents	1	
22 23	attached - two sections are needed (marked in	23	of subsets by titer in another assay, I
22		1	

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Page 314 Page 316 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 2 positives? 2 tell me how -- why this -- these two tables, 3 3 Quite frankly, I don't remember if provided to CBER, may lead them to increase 4 what HN stands for anymore. 4 the cutoff as identified by Keith Chirgwin? 5 5 Q. HN is the plaque reduction A. No, I personally don't think 6 neutralization assay done in Protocol 007? 6 that that would be the case because if they A. That's what I thought, but I interpret them the way I do, then they would 8 just wanted to make sure. Yeah, it's a say, okay, at a lower titer, the likelihood listing of numbers. I find these listings 9 is that the standard deviation of the assay 10 not very helpful because the cells, the 10 is higher and the likelihood for a 11 individual cells become relatively small and 11 discordance between two different assays is so the inferences you can draw from them are also higher. That doesn't mean that the 12 13 very limited. 13 assays are not concordant. It just means 14 Q. So when Chirgwin said that we 14 that you always see the discordance show up 15 didn't want to give these tables to CBER 15 at the extremes. because they may raise the serostatus cutoff 16 Q. I see. Was there any discussion 17 in the wild-type ELISA, what about these 17 about any kind of standard that CBER was 18 tables would indicate that this would suggest looking for with respect to what percentage of 19 that the serostatus cutoff that was proposed 19 false positives it would deem acceptable in 20 at ten should be raised? 20 this concordance analysis? 21 MR. SANGIAMO: Again, I object 21 A. You're assuming here two 22 22 to the preamble of your question. things. First of all, that there was a 23 THE WITNESS: I can't speculate 23 standard. The answer is no. Secondly, that 24 on what Keith might have thought. I these are false positives in one assay or the 25 25 look at these tables differently as other. The concordance just means that Page 315 Page 317 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 indicating absolutely nothing. they're differently interpreted in the 3 BY MR. KELLER: 3 different assays. It doesn't mean that one 4 Q. So when it says --4 is false and the other one is wrong. What 5 A. That's why it shouldn't have 5 CBER would also consider is what assay is 6 more robust, more reliable, and in which 6 been communicated, because they're 7 7 meaningless and they're fine, they appear to direction does it classify the samples. And 8 say something but they don't really. 8 as you have seen from the CBER's -- from Q. I see. So when it says 60, when CBER's previous comment, they noted that 10 it's looking at titers between 10 and 20, 20 10 actually the ELISA was more conservative. 11 and 40 and 40 and 80 and identifying the 11 Q. I see. But when you compared 12 12 numbers, the subset of negative samples in the the two assays, which it appears that Kathy PRN versus all samples, the number on 13 Carbone was asking about in terms of relying 14 percentage, that's identifying a -- discordant 14 upon a serostatus cutoff versus requiring some 15 results that were positive. Correct? 15 fourfold increase, she wanted Merck to compare around the cutoff. And so if I'm reading this 16 A. Well, it seems to be identifying 17 a percentage of titers that would be positive 17 document correctly, a cutoff between 10 and 20 18 by ELISA or positive by neut and negative by 18 would result in 24 percent false positive 19 the other assay. But it's always very small 19 rate, a cutoff between 20 and 40 would reduce 20 20 numbers. that false positive rate to 11.8 percent. Is 21 I see. Wasn't CBER concerned 21 that correct? No, that's an assumption based 22 about the discordant results around the 22 23 cutoff? 23 on a very small number. And, therefore, you 24 You have to ask CBER that. 24 cannot infer that as a general statement. A. 25 So you can't sit here today and You can just say that in this particular Q.

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Page 318 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 classification, one assay classified a 2 the data that's on this chart, that a titer at 3 certain proportion into one direction and the 40 or above would have had a false positive 4 other assay in the other direction. You 4 rate of 3.4 percent based on this chart? 5 5 can't make -- from such a small sample you Yes, that would be wrong. 6 can't make such a general statement. 6 Why is that wrong? 7 May I just come back to your A. Because you're extrapolating 8 8 from a small band 40 to 50 -- 40 to 80, intro? Kathy Carbone is a person, I don't 9 know what she was thinking and what she 9 sorry, to the whole behavior and you see that 10 wanted. You are referring this to me through 10 it actually changes and that the sample size 11 an e-mail from Keith Chirgwin who is specific 11 gets larger, too. as to what Kathy Carbone -- maybe he knows 12 Q. So when it says 20 -- titer 20 what Kathy Carbone wants. Neither is Kathy 13 to 40 and it says percentage 11.8 percent, 13 14 Carbone CBER nor am I, Keith Chirgwin, nor do 14 again, you're saying that's not a false 15 I know what Kathy Carbone was thinking. 15 positive rate for that range? 16 You're talking -- you're stating 16 A. It's a rate of discordance 17 17 that this is a small sample. This represents between the two assays. all the ELISA assays? 18 18 Q. I see. 19 19 A. Still remains a small sample. A. At that particular very narrow 20 I see. So these percentages, 20 bandwidth. 21 these are the discordant percentages. Correct? 21 O. I see. 22 A. Well, in this subset of 22 A. In this particular sample which 23 available samples at the time. 23 may not apply to any other sample. 24 Q. And so another way of saying 24 Q. So your testimony is that this 25 25 that are false positive rate. Correct? analysis has no relevance to whether or not Page 319 Page 321 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 2 The false positive rate always the serostatus cutoff is correct at 10? 3 3 assumes that one of them is the truth and the A. It shows -- it shows how the 4 other one is not. 4 two assays, so the answer is no. It shows 5 Q. So if you look at the top of 5 that the two assays show a certain this chart, "A further analysis of the 6 discordance and that the discordance is 6 7 post-vaccination titers is provided in Tables 7 larger around the cutoff, as you would 8 6c and 6d. Table 6d shows the frequency 8 expect. But it does not necessarily imply distribution of AIGENT titers for (a) all that one cutoff is better than the other. In AIGENT positive post-vaccination samples, and 10 fact, the other part that CBER noted is that 11 (b) the subset of ELISA negative in AIGENT 11 using the 10 cutoff in the ELISA moves you in positive post-vaccination samples." Then it 12 12 a more conservative direction. goes to "...relative distribution of Table c 13 Q. So is it fair to say from this 14 14 indicate that" -- let me go back to this. Let chart, that as you raise the cutoff, the 15 me strike that. 15 discordant results go down? A. That's fair. So you make a 16 Do you recall any discussion at 16 17 Merck that CBER was concerned that the 17 very reliable assay more concordant with a 18 discordant false positive rate be below a 18 very unreliable assay. 19 certain percentage? 19 Q. So is it fair to say that the 20 MR. SANGIAMO: Object to the 20 discordant results, if you increase the titer 21 21 from 10 to a range of 10 to 20, would go from 22 THE WITNESS: Beyond what I just 22 24 percent to a range of 20 to 40 down to 23 read in this e-mail, no. 23 11.8 percent? 24 BY MR. KELLER: 24 No, that's a -- that is --25 Q. Is it fair to say that based on 25 you're extrapolating too much and generalizing

81 (Pages 318 - 321)

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1	Page 322	1	Page 324
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	from a distribution in a small sample size.	$\frac{2}{3}$	Q. Here's a draft, and I'll
3	Q. I see.		represent to you that this ultimately became
5	A. You would have to build a	5	086 for the record. Under 1 on the first page
6	confidence interval around that. If you		it says, "CBER request that Merck provide
	think of it in terms of a confidence interval, it could be much wider.	6	additional justification for the cutoff chosen for the Mumps"
7 8	*	8	•
9	Q. So as you sit here today,	9	A. Where are we now, I'm not following you?
10	Dr. Schodel, it's your testimony that you have no idea why Keith Chirgwin was concerned that	10	Q. The first page.
		11	MR. SANGIAMO: We're on this
11 12	by providing these tables to CBER, that they would increase the serostatus cutoff?	12	
		13	document. Jeff, do you intend to give him a chance to read this
13 14	MR. SANGIAMO: Object to the form.	14	
15	THE WITNESS: I don't know what	15	MR. KELLER: No, I'm just going
16		16	to go through
17	Keith was thinking, but I don't share his concern.	17	MR. SANGIAMO: two-page document?
18	BY MR. KELLER:	18	
19		19	MR. KELLER: The topics are very
20	Q. I'm sorry, did you review the draft response that was going to go to CBER	20	general. MR. SANGIAMO: Are you going to
21	with respect to this justification for the	21	ask him questions about it?
22	serostatus cutoff?	$\begin{vmatrix} 21\\22\end{vmatrix}$	THE WITNESS: If you're going to
23	A. I don't know. I mean, I had	23	ask me questions, let me read it,
24	you know, I had Luwy in there who was a very	24	otherwise I'm not going to answer your
25	good clinical monitor, and I generally relied	25	question.
23		25	question.
1	Page 323 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 325 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	on my people doing work. So I don't know	2	BY MR. KELLER:
	on my people doing work. Bo'l don't know		
3	whether I reviewed it in detail	3	O Take all the time you need to
3	whether I reviewed it in detail. O Who would be the one that was	3 4	Q. Take all the time you need to
4	Q. Who would be the one that was	4	read it if that's what you need to do for me
4 5	Q. Who would be the one that was responsible for signing off on the response to	4 5	read it if that's what you need to do for me to ask you if you recall seeing this document?
4 5 6	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus	4 5 6	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only
4 5 6 7	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff?	4 5 6 7	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing
4 5 6 7 8	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question	4 5 6	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it?
4 5 6 7 8 9	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably	4 5 6 7 8 9	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other
4 5 6 7 8 9 10	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith	4 5 6 7 8 9	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions.
4 5 6 7 8 9 10 11	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure.	4 5 6 7 8 9 10 11	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he
4 5 6 7 8 9 10 11 12	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you?	4 5 6 7 8 9 10 11 12	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it.
4 5 6 7 8 9 10 11 12 13	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not.	4 5 6 7 8 9 10 11	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER:
4 5 6 7 8 9 10 11 12 13 14	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey?	4 5 6 7 8 9 10 11 12 13	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's
4 5 6 7 8 9 10 11 12 13 14 15	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible	4 5 6 7 8 9 10 11 12 13 14 15	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead.
4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there.	4 5 6 7 8 9 10 11 12 13 14 15 16	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much
4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there. Q. So if you look at 544515 which	4 5 6 7 8 9 10 11 12 13 14 15	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there.	4 5 6 7 8 9 10 11 12 13 14 15 16 17	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer. Q. The cover letter.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there. Q. So if you look at 544515 which is this draft response to Merck regarding	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer. Q. The cover letter. A. So you just want me to
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there. Q. So if you look at 544515 which is this draft response to Merck regarding A. Which one is that, the next one or	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer. Q. The cover letter.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there. Q. So if you look at 544515 which is this draft response to Merck regarding A. Which one is that, the next one or Q. It's Exhibit 544515.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer. Q. The cover letter. A. So you just want me to concentrate on the cover letter here, not on the not on where it
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there. Q. So if you look at 544515 which is this draft response to Merck regarding A. Which one is that, the next one or	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer. Q. The cover letter. A. So you just want me to concentrate on the cover letter here, not on the not on where it Q. We'll get there in a minute. If
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Who would be the one that was responsible for signing off on the response to CBER with respect to this issue of serostatus cutoff? A. That's an interesting question that I can't answer, because probably again, I'm speculating. Probably Keith Chirgwin and the lab, but I'm not sure. Q. It wasn't you? A. Oh, certainly not. Q. And it wasn't Dr. Musey? A. Not directly. He's responsible for the clinical data in there. Q. So if you look at 544515 which is this draft response to Merck regarding A. Which one is that, the next one or Q. It's Exhibit 544515. MR. SANGIAMO: Still within 12. BY MR. KELLER:	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	read it if that's what you need to do for me to ask you if you recall seeing this document? MR. SANGIAMO: Is that the only question, whether he recalls seeing it? MR. KELLER: I have some other questions. MR. SANGIAMO: Well, then he needs to read it. BY MR. KELLER: Q. Go ahead, you can read it. It's a two-page document. Go ahead. A. This document I have is much longer. Q. The cover letter. A. So you just want me to concentrate on the cover letter here, not on the not on where it
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	Page 326	,	Page 328
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	representation that this is the	2	agency.
3	document that was submitted to CBER?	3	Q. I just want to turn your
4	MR. KELLER: It's a draft.	4	attention just to the conclusion that's drawn
5	MR. SANGIAMO: It's a draft,	5	in this draft at 544524. I understand it's a
6	okay. I thought you said it was a	6	draft. Here it says, Conclusion: There is
7	document that was submitted.	7	good agreement between the Mumps wild-type
8	MR. KELLER: I said for the	8	ELISA and the AIGENT assays in terms of
9	record this draft is what was	9	serostatus classification when using a cutoff
10	submitted as 086.	10	of 10 units in the Mumps wild-type ELISA and a
11	THE WITNESS: Excuse me, I	11	cutoff of 1 to 32 in the AIGENT assay.
12	didn't hear that last one. The	12	Do you see that?
13	ultimate one submitted was different	13	A. Yes.
14	from this one?	14	Q. What is there a scientific
15	BY MR. KELLER:	15	term for good agreement? What does good
16	Q. I'm asking if this is the one	16	agreement mean? Let me strike that.
17	that was submitted to you, if you reviewed it?	17	What does good agreement mean in
18	Let me know when you're ready, sir.	18	the context of this analysis, if you know?
19	A. There's obviously there's	19	A. I don't know a specific number,
20	still questions in there and so	20	but apparently they showed the degree of
21	Q. It's a draft.	21	agreement, and it looked reasonably high, and
22	A. Okay.	22	so they called it a good agreement.
23	Q. If you look on the cover letter,	23	Q. And so the discordant results
24	the draft cover letter to CBER under "With	24	that were in charts 6c and 6d that had
25	focus on the following issues," it says, CBER	25	24 percent discordant results for a serostatus
	Page 327		Page 329
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	requests that Merck provide additional	2	cutoff between 10 and 20, and that went down
3	justification for the cutoff chosen for the	3	to 11.4 percent with a serostatus cutoff from
4	Mumps wild-type ELISA comparing the ELISA	4	20 to 40, that was considered a good
5	cutoff to the AIGENT assay cutoff and	5	agreement?
6	specifically to provide.	6	A. You're extracting an
7	Do you see that?	7	inappropriate comparison that is based on
8	A. Uh-huh.	8	small numbers and just a subfraction of the
9	Q. And so the attached the next	9	total results. If you look at Table 8 here,
10	page under B, "Identification of individual	10	for example, you see the expected percentages
11	titers in relative range around cutoffs of	11	of misclassified samples by the assays
12	both assays in order to confirm that both	12	standard deviations from the cutoff, that
13	assay are characterizing sera in a comparable	13	gives you a better measure of what would be
14	fashion."	14	expected and what would be observed.
15	Do you see that?	15	Q. So what standard deviation I
16	A. Yes.	16	mean, you have zero to three. Right?
17	Q. Then Merck attaches its response.	17	A. Yes.
18	Correct?	18	Q. And so in the previous e-mail,
19	MR. SANGIAMO: Object to the	19	in the e-mail that attaches this document,
20	form.	20	there's a discussion here that at three
21	BY MR. KELLER:	21	standard deviations we have more discrepancies
22	Q. This is a draft response?	22	than that can be explained by just assay
23	A. I don't know whether this was	23	variability. That seemed to be a big issue
24	sent to the agency, but this is a draft of	24	to
25	what would have eventually been sent to the	25	A. Joan Staub who was not

	Page 330	,	Page 332
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	MR. SANGIAMO: You have to let	2	BY MR. KELLER:
3	Mr. Keller finish his question.	3	Q. Exhibit 14 is a document that
4	MR. KELLER: Let him answer.	4	bears Bates stamp number 561199 through
5	MR. SANGIAMO: No, no, no.	5	561209. This is a series of e-mails and two
6	That's a big issue, what's the rest?	6	attachments. And if you look at the first
7	To and then what comes after that?	7	e-mail that's sent from Manal Morsy to Keith
8	MR. KELLER: Can you read back	8	Chirgwin and you, Dr. Schodel, on May 31,
9	my question?	9	2002, can you tell me, do you recall seeing
10		10	this e-mail?
11	(The court reporter read the	11	A. I don't recall seeing this
12	pertinent part of the record.)	12	specific e-mail, but if I read it, I can
13		13	probably figure out what it means.
14	BY MR. KELLER:	14	Q. Sure.
15	Q to Manal Morsy, the	15	A. Okay. I haven't read this
16	regulatory liaison.	16	attachment yet.
17	So my question is, three	17	Q. We're not even going to look at
18	standard deviation, is your testimony that	18	the attachment. So let's just talk about the
19	that's not significant?	19	e-mails.
20	MR. SANGIAMO: Object to the	20	In here Dr. Manal I'm sorry.
21	form.	21	Dr. Morsy sent you and Dr. Chirgwin an e-mail
22	THE WITNESS: I didn't say that.	22	and cc'd Joe Antonello, Dr. Antonello and
23	But what I said is that she may not	23	Dr. Hartzel, Dr. Schofield. Is Schofield a
24	have looked at the complete analysis	24	doctor?
25	that is presented here in this draft	25	A. Schofield.
	Page 331		Page 333
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	and that may be further enhanced in	2	Q. Schofield. Is he a doctor?
3	the ultimate what was ultimately	3	A. Yes, he is. I think anyway.
4	sent because I'm not sure that the	4	Q. And here Manal Morsy is saying,
5	analyses were even complete here. So	5	"The attached is completed based on," this
6	you're showing me something that at	6	is on 561200 which is her May 31, 2002,
7	the time was not completed.	7	e-mail, "The attached is completed based on
8	What I was starting to point out	8	feedback and edits received and incorporated
9	to you is that it's quite normal to	9	today (unless Keith, Florian," that's you,
10	see that as you get closer to the	10	Dr. Schodel, "or Tim send in comments
11	cutoff and no standard deviations, you	11	before noon tomorrow Friday)." It goes on, "I
12	would expect to see a higher mismatch.	12	plan to finalize for submission early next
13	At no standard deviation it's 50/50,	13	week pending auditing sign off for attachments
14	and then it goes up. And so I'm not	14	2 and 3 (attachment 2 was I believe previously
15	clear to it's not clear to me that	15	audited but is modified by deletion of
16	based on the analysis I see here in	16	Tables 6c, 6d and associated text)."
17	this draft Manal's concern is valid.	17	Do you see that?
18	MR. KELLER: Let me mark as	18	A. Uh-huh.
19	Exhibit 14.	19	Q. So that table that we went
20		20	through earlier has been deleted from what was
21	(Exhibit Schodel-14, E-mail	21	to be submitted to CBER?
22	chain with attachments, Bates	$\begin{vmatrix} 21\\22\end{vmatrix}$	A. Yeah, but read further down.
23	MRK-KRA00561199 - 00561209, was marked	23	Q. I will.
24	for identification.)	24	A. The information is still
25	for identification.)	25	Q. Yes. Joe - I removed Tables 6c
23	= = =	25	Z. 103. Joe - Hollioved Tables of

	Page 334	1	Page 336
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	and 6d and associated text you re-inserted in	l	THE WITNESS: Why would you
3	attachment 2 to avoid confusions since Table	3	submit why would you submit
4	6d has different ELISA titer grouping used to	4	redundant information to CBER and make
5	show number of discrepancies between the	5	it hard for them to interpret it?
6	AIGENT and the ELISA within each group than	6	BY MR. KELLER:
7	what we you have than which you have	7	Q. Well, evidently is it fair to
8	used in attachment 2 Table 2 of	8	say that Mr. Antonello, this biostatistician,
9	attachment 3, (titer groups in the deleted	9	wanted that data in here?
10	Table 6d are ELISA titers of 10 to 20, 20 to	10	MR. SANGIAMO: Object to the
11	40, and 40 to 60, et cetera, whereas they are	11	form. Calls for speculation.
12	based on sd from cutoff in table in	12	THE WITNESS: I don't know that
13	attachment 3 and so are grouped differently:	13	for sure. He may not have noted that
14	ELISA titer groups of 1sd (10 to 14), 2sd (14	14	he's already provided the same
15	to 20), 3sd (20 to 28) et cetera).	15	information on another table as well.
16	Do you see that?	16	BY MR. KELLER:
17	A. Uh-huh.	17	Q. He evidently re-inserted it
18	MR. SANGIAMO: I just want to	18	after Manal Morsy took it out in the last
19	note for the record, there were a	19	draft.
20	couple of points where you didn't read	20	A. I can't speculate.
21	the right word but we can go back to	21	MR. SANGIAMO: Object to the
22	the document as need be.	22	form.
23	MR. KELLER: Sure.	23	BY MR. KELLER:
24	BY MR. KELLER:	24	Q. You can't speculate. I see. So
25	Q. So here Joe Antonello, the	25	Manal Morsy goes on to say, "I understand that
	D 225	l	
1	Page 335	١.	Page 337
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis	2	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative
2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed	2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of
2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison	2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is
2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to	2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely
2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them	2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important."
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that?
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2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement?	2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement? MR. SANGIAMO: Object to the form. THE WITNESS: There's too much	2 3 4 5 6 7 8 9 10 11 12 13 14 15	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the different format that the biostatistician didn't agree to. Correct? A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement? MR. SANGIAMO: Object to the form. THE WITNESS: There's too much speculation in there. She had removed	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the different format that the biostatistician didn't agree to. Correct? A. No. MR. SANGIAMO: Object to the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement? MR. SANGIAMO: Object to the form. THE WITNESS: There's too much speculation in there. She had removed the tables because, as I read it, the information is adequately captured in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the different format that the biostatistician didn't agree to. Correct? A. No. MR. SANGIAMO: Object to the form. THE WITNESS: You're speculating.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement? MR. SANGIAMO: Object to the form. THE WITNESS: There's too much speculation in there. She had removed the tables because, as I read it, the information is adequately captured in the alternative table and actually	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the different format that the biostatistician didn't agree to. Correct? A. No. MR. SANGIAMO: Object to the form. THE WITNESS: You're speculating. BY MR. KELLER:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement? MR. SANGIAMO: Object to the form. THE WITNESS: There's too much speculation in there. She had removed the tables because, as I read it, the information is adequately captured in the alternative table and actually better understandable.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the different format that the biostatistician didn't agree to. Correct? A. No. MR. SANGIAMO: Object to the form. THE WITNESS: You're speculating. BY MR. KELLER: Q. I see.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL biostatistician working on this analysis between the PRN assay and the wild-type ELISA assay who wanted to insert these two tables in the way that it was presented, it was removed by Manal Morsy, the liaison, FDA liaison because she thought it may encourage CBER to increase the cutoff, and so she had them replaced with a different way of identifying that data from using groups of cutoffs to using groups of standard deviations. Is that a fair statement? MR. SANGIAMO: Object to the form. THE WITNESS: There's too much speculation in there. She had removed the tables because, as I read it, the information is adequately captured in the alternative table and actually better understandable. BY MR. KELLER: Q. I see. And so why didn't they just put it in both tables?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL you have a desire to include them but you have very nicely captured all the discrepancy information and how it is distributed relative to the ELISA 10 cutoff in table 2 of attachment 3 so the information in the end is included, reflected accurately and completely to CBER and that's what's critical and important." Do you see that? A. Yes. Q. But it's just included in the different format that the biostatistician didn't agree to. Correct? A. No. MR. SANGIAMO: Object to the form. THE WITNESS: You're speculating. BY MR. KELLER: Q. I see. A. We don't say that she doesn't say that he didn't agree to it. She just I mean, we often have people who

85 (Pages 334 - 337)

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1	Page 338		Page 340
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	a call. It's her call because she's the		VIDEOGRAPHER: Back on the
3	regulatory liaison to figure out which ones	3	record at 4:21. The beginning of disc
4	are more useful.	4	number five six.
5	Q. I see. So then she goes on,	5	MR. KELLER: Let me mark as the
6	"Please review to insure that no statements	6	next exhibit, Exhibit 15 which had
7	were accidentally left behind in attachment 2	7	previously been marked with by
8	that are specific to these two tables."	8	Fisher Exhibit 17.
9	So she's pretty adamant about	9	
10	removing his description of what was in those	10	(Exhibit Schodel-15, E-mail
11	tables from what was provided to CBER. Is	11	chain, Bates MRK-KRA00791315 -
12	that a fair assessment?	12	00791319, was marked for identification.)
13	A. No, not as far as the	13	
14	description goes. In fact, she makes extra	14	BY MR. KELLER:
15	sure that no statements are in there that	15	Q. Nor the record, Exhibit 15 is a
16	would wrongly refer to the tables, not to the	16	document bearing Bates stamp number 791315
17	now attached whatever number two was. Just a	17	through 19 which is a series of e-mails.
18	matter of editing the document at the end to	18	Doctor, I'd like to direct your
19	make sure that whatever statement is in there	19	attention to the last e-mail on page 791319.
20	is accurate.	20	This is an e-mail from Joe Antonello to Keith
21	Q. I see. And so okay.	21	Chirgwin, and you're cc'd on this. The
22	MR. KELLER: Let me mark as	22	subject is Comparing Mumps wild-type ELISA and
23	Exhibit 15.	23	AIGENT Assay, June 29, 2004. If you want to
24	THE WITNESS: May I just point	24	take a minute to review that.
25	out to you that actually the content	25	A. Okay.
	Page 339		Page 341
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	of these tables is in the document,	2	Q. Here this is an e-mail and
3	here in this draft, 3a and 3b.	3	Keith Joe was saying, writing to Keith, "In
4	BY MR. KELLER:	4	response to your MVX," that's a voicemail
5	Q. Where is the content of that	5	system that Merck had at the time. Correct?
6	information in these documents?	6	A. Yes.
7	A. The tables that you were	7	Q. So he got a this appears to
8	particularly asking about seem to be Tables	8	be a voicemail from Keith Chirgwin who he's
9	3a and 3b here.	9	responding to. In the middle of the page it
10	Q. Do you know whether or not this	10	says, In that response, we contended that
11	was provided to CBER?	11	there was reasonably good agreement between
12	A. Do you know whether it was	12	the two assays in terms of serostatus
13	provided to CBER? I don't.	13	classification when using a cutoff of 10 Ab
14	MR. SANGIAMO: Doctor, you just	14	units in Mumps wild-type and a cutoff of 1 to
15	have to answer his question.	15	32 in the AIGENT assay, so I am concerned when
16	BY MR. KELLER:	16	you say that the two assays are discordant
17	Q. I do.	17	around the cutoff. Concluding that the two
		18	assays agree reasonably well was important for
18	A. While you're looking, I'll take	10	
18 19	A. While you're looking, I'll take another short break. Is that okay?	19	the purpose of arguing that the ELISA was
	·		
19	another short break. Is that okay?	19	the purpose of arguing that the ELISA was
19 20	another short break. Is that okay? Q. Sure.	19 20	the purpose of arguing that the ELISA was acceptable substitute for the neutralizing
19 20 21	another short break. Is that okay? Q. Sure. VIDEOGRAPHER: Off the record at	19 20 21	the purpose of arguing that the ELISA was acceptable substitute for the neutralizing assay.
19 20 21 22	another short break. Is that okay? Q. Sure. VIDEOGRAPHER: Off the record at	19 20 21 22	the purpose of arguing that the ELISA was acceptable substitute for the neutralizing assay. Do you see that?
19 20 21 22 23	another short break. Is that okay? Q. Sure. VIDEOGRAPHER: Off the record at 4:15. This ends disc number five.	19 20 21 22 23	the purpose of arguing that the ELISA was acceptable substitute for the neutralizing assay. Do you see that? A. Yes.

	Page 342		Page 344
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	correlated their plaque reduction	2	when I am not sure we could meet.
3	neutralization assay to the ELISA assay?	3	And so this is Steve Rubin
4	A. No, it means exactly what it	4	saying that he wants specific criteria for
5	says, that a serostatus classification	5	concordance.
6	concordance testing was done and that the	6	His suggestion was that we focus
7	using the cutoffs of 1 of 10 and 1 to 32	7	on sera with low antibody titers just above
8	there was reasonable concordance.	8	the ELISA cutoff, and that they would like to
9	Q. And so Merck wanted to use that	9	see no more than 10 percent of such ELISA low
10	as a substitute, so to rely upon the ELISA as	10	positive sera score negative to PRN assay.
11	a substitute for the neutralization assay?	11	Do you see that?
12	A. Those are Joe's words. I don't	12	A. Yes.
13	know what he means with a substitute.	13	Q. So isn't that what Table c and
14	Q. I see.	14	Table d identify?
15	A. I mean, there were two assays	15	MR. SANGIAMO: I'm going to
16	used in 007. So ultimately the ELISA was	16	object to your reading of that, not
17	important for that particular study and it	17	just because there were a couple of
18	was also used for the ProQuad filings. So	18	mistakes in there, but you also
19	obviously CBER accepted that the ELISA was a	19	inserted something that was not from
20	reasonable assay to measure mumps activity.	20	the document itself.
21	Q. I see. Here he says, "I do	21	BY MR. KELLER:
22	agree with your key points," and he's	22	Q. I'll rephrase it if you need to.
23	responding to the Keith Chirgwin, "We don't	23	"His suggestion was that we focus on sero with
24	really know what a clinically protective level	24	low antibody titers just above the ELISA
25	is in either assay"	25	cutoff, and that they would like to see no
	Page 343		Page 345
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Do you see that?	2	more than 10% of such ELISA low positive sero
3	A. Yes.	3	score negative in the PRN."
4	Q. He's talking both about the	4	Do you see that?
5	wild-type ELISA and Merck's PRN assay as used	5	A. Yes, I see that.
6	in Protocol 0097. Correct?	6	Q. Isn't that exactly what Table c
7	A. Probably, yes.	7	and Table d were identifying?
8	Q. Do you agree with that statement?	8	A. No. It overlaps with that
-	A. Yes.	9	statement, but it's not exactly the same.
10	Q. So if you see on the next e-mail	10	Q. I see. How does it overlap?
11	on 791318, dated June 29, 2004, later on that	11	A. Well, it overlaps by showing in
12	evening Chirgwin responds to Dr. Antonello,	12	a selected small sample how the low antibody
13 14	and you're cc'd on here, Dr. Schodel, "Thanks	13 14	titers just above the ELISA cutoff are scored in the PRN.
15	Joe. Just to clarify, I understand that the PRN and ELISA track fairly well and this is	15	Q. Then he goes on and says, I do
16	what I conveyed to Steve Rubin. The question	16	not recall whether we ever did such a subset
17	is to what degree are these assays	17	analysis with low positives - this seems like
18	concordant."	18	a problematic approach as the low percentage
19	Do you see that?	19	of "false-positive" would depend on which
20	A. Yes.	20	specific sera are selected for inclusion in
21	Q. Do you understand what he meant	21	such an analysis.
22	by the term "concordant"?	22	Do you see that?
23	A. No.	23	A. Yes.
24	Q. He goes on and says, He was	24	Q. So this term "false-positive,"
25	suggesting specific criteria for concordance	25	what do you understand that to mean?
1 4. 1		1	jou and to mount.

	D 246		P 240
1	Page 346 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 348 FLORIAN SCHODEL, MD - CONFIDENTIAL
2		2	versus 92 percent). Then he writes is that
3	A. Well, I understand that to mean that they saw something a different result	3	significant with a question mark.
4	in one of the assays than in the other assay	4	Nonetheless, we opted for use of the wild
	•	5	WT ELISA for future studies.
5	which does not doesn't speak to absolute truth or falseness. It just simply speaks to	6	Do you see that?
7	the level of discordance or concordance.	7	A. That's how he summarized the
		8	situation, yeah.
8	Q. Let's go to the first page of	9	-
9	this e-mail. Here Michael Dekleva who is Michael Dekleva?	10	Q. And those future studies were
10		11	the ones that were done for ProQuad? MR. SANGIAMO: Objection. Calls
11	A. Mike at the time, he was at	12	-
12	some point regulatory and clinical. And	13	for speculation. BY MR. KELLER:
13	before that I think he was quality assurance	14	
14	and MMD. So I don't know what he was at that		Q. Do you understand that's what he's talking about?
15	time.	15 16	MR. SANGIAMO: Calls for
16	Q. I see. So he sends you an	17	speculation.
17	e-mail on July 2, 2004, regarding comparing	18	THE WITNESS: I don't know.
18	mumps wild-type ELISA or WT ELISA and AIGENT	19	BY MR. KELLER:
19	assay. You understand it to refer to the	20	Q. You don't know. And finally it
20 21	ELISA and PRN assays in Protocol 007? A. Yes.	21	goes, "Sowe are pulling the information
21 22		$\begin{vmatrix} 21\\22\end{vmatrix}$	together, including all prior CBER
	Q. Alison and I are pulling it	$\begin{vmatrix} 22 \\ 23 \end{vmatrix}$	communications. It may be that Steve Rubin is
23	together. In what we've been able to find so	24	simply 'coming up to speed,' or it could be
25	far, there doesn't seem to be any	25	that he's trying to understand our rationale
23	documentation that CBER actually concurred	23	that he's trying to understand our rationale
	Page 347	1	Page 349
1		1	
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL	1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT	2	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit		FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate
2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but	2 3 4	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their
2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response.	2 3	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay."
2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In	2 3 4 5	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that?
2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear	2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes.
2 3 4 5 6	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay	2 3 4 5 6 7	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that?
2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we	2 3 4 5 6 7 8	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a
2 3 4 5 6 7 8 9 10	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we claimed that there was strong concordance	2 3 4 5 6 7 8 9 10	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No.
2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we	2 3 4 5 6 7 8 9	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No. Q. Here he's saying that the
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2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we claimed that there was strong concordance between the PRN and wild-type ELISA, although	2 3 4 5 6 7 8 9 10 11 12	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No. Q. Here he's saying that the wild-type ELISA may overestimate seroconversion rates with compared to the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we claimed that there was strong concordance between the PRN and wild-type ELISA, although around the cutoff (less than 10 Ab) there's a greater chance of seeing positive results with the PRN rather than the ELISA. Do you see that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No. Q. Here he's saying that the wild-type ELISA may overestimate seroconversion rates with compared to the PRN assay. Do you see that? A. I think he's just speculating. We actually have just seen data to the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we claimed that there was strong concordance between the PRN and wild-type ELISA, although around the cutoff (less than 10 Ab) there's a greater chance of seeing positive results with the PRN rather than the ELISA. Do you see that? A. Yes. Q. And so this strong concordance, is that the analysis that you reviewed earlier	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No. Q. Here he's saying that the wild-type ELISA may overestimate seroconversion rates with compared to the PRN assay. Do you see that? A. I think he's just speculating. We actually have just seen data to the converse. Q. You don't agree with that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we claimed that there was strong concordance between the PRN and wild-type ELISA, although around the cutoff (less than 10 Ab) there's a greater chance of seeing positive results with the PRN rather than the ELISA. Do you see that? A. Yes. Q. And so this strong concordance, is that the analysis that you reviewed earlier where they were looking at whether or not the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No. Q. Here he's saying that the wild-type ELISA may overestimate seroconversion rates with compared to the PRN assay. Do you see that? A. I think he's just speculating. We actually have just seen data to the converse. Q. You don't agree with that? A. No, I don't agree with that.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL with our recommendations regarding the WT ELISA and choice of less than 10 Ab unit cutoff. We requested their concurrence, but never received a response. It goes on, in order In looking at the old documentation it's clear that CBER was very interested in the PRN assay for evaluating persistence. Afterwards we claimed that there was strong concordance between the PRN and wild-type ELISA, although around the cutoff (less than 10 Ab) there's a greater chance of seeing positive results with the PRN rather than the ELISA. Do you see that? A. Yes. Q. And so this strong concordance, is that the analysis that you reviewed earlier where they were looking at whether or not the two assays A. Yes. Q. It goes, Perhaps because of that there were slightly higher seroconversion	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	FLORIAN SCHODEL, MD - CONFIDENTIAL for selecting an assay that while more precise and easier to perform, may overestimate seroconversion rates relative to their 'preferred' (?) PRN assay." Do you see that? A. Yes. Q. So here is Mike Dekleva a doctor? A. No. Q. Here he's saying that the wild-type ELISA may overestimate seroconversion rates with compared to the PRN assay. Do you see that? A. I think he's just speculating. We actually have just seen data to the converse. Q. You don't agree with that? A. No, I don't agree with that. Q. It goes on to say, I spoke with Joe Antonello yesterday, and he re-emphasized that the decision with the PRN assay was very poor, and he felt that it was really hard to

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	2.00		
1	Page 350	1	Page 352
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	extent by the variability in the PRN assay	2	closed out the issue - which allowed us to
3	PRN data.	3	proceed with MMR and PQ studies"
4	Do you see that?	4	A. Where is that?
5	A. Yes.	5	Q. The top of this?
6	Q. SO do you agree with Joe	6	A. Oh, here it is, yeah.
7	Antonello that the PRN assay was very poor	7	Q. "at the time - hope this was
8	with respect to precision?	8	captured."
9	A. It was certainly relatively	9	MR. SANGIAMO: Let him read.
10	worse than the ELISA which is one of the	10	BY MR. KELLER:
11	reasons why CBER also preferred the ELISA.	11	Q. Sure. PQ there represents
12	Q. I see.	12	ProQuad. Correct?
13	A. It's generally harder to make a	13	A. Yes.
14	biological assay like a PRN assay as reliable	14	Q. You say, "Agree with Joe - could
15	as an ELISA. It's well known in the art.	15	not overemphasize the weakness of the PRN (50%
16	Q. So do you agree that the PRN	16	specifies!!!!!)."
17	assay was very poor?	17	Do you see that?
18	A. No, those were Joe's words or	18	A. Yes, I see that.
19	maybe they're Mike's interpretation of Joe's	19	Q. So is it your opinion that the
20	words. I don't think it was very poor, but	20	PRN assay was weak and only had 50 percent
21	the precision, it's a relative statement. If	21	specificity?
22	you compare it to the wild-type ELISA, it may	22	A. I think it had its weaknesses.
23	appear very poor because the ELISA is much	23	The 50 percent is a partial misquote. There
24	more reliable.	24	was not as we pointed out earlier, there
25	Q. Wasn't Merck comparing the	25	was not a formal specificity analysis
1	Page 351 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 353 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	cutoffs of the wild-type ELISA with the PRN	2	performed, so I couldn't know what the exact
3	cutoffs in order to confirm that the cutoff	3	specificity was. What I was reacting to was
4	used in the ELISA was accurate?	4	that in a very, very small sample, in half of
5	A. In order to satisfy a CBER	5	the samples some of the titers were reduced
6	desire. You cannot measure you cannot	6	by unspecific reagents such as measles
7	confirm that something is accurate with a lot	7	extracts, rubella extracts and Varicella
8	of precision with something that in itself is	8	extracts that summarized in the validation
9	imprecise.	9	report does not necessarily mean that the
10	Q. I see. That's what happened	10	overall specificity is only 50 percent
11	with Protocol 007. Correct?	11	because that wasn't formally analyzed. It
12		12	
13	MR. SANGIAMO: Object to the form.	13	just means exactly that, that there are other factors that contribute to the variability of
13	THE WITNESS: That's what	14	
			the assay. And, again, didn't matter for 007
15	happened not necessarily specifically	15	because it was a comparative study.
16	for Protocol 007. That is what will	16	Q. Well, Doctor, you seem to be
17	happen every time you use a biological	17	very well versed in the definition of
18	assay to try to measure concordance at	18	specificity. So here you write 50 percent
19	the extremes.	19	specificity with six exclamation points. So
20	BY MR. KELLER:	20	at this time that you wrote this, you agreed
21	Q. And so here on July 3rd, the	21	with Joe that the precision was very poor and
22	next day, 2004, Dr. Schodel, you responded to	22	that you could not overemphasize the weakness
122	Michael Dekleva. And here you write, "Dear	23	of the PRN assay. Is that a fair statement?
23			
23 24 25	Mike, Thanks - I distinctly remember a conversation with Kathy Carbone in which we	24 25	A. Yes, but I just explained to you that the specificity of 50 percent here

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			5 24
1	Page 354	1	Page 356
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	does not refer to a specific specificity	2	Q. When did you look it up?
3	analysis as could have been performed that	3	A. I looked it up whenever it was,
4	wasn't performed.	4	Monday.
5	Q. I see.	5	Q. So you went back and looked up
6	A. So I don't know what the real	6	that on Monday?
7	number was. I didn't know at the time.	7	A. Because I wanted to know what I
8	Q. So the 50 percent specificity	8	had referred to at the time. I don't I'm
9	you're talking about is whether or not the	9	sorry, maybe you're perfect, but I don't
10	neutralization that occurred in this PRN assay	10	remember everything that I said in 2004.
11	was the result of mumps I mean, measles or	11	Q. That was after you spoke to your
12	rubella?	12	lawyers. Correct?
13	A. Not at all. No. What I was	13	A. No, not at all. It was after I
14	reacting to was a data mentioned in the	14	saw this e-mail and they asked me what I
15	summary of the validation report which	15	meant.
16	essentially states if you reread it, that in	16	MR. SANGIAMO: Hold on.
17	a number of sera, in half of them the titer	17	Dr. Schodel, you can't discuss our
18	could only be reduced by mumps so that half	18	conversations.
19	of them were completely specific. And the	19	BY MR. KELLER:
20	other half, some of the plaque reduction, I	20	Q. So the validation document that
21	don't even know whether it's the titer, just	21	you reviewed, that was a validation document
22	the plaque reductions seemed to be reduced by	22	for the plaque reduction neutralization assay?
23	unspecific reagents. That does not yet mean	23	A. Yes.
24	that the assay overall has a 50 percent	24	Q. So it was looking at the
25	specificity. I just interpreted that as	25	specificity of other agents. What other
	Page 355		Page 357
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	meaning that half is 50 percent. It is a	2	agents was it looking at?
3	sloppy expression which I should probably not	3	A. It was not testing, formally
4	have used, but it does not reflect on the	4	testing specificity so I shouldn't have used
5	overall specificity, nor does it matter.	5	that term. But it was using rubella,
6	Q. So it's your testimony today	6	Varicella rubella, measles and cell
7	when you say specificity, you didn't really	7	extract, uninfected cell extract.
8	mean specificity?	8	
9	MR. SANGIAMO: Object to the	9	(Exhibit Schodel-16, Excerpted
10	form. It's argumentative. He's	10	document of Clinical Study Report,
11	already addressed this.	11	Bates MRK-KRA00001270 - 00001466, was
12	THE WITNESS: My testimony today	12	marked for identification.)
13	is that I just translated four out of	13	
14	eight with something that doesn't	14	BY MR. KELLER:
15	translate into specificity as 50	15	Q. I'm going to mark as Exhibit 16
16	percent.	16	a document that bears Bates stamp numbers 1270
17	BY MR. KELLER:	17	through 1466. This is an excerpted document
18	Q. So you're talking about with	18	of the entire clinical study report. It
19	something in the clinical study report?	19	doesn't have all the attachments. But I ask
20	A. No, it's in the validation	20	you if you recognize this as the clinical
21	report for the mumps neutralizing assay.	21	study report that was used for Protocol 007
22	Q. When did you review that?	22	and was submitted to CBER?
23	A. I must have reviewed it around	23	A. It looks like it.
24	that time, but because that question arose	24	Q. Let me direct your attention to
25	again, I looked it up and that's what it was.	25	1328 of the clinical study report. What is a
122	again, i looked it up and mats what it was.	125	1526 of the chimear stady report. What is a

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Page 358 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 2 clinical study report? 2 seems to appear to be signed by you, 3 3 A. A clinical study report is a Dr. Schodel. Does this refresh your memory 4 report on the data generated in a clinical 4 that you did review it and made comments? 5 5 study. A. It looks like my handwriting 6 6 This is the backup data support, for sure. 7 the label change for Protocol 007 to reduce 7 Q. Let me direct your attention 8 the potency from 4.3 to 4.1? 8 back to Exhibit 16 which is the formal CSR and 9 A. That's certainly part of the I will represent to you that was submitted to 10 information. I suspect it's not all the 10 CBER, according to Merck. If you go back to information. 11 11 1328 -- let me back up a little bit. 12 There's also a supplemental BLA 12 Let me go back to 1325 and start 13 13 there. Here under 5.5.4.1. that goes -- that this is attached to. Correct? 14 Yeah, probably. 14 A. Wait, wait, wait. On 1325 I 15 Did you ever review this CSR 15 have 5.7.3.3. 16 before it was submitted? 16 Q. I apologize, I'm looking --17 17 A. I don't remember. It depends Oh, oh, oh. Okay. 18 on the time. I generally reviewed CSRs when 18 Q. It's the center number, not the 19 I was responsible for them and didn't when I one on the right. It's a different number. I wasn't, so I don't remember. I mean, the 20 apologize. Let me know when you're there. 21 direct responsible probably at the time would 21 I think I'm there. 22 22 have been Luwy or another physician. And I Q. Here at 5.5.4.1 it says, 23 would not always have reviewed all the 23 "Anti-IgG Enhanced Mumps Plaque Reduction 24 details of a clinical study report. There 24 Neutralization Assay." Do you see that? 25 were a lot of them. Yes. A. Page 359 Page 361 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 2 MR. KELLER: Let me mark as Q. That's the PRN assay that was 3 Exhibit 17. 3 used in Protocol 007. Correct? 4 4 A. Yes. 5 (Exhibit Schodel-17, 10/21/03 5 Q. If you look on 1328 there's a 6 Memo, Bates MRK-KRA01638866 topic of "Specificity." Is this a summary of 6 7 7 01639147, was marked for identification.) the specificity analysis that Merck did on 8 8 Protocol 007, the PRN assay? - - -9 9 BY MR. KELLER: Yes, I think it is. It is here. 10 10 Exhibit 17 is a document --Q. Is that what you're relying upon 11 A. That's all you want to know on 11 to say it was only 50 percent specific? 12 16? A. As I said, I -- this was a bit 12 13 We're going to go back to it. 13 of an overstatement. But what I translated Q. 14 Just keep it in front of you. 14 here was that in that "Absorption with the 15 You want me to read it? mock measles or rubella extract yielded similar 16 Q. No, I'll show you what to look results, whereas absorption with the mumps 17 at. 17 extract yielded a further reduction in...3 to 18 So Exhibit 17 is a document that 18 4...." I don't remember whether this is what 19 bears Bates stamp number 1638866 through I based it on. I think it was more the 20 20 1639147. And it's a document dated statement in the validation report. 21 October 21, 2003, from Mandie Lyon to 21 Q. I see. 22 Dr. Schodel and a bunch of other people, 22 So I don't really remember, I subject: "V205C Protocol 007 Clinical Study 23 don't remember, but I think that's a little Report for Review 2." And there's handwritten 24 different statement in the validation report. documents -- handwritten notes on this and it It's a little different than the statement

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Page 362 Page 364 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 here. 2 mumps potencies have relatively similar 3 3 Q. Fair enough. Let me direct your immune responses and, therefore, would 4 attention to page 12 -- to 1462. 1461 and 4 expect -- be expected to protect in a similar 1462 under title 9 "Discussion." 5 5 way. The assay is just an adjunct. It's 6 A. Okay. 6 not -- since there is no correlative 7 Q. Here -- actually let me do this: protection in the assay, it just shows that 8 8 Let me direct your attention -- this is under they're similar. 9 9 section 9 "Discussion." What is typically the Q. Well, you testified there's a 10 discussion section in the clinical study 10 difference between the concordance, between a 11 report, does that discuss the -- what is 11 PRN assay and ELISA assay and a correlation that -- the purpose of a discussion section? 12 between the two. Here Merck is representing 13 that it correlated those two assays, isn't it? A. Well, the purpose of the 13 14 discussion section is to discuss any issues 14 A. I didn't say -- while the 15 that need further discussion. It could be 15 difference is -- the difference I pointed out the endpoints, it could be the assays, it 16 was more in how you look at the comparison of 17 could be the selection of the population in 17 two assays. It doesn't -- I didn't 18 which something was done. It's not a very specifically say that one is worse or better 19 narrow definition of that. than the other. It's just how you do things. 20 Q. Let me direct your attention to 20 But I never said that there was a correlation 21 1463 in the last paragraph. Let me know when 21 between any specific titer or any specific 22 assay and the prevention of disease. you get there. 22 23 23 Q. Are you surprised to see Merck In this paragraph Merck is 24 representing to CBER that, The mumps wild-type 24 representing to CBER that it did correlate ELISA used in this study was shown to 25 those two assays, the PRN and wild-type ELISA? Page 363 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 correlate with the PRN assay, and previous 2 2 Well, you already know that 3 3 studies have established a strong correlation CBER asked that that be done and so, of 4 between the development of mumps-specific 4 course, it was done. Because it was done it neutralizing antibodies and vaccine efficacy. 5 had to be summarized in a clinical study Therefore, the mumps PRN assay and ELISA 6 6 report. 7 7 results from this study support the You understand that the use of 8 effectiveness of M-M-R II containing a mumps 8 these two assays was to show that the 9 virus potency of no more than 4.1 log TCID and vaccine -- to support vaccine effectiveness? the lowering of the mumps virus end expiry 10 Among other data, yes. potency from the currently assigned potency of So vaccine effectiveness means 11 11 12 4.3 to no less than 4.1 log TCID. 12 that the vaccine works in the real world, 13 Do you see that? 13 correct, based on your definition? 14 14 Yes, I see that. A. That's correct, but that's not 15 So Merck submitted to CBER that 15 based on the PRN assay result. it correlated its wild-type ELISA assay to its 16 Q. So when you agreed with Joe that 17 PRN. Does that surprise you? 17 the PRN assay that's being used to correlate 18 No, as requested by CBER. 18 to the wild-type ELISA is very poor and could 19 Q. So Merck is representing as part 19 not overemphasize the weakness of the PRN 20 of the CSR that, in fact, it is correlating 20 assay, you think that's appropriate to submit its wild-type ELISA assay to its PRN assay to 21 to CBER that the wild-type assay was 22 support the effectiveness of MMR II? 22 correlated to the PRN assay? 23 A. Well, indirectly because the 23 A. Yes. It's actually only very 24 immunologic comparison between these 24 weak around this particular definition of a different preparations of MMR with different cutoff. It's not overall very poor. That's

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	not what anybody said. And therefore, overall	2	therefore, be considered a surrogate for
3	the correlation is pretty good. Most people	3	vaccine effectiveness.
4	are vaccinated at very high titers and then	4	What do you understand surrogate
5	it would have an almost perfect correlation.	5	of vaccine effectiveness to mean, Doctor?
6	Q. So if Merck submitted this PRN	6	A. I think that's a bit of
7	assay as support and to be considered as a	7	a surrogate for vaccine. I mean, it's
8	surrogate of vaccine effectiveness, would that	8	supportive data that the vaccine has not
9	cause you concern?	9	changed in that context of the comparison.
10	MR. SANGIAMO: Object to the	10	You can use it as vaccine effectiveness
11	form.	11	because the vaccine has shown effectiveness.
12	THE WITNESS: It's not what	12	The immunogenicity to it has not changed and,
13	Merck has done as far as I can tell.	13	therefore, you would expect the same
14	BY MR. KELLER:	14	effectiveness does not mean that it directly
15	Q. Let me show you the BSLA SBLA	15	correlates with effective.
16	which I'd like to mark as Exhibit 32 I'm	16	Q. I see. But isn't Merck
17	sorry, Exhibit 18.	17	representing
18		18	A. The surrogate simply means that
19	(Exhibit Schodel-18,	19	you can't measure the original, so it means
20	Supplemental Biologics License	20	it stands in for.
21	Application, Bates MRK-KRA00000032 -	21	Q. Because you couldn't do an
22	00000139, was marked for identification.)	22	efficacy study today, that's unethical?
23		23	A. That's correct.
24	BY MR. KELLER:	24	Q. So the best assay that you can
25	Q. Exhibit 18 bears Bates stamp	25	use is a surrogate of vaccine effectiveness.
	Page 367		Page 369
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	number 32 through 139. Again, this is a	2	Correct?
3	excerpted document, doesn't have thousands of	3	A. Any assay that you can use you
4	pages, it has the supplemental biologics	4	would try to use as a surrogate for vaccine
5	license application.	5	effectiveness showing that the vaccine hasn't
6	Doctor, have you seen this	6	changed since it's been started to use and
7	document before?	7	looking at the field effectiveness data that
8	A. Probably, but I don't remember.	8	you constantly get. So it doesn't
9	Q. Let me direct your attention to	9	necessarily have to be the best. It is what
10	Bates number 111.	10	the best effort that you can make. And in
11	A. 111?	11	6
12	Q. Yes. Under section 2.5.1.5.3,	12	used to support that the vaccine had not
13	Study Endpoints, what is a study endpoint	13	changed.
14	again, Doctor?	14	Q. I see. And so you're not
15	A. It's a measure taken in the	15	concerned that any assay that you considered
16	study.	16	to be that you stated you cannot
17	Q. Here it says, The Mumps	17	overemphasize the weakness of this assay, you
18	neutralizing antibodies were measured	18	agreed with Joe Antonello that it was very
19	immediately prior to vaccination and 6 weeks	19	poor with regard to precision is being
20	postvaccination using the plaque reduction	20	represented by Merck to CBER as a surrogate
21	neutralization assay. The PRN assay was used	21	for vaccine effectiveness?
22	as a priority endpoint because it is a	22	A. No, that doesn't concern me
23	functional assay that can measure the ability	23	because you're taking my statements of its
2.4			
24 25	of vaccine-induced immune response to inhibit viral replication in vitro, and can,	24 25	weakness out of context. It's not weak across the board. It's very precise in

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	Page 370	1	Page 372
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	estimating high titers, for example.	2	questions this evening.
3	Q. It's just weak around the	3	A. Okay, John.
4	cutoff?	4	Q. I'm going to show you what we
5	A. It's relatively weaker than the	5	just marked as Exhibit 19, which I believe is
6	ELISA.	6	a draft of an academic article for which you
7	Q. I see. And Merck in the	7	were one of the authors. Correct?
8	clinical study report stated that it	8	A. Yes.
9	correlated its wild-type ELISA to its PRN	9	Q. Do you remember working on this?
10	assay. Correct?	10	A. I saw it at some point and I
11	A. That's correct.	11	made some comments on it, yes.
12	Q. Do you know that Merck was able	12	Q. So you were not the principal
13	to convince CBER to rely only on wild-type	13	drafter, I take it?
14	ELISA assays going forward based on this	14	A. No.
15	correlation analysis?	15	Q. Who was?
16	MR. SANGIAMO: Object to the	16	A. I suspect it was Tim Schofield,
17	form.	17	but I don't really know.
18	THE WITNESS: That is an	18	Q. Who is the first person the
19	assumption that you make too many	19	first author is C. Marchant. Who is that?
20	assumptions in your question. Even in	20	A. I don't know.
21	the document that you showed me, CBER	21	Q. Not a Merck employee I take it.
22	itself provided other reasons why it	22	Right?
23	would rely on the ELISA and which you	23	A. I really don't know. I don't
24	have read and we talked about. So I	24	know. I don't know.
25	would certainly not support the notion	25	Q. Okay. Fair enough. I want to
	Page 371		Page 373
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	that CBER accepted that solely on the	2	talk to you towards the end, if you go towards
3	correlation. That being said, the	3	the end, the Bates numbered page ending in
4	correlation wasn't all that bad.	4	517.
5	MR. KELLER: I see. Let's take	5	A. 517. Okay.
6	a break.	6	Q. If you see at the top there's a
7	VIDEOGRAPHER: Off the record at	7	sentence that's highlighted with a comment, it
8	4:56.	8	says, "Comment (FS12)." Take a look at that
9	4.50.	9	comment.
10	(A recess was taken.)	10	A. Yeah, I can't read this, it's
11		11	too small print.
12	VIDEOGRAPHER: Back on the	12	Q. I don't know how to help you
13	record at 5:08.	13	with that. I mean, I can read what the
14	record at 5.00.	14	comment says and then your lawyer can tell you
	(Exhibit Sahadal 10 Autiala		
15	(Exhibit Schodel-19, Article	15	if I got it wrong, is about the only other
16	draft, Bates MRK-KRA00032482 -	16	solution I have to that.
17	00032519, was marked for identification.)	17	MR. SANGIAMO: That's fine.
18		18	BY MR. MACORETTA:
19	EXAMINATION	19	Q. I can read it. So can you read
20		20	the sentence that's talking about that
21	BY MR. MACORETTA:	21	starts with "The mumps wild-type ELISA"?
22	Q. All right. Good evening,	22	A. Yes, yes, yes. I can read part
	Dr. Vahadal Wa mat appliar My nama is John	23	of it, but I'm not sure I read the whole
23	Dr. Schodel. We met earlier. My name is John		
23 24 25	Macoretta. Mr. Keller had to leave so I'm going to finish up with a few additional	24 25	thing right. Q. Why don't I do the whole thing

Appx4686

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	and then your lawyer will tell me if I got it	2	They do not cite any correlation study by
3	wrong.	3	Merck. Right?
4	It says, "Comment (FS12): Did	4	A. Yes.
5	we really do a correlation study and if so,	5	Q. So does that indicate to you
6	where is it. I don't think I have ever seen	6	that there was no correlation study by Merck?
7	the data. If not, remove specific statement	7	MR. SANGIAMO: Object to the
8	and only cite literature."	8	form.
9	So you're asking about whether a	9	THE WITNESS: No, not
10	correlation study was done between the	10	necessarily. That's one of the
11	wild-type ELISA assay and the PRN assay.	11	interpretations. The other
12	Right?	12	interpretation was that it hadn't been
13	A. I didn't remember that, yes.	13	published or wasn't included and,
14	Q. And the answer was you didn't do	14	therefore, they preferred to follow my
15	a study. Correct?	15	advice if they can't produce cite
16	MR. SANGIAMO: Object to the	16	literature. You just wanted to have a
17	form.	17	reference for what was done. That was
18	THE WITNESS: I'm not sure	18	all I was asking for.
19	anymore whether I I mean there was	19	BY MR. MACORETTA:
20	this concordance analysis and a number	20	Q. Whatever reference they used was
21	of other analyses, so there was some	21	not some study that was done by Merck?
22	sort of correlation established. They	22	A. That's irrelevant. I just
23	could have simply shown it to me at	23	wanted to have a reference as to whether they
24	the time. So I that might have	24	correlate or not.
25	satisfied me actually.	25	Q. The correlations we're using,
	Page 375		Page 377
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	BY MR. MACORETTA:	2	numbers 29 and 30, are papers done in 1984 and
	Q. So let me show you well, let		
3		3	1992. Right?
4	me show you the next draft where this is I	4	A. Well, this is when this was a
4 5	me show you the next draft where this is I can show you the next draft where this came	4 5	A. Well, this is when this was a hot topic. It's only become one with you
4 5 6	me show you the next draft where this is I can show you the next draft where this came out. We'll show you what we're going to mark	4 5 6	A. Well, this is when this was a hot topic. It's only become one with you again.
4 5 6 7	me show you the next draft where this is I can show you the next draft where this came	4 5 6 7	A. Well, this is when this was a hot topic. It's only become one with you again. Q. I'm going to go back to the
4 5 6 7 8	me show you the next draft where this is I can show you the next draft where this came out. We'll show you what we're going to mark as Exhibit 20.	4 5 6 7 8	A. Well, this is when this was a hot topic. It's only become one with you again. Q. I'm going to go back to the we'll use the later draft, Exhibit 20. At the
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	Page 378		Page 380
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	A. Yes, that's at least one of the	2	on an ad hoc basis, not permanently. I don't
3	limitations.	3	remember that anymore, to tell you the truth.
4	Q. Well, did you agree that the PRN	4	Q. There's a discussion of house
5	was considered the gold standard assay for	5	standard. What is the house standard as it
6	measurement of mumps specific neutralizing	6	relates to the mumps vaccine?
7	antibodies?	7	A. Well, the house standard for
8	A. By some it is. And that's why	8	any vaccine is an internal lot of the vaccine
9	this is in reference marks. I mean, it's not	9	that has been very carefully assigned a
10	a that's not I wouldn't agree with	10	potency with more multiples of testing than
11	that, but it is considered that by some	11	would normally be used for release to assure
12	people.	12	relative accuracy. That is done repeatedly
13	Q. I'm going to change topics now.	13	over the course of a longer period of time
14	I'm going to show you what has previously been	14	because assays tend to vary over time. And
15	marked as Fisher Exhibit 3. We're going to	15	then it is this particular lot is assigned
16	talk about the house standard for a little	16	a potency out of this testing period. And
17	bit. Now we're marking it as 21, Schodel-21.	17	that particular potency is used to compare
18		18	the release titers when releasing a vaccine
19	(Exhibit Schodel-21, E-mail	19	so that you have something that links it back
20	chain, Bates MRK-KRA01481843 -	20	to the manufacturing history.
21	01481846 & 00566614 - 00566623, was	21	Q. So the idea is that the lots in
22	marked for identification.)	22	the house standard, we know what their potency
23		23	is supposed to be. Right?
24	BY MR. MACORETTA:	24	A. At a given point in time.
25	Q. So you can look at all of this	25	Q. And when we do an assay and we
	Page 379		Page 381
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	if you want, Dr. Schodel. The only e-mail	2	test both the new lot and the house standard
3	from you is on the first page. I want to talk	3	and we see how the what the assay says the
4	to you about that, but I am going to ask you	4	house standard is. Right?
4 5	about a couple other things in here. Let me	5	A. Uh-huh.
5 6	about a couple other things in here. Let me know when you're ready to talk about it.	5 6	A. Uh-huh.Q. And then we make some correction
5 6 7	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay.	5 6 7	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we
5 6 7 8	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It	5 6 7 8	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be?
5 6 7 8 9	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the	5 6 7	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a
5 6 7 8 9 10	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment	5 6 7 8 9 10	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment from the June 3 BPC meeting." So I'm going to ask you what those acronyms are, BPC and BSEC? A. So BPC is the Biological Process Council. BSEC, I don't remember exactly anymore what that stood for. Q. I believe somebody said it was the Biologic Standards Evaluation Committee or something like that? A. Sounds very reasonable but what those acronyms are after many years, I don't	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used that way. That would be introducing a factor. Or whether it's just simply a control to establish an expected range in which the new material should run without actually calibrating. Q. So what does A. So I don't know how it was used in this particular case. Q. Well, this the last page talks about "To reach consensus on the M-M-R®
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment from the June 3 BPC meeting." So I'm going to ask you what those acronyms are, BPC and BSEC? A. So BPC is the Biological Process Council. BSEC, I don't remember exactly anymore what that stood for. Q. I believe somebody said it was the Biologic Standards Evaluation Committee or something like that? A. Sounds very reasonable but what those acronyms are after many years, I don't remember it.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used that way. That would be introducing a factor. Or whether it's just simply a control to establish an expected range in which the new material should run without actually calibrating. Q. So what does A. So I don't know how it was used in this particular case. Q. Well, this the last page talks about "To reach consensus on the M-M-R® II House Standard which is required as part of
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment from the June 3 BPC meeting." So I'm going to ask you what those acronyms are, BPC and BSEC? A. So BPC is the Biological Process Council. BSEC, I don't remember exactly anymore what that stood for. Q. I believe somebody said it was the Biologic Standards Evaluation Committee or something like that? A. Sounds very reasonable but what those acronyms are after many years, I don't remember it. Q. Were you on either of these	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used that way. That would be introducing a factor. Or whether it's just simply a control to establish an expected range in which the new material should run without actually calibrating. Q. So what does A. So I don't know how it was used in this particular case. Q. Well, this the last page talks about "To reach consensus on the M-M-R® II House Standard which is required as part of the move to potency calibration." So what's
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment from the June 3 BPC meeting." So I'm going to ask you what those acronyms are, BPC and BSEC? A. So BPC is the Biological Process Council. BSEC, I don't remember exactly anymore what that stood for. Q. I believe somebody said it was the Biologic Standards Evaluation Committee or something like that? A. Sounds very reasonable but what those acronyms are after many years, I don't remember it. Q. Were you on either of these entities?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used that way. That would be introducing a factor. Or whether it's just simply a control to establish an expected range in which the new material should run without actually calibrating. Q. So what does A. So I don't know how it was used in this particular case. Q. Well, this the last page talks about "To reach consensus on the M-M-R® II House Standard which is required as part of the move to potency calibration." So what's potency calibration?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment from the June 3 BPC meeting." So I'm going to ask you what those acronyms are, BPC and BSEC? A. So BPC is the Biological Process Council. BSEC, I don't remember exactly anymore what that stood for. Q. I believe somebody said it was the Biologic Standards Evaluation Committee or something like that? A. Sounds very reasonable but what those acronyms are after many years, I don't remember it. Q. Were you on either of these entities? A. Yes, I was on BPC at times.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used that way. That would be introducing a factor. Or whether it's just simply a control to establish an expected range in which the new material should run without actually calibrating. Q. So what does A. So I don't know how it was used in this particular case. Q. Well, this the last page talks about "To reach consensus on the M-M-R® II House Standard which is required as part of the move to potency calibration." So what's potency calibration? A. Well, that would be what I just
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	about a couple other things in here. Let me know when you're ready to talk about it. A. Okay. Q. So let me start at the back. It talks about on the last page before the attendees, it says, "This is a BSEC assignment from the June 3 BPC meeting." So I'm going to ask you what those acronyms are, BPC and BSEC? A. So BPC is the Biological Process Council. BSEC, I don't remember exactly anymore what that stood for. Q. I believe somebody said it was the Biologic Standards Evaluation Committee or something like that? A. Sounds very reasonable but what those acronyms are after many years, I don't remember it. Q. Were you on either of these entities?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Uh-huh. Q. And then we make some correction between what the assay says it is and what we think it's supposed to be? A. The second one is a can be a use. And I don't know whether it is used that way. That would be introducing a factor. Or whether it's just simply a control to establish an expected range in which the new material should run without actually calibrating. Q. So what does A. So I don't know how it was used in this particular case. Q. Well, this the last page talks about "To reach consensus on the M-M-R® II House Standard which is required as part of the move to potency calibration." So what's potency calibration?

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Page 382 FLORIAN SCHODEL, MD - CONFIDENTIAL FLORIAN SCHODEL, MD - CONFIDENTIAL 2 would be the use of a house standard, not 2 your knowledge and bright procedure assign a 3 3 just to control but also to adjust the new house standard potency. 4 4 measured potency because of changes over time Q. But over time the number of 5 5 so that they're always linked to something actual virus particles in those vials is not 6 which is as much as that's possible for 6 going to go up. Right? 7 7 biologics kept constant. MR. SANGIAMO: Objection to --8 8 BY MR. MACORETTA: Q. Around this time there's a 9 9 discussion that the house standard for mumps O. In the house standard lot? 10 10 is going to change, right, that it's going to MR. SANGIAMO: Object to the go up by .1 log? 11 11 form. 12 A. Yeah, and I don't remember the 12 THE WITNESS: No, but the 13 details of that, but remember as we said 13 appearance of testing can suggest that 14 initially in the explanation for the house 14 it's going up which is a strange 15 standard, was house standards do change from 15 phenomenon because of assay 16 time to time because the material comes to an 16 variability. So just like over time 17 17 end. And then you have to have enough left the vaccine doesn't really change 18 to test it repeatedly to compare it to the because you make it the same way, you 19 19 dilute it the same way. But you new material and to assign a new potency. 20 And in that process there can be changes. 20 measure it repeatedly. And when you 21 Does that mean that the number 21 measure something repeatedly, you're 22 22 also prone to the variability of any of virus particles in -- and I think 23 Mr. Stannard who was here the other day said 23 assay over time. 24 it's lot nine that is the house standard lot 24 BY MR. MACORETTA: 25 25 for mumps. I don't know if you know that. Fair enough. On the first page Page 383 Page 385 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 A. No, I don't. I was not in 2 of this is an e-mail from you to Roberta McKee 3 3 manufacturing. This is way outside of my and a bunch of other people. Right? 4 responsibilities. 4 A. Uh-huh. 5 Q. So when we talk about changing 5 And then it looks like somebody the house standard potency, does that mean named Carl Burke sends your e-mail to Joye 6 7 that the number of virus particles in each 7 Bramble who then sends it to Keiko Simon. Do 8 vial in the house standard lot has change or you see that right above it? 9 9 the assay to measure them has changed? A. Yeah, that looks like it. 10 10 A. It could be either/or. If O. So who are these -- who is Carl 11 the -- so the goal of the effort is always to 11 Burke? 12 12 keep the number in the product constant to Carl Burke is an engineer who the best of our knowledge. Now, in the 13 was -- where was Carl at the time? I don't 14 standard, you have assay as in release, you 14 know whether he was manufacturing or in have to deal with assay variability so the 15 analytics, but he -- probably analytics, but impression that you may have more or less he was an engineer. And I think they're 17 material in there than really there is and 17 all -- what these three people have in common 18 you have to deal with the change in house 18 is that they're -- that they were probably in 19 standard which means moving from one 19 some way associated with MMR, the MMR project 20 20 manufactured lot that becomes the new house team that would take care of MMR issues, 21 standard, from the old to the new house 21 whereas I was primarily taking care at that 22 standard. And that may have a different time of ProQuad issues. But because they 23 assigned potency. In most cases it will 23 both contain MMR, these things had to be 24 because it's a different lot. So you have to 24 aligned and so that's how this somewhat do some careful analysis and to the best of convoluted e-mail traffic is understandable.

Page 386 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 Because one thing is done in MMR to be 2 collaborate in making product. And within 3 3 translated into ProQuad and vice versa. that division a person would be responsible. 4 Q. Because at least for mumps it 4 And she may still have been the project team 5 5 was the same product in both? leader for MMR at the time. She was at that 6 Yes, for measles, mumps and 6 at some point in time. Maybe that's where 7 rubella it is the same product in both. this originates, but I don't remember that. 8 Q. So who is Joye Bramble? What I don't remember the time frames. I'm very 9 was her job at this time? bad with the exact time frames. It's a long 10 A. Joye Bramble is also an 10 time. 11 engineer. She was for -- she was reporting 11 Q. That's fine. I'm trying to to me for quite a while. She was actually 12 understand the overall structure. You said at this time you were involved with ProQuad? 13 the person responsible for developing the CTT 13 14 SOP for -- so basically the manufacturing 14 A. Yes. 15 piece of filings. She was in my department 15 Q. What was your -- were you in at the time. And then she was also at some charge of ProQuad or --16 17 point in time in project management. By that 17 Well, in charge, I was -- I had point in time it may be -- it's possible that 18 different functions with ProQuad. I was --19 for quite a while I was the project team she was back in the biologics pilot plant. 20 She was an engineer who oversaw the biologics 20 co-leader of the Varicella-containing 21 pilot plant for quite a while. And she did 21 vaccines which encompassed, of course, 22 that after she -- after my department was 22 ProQuad but also Zostavax and Varivax. We 23 reassigned and some structural changes. So I 23 often invited MMR folks because we had this 24 don't remember at that point in time where 24 overlap of the common vaccine in ProQuad. 25 she was at, was she still working with me or 25 Then I was responsible for the clinical team Page 387 Page 389 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 was she already in the pilot plant. 2 that actually did the clinical development of 3 3 Q. So were you an MM -- you were in ProQuad. It was Barb Kuter primarily who was 4 MRL. Right? 4 reporting to me. And that was the extent of 5 A. I was in MRL. 5 my involvement. Was Joye Bramble an MRL or an 6 6 Q. Q. So let me try it this way: At 7 7 MMD person? this time, June 2003 ProQuad wasn't on the 8 Joye Bramble was always an MRL 8 market yet. Right? A. 9 9 A. person. 10 When you said she's the project 10 Q. It hadn't been approved? Q. 11 manager for a point in time --11 Α. No, it hadn't even been filed, 12 At some point in time she also 12 I think. 13 13 So who at Merck was in charge of worked as a head of a group in project 14 management. She was also a project manager. 14 overseeing the various aspects of getting the 15 Q. Okay. So what is --15 product, ProQuad approved? 16 A. But not at this time, not 16 Well, that would have been 17 likely. 17 essentially the regulatory liaison. 18 So what I'm trying to understand 18 Well, when we -- was the 19 is at this time was there some person who was 19 regulatory liaison's job to say to the 20 20 responsible or in charge of MMR overall? clinical people, I need these results from 21 Well, you know, Merck is a 21 you, or to say -- or to make sure the 22 highly collaborative company. I don't think 22 regulatory filings were responded to on time 23 that there is a single person that is 23 or to do whatever else was necessary to get it responsible for any one single product. 24 approved? There are three different divisions that 25 MR. SANGIAMO: Object to form.

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	THE WITNESS: In principle. I	2	not my responsibility.
3	mean, that's one way of describing.	3	BY MR. MACORETTA:
4	Of course the whole project team knew	4	Q. So when we say the project team,
5	what the expectations were, and so	5	the projects team, the project was to get
6	different jobs had to be done and	6	ProQuad on the market for the ProQuad project
7	different pieces were coming in and	7	team?
8	the regulatory person was ultimately	8	A. The project for the ProQuad
9	responsible for collating and	9	team was the development team, was to develop
10	interacting with the agency, with the	10	the product, get all the relevant clinical
11	agencies, but wasn't solely	11	studies run, get all the relevant testing
12	responsible for the content. There	12	run, develop a manufacturing process and
13	were also two regulatory people, one	13	ultimately compile all the data and the
14	who was on the clinical side and	14	information into a filing. Bring it on the
15	another one who was on the CMC side.	15	market was not the it was not the
16	BY MR. MACORETTA:	16	responsibility of the project development
17	Q. That's the manufacturing side?	17	team. That was the develop that is the
18	A. The manufacturing side.	18	responsibility of MMD just like manufacturing
19	Q. So if let me try it this way:	19	is the responsibility of the sorry, I have
20	If the president of Merck in June 2003 wanted	20	to shut down
21	to know what the status of ProQuad was and	21	Q. Sure. But the project team
22	where it was in getting approval, or be	22	would need help from manufacturing to get the
23	getting on the market, who would be the person	23	product approved. Right?
24	that would have overall responsibility or	24	A. Oh, yes, of course.
25	would ask or would have overall responsibility	25	Q. So earlier there was a lot of
	Page 391		Page 393
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	for that?	2	discussion about some of the exhibits we
3	MR. SANGIAMO: Object to the	3	looked at. Should we say what do we say in
4	form. Calls for speculation.	4	response to the FDA when they ask the question
5	THE WITNESS: I don't really	5	should we include this information or not
6	know. I mean, as a project team	6	include that information? Who makes the
7	co-leader, I would probably be	7	ultimate decision about we're saying this,
8	involved in that. I mean, it depends	8	we're not saying this? Is that the person
9	on where the issues are.	9	signing the letter?
10	BY MR. MACORETTA:	10	MR. SANGIAMO: Object to the
11	Q. So who coordinated the issues	11	form.
12	between manufacturing and regulatory and	12	THE WITNESS: This is not a
13	MRL regulatory?	13	question I can really answer. It
14	A. Well	14	depends on what the content is. I
15	MR. SANGIAMO: I'm sorry, John,	15	mean, obviously the person who signs
16	are you saying between manufacturing	16	the letter is responsible for what's
17	regulatory and MRL regulatory?	17	written in the letter, but every
18	MR. MACORETTA: I'll start with	18	department within Merck would be
19	that, yeah.	19	responsible for the veracity of its
20	MR. SANGIAMO: Go ahead.	20	contribution to these filings. So,
21	THE WITNESS: That, I don't	21	you know, in the CMC section you will
22	really know. I mean, they came up in	22	have statements that come from
-1	the project team and ultimately each	23	manufacturing, in the clinical section
23			
23 24	function was responsible to get their	24	you would have statements that come
	function was responsible to get their issues sorted out. So regulatory was	24 25	you would have statements that come from clinical. And ultimately

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	clinical would be responsible for the	2	change the compendial spec. I don't know.
3	veracity of those statements. Then	3	Maybe I'm talking about something else. It's
4	there is a layer of quality assurance	4	out of context. I don't remember the details
5	and quality control where source	5	of these discussions. Remember this was
6	documents are checked against the	6	manufacturing, I was just one voice sometimes
7	final document and the people who do	7	as an outsider and sometimes as somebody who
8	that are responsible that everything	8	did not completely understand what they were
9	is actually truthfully transcribed and	9	talking about.
10	transmitted. So they're responsible	10	Q. So I guess I should ask then why
11	for that particular piece. If I give	11	do you get to have an opinion on this, why
12	them wrong data, they're responsible	12	were you giving this opinion?
13	for having them wrong in the filing,	13	A. Well, because I was in between
14	but I'm responsible if the data are	14	the different projects and there were not so
15	wrong.	15	many people that were. And also because I
16	BY MR. MACORETTA:	16	had a background in the assays. But, you
17	Q. So the way you're describing it,	17	know, there are pieces to that which I just
18	then, there isn't one person who has overall	18	simply don't know.
19	responsibility?	19	Q. So who would who is the
20	A. Below the president of Merck or	20	expert on the house standard assignment?
21	MRL for that matter, not really, no. I mean,	21	A. At the time it would have been
22	the regulatory person takes a higher degree	22	Roberta. I mean, Roberta was the regulatory
23	of responsibility than anybody else in that	23	person in MMD.
24	chain because they're the direct counterparts	24	Q. And her equivalent at this time
25	to the agencies. But ultimately if it's a	25	would have been Alison Fisher for MRL. Right?
1	Page 395 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 397 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	matter of data, they would have to concur,	2	A. No. No. Her equivalent would
3	there would have to be concurrence.	3	have been Keith Chirgwin probably.
4	Q. That's right. Okay. All right.	4	Q. In the next sentence you talk
5	Now I want to talk about your e-mail here that	5	about retaining the measles overfill. And
6	we looked at. You're talking about the	6	then you say at the end of that line, "you
7	points, I think, on Roberta McKee's e-mail	7	could as well use the 0.1 you gain on mumps
8	right below yours which goes on to the	8	now to claim a 24 months shelf-life."
9	following page. The end of the first	9	Do you see that?
10	paragraph, you have a sentence that says, "The	10	A. Yes.
		١	
11	responses should also be revised to explain	11	Q. What does that refer to?
12	the changed interpretation of the compendial	12	A. I don't even remember whether
13	spec that follows from house standard	13	this refers to ProQuad or whether it refers
14	reassignment and why we think it is o.k. to do	14	to MMR. So I truthfully cannot tell you.
15	that." What does that mean?	15	But if so I have to speculate. I mean, if
16	A. It sounds very good, but I	16	you have a .1 gain
17	don't really remember exactly what that	17	MR. SANGIAMO: Wait.
18	means.	18	BY MR. MACORETTA:
19	Q. Well, okay.	19	Q. Go ahead, you can answer.
20	A. I mean a compendial spec would	20	MR. SANGIAMO: I'm going to
21	be something that is written into a	21	object. Jeff told him he's not
22	compendium such as, for example, the European	22	supposed to speculate.
23	pharmacopeia with 3.7 for mumps. I don't	23	BY MR. MACORETTA:
24	really remember why I thought at the time	24	Q. You can speculate. Go ahead.
25	that a house standard reassignment might	25	MR. SANGIAMO: No, no. If this

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1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	is speculation	2	BY MR. MACORETTA:
3	MR. MACORETTA: Come on, you	3	Q. Do you ever remember any
4	can't stop the guy in the middle of	4	discussion about having a shelf life less than
5	his answer because you don't like it.	5	24 months for MMR?
6	MR. SANGIAMO: I don't know what	6	A. With the exception of what we
7	his answer is.	7	had discussed before, no.
8	MR. MACORETTA: Well, we're	8	Q. What was it we had discussed
9	going to find out.	9	before?
10	MR. SANGIAMO: Well, no. He	10	A. The stability data e-mails that
11	just said he's going to be	11	were just moved around.
12	speculating. Jeff, your colleague,	12	Q. When you say, "the 0.1 you
13	told him at the beginning don't	13	gain on mumps now," does that mean that
14	speculate.	14	because house standard potency has gone up by
15	MR. MACORETTA: Unless he asked	15	.1 log?
16	him to.	16	A. I don't know. I would it
17	BY MR. MACORETTA:	17	seemed to me, but, again, I'm extrapolating
18	Q. If you feel you can speculate to	18	from my own sentences, that there is a gain
19	answer that question, please go ahead,	19	in .1 through end expiry which may well mean
20	Dr. Schodel.	20	that the .1 loss before was due to a
21	MR. SANGIAMO: Do not speculate	21	different house standard calibration or it
22	in your testimony, Dr. Schodel.	22	was due to an error in house standard
23	THE WITNESS: Okay.	23	calibration. So by doing it more properly,
24	BY MR. MACORETTA:	24	you actually gained one log. So you had less
25	Q. Let me try we'll do it this	25	loss.
	Page 399		Page 401
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	way: It says, "to claim a 24 months	2	Q. So the house standard was
3	shelf-life." Wasn't it always the case that	3	recalibrated in a way that added .1 log?
4	every mumps vaccine Merck sold in the United	4	A. I don't know that. It could
5	States had a 24-month shelf life?	5	have, as far as the house standard was
6	A. As I just said, I don't	6	concerned, gone down but the net result would
7	remember whether this applied to MMR or	7	be that you in the modeling you gain .1 in
8	ProQuad. ProQuad hadn't been filed anywhere	8	potency.
9	so it didn't have any shelf life.	9	Q. If the house standard goes down,
10	Q. Let's look at the back. Do you	10	how does the potency go up?
11	know, what the the next page, the third	11	A. Because you calibrate it to the
12	bullet point in Ms. McKee's e-mail. "Quickly	12	house standard.
13	prepare and submit the mumps supplement to	13	Q. But if it's calibrated before
14	reduce expiry to 18 months" Do you know	14	and after you change the house standard and
15	what she's talking about there?	15	the house standard goes down, how could the
16	A. No, I don't remember that	16	potency go up?
17	anymore.	17	A. Well, because it's relative to
18	Q. Well, is it you're in charge	18	the house standard. So if your assay
19	of ProQuad. Was there a discussion that there	19	point it goes in the other direction
20	was going to be an 18 months as opposed to a	20	essentially. I mean, you calibrate it to the
21	24-month shelf life?	21	house standard. So if your if you do a
$\alpha \alpha$	MR. SANGIAMO: Object to the	22	calibration, you use the same measure over
22		122	and aver again and you calibrate it in the
23	form.	23	and over again and you calibrate it in the
	form. THE WITNESS: I don't remember that.	23 24 25	direction that the standard is going. Q. So if the standard yesterday was

101 (Pages 398 - 401)

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Page 402 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 2 3.7 and it's 3.6 today, that means that a lot 2 Correct. 3 3 that we thought was 3.7 yesterday, we now Q. The same end expiry potency. 4 4 think is 3.6. Right? Right? 5 5 A. Not necessarily. You measure Correct. A. the same amount twice. Now it appears to be 6 Because it's the same product, lower. So you put in more to get to the same right, the mumps bulk is made -- it's the same 8 mumps bulk for MMR as it is for ProQuad. number. 8 9 Q. You put in more product to get 9 Right? 10 10 to the same number? Correct. Α. 11 A. Well, your release number goes 11 Q. Okay. So now you're asking here up. The same number appears to be higher. if you change -- when you say change the mumps 13 It's a bit counterintuitive, but it -specs, you're talking about changing something 13 14 Q. It is. And that's what if the 14 because the house standard changes. Right? 15 release spec for this -- let's assume --15 I'm not sure. This could be 16 A. That's at least -- I mean, I'm 16 referring to house standard or it could be 17 not the specialist on house standard for MMD. 17 referring to the changes that we discussed I was never in manufacturing. So that's a 18 previously with the introduction of a speculation that I would make. But I don't 19 different view of CBER on what an end expiry 20 know how it was exactly used in calibration, 20 means and, therefore, as a result and 21 so... 21 relative overfill that was done since '99 22 22 from what I saw in these documents. And I Q. I'm just asking you how you used 23 it here? 23 think that some of these changes in data for 24 Well, I just use -- I didn't --24 MMR had not made their way into the ProQuad Α. 25 that didn't -- it didn't -- for me, in this 25 manufacturing documentation yet. And, Page 403 Page 405 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 2 particular statement, it was simply stating 2 therefore, I was just asking the question if 3 that if you have a better measure now, we have agreement that they're the same, how 4 whatever that is, not opining on the house 4 are we going to introduce the changes that 5 standard, that let's you show with credible 5 which you're currently working on at MMR for the agency, how are we going to introduce 6 data that you have .1 log more than you 6 7 thought before in the product through end 7 them into ProQuad to make sure that they 8 expiry, then that also means that actually 8 remain the same. 9 9 the product will have a longer shelf life. O. What's the ultimate answer to 10 Then the next paragraph you say, 10 that question? 11 "I'm still not sure how the ProQuad filing 11 I don't know. Well, you were -- when did you 12 will be handled as you go forward and change 12 the mumps specs without changing the mumps 13 stop working on ProQuad? 14 14 maximum release spec in the ProQuad file which A. When did I stop working on 15 is supposed to reference the MMR license...." 15 ProQuad? I mean, I think I probably completely stopped working on ProQuad 2008 or 16 Do you see that? 17 2009 or so. This was not the same level of A. Uh-huh. 17 18 The idea is that ProQuad is 18 attention anymore. 19 going to reference the MMR license for the 19 Q. Let me show you what we're going 20 specifications of the M, M and R parts of 20 to mark as Schodel-22. 21 ProQuad. Right? 21 MR. MACORETTA: How much time do 22 A. Yes. 22 we have left? 23 23 VIDEOGRAPHER: About 21 minutes. So it's going to be the same 24 release spec for mumps in MMR as it is for 24 MR. MACORETTA: Thank you. ProQuad. Right? 25

102 (Pages 402 - 405)

212-279-9424

1	Page 406	1	Page 408 FLORIAN SCHODEL, MD - CONFIDENTIAL
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	•
3	(Exhibit Schodel-22, 2/25/03		HS assigned value differs from historic
	E-mail, Bates MRK-KRA00566606, was	3	performance."
4	marked for identification.)	4 5	Do you see that?
5			A. Yeah, I see that.
6	BY MR. MACORETTA:	6	Q. What is MuV?
7	Q. All right. Let me know when	7	A. Mumps virus.
8	you've had a chance to look at this.	8	Q. What does it mean that its
9	A. Yeah, I've looked at that. Not	9	assigned value differs from historic
10	completely yet.	10	performance?
11	Q. The top e-mail is from you to	11	A. That it's being given a value
12	Tim Schofield. Do you see that?	12	in when as we discussed before, in that
13	A. Uh-huh.	13	crossover period when it was assigned a
14	Q. And it says, "soyou can see	14	value, that is different from historic
15	the presentation in addition to my diatribe."	15	performance of that same house standard.
16	What diatribe are you talking about?	16	Q. So when you say assigned value,
17	A. I have no idea. Tim and I	17	is that house standard?
18	talked about stuff. I may have told him	18	MR. SANGIAMO: Object to the
19	something about anything.	19	form.
20	Q. Okay. And this says the	20	THE WITNESS: Yeah.
21	e-mail below says the subject matter is "MMR	21	BY MR. MACORETTA:
22	House Standard assignment discussion," and it	22	Q. So recognized mumps, MuV HS
23	says, "Attached please find slides that were	23	assigned value, that's the house standard
24	to be shown for tomorrow's Net Meeting"	24	value?
25	Do you see that?	25	A. That's the house
	Page 407		Page 409
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1	FLORIAN SCHODEL, MD - CONFIDENTIAL
2	A. Uh-huh.	2	MR. SANGIAMO: Object to the
3	Q. What's a net meeting?	3	form.
4	A. Probably a meeting over the	4	THE WITNESS: That's the house
5	Internet.	5	standard value that was assigned at a
6	Q. Okay.	6	given period in time when that house
7	A. Or the intranet.	7	standard was introduced.
8	Q. Okay. Were you involved at all	8	BY MR. MACORETTA:
9	in creating any of these slides?	9	Q. Then it says, "differs from
10	A. Nope. This is manufacturing	10	historic performance." What does that mean,
11	stuff. This is not my direct responsibility	11	when you measure the potency of a lot what
12	at all.	12	does that mean?
13	Q. I got it. I understand that,	13	MR. SANGIAMO: Object to the
14	but you looked at it and passed it on and had	14	form.
15	a diatribe about it apparently.	15	THE WITNESS: Well, it means
16	A. Or I had a diatribe unrelated	16	look onto 616 and you can see what
17	to that.	17	that means. So you'll see here
18	Q. Maybe.	18	historic performance of house
	A. Much more likely actually.	19	standards, and you see that it
19		20	measures as 4.2, 4.3, 4.1, up to 4
19 20	Q. So well, let me start at the		•
	Q. So well, let me start at the first page of the slide, the first one. It	21	4.4, down to 4.2. This is different
20	first page of the slide, the first one. It	21 22	
20 21	first page of the slide, the first one. It says there's a question from CBER, please		data points from '95 to '02. And then
20 21 22 23	first page of the slide, the first one. It says there's a question from CBER, please give data concerning house standard potency	22 23	data points from '95 to '02. And then it was assigned a value. And the
20 21 22	first page of the slide, the first one. It says there's a question from CBER, please	22	data points from '95 to '02. And then

1	Page 410	1	Page 412
1 2	FLORIAN SCHODEL, MD - CONFIDENTIAL assigned value which is not too	2	FLORIAN SCHODEL, MD - CONFIDENTIAL yeah.
3	surprising in these things because	3	Q. Would you consider that a lot of
4	assays do change, and they change	4	variability for a house standard test, a one
5	unfortunately in sometimes long	5	log?
6	periodicities. You will sometimes	6	A. The question is here more
7	have an assay that for unknown reasons	7	MR. SANGIAMO: The object to the
8	runs a little different in the summer	8	form.
9	period or in a given year than in	9	THE WITNESS: The question is
10	another year. Now, if you have a	10	here well, first of all, it's not
11	long-time assigned potency for a house	11	really my field to opine on. I the
12	standard, that has long-time	12	question here is more does it behave
13	consequences on manufacturing.	13	differently in different periods of
14	BY MR. MACORETTA:	14	time.
15	Q. And it looks like I'm going	15	BY MR. MACORETTA:
16	to go back to page 615, the previous page	16	Q. Well, this is showing that it
17	under "How are potencies assigned," it seems	17	behaves, the period of time for these tests is
18	to say for mumps that the house standard	18	over what, seven years, '95 to '02?
19	assigned was 4.2. Right?	19	A. Yeah.
20	A. Yeah, that's what it says here.	20	Q. If we look at 615, the top
21	Q. But there's a when it says	21	chart, it says, "What are the assigned
22	limits plus or minus .3, that's the	22	potencies," and then for mumps it has
23	variability. Right?	23	"Assigned Potency* 4.2 (4.9)."
24	A. Those are controlled limits,	24	Now, is that the difference
25	not necessarily variability.	25	between a .1 mL and a per dose?
1	Page 411 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 413 FLORIAN SCHODEL, MD - CONFIDENTIAL
2	Q. Well, if we look back on 416,	2	A. Yes.
3	this would show us the variability. Right?	$\frac{2}{3}$	Q. And if I'm reading Table 2 on
4	We see some tasks as high as 4.8 and some down	4	page 615 right, they did 32 runs to come up
5	to 3.8. Right?	5	with the house standard. Is that what that
6	A. Now you're on 16?	6	means?
7	Q. Yes.	7	A. You know, that's what it could
8	A. On the lower half. Yeah, I	8	mean, but I don't know that. These are
9	mean, I see it going from 4.1 up to I	9	obviously not data that I have generated or
10	mean, I was looking at the average line but	10	am that familiar with. So, for example, I
11	if you look at the individual data points,	11	can't tell you how many multiples are in
12	yes, you can see anything from 3.9 up to 4.8		
13	or so. Or 3 you were right, 3.8 even.	12	there. So anyway. Q. But if you were in charge of
13		14	
15		15	since you were in charge of ProQuad at this time, you had responsibility for ProQuad, how
16	A. From 3.8 to 4.8, that's almost	16	the house standard was calculated and applied
17	a log variability.	17	was an issue for you, wasn't it?
18	Q. That's almost a what?	18	MR. SANGIAMO: Object to the
18	A. That's almost a what?	19	form.
20	Q. And a log is ten times. Right?	20	THE WITNESS: In principle, no,
21	A. Yes.	21	as long as it remained stable. If it
22	Q. So when we so variability	21 22	led to a change in the product or a
23	so when we change the log .1, that means	23	change in how the product was made,
24	that's 25 percent more or less product. Right?	24	then potentially yes.
25	A. You could see it that way,	25	BY MR. MACORETTA:
23	11. I ou could see it that way,	23	DI MIK. MIACOKETTA.

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2 Q. But the application and 3 calculation of the house standard was something 4 that CBER had to know about. Right? 5 A. Yes, of course. 6 Q. If you could go to the next 7 to the let's go to the last page, the 8 "Summary" page. The second bullet point says, 2 more virus particles 3 you don't change the 4 house standard recognisit. 5 in it? 6 A. No. No, y 7 different number. 8 Q. So it's the	Page 416 ODEL, MD - CONFIDENTIAL in the same product if e release potencies but the genizes there's more product you just call it a same kactly the same thing.
2 Q. But the application and 3 calculation of the house standard was something 4 that CBER had to know about. Right? 5 A. Yes, of course. 6 Q. If you could go to the next 7 to the let's go to the last page, the 8 "Summary" page. The second bullet point says, 2 more virus particles 3 you don't change the 4 house standard recognisit. 5 in it? 6 A. No. No, y 7 different number. 8 Q. So it's the	in the same product if e release potencies but the gnizes there's more product you just call it a same
3 calculation of the house standard was something 4 that CBER had to know about. Right? 5 A. Yes, of course. 6 Q. If you could go to the next 7 to the let's go to the last page, the 8 "Summary" page. The second bullet point says, 3 you don't change the 4 house standard recognized in it? 6 A. No. No, y 7 different number. 8 Q. So it's the	e release potencies but the gnizes there's more product you just call it a
4 that CBER had to know about. Right? 5 A. Yes, of course. 6 Q. If you could go to the next 7 to the let's go to the last page, the 8 "Summary" page. The second bullet point says, 8 Q. So it's the	ognizes there's more product you just call it a same
5 A. Yes, of course. 6 Q. If you could go to the next 7 to the let's go to the last page, the 8 "Summary" page. The second bullet point says, 5 in it? 6 A. No. No, y 7 different number. 8 Q. So it's the	you just call it a
6 Q. If you could go to the next 6 A. No. No, y 7 to the let's go to the last page, the 7 different number. 8 "Summary" page. The second bullet point says, 8 Q. So it's the	same
7 to the let's go to the last page, the 8 "Summary" page. The second bullet point says, Q. So it's the	same
8 "Summary" page. The second bullet point says, 8 Q. So it's the	
2there is general agreementwith the	ractly the same timig.
10 exception of mumps." 10 Q. It's the num	mher
	facturing process
* *	emains exactly the same
	what you've done before.
14 A. This is the very last one, I 14 The difficulty here i	
15 see. 15 related to the accura	
	or not it meets release
	don't put in more or
	t a different number.
	vas 5 yesterday is 5.1
20 MR. MACORETTA: I just asked him 20 today?	vas s yesteraay is s.r
	f more data what you
	erday you now realize is in
23 like he wrote the document. 23 reality 5.1.	1200, 100 110 11 1201120 10 111
	release spec is 5.0,
25 BY MR. MACORETTA: 25 isn't if I measured	
Page 415	Page 417
1 FLORIAN SCHODEL, MD - CONFIDENTIAL 1 FLORIAN SCHO	ODEL, MD - CONFIDENTIAL
2 Q. You can answer the question. 2 yesterday, that's 5.0	today. Right?
3 A. I mean, the only thing I can 3 A. Well, I'm	not sure I follow.
4 see here and you can see that for yourself is 4 Q. You know	w what, strike that. Let
5 on 618, if you look at all the data, you have 5 me I'll withdraw t	that question.
6 a total number of 2,900 runs and you have an 6 Let's look a	at the last bullet
	se standard assigned potency
8 standard has behaved. Then you have the 8 has important impact	ct on - MMR II near-term
9 qualification data that were done over a 9 manufacturability.	What does that mean?
	u the truth, I don't
11 of runs and that resulted in an assignment of 11 exactly know, but	
	said that nothing
	hange in the number. If
14 available very large quantity of data that 14 nothing changes, wh	hy would it impact
15 suggested that the house standard may have 15 manufacturability?	
	ou I don't know. I
17 increased. 17 mean, you may I i	*
	ld be something that you
	v about, right, since you're
20 Q. But the release potency does 20 in charge of ProQua	
21 not the minimum and maximum release 21 A. Yeah, absorption	•
	GIAMO: Object to the
23 5.0 or 5.5. Right? 23 form.	
24 A. They don't change. 24 BY MR. MACORE	
25 Q. Well, but aren't you putting 25 Q. Okay. An	nd it also says, "MMR®II

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	Page 418		Page 420
1	FLORIAN SCHODEL, MD - CONFIDENTIAL	1 2	CERTIFICATE
2	shelf-life, recon/store time," and "calibrated	3	OBKIII ICIII E
3	stability." Do you have an understanding of	4	I de heneber en d'Érabet I en la Nictoria
4	why changing the house standard potency would	5	I do hereby certify that I am a Notary Public in good standing, that the aforesaid
5	impact them?	-	testimony was taken before me, pursuant to
6	A. Yeah. That we just	6	notice, at the time and place indicated; that
7	discussed that, because the numbers that you	7	said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but
8	assign to the potencies at given points in		the truth; that the testimony of said
9	time change with a calibration to the house	8	deponent was correctly recorded in machine shorthand by me and thereafter transcribed
10	standard. The house standard is different,	9	under my supervision with computer-aided
11	they go up or down.	10	transcription; that the deposition is a true
12	Q. So does that mean that if my end	10	and correct record of the testimony given by the witness; and that I am neither of counsel
13	expiry potency was 4.2 yesterday, it's 4.3	11	nor kin to any party in said action, nor
14	today when we increase the house standard?	12	interested in the outcome thereof.
15	A. No, it's still 4.3.	12	WITNESS my hand and official seal this
16	Q. No, it's if 4.2 yesterday. 4.0.	13	5th day of January, 2017.
17	Let's say if I	14 15	
18	A. You're not changing the end	16	· • · · · · · · · · · · · · · · · · · ·
19	expiry potency, we're just changing what		Emula NOSSI NIOS, RPR, CSR
20	number we give the measurement.	17 18	Notary Public
21	Q. So the end expiry potency is the	19	
22	same but what measured 4.2 yesterday measures	20	
23	at 4.3 today?	21 22	
24	A. It may still measure at 4.3,	23	
25	but it gets calibrated to a differently	24 25	
		23	D 421
1	Page 419 FLORIAN SCHODEL, MD - CONFIDENTIAL	1	Page 421
2	assigned house standard and, therefore, it	2	INSTRUCTIONS TO WITNESS
3	gets called a different number with more	3	Please read your deposition over
4	data.	4	carefully and make any necessary corrections.
5	Q. Okay.	5	You should state the reason in the
6	A. I think we're coming to the	6	appropriate space on the errata sheet for any
7	end	7	corrections that are made.
8	MR. MACORETTA: That's fine. We	8	After doing so, please sign the errata
9	are. And I'm not going to start and	9	sheet and date it.
10	do something else. I don't have any	10	You are signing same subject to the
11	more questions today, Dr. Schodel.	11	changes you have noted on the errata sheet,
12	THE WITNESS: Thank you.	12	which will be attached to your deposition.
13	MR. MACORETTA: Thank you.	13	It is imperative that you return the
14	MR. SANGIAMO: No questions	14	original errata sheet to the deposing
15	here.	15	attorney within thirty (30) days of receipt
16	VIDEOGRAPHER: The time now is	16	of the deposition transcript by you. If you
17		17	fail to do so, the deposition transcript may
/	5:57. This concludes the deposition.	18	be deemed to be accurate and may be used in
	Hand of discourse of six		· · · · · · · · · · · · · · · · · · ·
18	End of disc six of six.	10	court
18 19		19	court.
18 19 20	End of disc six of six (Witness excused.)	20	court.
18 19 20 21	(Witness excused.)	20 21	court.
18 19 20 21 22	(Witness excused.) (Deposition concluded at	20 21 22	court.
18 19 20 21 22 23	(Witness excused.)	20 21 22 23	court.
18 19 20 21 22	(Witness excused.) (Deposition concluded at	20 21 22	court.

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1	ACKNOWLEDGMENT OF DEPONENT
2	
3	I have read the foregoing transcript of
4	my deposition and except for any corrections or
5	changes noted on the errata sheet, I hereby
6	subscribe to the transcript as an accurate record
7	of the statements made by me.
8	,
9	
-	FLORIAN COHOREL MR
10	FLORIAN SCHODEL, MD
11	
12	SUBSCRIBED AND SWORN before and to me
13	this day of
14	
15	
16	
	NOTA DV DUDI IC
17	NOTARY PUBLIC
18	
19	
20	My Commission expires:
21	
22	
23	
24	
25	
23	
. —	
	Page 423
1	Page 423 ERRATA SHEET
1 2	-
2	ERRATA SHEET IN RE: USA ex rel. vs. MERCK
2 3	ERRATA SHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016
2 3 4	ERRATA SHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5	ERRATA SHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4	ERRATA SHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5	ERRATA SHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	ERRATASHEET IN RE: USA ex rel. vs. MERCK DATE: 12/22/2016 PAGE LINE CORRECTION AND REASON

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10/25/2019 Declaration of G. Reilly EXHIBIT 117

Case: 23-2553 Document: 42 Page: 300 Date Filed: 11/01/2023

To: 'Y. Kino'[kino-yo@kaketsuken.or.jp]; Morsy, Manal A.[manal_morsy@merck.com]

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From: Morsy, Manal A.
Sent: Fri 9/13/2002 9:59:17 AM
Importance: Normal

Subject: RE: Kaketsuken Questions regarding mumps end expiry potency

No trouble at all – in terms of the rHA history – I will have to get back to you on this one – for correction rHA is not a virus stabilizer – but rather like FBS, rHA is required for maintaining the mono-layer cell culture integrity.

in terms of the clinical trial – the study was designed to address a specific request made to us by the EU since rHA is a recombinant excipient to show that anti –HA antibodies are not generated.

in terms of why PRN and ELISA in the mumps end expiry and only ELISA in the MMRII/rHA – and this CBER's explanation because we asked the same question regarding the need for a PRN – CBER considers a neutralization assay essential for establishing efficacy were you need to define effectiveness for a product – the mumps end expiry trial is comparing release to expiry within the same product – however when you are comparing equivalence between two products – CBER considers ELISA sufficient.

Mana

----Original Message-----

From: Y. Kino [mailto:kino-yo@kaketsuken.or.jp] Sent: Friday, September 13, 2002 4:21 AM

To: 'Morsy, Manal A.'

Cc: 'Chirgwin, Keith D.'; 'Bramble, Joye L.'; 'Matthews, Holly'; 'Heyse, Joseph F.'; 'Schodel, Florian'; 'Simon, Keiko'; 'Musey, Luwy'; 'Schofield, Timothy L'; 'Antonello, Joseph M'; 'Galinski, Mark S.'; 'Abraham, Katalin G.'; 'Shaw, Alan'; 'Shiosaki'; 'Funatsu'; 'Kanehara'; 'Timothy A. Corrigan'; 'Tochihara'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '????'; '??????'; '????'; '?????'; '????'; '?????'; '?????'; '?????'; '?????'; '??????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '?????'; '????

Subject: RE: Kaketsuken Questions regarding mumps end expiry potency

Manal.

Thank you very much for your clarifications.

I understand that rHA is in a completely different category from FCS, because rHA is contained in the virus growth media and the stabilizer for the virus harvests, but FCS is not. However, I also understand that it is not appropriate to describe the M-M-R(TM)II with rHA as a "new formulation".

Because rHA is not a final excipient, a clinical study and even a partial change application would not be required upon replacement, as you previously expected. However, as a matter of fact, you are conducting a clinical study and are going to make a partial change application; therefore, the change of HSA from plasma-derived to recombinant is not supposed to be a mere replacement of one of the materials.

Because we also have to make a partial change application regarding rHA in Japan, I would appreciate it if you could summarize the history

Case: 23-2553 Document: 42 Page: 301 Date Filed: 11/01/2023

of rHA replacement, especially the reason for the clinical trial and partial application. I am not in a hurry for this.

Finally, I do not understand the end of the last paragraph of your e-mail of September 12th. "....in both the primary and secondary endpoint...." I understand the protocol of the mumps dose justification study in that there are two endpoints, PRN and ELISA; however, in the clinical study with MMRII/rHA, you employ only ELISA. In that sense, the two studies are not the same. My question is, why only ELISA was accepted for MMRII/rHA whereas both PRN and ELISA were required for the mumps end expiry trial. I really need your explanation on this point. I am very sorry to trouble you, but I would like to clarify the situation before holding our internal meeting.

I would appreciate your response.

Regards,

Yoichiro

----Original Message-----

From: Morsy, Manal A. [mailto:manal_morsy@merck.com]

Sent: Thursday, September 12, 2002 11:16 PM

To: 'Y. Kino'; Morsy, Manal A.

Cc: Chirgwin, Keith D.; Bramble, Joye L.; Matthews, Holly; Heyse, Joseph F.; Schodel, Florian; Simon, Keiko; Musey, Luwy; Schofield, Timothy L; Antonello, Joseph M; Galinski, Mark S.; Abraham, Katalin G.; Shaw, Alan; Shiosaki; Funatsu; Kanehara; Timothy A.

Corrigan; Tochihara; ????; ????; ????; ?? ??

Subject: RE: Kaketsuken Questions regarding mumps end expiry potency

Dear Yoichiro,

In terms of the 20,000 CCID50 and rationale - I will have to defer answering until we review the papers you are referring to - also please keep in mind that we are still evaluating the shelf life and what we (Merck) can support - so please think of that as one of the potential options that may or may not be viable once we complete our shelf life evaluation.

Also please note that the rHA replacement in MMRII is NOT a "new formulation" rather this is a bulk culture media excipient like fetal bovine serum which is what it is actually replacing in the bulk process when the virus infection is initiated, not a "formulation" excipient in the final container for stability. We have to make sure that there is clarity on this issue other wise this can lead to great confusion especially in agency communications.

In terms of your question – if we were going to conduct another end expiry trial for the MMRII/rHA – the answer as previously stated is NO – MMRII/rHA is the same as the current MMRII except for the excipient replacement – therefore what ever the end expiry assignment becomes for the the current MMRII is what would translate to minimum potency for MMRII/rHA – ie what ever the results are for the ongoing mumps end expiry trial are will affect current label and will be transferred to revised label for MMRII/rHA.

The criteria in the MMRII/rHA study are the same except the assays used are exclusively ELISA – ie the PRN (plaque reduction neutralization) assay is not used to evaluate immune response for mumps in the MMRII/rHA study. Recall that the primary end point in the mumps end expiry is based on measuring immune response using the PRN assay while the secondary end point in the that study is based on using the mumps ELISA assay – in both the primary and secondary end point scenarios the criteria of success are the same and are the same as those set forth for the

MMRII/rHA.

Hope this helps.

Manal

Manal Morsy, MD, PhD, MBA Director Worldwide Regulatory Affairs Vaccines/Biologics morsy@merck.com

tel: 484-344-3785 fax: 484-344-2962

-----Original Message-----

From: Y. Kino [mailto:kino-yo@kaketsuken.or.jp] **Sent:** Thursday, September 12, 2002 4:59 AM

To: 'Morsy, Manal A.'

Cc: 'Chirgwin, Keith D.'; 'Bramble, Joye L.'; 'Matthews, Holly'; 'Heyse, Joseph F.'; 'Schodel, Florian'; 'Simon, Keiko'; 'Musey, Luwy'; 'Schofield, Timothy L'; 'Antonello, Joseph M';

'Galinski, Mark S.'; 'Abraham, Katalin G.'; 'Shaw, Alan'; Shiosaki; Funatsu; Kanehara; Timothy

A. Corrigan; Tochihara; ????; ????; ????; ?? ??

Subject: RE: Kaketsuken Questions regarding mumps end expiry potency

Dear Manal,

Thank you very much for your quick response. The following are several additional questions I have for you:

Regarding Question #3, originally, we were going to use the results of your ongoing trial as a rationale for the end expiry potency of mumps; however, if we submit the JNDA with 20,000 CCID50, we will have to use another rationale. In such a situation, we will have to use the minimum immunizing titer reported in papers (J.A.M.A, 203:9–13, 1968 and The New England Journal of Medicine, 278(5), 227–232,1968). Is this OK for you, or could you suggest an alternative rationale?

For me, your reply to Question #4 is unclear. Are you going to conduct an additional clinical trial to determine the end expiry potency of the new formulation? Your explanation would be appreciated.

Finally, are the criteria for the endpoint of the ongoing clinical trial using M-M-R(TM)II with rHA the same as those of the mumps dose justification trial?

I am looking forward to your complete response. Thank you.

Regards,

Yoichiro

----Original Message----

From: Morsy, Manal A. [mailto:manal_morsy@merck.com]

Sent: Thursday, September 12, 2002 2:49 AM

To: 'Y. Kino'

Cc: Chirgwin, Keith D.; Bramble, Joye L.; Matthews, Holly; Heyse, Joseph F.; Schodel, Florian; Simon, Keiko; Musey, Luwy; Schofield, Timothy L; Antonello, Joseph M; Galinski,

Mark S.; Abraham, Katalin G.; Shaw, Alan

Subject: RE: Kaketsuken Questions regarding mumps end expiry potency

Dear Yoichiro,

Please note comments to questions – I will get back to you with complete responses as soon as possible following internal discussions.

Regards

Manal

Manal Morsy, MD, PhD, MBA

Director Worldwide Regulatory Affairs Vaccines/Biologics

morsy@merck.com tel: 484-344-3785 fax: 484-344-2962

----Original Message----

From: Y. Kino [mailto:kino-yo@kaketsuken.or.jp] **Sent:** Wednesday, September 11, 2002 3:06 AM

To: Morsy Manal

Cc: Shiosaki; Kanehara; Funatsu; Tochihara; ????; ????; ?????

Subject: Questions regarding mumps end expiry potency

Dear Manal,

As of the teleconference, we have been internally discussing possible options regarding the mumps end expiry potency. To make our discussions more concrete, I would like to confirm the following points:

- 1. Would it be possible to forward us the interim summary data of the study in which 265 samples were excluded? We are interested in the data for the subjects that were already fixed.

 [Morsy, Manal A.] we will discuss internally and determine feasibility and timing
- 2. If 20,000CCID50 is adopted as the end expiry potency, do you recommend 1 year as the shelf life?
 [Morsy, Manal A.] we are currently evaluating the shelf life recommendation
- 3. Is there any other basis regarding 20,000CCID50 as the end expiry potency other than the minimum required virus titer?

 [Morsy, Manal A.] please clarify I am not sure I understand your question.

 As you recall we had previously forwarded to you the historical events that led to CBER's request that Merck conducts an end expiry trial if Merck wanted to change mumps potency in the label from 20,000. please see attached:

4. What is the mumps end expiry potency of the investigational vaccine with rHA which is being used in the clinical trial? Further, is the mumps sero-conversion rate one of the endpoints of the trial?[Morsy, Manal A.] yes

[Morsy, Manal A.] the investigational vaccine is tested at release – end expiry potency for mumps would follow what would be in the label post the end expiry trial conclusion.

5. When you change HSA to rHA, is an additional end expiry trial with the new formulation required? [Morsy, Manal A.] No - see comment above

6. If the primary end point is not fulfilled and you negotiate with CBER, is there any possibility of going back to 5,000 CCID50?

[Morsy, Manal A.] unlikely the preliminary data from the mumps end expiry based on the criteria set forth by CBER would not support 5,000 — what we would negotiate if one of the two criteria is not met would be the 10,000 CCID50

We will hold an internal meeting next Wednesday to determine which option to pursue; therefore, I would appreciate it if you could forward your responses to the questions noted above by next Tuesday.

[Morsy, Manal A.] Additional comments will be provided as soon as internal discussion at our end are concluded to further address your questions.

Regards

Manal

As I explained previously, the timing of the JNDA submission is an extremely political issue both internally and externally. I would appreciate your cooperation.

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10/25/2019 Declaration of G. Reilly EXHIBIT 118

To: Chodakewitz, Jeffrey A[jeffrey_chodakewitz@merck.com]; Chirgwin, Keith D.[keith_chirgwin@merck.com]; Heyse, Joseph F.[joseph_heyse@merck.com]; Schodel, Florian[florian_schodel@merck.com]; Matthews, Holly[holly_matthews@merck.com]; Willison, Barbara W[barbara_willison@merck.com]; Morsy, Manal A.[manal_morsy@merck.com]; Musey, Luwy[luwy_musey@merck.com]; Dietrich, Gary J[gary_dietrich@merck.com]; Hartzel, Jonathan[jonathan_hartzel@merck.com]; Karnik, Shaila[shaila_karnik@merck.com]; Kuter, Barbara J.[barbara kuter@merck.com]

Cc: Schreader, Nancy T[nancy_schreader@merck.com]; Kriebel, Lonnie M[lonnie_kriebel@merck.com]; Daggett, Kathleen N[kathy_daggett@merck.com]; Shay, Charlotte[charlotte_shay@merck.com]

From: Simon, Keiko
Sent: Mon 10/27/2003 8:21:49 PM

Importance: Normal

Subject: VP Clinical planning meeting information

Final October25 VP PlanningMeeting MumpsEndExpiry2004.ppt oGOS versus GOS Comparison.ppt

Dear all,

Please find attached the presentation slides from Luwy and Jon for tomorrow's discussion.

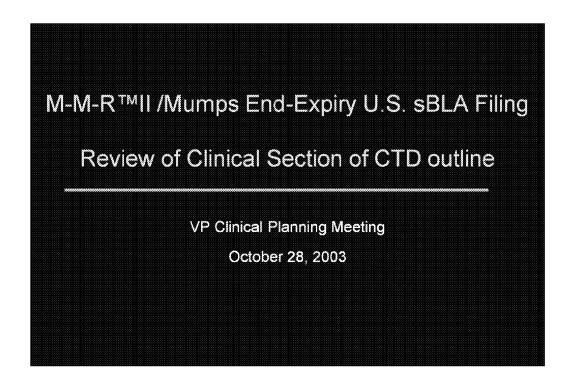
Apologies for the lateness of this distribution.

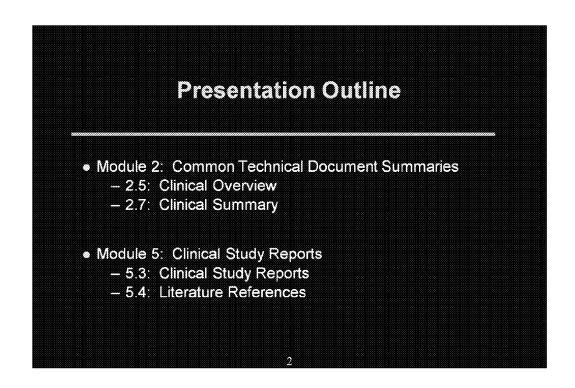
Outline of Clinical documentation

GOS vs. oGOS comparison

Thank you, Keiko

Thank you, Keiko O. Simon, PhD Project Management 484-344-7590 (phone) 484-344-3659 (fax)





Presentation Outline Module 2: Common Technical Document Summaries - 2.5: Clinical Overview - 2.7: Clinical Summary Module 5: Clinical Study Reports - 5.3: Clinical Study Reports - 5.4: Literature References

2.5: Clinical Overview

- 2.5.1: Product Development Rationale
- 2.5.2: Overview of Biopharmaceutics
- 2.5.3: Overview of Clinical Pharmacology
- 2.5.4: Overview of Efficacy
- 2.5.5: Overview of Safety
- 2.5.6: Benefits and Risks Conclusions
- 2.5.7: List of References

Date Filed: 11/01/2023

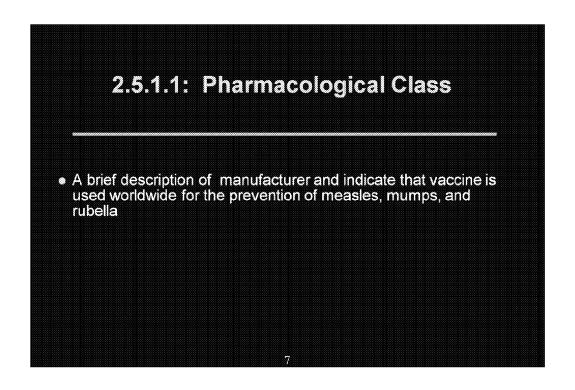
2.5.1: Product Development Rationale

- 2.5.1.1: Pharmacological Class
- 2.5.1.2: Chemical and Pharmaceutical Properties
- 2.5.1.3: Current and Targeted Indications
- 2.5.1.4: Scientific Background
- 2.5.1.5: Overview of Clinical Development Program
- 2.5.1.6: Standard Research Procedures
- 2.5.1.7: Regulatory Guidance and Advice
- 2.5.1.8: Good Clinical Practices

Date Filed: 11/01/2023

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Date Filed: 11/01/2023

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2.5.1.2: Chemical and Pharmaceutical Properties

- Vaccine composition as regards to how the different components are derived and reference the monovalent vaccines.
- Information will include manufacturing process, cell substrate, final product composition, and potency specifications.
- State that vaccine is sterile and used for subcutaneous injection.

2.5.1: Product Development Rationale

- 2.5.1.1: Pharmacological Class
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- 2.5.1.3: Current and Targeted Indications
- 2.5.1.4: Scientific Background
- 2.5.1.5: Overview of Clinical Development Program
- 2.5.1.6: Standard Research Procedures
- **☀ 2.5.1.7: Regulatory Guidance and Advice**
- 2.5.1.8: Good Clinical Practices

2.5.1.3: Current and Targeted Indications

- State that present submission will not propose any change to the vaccine's indication, but rather sought to reduce the expiry potency for mumps component of M-M-R™II from 4.3 to 4.1 log10TCID50/dose
- Provide the current indication against the 3 diseases
- Recommended schedule in the United States and precautions for some subjects with history of anaphylactic reaction to any vaccine component
- State that marketed application never been rejected nor withdrawn for safety reasons
- Refer to appendix for the list of countries where the vaccine is currently licensed
- · Refer to previous submission for additional information

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Date Filed: 11/01/2023

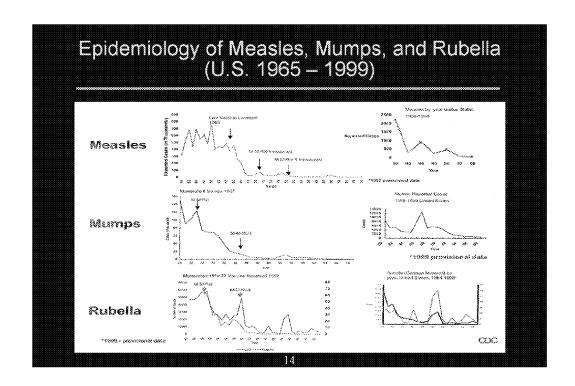
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- 2.5.1.8: Good Clinical Practices

2.5.1.4: Scientific Background

- Highlight the clinical presentation and epidemiology of the 3 targeted diseases before vaccination and the impact of vaccination
- Provide historical perspective on monovalent and multivalent measlesmumps-rubella live attenuated vaccines (impact on the incidence of the 3 diseases, clinical presentation of vaccine-induced symptoms).
- Provide general information about M-M-R™II: Safety, Immunogenicity, and Efficacy. Impact of maternal antibodies and kinetics of antibodies to measles, mumps, and rubella.
- Explain the evolution in mumps potency (minimum immunizing dose and change in end-expiry potency from 5,000 to 20,000 TCID50/dose)

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Vaccine Component	Minimum Immunizing Dose	End-Expiry Potency	Minimum Release Potency		
	(TCID ₅₀ /dose)	(TCID ₅₀ /dose)	(TCID ₅₀ /dose)		
REDACTED – OMI	P				
Mumps	~2.5 log ₁₀ (~317)§	3.7 log ₁₀ (5,000)¶	4.7 log ₁₀ (50,000)		
REDACTED - OM	P				
§ In 1972, potency v BSC-1 to Vero cells)	aiue had to be adjusted (4-fol	d increase) due to a cha	nge in cell substrate (fron		
BSC-1 to Vero cells)	alue had to be adjusted (4-folioned) release was changed from 4.				

2.5.1: Product Development Rationale

- 2.5.1.1: Pharmacological Class
- 2.5.1.2: Chemical and Pharmaceutical Properties
- 2.5.1.3: Current and Targeted Indications
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2.5.1.5: Overview of Clinical Development Program

- State that application is to obtain approval to lower mumps end-expiry potency in M-M-R™II based on the clinical data; that lowering will reduce amount of unneeded virus given to children while preserving safety and efficacy profiles of the vaccine
- Explain that lowering of mumps potency would more likely affect immunogenicity rather than safety
- Provide rationale for the conduct of this clinical trial (need to identify mumps endexpiry potency). What was the plan and How was it done?
- Vaccine aged at room temperature to mimic natural potency decay
- Briefly state that in agreement with CBER, study was done with oGOS as vaccine stabilizer, vaccine made with oGOS provides comparable immune responses to vaccine made with GOS (report provided in section 5.3.5).
- Describe briefly protocol 007: study objective, Rationale for evaluating the kinetics of immune responses (1 year persistence).

M-M-R™ _{ii} sublot	Antigen	Targeted Potency (log ₁₀ TCID ₅₀)	Estimated Potency (log ₁₀ TCID ₅₀)†	Adjusted Potency (log ₁ TCID ₅₀)‡				
M-M-R™ _{ii}	REDACTED - OMP							
containing ≤3.7 log ₁₀	Mumps	≤3.7	3.7	3.8				
TCID ₅₀	REDACTE	O – OMP						
M-M-R™ _{ii} containing ≤4.0 log ₁₀ TCID ₅₀	Mumps REDACTE	≤4.0 D – OMP	3.9	4.0				
M-M-R™ _{ii} containing ~4.9 log ₁₀ TCID ₅₀	Mumps REDACTE	~4.9 D – OMP	4.7	4.8				

2.5.1: Product Development Rationale

- 2.5.1.1: Pharmacological Class
- 2.5.1.2: Chemical and Pharmaceutical Properties
- 2.5.1.3: Current and Targeted Indications
- 2.5.1.4: Scientific Background
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- 2.5.1.8: Good Clinical Practices

2.5.1.6: Standard Research Procedures

- Conduct and Design of Study: Concordance with Standard Research Approaches (well-controlled, well powered, etc.)
- Vaccination Report Card (VRC)
- Similar to the one used in recent M-M-R™II studies
- Parameters prompted for on VRC and how often (Temperature, injection-site reaction, systemic AE)
- Statistical Analysis
- State that statistical analyses were pre-specified in the DAP
- Analyses performed according to standardized and validated methodology; refer section explaining methodology

2.5.1: Product Development Rationale

- 2.5.1.1: Pharmacological Class
- 2.5.1.2: Chemical and Pharmaceutical Properties
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- **2.5.1.8: Good Clinical Practices**

2.5.1.7: Regulatory Guidance and Advice

- · Selection of assays used for primary immunogenicity endpoints
- Assay cutoffs discussions with CBER
- Need to evaluate the kinetics of immune responses (1 year persistence).
- GOS and oGOS discussion
- Minutes of meetings with regulatory agencies (To be referenced)

2.5.1: Product Development Rationale

- 2.5.1.1: Pharmacological Class
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2.5.1.8: Good Clinical Practices

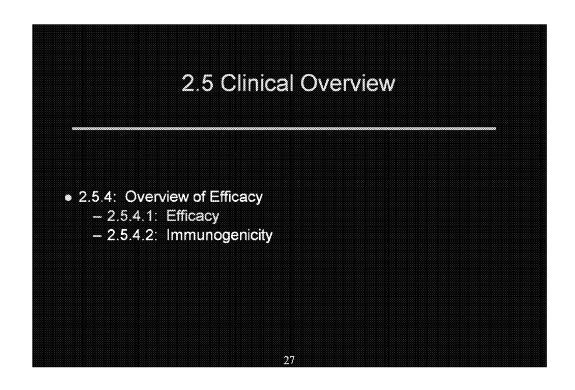
- Study was conducted using Good Clinical Practice (GCP) guidelines: study design, use of appropriate controls, power, appropriateness of the delta used to compare the different groups.
- Quality assurance audited by Merck WCQAR and audits meet US and International standards.
- Parameters used to evaluate safety were in harmony with previous experiences with the product (rash, fever).
- Laboratory assays met all required standards (assays were validated).

2.5: Clinical Overview

- 2.5.1: Product Development Rationale
- 2.5.2: Overview of Biopharmaceutics (Not Applicable)
- 2.5.3: Overview of Clinical Pharmacology (Not Applicable)
- 2.5.4: Overview of Efficacy
- 2.5.5: Overview of Safety
- 2.5.6: Benefits and Risks Conclusions
- 2.5.7: List of References

2.5: Clinical Overview

- 2.5.1: Product Development Rationale
- 2.5.2: Overview of Biopharmaceutics
- 2.5.3: Overview of Clinical Pharmacology
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BJK8

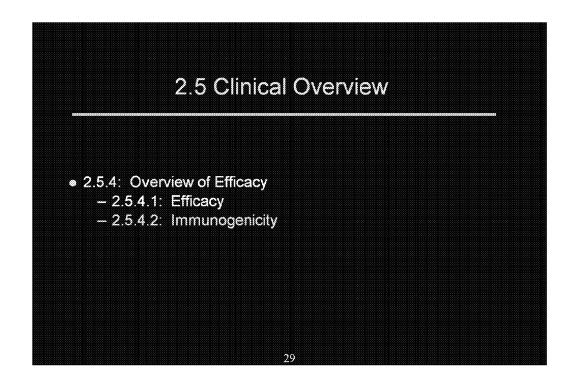
2.5.4: Overview of Efficacy

- 2.5.4.1: Efficacy
- Provide overview of the efficacy of M-M-R™II and state that efficacy was shown with monovalent products
- Provide importance of vaccine efficacy as provided by the fact that measles, mumps, and rubella (and associated complications) have been virtually eliminated from countries such as Finland, Sweden, and United States.
- Immunogenicity was shown to correlate well with efficacy.
- State that neutralization assay was used as primary immunogenicity endpoint in adfeement with the regulatory

Slide 28

BJK8 Suggest first bullet say this is a "brief" summary

Change "bleeding" in last bullet to "blood specimen" - not sure how persistence fits under efficacy? $\frac{10}{23}$

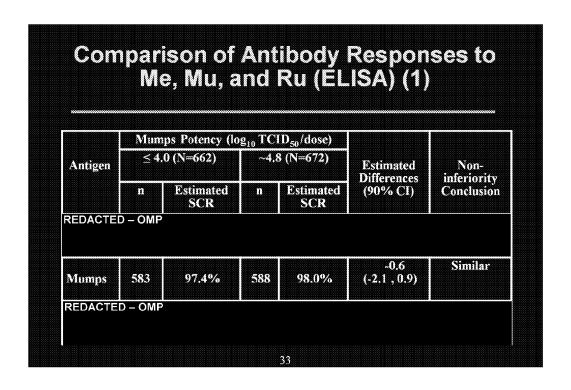


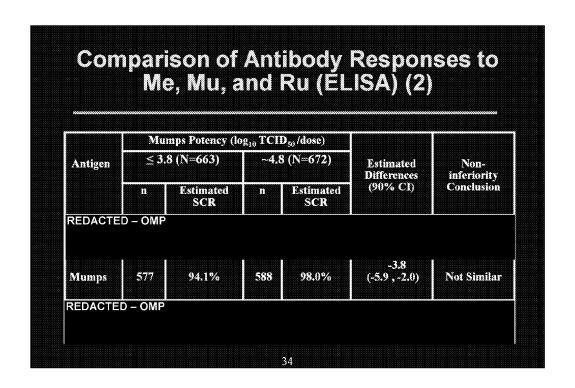
2.5.4: Overview of Efficacy

- 2.5.4.2: Immunogenicity
- State that 4.0 log10 TCID50 was satisfactory but not 3.8 log10 TCID50
- Indicate study hypotheses and statistical criteria for success
- Present study results by PRN then by ELISA (first 4.0 then 3.8)
- Present data related to the 1 year persistence showing that persistence was high (>95%) for all 3 antigens across treatment groups
- Conclusions on the immunogenicity: state that application supports an end-expiry dose of mumps virus in M-M-R™I to be no less than 4.0 log10 TCID50/dose based on the 3 key immunogenicity results (4.0 satisfactory but not 3.8; and responses persisted for at least 1 year)

		ı	IEa	uneni	Group:	5	
,			~4.8	log ₁₀ TCID ₅₀			
≤4.0 log ₁₀ TCID ₅₀ Mumps Potency (N=662)		Mumps Potency (N=672)		Estimated			
n	Observed SCR (95% CI)	Estimated SCR	n	Estimated SCR	Difference (90% CI)	Acceptability	Similarity
433	93.3% (90.5%, 95.5%)	93.4%	437	92.2%	1.2 (-1.8,4.1)	Acceptable	Similar

**							
≤ 3	≤3.8 log ₁₀ TCID ₅₀ Mumps Potency (N=663)	_{so} Mumps =663)	~4.8 log ₁₀ TCID ₅₀ Mumps Potency (N=672)				
n	Observed SCR (95% CI)	Estimated SCR	п	Estimated SCR	Estimated Difference (90% CI)	Acceptability	Similarity
459	89.3% (86.1%, 92.0%)	89.4%	437	92.2%	-2.9 (-6.1 , 0.3)	Not Acceptable	Not Similar





2.5: Clinical Overview

- 2.5.1: Product Development Rationale
- 2.5.2: Overview of Biopharmaceutics
- 2.5.3: Overview of Clinical Pharmacology
- 2.5.4: Overview of Efficacy
- 2.5.5: Overview of Safety
- 2.5.6: Benefits and Risks Conclusions
- 2.5.7: List of References

2.5.5: Overview of Safety

- Provide a summary of the safety results indicating comparable safety profile across treatment groups.
- State that no safety issues expected with lower potencies
- Population and Extent of exposure (how many subjects vaccinated, how many doses, how long were they followed, and mention that only vaccine-related SAEs were evaluated between day 42 and 1 year post-vaccination.)
- Explain how safety profiles were compared between each test group and the control group (risk difference)
- Provide safety results (injection site, systemic, elevated temperatures, serious AEs, death, discontinuations): All showing no significant difference across tested potencies

2.5.5: Overview of Safety (Cont.)

- Present a summary of the safety data from end-expiry clinical trial (Comparison between test and control groups, Critical analysis of safety results, importance of safety parameters)
 - Injection site reactions
 - Systemic adverse experiences
 - Elevated temperatures
 - Deaths, Serious AEs, and Discontinuation from the study
- Limitations of Safety Data
- Worldwide Marketing Experience: 400 million doses distributed and clear impact in the incidence of the 3 diseases; vaccine generally well tolerated with favorable benefit to risk ratio to support continued usage for prevention of the 3 diseases.
- Conclusions regarding safety: data support study safety hypothesis

Clinical Adverse Experiences Observed During 42 days Follow-up* (1)

	Mumps	M-M-R TM II with Mumps $\leq 3.8 \log_{10}$ TC1D _{S0} /dose		M-M-R TM H with Mumps \leq 4.0 \log_{10} TCID ₅₀ /dose		R™ II with s =4.8 log ₁₀ D ₈₀ /dose
	n	(%)	n	(%)	п	(%)
Total number of subjects	663		662		672	
Subjects with follow-up	631		636		643	
Number (%) of subjects:						
with no adverse experience	91	(14.4)	105	(16.5)	92	(14.3)
with one or more adverse experiences	540	(85,6)	531	(83.5)	551	(85.7)
MMR-related injection site reactions*	213	(33.8)	220	(34.6)	219	(34.1)
systemic adverse experiences	489	(77.5)	488	(76.7)	497	(77.3)
serious adverse experience	10	(1.6)	6	(0.9)	9	(1.4)

*Adverse experiences include those related to both M-M-R $^{\rm rel}$ I and $^{\rm Varivax}$, with the exception of injection site reaction

42 days F	ollo	w-up)* (Z	2)		
	M-M-R TM II with Mumps $\leq 3.8 \log_{10}$ TCID ₅₀ /dose $N = 631$		M-M-R TM II with Mumps \leq 4.0 log ₁₀ TCID ₅₀ /dose N = 636		M-M-R TM II with Mumps ~4.8 log ₁₀ T CID ₅₀ /dose N = 643	
	n	(%)	11	(%)	n	(%)
With vaccine-related adverse experiences	347	(55.0)	313	(49.2)	337	(52.4)
MMR-related injection-site adverse experiences*	213	(33.8)	220	(34.6)	219	(34.1)
systemic adverse experiences	181	(28.7)	148	(23.3)	150	(23.3)

2.5: Clinical Overview

- 2.5.1: Product Development Rationale
- 2.5.2: Overview of Biopharmaceutics
- 2.5.3: Overview of Clinical Pharmacology
- 2.5.4: Overview of Efficacy
- 2.5.5: Overview of Safety
- 2.5.6: Benefits and Risks Conclusions
- 2.5.7: List of References

2.5.6: Benefits and Risks Conclusions

- · Effectiveness and safety over the 25 years since licensure
- State that data presented in this application are consistent with historical immunogenicity and safety profiles of the vaccine, as shown with the control group receiving vaccine with mumps potency within typical release range
- Important benefit is that you can give vaccine with lower mumps potency and do not need to give more than needed
 - If any, possible risk would be for not giving enough mumps virus to allow protection. But study data showed that 4.0 is satisfactory and data from 3.8 is not dramatically low, therefore benefit is maintained, justifying the lowering of end-expiry potency
- Study did not change the indications and other safety parameters of the currently licensed vaccine but provides a more accurate determination of the mumps end-expiry potency, therefore will require a label change for the minimum mumps expiry potency
- Limitations of available data: sample size was not a problem

Presentation Outline

- Module 2: Common Technical Document Summaries
 - 2.5: Clinical Overview
 - 2.7: Clinical Summary (Not required based on discussion with CBER)
- Module 5: Clinical Study Reports
 - 5.3: Clinical Study Reports
 - 5.4: Literature References

Presentation Outline Module 2: Common Technical Document Summaries - 2.5: Clinical Overview - 2.7: Clinical Summary Module 5: Clinical Study Reports - 5.3: Clinical Study Reports - 5.4: Literature References

5.3 Clinical Study Reports

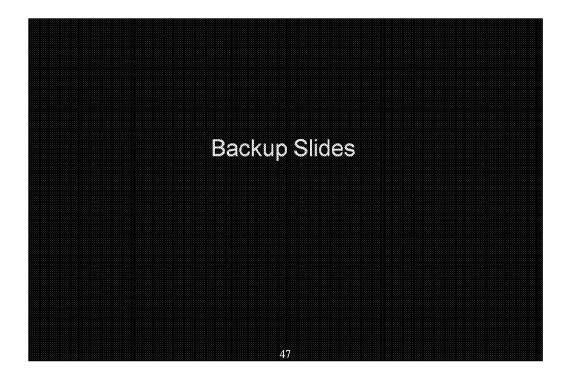
- 5.3.1: Reports of Biopharmaceutic Studies
 - Not Applicable
- 5.3.2: Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials
 - Not Applicable
- 5.3.3: Reports of Human Pharmacokinetics (PK) Studies
 - Not Applicable
- 5.3.4: Reports of Human Pharmacodynamic (PD) Studies
 - Not Applicable

5.3 Clinical Study Reports (Cont.)

- 5.3.5: Reports of Efficacy, Immunogenicity and Safety Studies
- Provide CSR for Protocol 007
- Provide report of the historical comparison of immunogenicity between M-M-R™II with oGOS and M-M-R™II with GOS
- 5.3.6: Reports of Post-marketing Experience
- Provide 5 year Post-marketing report (1996-2002)
- 5.3.7: Case Report Forms and Individual Subject Listings

Presentation Outline Module 2: Common Technical Document Summaries – 2.5: Clinical Overview – 2.7: Clinical Summary

- Module 5: Clinical Study Reports
 - 5.3: Clinical Study Reports
 - 5.4: Literature References



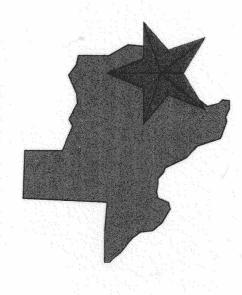
M-M-R™ _{ii} Sublots	Experimental Conditions
M-M-R™ _{II} containing ≤3.7 log ₁₀ TClD ₅₀	Room Temperature for 12 weeks
M-M-R™ _{ii} containing ≤4.0 log ₁₀ TCID ₅₀	Room Temperature for 7 weeks
M-M-R™ _{ii} containing ~4.9 log ₁₀ TCID ₅₀	No Manipulation

M-M-R™ _{ii} sublot	Antigen	Targeted Potency (log ₁₀	Estimated Potency (95% CI)	Adjusted Potency (log ₁
		TCID ₅₀)	(log ₁₀ TClD ₅₀)t	TCID ₅₀)‡
M-M-R™ _{ii}	REDACTE	O – OMP		
containing	Mumps	≤3.7	3,66 (3.69)	3.8
≤3.7 log ₁₀ TCID ₅₀	REDACTE	O – OMP	* * *	
M-M-R™,				
containing	Mumps	≤4.0	3.94 (3.98)	4.0
≤4.0 log ₁₀ TCID ₅₀	REDACTE	O – OMP		
M-M-R™,				
containing	Mumps	~4.9	4.7	4.8
~4.9 log ₁₀ TCID ₅₀	REDACTE	O – OMP		

10/25/2019 Declaration of G. Reilly EXHIBIT 119

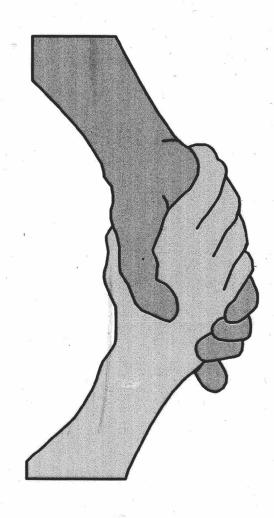
Date Filed: 11/01/2023 Page: 359

PESTIGATORS MEET M-M-RTMII EXPIR



March 15-16, 1999 Irving, Texas

INTRODUCTIONS



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MERCK PERSONNEI

Clinical

- Megan McBride
- Kara Stockett
- Colleen Taddeo

- Dr. Scott Thaler

- Statistics
- Dr. Stephanie Olsen
- Data Coordination
- Leighann Graham

- Quality Assurance
- Susan McNeill
- **Biometrics Research**
 - Timothy Schofield
- Virus & Cell Biology
- Dr. David Krah
- Mary Yagodich
- Merck Vaccine Division
- Gina Esposito
- Kim Haupt
- Maureen Walter

MERCK PERSONNEL (cont'd)

MRAS

Medical Research Associates

Yolie Amisola-Crume

- Cathy Anderson

- Joanne Bixler

- Jane Brunette

- Nicole Christison

- Michele Goldberg

- Madigan Harris

Darrell Johnson

- Julie Kennedy

Lee Lesneski

John Loder

- Karen Martin

Patricia MorganLawrence Peterson

- Nancy Reinhardt

- Jill Ryan

- John Smith

- Michelle Stallworth

- Eloise Watkins

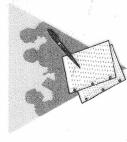
STUDY SITES



- Boston
- Buffalo
- Chapel Hill
- Dallas
- Denver
- Honolulu
- Jackson
- Marshfield

- Nashville
- Norfolk
- North Canton
- Oakland
- Pittsburgh
- Rochester
- Salt Lake City
- San Diego

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AGENDA



Protocol Background & Rationale - Dr. Scott Thaler

Protocol Overview & - Megan McBride / Kara Stockett Administrative Issues

Case Report Forms - Leighann Graham

Handling & Shipping of Sera - Megan McBride / Kara Stockett

Question & Answers -. ALL

LUNCH -

Video Adverse Event Review - Darrell Johnson

Study Monitoring -

Regulatory Aspects & - Susan McNeill

Quality Assurance

Questions & Answers

Dr. Scott Thaler Closing Remarks



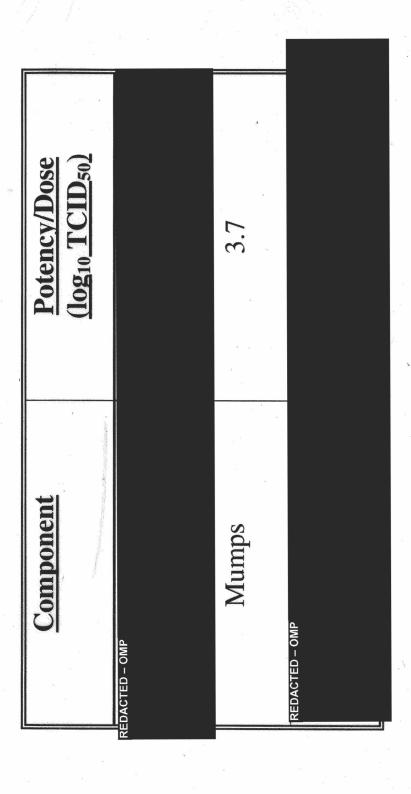


BACKGROUND AND RATIONALE

and lose potency over time when stored at 2-8°C The components of M-M-RTMII are live viruses or higher. The FDA (CBER) has requested expiry potencies be placed on the label of M-M-RTMII.

No data exist for mumps at the expiry potency Merck has selected. A clinical immunogenicity trial is necessary to provide these data.

M-M-RTMII END EXPIRY POTENCIES SUGGESTE FOR THE LABEL



DETERMINATION

Target or Fill Potency
Vaccine Stability
Minimum Immunizing Dose

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TABLE 3: Marketing Stability Results for Measles Containing Vaccines

REDACTED - OMP

TABLE 4: Marketing Stability Results for Mumps Containing Vaccines

		Total L	Total Loss: Release to 24 Mos.	to 24 Mos.		Predicted Expiry Potency at 24 Mos.	cy at 24 Mos.
Lot Subset	# of Lots	Lot Subset # of Lots Average	127 %56	95% UCL Average	Average	107 %56	95% UCL
Single Dose	65	0.52	0.36	0.68	4.45	4.29	4.61
Multi-Dose	2	0.37	0.21	0.52	4.53	4.37	4.68
All	75	0.50	0.37	0.64	4.45	4.32	4.59

MEASLES AND MUMPS DATA ON MINIMUM IMMUNIZING DOSE

Buynak EB et al. JAMA 1969; 207: 2259-62.

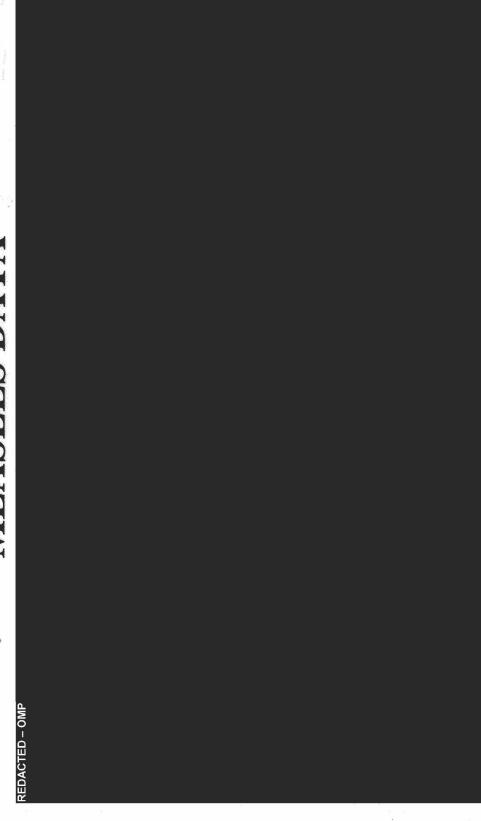
- Includes data on MeMu, MeMuRu bi/trivalent

Buynak EB et al. JAMA 1968; 203: 9-13.

- Mu only

Stokes J et al. Pediatrics 1967; 39: 363-7

Mu only



Vaccine	Dose	Z	SCR	GMT (SNT)
Trivalent (HPV-77)		28	93%	8
MeMu bivalent	3.8	13	77%	5
Mu mono	3.1	=	100%	4.5
Mu mono	3.1	13	100%	7.2
Mu mono	1.6	∞	75%	1.5

TION OF MEASLES AN

MUMPS SHELF LIFE

(all values in $\log_{10} TCID_{50}$)

	Expiry	32% NF	Target	Buffer	Minimum
	Potency	on 24	Fill		Immunizing
		Month		e e	Dose
		Loss		•	5
REDACTED – OMP					
Mumps	4.3	0.64	4.9	-0.04	3.1

PRODUCTION OF M-M-RTM AT EXPIRY

Natural Aging (2-8°C)

RoomTemperature (20-25°C Accelerated Aging at

Dilution of Components

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Study Type	Advantages	Disadvantages
Accelerated Aging at Room Temperature (20-25°C)	Material may be produced relatively quickly	 Heat-induced qualitative antigenic changes
	Change in live/inactive particle ratio similar to natural aging	• Effect on all 3 viruses in M-M-R TM _{II} not predictable
j		 Effect on more susceptible sub-populations
Dilution	Material available relatively quickly	 Least similar to natural aging process
	 No heat-induced change in antigenicity 	Alteration in protein concentration
	 Enhance theoretical interference between components 	 Ratio of live/inactive particles not maintained
	 Similar effects on all sub-populations 	
Natural Aging at 2-8°C	Measures real-time stability and	Very slow process
	decay	• Effect on all 3 viruses in
,		M-M-R TM _{II} not predictable

THE PRELIMINARY AGING EXPERIMENT

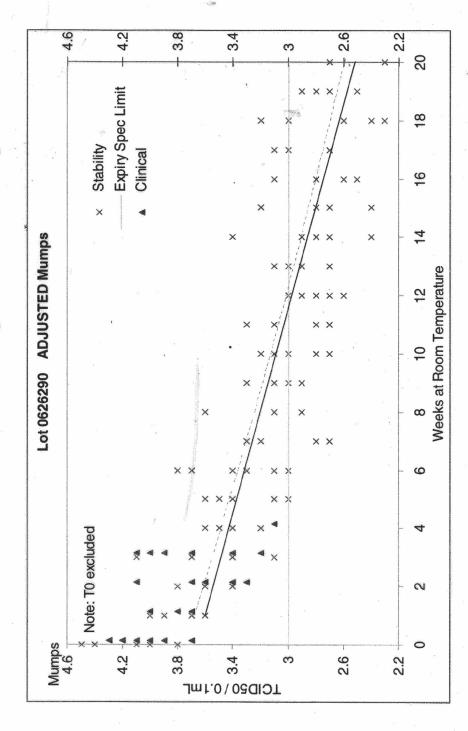
Goal:

- Reduce vaccine potency while minimizing the margin of error and ensure the true potency is no greater than the target.

Methods:

- Incubate 3 potential clinical lots at room temperature.
- Use a 1x6 potency testing scheme for 27 weeks.
- Generate best fit curves using all available data.
- Begin aging clinical material once decay understood.

Stability Data for Lot #0626290 Showing Results of Tests on Clinical Samples for Mumps.



Group	Z	Measles Titer (log ₁₀ TCID ₅₀)	Mumps Titer (log ₁₀ TCID ₅₀)	Rubella Titer (log ₁₀ TCID ₅₀)
Sublot #1	200	REDACTED – OMP	-4.9	REDACTED – OMP
Sublot #2	200		~3.98	
Sublot #3	200		~3.69	

MMUNOGENICITY MEASUREMENTS

REDACTED - OMP

For Mumps, a functional (neutralization) assay has been developed.

butter" plaque reduction neutralization (PRN) assay. - Neutralization will be measured using a "bread and

a wild type mumps strain will be used in the PRN assay to best assess protection from wild mumps infection.

PLAOUE REDUCTION MUMPS NEUTRALIZATION ASSAY

- Serum dilutions are mixed with TN wt mumps for one hour, quenched, then added to Vero cell monolayers:
- Presamples to be tested at 1:2 and 1:4.
- Postsamples to be tested at 1:4 and 1:8.
- A randomly selected subset ($\sim 20\%$) will be diluted out to titer to compute GMTs.
- Incubated 6 days with media supplemented with agarose.
- Stained with 0.2% Coomassie Blue R-250 in ETOH
- Titer is the highest dilution that leads to at least 50% plaque reduction.

PRELIMINARY GUIDELINES FOR THE PRN ASSAY

Negative (not protected)

-<1:2

Positive (protected)

>1:4

Seroconversion by PRN

- \geq 4 fold rise in antibody titer

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PARTICIPATION IN THIS TRIAL **ADVANTAGES TO** FOR SUBJECTS

- Avoid unnecessary exposure in the future to higher levels of mumps vaccine virus.
- almost certainly ensures protection from A positive mumps neutralization titer wild type infection.
- Lower doses of mumps may be associated with lower rates of side effects.

PROTOCOL 007



A Study of M-M-RTMII at Mumps Expiry Potency in Healthy Children 12 to 18 Months of Age

PRIMARY OBJECTIVES

- mumps by neutralization among subjects receiving M-M-RTMII containing an expiry dose of mumps To demonstrate a similar immune response to compared to subjects receiving M-M-RTMII containing a release dose of mumps.
- To demonstrate an adequate immune response to mumps among subjects receiving M-M-RTMH with an expiry dose of mumps.

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SECONDARY OBJECTIVES

- M-M-RTMII containing a release dose of mumps. ELISA) for measles, mumps and rubella among children who receive M-M-RTMII containing an To demonstrate similar immune responses (by expiry dose of mumps and children receiving
- rubella and varicella 42 days postvaccination in To summarize the GMTs to measles, mumps, both the expiry and control groups.

SECONDARY OBJECTIVES

(cont'd)

REDACTED - OMP

mumps PRN titers ≥ 1 :8 in both expiry and control To summarize the proportion of subjects with groups.

CONFIDENTIAL

MRK-CHA01888853 Appx4787

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SECONDARY OBJECTIVES

(cont'd)

randomly selected subset of subjects in both the To summarize the PRN titers (GMTs) in a expiry and control groups 42 days postvaccination.

mumps given concomitantly with VARIVAXTM M-M-RTMII containing an expiry dose of To describe the safety and tolerability of

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STUDY DESIGN SUMMARY

Randomized, Double-Blind, Multi-Center Study

3 Groups:

- Control ($\sim 4.9 \log_{10} TCID_{50} mumps$).

- Intermediate Expiry (~4.0 \log_{10} TCID₅₀ mumps).

- **Expiry** (~3.7 \log_{10} TCID₅₀ mumps).

Each subject receives a single injection of M-M-RTMII and VARIVAXTM. 3 Visits: Day 0, day 42-56, and at one year.

Study Flow Char

TEST/PROCEDURE	Sublot (C	lot #1 M-M-R ^{TN} (Control Group)	Sublot #1 M-M-R TM _{LI} A (Control Group)	Sublo (Mun	ot #2 M-1	Sublot #2 M-M-R TM _{II} B (Mumps Expiry Group)	Sublo (Mum	t #3 M-N ps Expir	Sublot #3 M-M-R TM _L C (Mumps Expiry Group)
9000	Day 0	Day 0 Day 42 (42-56)	Day 42 Day 365 (42-56) (335-395)	Day 0	Day 0 Day 42 (42-56)	Day 365 (335-395)	Day 0	Day 0 Day 42 (42-56)	Day 365 (335-395)
VACCINATION M-M-R TM I REDACTED - OMP	×			×		•	×	3. 3.	
OBTAIN BLOOD SAMPLE	×	×	×	×	×	X	X	X	×
LABORATORY TESTS Mumps Neutralization Assay ELISA REDACTED - OMP	××	××	××	××	××	× ×	××	××	××
CLINICAL FOLLOW-UP		×			×			X	

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INCLUSION CRITERIA



Children 12-18 months of age.

In good health based on medical history.

Signed informed consent form.

measles, mumps, rubella, varicella or zoster. No clinical history of vaccination for

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EXCLUSION CRITERIA

- Prior measles, mumps, rubella or varicella vaccine.
- Prior clinical history of measles, mumps, rubella, varicella or zoster.
- Any allergy to vaccine components including anaphylactoid allergy to eggs.
- Any exposure to measles, mumps, rubella, varicella or zoster in the past 4 weeks.



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STUDY FLOW CHART

Day 0:

- Review Eligibility

Obtain History/Consent

Obtain Blood Sample (~5-10 mLs)

Administer Vaccines:

M-M-RTMII to the Arm

VARIVAXTM to the Thigh

Hand-out and Review VRC with Parent

EXCLUSION CRITERIA

(cont'd)

Receipt of immune globulin or blood products within 3 months of entry or 42 days thereafter.

Febrile illness within 72 hours of vaccination.

Any immune impairment including immunosuppressive chemotherapy. Vaccination with other live attenuated vaccines 30 days prior to entry or 42 days thereafter.

Vaccination with any inactivated vaccine 14 days prior to entry or planned 42 days thereafter.

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CONCURRENT TREATMENTS

No live virus vaccine for 30 days before and 42 days after each dose of vaccine administered in this study. No inactivated vaccines (Hib, DTP, etc.) for 14 days before and 42 days after receipt of each dose of the vaccine.

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STUDY FLOW CHART

(cont'd)

Day 42 to 365:

Follow-up for vaccine-related SAEs

Day 365 (335 to 395 days):

Obtain Blood Sample (~ 5-10 mLs)

Complete 1-year Persistence Bleed Workbook

Collect Exposure Information

STUDY FLOW CHART

(cont'd)

• Day 0 to 42:

- Safety Follow-up

• Day 42 (42 to 56 days):

Obtain Blood Sample (~5-10 mLs)

- Collect VRC and Review

Collect Exposure Information

Day 279 (9 months Post-Vaccination):

- Telephone Contact with Parent

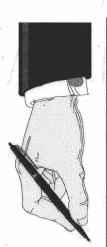
ALLOCATION NUMBERS

reviewed, and pre-vaccination blood draw is consented, inclusion/exclusion criteria are Assign allocation number after subject is performed.

the subject is consented but the vaccination A baseline number will only be assigned if does not occur. Contact MPC for assignment of baseline number.

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CONSENT



- Investigator must obtain written consent parent/guardian prior to performing any from each potential subject's clinical research procedures.
- *One signed copy for parent/guardian Parent/guardian must sign two copies: *One signed copy for study files

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CONCURRENT TREATMENTS

(cont'd)

- before or 42 days after vaccination unless No administration of immune globulin or there is a medical emergency warranting blood products for 3 months (90 days) their use.
- vaccination because the use of salicylates in children with varicella has been associated No salicylates during the 6 weeks after with Reye's syndrome.

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BLINDING (cont'd)

- Sites will unblind a subject only in the event of a medical emergency.
- maintained with the SPONSOR and at the primary Masked Schedules for unblinding subjects will be
- Masked Schedules should be maintained in a secure location.
- At the end of the study, all masked schedules should be returned to the SPONSOR either intact or with the unblinding log.

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BLINDING

- The following persons will be blinded until all subjects have completed the study and data is screened for completeness:
- SPONSOR personnel directly involved in study.
- Subject/Parent/Guardians.
- Investigators.
- All vials of M-M-RTMII will appear identical.
- Any vial of supplied VARIVAXTM may be used.

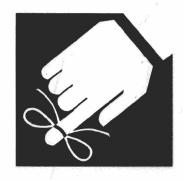
SUGGESTED METHOD FOR BLOOD COLLECTION

- Blood should be drawn (~ 5-10 mLs).
- Blood should be allowed to clot in the collection tube for 30-60 minutes.
- Clotted blood should not sit at room temperature or refrigerated for more than 2 hours before centrifugation and separation.
- Do not refrigerate newly collected blood.
- After separation place the serum in a vial provided prior to freezing. Use only Merck provided vials by Merck and place the correct label on the vial and labels.

SERUM VIAL LABELS

abel Color

Bleed Interva



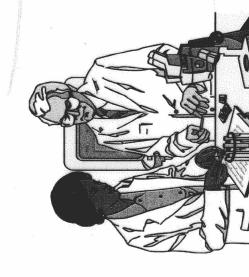
Megan or Kara: CRFs and

Kyna: Serum Samples

Correspondence







VACCINE SHIPPING AND STORAGE

artificially aged, all M-M-RTMII vaccine will be Because the M-M-RTMII in this trial is shipped and stored frozen at -15°C.

REDACTED - OMP

VARIVAXTM should be used within 30 minutes For consistency, both M-M-RTMII and of reconstitution.

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STORAGE OF VACCINE

M-M-RTMII / VARIVAXTM

- 15°C (+5°F) or colder, frost-free freezer.

All vaccines supplied in 0.7 mL vials for a 0.5 mL injection.

The vaccines must be administered within 30 minutes Daily monitoring and documentation must be maintained for freezers and refrigerators.



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STORAGE

2 to 8°C (36 to 46°F) or room temperat

Supplied in 0.7 mL vials.

For use with M-M-RTMII and VARIVAXTM

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RETENTION VIALS

- Use to monitor shipping, handling and storage of vaccines.
- VARIVAXTM) designated as retention vials. 12 Vials of each vaccine (M-M-RTMII,
- Must be stored with the study vaccine but not used during the trial.
- months of study completion or as requested Must be returned to SPONSOR within 3

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REPLACEMENT VIALS

- Replacement vials will be available at each site to be used in the event of an error in reconstitution of vaccine or if not administered within 30 minutes.
- Contact MPC or Monitor (at home if needed) for replacement number.

ADVERSE EXPERIENCE

body temporally associated with any use of a "Any unfavorable and unintended change in the structure, function, or chemistry of the Merck product in humans." Whether or not considered related to the use of the product



ADVERSE EXPERIENCES

AE NO

Pre-existing condit

RECURRENCE/WORSENING

of a pre-existing condition

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CLASSIFYING AES BY NTENSIT

Awareness of symptom, but easily tolerated.

Moderate:

Definitely acting like something is wrong.

Severe:

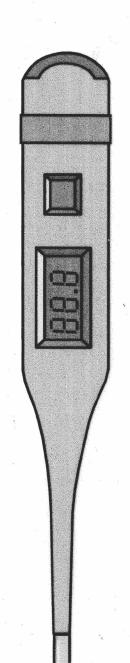
Extremely distressed or unable to do usual activities.

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SAFETY MEASUREMENTS

occurring 42 days after each injection must be All AEs, whether systemic or injection-site reported.

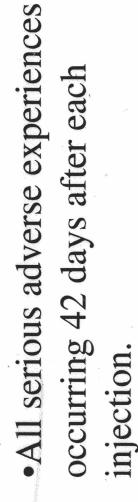
temperatures for 42 days after each injection. Parent/guardian will record numerical



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SAFETY MONITORING

Report to Merck within 24 hours



 Only vaccine-related SAEs after Day 42 through Day 365.



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SERIOUS ADVERSE EVENTS

- Is life threatening.
- Results in a persistent or significant disability or incapacity.
- Results in or prolongs an existing in-patient hospitalization.
- Is a congenital anomaly or birth defect.
- Is cancer.
- Is the result of an overdose.
- Other important medical event – (ex. Febrile seizures)



AES MUST BE REPORTEL

Serious AEs - within 24 hours to one of the individuals listed on the SPONSOR contact page of the protocol (usually via MPC):

Megan McBride

Kara Stockett

(610) 397-2941 **(610)** 397-2207

Scott Thaler, M.D. 🖀 (6

(610) 397-2625

All AEs are to be recorded on case report

torms

RASHES

- Measles or rubella-like and/or varicella-like rashes should be seen by study physician.
 - varicella or zoster should be documented Exposure to measles, mumps, rubella,



the appropriate CRF



Case: 23-2553

RASHES

(cont'd)

mumps, mumps-like symptoms, varicella If a child is thought to have measles, rubella, measles or rubella-like rash, varicella-like rash or zoster: Collect exposure information and complete appropriate CRFs.



Date Filed: 11/01/2023 Page: 419 Document: 42

STUDY DURATION

Subject has completed study if:

42 days of safety follow-up after each

vaccination.

Pre- and Post-vaccination serum samples Received all scheduled vaccinations, and

obtained.

Date Filed: 11/01/2023 Page: 420

CONFIDENTIALITY

- affirms that information furnished by MRI By signing the protocol the investigator will be maintained in confidence.
- under the understanding of confidentiality. affiliated institution; and employees only Information will be provided to the IRB;
- Records must be maintained in a secure location.

Date Filed: 11/01/2023 Page: 421

PUBLICATIONS

- We will establish a publications committee during the trial.
- MRL must review all publications 60 days prior to submission.
- confidential must be deleted from any Information identified by MRL as publication.

IRB APPROVAL

supplies will be shipped. For continuing Written approval from the IRB must be must be sent to MRL at intervals not to studies, written approval from the IRB forwarded to MRL before clinical exceed one year.

Date Filed: 11/01/2023 Document: 42 Page: 423 Case: 23-2553

STUDY REQUIREMENTS

IRB approval of protocol/consents.

FDA 1572 Form.

Signed Protocol/Completed Title Page.

Copy of approved consent forms.

CVs for all personnel working on study.

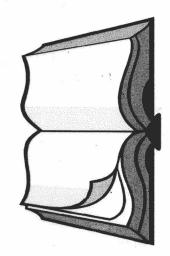
Pre-study site visit (Merck MRA).

IRB Compliance Letter

Date Filed: 11/01/2023

ADMINISTRATIVE BINDER

- Merck Contacts.
- Protocol/Amendments.
- Consent Form.
- IRB Approval.
- Personnel Signature Page.
- Allocation Numbers/Study Enrollment Log.

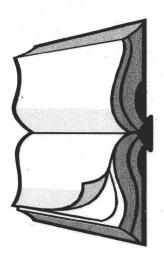


Case: 23-2553

ADMINISTRATIVE BINDER

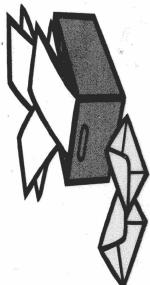
(cont'd)

- Data Collection Forms/Instructions.
- Vaccine Storage/Temperature Log.
- Vaccine Accountability/Returns
- Good Clinical Practices.
- Serious AEs.
- Merck Monitoring Log.
- Correspondence.



RECORDS RETENTION

directives require documentation pertaining investigator for a minimum of 2-years after notification by MRL, or longer if requested to a clinical trial must be retained by the Government agency regulations and by MRL.



Date Filed: 11/01/2023

MEDICAL PROGRAM COORDINATOR



Primary contact for study information.

- Serious Adverse Experiences

Responsible for study initiation, data collection and review.

Summarization of study findings.



MERCK CONTACTS

Clinical Monitor

Scott Thaler, M.D.

(610) 397-2625

FAX (610) 397-3371

Medical Program Coordinators

Megan McBride

(610) 397-2941

FAX (610) 397-3371

Kara Stockett

(610) 397-2207

FAX (610) 834-7555

ING AND SHI

• * .

Megan McBride and Kara Stocket Presenters:

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AGENDA

Supplies received from Merck

Checklist for shipping serum samples

Packaging and shipping demonstration

Federal Express Form

Investigator mem

Date Filed: 11/01/2023 Page: 431 Document: 42

FROM MERCK (via MPC SUPPLIES RECEIVED

Barcoded Labels for Vials

Cell Boxes

Shipping Boxes

Shipping Labels (as needed

Date Filed: 11/01/2023 Page: 432 Document: 42

CHECKLIST FOR SHIPPING VACCINE SERA SAMPLES

- All samples MUST be in standard Merck-provided vials.
- Vials should not be overfilled (sera expands with freezing).
- Caps on vials must be tight to prevent leakage.
- All sera (not whole blood) must be frozen at the time of shipment
- Do <u>not</u> use parafilm or any other sealing device on Merck vials.

LABELS

Use only Merck-provided barcoded labels on the sample vials

** If the correct label for a specific sample is not available information on the vial with a non water-based writing refers specifically to one sample. Print the following utensil: V# Study # Case # Bleed Date Patient do not use any other barcoded label -- each barcode Initials Bleed Interval No other non-Merck labels should be affixed on top of the barcoded labels

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ABELS (contd

- Only initials and sample date are to be written on barcoded labels.
- Use indelible ink to write on labels.
- DO NOT use correction fluid
- DO NOT write over or change any bar-coded information (Case #, Study #, etc.)

Each barcode is unique in the database and specific to that particular sample.

Date Filed: 11/01/2023 Page: 435

ABELS (contd.

- Labels should be affixed so sample volumes may be seen and barcodes appear horizontally on vials.
- Date format on labels must match the date format on IN sheet (MM/DD/YY or DD/MM/YY).
- If the bar-coded labels do not adhere to the sample vial for any reason, affix with one strip of clear tape so that the barcode is clear and legible.

INVENTORY LIST (IN Form)

Include white & yellow copies of IN sheet in each shipment

Retain pink copy of the IN form at the site.

Samples will not be inventoried if they are not accompanied by a completed IN form. List Case #, Bleed Interval, & Bleed Date on the IN form for each sample

listed on the IN sheet along with the bleed interval Samples will not be inventoried without being and bleed date.

Date Filed: 11/01/2023

NVENTORY LIST (contd.)

SAMPLES ARE TO BE PLACED IN THE CELL **BOXES IN THE SAME ORDER AS THEY ARE** LISTED ON THE IN FORM. This is critical in order to expedite the movement of samples and ultimately to obtain assay results.

All comments/error corrections on IN form must be initialed and dated.

SA CELL DOVER

tor storage of serum vials 54 CELL BOXES

- Order of samples in cell box must match order in which they are listed on the IN form.
- Vials must be upright in cell boxes.
- (rubber band or tape) so that all vials will When full, cell box must be secured shut remain in the cell box in transit

Date Filed: 11/01/2023 Page: 439 Document: 42 Case: 23-2553

SHIPPING BOXES

- Sufficient dry ice must be included to keep samples frozen & hold cell box securely
- Use 10 lbs (~4.5 kg) of dry ice
- On outside of shipping box, write
- Investigator name
- Vaccine Name (M-M-RTMII)
- Study number (007-XXX

SHIPPING BOXES (contd.

Shipping container must be marked or labeled "KEEP FROZEN at -20°C".

Dangerous Goods Shippers Declaration form. Use a regular FEDEX shipping form and check the box that asks whether Place Dry Ice stickers on outside of shipping container. Dry Ice is a dangerous good but it does not require a Dry Ice is contained in the shipment. IATA regulations require a BIOHAZARD label to be placed on the outside of any shipment which contains biological specimens. This does not signify that the samples are infectious.

GENERAL

Serum samples should be shipped only on Mondays or **Tuesdays** by overnight express mail (Federal Express).

Notify the MPC prior to shipping out and give the following information:

V#, Study #, # of samples, and # of shipping containers/boxes. Do not send any CRFs or other correspondence with the IN form and samples.

Date Filed: 11/01/2023 Page: 442 Document: 42

OF SERA ADDRESS FOR SHIPMENT

Asst. Medical Program Coordinator Building 26 Research Stockroom Merck Research Laboratories West Point, PA 19486 USA Ms. Kyna De Horsey Sumneytown Pike

(215) 652-0925 Telephone:

(215) 652-6314 Facsimile:

PACKAGING & SHIPPING OF DIAGNOSTIC SAMPLES

(Based on IATA Packing Instructions 650)

INNER PACKAGING

- Leak-proof primary receptacle (Merck standard tubes) where the maximum quantity of substance does not exceed 100 mL.
- receptacles (Merck standard cell boxes) to prevent contact Compartmentalized containers for multiple primary and/or breakage.
- Absorbent material (durasorb pads) between primary and secondary packaging.
- maximum quantity of substance does not exceed 500 mL. Leak-proof secondary packaging (plastic bag) where the

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PACKAGING & SHIPPING OF DIAGNOSTIC SAMPLES

TER PACKAGING

- Must be of adequate strength
- "Non-infectious Clinical Samples" Mark "Diagnostic Specimen" or
- Label with orange "Biohazard" sticker (OSHA standard)

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PACKAGING & SHIPPING OF DIAGNOSTIC SAMPLES

- used as a refrigerant in the transport of clinical samples. should NOT be marked as a dangerous good when Dry Ice is a dangerous good in and of itself, but it
- (Shippers' Declaration not required) On Fedex Form, Check "Dry Ice"
- Place "Dry Ice" label on outside of shipping container

Attention to detail prior to shipment of sera will result in less time spent resolving data issues later

Sera cannot be delivered to assay lab at Merck until all data issues are resolved

handling sera are adequately trained Make sure all personnel involved in

10/25/2019 Declaration of G. Reilly EXHIBIT 120

To: Simon, Keiko[simonkei@NorthAmerica.msx.merck.com]

Cc: Krah, David[Krahda@NorthAmerica.msx.merck.com]; Byrnes, Vera

D.[BYRNESV@NorthAmerica.msx.merck.com]; Staub, Joan

M.[STAUBJ@NorthAmerica.msx.merck.com]; Arena, Deitra E.[loydei@NorthAmerica.msx.merck.com];

Yagodich, Mary[Yagodicm@NorthAmerica.msx.merck.com]; Shaw,

Alan[Shawal@NorthAmerica.msx.merck.com]

From: Arena, Deitra E.

Sent: Fri 6/16/2000 12:46:37 PM

Importance: High

Subject: Backgrounder for CAS, 6/20/00 MPS Nt backgrounder for June 20 CAS.doc

June CAS Table 3.xls June CAS Table 4.xls June CAS Table 5.xls June CAS, Table 6.doc June CAS, Table 7.doc

Microsoft Word - MPS Nt backgrounder for June 20 CAS.pdf

Keiko

Attached is the Background document for CAS in pdf format.

Deitra

From:

Krah, David

Sent:

Friday, June 16, 2000 8:06 AM

To:

Staub, Joan M.; Arena, Deitra E.; Yagodich, Mary; Shaw, Alan

Subject:

REvised MPS Nt backgrounder for CAS

All,

Attached is a re-revised backgrounder for the MPS Nt presentation to CAS. I had reversed some of the discussion on different viruses (tables 3 and 4)-These are now correct.

Thanks,

Dave

Pilot Study of Mumps Nt Titers for Pediatric Sera

TABLE 4

Serum	Nt Titer Against Indicator Mumps			
Sample	Vaccin	e JL135 p8	<u>LO1</u>	
48	4 1024	1024	128	
15	2 512	256	64	
21	1 256	256	32	
3	8 512	128	16	
6	7 512	256	256	
20	7 256	128	16	
21	6 256	128	32	
13	1 512	256	32	
13	2 256	64	64	
13	5 256	64	64	
22	4 256	128	32	
26	7 256	128	64	
41	9 512	256	512	
42	2 512	<64	32	
45	6 256	<64	32	
51	4 128	256	32	
	3 128	64	64	
12	9 128	64	64	
13	8 128	64	32	
51	9 128	128	64	
23	7 128	256	16	
26	4 128	64	32	
26	5 128	64	32	

MKY/DK 5/5/00

Comparison of Mumps Nt Titers for Adult Sera Using different Indicator Viruses

TABLE 3

	Neutralization titler against mumos indicator virus				
Serum	Barnes	TN	Lo1	JL-135	JL-vaccine
MKY	<2, 8, 8	nd, 8, 8	nd, 8, 16	4, 16, 16	2, 8, 4
DK	<2, nd, nd	nd, nd, nd	nd, nd, nd	4, nd, nd	2, nd, nd
AS	32, 32, 64	nd, 32, 64	nd, 64, 64	64, 128, 64	64, 64, 128
CM	<32, 32, 64	nd, 64, 64	nd, 32, 64	128, 128, 256	128, 256, 128
PK	32, 32, 32	nd, 32, 32	nd, 64, 64	128, 256, 256	128, 128, 128
DW	512, 256, 256	nd, 512, 1024	nd, 512, 512	1024, 1024, 1024	1024, 1024, 1024

ND = not tested

DK 8June 2000

Mumps Plaque-Reduction Neutralization Assay Development Update Backgrounder

June 20, 2000 CAS presentation

CONFIDENTIAL

MRK-KRA00026469 MRK-CHA00026469

I. Executive Summary

A plaque-reduction neutralization assay using a low-passage Jeryl Lynn™ preparation is being optimized for use in evaluation of sera from the M-M-R®II Expiry Trial, with a goal of providing an assay that permits measurement of a ≥95% seroconversion rate. The low-passage Jeryl Lynn™ virus has provided neutralization titers closest to those obtained using the vaccine-passage Jeryl Lynn™, and plaques are visualized by immunostaining. Optimization of the concentration of anti-human IgG for enhancement of the neutralization is underway. The utility of the Spearman-Karber method to calculate titers is also being considered as a final refinement to maximize the capacity of the assay to detect seroconversions.

II. Background and status of assay development

A need for a mumps neutralization (Nt) assay utilizing a wild-type indicator virus has been identified to support analysis of the immune responses to mumps in the ongoing M-M-R®II Expiry Trial (Protocol 007). Efforts to date have focused on evaluating conditions that affect assay sensitivity and in defining a suitable indicator virus in a multi-well plate plaque-reduction neutralization assay (PRN).

A summary of the mumps strains and some of the virus growth and assay parameters evaluated is presented in Table 1. Previous studies comparing neutralization titers to sera from adult lab volunteers (who had either wild-type infections or mumps vaccine-induced responses) and pediatric sera showed an effect of the virus strain on neutralization titers, with the highest seroconversion rates and titers observed for the vaccine-passage of Jeryl Lynn™ mumps. CBER has indicated that the vaccine passage Jeryl Lynn™ is not suitable for use in the PRN and has established a requirement to use a "wild-type" mumps strain to evaluate vaccine-induced immune responses. A range of wild-type isolates were therefore obtained and evaluated in the PRN to identify the optimum indicator strain. In early testing, the Tennessee (TN) isolate provided Nt titers close to those obtained using Jeryl Lynn™, but further evaluation of this strain was aborted due to difficulties in reliably detecting plaques. Several plaque staining methods were evaluated, including Coomassie Blue (general cell stain) and neutral red or tetrazolium salts (vital stains), without consistent success.

In addition to "mechanical" aspects of the assay (incubation times and temperatures, virus attachment times), two supplements were evaluated for their capacity to increase the Nt sensitivity. Complement supplementation provided modest titer increases for adult sera and was complicated by the anti-mumps activity of the complement sera. Further evaluation of this reagent was therefore not pursued. A second supplement, anti-human Ig, was evaluated to confirm its ability to increase Nt titers (approximately 100-fold titer increases), but was not immediately pursued.

Subsequent studies shifted to use the London 1 strain (Lo1) of mumps, which was also used in studies performed at CBER. This strain met the criterion of being a "wild-type" virus and became the "virus of choice" for development of

the PRN. Results of a series of pilot PRN assays of pediatric sera against Jeryl Lynn™, Lo1 and JL2 mumps strains showed respective seroconversion rates of 91% (63/69), 69% (43/62) and 56% (18/32). Testing of 169 paired sera from Protocol 006 (Competitive Trial) confirmed that the general assay format using Lo1 mumps would not provide the targeted ≥95% seroconversion rate.

In parallel with the studies of Lo1 mumps, a sample of SBL-1 mumps (reportedly antigenically similar to Jeryl Lynn™) was obtained and evaluated in the PRN assay. SBL-1 mumps did not provide increased Nt performance versus Lo1 using a panel of pediatric and adult sera (Table 2).

Through discussion with CBER staff, the following suggestions and comments were made for evaluation in increasing the sensitivity of the PRN:

- The use of "Low-passage" JL (between passages 7 and 12) would be acceptable
- Consider assay format used by Dr. Bagher Forghani (the State of California Department of Health Services) that reportedly provides >90% seronversion rates
- Immunostaining (distinct "plaques" observed 3 days post- infection for all mumps strains tested in our hands).
 - Assay performed in 48-well plates
 - Evaluate the Barnes strain of mumps
- Consider using anti-human IgG to enhance Nt sensitivity
- · Consider using the Spearman-Karber method to calculate Nt titers

In response to these suggestions, stocks of the Barnes and low-passage Jeryl Lynn™ (lot 135 [passage 7], used at passage 8 in PRN assays) were obtained and evaluated in the PRN. Due to the low-cytolytic activity of these viruses, immunostaining (polyclonal goat anti-mumps antibody, peroxidase-labeled anti-goat IgG and peroxidase substrate) was adopted for detection of plaques. The immunostaining method was found to be universally applicable to detect mumps plaques (for all available strains), and therefore also permitted reevaluation of previous strains such as TN. The 48- and 24-well plate formats (as alternatives to the 12-well plate format used in our previous studies) proved to be technically inconvenient for sample inoculation and were not pursued further.

Results of preliminary Nt assays using vaccine-passage ("house standard") and low-passage (lot 135, passage 8) Jeryl Lynn™ mumps showed that Nt titers for adult lab volunteer sera using these indicator viruses were comparable Table 3). A series of assays was done using adult lab volunteer sera and Barnes, TN, Lo1, low-passage (lot 135, P8) Jeryl Lynn™ and vaccine passage Jeryl Lynn™ mumps as indicator viruses to determine the relative Nt for the different viruses (Table 4). Nt titers to the low-passage lot 135 Jeryl Lynn™ mumps were comparable to those obtained using the vaccine-passage virus, and greater by 2-4-fold than those to Lo1, TN or Barnes mumps. TN and Lo1 titers were comparable and approximately 2-fold higher than those to the Barnes strain of mumps. Screening of a panel of 23 pediatric sera (selected to have a titer ≥128 to permit assay using small serum volumes) showed that Nt titers to the vaccine-passage virus were approximately 2-fold higher than those to the low-passage

Jeryl Lynn™ and approximately 4-fold higher than those to Lo1. The low-passage Jeryl Lynn™ virus therefore provides Nt sensitivity most close to the vaccine-passage virus.

The use of the Spearman-Karber method to interpolate titers is expected to provide an increased number of seroconversions, but not to the targeted ≥95% value. It is therefore expected that further enhancement of Nt by addition of antihuman IgG will be required. Previous studies demonstrated that this enhancement boosted post-vaccination titers approximately 100-fold, but the effect on pre-vaccination titers was not measured. In pilot studies, undiluted antihuman IgG provided positive titers to 75% of the pre-vaccination sera (9/12: titers ranging from 32 to 128) and 8-64-fold increases in post-vaccination titers, while lower amounts (1:2, 1:4 or 1:8 dilutions) of anti-lgG provided comparable enhancement of post-vaccination titers, but retained negative titers for 3/3 prevaccination sera (Table 5). The use of 1:4 or 1:8 dilutions of anti-IgG in a second study retained negative Nt responses for pre-vaccination sera (tested at an initial 1:32 dilution), and provided increases in titers for all three postvaccination sera (Table 6). Results of a third experiment, using sera that previously provided titers of <2, 2 or 4, showed that a 1:2 dilution of anti-IgG permitted measurement of titer enhancements for all post-vaccination sera (Table 7). The amount of anti-IgG used in this study also resulted in positive Nt responses for several of the pre-vaccination sera. Current studies are focusing on determining the optimum concentration of anti-IgG to boost post-vaccination titers but not shift pre-vaccination sera to a positive Nt response.

III. Path forward

The proposed assay format will include:

- 12-well plate format
- Low-passage Jeryl Lynn™ indicator virus
- · Enhancement of Nt with anti-human IgG
- Detection of plaques by immunostaining
- Calculation of Nt titers by 50% cutoff or Spearman-Karber method

Current studies (4-5 weeks) are designed to determine the optimum amount of anti-IgG for Nt enhancement while retaining negative titers for pre-vaccination sera. An evaluation can then be made of the effect of using the "50% Nt" cutoff (highest tested dilution tested that provides ≥50% Nt) versus the Spearman-Karber titer interpolation to finalize the assay format. It is proposed that the optimized assay format will then by applied to the sera from Protocol 006 (4 weeks after finalization of the assay format) to provide an estimate of the seroconversion rates detected.

Issues remaining to be addressed include:

- Serum dilutions to be tested
 - -the assay produces a "prozone" effect at dilutions approximately ≤32

-post-vaccination titers are expected to be increased approximately 100-fold

- Impact if a significant proportion of pre-vaccination sera register as Nt positive
- Impact if testing of "pre-evaluation" panel provides <95% seroconversion
- Transfer of the optimized assay

Table 1 Factors evaluated for effects on Mumps Nt sensitivity

Indicator virus
 Jeryl Lynn™
 Swiss isolates
 NY
 TN
 SA
 Jones
 Enders
 Lo1
 JL2
 JL5
 SBL-1
 Barnes
 Select viruses passaged in CEF vs Vero (Lo1, TN, Enders, Jones)

- Incubation time and temperature of virus and serum
- · Virus concentration
- · Virus harvest fractions and clarification methods
- · Cell substrate for virus stock growth
- Staining method for plaque visualization (Coomassie Blue, neutral red, tetrazolium salts, immunostaining)
- · Virus attachment time
- Enhancements to Nt

 Complement (≤8-fold enhancement)

 anti-human IgG (~100-fold enhancement)

Table 2
Evaluation of PRN Titers Using Jeryl Lynn™, Lo1 and SBL-1 Mumps Strains

Seru	<u>m</u>		Nt titer using	
		Jeryl Lynn™	Lo1	SBL-1
1	pre	<8	<8	<8
	post	16	<8	8
2	pre	<8	16	<8
	post	16	8	<8
3	pre	not tested		
	post	<8	<8	<8
4	pre	not tested		
	post	8	8	<8
5	pre not tested			
	post	16	8	<8
6	pre	<8	<8	<8
	post	16	32	<8
7	pre	<8	<8	<8
	post	<8	<8	<8
8	pre	<8	<8	<8
	post	16	16	<8
Adult control 1		≥128	32	16
	t control 2	16	16	4
Adul	t control 3	1024	512	256

Comparison of Mumps Nt Titers for Adult Sera Using different Indicator Viruses

TABLE 3
Neutralization titer against mumps indicator virus

	All the property of the proper		Country to be stored in this fig. 1987 - 1987 III		
Serum	Barnes	TN	Lo1	JL-135	JL-vaccine
MKY	<2, 8, 8	nd, 8, 8	nd, 8, 16	4, 16, 16	2, 8, 4
DK	<2, nd, nd	nd, nd, nd	nd, nd, nd	4, nd, nd	2, nd, nd
AS	32, 32, 64	nd, 32, 64	nd, 64, 64	64, 128, 64	64, 64, 128
CM	<32, 32, 64	nd, 64, 64	nd, 32, 64	128, 128, 256	128, 256, 128
PK	32, 32, 32	nd, 32, 32	nd, 64, 64	128, 256, 256	128, 128, 128
DW	512, 256, 256	nd, 512, 1024	nd, 512, 512	1024, 1024, 1024	1024, 1024, 1024

ND = not tested

DK 8June 2000

Pilot Study of Mumps Nt Titers for Pediatric Sera

TABLE 4

Serum	Nt Titer Against Indicator Mumps		
Sample	Vaccine	JL135 p8	LO1
484	1024	1024	128
152	512	256	64
211	256	256	32
38	512	128	16
67	512	256	256
207	256	128	16
216	256	128	32
131	512	256	32
132	256	64	64
135	256	64	64
224	256	128	32
267	256	128	64
419	512	256	512
422	512	<64	32
456	256	<64	32
514	128	256	32
3	128	64	64
129	128	64	64
138	128	64	32
519	128	128	64
237	128	256	16
264	128	64	32
265	128	64	32

MKY/DK 5/5/00

Effect of Anti-Human IgG Treatment on Mumps Nt Titers

TABLE 5

455 undiluted 455 1:2 455 1:4 455 1:8 455 mock anti lgG	321 undiluted 321 1:2 321 1:4 321 1:8 321 mock anti lgG	sample # anti human lgG dil 238 undiluted 238 1:2 238 1:4 238 1:8 238 mock anti lgG
32 432 432 432	32 <32 <32 <32	Pre serum Nt titer 128 128 256 256 232
>=2048 >=2048 >=2048 >=2048 >=2048	>=2048 >=2048 >=2048 >=2048 >=2048	Nt titer >=2048 >=2048 >=2048 >=2048 >=2048 >=32

Table 6
<u>Enhancement of Mumps Neutralization with Anti-Human IgG</u>

Serum <u>#</u> 98	Nt tite 1:4* <32	er to Pr 1:8* <32	re-serum <u>Mock*</u> <32	at anti-lgG <u>Historical</u> <2	Nt titer to Post-serum at anti-IgG 1:4 24096 ≥4096 <32 32
99	<32	<32	<32	<2	2048 2048 <32 8
101	<32	<32	<32	<2	2048 2048 128 128

^{* =} dilution of anti-human IgG Nt titers with anti-IgG = using Low passage Jeryl Lynn™ Historical titer = using Jeryl Lynn™ vaccine passage without anti-IgG treatment

DK 15 June 2000

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Table 7 Enhancement of Mumps Neutralization Using Anti-Human <u>lgG</u>

Serum ¹	Nt titer t	o low-pa	ssage Jer	yl Lynn™	Nt titer ² to
	Pre +	Pre +	Post +	Post +	Jeryl Lynn™
	anti-IgG	³ PBS	anti-IgG	<u>PBS</u>	Pre Post
147	32	<16	≥512	<16	<2 <2
291	<16	<16	256	<16	<2 <2
4	≥64	<16	≥512	<16	<2 2
80	<16	<16	128	<16	<2 2
212	≥64	<16	128	<16	<2 2
145	<16	<16	≥512	<16	<2 4
234	<16	<16	≥512	<16	<2 4
235	≥64	<16	256	<16	<2 4
199	not test	ed	≥4096	32	<2 32

¹Pediatric sera (protocol 006) ² Historical titers ³Anti-human IgG used at 1:2 dilution

Table 6
Enhancement of Mumps Neutralization with Anti-Human IgG

Serum <u>#</u> 98	Nt tite 1:4* <32	er to Pr 1:8* <32	e-serum Mock* <32	at anti-IgG <u>Historical</u> <2	Nt titer to Post-serum at anti-IgG 1:4 1:8 Mock Historical ≥4096 ≥4096 <32 32
99	<32	<32	<32	<2	2048 2048 <32 8
101	<32	<32	<32	<2	2048 2048 128 128

^{* =} dilution of anti-human IgG Nt titers with anti-IgG = using Low passage Jeryl Lynn™ Historical titer = using Jeryl Lynn™ vaccine passage without anti-IgG treatment

DK 15 June 2000

Effect of Anti-Human IgG Treatment on Mumps Nt Titers

TABLE 5

		Pre serum	Post Serum
sample #	anti human lgG dil	Nutiter	Nutiter
	238 undiluted	128	>=2048
	238 1:2	128	>=2048
	238 1:4	256	>=2048
	238 1:8	256	>=2048
	238 mock anti IgG	<32	32
	321 undiluted	32	>=2048
	321 1:2	<32	>=2048
	321 1:4	<32	>=2048
	321 1:8	<32	>=2048
	321 mock anti IgG	<32	32
	455 undiluted	32	>=2048
	455 1:2	<32	>=2048
	455 1:4	<32	>=2048
	455 1:8	<32	>=2048
	455 mock anti lgG	<32	32

Effect of Anti-Human IgG Treatment on Mumps Nt Titers

DK, 8 June 2000

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Table 7 Enhancement of Mumps Neutralization Using Anti-Human <u>lgG</u>

Serum ¹	Nt titer	to low-pa	ssage Je	ryl Lynn™	Nt titer2 to
	Pre +	Pre +	Post +	Post +	Jeryl Lynn™
	anti-lg@	B ³ PBS	anti-IgG	PBS	Pre Post
147	32	<16	≥512	<16	<2 <2
291	<16	<16	256	<16	<2 <2
4	≥64	<16	≥512	<16	<2 2
80	<16	<16	128	<16	<2 2
212	≥64	<16	128	<16	<2 2
145	<16	<16	≥512	<16	<2 4
234	<16	<16	≥512	<16	<2 4
235	≥64	<16	256	<16	<2 4
199	not test	ed	≥4096	32	<2 32

¹Pediatric sera (protocol 006) ² Historical titers ³Anti-human IgG used at 1:2 dilution

Mumps Plaque-Reduction Neutralization Assay Development Update Backgrounder

June 20, 2000 CAS presentation

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MRK-KRA00026484 MRK-CHA00026484 Case: 23-2553 Document: 42 Page: 468 Date Filed: 11/01/2023

I. Executive Summary

A plaque-reduction neutralization assay using a low-passage Jeryl Lynn™ preparation is being optimized for use in evaluation of sera from the M-M-R®II Expiry Trial, with a goal of providing an assay that permits measurement of a ≥95% seroconversion rate. The low-passage Jeryl Lynn™ virus has provided neutralization titers closest to those obtained using the vaccine-passage Jeryl Lynn™, and plaques are visualized by immunostaining. Optimization of the concentration of anti-human IgG for enhancement of the neutralization is underway. The utility of the Spearman-Karber method to calculate titers is also being considered as a final refinement to maximize the capacity of the assay to detect seroconversions.

II. Background and status of assay development

A need for a mumps neutralization (Nt) assay utilizing a wild-type indicator virus has been identified to support analysis of the immune responses to mumps in the ongoing M-M-R®II Expiry Trial (Protocol 007). Efforts to date have focused on evaluating conditions that affect assay sensitivity and in defining a suitable indicator virus in a multi-well plate plaque-reduction neutralization assay (PRN).

A summary of the mumps strains and some of the virus growth and assay parameters evaluated is presented in Table 1. Previous studies comparing neutralization titers to sera from adult lab volunteers (who had either wild-type infections or mumps vaccine-induced responses) and pediatric sera showed an effect of the virus strain on neutralization titers, with the highest seroconversion rates and titers observed for the vaccine-passage of Jeryl LynnTM mumps. CBER has indicated that the vaccine passage Jeryl LynnTM is not suitable for use in the PRN and has established a requirement to use a "wild-type" mumps strain to evaluate vaccine-induced immune responses. A range of wild-type isolates were therefore obtained and evaluated in the PRN to identify the optimum indicator strain. In early testing, the Tennessee (TN) isolate provided Nt titers close to those obtained using Jeryl LynnTM, but further evaluation of this strain was aborted due to difficulties in reliably detecting plaques. Several plaque staining methods were evaluated, including Coomassie Blue (general cell stain) and neutral red or tetrazolium salts (vital stains), without consistent success.

In addition to "mechanical" aspects of the assay (incubation times and temperatures, virus attachment times), two supplements were evaluated for their capacity to increase the Nt sensitivity. Complement supplementation provided modest titer increases for adult sera and was complicated by the anti-mumps activity of the complement sera. Further evaluation of this reagent was therefore not pursued. A second supplement, anti-human Ig, was evaluated to confirm its ability to increase Nt titers (approximately 100-fold titer increases), but was not immediately pursued.

Subsequent studies shifted to use the London 1 strain (Lo1) of mumps, which was also used in studies performed at CBER. This strain met the criterion of being a "wild-type" virus and became the "virus of choice" for development of the PRN. Results of a series of pilot PRN assays of pediatric sera against Jeryl LynnTM, Lo1 and JL2 mumps strains showed respective seroconversion rates of

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MRK-KRA00026485 MRK-CHA00026485

91% (63/69), 69% (43/62) and 56% (18/32). Testing of 169 paired sera from Protocol 006 (Competitive Trial) confirmed that the general assay format using Lo1 mumps would not provide the targeted ≥95% seroconversion rate.

In parallel with the studies of Lo1 mumps, a sample of SBL-1 mumps (reportedly antigenically similar to Jeryl Lynn™) was obtained and evaluated in the PRN assay. SBL-1 mumps did not provide increased Nt performance versus Lo1 using a panel of pediatric and adult sera (Table 2).

Through discussion with CBER staff, the following suggestions and comments were made for evaluation in increasing the sensitivity of the PRN:

- The use of "Low-passage" JL (between passages 7 and 12) would be acceptable
- Consider assay format used by Dr. Bagher Forghani (The State of California Department of Health Services) that reportedly provides >90% seronversion rates
 - Immunostaining (distinct "plaques" observed 3 days post-infection for all mumps strains tested in our hands).
 - Assay performed in 48-well plates
 - Evaluate the Barnes strain of mumps
- · Consider using anti-human IgG to enhance Nt sensitivity
- Consider using the Spearman-Karber method to calculate Nt titers

In response to these suggestions, stocks of the Barnes and low-passage Jeryl Lynn™ (lot 135 [passage 7], used at passage 8 in PRN assays) mumps viruses were obtained and evaluated in the PRN. Due to the low-cytolytic activity of these viruses, immunostaining (polyclonal goat anti-mumps antibody, peroxidase-labeled anti-goat IgG and peroxidase substrate) was adopted for detection of plaques. The immunostaining method was found to be universally applicable to detect mumps plaques (for all available strains), and therefore also permitted re-evaluation of previous strains such as TN. The 48- and 24-well plate formats (as alternatives to the 12-well plate format used in our previous studies) proved to be technically inconvenient for sample inoculation and were not pursued further.

A panel of adult lab volunteer sera was tested against Barnes, TN, Lo1, low-passage (lot 135, P8) Jeryl Lynn™ and vaccine passage Jeryl Lynn™ mumps indicator viruses to determine the relative Nt for the different viruses (Table 3). Nt titers to the low-passage lot 135 Jeryl Lynn™ mumps were comparable to those obtained using the vaccine-passage virus, and greater by 2-4-fold than those to Lo1, TN or Barnes mumps. TN and Lo1 titers were comparable and approximately 2-fold higher than those to the Barnes strain of mumps. Results of testing of a panel of 23 pediatric sera (selected to have a titer ≥128 from previous assays to permit further testing using small serum volumes) showed that Nt titers to the vaccine-passage virus were approximately 2-fold higher than those to the low-passage Jeryl Lynn™ and approximately 4-fold higher than those to Lo1 (Table 4). From the panel of wild-type mumps strains, the low-passage Jeryl Lynn™ virus therefore provides Nt sensitivity most close to the vaccine-passage virus.

The use of the Spearman-Karber method to interpolate titers is expected to provide an increased number of seroconversions, but not to the targeted ≥95%

value. It is therefore expected that further enhancement of Nt by addition of antihuman IgG will be required. Previous studies demonstrated that this enhancement boosted post-vaccination titers approximately 100-fold, but the effect on pre-vaccination titers was not measured. In pilot studies, undiluted antihuman IgG provided positive titers to 75% of the pre-vaccination sera (9/12: titers ranging from 32 to 128) and 8-64-fold increases in post-vaccination titers, while lower amounts (1:2, 1:4 or 1:8 dilutions) of anti-IgG provided comparable enhancement of post-vaccination titers, but retained negative titers for 3/3 prevaccination sera (Table 5). The use of 1:4 or 1:8 dilutions of anti-IgG in a second study retained negative Nt responses for pre-vaccination sera (tested at an initial 1:32 dilution), and provided increases in titers for all three post-vaccination sera (Table 6). Results of a third experiment, using sera that previously provided titers of <2, 2 or 4, showed that a 1:2 dilution of anti-IgG permitted measurement of titer enhancements for all post-vaccination sera (Table 7). The amount of anti-IgG used in this study also resulted in positive Nt responses for several of the prevaccination sera. Current studies are focusing on determining the optimum concentration of anti-IgG to boost post-vaccination titers but not shift prevaccination sera to a positive Nt response.

III. Path forward

The proposed assay format will include:

- · 12-well plate format
- Low-passage Jeryl Lynn™ indicator virus
- Enhancement of Nt with anti-human IgG
- Detection of plaques by immunostaining
- Calculation of Nt titers by 50% cutoff or Spearman-Karber method

Current studies (4-5 weeks) are designed to determine the optimum amount of anti-IgG for Nt enhancement while retaining negative titers for pre-vaccination sera. An evaluation can then be made of the effect of using the "50% Nt" cutoff (highest tested dilution tested that provides ≥50% Nt) versus the Spearman-Karber titer interpolation to finalize the assay format. It is proposed that the optimized assay format will then by applied to the sera from Protocol 006 (4 weeks after finalization of the assay format) to provide an estimate of the seroconversion rates detected.

Issues remaining to be addressed include:

- · Serum dilutions to be tested
 - -the assay produces a "prozone" effect at dilutions approximately ≤32
 - -post-vaccination titers are expected to be increased approximately 100-fold
- · Impact if a significant proportion of pre-vaccination sera register as Nt positive
- Impact if testing of "pre-evaluation" panel provides <95% seroconversion
- · Transfer of the optimized assay

Table 1 Factors evaluated for effects on Mumps Nt sensitivity

· Indicator virus

Jeryl Lynn™

Swiss isolates

NY

TN

SA

Jones

Enders

Lo₁

JL2

JL5

SBL-1

Barnes

Select viruses passaged in CEF vs Vero (Lo1, TN, Enders, Jones)

- Incubation time and temperature of virus and serum
- · Virus concentration
- · Virus harvest fractions and clarification methods
- · Cell substrate for virus stock growth
- Staining method for plaque visualization (Coomassie Blue, neutral red, tetrazolium salts, immunostaining)
- · Virus attachment time
- Enhancements to Nt

Complement (≤8-fold enhancement) anti-human IgG (~100-fold enhancement)

Table 2 <u>Evaluation of PRN Titers Using Jeryl Lynn™, Lo1 and SBL-1 Mumps Strains</u>

Seru	ım		Nt titer using	
		Jeryl Lynn™		SBL-1
1	pre	<8	<8	<8
	post	16	<8	8
2	pre	<8	16	<8
	post	16	8	<8
3	pre	not tested		
	post	<8	<8	<8
4	pre	not tested		
	post	8	8	<8
5	pre	not tested		
	post	16	8	<8
6	pre	<8	<8	<8
	post	16	32	<8
7	pre	<8	<8	<8
	post	<8	<8	<8
8	pre	<8	<8	<8
	post	16	16	<8
Adul	t control 1	≥128	32	16
Adul	t control 2	16	16	4
Adul	t control 3	1024	512	256

10/25/2019 Declaration of G. Reilly EXHIBIT 121

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Fechtenburg, Linda

From:

Morsy, Manal A.

Sent:

Sunday, October 10, 1999 1:25 PM Ukwu, Dr. Henrietta; Chirgwin, Keith D.

To:

Fechtenburg, Linda

Cc: Subject:

Re: highlights

Importance:

High

Enclosed please find highlights I drafted for MMRII and MMRV. I left a copy this morning Sunday 10/10 in both of your offices for comments back.

Please note in the MMRII section I have stressed the need for obtaining total particle to infective particle count for all viruses used in the Neut. assay since I believe this is a critical piece of information needed for establishing technical feasibility or limitation of the currently used PRN and CPE assays.

With regards to the MMRV, I have modified slightly over what Keith and I had discussed previously.

I have not included highlights on OGOS, rHA and Japan, three area I have great discomfort with still.

If neither of you have comments back on the highlights I will distribute these out first thing Monday morning (10/11/99)

Thanks for your patients with me through this painful - challenging and exciting all at the same time - learning process



Manal

Case: 23-2553 Page: 475 Date Filed: 11/01/2023 Document: 42



MEMO

TO: Henrietta Ukwu **DATE: October 8, 1999**

CC:

D. Blois, B. Buckland, C.Chan, H. Cohen, E. Emini, P. Kniskern, D. Krah, B. Kuter, L. Kuykens, S. Lenz, J. Lewis, W. Long, D. Margolskee, C. Russo, J. Sadoff, A. Shaw, R. Singhvi, E. Slater, J. Staub, S. Thaler, B. Thompson, R.

Zeldin

FROM:

Manal Morsy

SUBJECT: Monthly Highlights for September 1999 (M-M-R®II and MMRV)

M-M-R®II

End-expiry: The expiry trial has now enrolled ~50% of the subjects (Target 1500). The primary study hypothesis of a SCR ≥90% against WT mumps virus is unlikely to be met and therefore this should be revised either in terms of addressing the hypothesis or addressing the technical limitations of the assays used to date.

The implications of the low neutralizing antibody seroconversion rate in terms of study design and sample size require discussion with CBER. The timing for this discussion is dependent on the timing of the results of the M-M-R®II to Priorix comparison (data will be available by last week of October to 1st week of November).

Mumps neutralizing antibody assay: The results of the mumps plaque reduction neutralization (PRN) and cytopathic effect (CPE) assays were reviewed at the CAS. With JL as the test isolate, the SCR is ~90%, and with L01 as the test isolate, the SCR is ~70-75%. Prior to discussing the unanticipated low SCR for mumps with CBER, the sera from the head-to-head trial with M-M-R®II and Priorix will be assayed to confirm that this low SCR is observed with both products. The current timeline for this analysis is 4-6 weeks. An alternative assay that may overcome some of the potential technical limitations has been discussed. Preliminary data using a high through put OPA based Neut. Assay will be generated to determine if greater sensitivity can be attained (Time line 4Q99 – 1Q01).

The key information requested and elements of the discussion with CBER about the mumps neutralizing antibody assay include:

- 1) review of the arguments that the current WT neutralizing antibody assay may not capture all attributable protective efficacy;
- 2) argue against the use of WT virus in the Neut. assays since SCR against JL is reproducible and confirms label claims using the current Neut. assays;
- 3) review the total particle count to infective virus ratio for JL and the WT viruses (LO1, S. African and Swiss) used in the Neut. assay. If ratios of abortive to infective particle across the 4 viruses are not identical, and if abortive to infective particle ratio in the WT viruses is greater than that in the JL vaccine for which tissue culture growth conditions have been optimized, an argument against using WT viruses can be build supported by the technical

limitations of the PRN and CPE Neut. assays. Technically, both assays can not account for the percent of Neut. antibodies lost to abortive particle (unless the difference in ratios between total particle count and infective virus for each of the viruses is factored in).

4) review the extensive field experience in support of vaccine protective efficacy;

5) revision of the mumps expiry trial study hypotheses (if all viruses used in Neut. assays have similar total particle count to infective particles as found in JL, then we would review the mumps expiry trial study hypotheses and remove >90% SCR hypothesis; retain equivalence hypothesis with consideration of an increase in the equivalence margin to avoid an untenable increase in the sample size).

MMRV

- <u>Filing strategy</u>: The current strategy will be to accelerate MMRV licensure in the U.S. by pursuing a frozen product. The target date for submitting a frozen MMRV BLA is 3Q01. A refrigerated product will be licensed in the U.S. as a variation to the initial frozen quadrivalent. The current target date for submitting this sBLA is 3Q02.

 U.S launch dates approved at TPAC are: Frozen MMRV (3Q02) and 4°C MMRV (3Q03)
- <u>Preparation for End-of-Phase II meeting with CBER</u>: CBER concurrence with the CDP and registration package will be obtained at this meeting.
 <u>Studies proposed for Phase III</u>:
 - 1) Consistency lots: proposed FPI 1Q00.
 - 2) Concomitant use: proposed FPI 2Q00.
 - 3) Expanded safety: proposed FPI 2Q00.
- Outstanding issues requiring further discussion and closure with CBER include:
 - 1) Acceptable surrogate markers: for measles, mumps and rubella. The current serologic (EIA) assays lack an established correlation with protective efficacy and CBER has indicated that a functional antibody assay (e.g. WT Neut) will be required to establish equivalence. However, evidence of a correlation between the current assays and a WT Neut assay, or evidence of correlation with protective efficacy, would allow the current EIA-based assays to be used. This approach may be more feasible with measles and rubella than mumps. The proposed approach to surrogate markers for demonstrating equivalence between MMRV and M-M-R®II plus VARIVAX® will be finalized and confirmed with CBER
 - 2) <u>Demonstration of equivalence</u>: Approach to demonstrating equivalence with the licensed monovalent (VARIVAX®) and trivalent (MMR®II).
 - 3) Statistical criteria for success: The acceptable equivalence margins for each antigen.
 - 4) Expiry dose selection: (minimum acceptable immunogenicity). Preliminary data from the dose-ranging trial (25% accrual) was reviewed. These data will determine whether a feasible expiry dose (function of the maximum manufacturable release dose and estimated stability 28,000 pfu PUVV is the release dose selected in the Consistency lot trial protocol 013) provides adequate immunogenicity. Frozen MMRV must provide equivalent immunogenicity to the licensed monovalent.
 - 5) <u>Consistency evaluation</u>: (details of clinical consistency evaluation, lot selection) protocol reviewed and approved at CDOC Oct. 6
 - 6) Proposed product profile and label

<u>Timing</u>: An End-of-Phase II meeting is a Type B meeting under PDUFA, which means that the meeting should be scheduled to occur within 60 days of the FDA receiving the written

meeting request. The background document <u>must</u> be submitted no later than 30 days before the scheduled meeting date. Since the phase II dose-ranging data are an essential element of this background document, the timing for this CBER meeting is closely linked to the timing of availability of these data. At the present time the plan is to request a meeting for the 2-3 week in December.

MM UN-B121

cc: file, chron

10/25/2019 Declaration of G. Reilly EXHIBIT 122

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1	IN THE UNITED STATES DISTRICT COURT
	FOR THE EASTERN DISTRICT OF PENNSYLVANIA
2	
	UNITED STATES OF AMERICA : CIVIL ACTION
3	ex rel., STEPHEN A. : NO. 2:10-04374(CDJ)
	KRAHLING and JOAN A. :
4	WLOCHOWSKI, :
	Plaintiffs, :
5	:
	vs. :
6	:
	MERCK & CO., INC., :
7	Defendant. :
	: Master File No.
8	IN RE: MERCK MUMPS : 2:12-cv-03555(CDJ)
	VACCINE ANTITRUST :
9	LITIGATION :
	:
10	THIS DOCUMENT RELATES TO: :
	ALL ACTIONS :
11	
12	++ WTGWTV GOVERNMENT AMMODVENG FUNG OVEN ++
13 14	** HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY **
15	T1 11 2017
16	July 11, 2017
17	Videotaped deposition of DAVID KRAH,
18	taken at the offices of Spector Roseman &
19	Kodroff, 1818 Market Street, Suite 2500,
20	Philadelphia, Pennsylvania 19103, beginning at
21	8:58 a.m., before LINDA ROSSI-RIOS, a
22	Federally Approved RPR, CCR and Notary Public.
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11 Neutralizing	11	(None)
Assay-Update: 12 October 24, 2000,	12	
26912 - 26918 13	13	
Krah-33 Series of e-mails with 311	14	
14 attachment, 759836 - 759847	15	STIPULATIONS
15	16	Page Line
Krah-34 11/29/00 Memo, 330 16 1218 - 1221	17	(None)
17 Krah-35 Plaque Reduction 331 Neutralization Assay for	18 19	
18 Mumps Analytical	20	
Validation Protocol 19 (v.01), 780112 - 780116	20	QUESTIONS MARKED
20 Krah-36 Series of e-mails, 338	21	
52848 & 5284 21		Page Line
Krah-37 Plaque Reduction 347 22 Neutralization Assay for	22	
Mumps Analytical	20	(None)
23 Validation Protocol (v.02),	23 24	
24 337307 - 337318 25	25	
		D 0
Page 7	1	Page 9
1 EXHIBITS (cont'd.)	1	
1 E X H I B I T S (cont'd.) 2 Krah-38 12/10/99 E-mails, 363	2	VIDEOGRAPHER: We are now on the
1 E X H I B I T S (cont'd.) 2 Krah-38 12/10/99 E-mails, 363 52242	2 3	VIDEOGRAPHER: We are now on the record. Please note the microphones
1 EXHIBITS (cont'd.) 2 Krah-38 12/10/99 E-mails, 363 52242 3	2 3 4	VIDEOGRAPHER: We are now on the record. Please note the microphones are sensitive and may pick up
1 E X H I B I T S (cont'd.) 2 Krah-38 12/10/99 E-mails, 363 52242 3 Krah-39 2/22/01 Fax, 383	2 3 4 5	VIDEOGRAPHER: We are now on the record. Please note the microphones are sensitive and may pick up whispering and private conversations.
1 E X H I B I T S (cont'd.) 2 Krah-38 12/10/99 E-mails, 363 52242 3 Krah-39 2/22/01 Fax, 383 4 780093 & 780094	2 3 4 5 6	VIDEOGRAPHER: We are now on the record. Please note the microphones are sensitive and may pick up whispering and private conversations. Turn off all cell phones and place them
1 E X H I B I T S (cont'd.) 2 Krah-38 12/10/99 E-mails, 363 52242 3 Krah-39 2/22/01 Fax, 383 4 780093 & 780094 5	2 3 4 5 6 7	VIDEOGRAPHER: We are now on the record. Please note the microphones are sensitive and may pick up whispering and private conversations. Turn off all cell phones and place them away from microphones. They can
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	Page 10		Page 12
1	present on the stenographic record.	1	has spent some time with you explaining the
2	At this time our court reporter,	2	rules and sort of what to expect today, but it
3	Linda Rossi of Veritext will swear in	3	always helps for us to kind of do it again
4	the witness and you may proceed.	4	just to kind of go over it to make sure that
5		5	we're all on the same page and you sort of
6	DAVID KRAH, after having been	6	understand what's going to happen and so that
7	first duly sworn, was examined and	7	there's no confusion at the end of the day
8	testified as follows:	8	when the case the transcript in this case
9		9	is written up.
10	EXAMINATION	10	As you can see, Linda is going
11		11	to take down everything we say. Though she's
12	BY MR. KELLER:	12	amazing, it's very difficult for her to take
13	Q. Good morning, Dr. Krah. Can you	13	down when we speak at the same time. She will
14	state your full name for the record?	14	be able to do it, but at the end of the day
15	A. Yes. David L. Krah.	15	when they I'm sure when you were deposed
16	Q. And how old are you?	16	before, you saw a thing called a transcript
17	A. 61.	17	which had all the questions and answers. So
18	Q. 61. What is your current	18	we really want to have a complete question and
	residence address?		
19 20	A. 213 Brunswick Court, Lansdale,	19 20	a complete answer, not have them jumbled
	PA. 213 Brunswick Court, Lansdale,	1	together, which is what happens when people
21		21	speak over each other. So for purposes of
22	Q. You've lived there for quite a	22	today and tomorrow, please allow me to finish
23	while?	23	my question and you will see you'll get the
24	A. Yeah, I think 28 or 29 years, I	24	hang of this pretty quickly, but you'll see
25	believe.	25	that sometimes it may take me a second to
	Page 11		Page 13
1	Q. Have you ever had your deposition	1	formulate the second half of my question. Get
2	Q. Have you ever had your deposition taken before?	2	formulate the second half of my question. Get the first part down, then I have to figure out
	Q. Have you ever had your deposition		formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to
2	Q. Have you ever had your deposition taken before?	2 3 4	formulate the second half of my question. Get the first part down, then I have to figure out
2 3	Q. Have you ever had your deposition taken before? A. Yes.	2 3	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to
2 3 4	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times?	2 3 4	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best
2 3 4 5	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once.	2 3 4 5	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that
2 3 4 5 6	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that?	2 3 4 5 6	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair?
2 3 4 5 6 7	 Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s. Q. Is that with regard to your work 	2 3 4 5 6 7	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes.
2 3 4 5 6 7 8	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s.	2 3 4 5 6 7 8	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes. Q. Perfect. And you're doing a great job with using words to answer. Though
2 3 4 5 6 7 8 9	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s. Q. Is that with regard to your work or personal? A. Work.	2 3 4 5 6 7 8 9	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes. Q. Perfect. And you're doing a great job with using words to answer. Though the court reporter can probably pick up
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2 3 4 5 6 7 8 9 10 11 12	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s. Q. Is that with regard to your work or personal? A. Work. Q. Do you recall the nature of that lawsuit?	2 3 4 5 6 7 8 9 10 11 12	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes. Q. Perfect. And you're doing a great job with using words to answer. Though the court reporter can probably pick up uh-huhs and uh-uhs, for a clear record, we want a clear record, yeses or noes and using
2 3 4 5 6 7 8 9 10 11 12 13	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s. Q. Is that with regard to your work or personal? A. Work. Q. Do you recall the nature of that lawsuit? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes. Q. Perfect. And you're doing a great job with using words to answer. Though the court reporter can probably pick up uh-huhs and uh-uhs, for a clear record, we want a clear record, yeses or noes and using words instead of nonverbal communication. Is
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s. Q. Is that with regard to your work or personal? A. Work. Q. Do you recall the nature of that lawsuit? A. Yes. Q. What was the nature of that lawsuit? A. The nature was a claim, as best I can recall, that Merck and Beacon were	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes. Q. Perfect. And you're doing a great job with using words to answer. Though the court reporter can probably pick up uh-huhs and uh-uhs, for a clear record, we want a clear record, yeses or noes and using words instead of nonverbal communication. Is that fair? A. Yes. Q. You were interviewed by the Department of Justice. Do you recall that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Have you ever had your deposition taken before? A. Yes. Q. How many times? A. Once. Q. When was that? A. The late '90s. Q. Is that with regard to your work or personal? A. Work. Q. Do you recall the nature of that lawsuit? A. Yes. Q. What was the nature of that lawsuit? A. The nature was a claim, as best I can recall, that Merck and Beacon were making against GlaxoSmithKline for the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	formulate the second half of my question. Get the first part down, then I have to figure out the second part. Just give me a second to finish my question and then I will do my best to allow you to finish answering. Is that fair? A. Yes. Q. Perfect. And you're doing a great job with using words to answer. Though the court reporter can probably pick up uh-huhs and uh-uhs, for a clear record, we want a clear record, yeses or noes and using words instead of nonverbal communication. Is that fair? A. Yes. Q. You were interviewed by the Department of Justice. Do you recall that? A. Yes.
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4 (Pages 10 - 13)

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Page 14 1 can answer. medical conditions that would affect your 2 THE WITNESS: I don't recall 2 ability to tell the truth today? Just yes or 3 3 giving the oath as I did at the no. 4 beginning of this. I don't know. 4 A. No. 5 BY MR. KELLER: 5 Q. Who is representing you today? 6 Pardon me? 6 Q. You don't know. Were you truthful when you spoke 7 Who is representing you today? 7 8 Are these Merck's lawyers or your personal 8 to the Department of Justice? 9 9 A. Yes. lawyers? 10 10 MR. SANGIAMO: I'm serving as At the end of our two days here, both Merck's counsel and Dr. Krah's 11 Linda will prepare a transcript and you'll 11 have a chance to review that transcript and 12 counsel. make changes as you deem appropriate. Just be 13 BY MR. KELLER: 14 Q. Is that true? 14 aware that any changes that you make we'll be 15 able to make reference to that at trial. 15 A. Yes. Okay? So if you change your testimony in the 16 When did you -- let me back up 17 to the 1990s when you had the case with 17 transcript, we will be able to use your prior -- the original testimony and your 18 varicella. 19 Who sued who with regard to the 19 changes. Do you understand that? 20 20 varicella vaccine? MR. SANGIAMO: Let me just 21 21 A. I recall that Merck and Beacon interpose, Jeff, the rules are what 22 22 were involved. I don't recall specifically they are. We'll proceed according to 23 23 who the actual entity was that was suing GSK, 24 MR. KELLER: Fair enough, Dino. 24 GlaxoSmithKline. 25 25 BY MR. KELLER: Q. And GSK was trying to develop Page 15 Page 17 Q. One of the most important rules 1 their own varicella vaccine? 1 here is if you do not understand my question, 2 They were trying to develop a 2 3 varicella vaccine, yes. and you don't say anything, we're all going to 4 With a different virus strain? assume that you did. So if I ask a question Q. 5 you don't understand, please let me know; A. otherwise, we're all going to assume that the 6 Q. Same virus strain? 7 answer you gave was -- that you understood the A. Yes. 8 Do you know -- do you recall 8 question. Is that fair? 9 whether or not -- where that case was venued? 9 A. Yes. 10 Was it in federal court or state court? 10 Q. We are entitled to your best 11 understanding. We don't want you to guess at 11 I recall it was in Delaware, but I don't recall whether it was federal or anything, but we are entitled to your best 12 understanding. So if you need to -- you know, 13 state. 14 Q. Why were you deposed in that if you don't know specifically an answer but 15 matter? you know generally of an answer, you still need to answer, though you can identify that 16 I had -- it was my understanding 17 why I was deposed is that I had a detailed 17 to the extent that you have your knowledge. I 18 remember something, I don't remember 18 understanding of the varicella manufacturing 19 everything. But you can't say I don't 19 process and had -- including information that 20 remember when you remember something. Is that 20 we gained from Beacon. 21 Did Beacon, was that the entity 21 fair? 22 22 that developed the varicella vaccine and did Α. Yes. 23 Is there any reason today why 23 Merck purchase it from them? 24 you can't have your deposition taken? Are you MR. SANGIAMO: Object to the 25 on any sort of medication? Have you any form.

5 (Pages 14 - 17)

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1			
	Page 18	1	Page 20
	BY MR. KELLER:	1	along with me, but I was able to get
2	Q. Let me rephrase that. Who	2	firsthand information about the
3	developed the varicella vaccine that was at	3	discussions with Beacon.
4	issue in this lawsuit?	4	BY MR. KELLER:
5	MR. SANGIAMO: Objection. You	5	Q. Was that in preparation to
6	can answer.	6	take to sit for a deposition or was that
7	THE WITNESS: There are parts of	7	information you had before you were being
8	the process that were developed by	8	called as a witness?
9	Beacon and then parts of the process	9	MR. SANGIAMO: Objection.
10	that were extended, from my understanding,	10 11	THE WITNESS: That was
11	at the different, either Merck or GSK. In this case it was GSK.	12	information that was before I was
12	BY MR. KELLER:	13	deposed. BY MR. KELLER:
14		14	
	Q. You stated earlier that you were familiar with the manufacturing practice of	15	Q. So that's information you had as part of your normal job duties at Merck in
15	the varicella vaccine. How did you become	16	working on that particular vaccine?
16 17	knowledgeable about that topic?	17	A. Yes.
18	A. I didn't say practice. Process.	18	MR. SANGIAMO: Objection.
19	The process.	19	BY MR. KELLER:
20	Q. Sorry, I misheard you.	20	Q. When did you first learn that
21	A. I became familiar with that	21	you were going to be deposed in this case?
22	through two two actually at least one is	22	A. I can't remember a specific
23	interacting with our manufacturing group at	23	date. I would say sometime last year there
24	Merck to understand the manufacturing process	24	was a suggestion that I would be deposed.
25	that Merck was using. Also I was requested to	25	Q. What did you do in did you do
			· · ·
1	Page 19	1	Page 21
1	and made a trip to the to Beacon. It's	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	anything to prepare for your deposition today
2	when I refer to Beacon, it's I'm trying to	$\frac{2}{3}$	since last year when you first learned about it?
3	remember the name. It's Osaka University	4	
5	is, I think, like the parent organization. Beacon, as best I recall, is the manufacturing	5	MR. SANGIAMO: Object to the form.
6	part of that. So at any point I made a visit	6	THE WITNESS: Can you clarify as
7	to both Beacon and Osaka University, talked to		
/		/	
	one of the people that began the development	Q	far as specific examples?
8	one of the people that began the development	8	BY MR. KELLER:
8 9	of the vaccine to ask questions, understand	9	BY MR. KELLER: Q. What did you do personally? Did
8 9 10	of the vaccine to ask questions, understand details about their manufacturing process.	9 10	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare
8 9 10 11	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to	9 10 11	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition?
8 9 10 11 12	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to disclose any communications with counsel, but	9 10 11 12	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition? A. I didn't do anything. The only
8 9 10 11 12 13	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to disclose any communications with counsel, but do you know whether or not you were testifying	9 10 11 12 g13	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition? A. I didn't do anything. The only thing I did do was meet with counsel for the
8 9 10 11 12 13 14	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to disclose any communications with counsel, but do you know whether or not you were testifying as a person most knowledgeable or based on	9 10 11 12 g13 14	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition? A. I didn't do anything. The only thing I did do was meet with counsel for the preparation sessions.
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8 9 10 11 12 13 14 15 16	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to disclose any communications with counsel, but do you know whether or not you were testifying as a person most knowledgeable or based on your let me let me just start with that. Were you testifying as a person most	9 10 11 12 g13 14 15 16	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition? A. I didn't do anything. The only thing I did do was meet with counsel for the preparation sessions. Q. How many sessions did you have? A. I believe five.
8 9 10 11 12 13 14 15 16 17	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to disclose any communications with counsel, but do you know whether or not you were testifying as a person most knowledgeable or based on your let me let me just start with that. Were you testifying as a person most knowledgeable for the company?	9 10 11 12 g13 14 15 16 17	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition? A. I didn't do anything. The only thing I did do was meet with counsel for the preparation sessions. Q. How many sessions did you have? A. I believe five. Q. And were those full-day sessions?
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of the vaccine to ask questions, understand details about their manufacturing process. Q. Were you I don't want you to disclose any communications with counsel, but do you know whether or not you were testifying as a person most knowledgeable or based on your let me let me just start with that. Were you testifying as a person most knowledgeable for the company? MR. SANGIAMO: Object to the form. THE WITNESS: I wouldn't say I was most knowledgeable. I would say that it's my understanding that I	9 10 11 12 g13 14 15 16 17 18 19 20 21 22	BY MR. KELLER: Q. What did you do personally? Did you do anything personally to help prepare yourself for today's deposition? A. I didn't do anything. The only thing I did do was meet with counsel for the preparation sessions. Q. How many sessions did you have? A. I believe five. Q. And were those full-day sessions? A. I believe. As best I can recall, yes. Q. And when was the first full-day session? A. I don't recall.

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1	yesterday?	1	several years ago?
2	A. It was the majority of the day.	2	A. It was several years ago, but I
3	Q. And before yesterday, when did	3	don't recall the date.
4	you meet before that?	4	Q. Did you read the Amended
5	A. Friday, last Friday.	5	Complaint?
6	Q. And that was, again, a full day?	6	A. I recall seeing parts of it. I
7	A. The majority of the day.	7	didn't read every part of it.
8	Q. What about before that?	8	Q. What part do you recall seeing?
9	A. I think as best I recall,	9	A. I don't recall.
10	Thursday of last week.	10	Q. Do you recall discussing the
11	Q. And before that?	11	Complaint? Do you recall reviewing with
12	A. I don't recall.	12	anybody at Merck, excluding any attorneys?
13	Q. So you met yesterday and two	13	A. I did not discuss it with anyone
14	days last week. Correct?	14	else.
15	A. As best I can recall, yes.	15	Q. Have you so you did not
16	Q. And then the other two meetings,	16	discuss this case with anybody other than
17	do you recall when those occurred?	17	Merck's lawyers?
18	A. They were within the last few	18	A. That's correct.
19	weeks, but I don't recall specific dates.	19	Q. Are you married?
20	Q. Prior to the last few weeks,	20	A. No.
21	have you spoken to Merck's counsel regarding	21	Q. Do you have a girlfriend?
22	this case?	22	A. Not currently.
23	MR. SANGIAMO: That's a yes or	23	Q. And during the time that you
24	no, Dave.	24	first learned about this lawsuit, did you have
25	THE WITNESS: Yes.	25	a girlfriend between then and now?
	P. 22		
	Page 23		Page 25
1	Page 23 BY MR. KELLER:	1	Page 25 A. Not that I recall.
1 2	BY MR. KELLER:	1 2	A. Not that I recall.
2	BY MR. KELLER: Q. And how many conversations have		A. Not that I recall.Q. In preparation for your
2 3	BY MR. KELLER: Q. And how many conversations have you had?	2 3	A. Not that I recall. Q. In preparation for your deposition today, over those five full-day
2 3 4	BY MR. KELLER: Q. And how many conversations have you had? MR. SANGIAMO: I'm going to	2 3 4	A. Not that I recall. Q. In preparation for your deposition today, over those five full-day meetings that you had with your counsel, did
2 3 4 5	BY MR. KELLER: Q. And how many conversations have you had? MR. SANGIAMO: I'm going to object to that.	2 3 4 5	A. Not that I recall. Q. In preparation for your deposition today, over those five full-day meetings that you had with your counsel, did you look at documents?
2 3 4 5 6	BY MR. KELLER: Q. And how many conversations have you had? MR. SANGIAMO: I'm going to object to that. THE WITNESS: I don't recall.	2 3 4 5 6	A. Not that I recall. Q. In preparation for your deposition today, over those five full-day meetings that you had with your counsel, did you look at documents? A. Yes.
2 3 4 5 6 7	BY MR. KELLER: Q. And how many conversations have you had? MR. SANGIAMO: I'm going to object to that. THE WITNESS: I don't recall. BY MR. KELLER:	2 3 4 5 6 7	A. Not that I recall. Q. In preparation for your deposition today, over those five full-day meetings that you had with your counsel, did you look at documents? A. Yes. Q. Do you recall how many documents
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. KELLER: Q. And how many conversations have you had? MR. SANGIAMO: I'm going to object to that. THE WITNESS: I don't recall. BY MR. KELLER: Q. Was it more than one? A. It's more than one. Q. Was it less than ten? MR. SANGIAMO: That's invading the attorney-client privilege. MR. KELLER: The number of conversations? MR. SANGIAMO: Yeah. I'm going to instruct him not to answer that. BY MR. KELLER: Q. You're going to follow your counsel's instruction? A. Yes. Q. In preparation let me ask you, when did you first learn about this lawsuit?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Not that I recall. Q. In preparation for your deposition today, over those five full-day meetings that you had with your counsel, did you look at documents? A. Yes. Q. Do you recall how many documents you looked at? A. That, I don't recall. Q. More than one? A. Yes. Q. Less than 100? A. I can't say with any Q. Can you give me your best recollection of how many documents? A. There were at least they're running together in my head, so I can't really give a Q. It could have been two or it could have been 500? A. I can't recall the specific number. It's more than two, I would say. I don't recall.

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1	Page 26	1	Page 28
1	you. If you how big of a stack of	1	A. Yes.
2	documents can you recall looking at?	2	Q. How many journals did you
3	MR. SANGIAMO: You know, Jeff,	3	maintain? Let me rephrase that question.
4	the documents that are reviewed in	4	The journal that you maintained,
5	preparation for a deposition are work	5	was that kept on a computer program?
6	product. So you're certainly not	6	A. Yes.
7	allowed to ask him what those documents	7	Q. What was the did that
8	were. I'd have to think about whether	8	computer program change over the years?
9	you're allowed to ask him how many he	9	A. As best I can recall, it was
10	looked at, but I don't see where that's	10	Microsoft Word. I don't recall how that
11	going since you're not going to be able	11	changed over time.
12	to ask him what he looked at. He's	12	Q. And did you keep more than one
13	given you his best recollection.	13	journal?
14	BY MR. KELLER:	14	A. There the I'll say yes in
15	Q. Sir, did you look at a Bankers	15	that there was one general format for the
16	Box worth of documents?	16	journal but over multiple years, and they were
17	A. I can't there were as best	17	saved as separate by different years. So
18	I can recall, there were documents one at a	18	they exist as separate documents but are
19	time, and I there was no pile or assembly	19	one could view them as a continuation.
20	that would remind me of how many there were.	20	Q. So other than segregating them
21	Q. Can you recall how many	21	out by year in separate files, did you keep
22	documents you looked at in an hour?	22	any separate personal journals?
23	MR. SANGIAMO: Objection.	23	MR. SANGIAMO: Object to the
24	THE WITNESS: Some documents	24	form.
25	all I can offer for that is that some	25	THE WITNESS: Not
	Page 27		Page 29
1	documents took were reviewed more	1	BY MR. KELLER:
2	quickly than others. So I can't	2	Q. Let me rephrase the question.
3	exclude that some took an hour to	3	Did you keep a journal at home?
4	review and others were less than an	4	A. No.
5	hour.	5	Q. Did you maintain any documents
6	BY MR. KELLER:	6	at home from Merck?
7	Q. I'm asking how many documents do	7	A. No.
8	you recall looking at in an hour on average?	8	Q. Do you have a personal computer
9	A. That, I don't recall.	9	at home?
10	Q. You can't tell. Okay. How many	10	A. I have my work computer.
11	documents did you look at yesterday?	11	Q. That's a laptop?
12	A. That, I don't recall.	12	A. Currently it's a laptop, yes.
13	Q. Have you looked at any	13	Q. And back in let me just sort
14	deposition transcripts in this case? Did you	14	of back up.
15	review any deposition transcripts in this	15	Back in the late '90s, did you
16	case?	16	have a laptop?
17	A. For this case?	17	A. I don't recall I don't recall
18	Q. Yes.	18	when the Merck laptop was issued. I don't
19	A. No.	19	recall in the late '90s if we had a laptop
20	Q. Did you look at any deposition	20	or I didn't have a personal laptop.
21	summaries in this case?	21	Q. Did you have a personal computer
22	A. No.	22	at home?
23	Q. Sir, over the course of your	23	MR. SANGIAMO: In the late '90s?
24	professional life at Merck, did you maintain a	24	MR. KELLER: Yes.
25	journal?	25	THE WITNESS: Not that I recall.
25	Journal:		THE WITHLOS. NOT that I locall.

8 (Pages 26 - 29)

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1	Page 30	1	Page 32 form. You can answer.
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	BY MR. KELLER:	2	THE WITNESS: Not I think
3	Q. Did you have a desktop computer? A. At work?	$\frac{2}{3}$	
4	Q. At home.	4	that specific example I do not recall doing.
5	A. At home, no.	5	BY MR. KELLER:
6		6	Q. What specific example do you
7	Q. Do you have a personal computer at home currently?	7	recall?
8	A. No.	8	A. If there were personnel issues
9	Q. During so from the late '90's	9	or personnel discussions that I thought
10	to today you've never had a personal computer	10	were that were continuing that I wanted to
11	at home?	11	compile, I would excerpt the information from
12	A. Not that I recall.	12	the journal into a separate summary on that
13	Q. Back to your journals that you	13	personnel topic.
14	maintained on Word, did you ever have separate	14	Q. Well, in the case of a personnel
15	journals for work stuff and another journal	15	issue, why would you be excerpting different
16	for personal stuff?	16	references from different days into a
17	A. I did not have a separate	17	compilation?
18	journal, but I did, on occasion, excerpt	18	A. One application for that would
19	information from the one journal into a	19	be to compile, if there was a trend of
20	separate compilation, but it was the same	20	behavior or trend of events. And then include
21	information that was in the primary journal.	21	efforts I was making to try to understand or
22	Q. So your journal kept all the	22	address the questions.
23	information that you let me strike that.	23	Q. What did you do with that
24	When I say "strike," it means I'm just going	24	information once you compiled it?
25	to do it over again and forget that question.	25	MR. SANGIAMO: Object to the
	Page 31		
1		1	Page 33
1 2	So did you ever delete	1 2	form. You can answer.
2	So did you ever delete information from your journal?	2	form. You can answer. THE WITNESS: For the most part,
2 3	So did you ever delete information from your journal? A. Not that I recall other than a	2 3	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have
2 3 4	So did you ever delete information from your journal? A. Not that I recall other than a typographical error.	2 3 4	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have it available for reminding me of the
2 3 4 5	So did you ever delete information from your journal? A. Not that I recall other than a typographical error. Q. But you would copy things from	2 3 4 5	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have it available for reminding me of the summaries. I can't exclude that on
2 3 4 5 6	So did you ever delete information from your journal? A. Not that I recall other than a typographical error. Q. But you would copy things from your journal and move them into a different	2 3 4 5 6	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have it available for reminding me of the summaries. I can't exclude that on some cases that was forwarded to
2 3 4 5 6 7	So did you ever delete information from your journal? A. Not that I recall other than a typographical error. Q. But you would copy things from your journal and move them into a different file for other purposes. Correct?	2 3 4 5 6 7	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have it available for reminding me of the summaries. I can't exclude that on some cases that was forwarded to management for review.
2 3 4 5 6 7 8	So did you ever delete information from your journal? A. Not that I recall other than a typographical error. Q. But you would copy things from your journal and move them into a different file for other purposes. Correct? A. There are occasions where that	2 3 4 5 6 7 8	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have it available for reminding me of the summaries. I can't exclude that on some cases that was forwarded to management for review. BY MR. KELLER:
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2 3 4 5 6 7 8	So did you ever delete information from your journal? A. Not that I recall other than a typographical error. Q. But you would copy things from your journal and move them into a different file for other purposes. Correct? A. There are occasions where that was done. Q. And under what occasions would	2 3 4 5 6 7 8	form. You can answer. THE WITNESS: For the most part, as best I can recall, I would just have it available for reminding me of the summaries. I can't exclude that on some cases that was forwarded to management for review. BY MR. KELLER:
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	Page 34		Page 36
1	rudimentary skills. I had her work with	1	Q. Do you currently have your own
2	multiple people in the lab throughout the	2	office?
3	course of a week to see if everyone would have	3	A. I have an office where there's
4	the same observation. They confirmed that	4	no other person in the office.
5	this person wasn't appeared that they had	5	Q. Do you maintain files in your
6	basic lab skills. We recommended to the	6	office?
7	contract agency that she be terminated.	7	A. Yes.
8	Q. The second occasion?	8	Q. Did you ever go through those
9	A. The second occasion was another	9	files to see if there's any documents that are
10	contract employee who, as best I can recall,	10	related to this lawsuit?
11	was, I would say, technically competent but	11	A. Yes.
12	not from my recollection, not very	12	Q. Did you provide those documents
13	interested not interested in the work that	13	to your counsel?
14	he was doing, was not completing assignments	14	A. Yes.
15	on time. And after several weeks, we	15	Q. Did anybody else search those
16	recommended that he be terminated.	16	files other than you?
17	Q. Did you ever recommend any Merck	17	MR. SANGIAMO: Answer if you
18	employees be terminated?	18	know.
19	A. No.	19	THE WITNESS: A group came to
20	Q. Did you ever recommend any Merck	20	retrieve the files. I don't know if
21	employees be demoted?	21	that counts as counsel or not. But I
22	A. No.	22	don't recall who they were.
23	Q. Let me ask you, in response to	23	BY MR. KELLER:
24	this litigation, did you do anything to search	24	Q. So just so I understand, the
25	for any of your any documents that you kept	25	procedure that you followed in order to
	* * *		•
	Page 35		Page 37
1		1	
	Page 35	1 2	Page 37
1	Page 35 in your files?		Page 37 produce documents in this case from the files
1 2	Page 35 in your files? A. No.	2 3 4	Page 37 produce documents in this case from the files that you maintained in your office is that you
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10 (Pages 34 - 37)

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	Pro- 20		
1	Page 38 files that were that had any	1	Page 40 form.
2	relationship to the litigation.	2	THE WITNESS: Can you clarify as
3	BY MR. KELLER:	3	far as what are
4	Q. And you made that decision	4	BY MR. KELLER:
5	yourself?	5	Q. How do you maintain your files
6	A. Yes.	6	in your lab? Let me back up and get some more
7	Q. And so did that include files	7	foundation here.
8	outside of your physical office?	8	The lab that you currently work
9	MR. SANGIAMO: Object to the	9	in, how long have you been in that lab?
10	form.	10	A. Perhaps 14 years.
11	BY MR. KELLER:	11	Q. 14 years. So around 2003, where
12	Q. Do you understand my question?	12	did you did you work in a different lab?
13	A. I don't.	13	A. Yes.
14	Q. Yes or no?	14	Q. Where from 2003 to today,
15	A. No, I don't understand.	15	what's the does the lab have a location
16	Q. If you don't understand it, just	16	identifier?
17	say I don't understand. That's fine. That	17	A. Yes, there are room numbers.
18	wasn't a great question, I'll try to rephrase	18	Q. And what was the room number for
19	it.	19	the lab that you've worked in since 2003 to
20	Did you also look for documents	20	current?
21	responsive, that related to this case outside	21	A. There's if I maybe qualify
22	of the files that are kept in your physical	22	this in that there's the lab, there's an
23	office?	23	office area by the lab, so the labs themselves
24	MR. SANGIAMO: Object to the	24	are 309 and building 16, room 309 and 327.
25	form.	25	Q. And then there's an office that
	Page 39		Page 41
1	THE WITNESS: There were	1	you maintain near that lab. Correct?
2	documents that were kept in our	2	A. Yes.
3	laboratory, and those were provided.	3	Q. That's from 2003 to current.
4	BY MR. KELLER:	4	Correct?
5	Q. Did you do the same go	5	A. Yes, as best I recall.
6	through the same procedure of going through	6	Q. Now, from the time before 2003,
7	those files that were in your lab identifying	7	before you worked had a lab in room 309 and
8	those that you believe related to the case and	8	327, you worked in a different lab. Correct?
9	then provided those to counsel?	9	A. We had two other labs two
10	MR. SANGIAMO: Object to the	10	other labs, we were using those, the 309 and
11	form.	11	327 labs periodically but not exclusively.
12	THE WITNESS: As best I recall,	12	Q. What other lab did you work in
13	I provided an index of the experiments	13	more often?
14	and provided those to counsel, and	14	A. The other labs were same
15	counsel determined which files were	15	building 16, room 203, 213 and periodically
16	relevant.	16	212.
17	BY MR. KELLER:	17	Q. And so did you maintain the same
18	Q. So you only provided an index of	18	office they're in the same building.
19	the experiments. Did you provide an index of	19	Correct?
20	all the different documents that you had? You	20	A. Yes.
21	had more than just more than strike	21	Q. And those labs are organized
	that.	22	did you maintain the same office during that
22			
23	Is there a centralized filing	23	time frame?
23 24	Is there a centralized filing system that you have in your lab?	24	A. I moved my office, I believe,
23	Is there a centralized filing	l .	

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Page 42 1 Q. In the same building? 2 A. In the same building. 3 Q. On the same floor? 4 A. No. 5 Q. So that when you — they're on 6 different floors. Prior to 2003 you moved to the 8t third floor, Correct? 9 MR, SANGIAMO: Object to the 10 form. 11 THE WITNESS: The labs that we were using were on the second floor approximately 2 were primary labs that we were using were on the second floor approximately 2 wore on the second floor to the third floor? 18 Ware — primary labs that we were using were on the second floor approximately 2 2003 and then third floor 2003. 17 BY MR, KELLER: 18 Q. So you moved your offices in 198 MR, SANGIAMO: Object to the 16 form. 19 2003 from the second floor to the third floor? 20 MR, SANGIAMO: Object to the 16 form. 21 THE WITNESS: If I could clarify. 22 THE WITNESS: If I could clarify. 23 What I was referring to were the 24 laboratories. Laboratories in my view are separate from the offices. 24 I aboratories. Laboratories in my view 24 are separate from the offices. 25 MR, SANGIAMO: Object to the 16 form. 26 THE WITNESS: Not all the time. 27 THE WITNESS: Not all the time. 28 BY MR, KELLER: 9 Q. On the second and third floor of 16 building 16, there's offices on each floor? 10 building 16, there's offices on each floor? 11 MR, SANGIAMO: Object to the 16 form. 12 BY MR, KELLER: 9 Q. On the second and third floor of 16 building 16, there's offices on each floor? 11 MR, SANGIAMO: Object to the 17 form. 12 G. Were they kept in file cabinets? Let me back up a second. 13 BY MR, KELLER: 9 Q. Did wounder each floor? 14 A. No. 15 A. My office did not the third floor? 16 Were working — when you had alabs on the second floor of the third floor? 18 A. No. 19 What I was referring to were the 20 A. No me the second floor to the third floor of 10 building 16, there's offices on each floor? 10 building 16, there's offices on each floor? 11 MR, SANGIAMO: Object to the 16 form. 12 G. A. How did you were your documents prior to 2003, your files that you maintain in 19 floor of 10 building 16, there's of		HIGHLI CONFIDENTIAL -	711	
2 A. In the same building. 3 Q. On the same floor? 4 A. No. 5 Q. So that when you — they're on 6 different floors. Prior to 2003 you were on 7 the second floor, after 2003 you moved to the 8 third floor. Correct? 9 MR. SANGIAMO: Object to the 10 form. 11 THE WITNESS: The labs that we were using were on the third floor 2003 and beyond. So the labs that we were — primary labs that we were — primary labs that we were — or mind of the second floor approximately 2003 and then third floor approximately 2003 from the second floor to the third floor? 18 BY MR. KELLER: 19 QO. So that when you — disconding the date of that. Q. When the office moved, did it move from the second floor to find floor? 10 MR. SANGIAMO: Object to the form. 11 BY MR. KELLER: 20 MR. SANGIAMO: Object to the form. 21 BY MR. KELLER: 21 Q. Is it fair to say that the 3 office, there's offices on each floor. 22 THE WITNESS: Not all the time. 33 A. My office did move, but I don't recall that it was part of that renovation move or not. 4 A. My office did move, but I don't recall that it was part of that renovation move or not. 4 A. My office did not— 4 A. My office did nove, but I don't recall that it was part of that trenovation move or not. 4 A. My office did not— 5 Q. Wher the office did not— 6 Q. When				6
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9 Q. On the second and third floor of 10 building 16, there's offices on each floor? 11 MR. SANGIAMO: Object to the 12 form. 13 BY MR. KELLER: 14 Q. Let me just sort of cut through 15 this if you can. Can you describe, when you 16 were working when you had labs on the 17 second floor, 203 and 213 and sometimes 212, 18 how long were you in those labs? Just to get 19 some more foundation. 20 A. I was using those labs since I 21 started in 1988. 22 Q. 1988, okay. Why did you move to 23 the third floor? 24 A. As best I recall, the second 9 A. Yes. 10 Q. Were they kept in file cabinets? 11 A. Yes. 12 Q. Were they kept anywhere else? 13 A. There were some experiments that 14 were kept on shelves. 15 Q. And so what experiments would 16 you keep on shelves? 17 A. They were experiments that were 18 in notebook binders that were lab 19 experiments that were in binders. 20 Q. And those binders, are those 21 called workbooks? 22 A. No. They're like I view them 23 as like three-ring binders. Like, I don't 24 know, there must be other names for them. I	1 -		1	
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24 A. As best I recall, the second 24 know, there must be other names for them. I				
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14.) HOUL WAS DELITY TEHOVALED. 14.) WOULDITE CALL HIGHT A WOLKDOOK.	2/			
			1	

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1	Page 46 Q. So those were your experimental	1	Page 48 moved back to the, what was the
	- · · · · · · · · · · · · · · · · · · ·	1	,
2	experiments that you were running, you kept		previous office on the first floor.
3	those in binders in your office?	3	BY MR. KELLER:
5	MR. SANGIAMO: Object to the form.	4	Q. So these moves were you moved
		5	to a temporary office when they were
6	THE WITNESS: Not all experiments	6	renovating and you moved back to your original
7	were kept in binders, but I did have	7	office?
8	experiments in binders.	8	A. There were two renovations
9	BY MR. KELLER:	9	involved. So one move was related to
10	Q. What did you keep in your file	10	renovation of the second floor, I don't recall
11	cabinets?	11	that they're exactly the same time, but then
12	MR. SANGIAMO: Object to the	12	when I moved to the first floor, there was a
13	form. You can answer.	13	renovation that was happening there as well
14	BY MR. KELLER:	14	and I had to move to a temporary spot.
15	Q. In this 2003 through 1998	15	Q. So the files that were
16	through 2003 period.	16	maintained in the labs in 203, 213 and 212,
17	A. A variety of documents and some	17	when you moved to the labs at 309 and 327, did
18	of the lab experiments.	18	those file cabinets did those files get
19	Q. When you moved your offices, did	19	moved as well?
20	somebody come in and move all the binders on		A. Some of the documents from it
21	the shelves and all the file cabinets?	21	were moved to my office and some were moved
22	A. Someone did move them. I packed	22	and I don't recall what percentage of them
23	them up and somebody moved them.	23	were moved to the new file cabinets in the
24	Q. When you packed them up, did you	24	third floor space.
25	go through them and discard anything?	25	Q. Were any documents destroyed, do
	Page 47		Page 49
1	A. No.	1	you recall?
2	Q. So those documents that were in	2	A. No.
3	your office from 1998 through 2003, those were	3	Q. When you in response to this
4	moved when you moved your offices. Correct?	4	case when you were looking when you were
5	MR. SANGIAMO: Object to the	5	going through the documents to identify
6	form.	6	documents that were relevant to this case, you
7	THE WITNESS: All of the		1 1 1 1 1 1 1 1 1 1 1 1
1 0		7	also searched the files in the labs in rooms
8	documents that I had at the time of the	8	309 and 327 in building 16. Correct?
9	documents that I had at the time of the move were moved.	8 9	309 and 327 in building 16. Correct? MR. SANGIAMO: Object to the
9 10	documents that I had at the time of the move were moved. BY MR. KELLER:	8 9 10	309 and 327 in building 16. Correct? MR. SANGIAMO: Object to the form.
9 10 11	documents that I had at the time of the move were moved. BY MR. KELLER: Q. You said you moved again twice.	8 9 10 11	309 and 327 in building 16. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: There were as
9 10 11 12	documents that I had at the time of the move were moved. BY MR. KELLER: Q. You said you moved again twice. And the same, did you go through the documents	8 9 10 11 12	309 and 327 in building 16. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: There were as best I recall, there were no files in
9 10 11 12 13	documents that I had at the time of the move were moved. BY MR. KELLER: Q. You said you moved again twice. And the same, did you go through the documents when you moved the next time to see to sort	8 9 10 11 12 13	309 and 327 in building 16. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: There were as best I recall, there were no files in those laboratories.
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9 10 11 12 13 14 15 16 17 18 19 20 21 22	documents that I had at the time of the move were moved. BY MR. KELLER: Q. You said you moved again twice. And the same, did you go through the documents when you moved the next time to see to sort through and get rid of anything or did you just move everything to the next office? MR. SANGIAMO: Object to the form. THE WITNESS: I can't exclude that in the next move that I didn't sort through I think examples are like old journal articles that I didn't feel were relevant anymore. But as	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	309 and 327 in building 16. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: There were as best I recall, there were no files in those laboratories. BY MR. KELLER: Q. So the only files that you recall searching that were relevant were in your office. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: That's not fully correct. The third floor, not in the laboratory space, we had an office

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	Page 50		Page 52
1	BY MR. KELLER:	1	documents at your house in a file?
2	Q. You searched those files?	2	A. No.
3	A. Yes.	3	MR. SANGIAMO: Object to the
4	Q. You determined what was relevant	4	preamble of your question. If you want
5	and you gave those to your lawyers. Correct?	5	to ask what they were kept in, that's
6	A. In that case	6	fine.
7	MR. SANGIAMO: Object to the	7	THE WITNESS: I never retained
8	form. You can answer.	8	anything. They were returned to Merck.
9	THE WITNESS: In that case, at	9	
10	least as best I can recall, we provided	10	(Exhibits Krah-1, Curriculum
11	the indexes of the lab experiments to	11	vitae, 00000695 - 00000702, was marked
12	counsel and counsel reviewed them and	12	for identification.)
13	decided what was relevant.	13	
14	BY MR. KELLER:	14	BY MR. KELLER:
15	Q. Was there anything other than	15	Q. Let me mark as Exhibit 1 a
16	lab experiments in those file cabinets?	16	document that bears Bates stamp number 695
17	A. Not that I recall.	17	through 702, which is an older CV of yours,
18	Q. Were there did you maintain	18	sir. Can you tell me if you recognize this
19	any notes that were not in lab experiments as	19	document?
20	part of the ordinary course of running your	20	A. I can't say that I recall the
21	labs? In the files that you maintained in	21	specific date on it, but the general content
22	your office after 2003, or in a shared office,	22	looks familiar to me.
23	were those just experiments?	23	Q. When is the last time you saw
24	A. I'm sorry, the first half of	24	this document?
25	that, did you say in my office were the only	25	A. The one dated January 1998?
1			
	Page 51		Page 53
1	Page 51 experiments?	1	Q. Yes.
1 2	experiments?	1 2	Q. Yes.
	experiments? Q. Let me ask I'll break it up.	1	Q. Yes. A. That, I don't recall.
2	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab	2	Q. Yes.
2 3	experiments? Q. Let me ask I'll break it up.	2 3	Q. Yes.A. That, I don't recall.Q. Do you have a current CV?A. Yes.
2 3 4	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No.	2 3 4	Q. Yes.A. That, I don't recall.Q. Do you have a current CV?
2 3 4 5	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No.	2 3 4 5	 Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall.
2 3 4 5 6	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain? A. Reports, minutes of meetings,	2 3 4 5 6	 Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall. Q. Can you take a second and tell
2 3 4 5 6 7	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain?	2 3 4 5 6 7	 Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall.
2 3 4 5 6 7 8	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain? A. Reports, minutes of meetings, journal articles, safety information, manuals, equipment manuals.	2 3 4 5 6 7 8	 Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall. Q. Can you take a second and tell me if there's anything in this CV that you
2 3 4 5 6 7 8 9	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain? A. Reports, minutes of meetings, journal articles, safety information, manuals, equipment manuals.	2 3 4 5 6 7 8 9	Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall. Q. Can you take a second and tell me if there's anything in this CV that you believe to be is this to be accurate as
2 3 4 5 6 7 8 9	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain? A. Reports, minutes of meetings, journal articles, safety information, manuals, equipment manuals. Q. And so you went through those to	2 3 4 5 6 7 8 9	Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall. Q. Can you take a second and tell me if there's anything in this CV that you believe to be is this to be accurate as of the date of January 1998?
2 3 4 5 6 7 8 9 10	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain? A. Reports, minutes of meetings, journal articles, safety information, manuals, equipment manuals. Q. And so you went through those to determine what was relevant to provide your	2 3 4 5 6 7 8 9 10 11	Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall. Q. Can you take a second and tell me if there's anything in this CV that you believe to be is this to be accurate as of the date of January 1998? MR. SANGIAMO: I'm sorry, what
2 3 4 5 6 7 8 9 10 11 12	experiments? Q. Let me ask I'll break it up. In your office, did you maintain just lab experiments? A. No. Q. What else did you maintain? A. Reports, minutes of meetings, journal articles, safety information, manuals, equipment manuals. Q. And so you went through those to determine what was relevant to provide your counsel?	2 3 4 5 6 7 8 9 10 11 12	Q. Yes. A. That, I don't recall. Q. Do you have a current CV? A. Yes. Q. Did you provide that to counsel? A. I don't recall. Q. Can you take a second and tell me if there's anything in this CV that you believe to be is this to be accurate as of the date of January 1998? MR. SANGIAMO: I'm sorry, what was your question, Jeff?
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14 (Pages 50 - 53)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

1	Page 54 MR. KELLER: In fairness I will	1	Page 56
1		1	principal scientist or something of that sort.
2	identify for the record that page 7 of	2	Q. It's the same level?
3	this CV is missing from the production	3 4	A. Yes.
4	that was given to us.	5	Q. So from 1998 to 2017 you've had
5	THE WITNESS: I don't have any	6	the same job? A. Yes.
6 7	reason to expect that anything is not	7	
8	correct. BY MR. KELLER:	8	Q. What is so if I say senior
9		9	investigator, is that a fair way to describe your title? How would you like me to describe
10	Q. So the education and employment history, that's accurate. Correct?	10	your title between 1998 and 2017?
11	A. To the best of my understanding,	11	A. Senior investigator is as good
12	yes.	12	as any. It's just a set of words.
13	Q. So after 1998 I'm sorry,	13	Q. Fair enough. And did your job
14	after 1995, it says you are the "Senior	14	duties change from 1998 to 2017?
15	Research Fellow Department of Virus and Cell		A. So projects changed. I don't
16	Biology." Do you see that? Can you tell me	16	know if one could infer from that
17	what your positions were from 1998 through	17	responsibilities changed. There's a broad
18	current? I don't have a current CV, so we	18	so there's not a it's my understanding a
19	have to fill in the gap. So if you can	19	formal change of range of job
20	identify what your employment history is at	20	responsibilities between 1998 and present.
21	Merck after 1995 to fill in the gaps in the	21	Q. Sorry, I didn't mean to
22	CV.	22	interrupt you.
23	A. The title names have changed	23	MR. SANGIAMO: Are you done with
24	over the years. As best I can recall, 1998 I	24	your answer?
25	was promoted to senior investigator.	25	THE WITNESS: I guess getting to
	Dog 55		
1	Page 55 O That is the department of virus	1	Page 57
1 2	Q. That is the department of virus	1 2	Page 57 the point that the there are core
1 2 3	Q. That is the department of virus and cell biology?	2	Page 57 the point that the there are core job responsibilities for a given
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. That is the department of virus and cell biology? A. Our department name changed many times so I think that like we were virus and cell biology and cellular/microbiology and then I can't I don't recall how many it's in the same theme of virus and cell biology. The department number changed and the name changed, but the same entity, basically. The same group. Q. The same group. It was still in the same group. A. Yes. Q. Your job duties were the same even though the department may have changed names? A. Within a given within a given job title, yes. Q. So in 1998 you were promoted to a senior investigator. Correct? A. The best I can recall is 1998. Q. Can you tell me your next promotion or next position? A. That's been still the same	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	the point that the there are core job responsibilities for a given position, but the project responsibilities can vary between projects even with the same title. BY MR. KELLER: Q. You're researching different you may be researching different viruses. Correct? A. Yes, as an example. Q. Can you just give me a description of what you do as a senior investigator during this time frame? I understand you worked on different projects, but is there a way to describe what your job responsibilities were in a very general way? MR. SANGIAMO: You said this time frame, that being? BY MR. KELLER: Q. 1998 to 2017 you've had the same job title, and my question is, were you generally doing the same work? A. There were some I would break it up into two time periods.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. That is the department of virus and cell biology? A. Our department name changed many times so I think that like we were virus and cell biology and cellular/microbiology and then I can't I don't recall how many it's in the same theme of virus and cell biology. The department number changed and the name changed, but the same entity, basically. The same group. Q. The same group. It was still in the same group. Q. The same management group? A. Yes. Q. Your job duties were the same even though the department may have changed names? A. Within a given within a given job title, yes. Q. So in 1998 you were promoted to a senior investigator. Correct? A. The best I can recall is 1998. Q. Can you tell me your next promotion or next position?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the point that the there are core job responsibilities for a given position, but the project responsibilities can vary between projects even with the same title. BY MR. KELLER: Q. You're researching different you may be researching different viruses. Correct? A. Yes, as an example. Q. Can you just give me a description of what you do as a senior investigator during this time frame? I understand you worked on different projects, but is there a way to describe what your job responsibilities were in a very general way? MR. SANGIAMO: You said this time frame, that being? BY MR. KELLER: Q. 1998 to 2017 you've had the same job title, and my question is, were you generally doing the same work? A. There were some I would break

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A. From 1998 through 2013 I was in 1 Q. What do you mean by -- can you 2 some version of virus and cell biology. 2 describe what you mean by an objective? 3 Again, I don't recall the name of the 3 Objective meaning work on a 4 department at the time. With the 4 specific program or in our case largely 5 responsibility of, as best I can recall, 5 vaccines. In my personal experience, largely applying cell biology and virology to answer 6 vaccines. questions for projects that the project --7 Do you consider yourself to be Q. an expert in vaccine research? 8 that the department was supporting. That 8 9 ranged from looking at alternate cell A. I consider myself -substrates for virus growth, increasing 10 MR. SANGIAMO: Object to the form. productivity, evaluating different virus 11 strains, looking into animal models for 12 THE WITNESS: -- to be an expert infection. So a range of applications. My 13 in cell biology and virology. Perhaps 14 responsibility was to lead a group who 14 less so in the cell biology, more so in 15 contributed to that area. 15 the virology part. Not specifically in vaccine research. 16 Q. These are basically research 16 17 projects. Correct? 17 BY MR. KELLER: 18 Yes. 18 Q. And so -- and that's your A. 19 19 educational training, is in virology. Correct? O. So you were a research lab. 20 20 Correct? A. 21 21 Can you tell me during this time MR. SANGIAMO: Object to the 22 22 frame -- let me sort of narrow this down a form. 23 23 THE WITNESS: We were a lab in a little bit. 24 research department. 24 Between 1998 and 2002, how many 25 BY MR. KELLER: 25 people were in your lab that you had Page 59 Page 61 1 Did you do any manufacturing 1 responsibility for? 2 testing? 2 A. I don't recall specific number. 3 MR. SANGIAMO: Object to the 3 I would estimate between four and something 4 form. 4 more than four. I don't remember the upper 5 5 MR. KELLER: Strike that. 6 BY MR. KELLER: 6 Were there people that reported 7 Q. Did you work with Merck 7 to you that other people reported to in your manufacturing on any of the products that were 8 lab --9 on the market for purposes of -- let me strike 9 MR. SANGIAMO: Object to the 10 that. 10 form. 11 So you said that you were doing 11 BY MR. KELLER: 12 research under virus and cell biology. Those 12 Q. -- during this time frame 1998 13 projects were changed based on whatever the 13 to 2002? 14 department was interested in pursuing. 14 A. There -- as far as formal 15 Correct? Is that fair? 15 reporting structure, everyone reported to me. 16 MR. SANGIAMO: Object to the There were some informal, I don't know if they 16 17 17 called it reporting structure, but someone who form. 18 THE WITNESS: Our -- the 18 might oversee other -- another group's 19 department had objectives, the research 19 activities in the lab. 20 labs had objectives, and our department 20 Q. During this time frame, from 21 had objectives that were a subset of 21 1988 to 2002, I'm going to talk about that for 22 that. And then our lab contributed to 22 a while. Unless I say otherwise, that's the 23 time frame I'm talking about for purposes of whatever the objectives were for the 23 24 24 this series of questions. This informal area. BY MR. KELLER: reporting structure, who was -- was there a

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	Page 62		Page 64
1	second in command in your lab at this time	1	form.
2	frame?	2	THE WITNESS: There is one other
3	MR. SANGIAMO: Object to the	3	person who I don't know if it fits
4	form.	4	into the seniority part, but another
5	THE WITNESS: There were	5	person, DeeMarie Watson whoand this
6	people or there were people, some	6	actually may precede 1998, the dates.
7	people with more seniority than others.	7	Had her oversee largely a group of
8	I wouldn't characterize them as second	8	contract employees while another group
9	in command.	9	of the lab was busy with other
10	BY MR. KELLER:	10	activities.
11	Q. Ever hear that term used at	11	BY MR. KELLER:
12	Merck before?	12	Q. So Ms. Yagodich, she's a
13	A. I've heard it used in general	13	virologist as well?
14	before. I don't can't say that	14	MR. SANGIAMO: Object to the
15	specifically specific to Merck or that I heard	15	form.
16	it at Merck.	16	THE WITNESS: Her undergraduate
17		17	education, I actually, I don't
		l	recall what her undergraduate degree is
18	seniority, who had the highest seniority in	18	e e
19	your lab during this time frame?	19	in. Her undergraduate education would
20	A. Mary Yagodich.	20	not be focused on virology, but from
21	Q. Did you depend on Ms. Yagodich	21	her experience in the lab, I would
22	MR. SANGIAMO: Object.	22	consider her a virologist.
23	BY MR. KELLER:	23	BY MR. KELLER:
24	Q to oversee certain aspects of	24	Q. You believe her to be competent?
25	the lab?	25	A. Yes.
	Page 63		Page 65
1	MR. SANGIAMO: Object to the	1	Q. Honest?
2	form. You can answer.	2	A. Yes.
3	THE WITNESS: I looked to Mary	3	Q. Do you recall that she had a
4	to be the most highly trained,	4	good memory?
5	experienced person in the lab who I	5	MR. SANGIAMO: Object to the
6	would go to to ask questions or have	6	form.
7	her if other people needed help,	7	THE WITNESS: I recall that she
8	help her go to them.	8	was fluid in the work she that was
9	As far as I forget what your	9	doing. Whether that constitutes a good
10	original	10	memory, I can't say.
10			
11	BY MR KELLER		BY MR KELLER
11 12	BY MR. KELLER: O I'm trying to get this formal	11	BY MR. KELLER: O Do you recall her let me back
12	Q. I'm trying to get this formal	12	Q. Do you recall her let me back
12 13	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what	12 13	Q. Do you recall her let me back up.
12 13 14	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it?	12 13 14	Q. Do you recall her let me back up. Did you have a romantic
12 13 14 15	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER:	12 13 14 15	Q. Do you recall her let me back up. Did you have a romantic relationship with her?
12 13 14 15 16	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped	12 13 14 15 16	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No.
12 13 14 15 16 17	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again	12 13 14 15 16 17	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her?
12 13 14 15 16 17 18	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again if you're done answering. Are you done	12 13 14 15 16 17 18	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her? A. No.
12 13 14 15 16 17 18 19	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again if you're done answering. Are you done answering?	12 13 14 15 16 17 18 19	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her? A. No. Q. Did you ever date anybody's
12 13 14 15 16 17 18 19 20	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again if you're done answering. Are you done answering? A. Yes.	12 13 14 15 16 17 18 19 20	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her? A. No. Q. Did you ever date anybody's family members in the lab?
12 13 14 15 16 17 18 19 20 21	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again if you're done answering. Are you done answering? A. Yes. Q. Other than Mary Yagodich, was	12 13 14 15 16 17 18 19 20 21	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her? A. No. Q. Did you ever date anybody's family members in the lab? A. Yes.
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12 13 14 15 16 17 18 19 20 21 22 23 24	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again if you're done answering. Are you done answering? A. Yes. Q. Other than Mary Yagodich, was there anybody else in this informal hierarchy that you thought of as having seniority in terms of overseeing other people?	12 13 14 15 16 17 18 19 20 21 22 23 24	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her? A. No. Q. Did you ever date anybody's family members in the lab? A. Yes. Q. And who was that? A. Sister of Mary Yagodich. Q. So you were close to Mary?
12 13 14 15 16 17 18 19 20 21 22 23	Q. I'm trying to get this formal MR. SANGIAMO: I'm sorry, what is it? BY MR. KELLER: Q. Let me just we just stepped on each other. Let me ask the question again if you're done answering. Are you done answering? A. Yes. Q. Other than Mary Yagodich, was there anybody else in this informal hierarchy that you thought of as having seniority in	12 13 14 15 16 17 18 19 20 21 22 23	Q. Do you recall her let me back up. Did you have a romantic relationship with her? A. No. Q. Were you in love with her? A. No. Q. Did you ever date anybody's family members in the lab? A. Yes. Q. And who was that? A. Sister of Mary Yagodich.

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1	Page 66 form.	1	Page 68 '95. Do you see that?
2	THE WITNESS: Not I was close	2	A. Yes.
3	to her being a long time member of the	3	Q. Was that required to take GMP
4	laboratory, not because of any other	4	training yearly at Merck
5	factor.	5	MR. SANGIAMO: Object to the
6	BY MR. KELLER:	6	form.
7	Q. Did you ever socialize with her	7	BY MR. KELLER:
8	outside the office?	8	Q through this 1998 through
9	A. I remember one occasion, at a	9	2002 period? Let me back up.
10	Christmas party when she first moved into her	10	Did you take GMP let me
11	house. That's the only event I recall.	11	strike that.
12	Q. Did you ever socialize with	12	What does GMP what's your
13	anybody in the lab outside of the office?	13	understanding of GMP?
14	A. Periodically the group would go	14	A. It's a changing target of
15	to a restaurant or bar like Friday's after	15	technically CGMP, current good manufacturing
16	work. I remember going once, so not on a I	16	practices, reflecting whatever the
17	do recall doing it occasionally, but not on a	17	expectations are or requirements at the time
18	regular basis.	18	for manufacturing things like clinical
19	Q. Did you ever take any of your	19	supplies or indoor manufactured product or
20	employees to lunch? Let me strike that.	20	product for human use.
21	Did you ever take anybody in	21	Q. Do you know what the difference
22	your lab that you had supervisory	22	between CGMP is and Good Clinical Practices?
23	responsibilities over to lunch?	23	A. No.
24	A. I did take lab members to	24	Q. You never were trained in that?
25	Christmas lunches. There were other lunches	25	A. I don't recall being trained in
	Page 67		Page 69
1	41-4 T-44-4 1-4 T-4-4 1-4 1		
	that I attended, I don't know if that qualifies	1	Good Clinical Practices.
2	as taking them. I was with them at lunch.	2	Q. Your lab was not certified as a
2 3	as taking them. I was with them at lunch. Q. Would that include the entire	2 3	Q. Your lab was not certified as a GCP lab. Correct?
2 3 4	as taking them. I was with them at lunch. Q. Would that include the entire lab or just a subset of the lab	2 3 4	Q. Your lab was not certified as a GCP lab. Correct? MR. SANGIAMO: Object to the
2 3 4 5	as taking them. I was with them at lunch. Q. Would that include the entire lab or just a subset of the lab MR. SANGIAMO: Object to the	2 3 4 5	Q. Your lab was not certified as a GCP lab. Correct? MR. SANGIAMO: Object to the form.
2 3 4 5 6	as taking them. I was with them at lunch. Q. Would that include the entire lab or just a subset of the lab MR. SANGIAMO: Object to the form.	2 3 4 5 6	Q. Your lab was not certified as a GCP lab. Correct? MR. SANGIAMO: Object to the form. BY MR. KELLER:
2 3 4 5 6 7	as taking them. I was with them at lunch. Q. Would that include the entire lab or just a subset of the lab MR. SANGIAMO: Object to the form. BY MR. KELLER:	2 3 4 5 6 7	Q. Your lab was not certified as a GCP lab. Correct? MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. At any time during the 1998 to
2 3 4 5 6 7 8	as taking them. I was with them at lunch. Q. Would that include the entire lab or just a subset of the lab MR. SANGIAMO: Object to the form. BY MR. KELLER: Q during this time frame 1998	2 3 4 5 6 7 8	Q. Your lab was not certified as a GCP lab. Correct? MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. At any time during the 1998 to 2002 period?
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18 (Pages 66 - 69)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

1	Page 70	1	Page 72
1	GMP lab from 1998 to 2002. Is that correct?	1	A. My first thought was it was
2	A. I cannot exclude that there was	2	after 2002, but it may have been it may
3	a again, with the inspection that our	3	have been in the late 2001 to 2002 period. I
4	internal quality assurance group did, what	4	don't recall the date.
5	that what the outcome of that was, if that	5	Q. So there may have been another
6	said that we were behaving as GMP or not. I don't recall.	6	inspection with respect to that?
1		7	A. Internal inspection by Merck to
8	Q. You weren't trained in GMP	8	see if we would if our lab would be capable
9	compliance to run your lab. Correct? MR. SANGIAMO: Object to the	9	of making, basically, clinical supplies.
11	form.	10	Q. Do you recall the results of
12	THE WITNESS: I did receive GMP	11 12	that inspection?
13	training. As far as what GMP training	13	A. I have a general recollection.
14	would be needed to run the lab, I can't	14	They had recommendations and we complied with.
15	say that I know that there is specific	15	I don't recall that they had major reservations.
16	training for that.	16	
17	BY MR. KELLER:	17	Q. Did you have any procedures in place to ensure compliance with GMP
18	Q. Was your lab ever certified as a	18	requirements?
19	GMP lab during this 1998 through 2002 time	19	MR. SANGIAMO: Object to the
20	frame?	20	form.
21	A. Come back to the inspection that	21	THE WITNESS: We had SOPs, as
22	our quality assurance group did. We passed	22	best I can recall, that we obtained
23	I don't recall if that constitutes a	23	from the manufacturing division that we
24	certification.	24	were using as a guide. Then we
25	Q. That was just one inspection.	25	generated additional documents,
			Page 73
1	Page 71 Correct?	1	additional SOPs within our department
2	A. Yes, that's the only one I	2	to try to be compliant with the GMP
3	recall.	3	expectations.
4	Q. And that came, that inspection	4	BY MR. KELLER:
5	occurred after the FDA inspected your lab.	5	Q. That was after the FDA
6	Correct?	6	
-			inspection in August of 2001. Correct?
7	A. Yes.	7	inspection in August of 2001. Correct? A. Yes.
8	A. Yes.Q. And other than that one		
	Q. And other than that one	7	A. Yes.
8		7 8	A. Yes.Q. But before that, you didn't have
8 9	Q. And other than that one inspection, you don't recall ever being	7 8 9	A. Yes. Q. But before that, you didn't have any SOPs?
8 9 10	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck?	7 8 9 10	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the
8 9 10 11	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the	7 8 9 10 11	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form.
8 9 10 11 12	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form.	7 8 9 10 11 12	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were
8 9 10 11 12 13	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the	7 8 9 10 11 12 13	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall
8 9 10 11 12 13 14	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the 1998 to 2002 period.	7 8 9 10 11 12 13 14	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall that we had any that were applying to
8 9 10 11 12 13 14 15	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the 1998 to 2002 period. BY MR. KELLER:	7 8 9 10 11 12 13 14 15	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall that we had any that were applying to the work that we were doing.
8 9 10 11 12 13 14 15 16	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the 1998 to 2002 period. BY MR. KELLER: Q. What about after?	7 8 9 10 11 12 13 14 15 16	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall that we had any that were applying to the work that we were doing. MR. SANGIAMO: Jeff, we've been
8 9 10 11 12 13 14 15 16 17	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the 1998 to 2002 period. BY MR. KELLER: Q. What about after? A. There was a we were doing	7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall that we had any that were applying to the work that we were doing. MR. SANGIAMO: Jeff, we've been going about probably about an hour
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8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the 1998 to 2002 period. BY MR. KELLER: Q. What about after? A. There was a we were doing some work, and this actually may fall into the 2002 period, where we were working on an emergency vaccine program where our CGMP group	7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall that we had any that were applying to the work that we were doing. MR. SANGIAMO: Jeff, we've been going about probably about an hour and ten, so when you get to a good stopping point. MR. KELLER: Take a break,
8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And other than that one inspection, you don't recall ever being inspected by the CGMP folks at Merck? MR. SANGIAMO: Object to the form. THE WITNESS: Not during the 1998 to 2002 period. BY MR. KELLER: Q. What about after? A. There was a we were doing some work, and this actually may fall into the 2002 period, where we were working on an emergency vaccine program where our CGMP group did a review of our lab just to assess whether	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. But before that, you didn't have any SOPs? MR. SANGIAMO: Object to the form. THE WITNESS: There were documents existed, but I don't recall that we had any that were applying to the work that we were doing. MR. SANGIAMO: Jeff, we've been going about probably about an hour and ten, so when you get to a good stopping point. MR. KELLER: Take a break, that's fine.
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Appx4898

			5
1	Page 74	1	Page 76 format?
2	VIDEOGRAPHER: The time is now	2	A. I recognize the format, yes.
3	10:26. This begins disc two. You may	3	Q. Do you have any reason to
4	proceed.	4	believe that this is not a printout of your
5	BY MR. KELLER:	5	journal that you maintained in Microsoft Word?
6	Q. Sir, I'm going to show you what	6	A. Yeah, I can't just to look to
7	has been we're going to mark as Exhibits 2	7	see if can't immediately verify
8	through 19 which have been produced to us as	8	completeness that there's not a day missing or
9	your journals from 1999 through 2015. You	9	something. But it looks like the format that
10	testified earlier that you kept a journal in	10	I would use. And the dates look like they're
11	Microsoft Word. Correct?	11	covering the period that you mentioned.
12	A. Yes.	12	Q. Do you have any reason to
13		13	believe that this is not a full and complete
14	(Exhibits Krah-2, 1998 Journal,	14	set of the journals that you maintained?
15	488056 - 488404, Krah-3, 1999 Journal,	15	MR. SANGIAMO: Object to the
16	455405 - 488932, Krah-4, 2000 Journal,	16	form.
17	490081 - 490591, Krah-5, 2001 Journal,	17	THE WITNESS: I have no reason
18	490592 - 491038, Krah-6, 2002 Journal,	18	to suspect or anticipate or expect
19	491039 - 491419, Krah-7, 2003 Journal,	19	that this is not a complete version.
20	491420 - 491835, Krah-8, 2004 Journal,	20	BY MR. KELLER:
21 22	489194 - 489500, Krah-9, 2005 Journal,	21	Q. And the journal that you created
23	488933 - 489193, Krah-10, 2006 Journal, 489501 - 4897111, Krah-11, 2007	22 23	from at least 1998 through 2015 that was produced to us, those journals were created in
24	Journal, 489903 - 490080, Krah-12, 2008	24	the ordinary course of your job duties at
25	Journal, 489712 - 489902, Krah-13, 2009	25	Merck. Correct?
	Page 75		Page 77
1 1	Journal 491836 - 492024 Krah-14 2010	1	
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Journal, 491836 - 492024, Krah-14, 2010 Journal, 492025 - 492278, Krah-15, 2011	1 2	MR. SANGIAMO: Object to the
2	Journal, 492025 - 492278, Krah-15, 2011	2	MR. SANGIAMO: Object to the form.
	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012	2 3	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry.
2 3	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17,	2	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if
2 3 4	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18,	2 3 4	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry.
2 3 4 5	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17,	2 3 4 5	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job
2 3 4 5 6 7 8	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19,	2 3 4 5 6	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or
2 3 4 5 6 7 8 9	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were	2 3 4 5 6 7	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER:
2 3 4 5 6 7 8 9	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were marked for identification.)	2 3 4 5 6 7 8	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER: Q. Yes, was it part of your job duties? A. It's not at least my
2 3 4 5 6 7 8 9 10	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were marked for identification.)	2 3 4 5 6 7 8 9 10 11	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER: Q. Yes, was it part of your job duties? A. It's not at least my understanding, it's not a requirement for my
2 3 4 5 6 7 8 9 10 11 12	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were marked for identification.) BY MR. KELLER: Q. Let me show you Exhibit 2 which I put in front you, sorry, which is the 1998	2 3 4 5 6 7 8 9 10 11 12	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER: Q. Yes, was it part of your job duties? A. It's not at least my understanding, it's not a requirement for my job.
2 3 4 5 6 7 8 9 10 11 12 13	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were marked for identification.) BY MR. KELLER: Q. Let me show you Exhibit 2 which I put in front you, sorry, which is the 1998 journal. Take a look at Exhibit 2, starts at	2 3 4 5 6 7 8 9 10 11 12 13	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER: Q. Yes, was it part of your job duties? A. It's not at least my understanding, it's not a requirement for my job. Q. Did you do it as part of your
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were marked for identification.) BY MR. KELLER: Q. Let me show you Exhibit 2 which I put in front you, sorry, which is the 1998 journal. Take a look at Exhibit 2, starts at Bates stamp number 488056, and tell me if you recognize this document as a journal from starting in 1998 through from January through the end of December for 1998? MR. SANGIAMO: Object to the form. THE WITNESS: Just to clarify, you're asking if this looks like one of my a journal that I had that spanned those periods that you mentioned?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER: Q. Yes, was it part of your job duties? A. It's not at least my understanding, it's not a requirement for my job. Q. Did you do it as part of your though it wasn't a requirement, was it something that you did to help you perform your job at Merck? A. I did it to help increase my efficiency, for example, be able to recall or recall old information. Q. So you as part of your job duties, you used these journals that we've marked Exhibit 2 through 19 from 1998 through 2015 as part of your to help you do your
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Journal, 492025 - 492278, Krah-15, 2011 Journal, 492279 - 492511, Krah-16, 2012 Journal, 492516 - 4925738, Krah-17, 2013 Journal, 486274 - 486490, Krah-18, 2014 Journal, 486593 - 486830, Krah-19, 2015 Journal, 486491 - 486592, were marked for identification.) BY MR. KELLER: Q. Let me show you Exhibit 2 which I put in front you, sorry, which is the 1998 journal. Take a look at Exhibit 2, starts at Bates stamp number 488056, and tell me if you recognize this document as a journal from starting in 1998 through from January through the end of December for 1998? MR. SANGIAMO: Object to the form. THE WITNESS: Just to clarify, you're asking if this looks like one of my a journal that I had that spanned	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. SANGIAMO: Object to the form. THE WITNESS: Are sorry. Just to clarify, are you asking if having a journal was part of my job duties or BY MR. KELLER: Q. Yes, was it part of your job duties? A. It's not at least my understanding, it's not a requirement for my job. Q. Did you do it as part of your though it wasn't a requirement, was it something that you did to help you perform your job at Merck? A. I did it to help increase my efficiency, for example, be able to recall or recall old information. Q. So you as part of your job duties, you used these journals that we've marked Exhibit 2 through 19 from 1998 through

	INGILI CONTIDENTIAL -		
1	Page 78 form.	1	Page 80 A. There are occasions where that
2		$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	A. There are occasions where that was included.
3	THE WITNESS: I did it to help me be more efficient in my job at	3	Q. Why would you capture a
4	Merck.	4	communication between another for example,
5	BY MR. KELLER:	5	a superior?
6	Q. Did anybody know did your	6	MR. SANGIAMO: Object to the
7	superiors know that you were using a journal	7	form.
8	at Merck?	8	MR. KELLER: Let me strike that.
9	MR. SANGIAMO: Object to the	9	BY MR. KELLER:
10	form.	10	Q. Did you ever capture communications
11	THE WITNESS: I can't say that	11	with your superiors?
12	they did or didn't, no.	12	A. Yes.
13	BY MR. KELLER:	13	Q. Who were your superiors, who did
14	Q. Was it your practice during your	14	you report to from this 1998 to 2002 time
15	time that you worked at Merck, at least from	15	frame?
16	1998, you maintained a daily journal of	16	A. Alan Shaw.
17	your what you were strike that.	17	Q. Who did Alan Shaw report to?
18	What was the purpose of you	18	A. Emilio Emini.
19	maintaining a journal on a daily basis?	19	Q. Who did Mr. Emini report to?
20	A. The original intent, as best I	20	A. That, I don't recall.
21	can recall, is to keep track of experiments,	21	Q. During this time frame, did you
22	both progress and experiments, in some cases	22	ever have any communications with Emilio Emini?
23	experiment numbers, in some cases results of	23	A. Yes.
24	those experiments. And then additionally over	24	Q. Did you ever capture those in
25	time began to include summaries of meetings or	25	your journals?
	Page 79		Page 81
1	points that I thought were relevant to being a	1	A. As best I can recall, yes.
2	more easily retrievable form for my personal	2	Q. Did you have any communications
3	efficiency.	3	with Alan Shaw?
4	Q. You didn't use this journal for	4	A. Yes.
5	your personal life. Correct?	5	Q. Did you capture those in your
6	A. I can't exclude that there were	6	journals?
7	no in fact, I expect there are entries,	7	MR. SANGIAMO: Object to the
8	have a car service done today or something	8	form.
9	like that. So it was a journal to keep track	9	THE WITNESS: Yes.
10	primarily of work-related things, but there	10	BY MR. KELLER:
11	are some work life-related events that I	11	Q. Did you have communications with
12	would have like reminders, for example.	12	individuals in the lab that you captured in
13	Q. Did it act as your calendar as	13	the journals during this 1998 to 2002 time
14	well? A. It was a reminder for certain	14	frame?
15		15 16	A. I don't recall specific examples,
16 17	items that would be part of a calendar. Q. I noticed in your journals that	17	but I would anticipate so. Q. Do you have any reason to believe
18	Q. I noticed in your journals that some things had checks on it and some things	18	Q. Do you have any reason to believe that the entries that you entered into your
19	just had bullet points.	19	journals were inaccurate?
20	A. Yes.	20	MR. SANGIAMO: Object to the
21	Q. What do the checks mean?	21	form.
22	A. The check typically means that	22	THE WITNESS: The entries that I
	that comment was completed or addressed.	23	made are, to the best of my understanding,
1.2.3	John John Completed of addressed.		
23 24		24	my impression or so as far as whether
23 24 25	Q. And did you also capture communications with other Merck employees?	24 25	my impression or so as far as whether they're accurate, I would say they

1			
	Page 82		Page 84
	reflect my impression, my understanding.	1	as part of your duties as you described in
2	Whether that constitutes accuracy I	2	your testimony?
3	guess one could debate, but there	3	MR. SANGIAMO: Object to the
4	were it was represented my	4	form.
5	understanding.	5	THE WITNESS: The 2001, at least
6	BY MR. KELLER:	6	the format looks consistent with the
7	Q. And you would enter things in	7	format that I had used previously.
8	the journal contemporaneous when those things		There is this may have been an error
9	were happening. Correct?	9	in the date entry. The back end of it,
10	MR. SANGIAMO: Object to the	10	the dates, the year kind of jumps from
11	form.	11	2001 back to 2000.
12	THE WITNESS: The objectives was	12	BY MR. KELLER:
13	to enter them as or ideally on the	13	Q. Did you understand that the
14	same day, but I can't guarantee that in	14	journal, the Word the Microsoft Word
15	all cases it was done on the same day.	15	were there strike that.
16	BY MR. KELLER:	16	As part of you using Microsoft
17	Q. Was part of the use of the	17	Word to do your daily journal entry, did you
18	journal to track the flow of the running of	18	ever edit an entry?
19	the experiments?	19	MR. SANGIAMO: Object to the
20	A. In the context of so I'll say	20	form.
21	yes in the context of, for example, I recall	21	THE WITNESS: Edit in what? Can
22	cases where I would have a list of experiments	22	you give an example?
23	that were in progress and then as they were	23	BY MR. KELLER:
24	completed, confirmation that they were	24	Q. Did you ever copy sections from
25	completed so we can basically have a reminder	25	one day and move it to the next day?
	Page 83		Page 85
1	of what is still to be completed.	1	A. Yes.
2	Q. Did you ever capture results in	2	Q. Do you understand what metadata
3	your journal of certain experiments?	3	is? Metadata?
4	Å. Yes.	4	A. I've heard the term before, but
5	Q. Did you ever discuss issues	5	I can't say that I know what it means.
6	within the lab in your journals, for example,	6	Q. So you don't know whether or not
7	problems with equipment?	7	the information that's at the back of these
8	MR. SANGIAMO: Object to the	8	journals were captured in Microsoft Word and
9	form.	9	when the lawyers produced these documents,
10	BY MR. KELLER:	10	produced all the data that was in Microsoft
10	O D : 41: 1000 / 2000 /:	11	
11	Q. During this 1998 to 2002 time	11	Word but not viewable as your daily journal?
	8	12	Word but not viewable as your daily journal? MR. SANGIAMO: Object to the
11	period?	12	MR. SANGIAMO: Object to the
11 12 13	period? MR. SANGIAMO: Same objection.		
11 12 13 14	period? MR. SANGIAMO: Same objection. THE WITNESS: I don't recall. I	12 13	MR. SANGIAMO: Object to the form. THE WITNESS: That's not a
11 12 13 14 15	period? MR. SANGIAMO: Same objection.	12 13 14	MR. SANGIAMO: Object to the form. THE WITNESS: That's not a situation I'm aware of. The dates that
11 12 13 14 15 16	period? MR. SANGIAMO: Same objection. THE WITNESS: I don't recall. I don't recall examples of that. BY MR. KELLER:	12 13 14 15	MR. SANGIAMO: Object to the form. THE WITNESS: That's not a situation I'm aware of. The dates that I had questioned looked like the right
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	Page 86		Page 88
1	instead of 2001.	1	is of a protocol?
2	BY MR. KELLER:	2	MR. SANGIAMO: Object to the
3	Q. Or you could have been do you	3	form.
4	recall ever using the same file folder for	4	BY MR. KELLER:
5	your journal and then moving that data into	5	Q. Let me back up.
6	the next year in a different file or do you	6	Do you know what a protocol is?
7	recall just every January 1st starting a new	7	A. I've heard of them and seen
8	file?	8	them, but I can't say that I understand all
9	A. I at least the best of my	9	the components that are in there.
10	recollection, the practice I was using	10	Q. And so did you ever see the
11	typically was to, for the next year, include	11	protocol for Protocol 007?
12	this one that comes to mind, one going back	12	MR. SANGIAMO: Object to the
13	to December 1st of the previous year and carry	13	form.
14	that over to the next year. So it wasn't a	14	THE WITNESS: I don't recall
15	January 1st to January 31st January 1st to	15	seeing the full protocol. I can't
16	December 31st.	16	exclude that I saw some part of the
17	Q. That explains why the beginning	17	protocol.
18	of every journal may have dates from December	18	BY MR. KELLER:
19	the prior year?	19	Q. What does the protocol, based on
20	A. Yes. Yes.	20	your understanding, describe? What is the
21	Q. Fair enough. Let me have you	21	purpose strike that.
22	look on the you're looking in the 2000	22	What is the purpose of a
23	journal. Right?	23	protocol?
24	A. Yes.	24	A. It's an area outside of my
25	Q. Can you turn to page 428 of that	25	expertise. I've read them, I've seen them,
	Page 87		Page 89
1	journal? There's a page number at the top of	1	but I can't speak with confidence about what
2	the journal.	2	their the purpose is or what it includes.
3	A. Okay.	3	Q. When you said that your
4	Q. Do you see that?	4	understanding of the Protocol 007 was to
5	A. Okay. Yes.	5	compare the immunogenicity between three
6	Q. And here you have Wednesday,	6	doses, is that a fair statement of what you
7	December 6, 2000. Correct? Do you see that?	7	just testified to?
8	A. Yes.	8	A. That's my recollection of my
		9	understanding.
9	Q. What is the first entry there?	🤊	understanding.
9	Q. What is the first entry there?A. What it says is "Start mumps	10	Q. Did you understand that to be
10	A. What it says is "Start mumps	10	Q. Did you understand that to be
10 11	A. What it says is "Start mumps AIGENT assays for Protocol 007."	10 11	Q. Did you understand that to be the objective of Protocol 007?
10 11 12	A. What it says is "Start mumps AIGENT assays for Protocol 007." Q. Is that when you started running	10 11 12	Q. Did you understand that to be the objective of Protocol 007? MR. SANGIAMO: Object to the
10 11 12 13	A. What it says is "Start mumps AIGENT assays for Protocol 007." Q. Is that when you started running the sera for Protocol 007?	10 11 12 13	Q. Did you understand that to be the objective of Protocol 007? MR. SANGIAMO: Object to the form.
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	HIGHLY CONFIDENTIAL -		
	Page 90		Page 92
1	recall, my understanding.	1	that did you have any understanding that
2	Q. Do you recall what those three	2	the purpose of this assay was to identify an
3	doses were?	3	end expiry potency for Merck's marketed MMR
4	A. No.	4	product for the mumps component?
5	Q. Do you recall what the purpose	5	A. I recall that the title of the
6	was behind those three doses were?	6	study was an end expiry study. So that would
7	MR. SANGIAMO: Object to the	7	imply that an expiry was part of the study.
8	form.	8	But I don't know, I don't recall how the data
9	THE WITNESS: All I recall is	9	factored into that calculation.
10	that they were comparing the	10	Q. When you say that you did
11	immunogenicity of those three doses. I	11	development work, can you describe for me what
12	don't recall further details.	12	you mean by development work?
13	BY MR. KELLER:	13	MR. SANGIAMO: Object to the
14	Q. So you don't know how that data	14	form.
15	was going to be used?	15	THE WITNESS: Just to clarify,
16	A. I recall that there was going to	16	you're looking for, like, variables
17	be a comparison of immunogenicity between	17	that we are looked at in developing
18	doses, but I don't recall details of how that	18	the assay?
19	was going to be used.	19	BY MR. KELLER:
20	Q. Did that comparison have any	20	Q. Sure.
21	clinical relevance to whether or not the	21	A. So initial work was largely
22	vaccine would protect a kid from getting sick	22	based on any discussion with the FDA where we
23	from mumps?	23	ran options for the assay format, meaning
24	A. I don't I'm not it's	24	different virus strains, different supplements
25	outside of my area of expertise. I don't know	25	to the media, different means of calculating
		1	
	Page 91		Page 93
1	what the clinical connection for clinical	1	an endpoint, different means of visualizing
2	what the clinical connection for clinical relevance was intended.	2	an endpoint, different means of visualizing plaques. So in discussion with the FDA, we
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24 (Pages 90 - 93)

	D 04		D 06
1	Page 94 testimony is you don't know why Protocol 007	1	Page 96 form.
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	was being conducted?	2	THE WITNESS: My opinion is that
$\frac{2}{3}$	A. As best I can recall, my	$\frac{2}{3}$	the my understanding and opinion is
		4	that the an antibody assay is an
4	recollection and understanding was to compare	5	
5	the immunogenicity of the three vaccine doses.	6	imperfect model, imperfect measure of
6	Q. Do you recall there being any	-	an immune response to a vaccine. It's
7	requirement by CBER you understand what	7	not a given correlate of protection.
8	CBER is, right?	8	The assay itself is not does not
9	A. Yes.	9	provide an automatic correlate of
10	Q. What's CBER?	11	protection. BY MR. KELLER:
11	A. Center for Biologics Evaluation		
12	and Research.	12	Q. Do you understand what a
13	Q. And they're a division of the	13	surrogate of protection is?
14	FDA. Correct?	14	A. I've heard of correlates of
15	A. Yes.	15	protection. Surrogate I'm not sure about.
16	Q. And they specialize, for the	16	Q. You don't know what a surrogate
17	purposes of this case, in vaccine, correct,	17	of protection is?
18	biologics?	18	A. I've heard of correlate of
19	A. Biologics of vaccines, yes.	19	protection. Surrogate of protection, it's not
20	Q. So do you recall any	20	a familiar term to me.
21	communications with the FDA or CBER where they		Q. You said that antibody assays
22	required for Protocol 007 that the assay be	22	are imperfect. Are any antibody assays more
23	linked to protection from disease?	23	relevant to a clinical link to protection than
24	MR. SANGIAMO: Object to the	24	others?
25	form.	25	A. I can't I'm not an expert in
	Page 95		Page 97
1	THE WITNESS: I do not recall	1	the area of the of clinical as far as
2	any connection to protection.	2	making a comment on protection from disease.
3	BY MR. KELLER:	3	My personal opinion is that none of at
4	Q. If the assay was required to be	4	least from my knowledge and experience, none
5	linked to protection from disease, would you		
		5	of the assays are an exact mimic of the immune
6	have developed a different assay?	6	response that people would have.
7	MR. SANGIAMO: Object to the		response that people would have. Q. Right. But some assays are
7 8	MR. SANGIAMO: Object to the form.	6 7 8	response that people would have. Q. Right. But some assays are better than others at predicting whether or
7 8 9	MR. SANGIAMO: Object to the form. THE WITNESS: No.	6 7 8 9	response that people would have. Q. Right. But some assays are better than others at predicting whether or not a result from that assay is linked to a
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7 8 9 10 11	MR. SANGIAMO: Object to the form. THE WITNESS: No. BY MR. KELLER: Q. You would have ran the same	6 7 8 9 10 11	response that people would have. Q. Right. But some assays are better than others at predicting whether or not a result from that assay is linked to a clinical clinically relevant connection to protection from disease?
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	Page 98		Page 100
1	A. There are some versions of ELISA	1	correlate.
2	that have functional activity, but the	2	BY MR. KELLER:
3	majority of them are binding assays.	3	Q. Do you know whether or not Merck
4	Q. Do you know what are you	4	ever correlated its plaque reduction
5	familiar with the ELISA assay that was run in	5	neutralization assay to an ELISA assay?
6	Protocol 007? Let me strike that.	6	MR. SANGIAMO: Object to the
7	Do you understand that an ELISA	7	form.
8		8	THE WITNESS: I am aware of a
9	assay was run in Protocol 007? A. I recall that an ELISA was run	9	
	·-	10	correlation that was done as part of
10	as part of the Protocol 007 study.	11	as best I can recall, Protocol 007, the
11	Q. And did you ever review the	12	ELISA and the AIGENT assay.
12	protocol for that ELISA assay?		BY MR. KELLER:
13	MR. SANGIAMO: Object to the	13	Q. Do you recall what do you
14	form.	14	mean what's your understanding of the
15	BY MR. KELLER:	15	correlation that was conducted as part of the
16	Q. Let me strike that.	16	Protocol 007?
17	Do you recall whether or not a	17	A. I don't have any details on how
18	protocol was developed for that ELISA assay	18	the comparison was done.
19	using Protocol 007?	19	Q. Were you involved in that at
20	MR. SANGIAMO: Object to the	20	all?
21	form.	21	A. I can't exclude that I might
22	THE WITNESS: I don't know.	22	have received some e-mails about it, but I was
23	BY MR. KELLER:	23	not involved in the planning of it or, as far
24	Q. You don't know. Do you recall	24	as I can recall, the exclusion other than the
25	ever reviewing a protocol for the ELISA	25	neutralization part.
١.	Page 99		Page 101
1	assay	1	Q. When did you first learn about
2	assay MR. SANGIAMO: Object to the	2	Q. When did you first learn about Protocol 007?
2 3	assay MR. SANGIAMO: Object to the form.	2 3	Q. When did you first learn about Protocol 007? A. I don't recall a specific date.
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1	Page 102		Page 104
1	Q. What is the purpose?	1	form.
2	A. The purpose is described the	2	THE WITNESS: The purpose was to
3	method of material, reagents, equipment that	3	evaluate assay variables and see if any
4	are needed, and in some cases the interpretation	4	of them would allow us to have the
5	of the results.	5	capability of entering 95 percent
6	Q. You say interpretation of the	6	seroconversion.
7	results, how to calculate a result?	7	BY MR. KELLER:
8	A. What I'm thinking of there, for	8	Q. That's what you did, isn't it?
9	example, defining a negative result versus a	9	You developed that assay, didn't you?
10	positive result.	10	A. We developed in collaboration
11	Q. Seroclassification cutoff?	11	and discussion with the FDA.
12	Let's talk in particular about	12	Q. You disclosed everything about
13	MR. SANGIAMO: Wait a minute.	13	that assay to the FDA. Is that your testimony?
14	You're withdrawing the last question?	14	A. Yes.
15	MR. KELLER: I'll withdraw the	15	Q. Yes?
16	question.	16	A. Yes.
17	BY MR. KELLER:	17	Q. And so the FDA knew let me
18	Q. When you learned about Protocol	18	we'll get to that.
19	007, did you learn that you would be did	19	I just want to make sure,
20	anybody ask you to develop an assay for	20	because you're under oath, you understand
21	Protocol 007?	21	that. Correct?
22	A. Yes.	22	A. Yes.
23	Q. At that point, had an assay	23	Q. So it's your testimony under
24	already been developed and you were asked to	24	oath that you disclosed every aspect of the
25	fine tune that assay or were you starting from	25	assay to the FDA?
	Page 103		Page 105
1	fresh?	1	MR. SANGIAMO: Object to the
1 2	fresh? MR. SANGIAMO: Object to the	1 2	<u>o</u>
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1 2			
	Page 106		Page 108
2	the meetings with Cathy Carbone, is a CBER	1	form.
	representative, one of the CBER	2	THE WITNESS: For which assay?
3	representatives, she wanted a plaque reduction	3	BY MR. KELLER:
4	neutralization assay.	4	Q. The plaque reduction neutralization
5	Q. Are you sure that they didn't	5	assay.
6	just ask for a functional neutralizing assay?	6	A. The objective for the plaque
7	They specifically said a plaque reduction	7	reduction neutralization assay was to provide
8	neutralizing assay?	8	an assay that was capable of providing 95
9	MR. SANGIAMO: Object to the	9	percent seroconversion. Whether that
10	form.	10	beyond that, I don't have any understanding.
11	THE WITNESS: The best of my	11	Q. The plaque reduction neutralization
12	recollection, it was a plaque reduction	12	assay let me strike that.
13	neutralization assay. I can't exclude	13	We talked about SOPs. Did you
14	that they might have used a different	14	draft an SOP for the plaque reduction
15	term, but my recollection, it was a	15	neutralization assay?
16	plaque reduction neutralization assay.	16	MR. SANGIAMO: Object to the
17	BY MR. KELLER:	17	form.
18	Q. Do you recall, in any of those	18	THE WITNESS: I don't recall if
19	communications with CBER, why CBER wanted a	19	I did or someone else, another I
20	plaque reduction neutralization assay?	20	don't recall if I was the author of the
21	MR. SANGIAMO: Object to the	21	SOP or not.
22	form.	22	BY MR. KELLER:
23	THE WITNESS: I do not recall	23	Q. Did you approve that SOP for the
24	them, at least in my presence, giving	24	original plaque reduction neutralization
25	an explanation of why.	25	assay strike that.
	Page 107		Page 109
1	BY MR. KELLER:	1	When I say "plaque reduction
2	Q. Do you recall you don't as	2	neutralization assay," if I use PRN, you
3	you sit here today right now, you don't recall	3	understand that to be the same?
4	ever hearing from CBER that they wanted a	4	A. I'm sorry, PRN meaning the one
5	plaque reduction neutralization assay that	5	used for Protocol 007? There are other plaque
1	could be clinically linked to protection from	6	
6	could be clinically linked to protection from	6	reduction neutralization assays that we've had
7	disease?	7	in place.
	disease? A. I do not recall that a	7 8	in place. Q. Let's start with the one you
7	disease?	7 8 9	in place. Q. Let's start with the one you start there was do you recall there
7 8 9 10	disease? A. I do not recall that a comment about a link to protection from disease.	7 8 9 10	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization
7 8 9 10 11	disease? A. I do not recall that a comment about a link to protection from disease. Q. Do you believe that an ELISA	7 8 9 10 11	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization assay that was used for Protocol 007?
7 8 9 10 11 12	disease? A. I do not recall that a comment about a link to protection from disease. Q. Do you believe that an ELISA assay is just as good as a plaque reduction	7 8 9 10 11 12	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization assay that was used for Protocol 007? Correct?
7 8 9 10 11 12 13	disease? A. I do not recall that a comment about a link to protection from disease. Q. Do you believe that an ELISA assay is just as good as a plaque reduction neutralization assay in terms of identifying	7 8 9 10 11 12 13	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization assay that was used for Protocol 007?
7 8 9 10 11 12 13 14	disease? A. I do not recall that a comment about a link to protection from disease. Q. Do you believe that an ELISA assay is just as good as a plaque reduction neutralization assay in terms of identifying whether or not a result from those assays is	7 8 9 10 11 12 13 14	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization assay that was used for Protocol 007? Correct? A. I recall two versions of it, yes.
7 8 9 10 11 12 13 14 15	disease? A. I do not recall that a comment about a link to protection from disease. Q. Do you believe that an ELISA assay is just as good as a plaque reduction neutralization assay in terms of identifying whether or not a result from those assays is linked to protection from disease, from mumps?	7 8 9 10 11 12 13 14 15	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization assay that was used for Protocol 007? Correct? A. I recall two versions of it, yes. Q. And the first version, can you
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	disease? A. I do not recall that a comment about a link to protection from disease. Q. Do you believe that an ELISA assay is just as good as a plaque reduction neutralization assay in terms of identifying whether or not a result from those assays is linked to protection from disease, from mumps? A. I would say I'm not familiar with the ELISA results either at Merck or outside of Merck to be able to comment on how well it correlates with protection from disease. Q. And that's not what you used to develop the assay, is trying to find an assay	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	in place. Q. Let's start with the one you start there was do you recall there being multiple SOPs for the neutralization assay that was used for Protocol 007? Correct? A. I recall two versions of it, yes. Q. And the first version, can you describe that assay to me? That was was that a PRN assay? A. Yes. Yes. Q. So when we say PRN throughout the rest of the deposition, we understand that to be a plaque reduction neutralization assay. Is that fair?

28 (Pages 106 - 109)

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1			
1 1	Page 110		Page 112
1	neutralization assay.	1	MR. SANGIAMO: Object to the
2	Q. You said there was two	2	form.
3	versions another version. Did you prepare	3	THE WITNESS: There were
4	that SOP?	4	there was a previous plaque reduction
5	A. Again, I don't recall if I was	5	neutralization assay not using anti-IgG
6	the author of it. I just recall that there	6	that had some common, some common
7	was another version prepared.	7	steps. So I my expectation is that
8	Q. And that second version modified	8	that was used as a template since some
9	the SOP from the first version. Correct?	9	of the steps were common I mean,
10	A. The procedure did not it's my	10	common cells, medium, overlay it, a
11	understanding did not change the assay	11	couple, various steps. So that would
12	procedure did not change. To the best of my	12	have been used as a template for the
13	recollection, the changes in the revised	13	Protocol 007 development.
14	procedure were additional criteria for	14	BY MR. KELLER:
15	specific, like, retests of samples or assays,	15	Q. I see.
16	responses to flags from a workbook that was in	16	Who drafted that, I mean, that
17	place.	17	other PRN that was used before the use of
18	Q. The first version, did the first	18	anti-IgG step?
19	version that you worked on include antihuman	19	MR. SANGIAMO: Object to the
20	IgG?	20	form.
21	A. For protocol the assay that	21	THE WITNESS: I don't recall who
22	we used to start the testing of Protocol 007	22	the author.
23	included anti-IgG.	23	BY MR. KELLER:
24	Q. Was there an assay before an	24	Q. Did you run any experiments off
25	SOP before that?	25	of that original PRN SOP?
	Page 111		Page 113
1	MR. SANGIAMO: Object to the	1	MR. SANGIAMO: Object to the
2	form.	2	form.
3	THE WITNESS: An assay for?	3	THE WITNESS: We ran plaque
4	BY MR. KELLER:	4	
			reduction assays with an assay without
5	O. Strike that.	5	reduction assays with an assay without anti-IgG. What I'm not remembering
5 6	Q. Strike that. Was there an SOP for a PRN assay	5	anti-IgG. What I'm not remembering
	Was there an SOP for a PRN assay		anti-IgG. What I'm not remembering with clarity is whether there was only
6 7	Was there an SOP for a PRN assay that was run in the development of Protocol	6	anti-IgG. What I'm not remembering with clarity is whether there was only one plaque reduction neutralization
6	Was there an SOP for a PRN assay that was run in the development of Protocol 007 before the AIGENT SOP?	6 7	anti-IgG. What I'm not remembering with clarity is whether there was only one plaque reduction neutralization assay without anti-IgG. So there was a
6 7 8	Was there an SOP for a PRN assay that was run in the development of Protocol 007 before the AIGENT SOP? MR. SANGIAMO: Object to the	6 7 8 9	anti-IgG. What I'm not remembering with clarity is whether there was only one plaque reduction neutralization assay without anti-IgG. So there was a plaque reduction neutralization assay
6 7 8 9 10	Was there an SOP for a PRN assay that was run in the development of Protocol 007 before the AIGENT SOP? MR. SANGIAMO: Object to the form.	6 7 8 9 10	anti-IgG. What I'm not remembering with clarity is whether there was only one plaque reduction neutralization assay without anti-IgG. So there was a plaque reduction neutralization assay without anti-IgG that was used to test
6 7 8 9 10 11	Was there an SOP for a PRN assay that was run in the development of Protocol 007 before the AIGENT SOP? MR. SANGIAMO: Object to the form. THE WITNESS: I'm sorry, I don't	6 7 8 9	anti-IgG. What I'm not remembering with clarity is whether there was only one plaque reduction neutralization assay without anti-IgG. So there was a plaque reduction neutralization assay without anti-IgG that was used to test in some testings.
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6 7 8 9 10 11 12 13 14	Was there an SOP for a PRN assay that was run in the development of Protocol 007 before the AIGENT SOP? MR. SANGIAMO: Object to the form. THE WITNESS: I'm sorry, I don't understand. BY MR. KELLER: Q. Sure. You testified that you	6 7 8 9 10 11 12 13 14	anti-IgG. What I'm not remembering with clarity is whether there was only one plaque reduction neutralization assay without anti-IgG. So there was a plaque reduction neutralization assay without anti-IgG that was used to test in some testings. BY MR. KELLER: Q. When you were brought into the project to work on Protocol 007, had
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	Page 114		Page 116
1	the SOP that used without the IgG step.	1	MR. SANGIAMO: Object to the
2	Correct?	2	form.
3	A. I don't recall who the author.	3	MR. KELLER: Let me strike that.
4	There's an equal chance I wasn't the author, I	4	BY MR. KELLER:
5	don't remember.	5	Q. Did you draft the validation
6	Q. Do you recall whether or not the	6	protocol for the AIGENT SOP that was used for
7	original PRN SOP before the anti-IgG step was	7	Protocol 007?
8	added, was that a considered a standard	8	MR. SANGIAMO: Object to the
9	bread and butter PRN assay?	9	form.
10	MR. SANGIAMO: Object to the	10	THE WITNESS: I don't I do
11	form.	11	recall drafting a document that
12	THE WITNESS: It's I don't	12	included aspects of the validation. I
13	know the term "bread and butter," I	13	don't consider that to be the protocol
14	guess I would not clear on how to	14	itself, but and I don't recall
15	respond to that. But it's an assay	15	drafting the formal protocol.
16	format that others had or other labs	16	BY MR. KELLER:
17	had used.	17	Q. Do you know who did?
18	BY MR. KELLER:	18	A. I know who issued the report on
19	Q. Had that assay do you know	19	it. I don't know who I don't recall who
20	what validation means of an assay?	20	drafted it.
21	A. I'm familiar with some aspects	21	Q. Do you understand the difference
22	to it.	22	between a validation report and a validation
23	Q. Have you ever do you know	23	protocol?
24	what a validation protocol is?	24	A. I can't say I don't have
25	A. I've seen validation protocols	25	confidence of what how they relate.
	Page 115		Page 117
1	for assays. I don't know if there's	1	Q. Have you ever been trained in
2	validation for assays for other things. But	2	any way on validating an assay in terms of the
3	for protocols of assays, I have seen them.	3	steps that are required?
4	Q. Have you ever validated an assay	4	A. I have consulted with our, for
5	yourself?	5	example, our biometrics group on what is
6	A. I've been involved in assay	6	required for the validation study. Whether
7	validation.	7	that constitutes training, I can't comment.
8	Q. Have you ever validated a plaque	8	Q. Who did you and that's for
9	reduction neutralization assay before?	9	Protocol 007? Strike that.
10	MR. SANGIAMO: Object to the	10	Did you confer with the
11	form.	11	person that you conferred with for from
12	THE WITNESS: I was or did	12	biometrics research for validating an assay,
13	part of the work for validation of a	13	was that for Protocol 007?
14	plaque reduction neutralization assay.	14	A. That's an example where a
15	BY MR. KELLER:	15	biometrics person was consulted.
16	Q. And that was part of Protocol	16	Q. The biometrics person, is that a
17	007?	17	statistician?
18	MR. SANGIAMO: Object to the	18	A. That's my genericized view of
19	form.	19	them. I don't I can't say with certainty
20	THE WITNESS: There was a	20	what their full background is.
21	validation protocol done, assay	21	Q. So have you ever drafted a
22	protocol done for Protocol 007 which I	22	validation protocol prior to Protocol 007?
23	did contribute to.	23	MR. SANGIAMO: Object to the
24	BY MR. KELLER:	24	form.
25	Q. Did you draft that protocol?	25	THE WITNESS: Again, I don't

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	Page 118		Page 120
1	recall if I remember preparing a	1	MR. SANGIAMO: Object to the
2	document, whether it was a protocol or	2	form.
3	not, but there was a series of them	3	THE WITNESS: Yes.
4	before Protocol 007.	4	BY MR. KELLER:
5	BY MR. KELLER:	5	Q. Were those used to do you
6	Q. Let's start before Protocol 007.	6	recall what that product was?
7	Have you ever validated an assay	7	A. It was a comparison between MMR
8	where you were required to draft the	8	and Priorix.
9	validation protocol for that assay?	9	O. Other than that that was
10	A. Again, with the reservation of	10	Protocol 006, do you recall that?
11	the term validation protocol. I'm not sure if	11	A. Yes.
12	whatever I drafted was a protocol, but	12	
13		13	-
	Q. Let's start from the beginning.		ever run any clinical samples? A. Yes.
14	MR. SANGIAMO: Wait a minute.	14	
15	You have to let him finish the	15	MR. SANGIAMO: Object to the
16	question	16	form.
17	MR. KELLER: Sure.	17	BY MR. KELLER:
18	MR. SANGIAMO: finish the	18	Q. When would that happen?
19	answer.	19	A. That was in I don't remember
20	THE WITNESS: So there are other	20	the exact date, but it was a mid in the
21	assays for which I have contributed to	21	1990s. I was going to say mid-1990s, but I
22	a validation study. Whether the	22	don't recall specifically.
23	document that I document or	23	Q. When you ran those clinical
24	documents I prepared were a formal	24	studies in the 1990s, do you recall whether or
25	validation protocol or just an outline	25	not you ran those studies in accordance with
	Page 119		Page 121
1	Page 119 of what was being done, I can't say. I	1	Page 121 the rules of current GMP?
1 2	Page 119 of what was being done, I can't say. I don't recall.	1 2	the rules of current GMP?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	of what was being done, I can't say. I don't recall. BY MR. KELLER: Q. Was Protocol 007 a clinical study? A. That was a clinical study. Q. Was it a Phase III study? A. I don't recall what the phase is. I have an expectation just based on just general exposure to clinical studies, but it would be a guess. Q. Do you know whether or not Protocol 007 was a pivotal study? Let me strike that. Do you know what a pivotal study is? A. No. Q. Had you ever run clinical samples with human sera in your lab prior to Protocol 007? MR. SANGIAMO: Objection. Form. THE WITNESS: Yes. BY MR. KELLER:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the rules of current GMP? MR. SANGIAMO: Object to the form. THE WITNESS: Well, they were not clinical studies, they were clinical samples. They were as best as I understand, they were not run under GMP requirements, nor did we expect that they needed to be run under GMP. BY MR. KELLER: Q. Protocol 006, did you understand that had to be run under GMP? A. My understanding was that it did not. Q. Did you understand that Protocol 007 had to be? A. No. Q. Where did you gain that understanding from, that it didn't have to be run under GMP? MR. SANGIAMO: Object to the form.

	HIGHLI CONFIDENTIAL -		
1	Page 122 Where did you learn that	1	Page 124 that refers to.
2	Protocol 007 did not have to be run under GMP	2	Q. Under in the first page of
3	studies?	3	the agenda it identifies Dr. Scott Thaler. Do
4	A. Management had no one had	4	you see that?
5	made any indication in the assay development	5	A. Yes.
6	discussions that it was required to be run	6	Q. It identifies him as a clinical
7	under GMP conditions. I'm sorry, qualify that	7	monitor. Do you see that?
8	up and to the point of the FDA inspection.	8	A. Yes.
9	Q. After the FDA inspected in	9	Q. Do you understand what a
10	August of 2001, is that the first time that	10	clinical monitor is in a clinical study?
11	you learned that Protocol 007, the assays that	11	A. I have a very general
12	you ran were supposed to be run under GMP	12	understanding of it, but not I don't have
13	conditions?	13	any details or a full understanding of what
14	MR. SANGIAMO: Object to the	14	that person's responsibilities are.
15	form.	15	Q. What's your understanding?
16	THE WITNESS: That was the first	16	A. For one to perhaps adding a
17	I heard of the expectation that the	17	little someone who monitors the clinical
18	assays were run under GMP conditions.	18	the progress the design and actually and
19	MR. KELLER: Let me do this.	19	progress of the clinical study. That's just
20	Let me mark as Exhibit 20.	20	my personal, the way I frame what the
21		21	responsibility is. But, again, what that
22	(Exhibit Krah-20, 3/15&16/1999	22	really means what the roles are, what they
23	MMR II Mumps Expiry Study Investigators	23	actually do, I don't know.
24	Meeting Agenda, 17644 - 17666, was	24	Q. Fair enough. If you look under
25	marked for identification.)	25	the attendees, it has Ms. Yagodich was also an
1	Page 123		Page 125
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	MD VELLED. For the record	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	attendee. Do you see that? A. Yes.
$\frac{2}{3}$	MR. KELLER: For the record, Exhibit 20 is a document that bears	3	
4	Bates stamp number 17644 through 66,	4	Q. This is an investigator's meeting. Do you understand what investigators
5	and it's an agenda for a March 15 and	5	do you understand what the purpose of this
6	16, 1999 investigator's meeting, MMR II	6	
7			meeting was?
	mumns evniry study		meeting was?
	mumps expiry study. BY MR. KELLER:	7	A. I don't recall, no.
8	BY MR. KELLER:	7 8	A. I don't recall, no.Q. Do you know what an investigator
8 9	BY MR. KELLER: Q. Sir, can you tell me, if you	7	A. I don't recall, no. Q. Do you know what an investigator is?
8 9 10	BY MR. KELLER:	7 8 9 10	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is.
8 9 10 11	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it	7 8 9 10 11	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator?
8 9 10	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I	7 8 9 10	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who
8 9 10 11 12	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are	7 8 9 10 11 12	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator?
8 9 10 11 12 13	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this	7 8 9 10 11 12 13	 A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical
8 9 10 11 12 13 14	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting.	7 8 9 10 11 12 13 14 15	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study.
8 9 10 11 12 13 14 15	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see	7 8 9 10 11 12 13 14 15	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for
8 9 10 11 12 13 14 15 16	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't	7 8 9 10 11 12 13 14 15 16	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007?
8 9 10 11 12 13 14 15 16 17	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't recall it. Q. Do you have any reason to believe you didn't attend?	7 8 9 10 11 12 13 14 15 16 17	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007? A. No, my understanding maybe qualify the investigator, that my understanding is it's an external person who
8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't recall it. Q. Do you have any reason to	7 8 9 10 11 12 13 14 15 16 17	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007? A. No, my understanding maybe qualify the investigator, that my
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't recall it. Q. Do you have any reason to believe you didn't attend? A. If they have me listed as an	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007? A. No, my understanding maybe qualify the investigator, that my understanding is it's an external person who is involved in the clinical study execution in
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't recall it. Q. Do you have any reason to believe you didn't attend? A. If they have me listed as an attendee, I would take that to mean that I did attend. Q. This MMR mumps expiry study, do	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007? A. No, my understanding maybe qualify the investigator, that my understanding is it's an external person who is involved in the clinical study execution in the field. I don't consider myself an
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't recall it. Q. Do you have any reason to believe you didn't attend? A. If they have me listed as an attendee, I would take that to mean that I did attend. Q. This MMR mumps expiry study, do you understand it to be Protocol 007?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007? A. No, my understanding maybe qualify the investigator, that my understanding is it's an external person who is involved in the clinical study execution in the field. I don't consider myself an investigator in the context of the investigator's meeting. Q. I see.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. KELLER: Q. Sir, can you tell me, if you recall, seeing this document before? And I will direct your attention to 17646 where it identifies the Merck attendees, and you are identified as one of the attendees of this particular meeting. A. I don't recall this. I do see my name there as a Merck attendee, but I don't recall it. Q. Do you have any reason to believe you didn't attend? A. If they have me listed as an attendee, I would take that to mean that I did attend. Q. This MMR mumps expiry study, do	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I don't recall, no. Q. Do you know what an investigator is? A. I know what an investigator is. Q. What is an investigator? A. And investigator is someone who is going to be taking part in a clinical study. Q. Were you an investigator for Protocol 007? A. No, my understanding maybe qualify the investigator, that my understanding is it's an external person who is involved in the clinical study execution in the field. I don't consider myself an investigator in the context of the investigator's meeting.

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1 studies that you ran in your lab, do you 2 consider yourself an investigator for that 3 function? 4 MR. SANGIAMO: Object to the 5 form. 6 THE WITNESS: I was a research 7 scientist supporting the studies. 8 Whether one calls that an investigator, 9 I wouldn't specifically term or phrase 10 it as an investigator. 11 BY MR. KELLER: 12 Q. Do you know what a sponsor is in 13 a clinical study? 14 A. I don't have a full understanding 15 of it. It would be a guess of what that means. 16 Q. You don't know? 17 A. No. 18 Q. Here Mary Yagodich was also an 19 attendee. Do you know why she would have 20 attended an investigator's meeting for 21 Protocol 007? 22 A. I can't say with certainty. 23 Q. Who is Timothy Schofield? 24 A. Timothy Schofield was listed 25 here as someone in the biometrics research. 6 regarding the validation of the AIGENT? 7 A. Yes. 8 Q. Is that who you conferred with? 9 A. I can't say with certainty that 10 he wasn't the person. The person I was 11 thinking of was someone else. 12 Q. And Dr. Thaler was at this 13 meeting as well. Correct? 14 A. He's listed here as being one of 15 the attendees. 16 Q. There's also a Susan McNeill 27 Q. There's three people from MPC. 28 Poyou know what that represents? 29 Q. There's three people from MPC. 20 Q. There's three people from MPC. 21 Production? 22 Q. There's also a Susan McNeill 23 A. I don't recall what that stands 24 A. He's listed here as being one of 25 the attendees. 26 C. There's also a Susan McNeill 27 C. There's also a Susan McNeill 28 A. Thant does not at least it's		INGILI CONTIDENTIAL		D 100
2 consider yourself an investigator for that 3 function? 4 MR. SANGIAMO: Object to the 5 form. 5 THE WITNESS: I was a research 7 scientist supporting the studies. 8 Whether one calls that an investigator, 9 I wouldn't specifically term or phrase 10 it as an investigator. 11 BY MR. KELLER: 12 Q. Do you know what a sponsor is in 13 a clinical study? 14 A. I don't have a full understanding 15 of it. It would be a guess of what that means. 16 Q. You don't know? 17 A. No. 18 Q. Here Mary Yagodich was also an 19 attendee. Do you know why she would have 19 attended an investigator's meeting for 21 Protocol 007? 22 A. I can't say with certainty. 23 Q. Who is Timothy Schofield? 24 A. Timothy Schofield was listed 25 here as someone in the biometrics research. 2 statistician. I don't recall what his role 2 was in the overall statistics evaluation. 4 Q. You testified earlier that you 2 conferred with somebody in biometric research 6 regarding the validation of the AIGENT? 7 A. Yes. 8 Q. Is that who you conferred with? 9 A. I can't say with certainty that 10 he wasn't the person. The person I was 11 thinking of was someone else. 12 Q. And Dr. Thaler was at this 13 meeting as well. Correct? 14 A. He's listed here as being one of 15 the attendees. 16 Q. There's three people from MPC. 17 Do you know what that represents? 18 A. I don't recall what that stands 19 for. 20 Q. There's also a Susan McNeill 21 from clinical quality assurance. Do you know what that priore composibilities were? 2 what her job responsibilities were? 2 Lexhibit Is read cument the bear an impersent to you that these documents all came from a single file. 8 BY MR. KELLER: 7 Q. I'll represent to you that these documents all came from a single file. 8 bexhibit 2 lis a document that learne from a single file. 9 Lexhibit 2 lis a document that learne from a single file. 9 Lexhibit 2 lis a document that learne from a single file. 9 Lexhibit 2 lis a document that learne from a single file. 9 Lexhibit 2 lis a document that learne from a single file. 9 Lexhibit 2	1	Page 126	1	Page 128
form. MR. SANGIAMO: Object to the form. THE WITNESS: I was a research scientist supporting the studies. Whether one calls that an investigator, I wouldn't specifically term or phrase in a an investigator. Do you know what a sponsor is in a clinical study? A. I don't have a full understanding of it. It would be a guess of what that means. Q. You don't know? A. No. MR. KELLER: MR. SANGIAMO: Object to the for identification.) BY MR. KELLER: Sir, can you tell me if you recall seeing this document before, and if you recognize any of the handwriting on this document? MR. SANGIAMO: Dr. Krah, make to document of the handwriting on this document? MR. SANGIAMO: Dr. Krah, make to stempth of the handwriting on this document? MR. SANGIAMO: Dr. Krah, make to stempth of the handwriting on this document? MR. KELLER: MR. SANGIAMO: Dr. Krah, make to stempth of the handwriting on this document? MR. KELLER: Strike that question. MR. KELLER: Object to you that these documents all came from a single file. Sir, can you tell me if you recognize any of the handwriting on this document? MR. KELLER: Strike that question. MR. KELLER: Strike that question seeing the handwriting on this document? MR. KELLER: Strike that question. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SANGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: MR. SanGIAMO: Dr. Krah, make to you're saying yes or no to. MR. KELLER: A. I don't ont on the document before? A. No, it's not my				(Exhibit Krah-21, PowerPoint
MR. SANGIAMO: Object to the form. 5		•		
5				
6 THE WITNESS: I was a research scientist supporting the studies. 8 Whether one calls that an investigator, 9 I wouldn't specifically term or phrase it as an investigator. 10 a clinical study? 11 BY MR. KELLER: 12 Q. Do you know what a sponsor is in a clinical study? 13 a clinical study? 14 A. I don't have a full understanding of it. It would be a guess of what that means. 16 Q. You don't know? 17 A. No. 18 Q. Here Mary Yagodich was also an attendee. Do you know why she would have attended an investigator's meeting for 21 Protocol 007? 19 Protocol 007? 20 A. I can't say with certainty. 21 Q. Who is Timothy Schofield'? 22 A. I can't say with certainty. 23 Q. Who is Timothy Schofield was listed 25 here as someone in the biometrics research 6 regarding the validation of the AIGENT? 24 A. Yes. 25 Q. Is that who you conferred with? 26 A. Yes. 27 Q. Under the third this is a powerPoint presentation. 28 Q. And Dr. Thaler was at this meeting as well. Correct? 29 Q. And Dr. Thaler was at this meeting as well. Correct? 30 Q. There's three people from MPC. 31 The does not at least it's pour look on the real op you what that trepresents? 32 Q. There's three people from MPC. 33 A. I don't recall what that stands for confirmed with somebody in biometric research 6 regarding the validation of the AIGENT? 4 A. Yes. 4 Q. Thaler was at this meeting as well. Correct? 4 A. He's listed here as being one of the attendees. 4 A. I don't recall what that stands for confirmed with a carried the validation of the AIGENT? 4 A. He's listed here as being one of the attendees. 4 C. There's also a Susan McNeill form clinical quality assurance. Do you know what ther job responsibilities were? 5 C. There's also a Susan McNeill form clinical quality assurance. Do you know what ther job responsibilities were? 5 C. There's also a Susan McNeill form clinical quality assurance. Do you know what ther job responsibilities were? 5 C. There's also a Susan McNeill form clinical quality assurance. Do you know what ther job responsibilities were? 5 C		3		
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9 I wouldn't specifically term or phrase it as an investigator. 10 10 10 10 10 10 10 1				
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meeting as well. Correct? 14 A. He's listed here as being one of 15 the attendees. 16 Q. There's three people from MPC. 17 Do you know what that represents? 18 A. I don't recall what that stands 19 for. 20 Q. There's also a Susan McNeill 21 from clinical quality assurance. Do you know 22 what her job responsibilities were? 13 on the first page, it identifies Merck 14 personnel, and you're identified there along 15 with Ms. Yagodich. Do you see that? A. Yes. Q. Do you are you familiar with 18 Ms. Yagodich's handwriting? 19 A. Yes. 20 Q. Do you recognize that to be the 21 handwriting of Ms. Yagodich's at 17611? 22 A. That does not at least it's		e	11	1
14 A. He's listed here as being one of 15 the attendees. 16 Q. There's three people from MPC. 17 Do you know what that represents? 18 A. I don't recall what that stands 19 for. 20 Q. There's also a Susan McNeill 21 from clinical quality assurance. Do you know 22 what her job responsibilities were? 14 personnel, and you're identified there along 15 with Ms. Yagodich. Do you see that? A. Yes. 17 Q. Do you are you familiar with 18 Ms. Yagodich's handwriting? 19 A. Yes. 20 Q. Do you recognize that to be the 21 handwriting of Ms. Yagodich's at 17611? 22 A. That does not at least it's			12	~
15 the attendees. 16 Q. There's three people from MPC. 17 Do you know what that represents? 18 A. I don't recall what that stands 19 for. 20 Q. There's also a Susan McNeill 21 from clinical quality assurance. Do you know 22 what her job responsibilities were? 15 with Ms. Yagodich. Do you see that? A. Yes. 17 Q. Do you are you familiar with 18 Ms. Yagodich's handwriting? 19 A. Yes. 20 Q. Do you recognize that to be the 21 handwriting of Ms. Yagodich's at 17611? 22 A. That does not at least it's			13	
16 Q. There's three people from MPC. 17 Do you know what that represents? 18 A. I don't recall what that stands 19 for. 20 Q. There's also a Susan McNeill 21 from clinical quality assurance. Do you know 22 what her job responsibilities were? 16 A. Yes. 17 Q. Do you are you familiar with 18 Ms. Yagodich's handwriting? 19 A. Yes. 20 Q. Do you recognize that to be the 21 handwriting of Ms. Yagodich's at 17611? 22 A. That does not at least it's				
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21 from clinical quality assurance. Do you know 21 handwriting of Ms. Yagodich's at 17611? 22 what her job responsibilities were? 22 A. That does not at least it's				
22 what her job responsibilities were? 22 A. That does not at least it's		•		
		¥ .		
	23		23	my recollection, does not look like her
24 MR. KELLER: Let me mark this 24 handwriting.				
25 next exhibit as Exhibit 21. 25 Q. Do you have any reason to	25	next exhibit as Exhibit 21.	25	Q. Do you have any reason to

33 (Pages 126 - 129)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLY CONFIDENTIAL -	111	
	Page 130		Page 132
1	believe that you didn't receive this document	1	says, "The FDA (CBER) has requested expiry
2	as part of your the meeting that happened	2	potencies be placed on the label of MMR II."
3	on March 15th and 16th	3	Do you see that?
4	MR. SANGIAMO: Object to the	4	A. Yes.
5	form.	5	Q. Is this the first time you're
6	BY MR. KELLER:	6	learning that
7	Q regarding the Protocol 007	7	MR. SANGIAMO: Object to the
8	investigator's meeting?	8	form.
9	MR. SANGIAMO: Object to the	9	BY MR. KELLER:
10	form. You can answer.	10	Q today?
11	THE WITNESS: I don't have any	11	MR. SANGIAMO: Object to the
12	recollection of seeing it. I can't	12	form.
13	I don't recall that this was handed out	13	MR. KELLER: Let me strike that.
14		14	BY MR. KELLER: Let lie strike that.
15	at the meeting. I have no recollection	15	
16	of it. BY MR. KELLER:	16	Q. Did you have that understanding of of this statement?
		l	
17	Q. You don't recall?	17	MR. SANGIAMO: Wait until he
18	A. No.	18	finishes. I'm sorry, what's your
19	Q. You don't recall going to a	19	question?
20	meeting where Protocol 007 was discussed to	20	MR. KELLER: I'll rephrase it.
21	the investigators of the clinical study?	21	BY MR. KELLER:
22	A. I don't yeah, I don't recall	22	Q. Do you recall ever hearing that
23	that.	23	statement before?
24	Q. Let me turn your attention to	24	A. I can't I don't recall.
25	17607 in the second slide. It says the	25	Q. You don't recall. So you don't
	Page 131		Page 133
1	Page 131 "BACKGROUND AND RATIONALE."	1	Page 133 recall participating in this meeting, but you
1 2		1 2	
	"BACKGROUND AND RATIONALE."	l	recall participating in this meeting, but you
2	"BACKGROUND AND RATIONALE." Do you see that? A. Yes.	2	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct?
2 3	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says,	2 3 4	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an
2 3 4	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses	2 3 4 5	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the
2 3 4 5	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to	2 3 4 5 6	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting.
2 3 4 5 6 7	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher.	2 3 4 5 6 7	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to
2 3 4 5 6 7 8	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that?	2 3 4 5 6 7 8	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas?
2 3 4 5 6 7 8 9	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes.	2 3 4 5 6 7 8 9	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't.
2 3 4 5 6 7 8 9	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you	2 3 4 5 6 7 8 9	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving,
2 3 4 5 6 7 8 9 10	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was	2 3 4 5 6 7 8 9 10 11	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas?
2 3 4 5 6 7 8 9 10 11 12	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue?	2 3 4 5 6 7 8 9 10 11 12	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't
2 3 4 5 6 7 8 9 10 11 12 13	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic	2 3 4 5 6 7 8 9 10 11 12 13	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting
2 3 4 5 6 7 8 9 10 11 12 13 14	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over	2 3 4 5 6 7 8 9 10 11 12 13 14	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni
2 3 4 5 6 7 8 9 10 11 12 13 14 15	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines	2 3 4 5 6 7 8 9 10 11 12 13 14 15	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall the Omni in Irving.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Irving. Q. So you don't recall ever learning
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall ever learning that CBER required that end expiry potencies
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as part of your development strike that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall ever learning that CBER required that end expiry potencies be placed on the label?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as part of your development strike that. Do you recall learning that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall ever learning that CBER required that end expiry potencies be placed on the label? A. I'm sorry, did I ever? I
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as part of your development strike that. Do you recall learning that statement as part of your work on Protocol	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall the Omni in Irving. Q. So you don't recall ever learning that CBER required that end expiry potencies be placed on the label? A. I'm sorry, did I ever? I didn't I'd say, yes. I don't I'm not
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as part of your development strike that. Do you recall learning that statement as part of your work on Protocol 007?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall the Omni in Irving. Q. So you don't recall ever learning that CBER required that end expiry potencies be placed on the label? A. I'm sorry, did I ever? I didn't I'd say, yes. I don't I'm not that familiar with the label or what goes in
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as part of your development strike that. Do you recall learning that statement as part of your work on Protocol 007? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall the Omni in Irving. Q. So you don't recall ever learning that CBER required that end expiry potencies be placed on the label? A. I'm sorry, did I ever? I didn't I'd say, yes. I don't I'm not that familiar with the label or what goes in the label to be able to say that that is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	"BACKGROUND AND RATIONALE." Do you see that? A. Yes. Q. The first bullet point, it says, The components of the MMR II are live viruses and lose potency over time when stored at 2 to 8 degrees Celsius or higher. Do you see that? A. Yes. Q. Do you recall ever do you have any reason to believe that statement was untrue? A. All I can say is a generic statement that live viruses lose potency over time. So the statement about live vaccines that lose potency over time are stored at 2 to 8 or higher. I have no reason to question that statement. Q. Do you recall learning that as part of your development strike that. Do you recall learning that statement as part of your work on Protocol 007?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	recall participating in this meeting, but you have no reason to believe you didn't participate. Correct? A. My name is listed as an attendee. Just I don't have any memory of the meeting. Q. You don't recall traveling to Texas; Irving, Texas? A. I don't. Q. Have you ever been to Irving, Texas? A. I've been in Texas. I don't recall what the meeting Q. Have you ever been to the Omni Mandalay Hotel? It's a nice hotel. A. I recall being at the Omni in Atlanta. I don't recall the Omni in Irving. Q. So you don't recall ever learning that CBER required that end expiry potencies be placed on the label? A. I'm sorry, did I ever? I didn't I'd say, yes. I don't I'm not that familiar with the label or what goes in

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	HIGHLI CONFIDENTIAL -		
	Page 134		Page 136
1	Q. So you don't know?	1	A. So I can't say with certainty
2	A. I don't know.	2	that that check mark means I attended. The
3	Q. The next bullet point says, "No	3	PowerPoint presentation has me listed not
4	data exist for mumps at the expiry potency	4	the PowerPoint. The slides have me listed as
5	Merck has selected."	5	an attendee, but the check mark, and the only
6	Do you see that?	6	reason I'm saying that is, I may not
7	A. Yes.	7	necessarily mean that, because I don't
8	Q. In the next slide, it identifies	8	there are some meetings for which I might have
9	"MMR II END EXPIRY POTENCIES SUGGESTED FOR THE	9	called in or taken part in part of the meeting
10	LABEL Mumps 3.7."	10	but not physically been there and I might have
11	Do you see that?	11	still put a check mark.
12	A. I'm sorry.	12	Q. That would mean that you had
13	Q. The third slide on this page.	13	participated, you may not have been there
14	A. Oh, okay.	14	physical present, you may have done it on the
15	Q. Is that a fair representation of	15	phone?
16	that statement?	16	A. Yes. It may have been on the
17	MR. SANGIAMO: Object to the	17	phone, may have been included a subset of
18	form.	18	the presentation.
19	MR. KELLER: Strike that.	19	Q. So if you go back to Exhibit 21,
20	BY MR. KELLER:	20	in the second slide, the last bullet point
21	Q. Is that a fair representation of	21	says, "A clinical immunogenicity trial is
22	that slide?	22	necessary to provide these data."
23	A. It says that the end expiry	23	Do you see that?
24	potency suggests that the label for mumps is	24	MR. SANGIAMO: I'm sorry. You
25	3.7 TCID50 per dose.	25	said second slide?
	Page 135		Page 137
1	Q. So are you aware that Merck had	1	BY MR. KELLER:
2	no data for mumps at end expiry of 3.7	2	Q. 17607, the second slide, the
3	MR. SANGIAMO: Object to the	3	last bullet point, do you see that?
4	form.	4	A. The fourth bullet point on the
5	BY MR. KELLER:	5	second slide
6	Q at this time frame?	6	
			Q. Yes.
7	MR. SANGIAMO: Objection. Form.	7	A you have "clinical
8	THE WITNESS: I don't recall	7 8	A you have "clinical immunogenicity trial is necessary to provide
8 9	THE WITNESS: I don't recall that lack of data.	7 8 9	A you have "clinical immunogenicity trial is necessary to provide the data." Yes.
8 9 10	THE WITNESS: I don't recall that lack of data. BY MR. KELLER:	7 8 9 10	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory
8 9 10 11	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what	7 8 9 10 11	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to
8 9 10 11 12	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502,	7 8 9 10 11 12	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used
8 9 10 11 12 13	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502, page 98, dated Tuesday, March 16, 1999. Can	7 8 9 10 11 12 13	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used as the end expiry on the label for the mumps
8 9 10 11 12 13 14	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502, page 98, dated Tuesday, March 16, 1999. Can you tell me if that if your journal	7 8 9 10 11 12 13 14	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used as the end expiry on the label for the mumps component of MMR II?
8 9 10 11 12 13 14 15	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502, page 98, dated Tuesday, March 16, 1999. Can you tell me if that if your journal references you participating in this	7 8 9 10 11 12 13 14 15	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used as the end expiry on the label for the mumps component of MMR II? A. It does not. Again, my
8 9 10 11 12 13 14 15 16	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502, page 98, dated Tuesday, March 16, 1999. Can you tell me if that if your journal references you participating in this investigator's meeting on March 15 and 16,	7 8 9 10 11 12 13 14 15 16	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used as the end expiry on the label for the mumps component of MMR II? A. It does not. Again, my recollection is that this was comparing three
8 9 10 11 12 13 14 15 16 17	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502, page 98, dated Tuesday, March 16, 1999. Can you tell me if that if your journal references you participating in this investigator's meeting on March 15 and 16, 1999?	7 8 9 10 11 12 13 14 15 16 17	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used as the end expiry on the label for the mumps component of MMR II? A. It does not. Again, my recollection is that this was comparing three different vaccine doses. I don't have a
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	THE WITNESS: I don't recall that lack of data. BY MR. KELLER: Q. Sir, I'm going to show you what is marked as Exhibit 3, Bates page 488502, page 98, dated Tuesday, March 16, 1999. Can you tell me if that if your journal references you participating in this investigator's meeting on March 15 and 16, 1999? A. Let's see. So it lists the mumps expiry file clinical investigator's meeting in Dallas, Texas and has a check mark next to it which implies the check mark implies that that happened.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A you have "clinical immunogenicity trial is necessary to provide the data." Yes. Q. Does that refresh your memory that the purpose of Protocol 007 was to try to establish that a potency of 3.7 would be used as the end expiry on the label for the mumps component of MMR II? A. It does not. Again, my recollection is that this was comparing three different vaccine doses. I don't have a recollection of which was what those three were or what the implications were. Q. Was 3.7 one of the doses that you were testing? A. I don't recall. I recall there

35 (Pages 134 - 137)

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1 17611, in particular to the last slide. 2 MR. SANGIAMO: You're asking a lot of questions about this document. 4 I don't think he's had a chance to review the whole document yet. Dr. 6 Krah, certainly feel free to read the document. 8 MR. KELLER: Could we off the record? 10 MR. SANGIAMO: It's not going to take long. Stay on the record. 11 BY MR. KELLER: 12 BY MR. KELLER: 13 Q. Let me know when you're done. 14 A. Okay. 15 MR. SANGIAMO: Yes. Never went off. 16 MR. SANGIAMO: Yes. Never went off. 17 off. 18 BY MR. KELLER: 19 Q. Sir, you've had a chance to review every slide on Exhibit 21. Do any of these iddes refresh your recollection that you've seen these slides before or this you've seen these slides before or this 12 MR. SANGIAMO: Object to the 17611, see if I can't refresh your memory of this time frame. Under "IMMUNOGENICITY MEASUREMENTS," do you see that? 10 Q. What do you understand functional to mean? 11 Says, "For Mumps, a functional (neutralization) assay has been developed." 12 Q. What do you understand functional for mean? 13 Do you see that? 14 A. Yes. 15 Q. What do you understand functional for mean? 16 MR. SANGIAMO: Object to the 17611, see if I can't refresh your memory of this time frame. Under "IMMUNOGENICITY MEASUREMENTS," do you see that? 18 A. Yes. 19 Q. What do you understand functional for memps, a functional (neutralization) assay such as a CPE reduction meutralizing assay you looking for any antibody that's capable binding to a mumps virus or are you looking for mumps viru		HIGHLI CONFIDENTIAL -		
2		٤		Page 140
or a plaque reduction assay would be to she that antibodies are capable of binding to to be see capable of forming of infecting and replicating in cell culture. 8				
I don't think he's had a chance to review the whole document yet. Dr. 6 Krah, certainly feel free to read the document. 8 MR. KELLER: Could we off the record?				
5 review the whole document yet. Dr. 6 Krah, certainly feel free to read the 7 document. 8 MR. KELLER: Could we off the 9 record? 10 MR. SANGIAMO: It's not going to 11 take long. Stay on the record. 12 BY MR. KELLER: 13 Q. Let me know when you're done. 14 A. Okay. 15 MR. SANGIAMO: Yes. Never went 16 MR. SANGIAMO: Yes. Never went 17 off. 18 BY MR. KELLER: 19 Q. Sir, you've had a chance to 20 review every slide on Exhibit 21. Do any of 21 these slides refresh your recollection that 22 you've seen these slides before or this 23 presentation? 24 A. No. Nothing - 25 MR. SANGIAMO: Object to the Page 139 1 form. 2 THE WITNESS: Nothing looks 3 familiar. 4 BY MR. KELLER: 5 Q. Let me direct your attention to 6 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY 8 MEASUREMENTS," do you see that? 9 A. Yes. 10 Q. In the second bullet point it 11 says, "For Mumps, a functional (neutralization) 12 assay has been developed." 13 Do you see that? 14 A. Yes. 15 Q. What do you understand functional 16 to mean? 17 A. To me it means a plaque 18 Virus and causing it to be less capable of 16 forming of infecting and replicating in 17 cell culture. Q. And so the antibodies that 19 you strike that. Are there any other functional 10 neutralization assays other than a plaque 11 reduction neutralization assays other than a plaque 12 reduction neutralization assays other than a plaque 14 is the one I'm most familiar with. Yes, ther 15 A. Yes. 19 Q. Do you know what a CPE assay in 20 A. Yes. 21 A. It's a when I said ran CPE 22 A. It's a when I said ran CPE 23 assays, I ran assays to monitor cytopathic effects in the titer virus, not in a neutralization format. But it I would say an assay such as a CPE reduction would be measure of the capacity of an antibody to reduce infectivity so that -1 guess, one could also call it a functional assay. Q. When you're talking about an antibody, Let's talk about mumps. In a mumps plaque reduction set with the term. 21 assays, I ran assays to monitor cytop	3	•		
6 Krah, certainly feel free to read the document. 8 MR. KELLER: Could we off the record? 9 record? 10 MR. SANGIAMO: It's not going to take long. Stay on the record. 11 by MR. KELLER: 12 BY MR. KELLER: 13 Q. Let me know when you're done. 14 A. Okay. 15 MR. KELLER: Back on the record. 16 MR. SANGIAMO: Yes. Never went off. 17 off. 18 BY MR. KELLER: 19 Q. Sir, you've had a chance to review every slide on Exhibit 21. Do any of these slides refresh your recollection that you've seen these slides before or this 22 presentation? 22 presentation? 24 A. No. Nothing 25 MR. SANGIAMO: Object to the 1 form. 2 THE WITNESS: Nothing looks a familiar. 4 BY MR. KELLER: 5 Q. Let me direct your attention to 6 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY 8 MEASUREMENTS," do you see that? 4 BY MR. KELLER: 5 Q. Let me direct your attention to 6 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY 8 MEASUREMENTS," do you see that? 9 A. Yes. 10 Q. In the second bullet point it 11 says, "For Mumps, a functional (neutralization) 12 assay has been developed." 13 Do you see that? 14 A. Yes. 15 Q. What do you understand functional 16 to mean? 16 MR. SANGIAMO: Object to the 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY 8 MEASUREMENTS," do you see that? 19 Q. Do you know what a CPE assay in 20 A. I'm familiar with the term. 21 assays, 1 ran assays to monitor cytopathic effects in the titer virus, not in a neutralization format. But it I would say an assay such as a CPE reduction would be measure of the capacity of an antibody to reduce infectivity so that I guess, one could also call it a functional assay. 24 an assay such as a CPE reduction would be measure of the capacity of an antibody to reduce infectivity so that in the left in	4		4	
7 document. 7 MR. KELLER: Could we off the record? 9 9 7 10 MR. SANGIAMO: It's not going to take long. Stay on the record. 12 BY MR. KELLER: 13 Q. Let me know when you're done. 14 A. Okay. 15 MR. SANGIAMO: Yes. Never went off. 17 MR. SANGIAMO: Yes. Never went off. 18 BY MR. KELLER: 18 Q. Sir, you've had a chance to review every slide on Exhibit 21. Do any of 21 these slides refresh your recollection that you've seen these slides before or this 22 presentation? 24 A. No. Nothing 25 MR. SANGIAMO: Object to the 25 MR. SANGIAMO: Object to the 26 MEASUREMENTS," do you see that? 9 A. Yes. 10 Q. In the second bullet point it says, "For Mumps, a functional (neutralization) assay has been developed." 13 Do you see that? Q. What do you understand functional to mean? 17 A. To me it means a plaque 17 MR. KELLER: Let me strike that. Q. And so the antibodies that you strike that. Are there any other functional neutralization assays other than a plaque 7 reduction neutralization assays other than a plaque 7 reduction neutralization assays other than a plaque 7 reduction neutralization assays of the than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 reduction neutralization assays of her than a plaque 7 Reduction neutralization assays of her than a plaque 7 Reduction neutralization assays of her than a plaque 7 Reduction neutralization assays of her than a pl	5	review the whole document yet. Dr.	5	virus and causing it to be less capable of
MR. KELLER: Could we off the record? 10	6	Krah, certainly feel free to read the	6	forming of infecting and replicating in
9 record? 10 MR. SANGIAMO: It's not going to take long. Stay on the record. 11 take long. Stay on the record. 12 BY MR. KELLER: 13 Q. Let me know when you're done. 14 A. Okay. 15 MR. KELLER: Back on the record. 16 MR. SANGIAMO: Yes. Never went off. 17 off. 18 BY MR. KELLER: 19 Q. Sir, you've had a chance to review every slide on Exhibit 21. Do any of these slides refresh your recollection that 22 you've seen these slides before or this 23 presentation? 24 A. No. Nothing 25 MR. SANGIAMO: Object to the 26 or review every slide on Exhibit 21. Do any of 22 these slides refresh your recollection that 23 presentation? 27 A. No. Nothing 28 presentation? 29 A. No. Nothing 29 form. 20 Let me direct your attention to 6 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY" 8 MEASUREMENTS," do you see that? 10 A. To me it means a plaque 9 you strike that. Are there any other functional neutralization assays other han a plaque reduction neutralization assay? A. There may be. Plaque reduction is the one I'm most familiar with. Yes, ther are. Q. The one you're most familiar with is the PRN. Correct? A. Yes. Q. Ever run one? 20 Ever run one? 21 assays, I ran assays to monitor cytopathic effects in the titer virus, not in a neutralization format. But it I would say an assay such as a CPE reduction would be reduce infectivity so that I guess, one could also call it a functional assay. Q. When you're talk about it in let's pick one antibody. Let's talk about it in let's pick one antibody. Let's talk about it in let's pick one antibody het's talk about it in let's pick one antibody. Let's talk about it in let's pick one antibody bat's capable binding to a mumps virus or are you looking for something else? MR. SANGIAMO: Object to the form. MR. KELLER: Let me strike that. A. To me it means a plaque	7	document.	7	cell culture.
10	8	MR. KELLER: Could we off the	8	Q. And so the antibodies that
11 take long. Stay on the record. 12 BY MR. KELLER: 13 Q. Let me know when you're done. 14 A. Okay. 15 MR. KELLER: Back on the record. 16 MR. SANGIAMO: Yes. Never went off. 17 off. 18 BY MR. KELLER: 19 Q. Sir, you've had a chance to 20 review every slide on Exhibit 21. Do any of 21 these slides refresh your recollection that 22 you've seen these slides before or this 23 presentation? 24 A. No. Nothing 25 MR. SANGIAMO: Object to the Page 139 1 form. 2 THE WITNESS: Nothing looks 3 familiar. 4 BY MR. KELLER: 5 Q. Let me direct your attention to 6 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY" 8 MEASUREMENTS," do you see that? 9 A. Yes. 10 Q. In the second bullet point it 11 says, "For Mumps, a functional (neutralization) 12 assay has been developed." 13 Do you see that? 14 A. Yes. 15 Q. What do you understand functional 16 to mean? 17 A. To me it means a plaque 18 A. There may be. Plaque reduction is the one I'm most familiar with. Yes, ther are. 18 A. There may be. Plaque reduction is the one I'm most familiar with. Yes, ther are. 16 Q. The one you're most familiar with is the PRN. Correct? 18 A. Yes. 19 Q. Do you know what a CPE assay in with is the PRN. Correct? 18 A. Yes. 19 Q. Do you know what a CPE assay in a well? 22 A. Yes. 23 Q. Is that a functional assay as well? 24 assays, I ran assays to monitor cytopathic effects in the titer virus, not in a neutralization format. But it — I would say an assay such as a CPE reduction would be measure of the capacity of an antibody to reduce infectivity so that — I guess, one mumps understand functional in mumps plaque reduction neutralization assay? 15 A. There may be. Plaque reduction is the one I'm most familiar with. Yes, ther are. 16 Q. The one you're most familiar with is the PRN. Correct? A. Yes. 19 Q. Do you know what a CPE assay in are. 17 A. Yes. 18 A. Yes. 19 Q. Do you know hat a CPE assay in the titer virus, not in a neutralization format. But it — I would say an assay such as a CPE reduction would be measure o	9	record?	9	you strike that.
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14 A. Okay. 15 MR. KELLER: Back on the record. 16 MR. SANGIAMO: Yes. Never went 17 off. 18 BY MR. KELLER: 19 Q. Sir, you've had a chance to 20 review every slide on Exhibit 21. Do any of 21 these slides refresh your recollection that 22 you've seen these slides before or this 23 presentation? 24 A. No. Nothing 25 MR. SANGIAMO: Object to the Page 139 1 form. 2 THE WITNESS: Nothing looks 3 familiar. 4 BY MR. KELLER: 5 Q. Let me direct your attention to 6 17611, see if I can't refresh your memory of 7 this time frame. Under "IMMUNOGENICITY" 8 MEASUREMENTS," do you see that? 9 A. Yes. 10 Q. In the second bullet point it 11 says, "For Mumps, a functional (neutralization) 12 assay has been developed." 13 Do you see that? 14 is the one I'm most familiar with. Yes, ther are. Q. The one you're most familiar with is the PRN. Correct? 18 A. Yes. 19 Q. Do you know what a CPE assay in A. Yes. 22 A. Yes. 23 Q. Is that a functional assay as well? A. It's a when I said ran CPE Page 139 1 assays, I ran assays to monitor cytopathic effects in the titer virus, not in a neutralization format. But it I would say an assay such as a CPE reduction would be measure of the capacity of an antibody to reduce infectivity so that I guess, one could also call it a functional assay. Q. When you're talking about an antibody, let's talk about mumps. In a mumps plaque reduction neutralizing assay you looking for any antibody that's capable binding to a mumps virus or are you lookin for something else? 15 MR. SANGIAMO: Object to the form. 17 MR. KELLER: Let me strike that	13	Q. Let me know when you're done.	13	
16	14	A. Okay.	14	is the one I'm most familiar with. Yes, there
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17 A. To me it means a plaque 17 MR. KELLER: Let me strike that		•		
LIV madriation maintedirection again. Thatle man 110 DV MD 1/1/111/D.	1			
18 reduction neutralization assay. That's my 18 BY MR. KELLER:	1	, ,		
19 personal interpretation of that. That it's Q. In the plaque reduction				
				neutralization assay using a mumps vaccine,
Q. When you say "reduction in 21 can you describe for me how that's run?				
22 infectivity," you're can you describe that 22 MR. SANGIAMO: Object to the	1	• •		
23 a little bit for me? What are you testing to 23 form.				
24 show reduction infectivity? 24 BY MR. KELLER:	1			
25 A. Phrase this so it's not 25 Q. You take serum. Correct?	25	A. Phrase this so it's not	25	Q. You take serum. Correct?

36 (Pages 138 - 141)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLY CONFIDENTIAL -		
	Page 142		Page 144
1	A. Yes.	1	Q. It has to be mumps specific?
2	Q. From a kid before they're	2	A. Yes.
3	vaccinated. Correct?	3	Q. If it's not mumps specific,
4	A. Typically.	4	would that be a problem?
5	MR. SANGIAMO: Object to this	5	MR. SANGIAMO: Object to the
6	line of questioning. Keep going.	6	form.
7	BY MR. KELLER:	7	THE WITNESS: If it's not mumps
8	Q. Let me for Protocol 007, did	8	specific, that difference in specificity
9	the plaque reduction neutralizing assay you	9	would need to be considered.
10	ran in that assay, you understood that you	10	BY MR. KELLER:
11	took kids before they were vaccinated,	11	Q. Why would it need to be
12	correct, you took their blood?	12	considered?
13	A. There was a serum before	13	A. It depends on how to interpret
14	vaccination.	14	what it means.
15	Q. And then you wait a certain	15	Q. So if what does specificity
16	number of days and then you took the kid is	16	mean? Can you describe that for me?
17	vaccinated and you wait a certain number of	17	A. My interpretation of specificity
18	days after vaccination and you take the kid's	18	is uniqueness of the in the case of an
19	blood after vaccination. Correct?	19	antibody, its ability to bind or neutralize a
20	MR. SANGIAMO: Object to the	20	virus, meaning that an antibody to one virus
21	form.	21	won't neutralize another virus.
22	THE WITNESS: The serum is drawn	22	Q. So if a virus other than mumps
23	before vaccination and then some	23	would bind strike that.
24	interval after vaccination.	24	If an antibody other than a
25	BY MR. KELLER:	25	mumps antibody were to bind to the virus and
23	BT WIK: REELEK.	23	manips untroody were to onid to the virus and
	Page 143		Page 145
1	Q. And in the plaque reduction	1	neutralize it, that would be part of an
2	Q. And in the plaque reduction neutralization assay you're comparing those	2	neutralize it, that would be part of an analysis of specificity. Correct?
2 3	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct?	2 3	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the
2 3 4	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct? A. That's part of the evaluation.	2 3 4	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the form.
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2 3 4 5 6	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct? A. That's part of the evaluation. Q. So in just so I understand how this process works, you take you're	2 3 4 5 6	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, an evaluation of
2 3 4 5 6 7	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct? A. That's part of the evaluation. Q. So in just so I understand how this process works, you take you're looking for, in the pre-vaccination sample to	2 3 4 5 6 7	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, an evaluation of specificity could include or amongst
2 3 4 5 6 7 8	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct? A. That's part of the evaluation. Q. So in just so I understand how this process works, you take you're looking for, in the pre-vaccination sample to see whether or not the kid has mumps	2 3 4 5 6 7 8	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, an evaluation of specificity could include or amongst other options looking for ability or
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct? A. That's part of the evaluation. Q. So in just so I understand how this process works, you take you're looking for, in the pre-vaccination sample to see whether or not the kid has mumps neutralizing antibodies. Correct? A. Yes. Q. Are you looking to see whether or not the kid has any antibodies that will neutralize the mumps virus? MR. SANGIAMO: Object to the form. THE WITNESS: My understanding is that we're looking for antibodies that are capable of binding to a neutralizing virus. BY MR. KELLER: Q. That could be any antibodies, whether it's mumps antibodies or any other	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, an evaluation of specificity could include or amongst other options looking for ability or capacity of antibodies unrelated to mumps to bind and neutralize. BY MR. KELLER: Q. Why would that be important in a plaque reduction neutralization assay that was run for Protocol 007 strike that. Was that important for to determine the specificity of nonspecific binding in the Protocol 007 assay? A. I'm not sure I understand your question. Q. Let me rephrase it if you don't understand it. As part of Protocol 007 validation, did you investigate whether or
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. And in the plaque reduction neutralization assay you're comparing those two blood samples. Correct? A. That's part of the evaluation. Q. So in just so I understand how this process works, you take you're looking for, in the pre-vaccination sample to see whether or not the kid has mumps neutralizing antibodies. Correct? A. Yes. Q. Are you looking to see whether or not the kid has any antibodies that will neutralize the mumps virus? MR. SANGIAMO: Object to the form. THE WITNESS: My understanding is that we're looking for antibodies that are capable of binding to a neutralizing virus. BY MR. KELLER: Q. That could be any antibodies, whether it's mumps antibodies or any other antibodies. Correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	neutralize it, that would be part of an analysis of specificity. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, an evaluation of specificity could include or amongst other options looking for ability or capacity of antibodies unrelated to mumps to bind and neutralize. BY MR. KELLER: Q. Why would that be important in a plaque reduction neutralization assay that was run for Protocol 007 strike that. Was that important for to determine the specificity of nonspecific binding in the Protocol 007 assay? A. I'm not sure I understand your question. Q. Let me rephrase it if you don't understand it. As part of Protocol 007 validation, did you investigate whether or not what the specificity of that assay was?

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	Page 146		Page 148
1	you look at to determine the specificity of	1	form.
2	that assay?	2	THE WITNESS: That's not my
3	A. As best I recall, we had lab	3	interpretation.
4	volunteer sera, meaning sera from adult lab	4	BY MR. KELLER:
5	volunteers, that then were absorbed with	5	Q. Did you ever come up with a
6	measles, mumps, or rubella antigens or just	6	percentage of specificity?
7	diluted in culture medium. And then the	7	A. No.
8	residual neutralizing capacity of that	8	Q. Did anybody ever discuss the
9	those sera were tested.	9	percentage of specificity?
10	Q. And do you recall the results of	10	A. No, and I never actually heard
11	that?	11	that.
12	A. I don't recall all the specific	12	Q. Did you ever test you never
13	results, but as a general recollection	13	heard that the assay was only 50 percent
14	Q. What's your general recollection?	14	specific to mumps specific antibodies?
15	A. General recollection was that	15	A. What I recall seeing was that
16	the antibody titers were reduced more by mumps	16 17	for half of the sera tested, there was
17	absorption than by measles or rubella		absorption of some of the sera with other
18 19	absorption. Q. And so did you ever come to a	18 19	antigens other than mumps. Q. That was measles and rubella.
20	•	20	Correct?
21	conclusion as to what the specificity of that assay was based on those experiments you ran?	21	A. I don't know that it was both of
22	A. So I have a personal conclusion	22	them. I do recall rubella giving some
23	that I reached	23	absorbing with rubella reduced the neutralizing
24	Q. Sure.	24	titers for some of the sera. But for some of
25	A which was that the assay was	25	the some number of the sera, the absorption
23			
1	Page 147	1	Page 149
1 2	specific. Those data were shared with others	1	was much greater for mumps antigen.
2	at Merck and with the FDA and with I never	2 3	Q. Do you recall that
3	received any feedback to the contrary.	4	MR. SANGIAMO: Jeff, we've been
5	Q. Did you understand that the	5	going about an hour and 20 minutes.
6	rubella virus was also neutralizing, the mumps virus in the PRN assay?	6	MR. KELLER: Why don't I finish this line of question.
7	A. I'm sorry, your question is	7	BY MR. KELLER:
8	Q. Sure. Did you understand that	8	Q. Do you recall that the control
9	the rubella had neutralizing impact on the PRN		medium was also neutralizing the mumps virus
10	assay?	10	as part of the specificity assay?
11	MR. SANGIAMO: Object to the	11	MR. SANGIAMO: Object to the
12	form.	12	form.
13	MR. KELLER: Let me strike that.	13	THE WITNESS: It was not
14	BY MR. KELLER:	14	neutralizing.
15	Q. Do you recall that the rubella	15	BY MR. KELLER:
16	antibodies were having a neutralizing effect	16	Q. Did you ever consider testing
17	on the PRN assay that was tested by your lab?	17	whether or not the use of the rabbit anti-IgG
18	MR. SANGIAMO: Object to the	18	was, in fact, causing neutralization in and of
19	form.	19	itself?
20	THE WITNESS: That is not my	20	A. Yes.
21	interpretation of the data.	21	Q. How did you do that?
22	BY MR. KELLER:	22	A. By incubating the virus with the
	Q. What about the measles?	23	anti-IgG in the absence of serum.
23			_
23 24	A. No.	24	Q. Did you try it with serum?
	•	24 25	Q. Did you try it with serum? A. Yes, I

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	Page 150		Page 152
1	Q. Was there interaction	1	BY MR. KELLER:
2	MR. SANGIAMO: Whoa, whoa, whoa.	2	Q. Did you ever conduct a single
3	Hold on.	3	experiment, sir, taking a negative serum
4	BY MR. KELLER:	4	sample that has no antibodies in it, adding
5	Q. Finish your answer.	5	the IgG and adding the virus to see whether or
6	MR. SANGIAMO: The question is	6	not there would be neutralization caused by
7	did you try it with serum?	7	the anti-IgG?
8	THE WITNESS: Yes.	8	MR. SANGIAMO: Object to the
9	BY MR. KELLER:	9	form.
10	Q. And did you you ran	10	THE WITNESS: The prevaccination
11	experiments with serum and anti-IgG and virus	11	sera were included were part of the
12	without mumps antibodies	12	testing with the anti-IgG but, again,
13	MR. SANGIAMO: Object to the	13	you can't certify that those sera are
14	form.	14	truly devoid of antibody. They could
15	BY MR. KELLER:	15	have maternal antibody. What I don't
16	Q to see whether or not there	16	recall is how if that or how that
17	was any neutralization?	17	neutralization compared with the serum
18	MR. SANGIAMO: Object to the	18	sample versus a sample in each
19	form.	19	assay, the serum anti-IgG is present
20	THE WITNESS: That is almost an	20	along with the virus and no antibody.
21	undoable experiment. That would	21	There are pre-vaccination sera that are
22	require you showing that the serum is	22	present, some of which are, majority of
23	absent of antibodies.	23	which are negative. So, I guess, I'm
24	BY MR. KELLER:	24	having trouble understanding your
25	Q. That's an undoable experiment?	25	compare what you're trying to
	Page 151		Page 153
1	It's not standard to look at a serum sample, a	1	compare it to.
2	negative serum sample that's been that has	2	BY MR. KELLER:
3	no antibodies in it to see whether or not	3	Q. My question is, did you run any
4	A. Well, you can have a negative	4	experiments that took negative serum, rabbit
5	serum sample, a sample that is negative in the	5	anti-IgG and virus and test that
6	an assay, but the challenge is how to prove	6	MR. SANGIAMO: Objection.
7	that that serum is really devoid of an	7	BY MR. KELLER:
8	antibody.	8	Q to see whether or not there
9	Q. Do you know what a boost	9	was any neutralization
10	analysis is in a specificity test?	10	MR. SANGIAMO: Object to the
11	A. No.	11	form.
12	Q. You never discussed that with	12	BY MR. KELLER:
13	anybody?	13	Q at any time in your career at
1	• •	14	Merck?
14	A. Not that I recall.		
14 15	A. Not that I recall.Q. Nobody recommended doing a boost	15	MR. SANGIAMO: Object to the
		15 16	MR. SANGIAMO: Object to the form.
15	Q. Nobody recommended doing a boost		form.
15 16	Q. Nobody recommended doing a boost analysis specificity test?	16	· ·
15 16 17	Q. Nobody recommended doing a boost analysis specificity test?A. Not that I recall.	16 17	form. THE WITNESS: Again, what I'm
15 16 17 18	 Q. Nobody recommended doing a boost analysis specificity test? A. Not that I recall. Q. So you never looked at what would happen if you took blood, virus, and 	16 17 18	form. THE WITNESS: Again, what I'm struggling with is a negative serum.
15 16 17 18 19	 Q. Nobody recommended doing a boost analysis specificity test? A. Not that I recall. Q. So you never looked at what 	16 17 18 19	form. THE WITNESS: Again, what I'm struggling with is a negative serum. We had pre-vaccination sera that were
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Page 154 1 as post-vaccination sera are added to the 2 virus and the anti-IgG in a plaque reduction 3 neutralization assay. And results are 4 calculated as a percentage of plaques relative 5 to a control that didn't have any serum. 6 Q. I understand that. My question 7 is, did you run that assay, that experiment? 8 At any time in your career at Merck, did you 9 ever look and ran an experiment with
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5 MR. SANGIAMO: Object to the 5 didn't
6 form. Asked and answered multiple 6 MR. KELLER: Let me finish. I'm
7 times. And we've been going an hour 7 not done with this line of questions.
8 and a half, but go ahead and answer the 8 MR. SANGIAMO: Well, it's going
9 question, Doctor. 9 on forever. So we'll do one more and
THE WITNESS: Negative or 10 then we're taking a break.
11 pre-immune sera were tested. 11 MR. KELLER: If you want to pull
12 BY MR. KELLER: 12 your client out of here, you can.
13 Q. Yes or no, sir. Did you do that 13 BY MR. KELLER:
14 analysis? Did you do that, did you ever run 14 Q. Was there any analysis done with
15 that experiment, yes or no? 15 an off-the-shelf negative serum that tested
A. Well, the negative serum part is 16 with anti-IgG and without anti-IgG in virus in
17 what I'm struggling with because we don't have 17 each sample? Did you ever do that analysis?
18 a serum that's a proven absolute negative. 18 MR. SANGIAMO: Object to the
19 Q. The FDA does, doesn't it? 19 form.
20 Didn't you actually ask for a sample of that 20 THE WITNESS: The only samples
21 at some point? 21 that I recall testing were pediatric
21 at some point? 22 MR. SANGIAMO: Object to the 21 that I recall testing were pediatric samples where you would have a
21 at some point? 22 MR. SANGIAMO: Object to the 23 form. Jeff, take one or two more 21 that I recall testing were pediatric 22 samples where you would have a 23 pre-vaccination, post-vaccination
21 at some point? 22 MR. SANGIAMO: Object to the 21 that I recall testing were pediatric samples where you would have a

40 (Pages 154 - 157)

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1	Page 158	1	Page 160 time frame, but it was circulating.
1	identified as negative by some other	2	Q. That's considered a wild type
2	assay and run that analysis.	$\frac{2}{3}$	Tennessee?
3	MR. KELLER: Take a break.	4	A. WT indicates wild type.
4	VIDEOGRAPHER: The time is now	5	Q. What does wild type mean to you?
5	11:55. This ends disc two.	6	A. Wild type to me means minimal
6		7	passage, at least my personal interpretation,
7	(A recess was taken.)	8	minimal passage from a clinical isolate.
8	VIDEOGRAPHED THE	9	
9	VIDEOGRAPHER: The time is now	10	Q. What do you mean by "a clinical isolate"?
10	12:11. This begins disc three. You	11	A. Clinical isolate meaning a
11	may proceed.	12	sample that's collected from an infected
12	BY MR. KELLER:	13	individual.
13	Q. Sir, can I turn your attention	14	Q. And do you understand that
14	to the last page of Exhibit 21 which is 17612.	15	viruses change over time?
15	A. Okay.	16	MR. SANGIAMO: Object to the
16	Q. In the first slide there it	17	form.
17	says, "PLAQUE REDUCTION MUMPS NEUTRALIZATION	18	BY MR. KELLER:
18	ASSAY."	19	Q. Do viruses do mumps viruses
19	Do you see that?	20	evolve over time?
20	A. Yes.	21	MR. SANGIAMO: Object to the
21	Q. Do you understand it to be the	22	form.
22 23	standard PRN assay that you're familiar with?	23	THE WITNESS: There are different
24	MR. SANGIAMO: Object to the form.	24	genotypes of mumps that have appeared
25		25	over time. Whether so the frequency
23	THE WITNESS: I recognize it to	25	
1	Page 159	1	Page 161
1	be the serum dilutions I can't	1	of which I'm not familiar with. But there are occasions where whether
2	confirm, but a neutralization format	$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	
3	that we had run previously in our	l	it's an evolution or a change, I can't
4	laboratory. BY MR. KELLER:	4 5	speak to, but there are changes in the virus that have been detected across
5 6		6	
	Q. Is that the Protocol 006 format	l	years. BY MR. KELLER:
8	or methodology?	7 8	
	A. There are steps there that are	l	Q. Is Merck's vaccine strain a wild
10	common to mumps plaque assays. I can't say	9	type under your definition? MP_SANGIAMO: Object to the
10	with certainty that is the same one that's		MR. SANGIAMO: Object to the
11 12	used in was used in Protocol 006. Q. Did you design this assay that's	11 12	form.
13	Q. Did you design this assay that's identified in the first slide?	13	BY MR. KELLER: Q. The virus chain used to make
14	MR. SANGIAMO: Let him finish.	14	~
15	THE WITNESS: I don't recall if	15	Merck's mumps vaccine, is that do you consider that to be a wild type?
16	I did or someone else in the lab did.	16	A. It's the Jeryl Lynn strain. The
17	BY MR. KELLER:	17	passage level that it's at is not considered
18	Q. The reference there to TN wt	18	wild type.
19	mumps, that's Tennessee wild type mumps?	19	Q. If I were to get that passage
20	A. Yes.	20	strain, experience that in the wild, I
21	Q. And Tennessee wild is that a	21	wouldn't get sick?
22	strain of mumps virus that was circulating in	22	A. That would be the expectation.
23	the United States in this time frame?	23	
123		l	
	Δ It was a strain of virus mumps	24	vou believe that a kid would likely be
24 25	A. It was a strain of virus mumps circulating in the US. I don't recall the	24 25	you believe that a kid would likely be infected with the mumps disease if they're

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	Page 162		Page 164
1	exposed to a Jeryl Lynn with a lower passage?	1	and others' position.
2	A. I don't recall the specific	2	Q. That using Jeryl Lynn in
3	passage level, but I recall that Maurice	3	Protocol 007 was proper. Correct?
4	Hilleman did a study with what he was calling	4	A. That was his, the view that
5	an A level and B level of Jeryl Lynn. I don't	5	he that was the implication from the
6	recall the passage levels but there was the	6	comment he made, but others at CBER at the
7	lower passage level that he evaluated, there	7	time we were doing Protocol 007 had approved
8	was evidence of parotitis, as best I recall,	8	its low passage virus use.
9	in some percentage of the children.	9	Q. Was Steven Rubin considered the
10	Q. You just don't recall what those	10	preeminent expert on mumps virus testing at
11	levels were?	11	CBER, based on your experience?
12	A. Offhand I don't remember the	12	A. My at the time of our
13	numbers.	13	discussions with the FDA and CBER, at the time
14	Q. You don't recall what passage	14	my understanding was that Cathy Carbone was
15	level would be considered wild type for Jeryl	15	the expert. I think, as I understand it,
16	Lynn?	16	Cathy Carbone has since moved on to either
17	MR. SANGIAMO: Object to the	17	I don't know if she's retired, but moved on to
18	form.	18	other assignments, and Steve Rubin has been
19	THE WITNESS: I have so I	19	publishing a lot in the area.
20	don't have a personal opinion on it,	20	Q. So he's you believe he
21	but I recall CBER making a statement of	21	stepped in to be the CBER expert on mumps
22	what passage level they consider to be	22	virus now?
23	wild type.	23	MR. SANGIAMO: Objection.
24	BY MR. KELLER:	24	THE WITNESS: Whether he's
25	Q. Do you recall what that was?	25	CBER's expert, I don't know who else at
	Page 163		Page 165
1	A. I believe it was 12, as best I	1	CBER who would be contributing.
2	recall.	2	BY MR. KELLER:
3	Q. So anything lower than 12 would	3	Q. Let me direct your attention
4	be considered wild type?	4	back to Exhibit 21 on 17612. In the third
5	A. That was my understanding of	5	PowerPoint presentation, in the second bullet
6	their comment.	6	point it says, "A positive mumps neutralization
7	Q. Do you recall there being any	7	titer almost certainly ensures protection from
8	discussion in any of the meetings you had	8	wild type infection."
9	where there was a dispute about whether or not		Do you see that?
10	the Jeryl Lynn strain at any passage should be	10	A. Yes.
11	used in Protocol 007 PRN assay?	11	Q. This is based on do you
12	MR. SANGIAMO: Object to the	12	understand that to be based on the PRN assay
13	form.	13	identified in this assay?
14	THE WITNESS: I recall a comment	14	A. In which I'm sorry, in which
15	from Steven Rubin in response to a	15	assay?
16	publication that he submitted for	16	Q. Identified in the first slide.
17 18	review where he made a comment about	17 18	MR. SANGIAMO: Object to the
	the choice of Jeryl Lynn. BY MR. KELLER:	19	form. THE WITNESS: My understanding
19 20		20	THE WITNESS: My understanding
20	Q. What was his comment? A. I don't recall the specifics of	20	is that the assay that we described,
21 22	1	22	that's described with the Tennessee
122	it. My general recollection is that he I	22 23	mumps, that there was no protection aspect to that study.
1	don't ramambar the appoints mording at it but		
23	don't remember the specific wording of it, but		· ·
1	the understanding I had from it was that he didn't necessarily agree with Cathy Carbone	24 24 25	BY MR. KELLER: Q. So do you understand what

42 (Pages 162 - 165)

_	HIGHLY CONFIDENTIAL -		
	Page 166		Page 168
1	under this slide it says, "ADVANTAGES TO	1	form.
2	PARTICIPANTS IN THIS TRIAL FOR SUBJECTS."	2	THE WITNESS: That's what it
3	Do you see that?	3	says.
4	A. Yes.	4	BY MR. KELLER:
5	Q. You understand that they're	5	Q. In that greater than 1 to 4,
6	talking about the assay that's going to be run	6	that is that the same serostatus cutoff
7	in this Protocol 007, correct, the purposes	7	that was used in your PRN
8	behind this protocol?	8	MR. SANGIAMO: Object to the
9	A. I can't say with certainty that	9	form.
10	they are talking about this particular assay	10	BY MR. KELLER:
11	or mumps neutralization in general.	11	Q for definition of seroconverter?
12	Q. Let me ask you more directly. A	12	A. I don't recall what dilutions we
13	positive mumps neutralization titer in your	13	used.
14	assay, the AIGENT, do you believe that ensures	14	MR. KELLER: Fair enough. Let
15	protection from wild type infection?	15	me mark this next exhibit as Exhibit 22.
16	A. I have no experience in that	16	
17	area. I don't have any direct experience	17	(Exhibit Krah-22, PowerPoint
18	with	18	presentation, 17647 - 17762, was marked
19	Q. Were you ever go ahead.	19	for identification.)
20	A with clinical relevance.	20	
21	Q. Were you ever did you ever	21	BY MR. KELLER:
22	discuss the development of Protocol 007 with	22	Q. For the record, Exhibit 22 is
23	anybody at Merck?	23	also part of the same packet, the file
24	A. I'm sorry?	24	regarding the March 15 and 16, 1999,
25	Q. Strike that. That's a bad	25	investigator meeting relating to the mumps
	Page 167		Page 169
1	ruge 107	1	rage 109
1	question.	1	expiry study. And it bears Bates stamp number
1 2	_	1 2	2
	question.		expiry study. And it bears Bates stamp number
2	question. Did you ever discuss the	2	expiry study. And it bears Bates stamp number 17647 through 17762.
2 3	question. Did you ever discuss the clinical relevance of the assay you were	2 3	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall
2 3 4	question. Did you ever discuss the clinical relevance of the assay you were developing for Protocol 007 with anybody at	2 3 4	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall seeing there's two documents in this
2 3 4 5	question. Did you ever discuss the clinical relevance of the assay you were developing for Protocol 007 with anybody at Merck?	2 3 4 5	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall seeing there's two documents in this packet. One is a PowerPoint presentation and
2 3 4 5 6	question. Did you ever discuss the clinical relevance of the assay you were developing for Protocol 007 with anybody at Merck? A. Not that I recall.	2 3 4 5 6	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall seeing there's two documents in this packet. One is a PowerPoint presentation and then the second one starting at 17654 is a
2 3 4 5 6 7	question. Did you ever discuss the clinical relevance of the assay you were developing for Protocol 007 with anybody at Merck? A. Not that I recall. Q. In the second bullet point, the	2 3 4 5 6 7	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall seeing there's two documents in this packet. One is a PowerPoint presentation and then the second one starting at 17654 is a Protocol 007-00 product V205C. I'll ask you,
2 3 4 5 6 7 8	question. Did you ever discuss the clinical relevance of the assay you were developing for Protocol 007 with anybody at Merck? A. Not that I recall. Q. In the second bullet point, the second slide it says primary sorry, strike	2 3 4 5 6 7 8	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall seeing there's two documents in this packet. One is a PowerPoint presentation and then the second one starting at 17654 is a Protocol 007-00 product V205C. I'll ask you, if you recall, seeing either of these two
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2 3 4 5 6 7 8 9 10 11 12	question. Did you ever discuss the clinical relevance of the assay you were developing for Protocol 007 with anybody at Merck? A. Not that I recall. Q. In the second bullet point, the second slide it says primary sorry, strike that. In the second slide of this investigator meeting presentation it says, "PRELIMINARY GUIDELINES FOR THE PRN ASSAY."	2 3 4 5 6 7 8 9 10 11 12	expiry study. And it bears Bates stamp number 17647 through 17762. Sir, I'll ask you if you recall seeing there's two documents in this packet. One is a PowerPoint presentation and then the second one starting at 17654 is a Protocol 007-00 product V205C. I'll ask you, if you recall, seeing either of these two documents before today? A. They don't look familiar to me. Q. Do you recall again, you don't recall participating in this
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1	Page 170		Page 172
1	Q. Yes.	1	time you want to to look at this
2	MR. SANGIAMO: You don't have to	1	protocol.
3	accept that representation, but he's	3	MR. SANGIAMO: No, I don't
4	premising his question on the	4	agreed that you get to soak up his day
5	supposition that it is. It's possible.	5	by handing him really long documents
6	THE WITNESS: If it was that	6	and then having it be off the record.
7	meeting and that meeting said I was an	7	So let's just see if we can avoid a
8	attendee, then I would have been there,	8	fight, see if it works. And if there
9	but I don't have a recollection of	9	might just be sections that he can read
10	seeing I don't recall seeing these	10	depending on what your questions are,
11	or have a memory of them.	11	that might solve the problem.
12	BY MR. KELLER:	12	MR. KELLER: This is the
13	Q. That's fine. Let me direct your	13	protocol for Protocol 007, and the fact
14	attention, then, to 17654, the protocol. Take	14	that he says he doesn't recall ever
15	whatever time you want to look at this	15	seeing it again, you want him to spend
16	protocol, it's very long. We can go off the	16	the next 30 minutes on the record
17	record if you want to read it cover to cover	17	reviewing it the first time to answer
18	because I may have some questions for you on	18	questions about it, I don't think
19	it.	19	that's fair, and we would likely go
20	Do you recall ever seeing the	20	back to the court for more time if
21	protocol for Protocol 007?	21	that's the position you want to take.
22	A. I don't remember.	22	Because there are a lot of documents
23	Q. And so do you recall let me	23	and unfortunately some of these
24	direct your attention to have you ever seen	24	documents are longer and we have
25	a protocol before?	25	limited time with him. If you are
	Page 171		Page 173
1	A. I've seen sections of protocols.	1	going to require us to take that time
2	It doesn't mean I read it and understood it,	2	for him to review a document on the
3	but I remember seeing documents that were part	3	record, then we're going to go back and
4	of protocols before. I don't remember how	4	seek additional time with this court.
5	much I understood it.	5	You decide.
6	Q. Fair enough. Let's look at a	6	MR. SANGIAMO: I suggest we see
7	couple pages here and see if that refreshes	7	where it goes.
8	your memory if you've seen parts of this	8	MR. KELLER: Sure.
9	protocol as part of your job developing and	9	
- 11		1	MR. SANGIAMO: Start your
10	running the experiments for Protocol 007's	10	questions, if it looks like he needs to
11	AIGENT assay.	10 11	questions, if it looks like he needs to read, he will read as much of it as he
11 12	AIGENT assay. MR. SANGIAMO: What I propose we	10 11 12	questions, if it looks like he needs to read, he will read as much of it as he needs to read and maybe we won't have
11 12 13	AIGENT assay. MR. SANGIAMO: What I propose we do here, if you're going to	10 11 12 13	questions, if it looks like he needs to read, he will read as much of it as he needs to read and maybe we won't have any kind of problem.
11 12 13 14	AIGENT assay. MR. SANGIAMO: What I propose we do here, if you're going to MR. KELLER: Why don't we go off	10 11 12 13 14	questions, if it looks like he needs to read, he will read as much of it as he needs to read and maybe we won't have any kind of problem. MR. KELLER: Sure.
11 12 13	AIGENT assay. MR. SANGIAMO: What I propose we do here, if you're going to MR. KELLER: Why don't we go off the record.	10 11 12 13 14 15	questions, if it looks like he needs to read, he will read as much of it as he needs to read and maybe we won't have any kind of problem. MR. KELLER: Sure. BY MR. KELLER:
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	HIGHLY CONFIDENTIAL -		
	Page 174		Page 176
1	"CLINICAL SECTIONS," "ADMINISTRATIVE AND	1	subjects enrolled in each of the treatment
2	REGULATORY SECTIONS." Do you see that? And	2	groups, 5 percent are expected to be initially
3	"SIGNATURES." Do you see that on 17655 and	3	seropositive.
4	A. The second one I don't.	4	Do you see that? The first
5	Q. On 17657. Roman numeral I,	5	sentence.
6	Roman numeral II, Roman numeral III. Do you	6	A. Yes.
7	see that?	7	Q. The treatment groups, did you
8	A. Yes.	8	understand that to be the three doses that
9	Q. On the "CLINICAL SECTIONS" under	9	were run in the AIGENT?
10	III [sic] it says, "OBJECTIVES." Do you see	10	MR. SANGIAMO: Object to the
11	that on 17655?	11	you said did he understand?
12	MR. SANGIAMO: Number III?	12	MR. KELLER: Yes.
13	BY MR. KELLER:	13	MR. SANGIAMO: Object to the
14	Q. Roman numeral I(C), "OBJECTIVES."	14	form.
15	Do you see that?	15	THE WITNESS: I don't recall
16	A. Yes.	16	that specific part of the document,
17	Q. Do you understand what	17	seeing that before in this document.
18	objectives are in a protocol?	18	BY MR. KELLER:
19	A. No.	19	Q. Did you ever learn that there is
20	Q. Let me direct your attention to	20	an expectation that only what do you
21	17665 strike that.	21	understand initially seropositive to mean in a
22	Let me direct your attention to	22	plaque reduction neutralization assay?
23	17693 under F, "EFFICACY/PHARMACOKINETICS	23	A. My general understanding of that
24	/IMMUNOGENICITY, ETC., MEASUREMENTS." In the	24	would be that the pre-vaccination, 5 percent
25	second paragraph it says, "Serologic testing	25	of the pre-vaccination sera would be expected
	Page 175		Page 177
	1 uge 175	1	1 age 177
1	will be performed by Merck Research	1	to be positive.
1 2		1 2	- 1
	will be performed by Merck Research	1	to be positive.
2	will be performed by Merck Research Laboratories, West Point, PA."	2	to be positive. Q. What does that mean to you, what
3	will be performed by Merck Research Laboratories, West Point, PA." Do you see that?	2 3	to be positive. Q. What does that mean to you, what does seropositive mean?
2 3 4	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes.	2 3 4	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive
2 3 4 5	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic	2 3 4 5	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the
2 3 4 5 6	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic testing to mean generally outside of this	2 3 4 5 6	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the it's giving a positive neutralization result.
2 3 4 5 6 7	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic testing to mean generally outside of this protocol?	2 3 4 5 6 7	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the it's giving a positive neutralization result. Q. For mumps specific antibodies?
2 3 4 5 6 7 8	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic testing to mean generally outside of this protocol? A. It could be a variety of things.	2 3 4 5 6 7 8	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the it's giving a positive neutralization result. Q. For mumps specific antibodies? A. Yes.
2 3 4 5 6 7 8 9 10	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic testing to mean generally outside of this protocol? A. It could be a variety of things. It would depend on what this the document indicates is the specific assay. Q. Let me ask you, for Protocol	2 3 4 5 6 7 8 9	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the it's giving a positive neutralization result. Q. For mumps specific antibodies? A. Yes. Q. So is it the understanding that
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic testing to mean generally outside of this protocol? A. It could be a variety of things. It would depend on what this the document indicates is the specific assay. Q. Let me ask you, for Protocol 007, did you do serologic testing in your lab? A. Yes. Q. And what serologic testing did you do? A. For Protocol 007? Q. Yes. A. The mumps AIGENT assay. Q. So you ran the kid's serum in that assay. Correct? A. Yes. Q. Let me direct your attention to 17706, under "DATA ANALYSIS." In the first sentence it says let me know when you're	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 t23 24	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the it's giving a positive neutralization result. Q. For mumps specific antibodies? A. Yes. Q. So is it the understanding that those kids are immune from the disease because they've already got mumps neutralizing antibodies in their bloodstream? MR. SANGIAMO: Object to the form. THE WITNESS: I don't know that the clinical conclusion from that result. BY MR. KELLER: Q. You don't. This expectation of 5 percent being pre-positive, have you ever heard that expectation before? A. I've heard of estimates of initially seropositive. I can't say that the 5 percent is familiar.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	will be performed by Merck Research Laboratories, West Point, PA." Do you see that? A. Yes. Q. What do you understand serologic testing to mean generally outside of this protocol? A. It could be a variety of things. It would depend on what this the document indicates is the specific assay. Q. Let me ask you, for Protocol 007, did you do serologic testing in your lab? A. Yes. Q. And what serologic testing did you do? A. For Protocol 007? Q. Yes. A. The mumps AIGENT assay. Q. So you ran the kid's serum in that assay. Correct? A. Yes. Q. Let me direct your attention to 17706, under "DATA ANALYSIS." In the first	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 t23	to be positive. Q. What does that mean to you, what does seropositive mean? A. It means that there's a positive neutral the serum is neutralizing in the it's giving a positive neutralization result. Q. For mumps specific antibodies? A. Yes. Q. So is it the understanding that those kids are immune from the disease because they've already got mumps neutralizing antibodies in their bloodstream? MR. SANGIAMO: Object to the form. THE WITNESS: I don't know that the clinical conclusion from that result. BY MR. KELLER: Q. You don't. This expectation of 5 percent being pre-positive, have you ever heard that expectation before? A. I've heard of estimates of initially seropositive. I can't say that the

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1	Page 178	1	Page 180
1	determine what would be expected for kids to	1	pre-positive results were for the ELISA
2	be immune from mumps prior to being vaccinated?	$\begin{vmatrix} 2 \\ 3 \end{vmatrix}$	testing?
3	A. Personally, no.	3	A. No.
5	MR. SANGIAMO: Object to the form.	5	MR. SANGIAMO: Object to the form.
6	BY MR. KELLER:	6	BY MR. KELLER:
7		7	Q. Nobody ever told you?
8	Q. Has anybody, are you aware of anybody strike that.	8	MR. SANGIAMO: Object to the
9	Are you aware of anybody	9	form.
10	connected with Protocol 007 doing any research	10	THE WITNESS: I don't recall.
11	to determine what the expectation was for kids	11	BY MR. KELLER:
12	before they're vaccinated to be immune from	12	Q. Would that have been relevant
13	mumps disease?	13	for you to understand a kid identified as
14	MR. SANGIAMO: Object to the	14	having no mumps antibodies in an ELISA, to use
15	form.	15	that as a comparison to what was being seen in
16	THE WITNESS: I'm not aware, I'm	16	the AIGENT?
17	not familiar with whether such studies	17	MR. SANGIAMO: Object to the
18	were done.	18	form.
19	BY MR. KELLER:	19	THE WITNESS: I'm sorry, that
20	Q. You made projections for	20	doesn't make sense.
21	pre-positive rates, didn't you, when you ran	21	BY MR. KELLER:
22	the AIGENT?	22	Q. It doesn't make sense to you?
23	A. There were estimates of the	23	An ELISA identifies mumps antibodies.
24	expected pre-positive rates based on the	24	Correct? Isn't that the whole purpose of an
25	results of our development studies.	25	ELISA, a mumps ELISA assay, to identify mumps
	Dog 170		Dogg 191
1	Page 179 Other than running your	1	Page 181
1 2	Q. Other than running your	1 2	antibodies?
2	Q. Other than running your development studies to get a pre-positive	2	antibodies? A. Yes.
2 3	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to	2 3	antibodies? A. Yes. Q. So if a kid is pre-positive for
2	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in	2 3 4	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would
2 3 4	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps?	2 3	antibodies? A. Yes. Q. So if a kid is pre-positive for
2 3 4 5	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in	2 3 4 5	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct?
2 3 4 5 6	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the	2 3 4 5 6	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the
2 3 4 5 6 7	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of	2 3 4 5 6 7	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct?
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2 3 4 5 6 7 8 9 10	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER:	2 3 4 5 6 7 8 9 10 11	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the this nature PRN study?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction neutralization assay?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the this nature PRN study? MR. SANGIAMO: Object to the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction neutralization assay? A. From my view, no.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the this nature PRN study? MR. SANGIAMO: Object to the form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction neutralization assay? A. From my view, no. Q. Why?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the this nature PRN study? MR. SANGIAMO: Object to the form. THE WITNESS: I didn't personally do it. BY MR. KELLER:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction neutralization assay? A. From my view, no. Q. Why? A. They're independent assays. I wouldn't at least in other assays that are other neutralization assays I've run, I'm
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the this nature PRN study? MR. SANGIAMO: Object to the form. THE WITNESS: I didn't personally do it. BY MR. KELLER: Q. Did you ever compare it against	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction neutralization assay? A. From my view, no. Q. Why? A. They're independent assays. I wouldn't at least in other assays that are other neutralization assays I've run, I'm not aware of any suggestion of a suggestion of using the ELISA as a guide for what to expect in that assay.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Other than running your development studies to get a pre-positive rate, are you aware of any other control to identify whether or not these kids are, in fact, immune from disease, from mumps? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not aware of other are you asking if there is another independent test of antibody in those sera? BY MR. KELLER: Q. Did you do any other independent testing to determine seropositive rates for kids that would expect in this study of the this nature PRN study? MR. SANGIAMO: Object to the form. THE WITNESS: I didn't personally do it. BY MR. KELLER: Q. Did you ever compare it against ELISA results for pre-positivity?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	antibodies? A. Yes. Q. So if a kid is pre-positive for an ELISA mumps antibody test, that would presume that the kid has mumps antibodies. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: It would indicate that that serum has detectible antibodies. BY MR. KELLER: Q. You don't think that information to be at all relevant in determining the pre-positive rate for your plaque reduction neutralization assay? A. From my view, no. Q. Why? A. They're independent assays. I wouldn't at least in other assays that are other neutralization assays I've run, I'm not aware of any suggestion of a suggestion of using the ELISA as a guide for what to

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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

Page 182 of anybody who has correlated an ELISA assay to a plaque reduction neutralization assay for mumps? A. Yes.	1 2 3 4	Page 184 protection in the broader population. Q. Do you recall ever representing in a document that the assay that you ran is
to a plaque reduction neutralization assay for mumps? A. Yes.	2 3	Q. Do you recall ever representing
mumps? A. Yes.	3	
Å. Yes.	l .	in a document that the assay that you ran is
Å. Yes.	l .	m a accument mat the assay that you fall is
	4	linked to efficacy?
Q. Who?	5	A. Not that I recall.
A. Steve Rubin is one of them, one	6	Q. Would that surprise you if you
	_	
person.	7	saw a document linked to your name, that you
	l .	represented that this assay, the assay that
		you ran was linked to efficacy?
		MR. SANGIAMO: Object to the
but he's published on those studies.	11	form.
Q. Has there been a correlation	12	THE WITNESS: I don't recall.
between an ELISA assay and protection from	13	I'm not aware of one study that I might
disease?	14	link to.
MR. SANGIAMO: Object to the	l .	BY MR. KELLER:
<u> </u>		Q. Would that surprise you if
		somebody represented that the assay that you
	l .	developed, the AIGENT, was linked
	l .	
		represented as being linked to efficacy?
<u> </u>		MR. SANGIAMO: Object to the
		form.
	l .	THE WITNESS: Well, the
"efficacy" means?	23	statement of the link to efficacy would
A. I have a general understanding	24	be a statement that would be beyond my
of that.	25	expertise, require clinical and
Page 183		Page 185
Q. What's your understanding?	1	regulatory input. So if a document did
A. That that's the in a	2	exist, my input would not have been
controlled clinical setting, the protection	3	beyond the assay description.
		BY MR. KELLER:
	'	
		Q. When you were developing the
- · · · · · · · · · · · · · · · · · · ·		AIGENT that ultimately got used in Protocol
		007 strike that.
<u> </u>	8	Let me direct your attention
	9	back to Exhibit 22, in particular at 17720,
•	10	under "COMPLIANCE WITH LAW, AUDIT, AND
	11	DEPARTMENT."
in the study. This was an	12	You testified that you may have
immunogenicity study. So efficacy,	13	seen pieces of protocols. Do you ever recall
from my understanding, would require	14	seeing pieces of protocols that discussed how
	15	the clinical studies would be conducted?
~ ·		A. I do not.
		Q. In this protocol for Protocol
Q. Did you ever do you know what		
effectiveness means?	18	007, it's dated February 2, 1999. Do you see
	19	that in the bottom right-hand corner?
	200	
A. I have a general understanding	20	A. Yes.
A. I have a general understanding of that.	21	Q. You were working on that on
A. I have a general understanding of that. Q. What's your understanding, sir?		
A. I have a general understanding of that. Q. What's your understanding, sir? A. My general understanding of that	21	Q. You were working on that on
A. I have a general understanding of that. Q. What's your understanding, sir?	21 22	Q. You were working on that on Protocol 007 at this time frame, weren't you?
11 11 0	between an ELISA assay and protection from disease? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, there is no correlate of protection from protection from disease for mumps. BY MR. KELLER: Q. Do you understand what the term "efficacy" means? A. I have a general understanding of that. Page 183 Q. What's your understanding? A. That that's the in a controlled clinical setting, the protection from the protection from disease achieved during a controlled clinical study. Q. Did your the AIGENT you developed, did that show efficacy? MR. SANGIAMO: Object to the form. THE WITNESS: There my understanding, there was no protection in the study. This was an immunogenicity study. So efficacy,	the assay is when did that happen? A. I don't recall specific years, but he's published on those studies. Q. Has there been a correlation between an ELISA assay and protection from disease? MR. SANGIAMO: Object to the form. THE WITNESS: From my understanding, there is no correlate of protection from protection from disease for mumps. BY MR. KELLER: Q. Do you understand what the term 22 and of that. Page 183 Q. What's your understanding 24 of that. Q. What's your understanding? A. That that's the in a controlled clinical setting, the protection from the protection from disease achieved during a controlled clinical study. Q. Did your the AIGENT you developed, did that show efficacy? MR. SANGIAMO: Object to the form. THE WITNESS: There my understanding, there was no protection in the study. This was an immunogenicity study. So efficacy, from my understanding, would require evaluating protection from disease in the vaccinees.

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the first paragraph, can you read the first 2 sentence on 17720? 3 A. The first, "By signing this 4 protocol," that one? 5 Q. Yes. 6 A. "By signing this protocol, the 7 investigator agrees to conduct the study in an 8 efficient and diligent manner and in 9 conformance with this protocol; generally 10 accepted standards of Good Clinical Practice; and all applicable federal, state, and local 12 laws, rules and regulations relating to the 13 conduct of the clinical study." 14 Q. It's your testimony that you 15 didn't have an understanding that the samples that you ran for Protocol 007 would be 17 required to be run under the Good Clinical 18 Practices because you didn't even know what 19 that was, did you? 20 A. I was not familiar with what 21 that term referred to nor that we were — that 21 it applying to the testing laboratory. 23 MR. SANGIAMO: Jeff, if you're 24 going to ask him questions about the 25 substance, why don't you just go ahead 1 Page 187 1 MR. SANGIAMO: Also read the 8 final paragraph. 9 BY MR. REILER: 9 Q. Just those two pages. 11 A. Okay. 12 Q. Having read these three 13 sections, does that refessly your memory 14 whether or not you've seen this language in 15 Protocol 607? MR. KELLER: Section 11 thought he read 18 two sections? I thought he read 18 two sections? I thought he read 18 two sections? I thought he read 18 two sections 18 MR. SANGIAMO: Imsorry, the 19 MR. SANGIAMO: Object to the 19 MR. SANGIAMO: Object		HIGHLY CONFIDENTIAL -	ЛІ	TORNETS ETES ONET
2 sentence on 17720? 3 A. The first, "By signing this 4 protocol," that one? 5 Q. Yes. 6 A. "By signing this protocol, the 6 A. "By signing this protocol, the 7 investigator agrees to conduct the study in an 8 efficient and diligent manner and in 9 conformance with this protocol; generally 10 accepted standards of Good Clinical Practice; and all applicable federal, state, and local 2 laws, rules and regulations relating to the 13 conduct of the clinical study." 14 Q. It's your testimony that you 15 didn't have an understanding that the samples 16 that you ran for Protocol 007 would be 17 required to be run under the Good Clinical Practices because you didn't even know what 19 that was, did you? 20 A. I was not familiar with what 21 that term referred to nor that we were that 22 it applying to the testing laboratory. 23 MR. SANGIAMO: Jeff, if you're 24 going to ask him questions about the 25 substance, why don't you just go ahead 1 1 and read that very short section. 2 BY MR. KELLER: 3 Q. Sure. Why don't you read this section, it's only three pages, take your 5 time. 4 A. Okay. 7 MR. SANGIAMO: Also read the 8 final paragraph. 9 BY MR. KELLER: 9 A. Okay. 11 Q. Last those two pages. 11 A. Okay. 12 Q. Having read these three 13 sections, docs that refresh your memory 14 whether or not you've seen this language in 15 Protocol 007. 15 MR. SANGIAMO: I'm sorry, the 17 which three section? I thought he read 18 two sections. 18 MR. SANGIAMO: Tim sorry, the 18 which there section? I thought he read 18 two sections. 19 MR. KELLER: 5 MR. SANGIAMO: Tim sorry, the 19 MR. KELLER: 5 MR. SANGIAMO: Tim sorry, the 19 MR. KELLER: 5 Section H and I. 19 MR. SANGIAMO: Object to the 19 ministration and in figurations and paragraph. 19 MR. SANGIAMO: Object to the 19 ministration and palaity sourcance? 11 the terms before. 19 do not familiar with. 20 Is it a department at Merck		<u> </u>		Page 188
A. The first, "By signing this 4 protocol," that one? 5 Q. Yes. 6 A. "By signing this protocol, the 7 investigator agrees to conduct the study in an 8 efficient and diligent manner and in 9 conformance with this protocol; generally 10 accepted standards of Good Clinical Practice; and all applicable federal, state, and local 12 laws, rules and regulations relating to the 13 conduct of the clinical study." 14 Q. It's your testimony that you 15 didn't have an understanding that the samples 16 that you ran for Protocol 007 would be 17 required to be run under the Good Clinical 18 Practices because you didn't even know what 19 that term referred to nor that we were that 12 it applying to the testing laboratory. 12 MR. SANGIAMO: Jeff, if you're 14 going to ask him questions about the 15 substance, why don't you just go ahead 17 MR. SANGIAMO: Also read the 18 section, it's only three pages, take your 18 mine. 19 MR. SANGIAMO: Also read the 19 mine paragraph. 19 MR. KELLER: 10 Q. Just those two pages. 11 A. Okay. 11 Q. Have it as a protocol, the SPONSOR agrees to be responsible for implementing and maintaining quality control and quality assurance? 10 there is a specific department that Covers 10 thought that L I don't recall whether there is a specific department that covers 10 thought there is a specific department that covers 10 thought there is a specific department that covers 11 though there is a protocol, and conduct of the protocol of they include other responsibilities. 12 quality control and quality assurance? 14 thought there is protocol of they one of they include other responsibilities. 15 quality control and quality assurance? 15 thought that the samples 15 though the there is a specific department that covers 16 though there is a protocol. 16 protocol of they one include other responsibilities. 16 quality assurance 17 quality control and quality assurance 18 though a paragraph. 17 quality control and quality assurance 18 though a protocol, the SPONSOR agrees to be responsible 19 for implementing a			1	
4 How it applies in this particular case I am not familiar with. 5 Q. Yes. 6 A. "By signing this protocol, the investigator agrees to conduct the study in an efficient and diligent manner and in 9 conformance with this protocol; generally 10 accepted standards of Good Clinical Practice; 11 and all applicable federal, state, and local 2 laws, rules and regulations relating to the 13 conduct of the clinical study." 14 Q. It's your testimony that you 2 didn't have an understanding that the samples that you ran for Protocol Off would be 17 required to be run under the Good Clinical 18 Practices because you didn't even know what 19 that term referred to nor that we were that 22 it applying to the testing laboratory. 23 MR, SANGIAMO: Jeff, if you're 24 going to ask him questions about the 25 wishstance, why don't you just go ahead 1 western and an and applicable federal, state, and local 2 reported in compliance with the protocol, accepted standards of Good Clinical Practice, and all applicable federal, state, and local 2 reported in compliance with the protocol, accepted standards of Good Clinical Practice, and all applicable federal, state, and local 2 reported in compliance with the protocol, accepted standards of Good Clinical Study." 1 and read that very short section. 2 BY MR, KELLER: 5 time. 5 Q. That's reference to Protocol 007. Correct? Is that a fair statement, the clinical study. " 2 and read that very short section. 2 BY MR, SANGIAMO: Also read the 3 section, it's only three pages, take your 4 A. Yes. 9 Q. Bat those two pages. 11 A. Okay. 11 Q. Bid you understand and you ran the serum for Protocol 007, correct, in you're 19 your lab? 12 ran the serum for Protocol 007, correct, in you're 19 your lab? 14 whether or not you've seen this language in 19 your lab? 14 whether or not you've seen this language in 19 your lab should have been complying with the accepted standard for Good Clinical Practice. 19 Protocol 007? 11 the protocol of the clinical study referenced there is Protocol 007? 11 the accept				* *
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19 MR. KELLER: Section H and I. 19 MR. SANGIAMO: Object to the	17	which three section? I thought he read	1	*
	18	two sections.		
20 BY MR KELLER: 20 form.	19	MR. KELLER: Section H and I.	1	=
	20	BY MR. KELLER:	20	form.
21 Q. Those two pages. 21 THE WITNESS: I don't have				
22 A. That does not change my I 22 experience whether that the	22			
23 don't recall. 23 description as written here applies to				
24 Q. So in the section I under 24 the testing laboratory.		· ·		
25 "QUALITY CONTROL AND QUALITY ASSURANCE," do 25 BY MR. KELLER:	25	"QUALITY CONTROL AND QUALITY ASSURANCE," do	25	DI WK. KELLEK:

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	Page 190		Page 192
1	Q. The reference here to sponsor,	1	who is Mande Lyon?
2	that's Merck, right? Merck was the sponsor	2	A. I don't recall.
3	for this protocol?	3	Q. The subject here is "MMR II
4	A. That's my I can't say for	4	Protocol 007 IDSA Poster Draft."
5	certain, but that's my understanding of the	5	Do you see that?
6	wording.	6	A. Yes.
7	Q. During the time that you ran the	7	Q. What's the IDSA?
8	samples for Protocol 007, were there any SOPs	8	A. It's, as best I recall, an
9	in place for quality control that related to	9	organization. I don't recall what it stands
10	those clinical samples?	10	for.
11	A. I don't recall.	11	Q. Do you recall ever giving a
12	Q. Were there any quality assurance	12	presentation at that organization regarding
13	SOPs that were in place with respect to the	13	Protocol 007?
14	running of the clinical samples in Protocol	14	A. Clarification, me personally
15	007 that you recall?	15	or
16	A. I don't recall.	16	Q. You personally.
17	MR. KELLER: Let me mark this	17	A. I don't recall personally giving
18	next exhibit as Exhibit 23.	18	a presentation.
19		19	Q. Do you recall, has anybody ever
20	(Exhibit Krah-23, E-mail string,	20	presented on the results of Protocol 007 to
21	337141 - 337157 & 121082, was marked	21	anybody outside of Merck other than the FDA or
22	for identification.)	22	CBER?
23 24	BY MR. KELLER:	23	MR. SANGIAMO: Answer if you know obviously.
25	Q. For the record, Exhibit 23 is a	24 25	THE WITNESS: I don't know.
23		25	THE WITNESS. I doll t know.
1	Page 191	1	Page 193
1	document that bears Bates stamp number 337141	1	This document suggested that this
2	document that bears Bates stamp number 337141 through 157. And there's a separate document	2	This document suggested that this was is the planned presentation, but
2 3	document that bears Bates stamp number 337141 through 157. And there's a separate document attached to this that bears Bates number	2 3	This document suggested that this was is the planned presentation, but I don't know what's presented.
2 3 4	document that bears Bates stamp number 337141 through 157. And there's a separate document attached to this that bears Bates number 121082. I'll keep these together as Exhibit 23.	2 3 4	This document suggested that this was is the planned presentation, but I don't know what's presented. BY MR. KELLER:
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLY CONFIDENTIAL -	111	TORIVETO ETED ONET
	Page 194		Page 196
1	Q. This is a 2004 poster. Correct?	1	A. This suggests, yeah, the e-mail
2	A. The date is from 2004. I don't	2	suggests that I reviewed it.
3	know when the actual	3	Q. When you reviewed it, did you
4	Q. Did you draft	4	see anything that was incorrectly stated in
5	MR. SANGIAMO: You don't know	5	this poster?
6	when the actual what?	6	A. Not that I was aware of.
7	THE WITNESS: Presentation was.	7	Q. And if there was something
8	BY MR. KELLER:	8	incorrect here, would you have you would
9	Q. Did you draft this?	9	have raised that, wouldn't you have?
10	A. That is not typical no, I did	10	MR. SANGIAMO: Dr. Krah, why
11	not draft it.	11	don't you take a look at the document
12	Q. Your name is on it, though.	12	since he's asking the substance of it.
13	Correct?	13	BY MR. KELLER:
14	A. Yes.	14	
			Q. I'm asking generally without
15	Q. So who would typically draft	15	looking at the document. If there was
16	these types of documents at Merck?	16	something incorrect in a poster like this, you
17	MR. SANGIAMO: Object to the	17	would have raised that objection, wouldn't you
18	form.	18	have?
19	THE WITNESS: It varies. I was	19	MR. SANGIAMO: You said a poster
20	looking typically the first author	20	like this. So that means he needs to
21	is the one who prepared it. But the	21	look at the document to find out what
22	first author is not a doesn't look	22	the document is about.
23	like is a Merck person. So I can't say	23	BY MR. KELLER:
24	with certainty who was the lead in	24	Q. You can't answer that question
25	drafting it.	25	without looking at the document?
	8		6
1	Page 195 BY MR. KELLER:	1	Page 197
1	Page 195 BY MR. KELLER:	1	Page 197 MR. SANGIAMO: What's your
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLY CONFIDENTIAL -		
	Page 198		Page 200
1	the neutralization assay details.	1	mumps-virus specific plaque reduction
2	Q. The numbers?	2	neutralization (PRN) assay was used as a
3	A. Either the numbers or the format	3	surrogate of vaccine efficacy; ELISA assays
4	of the assay.	4	for mumps antibodies were also performed."
5	Q. So under this poster that has	5	Q. So the statement here that the
6	your name on it, sir, it says, "Study	6	mumps virus specific plaque reduction
7	Rationale." Do you see that on the first page	7	neutralization (PRN) assay was used as a
8	of it?	8	surrogate for vaccine efficacy, that was
9	A. Okay.	9	Protocol 007, wasn't it?
10	Q. What do you understand the study	10	MR. SANGIAMO: Object to the
11	rationale to mean?	11	form.
12	A. All I can say literally what the	12	BY MR. KELLER:
13	words are written here. I don't have any	13	Q. The AIGENT that you worked on?
14	understanding beyond that.	14	MR. SANGIAMO: Object to the
15	Q. Your name is on this thing so	15	form.
16	why don't you tell me what your understanding		THE WITNESS: The Protocol
17	is?	17	007 the AIGENT assay was used in
18	MR. SANGIAMO: He just answered	18	Protocol 007.
19	your question, Jeff.	19	BY MR. KELLER:
20	BY MR. KELLER:	20	Q. Correct. So what they're
21	Q. Tell me what you understand it	21	referencing here, was there any other mumps
22	to be.	22	virus specific plaque reduction neutralization
23	A. Literally what the words say	23	assays as part of Protocol 007 other than the
24	here.	24	AIGENT?
25		25	A. Not that I'm aware of.
23	Q. Is it the rationale for Protocol	23	A. Not that I in aware of.
1	Page 199	1	Page 201
1	007? Is that a fair assessment?	1	Q. Here it represents that that
2	007? Is that a fair assessment? A. If there is	2	Q. Here it represents that that assay was used as a surrogate of vaccine
2 3	O07? Is that a fair assessment? A. If there is Q. Look at the on the next page,	2 3	Q. Here it represents that that assay was used as a surrogate of vaccine efficacy. Do you see that?
2 3 4	O07? Is that a fair assessment? A. If there is Q. Look at the on the next page, on the third bullet point from the bottom, do	2 3 4	Q. Here it represents that that assay was used as a surrogate of vaccine efficacy. Do you see that? A. Yes.
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

	HIGHLY CONFIDENTIAL -		
	Page 202		Page 204
1	going about 45 minutes.	1	read the content of everything.
2	MR. KELLER: Let's go for lunch.	2	Q. So it's fair to say if somebody
3	VIDEOGRAPHER: The time is now	3	of importance e-mailed you something, you
4	12:57. This concludes disc three.	4	would read that e-mail. Correct?
5		5	MR. SANGIAMO: Object to the
6	(A recess was taken.)	6	form.
7		7	THE WITNESS: I would say it
8	VIDEOGRAPHER: The time is now	8	would perhaps it would depend on the
9	2:08. This begins disc four. You may	9	subject and who the person was. A
10	proceed.	10	person of importance would be relative
11	MR. KELLER: I'm going to mark	11	to me. It may be an important person
12	as Exhibit 24 a document that bears	12	in the organization but not necessarily
13	Bates-stamped number 625837 through	13	in my reporting structure.
14	839, and it's an e-mail, and there's an	14	BY MR. KELLER:
15	attached document to the e-mail.	15	Q. Gotcha. Who is Henrietta Ukwu?
16		16	A. I don't recall her title. I'd
17	(Exhibit Krah-24, 10/6/98 E-mail	17	be guessing at what her even what group she
18	with attachment, 625837 - 625839, was	18	was in.
19	marked for identification.)	19	Q. She was senior management at
20		20	Merck, wasn't she, at this time frame?
21	BY MR. KELLER:	21	A. I don't know I don't know
22	Q. In the e-mail dated at the top	22	what constitutes well, I don't recall her
23	of the page October 6, 1998, from Henrietta	23	position and title and whether that
24	Ukwu to a series of individuals, and, sir, you	24	constituted senior management or not.
25	are one of the cc's on this e-mail entitled:	25	Q. And here under subject, it says,
	Page 203		Page 205
1	Page 203 Mumps expiry; summary of prep meeting on	1	Page 205 Mumps expiry; summary of prep meeting 600 for
1 2	8	1 2	2
	Mumps expiry; summary of prep meeting on	1	Mumps expiry; summary of prep meeting 600 for
2	Mumps expiry; summary of prep meeting on September 30 for CBER telecon.	2	Mumps expiry; summary of prep meeting 600 for CBER telecon. Would that have been of
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Mumps expiry; summary of prep meeting on September 30 for CBER telecon. Do you see that? A. Yes. Q. Do you recall receiving this e-mail? MR. SANGIAMO: Obviously take a minute to look at it, Dr. Krah, read it to your satisfaction. THE WITNESS: I don't have a recollection. I see my name on the cc list, but I don't recall it doesn't provide a memory. BY MR. KELLER: Q. Do you have any reason to believe you didn't receive it? A. If I'm on the cc list, it would imply that it was sent to me. So I don't have any reason to believe it was not sent to me. Q. Was it your practice to review e-mails that you received? A. My practice, as best I recall, was to read the or look at who it's from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Mumps expiry; summary of prep meeting 600 for CBER telecon. Would that have been of interest to you during this time frame? A. I don't I don't it's not obvious to me that it would have been of interest, but I so I can't say one way or the other whether it would be of interest. Q. In the first sentence it says, "Please note the summary, from Dr. Chirgwin" Who is Dr. Chirgwin? A. The Dr. Chirgwin I know is Keith Chirgwin. I don't know his position at the time. Q. Do you recall, is he do you recall when he left Merck? A. No. Q. Do you recall him working in regulatory affairs? A. I recall him working, as best I can recall, in regulatory affairs at some point in his career at Merck. Q. Do you recall him reporting to Henrietta Ukwu in regulatory affairs?

52 (Pages 202 - 205)

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	MONET CONTIDENTIAL	711	
1	Page 206	1	Page 208
1	don't recall if you were working on the	1	BY MR. KELLER:
2	development of the PRN assay during this time		Q. Did you understand that to be
3	frame?	3	the mumps expiry studies?
4	A. I don't recall.	4	MR. SANGIAMO: Object to the
5	Q. Let me direct your attention to	5	form.
6	the last sentence. It says, "The key members	6	THE WITNESS: My understanding
7	of the team are copied on this memo"	7	was that that was a component of the
8	Do you see that?	8	mumps expiry study.
9	A. Yes.	9	BY MR. KELLER:
10	Q. And under the cc, you understand	10	Q. So at some point you became part
11	that's carbon copy. Correct?	11	of that team. Correct?
12	MR. SANGIAMO: Object to the	12	MR. SANGIAMO: Object to the
13	form.	13	form.
14	BY MR. KELLER:	14	THE WITNESS: I would say
15	Q. Do you understand what copy	15	presumably because I'm copied on this.
16	means?	16	BY MR. KELLER:
17	A. cc yeah, cc just means it's	17	Q. So when it says the key members
18	someone who is copied, whether it's in the	18	of the team are copied, you just don't know
19	olden days my understanding was carbon copy.	19	whether or not you were a key member as of
20	I don't know if that still applies.	20	this date?
21	Q. Fair enough. You're identified	21	A. That's correct. Yes.
22	as in the cc's. Do you see that?	22	Q. But you became a key member at
23	A. Yes.	23	some point. Correct?
24	Q. As of this date, did you	24	MR. SANGIAMO: Object to the
25	consider yourself to be one of the key members	25	form.
	Page 207		Page 209
1	of the team for running the mumps expiry	1	THE WITNESS: I became a member
2	studies?	2	of the team. Whether a key member
3	MR. SANGIAMO: Object to the	3	would be a subjective assignment.
4	form.	4	BY MR. KELLER:
5	THE WITNESS: I can't say one	5	Q. So you can't you can't
6	way or the other at that time what	6	okay.
7	preparations we had been making to run	7	Who else is cc'd on here? You
8	the assay.	8	have Dr. Ukwu. Who is Kati Abraham, do you
9	BY MR. KELLER:	9	know?
10	Q. So you have no recollection as	10	A. I know Kati Abraham or Kati
11	to let me strike that.	11	Abraham, but I don't recall her position at
12	You were on the team that	12	the time. She has had multiple positions at
13	ultimately worked on running the clinical	13	Merck.
14	assays for Protocol 007. Correct?	14	Q. What was the position that she
15	MR. SANGIAMO: Object to the	15	had the last time you remember her position?
16	form.	16	A. She last I recall, she was
17	MR. KELLER: Let me strike that.	17	overseeing I have a general sense of what
18	BY MR. KELLER:	18	she was doing. I don't know what her official
19	Q. You were ultimately on the team	19	title was or overall responsibilities.
20	that ran the clinical serum as part of	20	Q. What's your general sense?
21	Protocol 007. Correct?	21	A. General sense is something along
22	MR. SANGIAMO: Object to the	22	the lines of quality control or quality
23	form.	23	assurance. And I'm not sure which, within
	THE WITNESS: In the AIGENT, the	24	our I don't recall if she was in our
24			11 1 4 4 4 4
25	mumps AIGENT assay, yes.	25	whatever our department was called at the time

53 (Pages 206 - 209)

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Page 212 or if she was -- I know she was supporting our where we had a workbook that were flagged --2 department. Whether she was actually part of for criteria that the workbook was flagging, 3 the department, I don't recall. 3 for example, extravariability is one example, 4 Q. Did she ever support Protocol 4 and then helping to identify sera then for a 5 007? 5 retest. 6 MR. SANGIAMO: Object to the 6 Was that something that you 7 7 asked her to help with? 8 THE WITNESS: She was at Merck 8 A. No. 9 9 and involved in a quality control/quality Was she -- were you providing O. 10 assurance role during Protocol 007 to 10 results of the clinical studies to her in the best of my recollection. Protocol 007? Strike that. 11 11 Were you providing results of 12 BY MR. KELLER: 12 Q. Did you ever interact with her 13 13 experiments to her during the running of 14 regarding quality control and quality Protocol 007? 14 15 assurance regarding the serum that you ran in 15 A. Workbooks from Protocol 007 were 16 Protocol 007? 16 being provided to her during the running of 17 A. I interacted with people in her 17 Protocol 007. group. Whether I interacted with her directly, 18 Q. And do you know why she was 19 19 reviewing them? I don't recall. 20 O. Who did you interact within her 20 A. I have an, I'll say an 21 group? 21 understanding of it. I don't know if it's the 22 22 only reason. A. The person, I think it was Leah 23 23 Gottlieb. O. What's your understanding? 24 Q. What was her position, do you 24 A. Emilio Emini asked how -- I'm 25 recall? 25 sorry. Emilio Emini and Alan Shaw were Page 211 1 looking for someone who could identify sera 1 A. I don't -- to be honest, I don't 2 for -- this is the best of my understanding, recall. 3 3 for retest, and having Leah look through them Q. How did you interact with her, 4 for what purpose? 4 allowed more expedited identification of sera 5 A. Leah, as best I can recall, for retest. helped in the SOP review and approval and also 6 Q. Was that after all the serum was 7 run for Protocol 007 through the experiments? 7 served a function in monitoring and reviewing 8 8 data from the Protocol 007 study. A. It was --9 9 MR. SANGIAMO: Object to the Q. How was she monitoring the data 10 10 and reviewing the data? For what purpose? form. THE WITNESS: It was -- the 11 Strike that. 11 12 For what purpose was Leah 12 reviews were done, as best I can 13 Gottlieb monitoring the serum in Protocol 007? 13 recall, whenever the data were 14 MR. SANGIAMO: Object to the 14 available from a particular experiment 15 15 or set of experiments. So it was not form. BY MR. KELLER: 16 at the end of a study but at the end of 16 17 an experiment. 17 Q. The data from the serum --18 strike that. You're right. 18 BY MR. KELLER: 19 Can I get his answer read --19 O. You also testified that she 20 reviewed the SOP. Correct? 20 sorry. 21 A. I don't believe I used the term 21 What -- how was she monitoring 22 reviewed, but one of her roles was to help in 22 and reviewing data for Protocol 007? 23 A. As best I can recall, she was 23 generating and having SOPs approved. 24 24 How were they -- who approved looking through the results spreadsheets Q. 25 identifying sera that were -- in the case them?

54 (Pages 210 - 213)

1	Page 214	1	Page 216
1	A. I don't recall who all the	1	Q. Did you ever talk to Dr. Ukwu
2	approvers were. I don't recall the procedure	2	about validating Protocol 007?
3	for review and approval at the time.	3	A. I don't recall talking to her
4	Q. Do you know why they were	4	about that.
5	approved, why somebody was approving the SOPs?	5	Q. Do you recall talking to anybody
6	MR. SANGIAMO: Objection.	6	about the criteria for validating the AIGENT
7	Objection to the form. Calls for	7	SOP?
8	speculation.	8	MR. SANGIAMO: Object to the
9	THE WITNESS: I would say that	9	form.
10	any approval of an SOP was done in	10	THE WITNESS: Yes.
11	order to have the SOP available in an	11	BY MR. KELLER:
12	approved form for use.	12	Q. Who did you speak to?
13	BY MR. KELLER:	13	A. I don't recall. It was someone
14	Q. You don't know what the criteria	14	in biometrics. I don't recall. I'm trying to
15	upon which it was reviewed for and approved?	15	remember. I'd be guessing, but it was someone
16	MR. SANGIAMO: Object to the	16	in the biometrics group.
17	form.	17	Q. Do you recall when that happened?
18	THE WITNESS: I don't recall.	18	A. That, I don't recall.
19	I'm not familiar with that.	19	Q. You testified earlier to that
20	BY MR. KELLER:	20	person, you just didn't recall.
21	Q. In Dr. Ukwu's e-mail she writes	21	Did you and just to go back,
22	in the second paragraph, "I would like us to	22	did you design the experiments that were going
23	have a firm plan for our assay development and	23	to be used in the validation protocol?
24	validation prior to their use in any clinical	24	A. I contributed to the design of
25	studies to support registration/claim."	25	the experiments that were going to be used in
	Page 215		Page 217
1	Do you see that?	1	the validation protocol.
2	A. Yes.	2	Q. What did you contribute?
3	Q. And so the assay development,	3	A. I don't recall the specifics.
4	that was something that you did as well for	4	Q. Who else worked on was that
5	Protocol 007, you did assay development, you	5	the manage from biometric research who believed
			the person from biometric research who helped
6		6	-
6 7	developed the AIGENT. Correct?		identify what experiments would be run as part
	developed the AIGENT. Correct? A. I was part of the team that	6	identify what experiments would be run as part of the validation protocol?
7	developed the AIGENT. Correct?	6 7	identify what experiments would be run as part of the validation protocol?
7 8	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay.	6 7 8	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they
7 8 9	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you	6 7 8 9	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or
7 8 9 10	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean?	6 7 8 9 10	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what
7 8 9 10 11	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as	6 7 8 9 10 11	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation
7 8 9 10 11 12	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever	6 7 8 9 10 11 12	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how
7 8 9 10 11 12 13	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be	6 7 8 9 10 11 12 13	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for
7 8 9 10 11 12 13 14	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever studies were appropriate for a validation plan.	6 7 8 9 10 11 12 13 14	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for example.
7 8 9 10 11 12 13 14 15 16	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever studies were appropriate for a validation plan. Q. So is it fair to say that	6 7 8 9 10 11 12 13 14 15	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for
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7 8 9 10 11 12 13 14 15 16 17 18 19 20	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever studies were appropriate for a validation plan. Q. So is it fair to say that Dr. Ukwu is saying that she wanted to have a plan for having the validation completed prior to running of any clinical sera in Protocol 007? Is that a fair statement here?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for example. Q. Did you follow their recommendations? A. As best I can recall, yes. Q. Did you run all the experiments that they recommended?
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever studies were appropriate for a validation plan. Q. So is it fair to say that Dr. Ukwu is saying that she wanted to have a plan for having the validation completed prior to running of any clinical sera in Protocol 007? Is that a fair statement here? MR. SANGIAMO: Objection. THE WITNESS: That's what the	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for example. Q. Did you follow their recommendations? A. As best I can recall, yes. Q. Did you run all the experiments that they recommended? A. I'm not aware of any that were recommended that we didn't run, so yes.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever studies were appropriate for a validation plan. Q. So is it fair to say that Dr. Ukwu is saying that she wanted to have a plan for having the validation completed prior to running of any clinical sera in Protocol 007? Is that a fair statement here? MR. SANGIAMO: Objection. THE WITNESS: That's what the words say in her e-mail, appear to be	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for example. Q. Did you follow their recommendations? A. As best I can recall, yes. Q. Did you run all the experiments that they recommended? A. I'm not aware of any that were recommended that we didn't run, so yes. MR. KELLER: Let me mark this
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	developed the AIGENT. Correct? A. I was part of the team that developed the AIGENT assay. Q. And validation, what do you understand validation to mean? A. My understanding of that as written here is that validation would be designing and performing the whatever studies were appropriate for a validation plan. Q. So is it fair to say that Dr. Ukwu is saying that she wanted to have a plan for having the validation completed prior to running of any clinical sera in Protocol 007? Is that a fair statement here? MR. SANGIAMO: Objection. THE WITNESS: That's what the	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	identify what experiments would be run as part of the validation protocol? A. As best I can recall, they provided, the biometrics representative or representatives provided guidance as to what sorts of experiments. And, again, I don't remember with certainty but my expectation would be they would give an indication of how many samples, how many runs of the assay, for example. Q. Did you follow their recommendations? A. As best I can recall, yes. Q. Did you run all the experiments that they recommended? A. I'm not aware of any that were recommended that we didn't run, so yes.

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	HIGHLY CONFIDENTIAL -		
	Page 218		Page 220
1	(Exhibit Krah-25, Agenda -	1	I don't have a recollection that I did.
2	revision 1, 1614153, was marked for	2	Q. Fair enough. There is a
3	identification.)	3	reference on the agenda to Nick Spring. Do
4		4	you know who Nick Spring is?
5	MR. KELLER: For the record,	5	A. I'm sorry?
6	Exhibit 25 is a single-page document	6	Q. On Exhibit 25.
7	bearing Bates stamp number 1614153,	7	A. I'm sorry, the name Nick Spring?
8	entitled, "AGENDA - Revision 1 Vaccine	8	Q. Nick Spring, do you know who
9	Tactical PAC June 21, 1999."	9	Nick Spring is?
10	BY MR. KELLER:	10	A. That name is not familiar to me.
11	Q. What is a what is the PAC, do	11	Q. You don't recall receiving a
12	you recall?	12	marketing update at this meeting?
13	A. I don't recall.	13	A. I don't recall I don't recall
14	Q. You don't know. Do you recall	14	one.
15	participating in this meeting on June 21,	15	Q. Do you recall receiving a
16	1999, regarding vaccine tactical PAC? You see	16	backgrounder in preparation for this meeting?
17	at 9:30 there's a discussion of the	17	A. I don't recall.
18	competitive update for MMR. Do you see that?	18	Q. Would you be surprised if you
19	A. Yes, I see it.	19	strike that.
20	Q. You're identified as one of the	20	MR. KELLER: Let me mark this
21	invitees. Do you see that?	21	next exhibit as Exhibit 26.
22	A. Yes.	22	
23	Q. Do you recall participating in	23	(Exhibit Krah-26, 6/16/99 E-mail
24	this meeting?	24	with attachments, 285267 - 285296, was
25	A. I don't recall.	25	marked for identification.)
		l	
	Page 219		Page 221
1	Q. If you could find on I've	1	Page 221
1 2	Q. If you could find on I've already marked the location of June 21, 1999,	1 2	MR. KELLER: Steve and Joanie,
	Q. If you could find on I've already marked the location of June 21, 1999, in your journals. Can you tell me if you can	l	MR. KELLER: Steve and Joanie, can you step out for a minute?
2 3 4	Q. If you could find on I've already marked the location of June 21, 1999, in your journals. Can you tell me if you can identify the page that's marked there, the	2 3 4	MR. KELLER: Steve and Joanie, can you step out for a minute? For the record, Exhibit 26 is a
2 3 4 5	Q. If you could find on I've already marked the location of June 21, 1999, in your journals. Can you tell me if you can identify the page that's marked there, the bottom right-hand corner?	2 3	MR. KELLER: Steve and Joanie, can you step out for a minute? For the record, Exhibit 26 is a document that bears Bates stamp number
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56 (Pages 218 - 221)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

1	HIGHLY CONFIDENTIAL -		
1	Page 222		Page 224
	Competitive Defense Task Force, weren't you?	1	you were a member of the TPAC. Correct?
2	A. That I I was invited to this	2	A. I do not recall that.
3	meeting. Whether I was a member of that, I	3	Q. You don't remember you don't
4	don't know.	4	recall if you were a member of the Competitive
5	Q. Your counsel has represented	5	Defense Task Force either, do you?
6	that you were a member during this time frame	1	A. No.
7	Does that refresh your memory that you were a		Q. But you recall being invited to
8	member of this particular committee?	8	meetings where the Competitive Defense Task
9	A. I don't recall.	9	Force gave presentations. Correct?
10	Q. Have you ever heard of the	10	A. At least this one example that
11	Competitive Defense Task Force before seeing	1	you had I was on the invitee list.
12	this document?	12	Q. Let me ask you, sir, why would a
13	MR. SANGIAMO: Object to the	13	research scientist be invited to a meeting to
14	form.	14	discuss competitive defense of the MMR II
15	THE WITNESS: I'm sorry, which	15	vaccine?
16	document?	16	
17	BY MR. KELLER:	17	MR. SANGIAMO: Objection.
			Answer if you know.
18	Q. Let me direct your attention to	18	THE WITNESS: I don't know. BY MR. KELLER:
19	285276, entitled: MMR II Defense Action Plan		
20	TPAC Background document, prepared by The		Q. And so did you learn about
21	Competitive Defense Task Force for MMR II	21	Merck's marketing plans for its MMR II
22	June 1999.	22	products at these meetings?
23	Do you see that?	23	MR. SANGIAMO: Object to the
24	A. Yes.	24	form.
25	Q. Sir, my question for you is, did	25	THE WITNESS: I don't there
	Page 223		Page 225
1	you ever you don't is it your testimony	1	may have been information presented on
2	you don't recall being a member of that	2	that, but I don't recall meaning
3	particular task force?	3	anything to me.
4	A. I remember attending or being	4	BY MR. KELLER:
5	invited to meetings of it, but I don't recall	5	Q. In the third paragraph it says,
6	if I was that I was a member.	6	
U		0	"Initiatives continue in MRL and MMD to
7	Q. Why would a research scientist	7	"Initiatives continue in MRL and MMD to ultimately provide a product line which will
	Q. Why would a research scientist be invited to let me back up a second.	1	
7		7	ultimately provide a product line which will
7 8	be invited to let me back up a second.	7 8	ultimately provide a product line which will be competitive and satisfy all regulatory
7 8 9	be invited to let me back up a second. Strike that. Let me direct your attention to	7 8 9	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated
7 8 9 10	be invited to let me back up a second. Strike that. Let me direct your attention to	7 8 9 10	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated in this background document include:" In
7 8 9 10 11	be invited to let me back up a second. Strike that. Let me direct your attention to the third page of the defense action plan at	7 8 9 10 11	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated in this background document include:" In number 3 is "the defense of Mumps expiry
7 8 9 10 11 12	be invited to let me back up a second. Strike that. Let me direct your attention to the third page of the defense action plan at 285278, under "EXECUTIVE SUMMARY."	7 8 9 10 11 12	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated in this background document include:" In number 3 is "the defense of Mumps expiry titers."
7 8 9 10 11 12 13	be invited to let me back up a second. Strike that. Let me direct your attention to the third page of the defense action plan at 285278, under "EXECUTIVE SUMMARY." A. Okay.	7 8 9 10 11 12 13	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated in this background document include:" In number 3 is "the defense of Mumps expiry titers." Do you see that? A. Yes.
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	be invited to let me back up a second. Strike that. Let me direct your attention to the third page of the defense action plan at 285278, under "EXECUTIVE SUMMARY." A. Okay. Q. The first sentence, it says, "The cross-functional defense of MMR II was created in 1996 when the Competitive Defense Task Force was chartered by TPAC." Do you see that? A. Yes. Q. You don't recall what TPAC stands for, do you? A. Not at this time. At the time I may have known, but I don't recall what it	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated in this background document include:" In number 3 is "the defense of Mumps expiry titers." Do you see that? A. Yes. Q. Do you recall whether or not Protocol 007 was part of this defense of the mumps expiry titers? A. I don't know whatever the date is for this, I don't recall what the status of whether Protocol 007 existed at that time. Q. This is June of 1999. MR. SANGIAMO: Dr. Krah, you
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	be invited to let me back up a second. Strike that. Let me direct your attention to the third page of the defense action plan at 285278, under "EXECUTIVE SUMMARY." A. Okay. Q. The first sentence, it says, "The cross-functional defense of MMR II was created in 1996 when the Competitive Defense Task Force was chartered by TPAC." Do you see that? A. Yes. Q. You don't recall what TPAC stands for, do you? A. Not at this time. At the time I	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	ultimately provide a product line which will be competitive and satisfy all regulatory requirements. Those programs will be updated in this background document include:" In number 3 is "the defense of Mumps expiry titers." Do you see that? A. Yes. Q. Do you recall whether or not Protocol 007 was part of this defense of the mumps expiry titers? A. I don't know whatever the date is for this, I don't recall what the status of whether Protocol 007 existed at that time. Q. This is June of 1999.

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	Page 226		Page 228
1	need to respond to Mr. Keller's	1	paragraph?
2	questions.	2	Q. Yes. Under "EXECUTIVE SUMMARY."
3	BY MR. KELLER:	3	MR. SANGIAMO: Dr. Krah, I would
4	Q. Let me direct your attention to	4	suggest that you read the executive
5	you don't know is what you're saying?	5	summary in its entirety and look over
6	A. I don't recall the dates.	6	the rest of the document and that will
7	MR. SANGIAMO: You don't	7	be sufficient to answer Mr. Keller's
8	recall the dates.	8	question, but we'll see.
9	BY MR. KELLER:	9	THE WITNESS: Okay.
10	Q. Do you recall any discussion,	10	BY MR. KELLER:
11	irrespective of dates, regarding the use of	11	Q. My question is, again, do you
12	Protocol 007 results in defending mumps expiry	12	recall ever learning that Protocol 007 was to
13	titers?	13	be used as part of the defense of the mumps
14	MR. SANGIAMO: Moving away from	14	expiry titers as part of Merck's competitive
15	the document?	15	defense?
16	MR. KELLER: I'm talking	16	MR. SANGIAMO: Object to the
17	generally about the document.	17	form.
18	MR. SANGIAMO: Then, Dr. Krah,	18	THE WITNESS: My understanding
19	take your time to familiarize yourself	19	was that Protocol 007 was being used to
20	with the content	20	support and characterize MMR whether
21	BY MR. KELLER:	21	I'm not I don't recall that it was
22	Q. I'm talking about one paragraph.	22	part of a like a competitive defense
23	You want to read the paragraph. If you want	23	strategy.
24	to go off the record, you can read every	24	BY MR. KELLER:
25	single page of this document.	25	Q. Fair enough. Look on page 285279
1	Page 227 MR. SANGIAMO: No, we're not	1	Page 229 under "Marketing Response to SB Competition."
2	going off the record.	2	Do you see that?
3	Dr. Krah, read the document to	3	A. Okay. Yes.
4	the extent necessary to familiarize	4	Q. "RESPONSE TO COMPETITION." Do
5	yourself with it.	5	you see that at the top of this page?
6	MR. KELLER: Let's go off the	6	A. Yes.
7	record. I think we should call the	7	Q. SB, do you understand that to be
8	magistrate at this point. This is	8	Smith Barney? I'm sorry, Smith Beecham.
9	getting ridiculous.	9	Sorry, strike that.
10	MR. SANGIAMO: You're telling	10	What do you recall SB to stand
11	_	11	for?
12	him he's only allowed to read one paragraph of this document?	12	
13	MR. KELLER: Sure. He can do it	13	A. Two paragraphs down it has SmithKline Beecham as SB. I don't have a
14	off the record. He's going to take	14	recollection of it, but the paragraph just
15			before or just under the graphs defines
1 1)	three hours to read a document by the		Defore Or fust under the graphs defines
	three hours to read a document, by the	15	
16	time	16	that SB as SmithKline Beecham.
16 17	time MR. SANGIAMO: What makes you	16 17	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that
16 17 18	time MR. SANGIAMO: What makes you think it's going to take him three	16 17 18	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product
16 17 18 19	time MR. SANGIAMO: What makes you think it's going to take him three hours to read a document?	16 17 18 19	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product that it was selling outside the United States
16 17 18 19 20	time MR. SANGIAMO: What makes you think it's going to take him three hours to read a document? BY MR. KELLER:	16 17 18 19 20	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product that it was selling outside the United States called Priorix?
16 17 18 19 20 21	time MR. SANGIAMO: What makes you think it's going to take him three hours to read a document? BY MR. KELLER: Q. Go back on the record.	16 17 18 19 20 21	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product that it was selling outside the United States called Priorix? MR. SANGIAMO: Object to the
16 17 18 19 20 21 22	time MR. SANGIAMO: What makes you think it's going to take him three hours to read a document? BY MR. KELLER: Q. Go back on the record. Sir, tell me when you're done	16 17 18 19 20 21 22	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product that it was selling outside the United States called Priorix? MR. SANGIAMO: Object to the form.
16 17 18 19 20 21 22 23	time MR. SANGIAMO: What makes you think it's going to take him three hours to read a document? BY MR. KELLER: Q. Go back on the record. Sir, tell me when you're done familiarizing yourself with the paragraph that	16 17 18 19 20 21 22 23	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product that it was selling outside the United States called Priorix? MR. SANGIAMO: Object to the form. THE WITNESS: I was aware that
16 17 18 19 20 21 22	time MR. SANGIAMO: What makes you think it's going to take him three hours to read a document? BY MR. KELLER: Q. Go back on the record. Sir, tell me when you're done	16 17 18 19 20 21 22	that SB as SmithKline Beecham. Q. Gotcha. Did you understand that SmithKline Beecham had its own MMR product that it was selling outside the United States called Priorix? MR. SANGIAMO: Object to the form.

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Page 232 1 I don't recall having familiarity CBER that -- so I don't -- it's correct I 2 with -- it wasn't being sold in the US. 2 don't know the overall study goals, but I do 3 It was being sold outside the US. 3 know from discussion with CBER that a 95 4 BY MR. KELLER: 4 percent seroconversion was a requirement. 5 Q. Do you recall as part of this 5 Q. And that requirement of 95 presentation in June of 1999 a discussion 6 percent, do you understand that that was what about Priorix and its threat of Priorix coming was represented in the then current label of 8 to the US market? 8 MMR II for mumps? 9 9 MR. SANGIAMO: Object to the I don't recall. 10 10 Just that they wanted 95 percent form. THE WITNESS: In reading through 11 seroconversion in a neutralizing assay. 11 12 the document, at the beginning of the 12 Correct? 13 discussion I recall seeing sections 13 A. Yes. 14 that comment on that aspect of the 14 What were the goals of Protocol 15 GSK -- I'm sorry, the SmithKline 15 007? I mean, sorry. What were the -- strike 16 Beecham vaccine being a competitive that. 16 17 threat to the MMR vaccine. What were the goals of Protocol 17 18 BY MR. KELLER: 18 006? 19 19 Do you recall -- other than A. I have a -- my perspective or my 20 reading this document today, do you recall any 20 understanding of the goals in the same context 21 discussions about it back in 1999? of Protocol 007, there may have been other 21 22 A. At least one aspect to it, yes. 22 study goals than are beyond what I was 23 Q. What is that? 23 thinking, the goals that I was aware of were 24 A. When we did -- conducted the 24 comparing the immunogenicity of the mumps 25 Protocol 006 study which was a head-to-head 25 component of MMR and Priorix against different study of MMR with Priorix, that was, from my 1 wild type mumps strains to see if there's a understanding, a competitive trial to compare 2 difference in the breadth of neutralization 2 immunogenicity of the mumps component of MMR 3 induced by MMR versus Priorix. 3 4 4 with Priorix. Q. What do you mean by 5 5 They may have used a plaque "immunogenicity"? reduction neutralization assay in that study. 6 A. Neutralization results, meaning 6 7 there are two, at least as best I can recall, 7 Correct? 8 two sets -- two forms of data that were 8 A. Yes. 9 provided in Protocol 006. One is a 9 That study, that was Protocol O. 10 10 006. Correct? seroconversion rate. The other is a geometric 11 A. Yes. 11 mean titer. So from a immunogenicity 12 That study didn't use any 12 standpoint I put those both in as 13 anti-IgG steps, did it? 13 immunogenicity measures that were part of 14 14 Protocol 006. A. That's correct. 15 Was Protocol 006 designed to Which assay do you think is a Q. 15 better assay for showing immunogenicity, the 16 determine whether or not kids would be 16 17 protected from mumps? 17 AIGENT or the assay used in Protocol 006? 18 A. Let me tell you, it depends on 18 A. Not -- not to my understanding, 19 the goals of the study. I would say both are 19 but I wasn't -- it's beyond my scope of 20 equally relevant and important. So at 1.1 is 20 responsibility. I had no awareness that it 21 was designed to show protection. 21 better than the other. 22 Q. If you go back to Exhibit 26. 22 Q. When you say the goals of the 23 23 study, you testified that you didn't know what In the second paragraph it says, MMR is 24 currently an exclusive license in the United 24 the goals were for the Protocol 007. Correct? 25 25 A. I knew from discussions with States.

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1	Page 234 Do you see that?	1	Page 236 The objectives of the Marketing element of
2	A. I'm sorry, what page?	2	The objectives of the Marketing element of
3	Q. 285279, the same page we were	3	MMR II Competitive Defenses are to, in 1, "Pursue a proactive tactical plan including
4	on.	4	initiatives to delay and disrupt the launch of
5	A. Okay.	5	Priorix into the market."
6	Q. Do you recall a discussion at	6	Do you see that?
7	this	7	A. Yes.
8	A. Could you repeat that?	8	Q. Do you recall any discussion at
9	Q. Sure. In the first sentence it	9	this meeting regarding that tactical plan to
10	says, MMR II is currently the exclusive	10	prevent Priorix from entering the market?
11	vaccine in the United States	11	A. I do not.
12	Do you see that?	12	Q. Have you ever discussed that
13	A. Yes.	13	with anybody at Merck outside of this
14	Q. Do you recall any discussion	14	presentation?
15	about that statement in June of 1999 at this	15	A. As part of the Protocol 006
16	meeting?	16	study I would say yes, because my understanding
17	A. I don't yeah, I don't recall?	17	of the study was a potential first step in
18	Q. Do you recall whether or not	18	trying to show whether MMR was superior to
19	there are any other mumps, measles and rubella	1	Priorix in protecting from a range of
20	vaccines being sold in the United States as of	20	different viruses.
21	1999?	21	Q. I thought you just testified
22	A. I would say I wasn't aware of	22	that Protocol 006 had nothing to do with
23	any others, but I'm not an expert in the area.	23	determining whether or not it was protective
24	Q. Are you aware of any other MMR	24	against disease. I'm confused.
25	vaccines that are being sold in the US today?	25	MR. SANGIAMO: Hold on a second.
	Page 235		Page 237
1	A. I am not aware of any.	1	What's your question?
2	Q. Are you aware of any MMR	2	BY MR. KELLER:
3	vaccines being sold in the US between 1999 and	3	Q. So my question is, can you
4	today?	4	explain yourself, what you mean?
5	A. I'm not aware of any.	5	MR. SANGIAMO: What he means by
6	Q. Have you ever used the term	6	what, I'm sorry?
7	"exclusive license" in any of your	7	BY MR. KELLER:
8	communications with anybody?	8	Q. The differences between
9	A. Yes.	9	protection in discussion of Protocol 006 and
10	Q. Can you when have you used	10	your discussion testimony earlier that
11	that term?	11	Protocol 006, as you understand it, was not
12	A. Early one example is if	12	linked to protection from disease?
13	we're for example, a scientist outside	13	MR. SANGIAMO: Object to the
14	Merck has a method or reagent that we're	14	form.
15	interested in, we might consider engaging in	15	THE WITNESS: It was not the
16	an exclusive license so Merck would be the	16	study Protocol 006 was not, to my
17	only organization to which they would license	17	understanding, designed to evaluate
18	the product, or the method or reagent.	18	protection. But from a scientific
19	Q. Do you recall ever discussing	19	standpoint, the concept of one vaccine
20	with anybody that Merck's MMR product, that	20	giving higher seroconversion rate and
21	they had that Merck had an exclusive	21	geometric mean titer to a wider range
22	license for MMR II in the US?	22	of viruses would be suggestive or
23	A. I do not recall discussing that	23	indicated in vitro at least one vaccine
24	with anyone.	24	versus the other would be able to
25	Q. In the next paragraph it says,	25	produce a more broadly neutralizing set
		24 25	

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	Page 238		Page 240
1	of antibodies. It's not a direct	1	looking at additional wild type viruses
2	indicator or measure of protection but	2	would be to gather more information
3	suggestive of a broader in vitro	3	about comparisons between the MMR
4	capacity of sera from the one	4	vaccine and Priorix. I wouldn't count
5	generated by one vaccine to induce a	5	this as a con, but the negative aspect,
6	different quality antibody.	6	which is my understanding of why we
7	BY MR. KELLER:	7	didn't proceed, was that there wasn't
8	Q. Do you recall how many different	8	sufficient vials of sera to test
9	wild type viruses you tested?	9	additional viruses. We had a limited
10	MR. SANGIAMO: Object to the	10	volume of sera from the pediatric
11	form.	11	samples. For each virus that you test,
12	THE WITNESS: I don't recall	12	there's more of a serum volume that you
13	specifically. I know at least two. I	13	need to use.
14	don't remember the exact number.	14	BY MR. KELLER:
15	BY MR. KELLER:	15	Q. Didn't you use sera from
16	Q. You say my question is, how	16	Protocol 006 to test, to develop the protocol
17	many you actually tested, not how many you	17	for Protocol 007?
18	reported. Did you only test two wild type	18	A. I don't recall if that we
19	viruses or did you test more than two wild	19	did.
20	type viruses and only report two?	20	Q. You could have, you just don't
21	MR. SANGIAMO: Object to the	21	remember?
22	form.	22	A. I don't remember. If we did, I
23	THE WITNESS: We reported	23	would offer if we did use it, the Protocol 007
24	results for all the viruses that we	24	study required a much smaller volume of sera
25	tested in Protocol 006.	25	than Protocol 006. So I would expect cases
			1
	D 220		D 241
1	Page 239 RY MR KELLER:	1	Page 241 where there's insufficient volume to do more
1 2	BY MR. KELLER:	1 2	where there's insufficient volume to do more
2	BY MR. KELLER: Q. Was there ever discussion about	2	where there's insufficient volume to do more testing in Protocol 006 but would be
2 3	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses?	2 3	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used
2 3 4	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the	2 3 4	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume.
2 3 4 5	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form.	2 3 4 5	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next
2 3 4 5 6	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can	2 3 4 5 6	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume.
2 3 4 5 6 7	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can recall, there was both discussion and	2 3 4 5 6 7	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next exhibit.
2 3 4 5 6 7 8	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can recall, there was both discussion and an initial plan, at least on my part,	2 3 4 5 6 7 8	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next exhibit.
2 3 4 5 6 7 8 9	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can recall, there was both discussion and an initial plan, at least on my part, to look at additional viruses.	2 3 4 5 6 7 8 9	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next exhibit. (Exhibit Krah-27, Handwritten note, 448146, was marked for
2 3 4 5 6 7 8 9	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can recall, there was both discussion and an initial plan, at least on my part, to look at additional viruses. BY MR. KELLER:	2 3 4 5 6 7 8 9 10	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next exhibit. (Exhibit Krah-27, Handwritten note, 448146, was marked for identification.)
2 3 4 5 6 7 8 9 10	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can recall, there was both discussion and an initial plan, at least on my part, to look at additional viruses. BY MR. KELLER: Q. Why didn't you look at	2 3 4 5 6 7 8 9 10	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next exhibit. (Exhibit Krah-27, Handwritten note, 448146, was marked for identification.)
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2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. KELLER: Q. Was there ever discussion about testing more than those two wild type viruses? MR. SANGIAMO: Object to the form. THE WITNESS: As best I can recall, there was both discussion and an initial plan, at least on my part, to look at additional viruses. BY MR. KELLER: Q. Why didn't you look at additional viruses? Who made the decision not to look at additional viruses? MR. SANGIAMO: Object to the	2 3 4 5 6 7 8 9 10 11 12 13 14	where there's insufficient volume to do more testing in Protocol 006 but would be sufficient volume to use in an assay that used less volume. MR. KELLER: Mark this next exhibit. (Exhibit Krah-27, Handwritten note, 448146, was marked for identification.) BY MR. KELLER: Q. Exhibit 27 which is a document that bears Bates number 448 448146, 448146.
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would this be written into a book on a page?		HIGHLY CONFIDENTIAL -		
2 Explain that to me. 3 MR. SANGIAMO: Objection. 4 BY MR. KELLER: 5 Q. Strike that. Let me start over. 6 What was the purpose of having a notebook policy of having a uniquely numbered book and page? 8 A. This was part of our general notebook policy of having a uniquely numbered book and page for documenting the experiments. 11 Q. Here it says, Project Number 12 V205C. That's a reference to MMR II. Correct? 13 A. That is a project code that has 14 been used previously for MMR II. 15 Q. Under "Project Page" it says, 16 "MMR/V 80-99." 16 "MMR/V 80-99." 17 Do you see that? 18 A. Yes. 19 Q. That identifies the experiment. 20 Correct? 21 A. That it's a unique a combination of letters and numbers and year 22 ombination of letters and numbers and year 23 that identify it's a shorthand that was 24 used to identify the experiment. 25 Q. And MMR/V, I've noticed 26 Throughout all the experiments that I've reviewed from the record, they all have MMR/V and not MMR for Protocol 007. Can you explain 4 to me why that is? 2 A. Yes. The basis for this, when 1 started the lab, we had and continued to work 7 on different viruses, so we had different 8 codes for different sets of viruses. For 9 example, hepatitis A might be HAV and then a number, did you unather all of the experiments under through whatever the end number is? 00.7? Did you start from one and went through whatever the end number is? 1 throughout all the experiments that set of page visual and the page visual throughout all the experiments that was 24 used to identify the experiments that was 24 used to identify the experiments that reverse of the system, as best I recall, for all experiments that rebeing done in the lab, they're not unique to one particular like Protocol 006 or any other protocol. 10 Prage 243 11 throughout all the experiments that was 24 used to identify the experiments that reverse of the subject line? 22 A. Yes. Q. And then the last two numbers are just the year that it is running? 23 A. Yes. Q. Here it says, "Investigator," what does t		Page 242		Page 244
BYMR. KELLER: 4 Q. Fair enough. In the first number, did you number all of the experiments of hook and page? 5 A. This was part of our general notebook policy of having a uniquely numbered book and page for documenting the experiments. 10 O77: Did you start from one and went through whatever the end number is? OMR. SANGIAMO: Object to the form. 11 SANGIAMO: Object to the form. 12 System, as best I recall, for all experiments that are being done in the lab, they're not unique to one particular like Protocol 006 or any other protocol. BYMR. KELLER: Q. And then the last two numbers are just the year that it's running? A. That — it's a unique a combination of letters and numbers and year that identify—it's a shorthand that was used to identify the experiment that was 24 used to identify the experiment that was 24 used to identify the experiment that leave the lab, we had and continued to work of offifrent viruses, so we had different codes for different sets of viruses. For example, hepatitis A might be HAV and then a number. Many experiments we were doing included measles, numps, rubella or varicella include something that's varicella. Q. So that's the purpose of the subject line? A. Yes. Q. And then it says, "Subject." Vahat is the purpose of the subject line? A. Yes. Q. Is it just sort of a general statement of what is followed in he details? A. It's more — I would characterize A. It's more — I would c	1	would this be written into a book on a page?	1	products, but it's a way of grouping
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Strike that. Let me start over. What was the purpose of having a book and page? A. This was part of our general notebook policy of having a uniquely numbered book and page for documenting the experiments. Q. Here it says, Project Number Correct? Ounder "Project Page" it says, "MMR/N 80-99." MR. SANGIAMO: Object to the form. THE WITNESS: The numbering system, as best I recall, for all experiments that are being done in the lab, they're not unique to one particular like Protocol 006 or any other protocol. What was the purpose of having a many barbar of our general obook and page for documenting the experiments. Q. Here it says, Project Number Do you see that? A. That it's a unique a combination of letters and numbers and year that identify it's a shorthand that was used to identify the experiment. D. Q. And MMR/V, I've noticed Page 243 throughout all the experiments that I've reviewed from the record, they all have MMR/V and not MMR for Protocol 007. Can you explain to me why that is? A. That is a project code that has to me why that is? A. That is a project code that has been used previously for MMR II. Do you see that? Do you see that? A. That it's a unique a combination of letters and numbers and year that identify it's a shorthand that was used to identify the experiment. D. A. That it's a unique a combination of letters and numbers and year that identify it's a shorthand that was used to identify the experiments. D. A. That it's a unique a combination of letters and numbers and year that identify it's a shorthand that was used to identify the experiments. D. A. That means that that's the person who was involved in running the experiment, writing up the experiment. D. Gorect? A. Yes. Q. And then it says, "Investigator," what does that mean? A. That means that that's the experiment, writing up the experiment. D. Q. So that's the person that actually wrote up this page, was you? A. Yes. Q. And then it says, "Subject." What is the purpose of the subject line	3	MR. SANGIAMO: Objection.	3	viruses.
6 — experiments you did in developing Protocol 7 book and page? 8 A. This was part of our general 9 notebook policy of having a uniquely numbered 10 book and page for documenting the experiments. 11 Q. Here it says, Project Number 12 V205C. That's a reference to MMR II. Correct? 13 A. That is a project code that has a 14 been used previously for MMR II. 15 Q. Under "Project Page" it says. 16 "MMR'N 80-99." 17 Do you see that? 18 A. Yes. 19 Q. That identifies the experiment. 20 Correct? 21 A. That — it's a unique a 22 combination of letters and numbers and year 23 that identify — it's a shorthand that was 24 used to identify the experiments that I've 25 Q. And MMR'N, I've noticed Page 243 1 throughout all the experiments that I've 27 reviewed from the record, they all have MMR'N 3 and not MMR for Protocol 007. Can you explain 4 to me why that is? 5 A. Yes. The basis for this, when I 5 tarted the lab, we had and continued to work 6 on different viruses, so we had different 8 codes for different sets of viruses. For 9 example, hepatitis A might be HAV and then a number. Many experiments were doing 11 included measles, mumps, rubella or varicella 12 so we needed a catchall MMR/V. So it could 13 included measles, mumps, rubella or varicella 15 Q. So that's tube purpose of the subject line? 16 Q. So that's ust a grouping within 17 that sort of — for that product line. 18 A. Yes. 19 Q. The throughout all the experiments were doing 11 included measles, mumps, rubella or varicella 12 so we needed a catchall MMR/V. So it could 13 included something that's rubella, 14 that's mumps, something that's rubella, 15 something that's varicella. 16 Q. So that's just a grouping within 17 that sort of — for that product line. 18 A. Yes. 29 A. Yes. 20 A. Yes. 21 Q. So that's the purpose of the subject line? 20 A. Yes. 21 Q. And then the last two numbers are just the year that it's running? 22 A. Yes. 23 A. Yes. 24 Q. And then the last two numbers are just the year that it's running? 25 A. Yes. 26 Q. And then the last that's the exp	4	BY MR. KELLER:	4	Q. Fair enough. In the first
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10 book and page for documenting the experiments. 10	9		9	MR. SANGIAMO: Object to the
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12	11		11	THE WITNESS: The numbering
A. That is a project code that has been used previously for MMR II. Q. Under "Project Page" it says, 16 "MMR/V 80-99." 17 Do you see that? 18 A. Yes. 19 Q. That identifies the experiment. 20 Correct? 21 A. That — it's a unique a 22 combination of letters and numbers and year 23 that identify — it's a shorthand that was 24 used to identify the experiment. 25 Q. And MMR/V, I've noticed 27 throughout all the experiments that I've 28 reviewed from the record, they all have MMR/V 3 and not MMR for Protocol 007. Can you explain 4 to me why that is? 5 A. Yes. The basis for this, when I 6 started the lab, we had and continued to work 7 on different viruses, so we had different 8 codes for different sets of viruses. For 9 example, hepatitis A might be HAV and then a 10 number. Many experiments we were doing 11 included measles, mumps, rubella or varicella 12 so we needed a catchall MMR/V. So it could 13 include something that's matella, 14 something that's varicella. 15 Correct? Is that fair? 16 Q. So that's that are being done in the lab, they're not unique to one 17 bak, they're not unique to one 18 tab, they're not unique to and other protocol. 18 YMR. KELLER: 20. And then the last two numbers are just the year that it's running? A. Yes. Q. Here it says, "Investigator," what does that mean? A. That means that that's the experiment, experiment, writing up the experiment. 1 Q. So that's the person that actually wrote up this page, was you? 3 A. Yes. Q. And then it says "Subject." What does that mean? A. That is a unique a 22 dused to identify the experiment and then a lab, they're not unique to other protocol. BY MR. KELLER: Q. Here it says, "Investigator," what does that mean? A. The means that that's the experiment set we have are investment of the sub that follow a catually wrote up this page, was you? A. Yes. Q. And then it says, "Subject." What	12	The state of the s	12	
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25 product occause some of the projects weren't 25 habeled by year and then letter, for example,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	reviewed from the record, they all have MMR/V and not MMR for Protocol 007. Can you explain to me why that is? A. Yes. The basis for this, when I started the lab, we had and continued to work on different viruses, so we had different codes for different sets of viruses. For example, hepatitis A might be HAV and then a number. Many experiments we were doing included measles, mumps, rubella or varicella so we needed a catchall MMR/V. So it could include something that's measles, something that's mumps, something that's rubella, something that's varicella. Q. So that's just a grouping within that sort of for that product line. Correct? Is that fair? A. It's more I would characterize it as a grouping, a convenience grouping for in the lab, for example, if we were doing work with rotavirus, we might have a rota 1-1-99 or MMR/V-1-99. So it's a it's a convenient	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. So that's the person that actually wrote up this page, was you? A. Yes. Q. And that's your handwriting? A. Yes. Q. And then it says, "Subject." What is the purpose of the subject line? A. The subject purpose of the subject line is to give a descriptive summary of the experiment that then can be put in an index and someone looking through the index could identify what the what that experiment referred relates to. Q. Is it just sort of a general statement of what is followed in the details? A. Yes, descriptive, the attempt is the goal is to be a descriptive general statement about what follows. Q. Gotcha. And then under "Filed in Book Number/Title," what is the purpose of that field? A. The notebooks, which were paper notebooks, we would put in three-ring binders
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Page 248 1999, if we had four binders, we would have an experiment? 2 A, B, C, D. 2 A. Yes. It says purpose to 3 Q. It just helped you find the 3 "determine the capacity of antihuman IgG 4 actual experiment in the binder? 4 antibody to enhance mumps neutralizing 5 Yes. It tells you what binder 5 activity of a human serum. A low-positive (by 6 it's in. 6 nonenhanced neutralization assay) serum is 7 This particular experiment, you Q. 7 being tested in this pilot experiment." 8 ran this -- it says date February 6, 1999? 8 Q. When you say "pilot experiment," 9 9 A. Yes. what do you mean by pilot? 10 So, if you recall, the Protocol 10 Pilot means it's an initial 007 -- in Protocol 007 I showed you earlier in 11 11 early probe experiment to look for a Exhibit 22, that was done on February 2, 1999 phenomenon to try to answer a general question So this was done a couple of days after that 13 without going into our yet defining multiple 14 protocol was finalized? 14 variables that could be considered. But just 15 MR. SANGIAMO: Exhibit 22. 15 to see like, in this case, if there's a BY MR. KELLER: 16 16 question of does the anti-human IgG antibody 17 Q. Strike that. So the protocol 17 enhance mumps neutralization activity, yes or 18 that is in Exhibit 22 I recall you testified no. And if it's yes, then design additional you don't recall seeing this one. This one 19 experiments to do further development. If no, 20 was dated February 2, 1999. Do you see that 20 consider why it might not have worked if it 21 at the bottom? It's on every page, so you 21 was expected to work or just say it didn't 22 can't miss it. 22 work, end of story. 23 A. Okay. 23 Why were you looking at 24 Q. Do you see that? 24 antihuman IgG at this time frame, do you 25 Α. Yes. 25 recall? Page 247 Page 249 Q. So this experiment that you ran 1 A. At this time I don't -- I can't in Exhibit 27 was done a couple of days after 2 say with certainty why it was being looked at 2 that protocol was drafted. Correct? 3 at that time. 3 4 MR. SANGIAMO: Object to the 4 Q. Were you considering using it as 5 5 form. Calls for speculation. part of Protocol 007 at this time? 6 THE WITNESS: The dates say that 6 A. It was being considered after 7 7 discussion with the FDA or CBER on including the experiment was done a couple of days after that protocol was approved. 8 it in Protocol 007. Whether that at this time 8 9 9 matches that, I don't recall. BY MR. KELLER: 10 10 Q. And so is it fair to say was Why were you focusing here on --11 this experiment, this experiment related to 11 in my review of your files, this is the first 12 Protocol 007 in Exhibit 27? 12 experiment that I could find where you were 13 A. I can't say with certainty. My 13 investigating antihuman IgG. Do you recall 14 expectation is that it would because it 14 doing any experiments prior to this date? 15 included anti-IgG. I don't recall other A. I don't recall. experiments that we were doing at the time. 16 MR. SANGIAMO: Object to the 17 17 Q. Do you recall preparing for a form. 18 meeting with CBER to discuss the methodology 18 BY MR. KELLER: 19 for running the neutralization assay in this 19 Q. Do you recall -- when do you 20 time frame? 20 recall the first time you considered using an 21 antihuman IgG in a plaque reduction 21 A. I don't recall the time -- I 22 neutralization assay? recall preparing for a meeting with CBER, but 23 23 I don't recall the time frame. A. For mumps? 24 24 Q. Could you read your handwriting Q. For any purposes. 25 for the purpose of this particular lab Early to mid-1990s.

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	Page 250		Page 252
1	Q. And you used that in a different	1	A. It's like often referred to as a
2	vaccine?	2	no serum control. One could call it a mock
3	A. Yes.	3	control, but I'd call it a no serum control
4	Q. That was used in varicella.	4	typically.
5	Correct?	5	Q. So you would take the medium
6	A. Yes.	6	antihuman IgG and virus and see what happens?
7	Q. And so in varicella you used	7	MR. SANGIAMO: Object to the
8	anti-IgG with complement. Correct?	8	form.
9	A. Yes.	9	BY MR. KELLER:
10	Q. Why?	10	Q. I'm trying to understand what
11	A. The two in evaluation of the	11	you mean.
12	anti-IgG and complement, it was found that	12	A. So it would be it's a
13	both had enhancing effect to neutralization	13	sequential kind of a small technical
14	but the two together had an the two	14	detail. It's a sequential addition, meaning
15	together had an increased enhancement versus	15	the virus and antibody is incubated first and
16	either alone.	16	then anti-IgG is added later.
17	Q. Did you try that with the mumps	17	The incubation is a sequential
18	virus strike that.	18	incubation of virus plus antibody or in this
19		19	*
	Did you try that with the PRN		case no anti serum or culture medium alone,
20	assay for mumps using both the complement and	20	no sera. And then anti-IgG is added. So the
21	the anti-IgG step?	21	no serum control would be the virus, culture
22	A. We evaluated complement. I	22	medium, which is the diluent, and the assay
23	don't recall that we evaluated complement and	23	and then anti-IgG.
24	anti-IgG together.	24	Q. Did you ever discuss with
25	Q. Why were you focused on low	25	anybody what an appropriate control would be
	Page 251		Page 253
1	Page 251 positives in this experiment?	1	for using the anti-IgG step?
1 2		1 2	-
	positives in this experiment?		for using the anti-IgG step?
2	positives in this experiment? A. I don't recall.	2 3	for using the anti-IgG step? MR. SANGIAMO: Object to the
2 3	positives in this experiment? A. I don't recall. Q. So it appears as a low positive	2 3	for using the anti-IgG step? MR. SANGIAMO: Object to the form.
2 3 4	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard	2 3 4	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others
2 3 4 5	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a	2 3 4 5	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any
2 3 4 5 6 7	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a the assay using the anti-IgG still?	2 3 4 5 6	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others thought might would be appropriate
2 3 4 5 6	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a the assay using the anti-IgG still? A. I can't say for certain what's	2 3 4 5 6 7	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others thought might would be appropriate controls. BY MR. KELLER:
2 3 4 5 6 7 8 9	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a the assay using the anti-IgG still? A. I can't say for certain what's written here. The wording implies that it	2 3 4 5 6 7 8 9	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others thought might would be appropriate controls. BY MR. KELLER: Q. Do you recall ever meeting with
2 3 4 5 6 7 8 9	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a the assay using the anti-IgG still? A. I can't say for certain what's written here. The wording implies that it was there was a result from using the	2 3 4 5 6 7 8 9	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others thought might would be appropriate controls. BY MR. KELLER: Q. Do you recall ever meeting with the FDA and asking them what appropriate
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2 3 4 5 6 7 8 9 10 11 12	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a the assay using the anti-IgG still? A. I can't say for certain what's written here. The wording implies that it was there was a result from using the non-enhanced neutralization assay. Q. When you say "neutralization	2 3 4 5 6 7 8 9 10 11 12	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others thought might would be appropriate controls. BY MR. KELLER: Q. Do you recall ever meeting with the FDA and asking them what appropriate controls would be for plaque reduction neutralization assay?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	positives in this experiment? A. I don't recall. Q. So it appears as a low positive by non-enhanced neutralization assay. Did you test that same sample in a standard neutralization assay and compare it to a the assay using the anti-IgG still? A. I can't say for certain what's written here. The wording implies that it was there was a result from using the non-enhanced neutralization assay. Q. When you say "neutralization assay," what do you mean by that? A. What I mean by that MR. SANGIAMO: Object to the form. You can answer. THE WITNESS: reduction, percent reduction in plaque relative to those serum control. BY MR. KELLER: Q. What's the serum control?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	for using the anti-IgG step? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall any specific discussion over what others thought might would be appropriate controls. BY MR. KELLER: Q. Do you recall ever meeting with the FDA and asking them what appropriate controls would be for plaque reduction neutralization assay? A. I recall meeting with the FDA talking about what controls we had in the plaque reduction neutralization assay. They did not have any other recommendations that I can recall. MR. KELLER: Let me mark this next exhibit as Exhibit 28.
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64 (Pages 250 - 253)

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	Page 254		Page 256
1	Exhibit 28 is a document that bears	1	Do you see that?
2	Bates stamp number 95046 through 53.	2	A. Yes.
3	The first page is an e-mail from	3	Q. Are you familiar with formal FDA
4	Dr. Chirgwin, dated February 24, 1999,	4	minutes and non-formal FDA minutes?
5	subject: MMR II; Summary of FDA	5	A. No.
6	conversation (February 19, 1999).	6	MR. SANGIAMO: Object to the
7	BY MR. KELLER:	7	form.
8	Q. Sir, you are one of the	8	BY MR. KELLER:
9	recipients of this document. Want to take a	9	Q. Did you have an understanding
10	minute and take a look at the document and the	l .	that did you have an understanding of this
11	attachments.	11	rule that required the FDA to generate
12	I want to just start with the	12	meeting formal meetings?
13	first document. We can	13	MR. SANGIAMO: Object to the
14	MR. SANGIAMO: He's not done.	14	form.
15	MR. KELLER: He can read the	15	MR. KELLER: Strike that.
16	other ones when we get to it.	16	BY MR. KELLER:
17	MR. SANGIAMO: No, no, no. No.	17	Q. Did you have an understanding of
18	It's an exhibit, he's reading the	18	the rules that the FDA had to follow for
19	exhibit.	19	producing formal minutes of meetings?
20	MR. KELLER: Sure.	20	A. No.
21	BY MR. KELLER:	21	Q. Let me turn your attention to
22	Q. Let me know when you're done.	22	the actual meeting minutes of the FDA of
23	A. Okay.	23	February 19th. It's on 59 95048. It
24	Q. Do you recall receiving this	24	identifies you, sir, as being one of the
25	e-mail and the attachments?	25	participants. You recall participating in
1			
	Page 255		Page 257
1	A. Parts of it look familiar to me.	1	this meeting. Correct?
2	A. Parts of it look familiar to me.Q. Which parts look familiar?	2	this meeting. Correct? A. I recall a discussion. I
2 3	A. Parts of it look familiar to me.Q. Which parts look familiar?A. The description or summary of	2 3	this meeting. Correct? A. I recall a discussion. I don't the CBER method description looks
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1	Page 258	1	Page 260
1	procedural differences between our assays. I	1	the protocol discussion that was used at the
2	don't recall at that time physically comparing	2	investigator's meeting where they talked about
3	the two assays.	3	using the Tennessee virus. Do you recall
4	Q. Under the "CBER method" it says	4	whether or not Merck first contemplated using
5	in the second bullet, "Uses no complement or	5	the Tennessee strain?
6	immunoglobin."	6	MR. SANGIAMO: You didn't show
7	Do you see that?	7	that in protocol. You showed him a
8	A. Yes.	8	slide that mentioned the Tennessee
9	Q. And immunoglobin would include	9	virus.
10	the anti-IgG step. Correct?	10	BY MR. KELLER:
11	MR. SANGIAMO: Object to the	11	Q. Go ahead.
12	form.	12	MR. SANGIAMO: So what was your
13	THE WITNESS: Anti-IgG would be	13	question?
14	an immunoglobulin.	14	BY MR. KELLER:
15	BY MR. KELLER:	15	Q. You can answer.
16	Q. Do you recall discussing the use	16	MR. SANGIAMO: The question is
17	of the anti-IgG step at this particular	17	do you recall whether or not Merck
18	meeting?	18	first contemplated using the Tennessee
19 20	A. That, I don't recall.	19	strain. So I object if that's the
20	Q. Do you recall CBER saying that	20 21	question, I object to the form. MR. KELLER: Fine.
22	they didn't think that maneuver was necessary?	22	BY MR. KELLER:
23	MR. SANGIAMO: Object to the form.	23	Q. You can answer.
24	THE WITNESS: I do not recall	24	A. I don't recall.
25	them saying that it was not necessary.	25	Q. The second question says, "What
23		23	
1	Page 259	1	Page 261
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	The assay that they were running did	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	is the appropriate control?"
$\frac{2}{3}$	not use it. But they did not say it	$\frac{2}{3}$	Do you see that? A. Yes.
	wasn't necessary for our application. BY MR. KELLER:	4	
5		5	Q. Do you recall what was discussed
	Q. You don't recall them saying that it should not be necessary for running	6	about what appropriate control would be used for a plaque reduction neutralization assay?
6 7	the assay that you guys were going to run for	7	MR. SANGIAMO: At this meeting?
8	Protocol 007?	8	MR. KELLER: At this meeting.
9		9	THE WITNESS: At this meeting I
10	MR. SANGIAMO: Object to the form.	10	
11	THE WITNESS: I don't recall	11	recall there well, that they have written here the immunoglobulin number
12	that they said that.	12	176 as a positive control. I don't see
13	BY MR. KELLER:	13	a comment here about media response
13	Q. Okay. Let's go on. It goes	14	to the media or negative human serum.
15	on there are two important questions, do	15	In our studies we use a media control.
16	you see that, in CBER's meeting minutes?	16	I don't recall that CBER suggested an
17	A. Okay. Yes.	17	alternative of an additional negative
18	Q. And the first one is, "What is	18	control.
19	the wild type strain of virus used?"	19	BY MR. KELLER:
20	Do you see that?	20	Q. So you don't know this reference
21	A. Yes.	21	here, where it says media or negative serum,
22	Q. In this case it is the Tennessee	22	human serum? Do you see that?
			<u> </u>
23	strain Do you see that?	/ ^	
23	strain. Do you see that?	23 24	
23 24 25	strain. Do you see that? A. Yes. Q. We've shown you I showed you	23 24 25	Q. You don't recall what was discussed about that?

66 (Pages 258 - 261)

1	Page 262	,	Page 264
1	A. No.	1	using, proposed using, including the controls,
2	Q. And you never attempted to use a	2	was provided to Merck and CBER for review.
3	negative human serum control. Correct?	3	I'm not aware that there was any so it was
4	MR. SANGIAMO: Object to the	4	provided to others for review and comment, and
5	form.	5	I don't recall any additional controls that
6	THE WITNESS: We did not have	6	they requested.
7	access to a negative serum control, as	7	Q. Did anybody other than yourself
8	best I understand.	8	determine what controls would be proposed to
9	BY MR. KELLER:	9	CBER?
11	Q. When you say that a positive serum control, what is that?	10 11	A. I'm not aware of others. I
12	A. That means a serum that is	12	recall proposing the controls that we planned
13	positive for which a titer could be measured	13	for the assay. I can't exclude that someone else might have proposed another that was not
14	so that one can monitor titer across assays.	14	included.
15	Q. Did you use that as a control?	15	
16	MR. SANGIAMO: Object to the	16	Q. I see. Fit for purpose, do you know where that comes from? Is that an
17	form.	17	industry standard?
18	BY MR. KELLER:	18	MR. SANGIAMO: Objection. You
19	Q. As part of the AIGENT?	19	can answer.
20	A. We did not use immunoglobulin	20	THE WITNESS: So I can't say at
21	number 176 in the AIGENT assay but we had	21	the time whether it was a phrase that
22	additional positive controls that CBER agreed	22	was used often, but in the current
23	to.	23	group that I'm in, when an assay is
24	Q. CBER required?	24	being developed, a characteristic or
25	MR. SANGIAMO: Object to the	25	an objective to the assay is fit for
			-
1	Page 263	1	Page 265
1 2	form.	1 2	purpose meaning that the assay meets
2	form. THE WITNESS: They were part of	2	purpose meaning that the assay meets the expectations as far as
2 3	form. THE WITNESS: They were part of the assay and CBER required limits on	2 3	purpose meaning that the assay meets the expectations as far as reproducibility or other validity
2 3 4	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they	2 3 4	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the
2 3 4 5	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they were part of the assay. CBER required	2 3 4 5	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the application.
2 3 4 5 6	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they were part of the assay. CBER required limits on them.	2 3 4 5 6	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the application. BY MR. KELLER:
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2 3 4 5 6 7	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they were part of the assay. CBER required limits on them. BY MR. KELLER: Q. Do you understand what is meant	2 3 4 5 6 7	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the application. BY MR. KELLER: Q. And so but you didn't know what the objective of Protocol 007 was, you
2 3 4 5 6 7 8	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they were part of the assay. CBER required limits on them. BY MR. KELLER: Q. Do you understand what is meant by appropriate control?	2 3 4 5 6 7 8	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the application. BY MR. KELLER: Q. And so but you didn't know what the objective of Protocol 007 was, you only knew one component of that objective
2 3 4 5 6 7 8 9	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they were part of the assay. CBER required limits on them. BY MR. KELLER: Q. Do you understand what is meant	2 3 4 5 6 7 8 9	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the application. BY MR. KELLER: Q. And so but you didn't know what the objective of Protocol 007 was, you
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	form. THE WITNESS: They were part of the assay and CBER required limits on those. As far as I understand, they were part of the assay. CBER required limits on them. BY MR. KELLER: Q. Do you understand what is meant by appropriate control? MR. SANGIAMO: Objection. Calls for speculation. THE WITNESS: It's a it would be a fit-for-purpose application, meaning that controls would be what controls apply would be dependent on the assay and a precedent. BY MR. KELLER: Q. In this fit-for-purpose application, did anybody evaluate the AIGENT	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	purpose meaning that the assay meets the expectations as far as reproducibility or other validity criteria that are needed for the application. BY MR. KELLER: Q. And so but you didn't know what the objective of Protocol 007 was, you only knew one component of that objective which you say was a comparison of the vary the three different doses. Correct? A. Yes. Q. So the other purposes you didn't know. Correct? The other objectives you didn't know? A. Yes, that's correct. Q. So this surrogate of efficacy, that objective, you weren't aware of that. Correct?
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Page 268 Q. So if you weren't aware of it, 1 Do you recall anybody? 2 you cannot make a determination of the 2 A. I couldn't pull a name out of 3 controls were fit for purpose of your AIGENT 3 the air. 4 you developed if you didn't know all the 4 Let me turn your attention to Q. 5 objectives, could you? 5 the memo dated February 22, 1999, that was 6 A. I wouldn't have all the 6 attached to Dr. Chirgwin's e-mail to you, 7 information, but the information was provided Dr. Krah. Do you recall receiving this memo 8 to others who would have that information, and 8 from Dr. Chirgwin to Dr. Ukwu summarizing the 9 they did not make a contrary recommendation. 9 meeting with the FDA? 10 Q. Who was it provided that would 10 There are lines in it where the 11 make those -- that determination? topic looks familiar, but I can't say the 11 12 CBER amongst the group. 12 document overall is familiar to me. 13 Q. What about internally at Merck? 13 Q. Was it Merck's practice to 14 Internally at Merck, I don't A. 14 create internal memos of meetings with CBER? 15 know who the -- there was a clinical assay 15 MR. SANGIAMO: Answer if you 16 sub-team I recall that was a group to which 16 know obviously. 17 the assay development was -- updates were 17 THE WITNESS: I don't --18 provided to them on the assay development. BY MR. KELLER: 18 19 Is that a management team that 19 Q. Have you -- sorry, I didn't mean 20 reviews assays for fit for purposes? 20 to interrupt you. 21 A. It's a group that develops, the 21 A. There are meetings where there 22 best of my recollection, clinical assays. I 22 are -- there have been, not necessarily mumps 23 don't -- I can't speak to what their overall 23 specific, but there have been internal 24 responsibilities are, but at that group, minutes, but I don't know what the Merck 25 clinical assays in development would be 25 practice was. Page 267 Page 269 discussed and discussions would be held, 1 Q. Well, did you review minutes as 2 include discussions over whether the assay was 2 part of your job duties of meetings that you 3 meeting the requirements. 3 had with CBER? 4 Q. Were you a member of that group? 4 A. I can't say with certainty that 5 5 I remember attending the I did. 6 meetings. Whether I was actually a member of 6 So you don't recall whether or 7 7 it, I can't say. not you ever saw those meeting minutes. Is 8 MR. SANGIAMO: Jeff, I know it's 8 that a fair statement? 9 9 unintentional, but I think you're A. I may have seen them, but I 10 starting in with some of your questions 10 don't recall. They're not looking familiar to 11 before letting Dr. Krah finish his 11 me right now. 12 answer. And you commented at the 12 Q. This executive summary that was 13 beginning about sometimes there would 13 prepared by Dr. Chirgwin and circulated to 14 be a pause before somebody completes. Dr. Ukwu and circulated again by Dr. Chirgwin 14 15 I just ask that you work harder in 15 to this laundry list of individuals at Merck, 16 trying to respect potential -- Dr. it says under the "Executive Summary," number 17 Krah's need to finish his answer. 4 "CBER does not use either complement or IgG 17 18 MR. KELLER: Sure. 18 to enhance sensitivity and feels that these 19 BY MR. KELLER: 19 maneuvers should not be necessary." 20 Q. Who do you recall was a member 20 Do you see that? 21 of the clinical assay sub-teams during the 21 A. Yes. 22 time frame of the development of Protocol 007 22 Q. You don't recall that being 23 and the AIGENT? 23 discussed at that meeting with CBER, or do 24 A. I can't say with certainty. I 24 you? don't recall. 25 A. I recall the anti-IgG and

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1	complementing discussed with CBER. Whether it	1	A. Okay.
2	was at this meeting or not, I can't say.	2	Q. Could you read what you wrote to
3	Q. Was it something that you	3	Mr. Rubinstein, please?
4	proposed to CBER to use in this AIGENT?	4	A. I'm sorry, for the Friday,
5	MR. SANGIAMO: Object to the	5	January 17th?
6	form.	6	Q. Friday, January 17th at 3:25 p.m.
7	THE WITNESS: As best I can	7	A. It says, "Len, Yes - The MMR II
8	recall, the complement, again, whether	8	Protocol 006 study used a straightforward,
9	it's in the context of this meeting or	9	non-enhanced neutralization, using several
10	not, but I as best I recall, we had	10	different indicator viruses. The MMR II
11	evaluated complement and then provided	11	study," which it doesn't say here but
12	those data. Or we evaluated complement	12	implies 007, "used an anti-IgG enhanced
13	and saw that it was not usable, meaning	13	neutralization and the low-passage Jeryl Lynn
14	that neutralized virus on its own in	14	indicator virus. We would have used the same
15	the absence of serum.	15	assay used in 006 and 007," meaning
16	BY MR. KELLER:	16	Protocol 006 and Protocol 007, "except that
17	Q. Just so I'm clear	17	we could not achieve the 90 percent
18	MR. SANGIAMO: Were you done,	18	seroconversion sensitivity with any of the
19	Dr. Krah, with your answer?	19	wild-type mumps strains without enhancing the
20	THE WITNESS: The other half to	20	assay sensitivity. We could measure greater
21	it would be anti-IgG, I remember it	21	than 90 percent seroconversion using the
22	being discussed at a meeting with CBER.	22	vaccine strain as the indicator, but CBER
23	Whether we proposed it or CBER proposed	23	required us to use a 'wild-type' indicator
24	it, I don't know.	24	virus for 007."
25	BY MR. KELLER:	25	Q. Do you recall writing that
	Page 271		Page 273
1	Q. Fair enough.	1	e-mail?
2	MR. SANGIAMO: We're an hour and		A. I can't say I recall. It's my
3	nine minutes out.	3	writing. I can't say it's my writing, but it
4	MR. KELLER: Take a break.	4	sounds like my wording and it's from me so I
5	VIDEOGRAPHER: The time is now	5	assume that it I don't recall writing it.
6	3:17. This concludes disc four.	6	It's from me in language that I would use.
7		7	Q. Do you recall that was the
8	(A recess was taken.)	8	reason why Protocol 006, protocol used for
9		9	Protocol 006 was not used in Protocol 007
10	VIDEOGRAPHER: The time is 3:36.		because you could not achieve the 90 percent
11	This begins disc five.	11	seroconversion sensitivity?
12		12	MR. SANGIAMO: Object to the
13	(Exhibit Krah-29, Series of	13	form. Also, Dr. Krah, if you'd like to
14	e-mails, 51640 - 51642, was marked for	14	review the document in its entirety,
15	identification.)	15	please read this.
16		16	BY MR. KELLER:
17	MR. KELLER: For the record, I'd	17	Q. I'm only asking about this
18	like to mark as Exhibit 29 a document	18	statement.
19	bearing Bates stamp numbers 51640 to	19	MR. SANGIAMO: Well, it's in
20	642, which is a series of e-mails.	20	context.
21	BY MR. KELLER:	21	THE WITNESS: My recollection
22	Q. And, sir, I'd like to direct	22	that the reason for not using one of
23	your attention to the January 17, 2003, e-mail	23	the viruses, one of the wild type
	T IDI' (A C)	0.4	' ' 1 D 1 1006 1
24 25	to Leonard Rubinstein on the first page regarding do you need any help?	24 25	viruses in the Protocol 006 the format for Protocol 006 was that we

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		_	
	Page 274		Page 276
1	could not achieve and, again, 90	1	mumps Nt studies. Do you recall drafting this
2	percent here seroconversion with that	2	e-mail?
3	assay format in any of those indicator	3	A. Again, it's I don't recall
4	viruses.	4	the specific e-mail, but it's from me in
5	BY MR. KELLER:	5	language that I looks familiar to me.
6	Q. That's why you used Protocol 007	6	Q. So is the purpose of this e-mail
7	in order to reach the targeted greater than 95	7	to update Emini and Shaw and Ms. Yagodich
8	percent?	8	about your developmental activities with
9	MR. SANGIAMO: Object to the	9	regard to the Protocol 007, praecipe that was
10	form.	10	going to be used for Protocol 007?
11	THE WITNESS: So the AIGENT	11	MR. SANGIAMO: Object to the
12	assay was developed as part of Protocol	12	form.
13	007 as an assay that was capable of	13	THE WITNESS: I can't tell at
14	measuring a 95 percent seroconversion.	14	least automatically from this that it
15	BY MR. KELLER:	15	was specifically for the purpose of
16	Q. You couldn't do that with	16	Protocol 007.
17	Protocol 006 with a standard PRN assay.	17	BY MR. KELLER:
18	Correct?	18	Q. Do you see on the last on
19	MR. SANGIAMO: Object to the	19	page 2 of your e-mail A. Yes.
20	form.	20	
21	THE WITNESS: Independent of	21	Q it says, We also plan to
22 23	this paragraph, I don't recall what the seroconversion rates were with the	22 23	readdress the use of anti-human IgG to enhance
23		24	Nt, as a back-up if we fall short of our 90 plus percent target.
25	different indicator viruses. The way this is worded suggests that the	25	Do you see that?
23	this is worded suggests that the	23	Do you see that?
	Page 275	1	P 255
- 1			Page 277
1	indicator viruses in the Protocol 006,	1	A. Yes.
2	indicator viruses in the Protocol 006, the format of the neutralization assay	2	A. Yes.Q. Does that lead you to believe
2 3	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving	2 3	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol
2 3 4	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate.	2 3 4	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007?
2 3 4 5	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER:	2 3 4 5	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make
2 3 4 5 6	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change	2 3 4 5 6	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail
2 3 4 5 6 7	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became	2 3 4 5 6 7	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions.
2 3 4 5 6 7 8	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became Protocol 007 and the AIGENT. Correct?	2 3 4 5 6 7 8	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions. BY MR. KELLER:
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2 3 4 5 6 7 8 9 10 11	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became Protocol 007 and the AIGENT. Correct? A. So I would describe it as the AIGENT assay. I wouldn't necessarily link them and say it's Protocol 007 and the AIGENT	2 3 4 5 6 7 8 9 10	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions. BY MR. KELLER: Q. Do you see it specifically calls out the 007 study? A. Some of the variables that we
2 3 4 5 6 7 8 9 10 11 12	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became Protocol 007 and the AIGENT. Correct? A. So I would describe it as the AIGENT assay. I wouldn't necessarily link them and say it's Protocol 007 and the AIGENT assay. But it's the AIGENT assay.	2 3 4 5 6 7 8 9 10 11 12	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions. BY MR. KELLER: Q. Do you see it specifically calls out the 007 study? A. Some of the variables that we were looking at are ones that are familiar to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became Protocol 007 and the AIGENT. Correct? A. So I would describe it as the AIGENT assay. I wouldn't necessarily link them and say it's Protocol 007 and the AIGENT assay. But it's the AIGENT assay. MR. KELLER: Let me mark this next exhibit as Exhibit 30. (Exhibit Krah-30, 3/30/00 E-mail, 336323 - 336325, was marked for identification.) BY MR. KELLER: Q. For the record, Exhibit 30 is a document bear Bates stamp number 336323	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions. BY MR. KELLER: Q. Do you see it specifically calls out the 007 study? A. Some of the variables that we were looking at are ones that are familiar to me from discussions with CBER as part of the discussions about Protocol 007. But I don't see here that it specifically identifies it as part of the Protocol 007 assay development. Q. The part you're referring to is the use of immunostaining? A. I think the well, immunostaining was part of it. The Spearman-Karber method. The part that I was regarding as the Barnes strain on page 2, the reference to the Barnes
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became Protocol 007 and the AIGENT. Correct? A. So I would describe it as the AIGENT assay. I wouldn't necessarily link them and say it's Protocol 007 and the AIGENT assay. But it's the AIGENT assay. MR. KELLER: Let me mark this next exhibit as Exhibit 30. (Exhibit Krah-30, 3/30/00 E-mail, 336323 - 336325, was marked for identification.) BY MR. KELLER: Q. For the record, Exhibit 30 is a document bear Bates stamp number 336323 through 325, and it's an e-mail from you,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions. BY MR. KELLER: Q. Do you see it specifically calls out the 007 study? A. Some of the variables that we were looking at are ones that are familiar to me from discussions with CBER as part of the discussions about Protocol 007. But I don't see here that it specifically identifies it as part of the Protocol 007 assay development. Q. The part you're referring to is the use of immunostaining? A. I think the well, immunostaining was part of it. The Spearman-Karber method. The part that I was regarding as the Barnes strain on page 2, the reference to the Barnes strain from Dr. Forghani. As best I recall,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	indicator viruses in the Protocol 006, the format of the neutralization assay used for Protocol 006 was not achieving that 90 percent seroconversion rate. BY MR. KELLER: Q. So a decision was made to change that assay with what ultimately became Protocol 007 and the AIGENT. Correct? A. So I would describe it as the AIGENT assay. I wouldn't necessarily link them and say it's Protocol 007 and the AIGENT assay. But it's the AIGENT assay. MR. KELLER: Let me mark this next exhibit as Exhibit 30. (Exhibit Krah-30, 3/30/00 E-mail, 336323 - 336325, was marked for identification.) BY MR. KELLER: Q. For the record, Exhibit 30 is a document bear Bates stamp number 336323	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Does that lead you to believe that this was, in fact, related to Protocol 007? MR. SANGIAMO: Dr. Krah, make sure you've aptly read the e-mail before you respond to questions. BY MR. KELLER: Q. Do you see it specifically calls out the 007 study? A. Some of the variables that we were looking at are ones that are familiar to me from discussions with CBER as part of the discussions about Protocol 007. But I don't see here that it specifically identifies it as part of the Protocol 007 assay development. Q. The part you're referring to is the use of immunostaining? A. I think the well, immunostaining was part of it. The Spearman-Karber method. The part that I was regarding as the Barnes strain on page 2, the reference to the Barnes

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	Page 278		Page 280
1	that strain.	1	being more consistent with what CBER
2	Q. For Protocol 007. Correct?	2	had experienced within their testing.
3	A. Yes.	3	BY MR. KELLER:
4	Q. And the low passage Jeryl Lynn,	4	Q. And so you saw a memo from CBER
5	JL135, that was what was used in Protocol 007,	5	saying that they didn't think that step was
6	wasn't it?	6	necessary. So was that one of the reasons why
7	A. Yes.	7	you considered it as only a backup plan if you
8	Q. So the antihuman IgG was also	8	couldn't get any other methods to get you to
9	used in Protocol 007. Correct?	9	reach the 95 percent seroconversion target?
10	A. Yes.	10	A. I can't say with certainty what
11	Q. So I'm confused by your answer	11	the thought process was at the time, but
12	why you don't think this was a discussion	12	looking back on it, if they thought it wasn't
13	about updating about your efforts to develop	13	necessary, I would if I were doing this
14	an assay for Protocol 007. Many of the things	14	today, would try it without and then if it
15	discussed were discussed about updating Emini	15	wasn't successful, then go with the anti-IgG.
16	and Shaw and Yagodich about your efforts to	16	Q. Do you recall any discussions at
17	come up with a methodology to find an answer	17	Merck about concerns with the use of this IgG
18	that would get you to 95 percent seroconversion.	18	maneuver?
19	Correct?	19	MR. SANGIAMO: Object to the
20	A. Yes.	20	form.
21	MR. SANGIAMO: Object to the	21	THE WITNESS: Not that I recall.
22	form. Misstates his testimony.	22	BY MR. KELLER:
23	BY MR. KELLER:	23	Q. Nobody voiced any criticism
24	Q. Here when you say we also plan	24	about using the IgG maneuver
25	to readdress the use antihuman IgG to enhance	25	MR. SANGIAMO: Object to the
23	to readdress the use antinuman 1gG to enhance	25	WIR. 57 II VOIT IVIO. Object to the
1	Page 279	1	Page 281
1	Nt. Nt, that's neutralizing. Right?	1	form.
2	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes.	2	form. BY MR. KELLER:
2 3	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes. Q. Neutralization. As a backup	2 3	form. BY MR. KELLER: Q in this assay in Protocol
2 3 4	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes. Q. Neutralization. As a backup plan if we fall short of the 90 percent plus	2 3 4	form. BY MR. KELLER: Q in this assay in Protocol 007?
2 3 4 5	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes. Q. Neutralization. As a backup plan if we fall short of the 90 percent plus target.	2 3 4 5	form. BY MR. KELLER: Q in this assay in Protocol 007? MR. SANGIAMO: Object to the
2 3 4 5 6	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes. Q. Neutralization. As a backup plan if we fall short of the 90 percent plus target. Why was it a backup plan?	2 3 4 5 6	form. BY MR. KELLER: Q in this assay in Protocol 007? MR. SANGIAMO: Object to the form.
2 3 4 5 6 7	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes. Q. Neutralization. As a backup plan if we fall short of the 90 percent plus target. Why was it a backup plan? A. I can't say with certainty, but	2 3 4 5 6 7	form. BY MR. KELLER: Q in this assay in Protocol 007? MR. SANGIAMO: Object to the form. THE WITNESS: No. And, in fact,
2 3 4 5 6 7 8	Nt. Nt, that's neutralizing. Right? A. Neutralization, yes. Q. Neutralization. As a backup plan if we fall short of the 90 percent plus target. Why was it a backup plan? A. I can't say with certainty, but my best recollection is that we were	2 3 4 5 6 7 8	form. BY MR. KELLER: Q in this assay in Protocol 007? MR. SANGIAMO: Object to the form. THE WITNESS: No. And, in fact, the assay was based on a publication
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	HIGHLY CONFIDENTIAL -		
	Page 282		Page 284
1	had with others I don't recall using it	1	Q. Do you recall presenting the use
2	personally, but discussions with other	2	of the anti-IgG at a CAS subcommittee meeting
3	colleagues that I've had of potentially using	3	or a Clinical Assay Subcommittee Meeting?
4	it.	4	A. I recall presenting the data. I
5	Q. What colleagues did you discuss	5	don't recall the specific meeting.
6	it with?	6	MR. KELLER: For the record,
7	A. I recall some colleagues in MMD	7	Exhibit 31 is an agenda, looks like
8	who were trying to identify means, as best I	8	there's a typo on the title of this, it
9	can recall, means to increase the	9	says, "CRITICAL ASSAY SUBCOMMITTEE
10	neutralization capacity of a serum in a	10	MEETING."
11	tissue I think what was called a tissue	11	BY MR. KELLER:
12	culture safety test. And one option that I	12	Q. You understand it to be
13	proposed was adding anti-IgG.	13	clinical, correct, October 24, 2000?
14	Q. Was that a was that test at	14	MR. SANGIAMO: Objection.
15	all linked to protection?	15	THE WITNESS: I can't I don't
16	A. No.	16	know.
17	Q. Do you recall ever at any of	17	BY MR. KELLER:
18	these CAS meetings you had, nobody voiced any	18	Q. Under "TEAM PRESENTATION," it
19	concern about nonspecific neutralization as a	19	says identifies you, Dr. Krah to present on
20	result of using rabbit anti-IgG step?	20	the enhanced mumps neutralization assay. Do
21	MR. SANGIAMO: Object to the	21	you see that?
22	form.	22	A. Yes.
23	THE WITNESS: I don't recall any	23	Q. That's the AIGENT. Correct?
24	objections.	24	A. That's my enhanced mumps
25	BY MR. KELLER:	25	mumps neutralization assay is what I refer to
	Page 283		•
1		1	Page 285
1 2	Q. Did Dr. Sadoff ever object?	1	as the AIGENT assay, and I would expect that
2	Q. Did Dr. Sadoff ever object?A. I don't recall.	2	as the AIGENT assay, and I would expect that that's what they're referring to here.
2 3	Q. Did Dr. Sadoff ever object?A. I don't recall.Q. Do you ever recall discussing	2 3	as the AIGENT assay, and I would expect that that's what they're referring to here. Q. Here it says, "Update on
2 3 4	 Q. Did Dr. Sadoff ever object? A. I don't recall. Q. Do you ever recall discussing the use of the anti-IgG maneuver with 	2 3 4	as the AIGENT assay, and I would expect that that's what they're referring to here. Q. Here it says, "Update on performance of the assay."
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4	Page 286		Page 288
1	Q. Did he also run clinical	1	wording. I can't exclude that someone didn't
2	study strike that.	2	contribute to it, but at least the majority of
3	Did he also run any experiments	3	the wording looks like it's my wording.
4	with the PRN assay	4	Q. In the experiments that
5	MR. SANGIAMO: Object to the	5	supported this particular document did you
6	form.	6	provide this copy to the CAS subcommittee or
7	BY MR. KELLER:	7	was it just a presentation strike that.
8	Q in developing Protocol 007,	8	Did you provide a copy of
9	do you know?	9	Exhibit 32 to the CAS subcommittee?
10	MR. SANGIAMO: Object to the	10	A. I don't recall.
11	form.	11	Q. And the individuals on
12	THE WITNESS: I am aware of, as	12	Exhibit 31, D. Arena, Dr. Chirgwin, William
13	best I can recall, a CPE-based assay	13	Long, S. Olsen, N. Morsy, J. Staub, Dr. Thaler
14	that he was working on, not a plaque	14	and Ms. Yagodich, were those members of the
15	reduction, to my knowledge.	15	CAS?
16		16	A. I can't say for certain.
17	(Exhibit Krah-32, Anti-IgG	17	Q. And if you look on the first
18	Enhanced Mumps Neutralizing	18	page of 269123 of Exhibit 32, can you read the
19	Assay-Update: October 24, 2000, 26912	19	objective that you wrote?
20	- 26918, was marked for identification.)	20	MR. SANGIAMO: Object to the
21		21	form.
22	MR. KELLER: For the record,	22	THE WITNESS: The objective, as
23	Exhibit 32 is a document that bears	23	listed, is "Identify a mumps
24	Bates stamp numbers 26912 through 918,	24	neutralization assay format using a
25	entitled: Anti-IgG Enhanced Mumps	25	'wild-type' mumps strain that permits
	Page 287		Page 289
1	Neutralizing Assay-Update: October 24.	1	measurement of a 95 percent
2	BY MR. KELLER:	2	seroconversion rate in MMR II
3	Q. Do you see that?	3	vaccinees."
4	A. I'm sorry, repeat the last part	4	BY MR. KELLER:
5	of that?	5	Q. Is that the objective you used to develop the AIGENT?
6	Q. I'm just reading the title. Do	6	to develop the AIGHNI'
7		_	-
	you see the title?	7	MR. SANGIAMO: Object to the
8	A. Anti-IgG enhanced, okay, yes.	8	MR. SANGIAMO: Object to the form.
9	A. Anti-IgG enhanced, okay, yes.Q. So is this the presentation that	8 9	MR. SANGIAMO: Object to the form. THE WITNESS: The AIGENT
9 10	A. Anti-IgG enhanced, okay, yes. Q. So is this the presentation that you gave to the CAS subcommittee on October 24?	8 9 10	MR. SANGIAMO: Object to the form. THE WITNESS: The AIGENT assay development of the AIGENT
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

1 A. I do not. 2 MR. SANGIAMO: Object to the form. 3 Frage 290 4 R. KELLER: 5 Q. Any reason you didn't if that's what it says? 6 what it says? 7 MR. SANGIAMO: Object to the form. 8 Form. 10 says, I have no contrary evidence that 1 I didn't. 11 I didn't. 12 BY MR. KELLER: 13 Q. Just so I understand, it says, 1 Evaluation of seroconversion rates achievable in the Anti-IgG Enhanced Nt - results from subset of Protocol 006 and another set of 60 paired PRN assay. 18 Do you see that? 19 A. Yes. 20 Q. So did you use the samples from 1 Protocol 006 to develop Protocol 007? 21 MR. SANGIAMO: Object to the form. 22 MR. SANGIAMO: Object to the form. 23 THE WITNESS: The wording of 25 this suggests that those were a subset 1 Os os explain to me serum set number one. It says, "Subset of sera from 7 Protocol 006 (includes set of 12 sera biased toward non-responders to Jeryl Lynn by "standard" Ni." 3 that fair to say? 10 A. No. I'm sorry, you're referring to the seroconversion rates for this set, "it says 10 Jeryl Lynn "standard" Ni: 31 out of 39, 179, 5 percent. I.125 at 1 to 4 anti-IgG neutralizing 32 to 34, 94 percent. 12 Do you see that? 13 A. Yes. 14 Do you see that? 15 A. Yes. 16 MR. SANGIAMO: Object to the form. 17 Protocol 006 to develop Protocol 007? 22 MR. SANGIAMO: Object to the form. 24 THE WITNESS: The wording of 25 this suggests that those were a subset 1 Os os explain to me serum set number one. It says, "Subset of sera from 7 Protocol 006 (includes set of 12 sera biased toward non-responders to Jeryl Lynn by "standard" Ni: 31 out of 39, 179, 5 percent. I.125 at 1 to 4 anti-IgG neutralizing 32 to 34, 94 percent. 15 Do you see that? 16 A. No. I'm sorry, ou're referring to the seroconversion rates for this set, "it says anti-IgG neutralizing 32 to 34, 94 percent. 12 Do you see that? 13 Do you see that? 14 A. Yes. 15 Q. So day ou use the sample from what? 16 MR. SANGIAMO: Object to the form. 17 THE WITNESS: The wording of this suggested that protocol 006 (includes set of 12 sera biased toward non-responders to Jer		IIIOIEI CON IDENTIAE -		
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24 were tested. 24 A. Yes.				
OF DVMD VELLED.		wara tastad	17/1	A Yes
25 BY MR. KELLER: 25 Q. That's what your experiments				

74 (Pages 290 - 293)

	HIGHLI CONFIDENTIAL -		
	Page 294		Page 296
1	showed, correct, with the use of anti-IgG	1	desirable number was set, I don't recall.
2	maneuver?	2	Q. I see. The third bullet point
3	MR. SANGIAMO: Object to the	3	you say, Continue evaluation of results using
4	form.	4	optimized anti-IgG (target less than equal 10
5	THE WITNESS: For serum set one,	5	percent pre-positive rate and greater than/
6	no. Serum set two on the page just	6	equal to 95 percent seroconversion).
7	before has a 96 percent seroconversion	7	Do you see that?
8	rate including anti-IgG. So there was	8	A. Yes.
9	a condition for one of the two one	9	Q. Where did you come up with that
10	of the serum panels that one is	10	10 percent pre-positive rate?
11	achieving a 95 percent seroconversion.	11	MR. SANGIAMO: Object to the
12	BY MR. KELLER:	12	form.
13	Q. So the standard panel only got	13	THE WITNESS: I don't recall
14	you 79.5 percent. But with using different	14	where that came from.
15	dilutions of anti-IgG, you can get that up to	15	BY MR. KELLER:
16		16	
17	96 percent. Correct?		- · ·
	MR. SANGIAMO: Object to the	17 18	developing the assay to try to reach that
18	form.	1	target. Correct?
19	THE WITNESS: At least in serum	19	MR. SANGIAMO: Object to the
20	set one we had approximately an	20	form.
21	80 percent seroconversion rate without	21	THE WITNESS: My recollection is
22	the anti-IgG. What I can't tell from	22	that we were still developing the assay
23	the wording here is if that is	23	to see if we could achieve 95 percent
24	refers to JL135 for the anti-IgG part.	24	seroconversion.
25	So what I'm not able to say with	25	BY MR. KELLER:
	Page 295		Page 297
1	certainty is the contribution of the	1	Q. Was one of the collateral
1 2	certainty is the contribution of the wild of the low passage Jeryl Lynn	2	Q. Was one of the collateral problems of using the anti-IgG step is a
	certainty is the contribution of the		Q. Was one of the collateral problems of using the anti-IgG step is a higher pre-positive rate than you would expect
2	certainty is the contribution of the wild of the low passage Jeryl Lynn	2	Q. Was one of the collateral problems of using the anti-IgG step is a
2 3	certainty is the contribution of the wild of the low passage Jeryl Lynn and the anti-IgG. By using the	2 3	Q. Was one of the collateral problems of using the anti-IgG step is a higher pre-positive rate than you would expect
2 3 4	certainty is the contribution of the wild of the low passage Jeryl Lynn and the anti-IgG. By using the combination of low passage Jeryl Lynn and anti-IgG, we were able to get 96 percent seroconversion.	2 3 4	Q. Was one of the collateral problems of using the anti-IgG step is a higher pre-positive rate than you would expect in the real world?
2 3 4 5	certainty is the contribution of the wild of the low passage Jeryl Lynn and the anti-IgG. By using the combination of low passage Jeryl Lynn and anti-IgG, we were able to get	2 3 4 5	Q. Was one of the collateral problems of using the anti-IgG step is a higher pre-positive rate than you would expect in the real world? A. What we did observe is an
2 3 4 5 6	certainty is the contribution of the wild of the low passage Jeryl Lynn and the anti-IgG. By using the combination of low passage Jeryl Lynn and anti-IgG, we were able to get 96 percent seroconversion.	2 3 4 5 6	Q. Was one of the collateral problems of using the anti-IgG step is a higher pre-positive rate than you would expect in the real world? A. What we did observe is an increase page 26916 is an example of that,
2 3 4 5 6 7	certainty is the contribution of the wild of the low passage Jeryl Lynn and the anti-IgG. By using the combination of low passage Jeryl Lynn and anti-IgG, we were able to get 96 percent seroconversion. BY MR. KELLER:	2 3 4 5 6 7	Q. Was one of the collateral problems of using the anti-IgG step is a higher pre-positive rate than you would expect in the real world? A. What we did observe is an increase page 26916 is an example of that, using different levels of anti-IgG can give
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	Page 298	1	Page 300
1	THE WITNESS: I don't recall	1	positive, it would be the post it
2	what the pre-positive rate was for the	2	depends on the post-vaccination serum
3	Protocol 007 set.	3	result, meaning that if a
4	BY MR. KELLER:	4	pre-vaccination serum was positive
5	Q. Were you focused on	5	single dilution, and then
6	pre-positives when you were running the serums	6	post-vaccination serum had an invalid
7	for Protocol 007?	7	result, that pre-vaccination serum will
8	MR. SANGIAMO: Object to the	8	be tested not because it's a
9	form. THE WITNESS: We were not	9 10	pre-vaccination positive. BY MR. KELLER:
10 11		11	
12	focused on the pre-positive. BY MR. KELLER:	12	Q. So you didn't retest valid assays in Protocol 007 that had a valid
13	Q. You didn't care whether or not	13	that had a pre-positive at one dilution to see
14	it was pre-positive or not, is that your	14	whether or not you could it would switch to
15	testimony?	15	a pre-negative?
16		16	MR. SANGIAMO: Object to the
17	MR. SANGIAMO: Object to the form.	17	form.
18	THE WITNESS: My testimony is	18	THE WITNESS: There were cases I
19	that we if we did have a	19	recall where we did have some samples
20	pre-positive, that we were interested	20	that included examples such as a
21	to make sure that it was an accurate	21	positive single pre-vaccination
22	representation of a plaque number.	22	serum that was positive single dilution
23	BY MR. KELLER:	23	that were retested with the intent of
24	Q. How did you do that?	24	trying to verify whether the result was
25	A. One way in which it was checked	25	confirmed.
	Page 299		D 201
1	would be to look at the plaque counts that	1	Page 301 BY MR. KELLER:
2	were recorded for, in some cases, pre-positives	2	Q. So when you were running the
3	but in other cases, specific situations, for	3	protocol samples, you could tell what is a
4	example, single pre not pre-positive, but	4	pre-vaccination sample and a post-vaccination
5	single positive dilution and a number of other	5	sample. Right?
6	I'll say unexpected neutralization results and	6	A. Yes.
7	have either the original counter or other	7	Q. Let me move on to the document
8	counter look at the plaques and see if plaques	8	26917. Here it says, "Proposal for Testing a
9	were being miscounted.	9	Subset of Samples from the End-Expiry Study.
10	Q. Did you do that for the	10	Do you see that?
11	post-vaccination positives?	11	A. Yes.
12	A. Yes.	12	Q. At a certain point there was a
13	Q. For both?	13	decision made that a subset analysis would be
14	A. For the single positive	14	run. Correct?
15	dilution, yes.	15	A. Using the AIGENT assay, yes.
16	Q. So you didn't see from your	16	Q. Do you recall what precipitated
17	development of Protocol 007 that if you	17	that decision?
18	retested I'm sorry.	18	A. I do not require I do not
19	Did you ever retest	19	recall the specific event that triggered it.
20	pre-positives out of a single dilution?	20	Q. Do you recall general discussion
21	MR. SANGIAMO: Object to the	21	with Emilio Emini where they discussed an
22	form.	22	emergency that was going on?
23	THE WITNESS: As best I can	23	A. Yes.
	recall, if a pre-positive positive	24	Q. What was that emergency?
24			= -
24 25	single dilution was confirmed to be	25	A. I don't recall him telling me.

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Page 302			_	
2 was a 483 that was issued out of MMD based on an FDA inspection with stability problems in the MMR product? 5 A. I recall that a warning letter 6 was issued. What that contained or involved, 7 I don't have a recollection. 8 Q. Do you recall a 483 that came 9 before the warning letter? 10 A. I do not. 11 Q. Back to 26917, the second bullet 11 opint says, "Validation runs concurrent with 12 clinical serum testing." 13 A. Yes. 14 Do you see that? 15 A. Yes. 16 Q. Henrietta Ukwu had sent an 16 e-mail earlier saying that do not run - do 18 not run the validation concurrent with testing 19 the serum but finish the validation and then 10 test the serum. Do you recall that e-mail? 21 MR. SANGIAMO: Object to the 22 characterization of the e-mail. 22 THE WITNESS: I recall the 23 THE WITNESS: I recall the 24 e-mail that you showed me previously 25 suggesting that the validation be done 26 Way. 27 Page 303 28 WYR. KELLER: 29 Q. Did they tell you why? 20 understand that what they're saying is 20 understand that what they're saying is 3 concurrent with clinical serum testing. You 20 understand that what they're saying is 3 concurrent with clinical serum testing. You 3 understand that what they're saying is 4 concurrent with clinical serum testing. You 3 understand that what they're saying is 4 concurrent with clinical serum testing. You 3 understand that what they're saying is 4 concurrent with clinical serum testing. You 4 understand that what they're saying is 5 validation would be characterizing the 6 validation would be characterizing the 7 that you're running the clinical samples? 8 A. Yes. And that was done in 9 collaboration with CBER. They were informed 9 collaboration with CBER. They were informed 10 that that was being done and approved that 11 approach. 12 Q. When did they approve that 13 approach? Were you at a meeting when that was 14 approach. 15 MR. SANGIAMO: Object to the 16 form. 17 THE WITNESS: I don't recall if 18 I was at a - with certainty that I was 19 at that meeting. 20 By MR. KELLER: 21 Q. Were		E		
an FDA inspection with stability problems in 4 the MMR product? 5 A. I recall that a warning letter 6 was issued. What that contained or involved, 1 Idon't have a recollection. 8 Q. Do you recall a 483 that came 9 before the warning letter? 9 MR. SANGIAMO: Whoa, whoa. 10 A. I do not. 10 Q. Back to 26917, the second bullet 11 point says, "Validation runs concurrent with 12 clinical serum testing." 14 Do you see that? 15 A. Yes. 16 Q. Henrietta Ukwu had sent an 17 e-mail earlier saying that do not run - do 18 not run the validation concurrent with testing 19 the serum but finish the validation and then 19 test the serum. Do you recall that e-mail? 10 test the serum. Do you recall that e-mail? 11 e-mail earlier saying that do not run - do 18 not run the validation concurrent with testing 19 the serum but finish the validation and then 19 test the serum. Do you recall that e-mail? 20 MR. SANGIAMO: Object to the 21 characterization of the e-mail. 22 mr. HE WITNESS: I recall the 23 mr. Fall war was done in 24 concurrent with Clinical serum testing. You 25 suggesting that the validation be done 26 validate the AIGENT assay at the same time 27 that you're running the clinical samples? 28 A. Yes. And that was done in 29 collaboration with CBER. They were informed 20 that that was being done and approved that 21 approach. Were you at a meeting when that was 22 approach? Were you at a meeting when that was 23 approach? Were you at a meeting when that was 24 approach? Were you at a meeting when that was 25 approach? Were you at a meeting when that was 26 at that meeting. 27 MR. SANGIAMO: Object to the 28 MR. SANGIAMO: Object to the 39 of the warning letter? 30 MR. SANGIAMO: Object to the 30 MR. SANGIAMO: Object to the 40 MR. SANGIAMO: Object to the 51 MR. SANGIAMO: Object to the 64 MR. SANGIAMO: Object to the 65 MR. SANGIAMO: Object to the 66 MR. SANGIAMO: Object to the 77 MR. SANGIAMO: Object to the 78 MR. SANGIAMO: Object to the 79 MR. SANGIAMO: Object to the 80 MR. SANGIAMO: Object to the 90 MR. SANGIAMO:	1	Q. He didn't tell you that there	1	experiments for the AIGENT SOP at the same
the MMR product? A. I recall that a warning letter was issued. What that contained or involved, 1 I don't have a recollection. Do you recall a 483 that came before the warning letter? A. I don tot. A. I do not. Before the warning letter? A. I don tot. A. I do not. Beak to 26917, the second bullet conit says, "Validation runs concurrent with clinical serum testing." Do you see that? A. Yes. Chemical earlier saying that do not run — do not run the validation and then to e-mail earlier saying that do not run — do not run the validation concurrent with testing the serum but finish the validation and then that warning letter? MR. SANGIAMO: By the way, I object because it's asked and answered. THE WITNESS: My recollection of how I know that is that the — someone in authority at Merck indicated that we would do the validation study in parallel, but before the clinical testing — sorry. We would start Protocol 007 testing for the interim, the subset analysis before completing the validation studies. THE WITNESS: I recall the -mail that you showed me previously suggesting that the validation of the — sail. Defore the clinical stering starts. Page 303 Defore the clinical testing starts. Why. Page 305 THE WITNESS: I recall the concurrent with clinical serum testing. You understand that what they're saying is validate the AIGENT assay at the same time that you're running the clinical samples? A. Yes. And that was done in collaboration with CBER. They were informed that that was being done and approved that approach. When did they approve that approach? MR. SANGIAMO: Whoa, whoa. Jeff, you have to let him finish his answer. MR. KELLER: Defore the walinish his answer. MR. SANGIAMO: Whoa that was to would be running the subset analysis, or the validation studies. THE WITNESS: I don't recall if THE WITNESS: I don't reca	2	was a 483 that was issued out of MMD based on	2	time or concurrently with running the clinical
A. I recall that a warning letter 6 was issued. What that contained or involved, 7 Idon't have a recollection. 8 Q. Do you recall a 483 that came 9 before the warning letter? 9 pefore the warning letter? 9 pefore the warning letter? 10 A. I do not. 11 Q. Back to 26917, the second bullet 12 point says, "Validation runs concurrent with 12 point says, "Validation runs concurrent with 13 clinical serum testing." 14 Do you see that? 15 A. Yes. 16 Q. Henrietta Ukwu had sent an 17 e-mail earlier saying that do not run — do 18 not run the validation concurrent with testing 19 the serum but finish the validation and then 19 the serum but finish the validation and then 10 test the serum. Do you recall that e-mail? 11 MR. SANGIAMO: Object to the 12 characterization of the e-mail. 12 THE WITNESS: I recall the 12 characterization of the e-mail. 13 THE WITNESS: I recall the 14 concurrent with clinical serum testing, You 15 understand that what they're saying is 16 validate the AIGENT assay at the same time 17 that you're running the clinical samples? 18 A. Yes. And that was done in 29 collaboration with CBER. They were informed that that was being done and approved that approach? Were you at a meeting when that was approach? Were you at a meeting when that was a proproach? Were you at a meeting when that was a at that meeting. 19 WR. KELLER: 20 Were you at that meeting or not? 21 Q. Were you at that meeting or not? 22 A. I don't recall. testing starts. 23 BY MR. KELLER: 34 Q. Were you at that meeting or not? 35 MR. SANGIAMO: Object to the 36 form. 37 THE WITNESS: I don't recall if 38 I was at a - with certainty that I was at a that meeting. 39 BY MR. KELLER: 30 Q. Were you at that meeting or not? 30 Q. Were you at that meeting or not? 31 Deff. you have to let him finish his answer. 32 MR. SANGIAMO: Object to the 33 concurrent with clinical samples? 44 A. Yes. And that was done in 45 Concurrent with clinical samples? 46 A. Yes. And that was done in 47 C. The WITNESS: I don't recall if 48 I was at a - with certainty that I wa	3	an FDA inspection with stability problems in	3	serum in the assay for Protocol 007?
6 was issued. What that contained or involved, 1 I don't have a recollection. 3	4	the MMR product?	4	A. I don't recall who
7 Idon't have a recollection. 8 Q. Do you recall a 483 that came 9 before the clinical stesting surgesting that the validation be done 11 Q. Back to 26917, the second bullet 12 point says, "Validation runs concurrent with 13 clinical serum testing." 14 Do you see that? 15 A. Yes. 16 Q. Henrietta Ukwu had sent an 16 e-mail earlier saying that do not run — do 18 not run the validation concurrent with testing 19 the serum but finish the validation and then 10 test the serum. Do you recall that—nail? 21 MR. SANGIAMO: Object to the 22 characterization of the e-mail. 23 THE WITNESS: I recall the 24 e-mail that you showed me previously 25 suggesting that the validation be done Page 303 1 before the clinical serum testing. 2 By MR. KELLER: 3 Q. Here it says validation runs 4 concurrent with clinical serum testing. 5 validate the AIGENT assay at the same time 7 that you're running the clinical samples? 8 A. Yes. And that was done in 9 collaboration with CEBR. They were informed 10 that that was being done and approve that 11 approach. 12 Q. When did they approve that 13 approach? Were you at a meeting when that was 14 approved? 15 I was at a — with certainty that I was 16 at that meeting. 17 THE WITNESS: I don't recall if 18 I was at a — with certainty that I was 19 at that meeting. 20 By MR. KELLER: 21 Q. Were you at that meeting or not? 22 Q. So you remember, you recall who 24 told you — who do you recall telling you that 25 THE WITNESS: I can't say I 26 THE WITNESS: I can't say I 27 THE WITNESS: I can't say I 28 THE WITNESS: I can't say I 29 THE WITNESS: I can't say I 20 THE WITNESS: I can't say I 21 Q. Were you at that meeting or not? 22 A. I don't recall tiling you that 23 Q. So you remember, you recall who	5	A. I recall that a warning letter	5	Q. How do you know that?
8 answer. 9 before the warning letter? 9 MR. KELLER: Sure. 10 A. I do not. 11 Q. Back to 26917, the second bullet 11 object because it's asked and answered. 12 point says, "Validation runs concurrent with 12 THE WITNESS: My recollection of 13 clinical serum testing." 14 Do you see that? 15 A. Yes. 15 would do the validation study in 16 parallel - not necessarily in 17 parallel - not necessarily in 18 parallel - not necessarily in 19 parallel - not necessaril	6	was issued. What that contained or involved,	6	MR. SANGIAMO: Whoa, whoa.
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THE WITNESS: I recall the e-mail that you showed me previously suggesting that the validation be done Page 303 before the clinical testing starts. BY MR. KELLER: Q. Here it says validation runs concurrent with clinical serum testing. You sudicated the AIGENT assay at the same time rithat you're running the clinical samples? A. Yes. And that was done in collaboration with CBER. They were informed that that was being done and approved that approach. Q. When did they approve that approach? Were you at a meeting when that was approach? Were you at a meeting when that was approach? Were you at a meeting when that was at that meeting. MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall if I was at a with certainty that I was at that meeting. MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall if I was at a with certainty that I was at that meeting. MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall if I was at a with certainty that I was at that meeting. MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall if I was at a with certainty that I was at that meeting. MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall who Way. Page 303 A. I don't recall them telling me why. Page 305 Why. Page 305 A. I don't recall testing starts. 2 you ran the clinical samples while you were validating the SOP? Correct? MR. SANGIAMO: Object to the form. THE WITNESS: We did, but I recall from the CBER discussion when we indicated we would be running the subset analysis, or the validation and parallel to subset analysis, that the assay and the results of the validation study would be characterizing the results of the subset analysis were reported. BY MR. KELLER: Q. What communication when was this? Was this before you started running the assays or after? MR. SANGIAMO: Object to the form. THE WITNESS: I can't say I recall from the CBER discussion when we indicated we would be running the assay would not change. So the validation would be characterizin	21	MR. SANGIAMO: Object to the	21	the validation studies.
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25 CBER approved running the validation 25 communicated.	9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	collaboration with CBER. They were informed that that was being done and approved that approach. Q. When did they approve that approach? Were you at a meeting when that was approved? MR. SANGIAMO: Object to the form. THE WITNESS: I don't recall if I was at a with certainty that I was at that meeting. BY MR. KELLER: Q. Were you at that meeting or not? A. I don't recall. Q. So you remember, you recall who	9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	indicated we would be running the subset analysis, or the validation and parallel to subset analysis, that the assay would not change. So the validation would be characterizing the assay and the results of the validation study would be applied before the results of the subset analysis were reported. BY MR. KELLER: Q. What communication when was this? Was this before you started running the assays or after? MR. SANGIAMO: Object to the form. THE WITNESS: I can't say I
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	HIGHLI CONFIDENTIAL -		
	Page 306		Page 308
1	BY MR. KELLER:	1	Do you see that?
2	Q. Is that was that a meeting	2	A. Yes.
3	that you were at that CBER approved of you	3	Q. Does that refresh your memory
4	running the clinical samples for Protocol 007	4	that you were working with Joe Antonello from
5	before you validated the assay?	5	biologics research?
6	A. I can't say with certainty that	6	A. Biometrics.
7	I was at the meeting, but my recollection is	7	Q. Biometrics research?
8	that there was an agreement that we were not	8	A. I recall he was one of the
9	changing the assay so running the doing the	9	people from that group who we were talking to
10	validation concurrently with testing of	10	in developing the validation plan or protocol.
11	Protocol 007 was acceptable to them.	11	Q. So did you you drafted the
12	Q. But you weren't at that meeting,	12	validation protocol. Correct?
13	that's just somebody at Merck told you that?	13	MR. SANGIAMO: Objection. Asked
14	A. I may have been at the meeting.	14	and answered. Misstates testimony.
15	I don't recall with certainty if I was or	15	BY MR. KELLER:
16	wasn't.	16	Q. You don't recall?
17	Q. Was that written down anywhere?	17	A. I don't I don't recall who
18	MR. SANGIAMO: Objection. Calls	18	drafted it.
19	for speculation.	19	Q. And here, if you look at this
20	THE WITNESS: I don't recall if	20	discussion, do you recall discussing you
21	it was or wasn't.	21	can feel free to read the reference on
22	BY MR. KELLER:	22	October 27 to your communications with Joe
23	Q. I see. Have you ever run a	23	Antonello. Do you recall discussing the
24	clinical study before Protocol 007?	24	parameters of what that protocol would look
25	MR. SANGIAMO: Object to the	25	like?
	D 207	1	D 200
1	Page 307	1	Page 309
1 2	form.	1 2	A. So at least the points I have
2	form. THE WITNESS: I have I and my	2	A. So at least the points I have listed here I wouldn't say it's all inclusive
2 3	form. THE WITNESS: I have I and my group have run assays in support of	2 3	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but
2 3 4	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical	2 3 4	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the
2 3 4 5	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study.	2 3 4 5	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting.
2 3 4 5 6	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER:	2 3 4 5 6	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three,
2 3 4 5 6 7	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that	2 3 4 5 6 7	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you
2 3 4 5 6 7 8	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006?	2 3 4 5 6 7 8	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that?
2 3 4 5 6 7 8 9	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006? A. Yes.	2 3 4 5 6 7 8 9	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that? A. Yes.
2 3 4 5 6 7 8 9 10	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006? A. Yes. Q. Did you validate that assay	2 3 4 5 6 7 8 9	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that? A. Yes. Q. Can you read that line from your
2 3 4 5 6 7 8 9 10 11	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006? A. Yes. Q. Did you validate that assay before you ran the serum in Protocol 006?	2 3 4 5 6 7 8 9 10	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that? A. Yes. Q. Can you read that line from your journal?
2 3 4 5 6 7 8 9 10 11 12	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006? A. Yes. Q. Did you validate that assay before you ran the serum in Protocol 006? A. There were some validation	2 3 4 5 6 7 8 9 10 11 12	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that? A. Yes. Q. Can you read that line from your journal? A. Yeah. Specificity can be
2 3 4 5 6 7 8 9 10 11 12 13	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006? A. Yes. Q. Did you validate that assay before you ran the serum in Protocol 006? A. There were some validation experiments, as best I can recall, that were	2 3 4 5 6 7 8 9 10 11 12 13	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that? A. Yes. Q. Can you read that line from your journal? A. Yeah. Specificity can be addressed from pre/post boost and absorption
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	form. THE WITNESS: I have I and my group have run assays in support of clinical at least one other clinical study. BY MR. KELLER: Q. That clinical study, is that Protocol 006? A. Yes. Q. Did you validate that assay before you ran the serum in Protocol 006? A. There were some validation experiments, as best I can recall, that were done before starting that testing. I don't recall if the validation was completed for all the viruses before the Protocol 006 testing started. Q. If you could go back to your journal for 2000. If I could direct your attention to October 27, at 490473 or 393 of your journal. A. 490473. Q. There's a reference here to a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. So at least the points I have listed here I wouldn't say it's all inclusive of all the points that were discussed, but these are some examples of aspects of the validation that he was suggesting. Q. If you look at one, two, three, four down, it talks about specificity. Do you see that? A. Yes. Q. Can you read that line from your journal? A. Yeah. Specificity can be addressed from pre/post boost and absorption experiment. Q. So did you understand that what that pre/post boost was, do you recall any discussion about what that experiment would be? MR. SANGIAMO: Object to the form. You're asking if he recalls any discussion of it? MR. KELLER: Yes. THE WITNESS: I don't.

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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

That's why I asked for clarification. THE WITNESS: I don't recall there being discussion over what he meant by that. BY MR. KELLER: So So you don't know what a prepost boost experiment would be for specificity? A. I am familiar not from mumps or lor-from other literature that I'm familiar with requires - at least ones I'm in the context of MMR. If a many mumps, mumps alone not in the context of MMR. Did you ever consider running that experiment as part of your validation of the ALGENT? A. As best I understand or can the ALGENT? A. As best I understand or can round. Ward in this many context of many context of many context of many context of MR. That's why I asked for clarification. A by MR. KELLER: Did you ever consider running that experiment as part of your validation of the ALGENT? MR. KELLER: Let me mark - let me mark this next exhibit as Exhibit 33. MR. KELLER: Let me mark - let emails with attachment, 759836 - 3759847, was marked for identification.) MR. KELLER: For the record, Exhibit 33 is a document that bears Batts stamp numbers 79 - 759836 through 847. It's a series of e-mails and an attachment of a validation protocol. MR. KELLER: For the record, Exhibit 33 is a document that bears Batts stamp numbers 79 - 759836 through 847. It's a series of e-mails with attachment, 759836 through 847. It's a series of e-mails and an attachment of a validation protocol. MR. KELLER: Q. Can you tell mecan you take a minute to look at this document and see if you recall receiving these e-mails and writing these e-mails that are identified in your recall receiving these e-mails and writing these e-mails that are identified in your recall receiving these e-mails and writing these e-mails that are identified in your recall receiving these e-mails and writing these e-mails that are identified in your recall receiving these e-mails and writing these e-mails that are identified in your recall receiving these e-mails and writing these e-mails that are identified in your recall receiving these e-mails and writi				TORNEYS' EYES ONLY
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4 meant by that. 5 BY MR. KELLER: 5 BY MR. KELLER: 5 Prolycost boost experiment would be for sepcificity? 7	2	THE WITNESS: I don't recall	2	start in
5 BY MR. KELLER: 5 protocol for anti-lgG enhanced mumps neut assay. Do you see that? 7 A. Yes. 9 MR. SANGIAMO: Object to the form. 10 Form. 11 with, of studies in which that has been looked at at, but it requires - at least ones I'm 13 familiar with requires a monovalent 14 vaccination. Meaning mumps, mumps alone not is in the context of MMR. 15 MR. KELLER: 16 Q. Did you ever consider running 16 the AIGENT? 17 that experiment as part of your validation of the AIGENT? 18 MR. KELLER: 19 A. As best I understand or can 18 Vard's lab - Dick Ward's group. Do you see that? 19 A. As best I understand or can 19 Vard's lab - Dick Ward's group. Do you see that? 19 Vard's lab - Dick Ward's group	3	there being discussion over what he	3	A. Yeah. Yes. Okay.
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10	8	specificity?	8	Q. That's Protocol 007. Correct?
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79 (Pages 310 - 313)

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		AT	
1	Page 314	1	Page 316
1	lab or at Merck. Validation protocol	1	samples have already been tested, the
2	would be prior to the potential	2	remaining samples can be divided among six
3	transfer to Dick Ward's lab.	3	runs used to assess precision).
4	BY MR. KELLER:	4	Do you see that?
5	Q. So as of October 30, the	5	A. Yes.
6	decision was made to run that 600 subset out	6	Q. Then it says, "The test sample
7	of your lab. Correct?	7	data will be used to establish a
8 9	MR. SANGIAMO: Object to the	8	'sero-positivity' cutoff and provide estimates
10	form. THE WITNESS: The date?	9	of pre- and post-vaccination sero-positive rates."
11	BY MR. KELLER:	11	
12		12	Do you see that? A. Yes.
13	Q. As of October 30, after the October meeting with the CAS, do you recall	13	Q. This 100 pediatric sample, that
14	having discussion with Emilio Emini where you	14	was the proposal by Joseph Antonello. Correct?
15	were informed that you would run the subset	15	MR. SANGIAMO: Object to the
16	out of your lab?	16	form.
17	A. I recall being informed by	17	BY MR. KELLER:
18	Emilio that our lab will be running the	18	Q. For the validation protocol? Is
19	subset. I don't recall the date, the specific	19	that a fair statement?
20	date.	20	MR. SANGIAMO: Object to the
21	Q. Fair enough. Here on	21	form.
22	October 30, on the first page of Exhibit 33,	22	THE WITNESS: That according
23	there's an e-mail from Joe Antonello to you,	23	to the way this is written, that's his
24	Dr. Krah. Do you see that?	24	recommendation for the serostatus
25	A. Yes.	25	cutoff part of the validation protocol.
	Page 315		Page 317
1	_	1	
1 2	Q. Again, it's, Validation of	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	BY MR. KELLER:
2	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut	1 2 3	
	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut assay.	2	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct?
2 3	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut	2 3	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct? MR. SANGIAMO: Object to the
2 3 4	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut assay. Do you see that? A. Yes.	2 3 4	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct?
2 3 4 5	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut assay. Do you see that? A. Yes. Q. It says, "Dave, To help in	2 3 4 5	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct? MR. SANGIAMO: Object to the form. BY MR. KELLER:
2 3 4 5 6	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut assay. Do you see that? A. Yes. Q. It says, "Dave, To help in preparing a Mumps PRN Validation Protocol, two	2 3 4 5 6	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct? MR. SANGIAMO: Object to the form.
2 3 4 5 6 7	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut assay. Do you see that? A. Yes. Q. It says, "Dave, To help in	2 3 4 5 6 7	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct? MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Is that how you calculate the mock control units?
2 3 4 5 6 7 8	Q. Again, it's, Validation of protocol for the anti-IgG enhanced mumps neut assay. Do you see that? A. Yes. Q. It says, "Dave, To help in preparing a Mumps PRN Validation Protocol, two recently completed validation protocols are	2 3 4 5 6 7 8	BY MR. KELLER: Q. That's part of the mock control limits as well. Correct? MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. Is that how you calculate the
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Page 320 1 it would be applied. I can say that 1 MR. SANGIAMO: Object to the 2 he's suggesting that that number of 2 form. 3 samples would be recommended to allow 3 BY MR. KELLER: 4 him to do that part of his analysis. 4 Q. A handful of kids, like four 5 But beyond that, I don't have any 5 kids in there? 6 6 information. MR. SANGIAMO: Object to the 7 BY MR. KELLER: 7 form. 8 8 You're not -- you don't know how BY MR. KELLER: 9 9 the sero classification cutoffs are generated, Q. Do you recall? A. I don't recall the number of 10 that's for the statisticians? 10 11 Α. The statisticians -- my 11 kids, but the mock serum control is not -- are understanding of the process is that the not related to the performance of the -- the 12 12 statisticians confirm what serostatus cutoff 13 question about whether anti-IgG is 14 is appropriate. So we'll have data, meaning 14 neutralizing on its own or not is not relevant 15 percent of mock and a titer, the statistician 15 to that assay. then would be able to, through the validation 16 Did you see any effect of -- you 17 protocol, evaluate what's a statistically 17 said you ran these assays to say that there 18 supported cutoff. 18 was no effect with or without the anti-IgG? 19 So this mock control, you 19 In the absence of serum. 20 20 testified that it's control medium, IgG, and But in the absence of serum O. 21 virus. Correct? 21 there's a huge effect. Correct? 22 22 A. Yes. MR. SANGIAMO: Object to the 23 23 Q. What was the purpose of having form. 24 the control medium? 24 THE WITNESS: It depends on the 25 The -- my -- it doesn't just 25 serum. It depends on the serum. Page 319 Page 321 apply to this assay but other assays. My 1 BY MR. KELLER: 2 objective for the control, the mock control is 2 Q. So because the IgG would 3 to have it be everything that's in the assay 3 interact with not only mumps antibodies but but the serum. So control for everything but 4 measles antibodies, rubella antibodies, and 4 5 5 the one variable. So it then serves as the antibodies for influenza, RSV, whatever 6 plaque number to use to compare to the 6 antibodies are in that kid's serum, the rabbit 7 7 serum-containing samples. antibodies -- the rabbit anti-IgG is going to 8 So would the -- if you removed 8 interact with that and bind it. Correct? 9 the IgG, would that have an effect on the mock 9 MR. SANGIAMO: Object to the 10 10 control? form. THE WITNESS: It has the 11 We did do studies where we 11 12 evaluated the impact of anti-IgG on virus 12 potential, the anti-IgG has the infectivity and did not see that effect in the 13 13 potential to bind to any IgG that's in absence of serum as well as the similar 14 the sera. 15 15 observation from the publication from the FDA BY MR. KELLER: on their anti-IgG assay development. So in a 16 Q. So when you did these 17 practical way, I would not expect an effect of 17 experiments with or without the IgG and the 18 not having the anti-IgG present but for the 18 mock, what indicator virus did you use? 19 sake of better control or minimizing variables 19 I don't recall with certainty. 20 in the assay, meaning having the only variable 20 Was it Jeryl Lynn 135? 21 be serum dilution, the mock contained 21 I have an expectation that that

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was it, but I don't have a recollection that

actually ran 100 pediatric samples for the

Q. Do you know whether or not you

that was the indicator virus.

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everything but the serum.

Q. There could have been -- what

was done in the original studies in 1972,

those are very limited studies. Correct?

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	Page 322		Page 324
1	validation of the AIGENT?	1	BY MR. KELLER:
2	A. I don't recall.	2	Q. Was it your testimony that these
3	Q. Do you recall that those 50	3	50 samples that these 100 samples that are
4	samples identified by Antonello, those were	4	identified here had controls that were used in
5	samples that were run as part of your	5	the actual running of Protocol 007, the same
6	developing the assay. Correct?	6	positive controls?
7	MR. SANGIAMO: Object to the	7	MR. SANGIAMO: Object to the
8	form. Calls for speculation.	8	form.
9	THE WITNESS: I can't say with	9	THE WITNESS: I don't have I
10	certainty that that was once I'm	10	don't have a recollection of whether
11	sorry, they were once part of the assay	11	they were or weren't.
12	development. One arm of the assay	12	BY MR. KELLER:
13	development would have included	13	Q. And if they weren't running the
14	whatever anti-IgG, whatever the	14	validation samples, would that be a concern
15	conditions were that we wound up using	15	for you, if they had controls that were not
16	in the assays. The development	16	the same as the controls that were run in the
17	included different concentrations of	17	actual SOP, running kids serum in Protocol
18	anti-IgG, for example, one	18	007?
19	concentration was chosen for the final	19	A. I need to defer to Joe Antonello
20	assay application. So a subset of the	20	whether those data would be usable for that
21	sera would be eligible if the indicator	21	appropriate to include in that.
22	if all the other assay conditions	22	Q. Do you recall sorry. Go
23	and the indicator virus and anti-IgG	23	ahead and finish.
24	concentration were the same as what was	24	A. Whether they would be
25	being used in the eventual assay.	25	appropriate to include that combination of
	2		appropriate to increase that conformation of
			** *
1	Page 323	1	Page 325 data.
	Page 323 Whether those particular samples were		Page 325 data.
1	Page 323 Whether those particular samples were included as part of that 50, I can't	1	Page 325 data. Q. Do you recall ever hearing that
1 2	Page 323 Whether those particular samples were	1 2	Page 325 data. Q. Do you recall ever hearing that the data that was generated as part of the
1 2 3	Page 323 Whether those particular samples were included as part of that 50, I can't say for sure. BY MR. KELLER:	1 2 3	Page 325 data. Q. Do you recall ever hearing that
1 2 3 4	Page 323 Whether those particular samples were included as part of that 50, I can't say for sure.	1 2 3 4	Page 325 data. Q. Do you recall ever hearing that the data that was generated as part of the validation was insufficient to generate
1 2 3 4 5	Page 323 Whether those particular samples were included as part of that 50, I can't say for sure. BY MR. KELLER: Q. Except you may have had a different control because the controls were	1 2 3 4 5	Page 325 data. Q. Do you recall ever hearing that the data that was generated as part of the validation was insufficient to generate reliable data to validate Protocol 007 AIGENT? A. Not that I recall.
1 2 3 4 5 6 7	Page 323 Whether those particular samples were included as part of that 50, I can't say for sure. BY MR. KELLER: Q. Except you may have had a different control because the controls were not set until after October of 2000, correct,	1 2 3 4 5 6	Page 325 data. Q. Do you recall ever hearing that the data that was generated as part of the validation was insufficient to generate reliable data to validate Protocol 007 AIGENT?
1 2 3 4 5 6	Page 323 Whether those particular samples were included as part of that 50, I can't say for sure. BY MR. KELLER: Q. Except you may have had a different control because the controls were not set until after October of 2000, correct, by CBER?	1 2 3 4 5 6 7	Page 325 data. Q. Do you recall ever hearing that the data that was generated as part of the validation was insufficient to generate reliable data to validate Protocol 007 AIGENT? A. Not that I recall. Q. Would that surprise you to learn
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1	Page 326	1	Page 328 of the AIGENT?
2	Q. So you wrote, Should the validation also include a requirement for	2	
3	up-front testing to evaluate pre-positive	3	MR. SANGIAMO: Object to the form.
4	rates (around 10 percent target?) and,	4	THE WITNESS: A goal in the
5	typo,seroconversion rates (greater or	5	development of the AIGENT was to have
6	equal to 95 percent) for a panel of 50 to	6	an assay that was capable of measuring
7	60pediatric sera.	7	95 percent seroconversion and had a
8	Do you see that?	8	minimum in my mind a minimize or
9	MR. SANGIAMO: You left out	9	minimal pre-positivity rate, whatever
10	paired.	10	that wound up being.
11	BY MR. KELLER:	11	BY MR. KELLER:
12	Q. Pediatric sera.	12	Q. And the goal was 10 percent
13	MR. SANGIAMO: You left out	13	around 10 percent pre-positive rate. Correct?
14	paired.	14	A. That was at least the target
15	BY MR. KELLER:	15	that was in some of the documents.
16	Q. I'm sorry, paired pediatric	16	Q. So that's what you that's
17	sera. Thank you.	17	what drove your developing the assay to get to
18	Do you recall writing that?	18	that target. Correct?
19	A. It's in an e-mail from me, but I	19	MR. SANGIAMO: Object to the
20	don't have an independent recollection.	20	form.
21	Q. Below that	21	THE WITNESS: The goal was to
22	MR. SANGIAMO: Jeff, you did it	22	find an assay that was capable of
23	again. You got to let him finish.	23	meeting those two targets.
24	THE WITNESS: In the I don't	24	BY MR. KELLER:
25	have an independent recollection of	25	Q. Fair enough. Have you ever
	Page 327		Page 329
			1 age 327
1	writing the wording is looks and	1	developed an assay where you developed the
1 2	writing the wording is looks and says it was wording I would use, but	2	developed an assay where you developed the assay to get a certain result
2 3	writing the wording is looks and says it was wording I would use, but I don't have an independent	2 3	developed an assay where you developed the assay to get a certain result MR. SANGIAMO: Object to the
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2 3 4 5 6 7	writing the wording is looks and says it was wording I would use, but I don't have an independent recollection of writing that. BY MR. KELLER: Q. Below that it says, "This would be the 'clinical validation' that I mentioned	2 3 4 5 6 7	developed an assay where you developed the assay to get a certain result MR. SANGIAMO: Object to the form. BY MR. KELLER: Q a predetermined result MR. SANGIAMO: Object to the
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1	Page 330	1	Page 332
1	THE WITNESS: Not that I recall,	1	Q. Do you see that? A. Yes.
2	but I remind you that the target that	2	
3	was set here was a CBER-imposed target.	3	Q. Was that your handwriting on
4	MR. KELLER: Let me mark this	5	page 2 at 780114?
5	next exhibit as Exhibit 34, which is a		A. It doesn't look like my
6	document that bears Bates stamp number	6 7	handwriting.
7	1218 through 1221, which is a memo from		Q. Do you recall on 78 back up.
8	Manal Morsy to a series of individuals,	8 9	Do you recall ever seeing this document before, Exhibit 35?
9	including you, Dr. Krah, regarding a	10	· ·
10	teleconference with CBER on November 29.	1	A. I recall there are parts of the protocol that look familiar to me. Whether I
11	(E-1):14 V - 1 24 11/20/00 M	11	
12	(Exhibit Krah-34, 11/29/00 Memo,	12	saw it in its entirety I can't say. In fact,
13	1218 - 1221, was marked for	1	looking on page 3, looks like it's a draft
14	identification.)	14	version since it has underlining. So I don't
15	DV MD VELLED	15 16	know, depending on who made the edits, if I would have seen those parts.
16	BY MR. KELLER:		Q. So this is a this Exhibit 35
17	Q. Do you see that?	17 18	is a draft. Correct?
18	A. Yes.	19	
19 20	Q. Do you recall why don't you take a minute to review this memo and let me	20	A. I can't say with certainty other
20		21	than page 3 and on page 3 at least there
21 22	know when you're done.	$\begin{vmatrix} 21\\22\end{vmatrix}$	are edits made, which would imply a draft. Q. And so this reference on page
23	MR. KELLER: Off the record so I	$\begin{vmatrix} 22 \\ 23 \end{vmatrix}$	Q. And so this reference on page 780114 where there's a circle around the 100
23	can use the restroom real quick.	23	pre- and post-vaccination paired pediatric
25	MR. SANGIAMO: We're going to take a break, take a break. That's	25	samples, it says 100 or fewer due to
23	take a break, take a break. That's	23	samples, it says 100 of fewer due to
	Page 331		Page 333
1	fine.	1	contamination. Do you believe that half of
2	VIDEOGRAPHER: The time is now	2	the samples that were being proposed to be
	4 4 4 TC1 ' 1 1 1' C'		the samples that were being proposed to be
3	4:41. This concludes disc five.	3	tested as part of the pediatric samples were
4		3 4	tested as part of the pediatric samples were not usable because of contamination in your
4 5	4:41. This concludes disc five. (A recess was taken.)	3 4 5	tested as part of the pediatric samples were not usable because of contamination in your lab?
4 5 6	(A recess was taken.)	3 4 5 6	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall.
4 5 6 7	(A recess was taken.) VIDEOGRAPHER: The time is now	3 4 5 6 7	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention
4 5 6 7 8	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may	3 4 5 6 7 8	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end
4 5 6 7 8 9	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed.	3 4 5 6 7 8 9	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if
4 5 6 7 8 9 10	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed. MR. KELLER: I'd like to mark	3 4 5 6 7 8 9 10	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if there was contamination, I do recall some sera
4 5 6 7 8 9 10 11	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed.	3 4 5 6 7 8 9 10 11	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if there was contamination, I do recall some sera we tested at some point, where there was
4 5 6 7 8 9 10 11 12	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed. MR. KELLER: I'd like to mark for the record Exhibit 35.	3 4 5 6 7 8 9 10 11 12	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if there was contamination, I do recall some sera we tested at some point, where there was contamination was the sera, not something
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed. MR. KELLER: I'd like to mark for the record Exhibit 35. (Exhibit Krah-35, Plaque Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.01), 780112 - 780116, was marked for identification.) MR. KELLER: For the record, Exhibit 35 is a document bearing Bates stamp number 780112 through 116, entitled: "Plaque Reduction	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if there was contamination, I do recall some sera we tested at some point, where there was contamination was the sera, not something introduced in the lab. Q. So it's your testimony that you recall there being contaminated serum but that was contaminated from someplace else but not in your lab. Correct? A. Yes. I don't recall if it was this particular set, but I do recall a period where a panel showed, that we were evaluating had a contamination problem. Q. Let me direct you to the 2001
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed. MR. KELLER: I'd like to mark for the record Exhibit 35. (Exhibit Krah-35, Plaque Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.01), 780112 - 780116, was marked for identification.) MR. KELLER: For the record, Exhibit 35 is a document bearing Bates stamp number 780112 through 116, entitled: "Plaque Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.01)."	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if there was contamination, I do recall some sera we tested at some point, where there was contamination was the sera, not something introduced in the lab. Q. So it's your testimony that you recall there being contaminated serum but that was contaminated from someplace else but not in your lab. Correct? A. Yes. I don't recall if it was this particular set, but I do recall a period where a panel showed, that we were evaluating had a contamination problem. Q. Let me direct you to the 2001 journals. Can you pull those in front of you? A. Okay.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	(A recess was taken.) VIDEOGRAPHER: The time is now 4:57. This begins disc six. You may proceed. MR. KELLER: I'd like to mark for the record Exhibit 35. (Exhibit Krah-35, Plaque Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.01), 780112 - 780116, was marked for identification.) MR. KELLER: For the record, Exhibit 35 is a document bearing Bates stamp number 780112 through 116, entitled: "Plaque Reduction Neutralization Assay for Mumps	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	tested as part of the pediatric samples were not usable because of contamination in your lab? A. I don't recall. Q. Let me direct your attention A. If I may add to that, at the end you put in in my lab. The source of the if there was contamination, I do recall some sera we tested at some point, where there was contamination was the sera, not something introduced in the lab. Q. So it's your testimony that you recall there being contaminated serum but that was contaminated from someplace else but not in your lab. Correct? A. Yes. I don't recall if it was this particular set, but I do recall a period where a panel showed, that we were evaluating had a contamination problem. Q. Let me direct you to the 2001 journals. Can you pull those in front of you?

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	HIGHLY CONFIDENTIAL -		
	Page 334		Page 336
1	attention to January 21, 2001, at 490623.	1	set number 24 are contaminated - any ideas of
2	A. I'm sorry?	2	the source?
3	Q. 490623. January 21, 2001. Do	3	Q. So does that lead you to believe
4	you see that reference to the last entry? Can	4	that the sera that you had anticipated testing
5	you read the last entry for me?	5	for the validation protocol that we had seen
6	A. Sorry, on Sunday 21st was that?	6	documents earlier where Antonello was
7	Q. Yes. Sorry.	7	recommending running 100 paired samples, and
8	A. Review Manal's info for CBER.	8	here on January 21st, you reference needed to
9	Revise validation protocol to be approximately	9	revise it from 50 down from 100 to 50, and
10	50 pediatric sera instead of 100.	10	in conjunction with the draft protocol in
11	Q. Does that refresh your	11	Exhibit 35 where there's a reference to
12	recollection that you, in fact, were at least	12	contamination, that, in fact, those 50 samples
13	editing the validation protocol at this point?	13	of sera that you had anticipated to be run for
14	A. That indicates that the	14	the validation pediatric sera was contaminated
15	validation protocol was edited, revised, if	15	and, therefore, you didn't have it and you
16	you will, on the 21st of January, 2001.	16	need to revise the validation protocol for
17	Q. And this revision of the	17	that purpose?
18	protocol from around 50 pediatric sera instead	18	7 7
19		19	MR. SANGIAMO: Object to the
20	of 100, do you recall that was due to	20	form.
21	contamination of the sera that you received? A. I don't	l	THE WITNESS: I can't tell from
		21	the wording here. But I can't confirm
22	MR. SANGIAMO: Object to the	22	that that sera set number 24 was
23	form.	23	intended for the validation study or
24	THE WITNESS: I don't recall the	24	not.
25	rationale for that change.	25	BY MR. KELLER:
	Page 335		Page 337
1	BY MR. KELLER:	1	Q. But it's fair to say that on
2	Q. Let me direct your attention	2	January 21st, you have a reference in your
3	back to your journal from 2000. If you can go	3	journal to revise the protocol to be around 50
4	to 490489, which is dated November 14, and ask	4	ped sera instead of 100. Correct?
5	you questions on the end of that journal entry	5	A. I'm sorry, what's the date again
6	on 489, which is pages 408 and 409 of your	6	C .1 . 0
7		"	for that one?
1	journal, if that helps.	7	Q. Right here.
8	journal, if that helps. A. Yes, okay.	l	Q. Right here. A. January 21, 2001?
		7	Q. Right here.
8	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00	7 8	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes.
8 9	A. Yes, okay.Q. So on 409, which is 490489 in	7 8 9	Q. Right here. A. January 21, 2001? Q. Yes.
8 9 10	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00	7 8 9 10	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes.
8 9 10 11	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from	7 8 9 10 11	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean
8 9 10 11 12	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly	7 8 9 10 11 12	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric?
8 9 10 11 12 13	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera).	7 8 9 10 11 12 13	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes.
8 9 10 11 12 13 14	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes.	7 8 9 10 11 12 13 14	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation
8 9 10 11 12 13 14 15	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes.	7 8 9 10 11 12 13 14 15	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50?
8 9 10 11 12 13 14 15 16	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the	7 8 9 10 11 12 13 14 15 16	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall.
8 9 10 11 12 13 14 15 16 17	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the validation samples from Kelly Buckley?	7 8 9 10 11 12 13 14 15 16 17	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall. Q. Do you recall any discussion
8 9 10 11 12 13 14 15 16 17 18	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the validation samples from Kelly Buckley? A. I don't recall who we received them from.	7 8 9 10 11 12 13 14 15 16 17 18	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall. Q. Do you recall any discussion with any e-mails from Dr. Schofield stating
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8 9 10 11 12 13 14 15 16 17 18	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the validation samples from Kelly Buckley? A. I don't recall who we received them from. Q. If you look on 490500, which is page 420 of your which is November 25,	7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall. Q. Do you recall any discussion with any e-mails from Dr. Schofield stating that if you reduced the number of pediatric serum that were tested in the validation protocol, that the results would be of limited
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the validation samples from Kelly Buckley? A. I don't recall who we received them from. Q. If you look on 490500, which is page 420 of your which is November 25, 2000, there's a reference to Saturday. Can	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall. Q. Do you recall any discussion with any e-mails from Dr. Schofield stating that if you reduced the number of pediatric serum that were tested in the validation protocol, that the results would be of limited data and unusable?
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the validation samples from Kelly Buckley? A. I don't recall who we received them from. Q. If you look on 490500, which is page 420 of your which is November 25, 2000, there's a reference to Saturday. Can you read your Saturday entry?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall. Q. Do you recall any discussion with any e-mails from Dr. Schofield stating that if you reduced the number of pediatric serum that were tested in the validation protocol, that the results would be of limited data and unusable? MR. SANGIAMO: Objection. Form.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes, okay. Q. So on 409, which is 490489 in the Bates numbers, it says, Assign MMRV-715-00 to the receipt of serum set number 24 from Serologic group (from October 31, Kelly Buckley: 60 paired sera). Do you see that? A. Yes. Q. Did you get the sera for the validation samples from Kelly Buckley? A. I don't recall who we received them from. Q. If you look on 490500, which is page 420 of your which is November 25, 2000, there's a reference to Saturday. Can	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Right here. A. January 21, 2001? Q. Yes. A. Yes. Q. And when you say ped, you mean pediatric? A. Pediatric, yes. Q. So did you revise the validation protocol from 100 to 50? A. I don't recall. Q. Do you recall any discussion with any e-mails from Dr. Schofield stating that if you reduced the number of pediatric serum that were tested in the validation protocol, that the results would be of limited data and unusable?

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	Page 338		Page 340
1	MR. KELLER: Let me mark this	1	A. Okay.
2	next exhibit as Exhibit 36.	2	Q. On the second page of this
3		3	e-mail there's an e-mail from you, Dr. Krah,
4	(Exhibit Krah-36, Series of	4	dated January 21, 2001, to Emini, Shaw,
5	e-mails, 52848 & 5284, was marked for	5	Washabaugh, Schofield, Heyse, Antonello and
6	identification.)	6	Yagodich, Karen Hencken and Jerry Sadoff. Do
7		7	you see that?
8	BY MR. KELLER:	8	A. Yes.
9	Q. Let me back up for a second.	9	Q. And the subject was the
10	You made a point of saying that	10	"Anti-IgG Enhanced mumps neutralization assay
11	there was no contamination of sera in your	11	validation protocol draft."
12	lab. During the time that you were running	12	Do you see that?
13	Protocol 007, you had a very serious problem	13	A. Yes.
14	of mold problems in your incubators, didn't	14	Q. Who was Karen Hencken?
15	you? Do you remember that?	15	A. I don't recall. I know of
16	MR. SANGIAMO: Object to the	16	Karen. She's had different positions over the
17	form.	17	time I knew her. I don't recall her position
18	THE WITNESS: I don't I	18	at the time of this e-mail.
19	remember we had mold occasionally in	19	Q. Was she involved in do you
20	the incubator, but I don't recall it	20	know if she's involved in GMP compliance?
21	being at that particular time.	21	MR. SANGIAMO: Object to the
22	BY MR. KELLER:	22	form.
23	Q. Do you recall having problems	23	MR. KELLER: Strike that.
24	in at the end of 2000?	24	BY MR. KELLER:
25	MR. SANGIAMO: Object to the	25	Q. Do you recall if she is involved
	Page 339		Page 341
1	form.	1	in any kind of quality control, quality
2	form. THE WITNESS: I don't recall.	2	in any kind of quality control, quality assurance functions?
2 3	form. THE WITNESS: I don't recall. BY MR. KELLER:	2 3	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the
2 3 4	form. THE WITNESS: I don't recall. BY MR. KELLER: Q. Do you recall having problems	2 3 4	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the form.
2 3 4 5	form. THE WITNESS: I don't recall. BY MR. KELLER: Q. Do you recall having problems in during the time that you were running	2 3 4 5	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the form. THE WITNESS: At some point
2 3 4 5 6	form. THE WITNESS: I don't recall. BY MR. KELLER: Q. Do you recall having problems in during the time that you were running the preliminary subset, having mold problems	2 3 4 5 6	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the form. THE WITNESS: At some point of the time that I knew her, she
2 3 4 5 6 7	form. THE WITNESS: I don't recall. BY MR. KELLER: Q. Do you recall having problems in during the time that you were running the preliminary subset, having mold problems in your incubators that those samples were run	2 3 4 5 6 7	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the form. THE WITNESS: At some point of the time that I knew her, she wasn't involved in a quality control
2 3 4 5 6 7 8	form. THE WITNESS: I don't recall. BY MR. KELLER: Q. Do you recall having problems in during the time that you were running the preliminary subset, having mold problems in your incubators that those samples were run on?	2 3 4 5 6 7 8	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the form. THE WITNESS: At some point of the time that I knew her, she wasn't involved in a quality control function. I don't recall at this
2 3 4 5 6 7 8 9	form. THE WITNESS: I don't recall. BY MR. KELLER: Q. Do you recall having problems in during the time that you were running the preliminary subset, having mold problems in your incubators that those samples were run on? A. Not that I recall.	2 3 4 5 6 7 8 9	in any kind of quality control, quality assurance functions? MR. SANGIAMO: Object to the form. THE WITNESS: At some point of the time that I knew her, she wasn't involved in a quality control function. I don't recall at this specific time what her role was.
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Page 344 what I showed you in Exhibit 35 is also 1 Might have. 2 version 1. Do you see that? 2 MR. SANGIAMO: Did you get that, 3 MR. SANGIAMO: Object to the 3 Linda? The document says you might 4 form. 4 have, not must have. 5 THE WITNESS: Yes. 5 MR. KELLER: I'll reread it. 6 BY MR. KELLER: 6 Strike the prior question. 7 Q. And so do you recall circulating 7 BY MR. KELLER: 8 8 versions of the draft validation protocol? Comment: On page 3 (and in the 9 9 A. I don't recall. last section) you mention using the data that 10 Q. On February 12, about, what is 10 you collect on the controls to establish that, three weeks later, you followed up with controls limit. This will be far too little 11 11 an e-mail to the same folks, same topic data to set reliable limits. You might add 12 12 saying, "Please review the attached draft that 13 that "The control criteria will be updated 14 was sent out in late January and either 14 after a sufficient number of runs have been 15 provide comments or the signed cover 15 performed, to obtain reliable estimates of assay performance (total N equal 20 runs)." (signature) page." It says, I only received 1 16 16 17 signature back (and 1 comment from the same 17 Do you see that? 18 person) so far. 18 Yes. 19 Do you see that? 19 Q. Did you address that language to 20 20 Yes. the draft protocol? 21 So on February 15th, based on 21 A. I don't recall. 22 your prompting, Timothy Schofield responded. 22 And so if you go back to O. 23 Do you see that? 23 Exhibit 35, can you tell what he's talking 24 MR. SANGIAMO: Object to the 24 about? Page 3, in the last section. Is he 25 25 talking about the seroclassification cutoff? form. Page 343 1 THE WITNESS: I see a reply from 1 A. My understanding and recollection 2 him, yes. And he says --2 of what he was referring to there are the 3 MR. SANGIAMO: Wait, hold on a 3 control limits, second paragraph, Each 4 4 validation run will also include testing on second. Did you finish your answer, 5 5 the mock control, and in parentheses, and on 6 THE WITNESS: I see a reply 6 low and high positive control samples (adult 7 following as listed on the 7 sera)..., as I recall discussion with Joe 8 February 15th. 8 Antonello when the validation report was being 9 BY MR. KELLER: 9 assembled that -- my understanding, my 10 10 Q. And here it says, Schofield recollection of the procedure that he would states, "David, I reviewed the protocol, and follow would be a tentative control limit 11 11 have one comment, and a couple of typos. would be set based on the available data that 12 12 13 Comment: On page 3 (and in the 13 number or value, or values, if there are 14 last section) you mention using the data that 14 multiple controls, would be updated as more 15 you collect on the controls to establish 15 data became available. control limit. This will be far too little 16 Q. And the data, as more data 17 data to set reliable units. You must add that 17 became available, is that running sera from Protocol 007 or running sera from sera outside 18 "The control criteria will be updated after a 18 19 sufficient number of runs have been performed 19 of Protocol 007? 20 to obtain reliable estimates of assay 20 A. My understanding of that comment 21 performance (total N equals 20 runs)." 21 and best recollection is that that refers to 22 Do you see that? 22 the adult -- the positive control sera which 23 23 are adult lab volunteer sera. So sera outside You used the word must, you must 24 24 of Protocol 007. add. I'm sorry. 25 25 You might have. So your testimony is that these Q.

87 (Pages 342 - 345)

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Page 346	1	Page 348
		mumps for the AIGENT? MR. SANGIAMO: Object to the
_		form.
· ·		THE WITNESS: It's version .02
		of at least from the title version
		.02 of the "Plaque Reduction
	_	Neutralization Assay for Mumps
		Analytical Validation Protocol."
·		BY MR. KELLER:
		Q. Is this the final?
•		A. It's marked sorry. The
•		signatures are initial review. I cannot tell
		from the document whether it's final or not.
		Q. If you look on the first page,
		that's your signature. Correct?
		A. Yes.
		Q. That's February 12, 2001, when
		you signed this?
		A. 21st of February 21, 2001.
		Q. And what was the date of the
		last signature? Is that March 6, 2001?
		A. Looks like March 6th looks
		like the last signature.
volunteers.		Q. In the first paragraph of the
Q. You don't think he was talking	25	signature part of this validation protocol, do
		Page 349
_	1	you recall whether or not there was a final
		validation protocol different from this
		exhibit?
		MR. SANGIAMO: Object to the
	5	form.
control sera. So it was not related to the	6	THE WITNESS: I don't recall.
dropping from 100 to 50 but was referring to	7	BY MR. KELLER:
	8	Q. Here it says, quote, the final
	9	review is not circled, only the initial
	10	review. Do you see that on the first page?
next exhibit as Exhibit 37.	11	A. Yes.
	12	Q. You don't recall ever seeing a
(Exhibit Krah-37, Plaque	13	final review that was circled. Correct?
(Exhibit Krah-37, Plaque Reduction Neutralization Assay for	13 14	A. I don't recall.
Reduction Neutralization Assay for	14	A. I don't recall.
Reduction Neutralization Assay for Mumps Analytical Validation Protocol	14 15	A. I don't recall.Q. Here it says in the first
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for	14 15 16	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for	14 15 16 17	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your acceptance of a validated protocol of the
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for identification.)	14 15 16 17 18	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your acceptance of a validated protocol of the attached validation protocol, given that no
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for identification.) MR. KELLER: For the record,	14 15 16 17 18 19	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your acceptance of a validated protocol of the attached validation protocol, given that no comments are provided by any of the reviewers.
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for identification.) MR. KELLER: For the record, Exhibit 37 is a document that bears	14 15 16 17 18 19 20	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your acceptance of a validated protocol of the attached validation protocol, given that no comments are provided by any of the reviewers. If comments are received, the protocol will be
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for identification.) MR. KELLER: For the record, Exhibit 37 is a document that bears Bates stamp number 337307 through 318.	14 15 16 17 18 19 20 21	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your acceptance of a validated protocol of the attached validation protocol, given that no comments are provided by any of the reviewers. If comments are received, the protocol will be revised and recirculated, with the comments
Reduction Neutralization Assay for Mumps Analytical Validation Protocol (v.02), 337307 - 337318, was marked for identification.) MR. KELLER: For the record, Exhibit 37 is a document that bears Bates stamp number 337307 through 318. BY MR. KELLER:	14 15 16 17 18 19 20 21 22	A. I don't recall. Q. Here it says in the first paragraph, Your signature below indicates your acceptance of a validated protocol of the attached validation protocol, given that no comments are provided by any of the reviewers. If comments are received, the protocol will be revised and recirculated, with the comments appropriately incorporated or addressed. Do
	volunteers. Q. You don't think he was talking Page 347 about the reduction from 100 pediatric sera down to 50? A. My reading of this and my recollection of this was that he was referring to the number of runs that we had with the control sera. So it was not related to the dropping from 100 to 50 but was referring to how many assays in which the adult lab volunteer control sera were run. MR. KELLER: Let me mark the	Protocol 007 sera. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: I don't believe you're capturing the assay format accurately. In a given assay, sera from a given study can be tested and there are control sera tested. So these are not 20 assays of only control sera but 20 assays, as best I understand this, 20 assays in which control sera were included. BY MR. KELLER: Q. That control sera, you said that would include the mock? A. Sorry, that in the paragraph it's listed as one of the controls, but the control sera that, my understanding, Tim Schofield is referring to are the positive control sera. Q. The adult sera? A. The adult sera, the lab volunteers. Q. You don't think he was talking Page 347 about the reduction from 100 pediatric sera down to 50? A. My reading of this and my recollection of this was that he was referring to the number of runs that we had with the control sera. So it was not related to the dropping from 100 to 50 but was referring to how many assays in which the adult lab volunteer control sera were run. MR. KELLER: Let me mark the next exhibit as Exhibit 37.

88 (Pages 346 - 349)

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	HIGHLY CONFIDENTIAL -		
	Page 350		Page 352
1	page 337314, Karen Hencken.	1	MR. SANGIAMO: Objection to the
2	A. Okay.	2	form. You said produced.
3	Q. So she is identified as a "World	3	MR. KELLER: Sorry. I'll start
4	Wide Quality Assurance." Do you see that?	4	over. Getting tired here. Strike my
5	A. Yes.	5	last question.
6	Q. She checked off "Comments." Do	6	BY MR. KELLER:
7	you see that?	7	Q. "It is understood that these
8	A. There is a check mark next to	8	experiments will be performed in a GLP
9	comments.	9	compliant laboratory to ensure the validity of
10	Q. Here under your instructions for	10	the data."
11	signing this document it states that if	11	Do you see that?
12	comments are received, the protocol will be	12	A. Yes.
13	revised and recirculated, with the comments	13	Q. Do you know whether or not these
14	appropriately incorporated or addressed. Do	14	submissions were ever given to CBER?
15	you see that on the first page, on every	15	A. I don't that, I don't know.
16	signature page?	16	Q. Who do you know, was that
17	A. Yes.	17	something that you put into the signature
18	Q. Would you be would you expect	18	page, this is only done pursuant to a GLP
19	that since Karen Hencken had checked the box	19	compliant laboratory and not a GMP or G
20	as having comments, that there would have been	20	Good Clinical Practices laboratory?
21	another version of this based on the	21	MR. SANGIAMO: Object to the
22	instructions of this signature page?	22	form.
23	A. I would not say given the	23	MR. KELLER: Strike that.
24	wording that is here, I would not say with	24	BY MR. KELLER:
25	certainty that a new version would be issued,	25	Q. This reference to GLP, do you
	D 251		D 252
	Page 351		Page 353
1	but indicates that the protocol would be if	1	recall who put that in the signature line?
1 2	but indicates that the protocol would be if comments are received, the protocol will be	1 2	recall who put that in the signature line? A. I don't
	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments	2 3	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the
2 3 4	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If	2 3 4	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form.
2 3	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If they're addressed in a way that doesn't	2 3	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form. THE WITNESS: recall with
2 3 4	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If they're addressed in a way that doesn't require incorporation, it may not require a	2 3 4	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form.
2 3 4 5	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If they're addressed in a way that doesn't require incorporation, it may not require a new version. In this case, I can't speak to	2 3 4 5 6 7	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form. THE WITNESS: recall with certainty. I don't recall that I put that in there.
2 3 4 5 6 7 8	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If they're addressed in a way that doesn't require incorporation, it may not require a new version. In this case, I can't speak to what the comments were or whether a new	2 3 4 5 6 7 8	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form. THE WITNESS: recall with certainty. I don't recall that I put that in there. BY MR. KELLER:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If they're addressed in a way that doesn't require incorporation, it may not require a new version. In this case, I can't speak to what the comments were or whether a new version was issued. Q. You don't know you don't recall what her comments were? MR. SANGIAMO: Object to the form. THE WITNESS: At least from this document, I don't see, or nothing looks I don't have any indication what the comments were. BY MR. KELLER: Q. If you go on in the signature instructions, in the first in front of every signature page it says, It is understood that these experiments will be produced in a GLP compliant laboratory to ensure the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form. THE WITNESS: recall with certainty. I don't recall that I put that in there. BY MR. KELLER: Q. And that really is that's a true statement, that your lab was only compliant to GLP. Correct? Strike that. Was your lab compliant with the GLP requirements MR. SANGIAMO: Object to the form. BY MR. KELLER: Q as of the date of this document? A. At this moment I'd say my understanding of GLP is not extensive, so I can't comment on whether we were or weren't compliant with GLP. Q. Let me direct your attention to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	but indicates that the protocol would be if comments are received, the protocol will be revised and circulated, with comments appropriately incorporated or addressed. If they're addressed in a way that doesn't require incorporation, it may not require a new version. In this case, I can't speak to what the comments were or whether a new version was issued. Q. You don't know you don't recall what her comments were? MR. SANGIAMO: Object to the form. THE WITNESS: At least from this document, I don't see, or nothing looks I don't have any indication what the comments were. BY MR. KELLER: Q. If you go on in the signature instructions, in the first in front of every signature page it says, It is understood that these experiments will be produced in a GLP compliant laboratory to ensure the validity of the data. Do you see that?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	recall who put that in the signature line? A. I don't MR. SANGIAMO: Object to the form. THE WITNESS: recall with certainty. I don't recall that I put that in there. BY MR. KELLER: Q. And that really is that's a true statement, that your lab was only compliant to GLP. Correct? Strike that. Was your lab compliant with the GLP requirements MR. SANGIAMO: Object to the form. BY MR. KELLER: Q as of the date of this document? A. At this moment I'd say my understanding of GLP is not extensive, so I can't comment on whether we were or weren't compliant with GLP. Q. Let me direct your attention to the body of the protocol. Have you when
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HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

Page 354 1 A. I don't recall. 2 Q. I assume you read it before you 3 signed it. Correct? 4 A. Yes. 5 Q. If you want to take a minute to 6 review this protocol, why don't you do that. 7 Let me know when you're done. 8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I don't recall with 22 experiments? 3 A. I can't I don't recall with 23 cetrainty. 4 cetrainty. 5 Q. Would you would it be fair to 6 say that the protocol reduced by half the 7 number of pediatric sera to be tested as part 8 of the validation experiments from what was 9 proposed by Joe Antonello in October of 20 10 to what ended up in the final or in this draft 11 of the validation protocol? 12 A. I would say numerically I can't 13 see if there are other pediatric sera included 14 in this, but it looks, at least from my 15 reading of it, approximately half the number 16 of pre- and post-vaccination paired pediatric 17 samples were included, but I would point out that amongst the evaluation or the validation 18 evaluations, it looks like the pediatric 20 samples will be divided among multiple assar 21 a. I do. It's 874.3679. You said 22 a. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? 18 MR. SANGIAMO: You also 26 protocol? 27 minute of pediatric sera to be tested as part 28 of the validation experiments from what was 29 proposed by Joe Antonello in October of 20 20 to what ended up in the final or in this draft 21 of the validation protocol? 22 A. I would say numerically I can't 23 see if there are other pediatric sera included 24 in this, but it looks, at least from my 25 reading of
2 Q. I assume you read it before you 3 signed it. Correct? 4 A. Yes. 5 Q. If you want to take a minute to 6 review this protocol, why don't you do that. 7 Let me know when you're done. 8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 MR. SANGIAMO: You also 2 experiments? 3 A. I can't I don't recall with 4 certainty. 5 Q. Would you would it be fair to 6 say that the protocol reduced by half the 6 number of pediatric sera to be tested as part 6 of the validation experiments from what was 7 proposed by Joe Antonello in October of 20 8 to what ended up in the final or in this draft 9 of the validation protocol? 10 to what ended up in the final or in this draft 11 of the validation protocol? 12 A. I would say numerically I can't 13 see if there are other pediatric sera included 14 in this, but it looks, at least from my 15 reading of it, approximately half the number 16 of pre- and post-vaccination paired pediatric 17 samples were included, but I would point on 18 that amongst the evaluation or the validation 19 evaluations, it looks like the pediatric 10 samples will be divided among multiple assar 11 runs that is not a number reduced from the 12 original proposal. 12 Q. So is it your testimony, sir, 13 that there was 100 paired samples tested of 14 pediatric serum as part of this validation
3 signed it. Correct? 4 A. Yes. 5 Q. If you want to take a minute to 6 review this protocol, why don't you do that. 7 Let me know when you're done. 8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 MR. SANGIAMO: You also 27 Page 355 28 Mould you would it be fair to certainty. 5 Q. Would you would it be fair to say that the protocol reduced by half the 6 retwinty. 5 Q. Would you would it be fair to say that the protocol reduced by half the 7 number of pediatric sera to be tested as part of the validation experiments from what was proposed by Joe Antonello in October of 20 to what ended up in the final or in this draft of the validation protocol? 10 to what ended up in the final or in this draft of the validation protocol? 11 to fit evalidation protocol? 12 A. I would say numerically I can't in this, but it looks, at least from my reading of it, approximately half the number of pre- and post-vaccination paired pediatric samples were included, but I would point out that amongst the evaluation or the validation evaluations, it looks like the pediatric samples will be divided among multiple assignment and proposal. 24 Q. So is it your testimony, sir, that there was 100 paired samples tested of
4 A. Yes. 5 Q. If you want to take a minute to 6 review this protocol, why don't you do that. 7 Let me know when you're done. 8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 MR. SANGIAMO: You also 26 Cartainty. 5 Q. Would you would it be fair to say that the protocol reduced by half the 16 say that the protocol reduced by half the 16 number of pediatric sera to be tested as part 10 to what ended up in the final or in this draft 10 to what ended up in the final or in this draft 11 see if there are other pediatric sera included 12 in this, but it looks, at least from my 13 reading of it, approximately half the number of pre- and post-vaccination paired pediatric 14 samples were included, but I would point ou that amongst the evaluation or the validation evaluations, it looks like the pediatric 15 samples will be divided among multiple assay runs that is not a number reduced from the original proposal. 16 Q. So is it your testimony, sir, 17 that there was 100 paired samples tested of
5 Q. If you want to take a minute to 6 review this protocol, why don't you do that. 7 Let me know when you're done. 8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? 2 MR. SANGIAMO: You also 2 Page 355 1 MR. SANGIAMO: You also 5 Q. Would you would it be fair to say that the protocol reduced by half the number of pediatric sera to be tested as part of the validation experiments from what was proposed by Joe Antonello in October of 20 to what ended up in the final or in this draft of the validation protocol? 10 to what ended up in the final or in this draft of the validation protocol? 11 to what ended up in the final or in this draft of the validation protocol? 12 A. I would say numerically I can't see if there are other pediatric sera included in this, but it looks, at least from my reading of it, approximately half the number of pre- and post-vaccination paired pediatric samples were included, but I would point ou that amongst the evaluation or the validation evaluations, it looks like the pediatric samples will be divided among multiple assar runs that is not a number reduced from the original proposal. Q. So is it your testimony, sir, that there was 100 paired samples tested of
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7 number of pediatric sera to be tested as part 8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 3489. Correct? That's the SOP for the 25 AIGENT. Correct? 27 Inumber of pediatric sera to be tested as part of this validation experiments from what was of the validation protocol? 10 to what ended up in the final or in this draft of the validation protocol? 11 A. I would say numerically I can't see if there are other pediatric sera included in this, but it looks, at least from my reading of it, approximately half the number of pere and post-vaccination paired pediatric samples were included, but I would point out that amongst the evaluations or the validation evaluations, it looks like the pediatric samples will be divided among multiple assated as part of this validation experiments. 10 to what ended up in the final or in this draft of the validation protocol? 12 A. I would say numerically I can't see if there are other pediatric sera included in this, but it looks, at least from my reading of it, approximately half the number experiments. 12 A. I do. I say sa
8 A. Okay. 9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? 2 Met water direct your attention to 10 to what ended up in the final or in this draft 11 of the validation protocol? 12 A. I would say numerically I can't 13 see if there are other pediatric sera included 14 in this, but it looks, at least from my 15 reading of it, approximately half the number 16 of pre- and post-vaccination paired pediatric 17 samples were included, but I would point out 18 that amongst the evaluation or the validation 19 evaluations, the I'm sorry, the validation 20 evaluations, it looks like the pediatric 21 samples will be divided among multiple assar 22 runs that is not a number reduced from the 23 original proposal. 24 Q. So is it your testimony, sir, 25 that there was 100 paired samples tested of Page 355 1 pediatric serum as part of this validation
9 Q. Let me direct your attention to 10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 3489. Correct? That's the SOP for the 25 AIGENT. Correct? 29 proposed by Joe Antonello in October of 200 to what ended up in the final or in this draft of the validation protocol? 10 to what ended up in the final or in this draft of the validation protocol? 11 to what ended up in the final or in this draft of the validation protocol? 12 A. I would say numerically I can't see if there are other pediatric sera included in this, but it looks, at least from my reading of it, approximately half the number of pre- and post-vaccination paired pediatric samples were included, but I would point out that amongst the evaluation or the validation evaluations, it looks like the pediatric samples will be divided among multiple assar runs that is not a number reduced from the original proposal. 24 Q. So is it your testimony, sir, that there was 100 paired samples tested of Page 355 1 MR. SANGIAMO: You also
10 page 2 where it says, "Assay Validation 11 Experiments." 12 Do you see that? 13 A. Yes. 14 Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? 10 to what ended up in the final or in this draft 11 of the validation protocol? 12 A. I would say numerically I can't 13 see if there are other pediatric sera included 14 in this, but it looks, at least from my 15 reading of it, approximately half the number of pre- and post-vaccination paired pediatric samples were included, but I would point out that amongst the evaluation or the validation evaluations, it looks like the pediatric samples will be divided among multiple assar runs that is not a number reduced from the original proposal. 24 Q. So is it your testimony, sir, 25 that there was 100 paired samples tested of Page 355 1 MR. SANGIAMO: You also
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A. Yes. Q. Here it says, The plaque 15 reduction neutralization assay will be 16 performed according to the Department of Virus 17 Biologic Research Procedure Number 474.3489, 18 rev. 00 ("Anti-IgG Enhanced Mumps 19 Plaque-Reduction Neutralization Assay"). 20 Do you see that? 21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? Page 355 1 MR. SANGIAMO: You also 13 see if there are other pediatric sera included 14 in this, but it looks, at least from my 16 reading of it, approximately half the number 17 reading of it, approximately half the number of pre- and post-vaccination paired pediatric samples were included, but I would point out that amongst the evaluation or the validation evaluations, it looks like the pediatric samples will be divided among multiple assage original proposal. 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? Page 355 1 MR. SANGIAMO: You also 13 see if there are other pediatric sera included in this, but it looks, at least from my 15 reading of it, approximately half the number reading of it, approximately half the number of pre- and post-vaccination paired pediatric samples were included, but I would point out that amongst the evaluations, the I'm sorry, the validation evaluations, it looks like the pediatric samples will be divided among multiple assage runs that is not a number reduced from the original proposal. 24 Q. So is it your testimony, sir, that there was 100 paired samples tested of page of the pediatric serum as part of this validation
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21 A. I do. It's 874.3679. You said 22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? Page 355 1 MR. SANGIAMO: You also 21 samples will be divided among multiple assard runs that is not a number reduced from the original proposal. 22 runs that is not a number reduced from the original proposal. 23 original proposal. 24 Q. So is it your testimony, sir, 25 that there was 100 paired samples tested of
22 4. 23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? 26 Page 355 1 MR. SANGIAMO: You also 27 runs that is not a number reduced from the original proposal. 28 original proposal. 29 vuns that is not a number reduced from the original proposal. 20 that there was 100 paired samples tested of page 355
23 Q. Sorry. I apologize. 874 24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? 20 original proposal. 22 Q. So is it your testimony, sir, 23 that there was 100 paired samples tested of Page 355 Page 355 Page 355 Page 355 Page 355
24 .3489. Correct? That's the SOP for the 25 AIGENT. Correct? Page 355 MR. SANGIAMO: You also 24 Q. So is it your testimony, sir, 25 that there was 100 paired samples tested of Page 355 1 pediatric serum as part of this validation
25 AIGENT. Correct? 25 that there was 100 paired samples tested of Page 355 MR. SANGIAMO: You also Page 355 pediatric serum as part of this validation
Page 355 1 MR. SANGIAMO: You also 1 pediatric serum as part of this validation
1 MR. SANGIAMO: You also 1 pediatric serum as part of this validation
2 misidentified the department. You said 2 protocol?
3 virus and biologic research. It's 3 MR. SANGIAMO: Objection.
4 virus and cell biologic research. 4 Misstates testimony.
5 MR. KELLER: Strike that whole 5 THE WITNESS: No, that's not
6 thing. 6 what I was saying.
7 BY MR. KELLER: 7 BY MR. KELLER:
8 Q. Dr. Krah, under "Assay 8 Q. So these runs that you're
9 Validation Experiments," the second sentence 9 saying, the 50 runs that you're talking about
10 it says, "The validation experiment will 10 are you testifying that those 50 runs
11 include sera from 4 adults and approximately 11 represent 100 pairs of pediatric samples?
12 50 pre- and post-vaccination paired pediatric 12 MR. SANGIAMO: Objection.
13 samples." 13 Misstates the testimony.
14 Do you see that? 14 THE WITNESS: What I'm
15 A. Yes. 15 representing is that there are this
16 Q. And in the prior draft of this 16 is written that there are
17 protocol on Exhibit 35, on page 870114, it 17 approximately, in addition to the four
18 said, "100 pre- and post-vaccination paired 18 adults here, there's approximately 50
19 pediatric samples," and circled is a reference pre- and post-vaccination paired sera.
20 to "or fewer due to contamination." 20 Pediatric samples will be divided among the first personal.
Do you see that? 21 the next sorry, the first paragraph 22 arrange 227217 "The padictains compile
A. Yes. In the document 780114. 22 on page 337317, "The pediatrics sample 23 on page 337317, "The pediatrics sample 24 on page 337317, "The pediatrics sample 25 on page 377317, "The pediatrics sample 27 on page 377317, "The pediatrics sampl
Q. Do you recall that the number of 23 will be divided among multiple (7) assay runs with pre- and
24 pediatric sera that was proposed went from 100 24 assay runs with pre- and 25 down to 50 because of a problem with the sera 25 post-vaccination sample pairs being
23 down to 30 occause of a problem with the sera 23 post-vaccination sample pairs being

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Page 360 1 tested together in the same assay run." specification limits for the mock and positive 2 That the number of replicate runs is 2 control samples. 3 not reduced from the original proposal. 3 Do you see that? 4 BY MR. KELLER: 4 Yes. 5 Q. So it's your understanding that 5 MR. SANGIAMO: Object to the there would be additional samples run as part 6 6 form. of this validation protocol in order to -- is 7 BY MR. KELLER: 8 8 it -- strike that. Q. Did you understand that the mock 9 9 control samples that they're talking about Is it your belief that because 10 it says, "The pediatric samples will be 10 there, that they were all run in pediatric divided among multiple (7) assay runs...," samples, in those 50 paired samples run over 11 11 that that was going to happen in the future? 12 12 seven assay runs? 13 My understanding and my 13 A. I'm sorry, the mock is an 14 interpretation of that is that those -- the 50 14 inherent part of each assay, so it would be 15 pre- and post-vaccination serum pairs would be 15 run in every assay regardless of what sera are 16 split up among seven different assays. 16 tested. 17 Q. Did you believe as of the date 17 I see. So the control criteria 18 of this --18 will be updated after a sufficient number of 19 19 runs have been performed to obtain reliable MR. SANGIAMO: I'm sorry, Jeff. 20 BY MR. KELLER: 20 estimates of assay performance (N equals 20 21 Q. I didn't mean to cut you off. 21 runs). 22 A. As part of this -- as part of 22 Do you see that? 23 23 the validation. A. Yes. 24 Q. I see. Did you understand that 24 Q. That's what Schofield had 25 those runs were already -- those assay runs recommended that you put into the protocol. Page 361 were already completed by the time you drafted 1 Correct? 2 this protocol? Correct? Strike that. 2 That looks like -- appears to be 3 Those experiments, those 50 3 the wording that he recommended, at least N paired serum through seven assay runs were equals 20 runs, and updating it -- updated 4 4 5 5 already completed when this protocol, after a sufficient number of runs had been 6 validation protocol was signed. Correct? 6 performed. 7 7 A. I can't say that with certainty. Q. You don't know whether or not 8 Well, Joe Antonello on 8 those runs were from runs using Protocol 007 Q. 9 October 30th said we've already run half of 9 sera or runs using sera from -- that Merck had them. Right? So half of the 50 -- half of 10 acquired through other sources? the 100 is 50. Correct? 11 11 MR. SANGIAMO: Object to the 12 12 A. I can't say with certainty that form 13 the 50 that he's referring to is the 50 that 13 THE WITNESS: I don't recall 14 we wound up using. 14 which sera were --15 15 BY MR. KELLER: I see. And so he goes on in the next paragraph to state that, Each validation 16 Q. Can you -- as you sit --MR. SANGIAMO: Jeff. 17 run will include testing on the mock control, 17 18 and on the positive control sample (adult 18 BY MR. KELLER: 19 sera). Note that some of the pediatric serum 19 Q. I'm sorry. Go ahead. A. I don't recall which sera 20 assays and specificity assays include a single 20 21 control serum. All assays of clinical sera 21 were -- where the source -- I can't tell from will include two control sera (low and high 22 this document what the source of the pediatric 23 23 titer). The data arising from the validation sera was. 24 experiment will be used to establish assay 24 As you sit here today, do you validity criteria in the form of tentative 25 see any problems with Merck using the sera

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	Page 362		Page 364
1	from Protocol 007 to run those 20 runs?	1	you, Dr. Krah, dated December 10, 2001.
2	MR. SANGIAMO: Object to the	2	Actually two of your e-mails. I'll draw your
3	form.	3	attention to the first e-mail on December 10th
4	THE WITNESS: I have a general	4	at 12:22 p.m.
5	understanding of the sorry, I'm not	5	A. I'm sorry, what was that?
6	familiar with the specific requirements	6	Q. The third paragraph down.
7	for a validation study. I have	7	A. Bottom e-mail, okay.
8	a general perception, this is personal	8	MR. SANGIAMO: Read the e-mail.
9	perception, that the sera from a	9	BY MR. KELLER:
10	pediatric sera the pediatric sera	10	Q. You write, "The testing of
11	from a clinical study would not be used	11	the"
12	as part of a validation study. That	12	MR. SANGIAMO: Hold on, he
13	would not apply, in my view, to adult	13	hasn't read it.
14	lab volunteer sera.	14	MR. KELLER: I'll read it.
15	BY MR. KELLER:	15	MR. SANGIAMO: He hasn't read
16	Q. Correct. Because those adult	16	the e-mail.
17	sera are not run in the Protocol 007 sera.	17	MR. KELLER: He can read it.
18	Those are Protocol 007 sera from the kids that	18	MR. SANGIAMO: He's going to
19	were gathered as part of the protocol in the	19	read a particular paragraph and when
20	study. Correct?	20	he's done reading the e-mail, then you
21	MR. SANGIAMO: Object to the	21	ask the question.
22	form.	22	BY MR. KELLER:
23	BY MR. KELLER:	23	Q. I'm just going to ask you
24	Q. Strike that. That was a	24	questions about this one sentence. It says,
25	terrible question. I'll leave it at that.	25	quote, The testing of the interim analysis set
	Page 363		Page 365
1	Let me have you turn did you	1	started on December 6, 2000, and ended
2	ever discuss with Joe Antonello those I	2	January 26, 2001.
3	showed you a document earlier where you state		My question is, is that a true
4	you started running samples in Protocol 007 on		and correct statement as to when the sera from
5	December 6, 2000. Do you recall that?	5	Protocol 007 preliminary subset was run?
6	A. I don't recall the specific	6	That's all I want to ask about this document.
7	date.	7	MR. SANGIAMO: Read the e-mail
8	Q. Do you recall that you were	8	and then answer the question.
9	already running clinical samples from Protocol	9	MR. KELLER: He doesn't need to
10	007 during the time that you were validating	10	read the entire e-mail to do that, but
11	the protocol?	11	go ahead.
12	MR. SANGIAMO: Object to the	12	THE WITNESS: I can't verify
13	form.	13	this independently, but I interpret
14	THE WITNESS: I'm not able to	14	that next to the next to the last
15	confirm dates.	15	paragraph to mean that no testing of
16	MR. KELLER: Let me mark the	16	protocol sera was started prior to the
17	next exhibit, Exhibit 38, which bears	17	start date listed as 06, December 2000.
18	Bates stamp number 52242.	18	BY MR. KELLER:
19		19	Q. That's not my question. My
20	(Exhibit Krah-38, 12/10/99	20	question is okay. That's fine.
21	E-mails, 52242, was marked for	21	MR. SANGIAMO: That is your
22	identification.)	22	question.
23		23	MR. KELLER: That is my
24	BY MR. KELLER:	24	question. You're right. Got you.
25	Q. It's a single-page e-mail from	25	BY MR. KELLER:

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	Page 366		Page 368
1	Q. So is it other than this	1	the validation protocol. February 15, 2001,
2	e-mail, you don't recall starting running	2	was before the final signature on the
3	samples from Protocol 007 before you had	3	validation protocol of March 6, 2001.
4	validated the SOP. Correct?	4	Correct?
5	MR. SANGIAMO: Object to the	5	A. I believe the
6	form.	6	Q. This is before you even signed
7	THE WITNESS: I don't recall the	7	the validation protocol. Correct?
8	dates. This has listed dates for the	8	A. Let's see. I signed it
9	validation. There are assays to	9	February 21st of 2001.
10	evaluate variability inter and	10	Q. Can I direct your attention to
11	intraassay for the adult lab sera panel	11	February 15th in your journal which is at
12	that are after that start date.	12	490641 640. Let me know when you're there.
13	BY MR. KELLER:	13	A. 641?
14	Q. And so going back to Exhibit 38,	14	Q. Right. 640, Tuesday,
15	the assays that are identified here, it	15	February 15th, do you see that? Or Thursday,
16	says you write to Alan Shaw, "The following	16	February
17	summarizes the timing of the experiments done	17	A. Thursday.
18	to support validation studies of the mumps	18	Q. I mean Thursday, February 15,
19	AIGENT assay."	19	2001. The second page of that, there is a
20	Do you see that?	20	reference to you having a meeting with
21	A. Yes.	21	Dr. Emini at 1:30 p.m. to update the MPS Nt
22	Q. Those are the validation studies	22	data. Do you see that?
23	that are that were to be run described	23	A. Yes.
24	in the validation protocol?	24	Q. Do you recall you testified
25	MR. SANGIAMO: Object to the	25	earlier that you recall having a meeting with
	Page 367		Page 369
1	form.	1	Dr. Emini regarding him describing a warning
2	THE WITNESS: I can say that	2	letter. Can you read, for the record, what
3	would say that those are experiments	3	you wrote in your journal?
4	that are experiments done in support	4	MR. SANGIAMO: Object to the
5	of the validation studies that would be	5	preamble. If you want him to read
6	part of the validation protocol.	6	what's written in the journal, that's
7	Whether this is all inclusive, I can't	7	fine.
8	say.	8	BY MR. KELLER:
9	BY MR. KELLER:	9	Q. Out loud, please.
10	Q. Do you have any reason to	10	A. What it says, it's a meeting
11	believe that this is not the list of	11	with Emilio 1:30 p.m. to update the mumps neut
12	experiments that were used to validate	12	data. Merck has been issued a "warning
	Protocol 007's AIGENT?	13	letter" from the FDA regarding mumps titers
13			
13 14		14	data - The data that we have generated will be
	MR. SANGIAMO: Object to the form.	14	data - The data that we have generated will be needed to include in the response (due within
14 15	MR. SANGIAMO: Object to the form.		needed to include in the response (due within
14 15 16	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell	15	needed to include in the response (due within 14 days from receipt) to provide a "comfort
14 15 16 17	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are	15 16	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data
14 15 16 17 18	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation	15 16 17	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to
14 15 16 17 18 19	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation studies. I don't have any information	15 16 17 18 19	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to change the label/license.
14 15 16 17 18 19 20	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation studies. I don't have any information to the contrary that they were not part	15 16 17 18 19 20	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to change the label/license. Q. Do you recall that conversation
14 15 16 17 18 19 20 21	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation studies. I don't have any information to the contrary that they were not part of what was used in the validation	15 16 17 18 19 20 21	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to change the label/license. Q. Do you recall that conversation with Mr with Dr. Emini?
14 15 16 17 18 19 20 21 22	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation studies. I don't have any information to the contrary that they were not part of what was used in the validation protocol.	15 16 17 18 19 20 21 22	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to change the label/license. Q. Do you recall that conversation with Mr with Dr. Emini? A. I have a recollection of a
14 15 16 17 18 19 20 21 22 23	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation studies. I don't have any information to the contrary that they were not part of what was used in the validation protocol. BY MR. KELLER:	15 16 17 18 19 20 21 22 23	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to change the label/license. Q. Do you recall that conversation with Mr with Dr. Emini? A. I have a recollection of a meeting where Emilio mentioned the warning
14 15 16 17 18 19 20 21 22	MR. SANGIAMO: Object to the form. THE WITNESS: All I can tell you, this lists assays that are indicated in support of validation studies. I don't have any information to the contrary that they were not part of what was used in the validation protocol.	15 16 17 18 19 20 21 22	needed to include in the response (due within 14 days from receipt) to provide a "comfort factor" with the vaccine dose. The full data set from Protocol 007 would be needed to change the label/license. Q. Do you recall that conversation with Mr with Dr. Emini? A. I have a recollection of a

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	Page 370		Page 372
1	Q. So your reference to comfort	1	Do you see that?
2	factor in quotes, you don't recall what he	2	A. "draft validation report
	said about that?	3	Thursday/Friday."
4	A. No, I don't.	4	Q. So Robin that's Robin
5	Q. Do you recall but you	5	Wolchko. Correct?
6	understood that the results of the preliminary	6	A. The sentence there are a
	subset would be used to respond to a warning	7	couple of sentences before it, it says, "Note:
	letter from the FDA. Correct?	8	all data sent to Robin Wolchko" I don't
9	MR. SANGIAMO: Object to the	9	know any other Robin.
10	form.	10	Q. And Robin sorry, I didn't
11	THE WITNESS: My interpretation	11	mean to cut you off.
12	is that, as it says, the data that we	12	A. That is the Robin.
13	have will be needed. I don't know what	13	Q. Robin worked she worked with
14	needed means. Needed to include.	14	Joe Antonello working on the validation
	BY MR. KELLER:	15	report. Correct?
16	Q. Do you recall whether or not the	16	A. As best I can recall, she was on
	results of the preliminary subset that was run	17	the validation report, one of the authors of
	by your lab was submitted to the FDA in	18	the validation report along with Joe
	response to the warning letter?	19	Antonello.
20	A. I recall that the data, or at	20	Q. Here, can you read what you
	least my I recall that the data from that	21	wrote under that statement about her having a
	subset analysis were provided. Whether it was	22	draft validation report Thursday/Friday?
	in response to the warning letter, I can't say	23	Strike that.
	with certainty.	24	Does this indicate that you had
25	Q. In the reference here to the	25	a conversation with Robin Wolchko
1 .	Page 371	1	Page 373
	full data set from Protocol 007 being needed	2	MR. SANGIAMO: Object to the form.
	to change the label/license. Do you understand what you meant when you wrote that?	3	BY MR. KELLER:
4	A. No.	4	Q on February 21, 2001? Is
5	Q. Do you recall what Protocol 007,	5	that a fair statement, to say that you spoke
	the purpose of Protocol 007 was to change the	6	to Robin on that date regarding the draft
	end expiry specifications for the mumps	7	validation report?
	component of the MMR II product?	8	A. All I can say is that she
9	MR. SANGIAMO: Object to the	9	indicated she expects to have a draft
10	form.	10	validation report Thursday or Friday which
	THE WITNESS: My understanding	l	would indicate some communication. Whether it
11 12	of the purpose of the study was to	12	was a conversation or e-mail, I don't know.
13	compare the immunogenicity of three	13	Q. Can you read what you wrote
14	different doses of mumps. As far as	14	under that?
15	what it's the data would be used	15	A. It says, "I commented on my
16	for, I don't have a recollection.	16	observations from the Protocol 007 serum set
10	BY MR. KELLER:	17	assays-mock value 8.67 was not," there's a
17		1 /	•
		18	typo of some kind Y-F-D. I don't know what
18	Q. Let me direct your attention to	18 19	typo of some kind Y-E-D. I don't know what
18 19	Q. Let me direct your attention to February your February 21, 2001, journal	19	that might be I don't know what that is.
18 19 20	Q. Let me direct your attention to February your February 21, 2001, journal entry on Wednesday, which is 490648.	19 20	that might be I don't know what that is. Comma,and all other runs were
18 19 20 21	Q. Let me direct your attention to February your February 21, 2001, journal entry on Wednesday, which is 490648. A. Okay.	19 20 21	that might be I don't know what that is. Comma,and all other runs were approximately 10.25 to 30.5 pfu for mock;
18 19 20 21 22	Q. Let me direct your attention to February your February 21, 2001, journal entry on Wednesday, which is 490648. A. Okay. Q. If you direct your attention to	19 20 21 22	that might be I don't know what that is. Comma,and all other runs were approximately 10.25 to 30.5 pfu for mock; control sera were with a range of fourfold
18 19 20 21 22 23	Q. Let me direct your attention to February your February 21, 2001, journal entry on Wednesday, which is 490648. A. Okay. Q. If you direct your attention to page 490650, there's a reference to Robin.	19 20 21 22 23	that might be I don't know what that is. Comma,and all other runs were approximately 10.25 to 30.5 pfu for mock; control sera were with a range of fourfold across all assays.
18 19 20 21 22 23 24	Q. Let me direct your attention to February your February 21, 2001, journal entry on Wednesday, which is 490648. A. Okay. Q. If you direct your attention to	19 20 21 22	that might be I don't know what that is. Comma,and all other runs were approximately 10.25 to 30.5 pfu for mock; control sera were with a range of fourfold

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	Page 374		Page 376
1	Robin about your observations from running the	1	"Note: signatures were," can you read the
2	serum from Protocol 007?	2	next reference?
3	MR. SANGIAMO: Object to the	3	A. Yes. Note: Signatures were
4	form.	4	received from first round of reviews of
5	THE WITNESS: I take the comment	5	validation protocol from everyone except Jerry
6	to mean that I was providing feedback	6	Sadoff.
7	to her on how the mock value was	7	Q. In the validation version .02
8	performing in the assays. Not the	8	that we have as Exhibit 37, he didn't sign the
9	assays overall, but just what the mock	9	protocol, the validation protocol, did he?
10	pfu value was.	10	A. I see next to his name an NA.
11	BY MR. KELLER:	11	Q. And is that your handwriting,
12	Q. And the assays you're referring	12	the NA?
13	to are the serum that was run as part of	13	A. That looks like, yeah, that's my
14	Protocol 007. Correct?	14	handwriting.
15	MR. SANGIAMO: Object to the	15	Q. And did you talk to Dr. Sadoff
16	form.	16	as to why he didn't sign the validation
17	THE WITNESS: No. They're in	17	protocol?
18	assays where serum was tested. The	18	A. I cannot say with certainty, but
19	mock results are in the absence of	19	I can say I would not have put NA next to his
20	serum.	20	name without some feedback on whether that was
21	BY MR. KELLER:	21	appropriate.
22	Q. But those are in the Protocol	22	Q. Did Dr. Sadoff voice any
23	007 experiments, correct, the kids serum in	23	reservations about signing the protocol?
24	Protocol 007?	24	A. Not that I recall.
25	MR. SANGIAMO: Object to the	25	Q. Did you get his approval to
	Page 375		Page 377
1	Page 375 form.	1	Page 377 write NA next to that his name on the
1 2	form.	1 2	-
			write NA next to that his name on the
2	form. THE WITNESS: They're data from	2	write NA next to that his name on the protocol? A. I don't recall.
2 3	form. THE WITNESS: They're data from experiments in which Protocol 007 were	2 3	write NA next to that his name on the protocol? A. I don't recall.
2 3 4	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving	2 3 4	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to
2 3 4 5	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical	2 3 4 5	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a
2 3 4 5 6	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera.	2 3 4 5 6	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's
2 3 4 5 6 7	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating	2 3 4 5 6 7	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do
2 3 4 5 6 7 8	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER:	2 3 4 5 6 7 8	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes.
2 3 4 5 6 7 8 9	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the	2 3 4 5 6 7 8 9	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)."
2 3 4 5 6 7 8 9	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the Protocol 007 assay using the SOP and the	2 3 4 5 6 7 8 9	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes. Q. Do you recall that meeting
2 3 4 5 6 7 8 9 10 11	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the Protocol 007 assay using the SOP and the AIGENT. Correct?	2 3 4 5 6 7 8 9 10 11	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes. Q. Do you recall that meeting happening?
2 3 4 5 6 7 8 9 10 11 12	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the Protocol 007 assay using the SOP and the AIGENT. Correct? MR. SANGIAMO: Object to the	2 3 4 5 6 7 8 9 10 11 12	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes. Q. Do you recall that meeting happening? A. I recall meetings with Emilio.
2 3 4 5 6 7 8 9 10 11 12 13	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the Protocol 007 assay using the SOP and the AIGENT. Correct? MR. SANGIAMO: Object to the form.	2 3 4 5 6 7 8 9 10 11 12 13	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes. Q. Do you recall that meeting happening? A. I recall meetings with Emilio. I don't recall what that particular meeting
2 3 4 5 6 7 8 9 10 11 12 13 14	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the Protocol 007 assay using the SOP and the AIGENT. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: Yes, but only in	2 3 4 5 6 7 8 9 10 11 12 13 14	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes. Q. Do you recall that meeting happening? A. I recall meetings with Emilio. I don't recall what that particular meeting was about.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	form. THE WITNESS: They're data from experiments in which Protocol 007 were tested but not directly involving they're not data from the clinical sera. BY MR. KELLER: Q. I see. But you were updating Robin about your experience from running the Protocol 007 assay using the SOP and the AIGENT. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: Yes, but only in the context of what the mock value was BY MR. KELLER: Q. And in the content of that I see what you're saying. Then it goes on to MR. SANGIAMO: Did you finish your answer? THE WITNESS: I was going to say the mock values in those assays.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	write NA next to that his name on the protocol? A. I don't recall. Q. Let me direct your attention to the next day, which is February 22nd, there's a reference in the middle of 490650 to a Meeting at 1:00 for our lab and Emilio do you see that? "(in his office)." A. Yes. Q. Do you recall that meeting happening? A. I recall meetings with Emilio. I don't recall what that particular meeting was about. Q. Do you recall a meeting with Emilio where there was discussions of bonuses if the Protocol 007 assay was completed successfully? MR. SANGIAMO: Object to the form. THE WITNESS: I do not recall that discussion. BY MR. KELLER:

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	Page 378	1	Page 380
1	you spoke to Robin. There's a reference in	1	actually proposed the limit or said we
2	the middle at top of the page, it says, "Reply	2	would like a limit. So as I my
3	to Joe Antonello's phone call"	3	first thought was that there may have
4	Do you see that?	4	been a limit that CBER suggested, but
5	A. I'm sorry, 1651?	5	in reading this, I'm my understanding
6	Q. Right here. Do you see that?	6	is that he's suggesting ten is a lower
7	A. Okay.	7	limit, and the upper limit there's some
8	Q. So under that can you read	8	exchange of what we mutually agree
9	what you wrote under that?	9	would be a suitable upper limit.
10	A. Yes. It says, "Extravariability	10	BY MR. KELLER:
11	evaluation - he can add this to our	11	Q. Is he proposing ten or are you
12	spreadsheets? I proposed - not for current	12	proposing ten?
13	set - no time to reevaluate and reaudit."	13	A. He is proposing ten.
14	Q. So this was for the preliminary	14	Q. How do you get that? Is that
15	subset, you were not going to use whatever	15	something you recall or just how you read
16	extravariability flags that were set up on a	16	this?
17	preliminary subset. Were those run? Is that	17	A. I don't it would not be a
18	true?	18	limit that I would have a basis on providing
19	MR. SANGIAMO: Object to the	19	or generating. I recall subsequent
20	form.	20	discussions with him to understand his
21	THE WITNESS: I can't tell with	21	rationale for ten is a lower limit.
22	certainty what set that applies to.	22	Q. So you weren't proposing using ten?
23	BY MR. KELLER:	23 24	
24 25	Q. And under that you say, "For the plaque count limit proposed by CBER." Can you	25	A. To the best of my recollection, Joe was the one, Joe Antonello was the one
23	plaque could fillit proposed by CBER. Call you	23	Joe was the one, Joe Antoneno was the one
1	Page 379	1	Page 381
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	read that?	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	proposing ten as the lower limit.
$\frac{2}{3}$	A. Yes. It says, "use 10 as lower limit. For upper limit, he proposes using	$\frac{2}{3}$	Q. You discussed with him the upper limit. He talked about 50 to 60 and you said
4	whatever is the upper counting range (50-60?).	4	10 to 40 seems best to you. Correct?
5	50 seems okay to me (although a range of 10 to		MR. SANGIAMO: Object to the
6	40 seems best to me, as an average of 20 plus	6	form.
7	or minus twofold range)."	7	THE WITNESS: That's what it
8	Q. So you're can you tell me	8	says there.
9	what you're doing here when you're this	9	BY MR. KELLER:
10	is your this is a conversation you're	10	Q. Is there any clinical
11	having with Joe Antonello. Correct?	11	significance to the mock control range?
12	MR. SANGIAMO: Object to the	12	MR. SANGIAMO: Object to the
13	form.	13	form.
14	THE WITNESS: There is a	14	THE WITNESS: Not that I'm aware
15	proposal that and I don't recall the	15	of.
16	specific CBER proposal of a limit that	16	BY MR. KELLER:
17	suggests for the plaque count limit	17	Q. Is that used to set the
18	based on the validation study that Joe	18	serostatus cutoff?
19	analyzed he is proposing. A limit, and	19	A. No.
20	I don't I can't tell from this	20	Q. What is the mock range set
21	what how that actually how that	21	for what is it used for in an assay?
22	compares to CBER's description. But as	22	A. It is used to calculate the
23	I'm reading this, the wording is such	23	percent value percent plaque numbers for
24	for the plaque count limit proposed by	24	test sample relative to a to the mocks and
25	CBER. I don't recall that CBER	25	then determine whether a sample is
- 1			1

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1	Page 382		Page 384
1	neutralizing or not.	1	780093 & 780094, was marked for
2	Q. So whether or not it's a the	2	identification.)
3	sample is a seroconverter or	3	
4	non-seroconverter. Correct?	4	BY MR. KELLER:
5	MR. SANGIAMO: Object to the	5	Q. Let me mark as Exhibit 39 a
6	form.	6	document that bears Bates stamp numbers 780093
7	BY MR. KELLER:	7	through 94. It's a fax from you, Dr. Krah, to
8	Q. It's used in that calculation.	8	Joe Antonello, dated February 22, 2001. And
9	Correct?	9	is that your handwriting on the second page?
10	A. Not directly. It's used on an	10	A. Yes, it looks like my handwriting.
11	individual sera basis to calculate the number	11	Q. Is this what you faxed to Joe
12	of plaques as a percent of the mock value. So	12	Antonello that's referenced in your journal on
13	it identifies whether a given serum, it	13	February 22, 2001?
14	identifies the titer for a given serum. The	14	A. I don't have an independent
15	seroconversion is a second calculation.	15	recollection of it. It indicates I'm sending
16	Q. And does the 10-40 play into	16	a summary of the mock serum pfu and titers for
17	that calculation at all?	17	MKY and CM serum, which is included in the
18	MR. SANGIAMO: Object to the	18	data on the back of page 2 of that. So I
19	form.	19	can't independently confirm it, but it looks
20 21	THE WITNESS: The range is only	20 21	consistent with what was on the is on the
$\begin{vmatrix} 21\\22\end{vmatrix}$	used, from my understanding, to		back pages, captures the same classification
$\begin{vmatrix} 22 \\ 23 \end{vmatrix}$	calculate the plaque count toward test sample relative to the mock for a given	22 23	or categories of data.
$\frac{23}{24}$	serum sample.	24	Q. So looking at this is your
25	BY MR. KELLER:	25	handwriting, though. Correct? A. Yes.
23	DI WIK. KELLEK.	23	A. 165.
١.	Page 383	١.	Page 385
1	Q. So later on you write, "Fax	1	Q. And here there's a listing of 44
2	summary of results from Protocol 007 testing	2	assays. Do you see that? There's a reference
3	to Joe Antonellomock pfu, MKY titer, CM	3	to the bottom right-hand corner says, "To
4	titer, by assay."	5	transfer 44 assays"?
5 6	Do you see that? A. Yes.	6	A. Yes.
7		7	MR. SANGIAMO: Object to the
8	Q. Why did you submit that data to Joe Antonello?	8	form. BY MR. KELLER:
9	A. I can't say with certainty. I	9	
10	have an expectation of that, but I don't I	10	Q. That's your handwriting. Correct? A. Yes, it is.
11	can't say with certainty.	11	Q. And here you're capturing for 44
12		12	assays that were run as part of Protocol 007
13	Q. What's your understanding, your best understanding?	13	the mock averages for those 44 assays. Is
14	A. My understanding is that Joe,	14	that a fair statement?
15	since he in the validation report it	15	A. The mock value for those 44
16	indicated to have tentative specification	16	assays.
17	limits for the control sera, that I would	17	Q. And it also references the low
18	provide additional control serum results	18	and high controls for those assays as well?
19	periodically to increase that number and allow	19	MR. SANGIAMO: Object to the
20	him to reassess the whether the control	20	form.
21	limits were appropriate.	21	THE WITNESS: The two controls,
22	MR. KELLER: Let me mark two	22	I don't recall that they were referred
	exhibits	123	to as filling flow but they are the
23	exhibits.	23 24	to as high and low, but they are the
	exhibits. (Exhibit Krah-39, 2/22/01 Fax,	23 24 25	two controls that were run in the BY MR. KELLER:

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Page 388 1 You also --1 Q. And each assay that's run has a 2 MR. SANGIAMO: Jeff, I shouldn't 2 mock control limit, an N2 positive control 3 3 limit that are run in that assay. Correct? have to enforce Dr. Krah's right to 4 finish his answers. 4 MR. SANGIAMO: Object to the 5 BY MR. KELLER: 5 form. 6 THE WITNESS: Each assay has a 6 Q. Are you done? 7 mock N2 positive control samples that 7 The control sera that were used 8 are run. Each of which has limits for 8 in each of the assays, adult lab volunteer 9 a valid assav. 9 control sera. 10 BY MR. KELLER: 10 Q. There is a chart that you Q. So based on your review of the 11 provided. Can you -- it says number -- I 11 can't quite read your handwriting. 12 44 assays that you captured the MKY controls, 13 A. Number of assays at titer. 13 was the MKY control performing consistently 14 throughout these 44 assays, based on your 14 Q. What are you trying to convey in 15 this reference here? 15 opinion? 16 A. My -- or I can't say with 16 A. Not being a statistician, I certainty at the time what I was conveying, 17 can't comment with statistical certainty, but 17 but I can say what I have there, which is a I'd say 39 of the assays that had one titer of 19 1,024, six times it was within a twofold range distribution of how many assays. For example, 20 20 the MKY serum was providing a titer of 1,024 of that. And in one case it was five -versus 2.048, down to 512 at the far 21 sorry, two cases it was 512, which is twofold 21 22 lower than 1,024. 22 right-hand column. And then for the CM serum, 23 23 the titers in -- how many times a serum had a Do you recall ever providing Joe 24 given titer in an assay. 24 Antonello before you finalized his validation 25 25 report all the data from Protocol 007 Q. Is it fair to say that Joe Page 387 Page 389 Antonello was using the data generated during 1 including the serum runs? the Protocol 007 clinical runs to establish 2 2 MR. SANGIAMO: Object to the 3 control runs? 3 4 4 THE WITNESS: I don't recall MR. SANGIAMO: Object to the 5 5 form. which, if any of the Protocol 007, the 6 THE WITNESS: Control -- my 6 mocks N2 and adult lab volunteer 7 understanding is that the control, 7 control sera from -- that were included 8 tentative control runs were set based 8 in Protocol 007 were provided to Joe. 9 on the validation protocol. Validation 9 BY MR. KELLER: 10 10 protocol indicated that additional Q. Let me direct your attention to 490656 which is on February 26, 2001. Let me 11 assays would be run to gather 11 know when you're there. If you look in the 12 additional data to verify or further 12 13 support the control limit titers. 13 middle of the page under "Transferred," can you read what you wrote in your journal? 14 These results are adult lab volunteer 14 A. It says, "Transferred Excel 15 sera and the mocks that are 15 16 involving -- they're from assays that 16 files to Joe Antonello and Robin from Protocol 17 involve Protocol 007 sera but these are 17 007 data summaries and the raw data files (44 18 not results related to Protocol 007 18 files each.)" 19 samples. 19 O. And those 44 files, are those 20 BY MR. KELLER: 20 the same 44 assays that you faxed to him, list 21 21 the controls -- the control data? Q. But they're run, each one of 22 these assays runs a paired sera from kids in 22 A. It's the same number of samples. 23 Protocol 007. Correct? 23 I can't say with certainty that it's the same 24 A. Each assay does, the data that 24 sample. It's the same number of assays. were provided do not include those results. 25 Why did you provide Joe

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1 Antonello the raw data from Protocol 006 2 before — at this time frame? Why did you do 3 that? 4 MR. SANGIAMO: Object to the 5 form. Are you going to let him read 6 the rest of it? 7 BY MR. KELLER: 8 Q. Strike that. 9 Dr. Krah, why did you provide 10 Joe Antonello on February 26th all the raw 1 data from Protocol 007? 12 MR. SANGIAMO: Feel free to read 13 the rest of the entry, Dr. Krah. 14 THE WITNESS: I can't recall. 15 Certainly I can read what it says, that 16 they would — this was that "They will 17 apply the extravariability criteria 18 test" to the data. 19 BY MR. KELLER: 20 Q. Do you know whether or not Joe 21 Antonello used any of the data you used to 22 validate Protocol 007 to add information to 23 those 20 runs — 24 MR. SANGIAMO: Object to the 25 form. 26 MR. SANGIAMO: Object to the 27 form. 28 PY MR. KELLER: 29 Q. — that were requested as part 20 of the protocol 007 to add information to 210 the protocol done of the reasons that 211 you provided the raw data to Joe Antonello to 212 lehelp will update those tentative results with 213 more protocol done of the reasons that 214 related to the validation report. 215 Q. Do you know when the validation 216 report? 217 A. I don't recall. Did you ever 218 disclose to CBER that you provided Joe 219 Antonello data from the Protocol 007 to and a sasays, the Protocol 007 assays would be the source of those control limits to tinclude. 110 be the source of those control limits to to include. 111 to time was the "Theo will assays" to to have a prequest to have data from additional assays, the Protocol 007 assays would be the source of those control limits to to include. 11 to time the was a request to have data from additional assays, the Protocol 007 assays would be the source of those control limits to include. 11 to include. 12 by MR. KELLER: 12 Q. You didn't expect that those tentative runs would didn't expect that those tentative runs would be run with sera from Protocol 007 to the lease of the tentative? 18 by MR. KELLER: 29 Q. Toth the through different		HIGHLY CONFIDENTIAL -		
before at this time frame? Why did you do that? MR. SANGIAMO: Object to the form. Are you going to let him read the rest of it? BY MR. KELLER: Q. Strike that. Dr. Krah, why did you provide lo Joe Antonello on February 26th all the raw data from Protocol 007: Krah. THE WITNESS: I can't recall. Certainly I can read what it says, that they would this was that "They will cantonello used any of the data you used to validate Protocol 007 to add information to to those 20 runs MR. SANGIAMO: Object to the form. MR. KELLER: MR. SANGIAMO: Object to the form. MR. KELLER: MR. SANGIAMO: Object to the form. MR. KELLER: Dearwing MR. KELLER: MR. SANGIAMO: Object to the form. MR. KELLER: Let me strike that. MR. SANGIAMO: Object to the form. MR. KELLER: Let me strike that. MR. SANGIAMO: Object to the form. MR. KELLER: Let me strike that. MR. SANGIAMO: Object to the form. A. I don't recall. A. I don't recall. Q. You didn't testify to that? A. Yes. Q. Let me have you go back to Page 391 Exhibit 38, which is your e-mail dated December 10, 2001. Exhibit 38, volu've read this e-mail already. Correct? A. Yes. Q. Toul done of the reasons that you provided the raw data to Joe Antonello to help him update those tentative results with more information to finalize the validation report. A. I don't recall. Q. You don't recall that it was related to the validation report. A. I don't recall. A. I don't recall. Q. You don't recall that it was related to the validation report. A. Yes. Q. Tould one of the reasons that you provided the raw data to Joe Antonello to help him update those tentative results with more information to finalize the validation report? A. I don't recall. Q. You didn't expect that those tentative results with more information to finalize the validation report? A. Yes. Q. Let me have you go back to Page 393 Exhibit 38, which is your e-mail dated December 10, 2001. Exhibit 38, You've read this e-mail already. Correct? A. Yes. Q. In the second paragraph you MR. SANGIAMO: Obj		Page 390		Page 392
data from Protocol 007? The protocol 007 testing. So my expectation was when there was a request to have data from additional data would be using data from the actual would be the swarp of expectation was when ther was a request to have data from the actual to be the source of those control limits to include. BY MR. KELLER: BY MR. KELLER: Q. You testified earlier that you through - the assays run through Protocol 007 or run through - the assays run through protocol 007 or run through - the assays run through fiferent assays? BY MR. KELLER: MR. SANGIAMO: Object to the form. BY MR. KELLER: Q. You dedit testify to that? A. Not - that's not what I believe 1 testified to. Q. Let me have you go back to Page 393 Exhibit 38, which is your e-mail dated 2 poeember 10, 2001. Exhibit 38, You've read this e-mail already. Correct? A. Yes. Q. In th	1	Antonello the raw data from Protocol 006	1	serum, the MKY and CM control limit
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providing to Joe the mock and control 25 recommended by Biometrics Research, the limits	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	BY MR. KELLER: Q that were requested as part of the protocol that were tentative? MR. SANGIAMO: Object to the form. MR. KELLER: Let me strike that. BY MR. KELLER: Q. Could one of the reasons that you provided the raw data to Joe Antonello to help him update those tentative results with more information to finalize the validation report? A. I don't recall that it was related to the validation report. Q. Do you know when the validation report was finalized? A. I don't recall. Q. You don't recall. Did you ever disclose to CBER that you provided Joe Antonello data from the Protocol 007 runs to help validate the AIGENT SOP? MR. SANGIAMO: Object to the form. THE WITNESS: The control	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Exhibit 38, which is your e-mail dated December 10, 2001. Exhibit 38. You've read this e-mail already. Correct? A. Yes. Q. In the second paragraph you write, "The pediatric serum sample panels (sets 8 and 5 from Bev Rich's group) were used to evaluate seroconversion rates, pre-positivity and the assay cutoff (titer of 32 assigned negative)." Do you see that? A. Yes. Q. And those pediatric serum panels, those are the ones that where Antonello proposed running 100 paired sample and you ultimately only had 50 paired sample. Correct? MR. SANGIAMO: Object to the form. THE WITNESS: I can't from this, reading this, I can't tell how many samples were in those sets. BY MR. KELLER: Q. I see. You go on to write, "As

99 (Pages 390 - 393)

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	HIGHLI CONFIDENTIAL -	711	TOTAL ETE ETES OF ET
	Page 394		Page 396
1	were re-evaluated after interim analysis set	1	sufficiently large number of runs,
2	was run to use a larger data set to establish	2	control serum values from assays that
3	the limits (I believe they recommended	3	were run as part of Protocol 007 were
4	re-evaluating after 20 runs, since the number	4	included in that analysis.
5	of runs in the validation studies were too low	5	MR. SANGIAMO: I got a feeling
6	to provide an evaluation of the limits to be	6	we're pretty much right at seven hours.
7	set for these)."	7	I think we got five minutes.
8	Do you see that?	8	VIDEOGRAPHER: Yeah. About two
9	A. Yes.	9	minutes.
10	Q. And so and that is is that	10	MR. KELLER: We're at our
11	your understanding why you provided Joe	11	seven-hour limit, Dr. Krah. Thank you
12	Antonello the results of running the controls	12	for your time.
13	in Protocol 007 assays to help provide	13	VIDEOGRAPHER: The time is now
14	sufficient data to set reliable controls?	14	6:14. This concludes the video
15	MR. SANGIAMO: Object to the	15	deposition.
16	form. Dr. Krah, you should feel free	16	
17	to read the parts of the paragraph that	17	(Witness excused.)
18	Mr. Keller elected to skip.	18	
19	THE WITNESS: I believe, as	19	(Deposition concluded at
20	instructed, that the 20 runs that we	20	6:14 p.m.)
21	had, it indicates that the number of	21	• '
22	runs in the validation study was too	22	
23	low to provide an evaluation of the	23	
24	limits for those.	24	
25	BY MR. KELLER:	25	
	Page 395		Page 397
1	Q. It's your testimony that those	1	CERTIFICATE
2	20 runs were run in the assays that were used	2 3	
3	in Protocol 007. Correct?	'	I do hereby certify that I am a Notary
4	A. The 20, I'm sorry.	4	Public in good standing, that the aforesaid
5	Q. The 20 runs to validate the	5	testimony was taken before me, pursuant to notice, at the time and place indicated; that
6	control limits were run through running the		said deponent was by me duly sworn to tell the
7	assays in Protocol 007?	6	truth, the whole truth, and nothing but the truth; that the testimony of said deponent was
8	A. My understanding and	7	correctly recorded in machine shorthand by me
9	recollection is that those 20 runs are assay		and thereafter transcribed under my
10	runs as part of the validation and not from	8	supervision with computer-aided transcription; that the deposition is a true and correct
11	Protocol 007.	9	record of the testimony given by the witness;
12	Q. So is it your testimony that	10	and that I am neither of counsel nor kin to any party in said action, nor interested in
13	when in the validation protocol you stated	10	the outcome thereof.
14	that these results were tentative and that 20	11	WHENESCO I I I COLL IN
15	more runs needed to be run, that those in	12	WITNESS my hand and official seal this 20th day of July, 2017.
16	order to validate the protocol with sufficient	13	J
17	enough reliable data, that you had to look to	14 15	
18	the running of the Protocol 007 data to get	13	Linua Kussi-Kios, RPR, CSR
19	sufficient data to have reliable data for the	16	Notary Public
20	controls?	17 18	
21	MR. SANGIAMO: Object to the	19	
22	form.	20	
23	THE WITNESS: In order to my	21 22	
24	understanding is in order to get the	23	
25	data from a large enough or	24 25	
		120	

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	Page 398				ī	Page 400
1	INSTRUCTIONS TO WITNESS	1		FRE	RATA SHEET	age 400
2	Please read your deposition over	2	IN DE		ex rel. vs. MERCK	
3	carefully and make any necessary corrections.	3	DATE:			
4	You should state the reason in the appropriate	4	PAGE.			NT .
5	space on the errata sheet for any corrections					IN
6	that are made.	5				_
7	After doing so, please sign the errata	6				_
8	sheet and date it.	7				_
9		8				_
_	You are signing same subject to the	9				_
10	changes you have noted on the errata sheet, which will be attached to your deposition.	10				_
11	• 1	11				_
12 13	It is imperative that you return the	12				_
	original errata sheet to the deposing attorney	13				_
14	within thirty (30) days of receipt of the	14				_
15	deposition transcript by you. If you fail to	15				_
16	do so, the deposition transcript may be deemed	16				
17	to be accurate and may be used in court.	17				_
18		18				_
19		19				_
20		20				_
21		21				_
22		22				_
23 24		23				
25		24				
23		25	(DATE)	DAVID KRAH	
	Page 399					
1	ACKNOWLEDGMENT OF DEPONENT					
2						
3	I have read the foregoing transcript of					
4	my deposition and except for any corrections or					
5	changes noted on the errata sheet, I hereby					
6	subscribe to the transcript as an accurate record					
7	of the statements made by me.					
8						
9						
10	DAVID KRAH					
11						
12	SUBSCRIBED AND SWORN before and to me					
13	this day of					
14						
15						
16						
17	NOTARY PUBLIC					
18						
19						
20	My Commission expires:					
21						
22						
23						
24						
25						

101 (Pages 398 - 400)

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	Page 401
1	IN THE UNITED STATES DISTRICT COURT
	FOR THE EASTERN DISTRICT OF PENNSYLVANIA
2	
	UNITED STATES OF AMERICA : CIVIL ACTION
3	ex rel., STEPHEN A. : NO. 2:10-04374(CDJ)
	KRAHLING and JOAN A. :
4	WLOCHOWSKI, :
	Plaintiffs, :
5	:
	vs. :
6	:
	MERCK & CO., INC., :
7	Defendant. :
	: Master File No.
8	IN RE: MERCK MUMPS : 2:12-cv-03555(CDJ)
	VACCINE ANTITRUST :
9	LITIGATION :
	:
10	THIS DOCUMENT RELATES TO: :
	ALL ACTIONS :
11	
12	
13	** HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY **
14	7 7 10 0017
15	July 12, 2017
16 17	Continued videotaped deposition of
18	DAVID KRAH, taken at the offices of Spector
19	Roseman & Kodroff, 1818 Market Street, Suite
20	2500, Philadelphia, Pennsylvania 19103,
21	beginning at 9:05 a.m., before LINDA
22	ROSSI-RIOS, a Federally Approved RPR, CCR and
23	Notary Public.
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19	BY: JEFFREY F. KELLER, ESQUIRE	00683514 - 00683518
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4	Inc.	3
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11	VENABLE LLP BY: DINO s. SANGIAMO, ESQUIRE	9 00065695 - 00065703
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1	D 404		TORNETS ETES ONET
1	Page 406	1	Q. That wasn't my question.
2	VIDEOGRAPHER: The date today is		MR. SCHNELL: Can you repeat my
$\frac{2}{3}$	July 12, 2017. The time is	3	question, please?
4	approximately 9:05. This begins disc	4	question, please:
5	one of the continuation deposition of	5	(The count reporter read the
6	David Krah. You may proceed.	6	(The court reporter read the pertinent part of the record.)
7	David Kian. Tou may proceed.	7	pertinent part of the record.)
8	DAVID KRAH, after having been	8	MR. SANGIAMO: Object to the
9	previously duly sworn, was examined and	9	statement. Object to the implication
10	testified as follows:	10	that he hasn't answered the question,
11	testified as follows.	11	but you're asking that question again?
12	EXAMINATION	12	MR. SCHNELL: Could you just
13	EAAMINATION	13	
	BY MR. SCHNELL:	14	object to form and leave the coaching
14			out, please.
15	Q. Good morning, Dr. Krah.	15	MR. SANGIAMO: I'm not coaching.
16	A. Good morning.	16	I will make the objections that are
17	Q. As I introduced myself, I'm	17	appropriate.
18	Gordon Schnell and I'm going to be asking you		MR. SCHNELL: Are you objecting
19	questions today.	19	to form?
20	A. Okay.	20	MR. SANGIAMO: Are you asking
21	Q. In your opinion well, let	21	that question again?
22	me let's get the record straight because I	22	MR. SCHNELL: I am asking that
23	want to make sure we understand what the	23	question again. Please limit the
24	AIGENT test is. We got it yesterday. It's	24	objection
25	spelled A-I-G-E-N-T. Correct, Dr. Krah?	25	MR. SANGIAMO: Then I object.
1	Page 407	1	Page 409
1 2	A. That's the acronym that we use for it, yes.	1 2	MR. SCHNELL: to object to the form.
3	•	3	MR. SANGIAMO: I'll object
4	Q. And that stands for anti-IgG enhanced neutralization test. Right?	4	consistent with the way objections are
5	A. Yes.	5	supposed to be made.
6		6	THE WITNESS: I would say it
7	Q. In your opinion, was the AIGENT test a reliable test?	7	•
8		/	
	A In my opinion it mot the	Q	was, in my view, a reliable test to
	A. In my opinion it met the	8	measure antibody. If antibody
9	appropriate criteria that were set in the	9	measure antibody. If antibody measurement was as antibody with the
9 10	appropriate criteria that were set in the validation plan, and as such, would be a	9 10	measure antibody. If antibody measurement was as antibody with the criteria that antibody measurement in
9 10 11	appropriate criteria that were set in the validation plan, and as such, would be a reliable assay.	9 10 11	measure antibody. If antibody measurement was as antibody with the criteria that antibody measurement in the neutralization assay was an
9 10 11 12	appropriate criteria that were set in the validation plan, and as such, would be a reliable assay. Q. And it was a reliable assay, in	9 10 11 12	measure antibody. If antibody measurement was as antibody with the criteria that antibody measurement in the neutralization assay was an assessment of immunogenicity, I would
9 10 11 12 13	appropriate criteria that were set in the validation plan, and as such, would be a reliable assay. Q. And it was a reliable assay, in your opinion, for what purpose?	9 10 11 12 13	measure antibody. If antibody measurement was as antibody with the criteria that antibody measurement in the neutralization assay was an assessment of immunogenicity, I would say it was a reliable measure of
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9 10 11 12 13 14 15	appropriate criteria that were set in the validation plan, and as such, would be a reliable assay. Q. And it was a reliable assay, in your opinion, for what purpose? A. It was a reliable assay for the purpose of testing human sera for mumps	9 10 11 12 13 14 15	measure antibody. If antibody measurement was as antibody with the criteria that antibody measurement in the neutralization assay was an assessment of immunogenicity, I would say it was a reliable measure of immunogenicity. BY MR. SCHNELL:
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9 10 11 12 13 14 15 16 17	appropriate criteria that were set in the validation plan, and as such, would be a reliable assay. Q. And it was a reliable assay, in your opinion, for what purpose? A. It was a reliable assay for the purpose of testing human sera for mumps neutralizing activity. Q. Was it a reliable test for measuring the immunogenicity of the mumps	9 10 11 12 13 14 15 16 17 18	measure antibody. If antibody measurement was as antibody with the criteria that antibody measurement in the neutralization assay was an assessment of immunogenicity, I would say it was a reliable measure of immunogenicity. BY MR. SCHNELL: Q. And was the antibody assessment an accurate measure of immunogenicity? MR. SANGIAMO: Object to the
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1	able to measure the immunogenicity.	1	MR. SANGIAMO: Objection. Asked
2	BY MR. SCHNELL:	2	and answered.
3	Q. I'm asking, is the antibodies	3	THE WITNESS: I have an opinion
4	that were measured in your AIGENT test an	4	that the assay was reliable in
5	accurate measure of immunogenicity of the	5	measuring antibodies to mumps. As far
6	mumps component of MMR II?	6	as the impact on or the conclusion
7	MR. SANGIAMO: Object to the	7	about whether it was reliable
8	form. Asked and answered.	8	assessment to immunogenicity, I can't
9	THE WITNESS: It was an assay	9	say.
10	format that was agreed to in discussion	10	BY MR. SCHNELL:
11	with CBER as a means to measure	11	Q. Do you have an opinion as to
12	antibody responses to measles to	12	whether or not the AIGENT assay was a reliable
13	measles, I'm sorry. To mumps.	13	measure of how well the mumps component of
14	MR. SCHNELL: Can you, please,	14	MMR II protects vaccine recipients from
15	repeat my question?	15	getting the mumps disease?
16		16	A. I don't have any opinion on
17	(The court reporter read the	17	that.
18	pertinent part of the record.)	18	Q. Do you have an opinion on how
19		19	well the mumps component of MMR II works today
20	THE WITNESS: I would say the	20	in protecting vaccine recipients from
21	assay, in my view, was a reliable	21	contracting mumps?
22	assay. The measurement endpoint of	22	A. I don't have an opinion on that.
23	measuring antibodies with the AIGENT	23	Q. You have no idea?
24	assay was discussed and agreed to in	24	MR. SANGIAMO: Object to the
25	collaboration with CBER. So given	25	form.
	Page 411		Page 413
1	Page 411 those statements, the expectation would	1	Page 413 THE WITNESS: I read reports and
1 2	Page 411 those statements, the expectation would be that it was a reliable measure of	1 2	THE WITNESS: I read reports and
	those statements, the expectation would be that it was a reliable measure of		THE WITNESS: I read reports and taken part in meetings discussing
2	those statements, the expectation would	2	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no
2 3	those statements, the expectation would be that it was a reliable measure of immunogenicity to mumps. BY MR. SCHNELL:	2 3	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no independent knowledge of or no
2 3 4	those statements, the expectation would be that it was a reliable measure of immunogenicity to mumps. BY MR. SCHNELL: Q. Do you believe it was an	2 3 4	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no independent knowledge of or no independent opinion other than what
2 3 4 5	those statements, the expectation would be that it was a reliable measure of immunogenicity to mumps. BY MR. SCHNELL: Q. Do you believe it was an accurate measure of immunogenicity?	2 3 4 5	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no independent knowledge of or no
2 3 4 5 6	those statements, the expectation would be that it was a reliable measure of immunogenicity to mumps. BY MR. SCHNELL: Q. Do you believe it was an accurate measure of immunogenicity? A. That's beyond my scope of	2 3 4 5 6	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no independent knowledge of or no independent opinion other than what I've read or discussed in meetings.
2 3 4 5 6 7	those statements, the expectation would be that it was a reliable measure of immunogenicity to mumps. BY MR. SCHNELL: Q. Do you believe it was an accurate measure of immunogenicity? A. That's beyond my scope of responsibility and training. I can speak to	2 3 4 5 6 7	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no independent knowledge of or no independent opinion other than what I've read or discussed in meetings. BY MR. SCHNELL: Q. And all the clinical testing
2 3 4 5 6 7 8	those statements, the expectation would be that it was a reliable measure of immunogenicity to mumps. BY MR. SCHNELL: Q. Do you believe it was an accurate measure of immunogenicity? A. That's beyond my scope of responsibility and training. I can speak to the assay performance itself, not to the	2 3 4 5 6 7 8	THE WITNESS: I read reports and taken part in meetings discussing protection from mumps, but I have no independent knowledge of or no independent opinion other than what I've read or discussed in meetings. BY MR. SCHNELL: Q. And all the clinical testing that you did while at Merck on the mumps
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Page 416 1 Yes. point, would you consider that original or 2 Q. And there were two sets of data corrected data? 3 that came out of the AIGENT testing. There 3 A. My view of the original data was 4 was what Merck has described as, 4 whatever the first number that was written 5 quote/unquote, original data, and what Merck 5 down was for the plaque count. So if -- I has described as, quote/unquote, corrected 6 6 would still consider that -- it's a number 7 data. Is that true? 7 that's -- gets into semantic argument. The 8 8 number would be a -- I would say it's a MR. SANGIAMO: Object to the 9 9 corrected number, but it's the same as the form. 10 THE WITNESS: Could you clarify 10 original -- in that description, as I what you mean by came out of Merck? I understood it, it's the same as the original 11 11 number. 12 believe you said data that came out of 12 13 Merck. 13 Q. In your earlier answer when you 14 BY MR. SCHNELL: 14 testified that in your opinion the AIGENT data 15 Q. I don't know if I said that, but 15 was reliable, were you referring to both the original data and the corrected data? 16 have you heard of the term "original data and 16 17 corrected data" as it relates to AIGENT -- the 17 A. Yes. 18 AIGENT study results? 18 Q. Do you have an opinion one way 19 MR. SANGIAMO: Object to the 19 or another as to which, if either, of the sets 20 of data was more reliable than the other? 20 form. 21 THE WITNESS: To the data -- I 21 A. I have an opinion based on 22 22 analysis that our -- I don't recall if it was do recall hearing those terms used in 23 connection with the data. 23 the biometrics group or another group did at 24 BY MR. SCHNELL: 24 Merck comparing corrected data with the 25 What's your understanding of 25 original data. Page 415 Page 417 what, quote/unquote, original data means in 1 Q. And what's your opinion based on 2 that context? 2 that? 3 A. My understanding of that term is 3 That the -- both results are A. that those are the plaque counts as 4 4 comparable. 5 5 recorded -- as the primary data recorded in Q. In terms of what? 6 counting the plaques. 6 A. Seroconversion rate, as best I 7 Q. What do you mean "primary data"? 7 recall. The first -- the data that the 8 8 What about in terms of Q. 9 person counting the assay recorded first. 9 pre-positive rates? 10 10 And then what's your That, I don't recall what understanding of what, quote/unquote, 11 11 difference there was between the groups. 12 corrected data means as it relates to the 12 Q. What about in terms of invalid 13 AIGENT study results? 13 assays? 14 A. My understanding of the 14 That, I don't recall. A. 15 corrected data, those are values that had been 15 So, again, is your opinion that Q. 16 changed from whatever the original entry was. 16 both sets of data are equally reliable? 17 And if an original data point 17 A. Yes. 18 So you don't believe the 18 was changed to become a corrected data point, 19 and then it was changed again, would you 19 corrected data is more reliable than the 20 consider that still corrected? 20 original data for the purposes of the AIGENT 21 A. I would consider anything beyond 21 test? 22 the original entry as a corrected value. 22 A. In looking at the global 23 23 compiled data, I feel that they're both --Q. And if an original data point 24 was changed so it became corrected but then it 24 they both gave comparable seroconversion was changed again back to the original data rates. Both are comparable estimates of

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Page 420 providing data that are equally usable. 1 They're all the steps that come 2 Equally usable for what? 2 to mind right now that capture the general 3 A. For assessing seroconversion 3 flow, the flow. 4 4 Q. Now, there was a correction log rate. 5 What about for assessing the 5 at some point that was instituted into this Q. reliability of the AIGENT test, do you have an 6 flow as well. Right? 6 opinion one way or another as to which was the There were plaque count checks 8 better set of data if one was indeed better 8 that were driven by observations from the 9 than the other in your view? workbook, meaning flags that -- it's different 10 MR. SANGIAMO: Object to the 10 for the first third of the data versus the second third and the third third of the data; 11 form 11 12 THE WITNESS: I don't have an meaning that in the second third and the third 12 13 opinion on that. 13 third a workbook was available that was 14 BY MR. SCHNELL: 14 implemented or included flags for various 15 Q. I want you to take me through 15 criteria that were identified as -- some of 16 the process in your lab that occurred with the 16 them I recall being part of the validation 17 AIGENT testing as it related to the counting 17 plan. They would identify samples that were of plaques. So could you kind of give me the 18 deemed or warranting a check to verify that 19 narrative of call it a flow as to what your 19 the plaque counts were accurate. 20 20 lab staff and you did in trying to calculate That was only for the first O. 21 plaque counts from the various assays that 21 third? 22 were being tested in the AIGENT? 22 A. I'm sorry. That was for the 23 23 A. As best I can recall, the -second third and the third third. For the 24 start from the point where the plates are 24 first third we did not have that, a workbook 25 stained and the plaques are visible, a counter 25 that displayed flags identifying samples would look at the plate typically with a light 1 warranting every check to verify accuracy. box to give some better visualization of the 2 Q. How did you check accuracy for 3 the first third? 3 plaques, mark plaques with a Sharpie pen or an 4 ink -- a laboratory ink pen, and then write 4 A. As best I recall, some examples 5 the plaque count typically on the, could be were looking for or screening -- looking the plate bottom or the plate lid. Different 6 through the data. Sample sera are tested at 7 multiple dilutions. We identify sera that 7 people had different preferences as to where 8 were positive at a single dilution. Another 8 to record the number. Those -- after an assay 9 example would be if we had samples where 9 was counted, then those plaque counts would be 10 transcribed into a notebook page which listed the -- there was -- I'm trying to think of the 11 the plate number and then for each sample 11 term, inconsistent neutralization or erratic 12 there are four -- sorry, three replicate 12 neutralization, meaning that it was jumping wells, so it would be a spreadsheet capturing 13 back and forth in multiple dilutions between 14 positive and negative. And at least in one the plaque counts by plate and by replicate other example, if we saw -- or one of the column row. Those plaque counts then would be 15 transcribed into an Excel spreadsheet where a 16 validity criteria for the test was to have no 17 17 plaques in the unaffected cell control. So if calculation would be done of the average 18 number of plaques for the replicates and then 18 we had an assay where there were plaques in 19 a calculation of the plaque count as a percent 19 the unaffected cell control, we would verify 20 of the mock value. And then an analyst would 20 that they were indeed plaques. I can't say 21 21 that that's all of the criteria that we used look at the data and assign a titer to the 22 at first, but at least those are the ones that sample based on the highest serum dilution

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come to mind.

O.

So I want to make sure I

understand this. So with the first third of

counting process?

providing 50 percent or more neutralization.

Q. Is that the total path of the

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Page 424 the data, and was that also referred to as the to why you wanted an early read on the data? 2 preliminary subset analysis? 2 A. I don't have a general -- I 3 A. I recall it as an interim 3 don't have a recollection of the reason. The 4 analysis, but it may have had different 4 only recollection I have was a discussion 5 descriptions. 5 we're getting -- having -- rather than waiting till the full study is done, have a read into Q. You recall a term "interim 6 6 7 analysis," is that what you said? the results from a subset of the data. I 8 A. That's the term that I'm 8 don't recall the official reason for that. 9 9 recalling. I don't know what the official, if O. In the clinical trial work that 10 there was an official description of that 10 you've done at Merck over the last, it's been first third. about 30 years. Right? 11 11 I've been at Merck about 12 Q. Did I say it right, interim 12 Α. 30 years. 13 analysis or was it interim subset analysis? 13 14 A. I can't recall with certainty, 14 Q. Yeah. In the clinical trial 15 but the phrase that's coming to mind is 15 work that you've done there, is it typical to interim analysis. But I can't say that's have an interim analysis done on the data that 17 the -- that is necessarily an official 17 you're testing? 18 description. 18 MR. SANGIAMO: Object to the 19 19 What period of time did the form. 20 20 counting of plaques for the interim analysis THE WITNESS: I can't say that 21 take place? 21 it's typical. In other studies that 22 22 I've been involved in, it's one other A. I don't recall specific dates, 23 23 but it would have been in the time frame of study, I don't recall there being an 24 when we were running assays for that first 24 interim analysis. 25 third. As best I recall, it was towards the 25 BY MR. SCHNELL: Page 423 Page 425 end of 2000. I don't recall -- and into the 1 Q. You've only been involved in one 2 early part, meaning, as best I can recall, the 2 other study at your time at Merck? 3 first quarter of 2001. 3 A. One other clinical study that I 4 So does November 2000 to 4 can recall. Q. 5 5 February of 2001 sound about right? Q. Is that Protocol 006? 6 MR. SANGIAMO: Object to the 6 A. Yes. 7 7 Those are the only two clinical form. 8 THE WITNESS: I don't recall. I 8 studies that you've been involved in at your 9 only recall it was late 2000 into the 9 30 years at Merck? 10 first quarter of 2001. 10 As best I can recall, yes, as 11 BY MR. SCHNELL: 11 far as running antibody assays, or any assays. Q. What was -- was there anything 12 Q. So let's talk about that period 12 13 of time and the counting that was done for the 13 special about Protocol 006 and Protocol 007 interim analysis. By the way, why was there 14 that led to you being tasked with running 15 an interim analysis done? 15 those assays? 16 A. I don't have a full understanding 16 MR. SANGIAMO: Objection. 17 of the reason for it. I have a general 17 Answer if you know. 18 THE WITNESS: I'm not aware of 18 understanding. I don't know if that's the 19 official reason. My general understanding is 19 anything special about the studies. I 20 that it was to provide an analysis of an 20 would offer that at least my manager 21 earlier read on the results of the 21 Alan Shaw approached our group to immunogenicity testing for Protocol 007 before 22 develop the assays given our virology 23 waiting till we had the full testing for the 23 expertise. 24 24 BY MR. SCHNELL: full set done. 25 25 And what's your understanding as So going back to the interim

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Page 428 analysis which occurred, as you say, in late counting training was done before any --2 2000, towards the first quarter of 2001, who 2 before those individuals counted plaques were, during that period, the staff members in 3 independently. 3 your lab who were involved in counting? 4 Q. So you wouldn't allow someone to 4 5 5 count plaques unless they pass that A. I can't say certainly who all of 6 preliminary test of counting ability. Is that them were. We had -- there were some 7 correct? personnel changes during that time, so I would 8 A. That's the best of my not be able to recite all of the people who 9 recollection, yes. 9 might have been involved in the counting. 10 10 Q. In the course of the counting, Q. Can you tell me who you do recall? and now I'm extending it not only to the 11 11 interim analysis but the full range of 12 A. At least some of the assays 12 13 would have included myself, Mary Yagodich, 13 counting, were there any counters that you 14 found particularly good or particularly bad? 14 Colleen Barr. I believe some with Elizabeth 15 Thoryk. I expect there are two other people, 15 A. I did -- later in the year I did Stephen Krahling and Joan Wlochowski were in 16 a review or a verification of plaque counts 17 against all the counters in the lab. As best 17 the lab in the first quarter. I don't 18 I recall, there was one counter who had some recall -- I expect that there would be assays 19 assays that were given beyond the 10 percent 19 that they counted. I don't recall that with 20 20 counting consistency target. certainty. 21 You didn't mention Jennifer 21 O. Just one? O. 22 22 Kriss, was she one of the ones also? A. As best I recall it was just 23 A. Jennifer Kriss was in the lab. 23 one. 24 I expect that she would have been one of the 24 Q. Was that Mr. Krahling? 25 25 counters. I expect that she would be. I A. Yes. Page 427 Page 429 can't say with certainty that she was one, but 1 Q. So what action, if any, did you 2 I expect that she would have been one. 2 take in response to that? 3 Q. Any others you can recall? 3 A. I recall talking to Mr. Krahling about the plaque counts were identified as 4 A. None that come to mind. 4 5 5 Q. In your opinion, were there any being extra variable, and asked him to be 6 individuals within that group, including you, 6 extra careful in counting plaques in 7 who were better at counting than others? 7 subsequent assays. 8 To my understanding, the best of 8 Q. So you didn't stop him from 9 9 my recollection, each of the counters was counting plaques? 10 compared to a -- their counting accuracy was A. I don't recall that I stopped 11 compared against a reference counter. So 11 him, but I don't recall that he had any --12 there was a reference counter, but in the --12 that any other assays were counted by him 13 as part of the training, the plaque 13 after we had identified the plaque count counting -- as best I can recall, the plaque 14 accuracy question. 15 Q. Who was the reference counter 15 counting verification was done with a subset of plates from, I'll say, an assay. It may 16 that you earlier testified about? 17 not be any particular study but just a set of 17 MR. SANGIAMO: Object to the 18 18 plates that had plaques on them and to -- and form. 19 verify that the new counters were counting 19 THE WITNESS: The reference 20 within a targeted range of the reference 20 counter that originally was established 21 counters. 21 was Mary Yagodich. 22 And that was something that was 22 BY MR. SCHNELL: 23 23 done before the actual counting of plaques and Was that because you thought she

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was a highly qualify counter?

That's because she was the

the AIGENT study commenced?

As best as I recall, that plaque

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Page 432 person in my view, who developed the assay and third, and the assignment of a titer was no 2 was the most experienced person in running the 2 different between the first third and the 3 second third and third third. The difference 3 assay. 4 Mary developed -- Mary Yagodich 4 was that in the second third and third third Q. developed the assay? 5 there was a workbook that indicated flags for 5 A. In collaboration with me and 6 various results being extra variability, 6 others in the lab. 7 invalid dilution as examples. 7 8 Q. Let's look at that because you 8 Q. Who else was involved in the 9 also mentioned for the first third there 9 development of the assay? 10 wasn't a flag system set up, but there was, I 10 A. I was -- there were others -think you described it as the counters looking 11 there were other people in the lab who may 11 have contributed experiments. I don't recall 12 for certain things. Were the things -- you 13 who -- I don't know who first was involved in 13 gave a couple of examples. Before we go 14 through those examples, I want us -- were the 14 running any of the development experiments. 15 Q. But in terms of who came up with 15 things that counters were looking for in the the assay, that was you and Mary? 16 first third of the AIGENT testing for accuracy 16 A. The assay was developed in 17 purposes ultimately incorporated into the 17 discussion with CBER as far as the assay 18 flagging system or was there a difference in 18 19 terms of measuring the accuracy between the design and specifics including the virus 20 20 two portions of the AIGENT testing? strain, use of anti-IgG, the endpoint, the 21 MR. SANGIAMO: Object to the 21 staining method. We had -- Mary and I and 22 22 others in the lab had done experiments to form. 23 23 evaluate effects of variables in the assay and BY MR. SCHNELL: 24 then relay that information to CBER to get a 24 Q. Let me make this easier. So for 25 25 the first third when you I asked earlier about consensus on the format for the assay. Page 431 1 Q. But in terms of who at Merck led 1 how you confirmed the accuracy of the 2 the design and development of the AIGENT test, 2 counting, you identified the counters would 3 look for data at a positive neutralization at 3 that was you and Mary. Correct? 4 a single dilution? Correct? 4 To the best of my recollection, 5 5 yes. A. Q. In terms of who led the testing, 6 Q. And you also mentioned they 7 would look for erratic neutralizations. 7 the AIGENT testing, that was you. Correct? 8 Correct? 8 A. I was in charge of the lab that 9 MR. SANGIAMO: Object to the 9 was running the AIGENT testing, the mumps 10 10 AIGENT testing. form. Was Mary Yagodich the only 11 11 THE WITNESS: That was an 12 reference counter in the AIGENT testing? 12 example of a case where plates were 13 A. I was -- I considered myself a 13 checked for accuracy. 14 14 BY MR. SCHNELL: reference counter as well. 15 15 But that was something that you Q. Anyone else? 16 A. I don't recall. I don't recall. directed the counters to be looking for when they were doing these counting for the first 17 17 So getting back to the flow of 18 the counting process, we'll start with the 18 third of the test? 19 interim analysis because you said it was 19 A. I don't recall -- in some 20 different for the first third of the AIGENT 20 cases -- so I don't recall necessarily 21 21 directing the counters to look for that in test than it was for the second two-thirds. 22 22 each assay, but in some cases, I would review Correct? 23 23 The analysis, the calculation of the data and notice these conditions and then A. 24 relay that information to the counter. 24 percent of mock was no different. What was

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And is that the same for the

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different was the second third and the third

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Page 436 positive neutralizations at a single dilution? looked at every single counting sheet for 2 A. There are cases for the single 2 these criteria to ensure accuracy of the data? 3 positive dilution where I relayed that 3 MR. SANGIAMO: Object to the 4 information to the original counter. 4 form. 5 Q. Is that the same for the plaques 5 THE WITNESS: As best I recall, in the unaffected cell control plate? 6 the reviews that were done with Emilio 6 7 Yes. 7 Emini were going through, as best I 8 Were there -- other than those 8 recall, each counting sheet. 9 9 three items, and, again, that's positive BY MR. SCHNELL: 10 neutralization a single dilution, erratic 10 Q. So your testimony is Dr. Emini neutralization or plaques in unaffected cell reviewed every counting sheet in the interim 11 11 control plate, were there any other criteria analysis? 12 13 that you were looking for in these -- in the 13 A. I can't say for the full interim 14 interim analysis to ensure the accuracy of the analysis, but at least some number of assays 14 15 counts? 15 from the interim analysis. 16 A. I do recall some other conditions. 16 Q. Was there any rhyme or reason as 17 I can't say that I recall each one of them. 17 to which assays he reviewed? One example is a sample that would have an 18 No. As best I can recall, they unexpected result, meaning, for example, 19 were whatever assays were available at the 20 20 pre-positive but post-negative. time. 21 Pre-vaccination positive and post-vaccination 21 When he would review them, would 22 22 negative. he come to the lab or you would bring them to 23 O. That would be an example of --23 him? 24 would that be an example of an unexpected 24 A. I would bring them to him. 25 result? 25 He directed you to do that? Q. Page 435 Page 437 1 It would be an example of an 1 Yes. A. 2 unexpected result with -- at least from my 2 What about what you did during 3 best recollection a question of whether 3 the interim analysis, did you review every there's a chance that the sera were reversed 4 4 counting sheet for these criteria to ensure 5 5 in the assay inadvertently. accuracy? 6 Q. Any other criteria you were 6 A. I recall at least looking 7 looking for to ensure accuracy with respect to 7 through each counting sheet for the single the interim analysis? 8 positive dilution criteria. My best 9 9 A. I believe there were others, but recollection is that I applied the rules I can't -- I don't recall others off the top 10 uniformly across all the assays. So I would 10 11 of my head. 11 say that each -- I did review each assay, each 12 Q. Now, for the first -- for the 12 counting sheet for those criteria. 13 interim analysis were you the only one who was 13 Q. So in the instances where 14 looking through the data for these types of 14 Dr. Emini reviewed the -- are we calling them criteria to ensure accuracy? 15 15 counting sheets, is that the right term? 16 A. 16 A. What actually is reviewed is not 17 Q. 17 the counting sheet but the Excel spreadsheet Who else was looking through the data? 18 18 where the counts are transcribed into. 19 Α. Emilio Emini. 19 And that Excel spreadsheet would 20 O. Anyone else? 20 contain what information? 21 I don't recall. I can't exclude 21 That would contain a plate code, 22 anyone else, but I don't recall anyone else. 22 the serum dilution, the plaque counts and 23 And the process under which you 23 average number of counts and percent --24 24 average number of plaques and then a percent and Dr. Emini went through, was it a formal process where you looked -- you or he or both 25 of mock that correlates with that number of

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Page 440 plaques. you needed to identify the criteria you 2 Q. So it would have all the 2 identified before for accuracy purposes? 3 3 information you would need to calculate A. I'm sorry, you referenced a full 4 review? 4 whether something was a pre- or post-positive 5 5 or a pre- or post-negative. Correct? Q. Well, a review that would enable 6 A. The counting sheet -- I'm sorry, 6 you to look for positive neutralizations at a not the counting sheet. The spreadsheet would 7 single dilution, erratic neutralizations, 8 not necessarily include the identification of 8 plaques in the unaffected cell control plate 9 which was a pre-vaccination or post-vaccination 9 and whether a pre-positive went to a 10 10 serum. post-negative or other what you might describe as unexpected behavior? 11 O. Isn't that -- the spreadsheet 11 does not contain that information? A. Often the first two of those, 12 12 13 A. At least the spreadsheet that we 13 the single positive dilution or erratic 14 used for the first, as best I recall, we -- as 14 neutralization could be viewed without knowing 15 best I recall, we wrote the -- I don't recall 15 whether it's a pre-vaccination or that the spreadsheet had -- as best I can 16 post-vaccination serum just looking at the 17 recall, the spreadsheet had the plate code and 17 data in column form where you have dilutions the plaque counts and then we wrote, as best 18 of the sera and looking at the percentage of as I can recall, the serum identification in 19 the neutralization across the dilutions of the 20 20 the right-hand column. So when the data was sera. To do the assessment of, for example, 21 being reviewed with Emilio, I don't -- or --21 pre-positive or post-negative or verify 22 with Emilio, I don't recall whether that 22 whether there were plaques in the unaffected 23 information was on the spreadsheet or not. 23 cell control, at that point we would -- I 24 Q. But didn't you say earlier that 24 would need the code to know what data cells 25 25 one of the criteria you looked for was whether corresponded with what plate code. Page 441 there was a pre-positive and a post-negative? 1 Sometimes you had information 2 A. Yes. 2 and sometimes you didn't? 3 Q. So how would you be able to 3 A. The data would be eventually 4 available. I can't exclude that I didn't do 4 determine that if you didn't know which were 5 the pres and which were the posts? 5 review of the -- the single positive dilution 6 A. Eventually we would assign a 6 or erratic neutralization before all that data 7 titer to those samples and compile the 7 was compiled. results. At that point we'd know which --8 Q. Is it you don't recall? Is 9 what titer was corresponding to what pre---9 it -- I didn't understand your answer. You 10 10 said vou can't exclude -the post-vaccination serum. 11 So for this review of accuracy 11 A. I can't exclude that there 12 you ultimately had all the information you 12 weren't cases that the data were -- the review 13 needed to determine which was a pre- or 13 of the single positive dilution and extra 14 post-positive or a pre- or post-negative. 14 variability was assessed before doing the 15 Correct? 15 compilation of sera codes to go along with the 16 Ultimately that information 16 samples. 17 was available. It doesn't necessarily follow 17 So were there instances when Q. 18 that the review always included that final 18 after you delivered to Dr. Emini the 19 compilation that included those details. 19 spreadsheet pages that had the information you 20 Q. Your review of the data did. 20 discussed on it, that he came back to you and 21 Correct? 21 said this looks questionable to me, have the 22 Some of it did, not all of it. 22 counter go back and take a second look? Α. 23 23 So how did you determine whether MR. SANGIAMO: Object to the 24 you were going to do a complete review or a 24 form. review that didn't have all the information 25 THE WITNESS: I do recall cases

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Page 444 1 reviewing the data with Emilio that he directly -- the plaque visibility or clarity 2 did -- I would have particular 2 is not directly related to the anti-IgG. 3 dilutions of samples where he had said 3 Q. And when you found a positive 4 this looks like, for example, single 4 neutralization of the single dilution, was it 5 positive dilution, this looks unusual, 5 always the case that it was an unreliable 6 result? 6 please have -- or have the counter 7 7 verify the count for accuracy. No. Α. 8 8 BY MR. SCHNELL: O. So sometimes they're reliable 9 9 Q. And were there other criteria and sometimes not? 10 that you recall him pointing out to you which 10 Α. Yes. led him to direct you to have the counter do a 11 O. Would you always retest those? 11 12 recheck? 12 Α. 13 A. I don't recall. The one I 13 Q. You would recount those? 14 recall is a single positive dilution. I don't 14 We would check the plaques to A. 15 recall others. 15 verify accuracy if there was a correction, if 16 Q. And when you say a single -- a the count was not accurate, in recounting it, 17 neutralization at a single positive dilution, 17 it turned out to not be neutralizing, that 18 what does that mean? 18 result would be reported. 19 A. It means that there are eight 19 Would you do a third time to 20 20 make sure that the second one was the accurate dilutions of -- or actually rephrase it. 21 Neutralization at a single dilution. It means 21 one and not the first one? 22 that there are eight dilutions of a serum 22 A. I'm sorry, for the counting or 23 23 tested. In the anti-IgG assay there is testing? 24 something called a prozone effect, meaning 24 Q. For the counting. 25 that the neutralization -- as the serum 25 Α. Not that I recall. Page 443 Page 445 dilutes out, there may not be neutralization 1 Well, then, how could you be sure that the second one was more accurate 2 at the early dilutions, but then the prozone 2 3 means that there's a region of antibody 3 than the first one? concentration where the anti-IgG is not 4 4 A. In the recheck, the counts were 5 5 effective in enhancing neutralization. So only -- changes to the counts were only made 6 instead of having a neutralization curve where 6 if there was confidence that the plaques were 7 you'd have neutralization that's diluting out, 7 miscounted in the first time. you can have a sample where there's no 8 Q. Why would there be more neutralization and at one or several dilutions 9 confidence that the second count was more 10 10 accurate than the first count? neutralization is detected. What single 11 dilution neutralization means that only one of 11 The confidence was that one was 12 the eight dilutions is showing neutralization. 12 looking more -- it's my interpretation that 13 Q. And why would that be a result 13 someone was looking more carefully at the well 14 that would lead you to believe that there was 14 to make sure that something wasn't being 15 a potential issue with accuracy? 15 missed or miscounted. 16 A. At least one of the thoughts for 16 Q. So it's your opinion that your 17 that was that the -- there may be something 17 staff, when they did a recount, did it more 18 accurately the second time than the first about the staining or plaque visibility in 18 19 those wells that allowed for an inaccurate 19 time? 20 count that then led to a reduced number of 20 A. Not -- I wouldn't say that as a 21 plaques being counted. 21 global statement, meaning that, for example, 22 Q. Didn't you testify that it had 22 in some rechecks the plaque counts there were 23 to do with the anti-IgG? 23 inaccuracies noted in some wells but not 24 A. The anti-IgG has an effect on 24 globally across the assay. So if someone the prozone. The plaque count itself is not 25 counted the second time, it did not mean that

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Page 448 they saw differences but they were specific would tell them to recount the entire assay? 2 dilutions of samples that were more typically 2 A. As best I can recall, I would 3 showing inaccurate counts. 3 identify that there was a question, identified 4 Q. You didn't institute any kind of 4 for particular sample or plate and could they 5 two out of three rule with recounts? 5 recheck that plate. I don't recall necessarily saying -- I don't recall saying to 6 Not that I recall, no. 6 7 Wouldn't that have been more 7 recheck the full assay. 8 accurate than just recounting a second --8 Q. So you would tell them to 9 recounting once and picking automatically the recheck the individual plate with which you 10 second count? 10 had a question. Correct? A. I don't have a view on that. A. I asked them to recheck the 11 11 12 You don't have a view that if individual plate. I don't recall if I asked O. 12 you had a first count that you had a question 13 them to look at additional plates, but I don't about and you did a second count, that relying recall them -- asking them to recall the full 14 15 on the second count is more accurate, would be 15 one -- to recheck the full assay. 16 just as reliable as doing a third count and 16 Q. When you asked them to recheck 17 taking whichever was two out of three? 17 the plates because of a concern you had on 18 MR. SANGIAMO: Object to the accuracy, did you tell them what your concern 19 form. Asked and answered. 19 was? 20 THE WITNESS: Not necessarily. 20 A. As best I can recall, at least 21 In fact, part of the recheck, 21 one example said there's a question about 22 recount -- I can't say with certainty this. Well, in looking at it, at least one 22 23 23 that it was applied in every assay but example, I said I see plaques that are missed, 24 the intention was to have the original 24 can you please verify whether or not you did 25 counter recheck the counts and verify 25 it -- when you check it, that you get -- you Page 447 1 whether they agreed that there were 1 see something. I don't think -- didn't give them a number to say, but just said I see a 2 miscounts or miscounted counts. 2 3 BY MR. SCHNELL: 3 difference in counts than what you recorded, 4 can you please recheck. 4 So when you had a question about 5 5 the accuracy of a count, you would go back to Q. So you would actually do the 6 the same counter? 6 recount first and then you would send it back 7 7 A. I can't say that that happened to the counter for them to do the recount? in -- well, I can't say it didn't happen in 8 MR. SANGIAMO: Object to the 9 all cases, but that was in some of the assays 9 form. 10 my intention. 10 THE WITNESS: As best I can 11 And it was your intention that 11 recall, the example I'm thinking of, I 12 having the same counter recount the original 12 would look at -- the most 13 count would be more accurate than having a 13 straightforward one to me is looking at a plate, spots were put on the plate to 14 different counter come in? 14 15 A. That in -- my interpretation at 15 identify where a plaque was counted. I the time was that rather than add on the 16 would look at the plate and say I see 17 additional potential variability between 17 spots that aren't marked by a Sharpie. counters, even though we had qualified all the 18 18 So those look like plaques that were 19 counters, that it would be more reliable to 19 missed. Or I see spots next to 20 have the original counter count. But in 20 something that doesn't look like a 21 subsequent assays that wasn't always 21 plaque. That would tell me that it practical, meaning that those people might not 22 looks like they're -- they counted 23 be available to recheck plaque counts. 23 something that wasn't a plaque. 24 Q. When you went back to the 24 BY MR. SCHNELL: 25 original counter and told them to recount, you So you wouldn't go back to the

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Page 452 counter and say, hey, we have a question about 1 sense that it happened on the pre-vaccination 2 this one, recount it, you would say, hey, we 2 side? 3 have a question about this one because of X, Y 3 A. No. 4 and Z, recount it to make sure you're 4 Q. Doesn't the prozone effect mask 5 accurate? 5 neutralization? 6 MR. SANGIAMO: Object to the 6 No. A. 7 7 It doesn't? Q. 8 THE WITNESS: As best I can 8 It doesn't mask neutralization A. 9 9 recall, I would say that I -- can you that was going to happen in the absence of 10 verify the counts for this. In some 10 anti-IgG. 11 cases saying I looked at the plate, I O. Is there a difference in terms 11 see a different plaque, I see more of neutralization depending on whether 12 12 13 plaques or less plaques than what you 13 anti-IgG is part of the solution? 14 have got, can you please recheck. It 14 A. There's -- if one titrates serum, I don't believe there's a difference in 15 doesn't mean that I counted the plate 15 16 but I -- just looking at the plate, I 16 quality of the antibody that's being detected. 17 can see that something was either not 17 If you had -- part of the -- this is largely 18 being counted or counted as a plaque 18 not based strictly on Protocol 007 experience 19 that didn't look like a plaque. 19 but other neutralization experiments, for 20 20 BY MR. SCHNELL: example, Protocol 006 where we tested at 21 Now, this positive neutralization 21 higher serum concentrations. For example, we 22 of a single dilution occurs predominantly in 22 could have a serum that neutralizes at 1 to 2 23 pre-vaccination samples because of the prozone 23 or 1 to 4 -- I don't recall 1 to 2 is the 24 effect. Correct? 24 first exposure. For example, 1 to 4 dilution 25 Α. I don't know that that's 25 or 1 to 8 dilution, that would neutralize Page 451 Page 453 correct. I agree with the prozone effect but 1 whether you had anti-IgG or not at that 2 I don't recall that it's specific or happens 2 dilution. It's much more likely at a higher 3 more frequently in the pre-vaccination sera. 3 dilution. In the anti-IgG assay, knowing that 4 there's a prozone effect and to conserve sera 4 Q. In your experience with this 5 5 assay, that wasn't the case. In virtually volumes, we started a 1 to 32 dilution. So we 6 every instance when there was a positive 6 did not have the capability of seeing whether 7 neutralization at a single dilution, it was a 7 or not serum would have been positive at 1 to 8 pre-positive and not a post-positive? 8 4, 1 to 8 or 1 to 16 dilution. So my 9 MR. SANGIAMO: Object to the 9 expectation is that the anti-IgG would not 10 form. Asked and answered. 10 mask neutralization if it was going to happen THE WITNESS: As best I can 11 11 at a higher serum concentration. But we did 12 recall, there were -- I don't recall 12 not test those higher serum concentrations. 13 the actual numbers but there were 13 The neutralization that you're 14 single positive dilution samples in 14 talking about when it comes to anti-IgG, are 15 15 post-vaccination sera as well as you talking about just mumps neutralization? 16 pre-vaccination sera. 16 MR. SANGIAMO: Object to the 17 BY MR. SCHNELL: 17 form. 18 18 Q. But I'm saying in terms of the THE WITNESS: I'm talking about 19 vast majority where this occurred, it occurred 19 mumps plaque reduction. 20 on the pre-vaccination side. Isn't that 20 BY MR. SCHNELL: 21 correct? 21 Anti-IgG also leads to 22 I do not know that that's 22 neutralization of non-mumps antibodies. A. 23 23 correct. Correct? 24 Well, in terms of how the 24 MR. SANGIAMO: Object to the 25 form. And asked and answered actually. prozone effect works, wouldn't it make more

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1	THE WITNESS: The anti-IgG is	1	specificity studies that were part of the
2	not specific for mumps antibodies so	2	validation, we took sera, absorbed it with
3	it's capable of binding to other	3	measles, mumps, rubella antigen, given these
4	antibodies. Whether or not it	4	were MMR recipients and we're comparing pre-
5	neutralizes or not, I don't I can't	5	and post-vaccination sera. The boost in titer
6	say.	6	would indicate between pre- and
7	BY MR. SCHNELL:	7	post-vaccination sera would indicate that
8	Q. So how do you know, then, if	8	within that time frame between the two bleeds
9	you're using anti-IgG, whether the	9	there was a boost in the antibody. And then
10	neutralization that occurs is mumps	10	with the absorption of measles, mumps, rubella
11	neutralizing or non-mumps neutralizing?	11	antigen demonstrated mumps, that absorbed with
12	A. That was addressed in the the	12	mumps antigen reduced the neutralization
13	specificity was an aspect that was addressed	13	capacity of the serum more than the other
14	as part of the validation plan to demonstrate	14	antigens, suggesting that the antibodies were
15	mumps specificity.	15	being attacked that were mumps specific.
16	MR. SCHNELL: Can you, please,	16	Q. I think it was 50 percent
17	repeat the question?	17	specificity. Correct?
18		18	A. That's not my interpretation of
19	(The court reporter read the	19	the results.
20	pertinent part of the record.)	20	Q. What was your interpretation?
21		21	A. My interpretation of the results
22	THE WITNESS: So anti-IgG on its	22	was that the antibody titers were reduced more
23	own does not neutralize mumps. We	23	significantly by mumps than any of the
24	showed in a paper by Sato from the FDA	24	other than measles or rubella. And some of
25	for a similar effect. In our studies	25	the sera, some of the sera were, from my view,
	Page 455		Page 457
1	we did did studies absorbing sera	1	not a valuable, meaning they were negative for
2	with measles, mumps, rubella antigens	2	all the absorbing antigens.
3	to demonstrate mumps specificity of the	3	For the pediatric sera, as best
4	neutralization.	4	I recall, two I don't know pediatric or
5	BY MR. SCHNELL:	5	adult sera, two of the four showed less or
6	Q. So if you mixed anti-IgG with	6	some effect of rubella absorption on titers,
7	human serum, it's going to neutralize it's	7	but I would argue that those, the lack of
8	going to show neutralization of mumps	8	absorbing more efficiently absorbing out
9	neutralizing antibodies and it's also going to	9	mumps antibodies for those who are
10	show a neutralization of non-mumps antibodies.	10	absorbing out the antibodies for mumps from
11	Correct?	11	those sera may be a reflection of the titer of
12	MR. SANGIAMO: Object to the	12	those sera rather than the specificity itself,
13	form.	13	meaning that we're adding a fixed amount of
14	THE WITNESS: It could in	14	antigen to absorb the antibodies. We don't
15	this assay we have there's the	15	have a guarantee that we're adding enough
16	indicator virus is mumps in the assay.	16	antigen to absorb out all of the antibodies.
17	So we're detecting mumps specific	17	Q. So the test that you say you
18	neutralization.	18	conducted, measles, mumps, and rubella, didn't
19	BY MR. SCHNELL:	19	show that 100 percent of the neutralizing
20	Q. But how? If there is anti-IgG	20	antibodies were mumps neutralizing. Right?
21	in there, how do you know if it's the	21	MR. SANGIAMO: Object to the
22	antibodies that are mumps neutralizing or the	22	form.
23	other types of antibodies that the anti-IgG	23	THE WITNESS: No, in fact, there
24	combined with?	24	are published absorption experiments.
24			
25	A. In an example I gave, the	25	I've never seen one that showed 100

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1	Page 458	1	Page 460 antibodies?
1	percent reduction of antibody	1	
2	specificity with the absorption.	2	A. Only IgG antibodies.
3	BY MR. SCHNELL:	3	Q. Okay. So is mumps the only one?
4	Q. So some of the neutralization	5	A. There are other potential IgG
5	that occurs when you're using anti-IgG in the	_	antibodies.
6	mumps testing that you did would have resulted	6	Q. Flu? Could it bind with flu
7	from non-mumps neutralizing antibodies.	7	antibodies?
8	Correct?	8	A. I can't exclude it. I don't
9	MR. SANGIAMO: Object to the	9	know what sera what the recipients of the
10	form.	10	vaccine, what antibodies they would likely
11	THE WITNESS: From my	11	have. But I would agree in theory, if it's an
12	interpretation, that's not a conclusion	12	appropriate IgG antibody, it could bind to the
13	that I would make from that from the	13	anti-IgG.
14	specificity data.	14	Q. So what are some other IgG
15	BY MR. SCHNELL:	15	antibodies that it could potentially bind to?
16	Q. So is your testimony that 100	16	A. Any whatever IgGs are in
17	percent of the neutralization that occurred in	17	serum.
18	the AIGENT testing was mumps neutralizing	18	Q. What are those?
19	antibodies?	19	A. In an infant I don't know what
20	A. My testimony is that the	20	Q. Do you know any?
21	specificity study demonstrated that the assay	21	A. I don't I just would be
22	was showing specificity for mumps. I can't	22	pulling virus names out of the air.
23	speak to whether it's 100 percent. I don't	23	Q. It could be measles. Right?
24	have familiarity or insight into the	24	A. Yes.
25	application to say whether one can say it's	25	Q. It could be rubella?
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1	100 percent. All I can say is that the assay	1	A. Yes.
2	from my view demonstrated specificity	2	Q. It could be flu?
3	absorption experiments demonstrated	3	MR. SANGIAMO: Object to the
4	specificity. Whether one can assign 100	4	form.
5	percent, that's it's not a term that I'm	5	THE WITNESS: I don't know. The
6	familiar with or have any familiarity with to	6	measles, mumps, rubella I agree to
7	say whether the 100 percent value applies.	7	because they're given more vaccine. As
8	Q. So you just don't recall one way	8	far as flu, I don't know. Again, I
9	or the other?	9	would agree in theory a flu antibody
10	MR. SANGIAMO: Object to the	10	could bind. Whether or not the infants
11	form.	11	would have flu anti-IgG, I don't know.
12	THE WITNESS: I would say my	12	BY MR. SCHNELL:
13	recollection is that the absorption	13	Q. So what steps, if any, did you
14	experiment showed mumps specificity.	14	take to control for the possibility that the
15	How one then assigns what not saying	15	anti-IgG was showing a false neutralization
16	it's specific or nonspecific, I'm not	16	because it was detecting or it was allowing
17	familiar with how one assigns a percent	17	you to detect in the AIGENT testing non-mumps
18	value.	18	neutralizing antibodies?
19	BY MR. SCHNELL:	19	MR. SANGIAMO: Objection. Asked
20	Q. You can see that anti-IgG binds	20	and answered.
21	with any kind of antibody in the blood.	21	THE WITNESS: The absorption
22	Right?	22	experiments from my view demonstrated
23 24	A. No.	23 24	the mumps specificity. Another aspect
	Q. So it binds with mumps	44	which is my I've seen it in other
25	antibodies, right, mumps neutralizing	25	publications, I don't I can't recall

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1	with certainty if this was included in	1	a control to verify that the anti-IgG was
2	the discussion of the current assay, is	2	not would account for would verify the
3	that we have a pre-vaccination serum	3	anti-IgG was not neutralizing mumps.
4	and then a post-vaccination serum. If	4	Q. How could it do that if the
5	they're given MMR, you only the	5	control didn't have serum?
6	expectation would be that the infants	6	A. That's the the intent of that
7	are only going to make antibodies to	7	control was to demonstrate or in previous
8	those three viruses in that time	8	experiments we looked at adding anti-IgG or
9	period. So if one had a question about	9	not to virus, and there was no impact and
10	flu antibodies or other antibodies, it	10	confirming the results of the Sato paper. So
11	would be unlikely that those	11	it's a control not for serum but for the
12	comparing the pre- and post-vaccination	12	anti-IgG. We did not have a control for
13	titers, that they would change	13	for example, we did not have a negative serum
14	concomitant with the MMR vaccination or	14	control.
15	integral between bleeds with the MMR	15	Q. Did the Sato paper talk about
16	vaccination.	16	controlling for anti-IgG?
17	BY MR. SCHNELL:	17	A. I'm sorry, in what way?
18	Q. Were the subjects in the AIGENT	18	Q. In any way.
19	testing screened beforehand to make sure that	19	A. I recall that they the
20	they didn't their blood didn't contain any	20	publication described dilutions of anti-IgG.
21	other IgG?	21	As best I can recall, they had a no serum
22	A. I'm not aware of any screening.	22	control. I don't recall if they had other
23	MR. SANGIAMO: Gordon, we've	23	what other controls, if any, were described.
24	been going about an hour and five	24	Q. Again, if there's a risk that
25	minutes. If you get to a good stopping	25	using anti-IgG will bind with non-mumps
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1	point.	1	neutralizing antibodies, how can you control
2	MR. SCHNELL: A few minutes.	2	for that possibility if you don't use serum in
3	BY MR. SCHNELL:	3	the control?
4	Q. So the AIGENT testing had	4	A. As we state here, in the case of

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- controls. Right?
- A. The AIGENT assay had a control of those serum, meaning virus anti-IgG in the absence of serum. It had a, call it a control, but a mock sample which is the control -- sorry, that's not right. The control which is the virus anti-IgG and no serum. Virus anti-IgG and no serum. And then 12 there were adult -- two control sera in each assay. And then uninoculated controls.
- Q. For the negative control you used the mock control I believe you said?
- That's not a negative -- I guess one could call it a negative control. I don't view it as a negative control. I view that as the baseline.
- 21 So how did that control, if at O. 22 all, control for the possibility that anti-IgG 23 was going to lead to false neutralization?
- 24 A. That sample included anti-IgG in the absence of serum. So it would -- that was

a paired sera, the pre-vaccination serum is not intended as a control but it serves as a -- in effect a control, meaning that if pre-vaccination serum are predominantly negative, post-vaccination serum are seroconverting, that that pre-vaccination serum indicates that -- negative pre-vaccination serum result indicates that there's no detectable mumps antibody or other -- it is my interpretation no mumps antibody from your description would -- if there's any potential -- would address the absence of mumps specific antibody in those sera. Whether or not other antibodies that were in there could or would or could neutralized mumps, we don't have other viruses in there to see what other viruses might be present and neutralized.

So how could you be sure, maybe this wasn't important to your experiment, but I would assume it would be, how could you be

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· · · · · · · · · · · · · · · · · · ·		THE WITNESS: I'm not yeah, I don't know the specific controls that
		-
		they used.
		MR. SCHNELL: Okay. We can take a break.
-		
	_	VIDEOGRAPHER: The time is now 10:16. This ends disc one.
		10:16. This ends disc one.
•		(A
*		(A recess was taken.)
		VIDEOCD A DIJED. The 4ime is a con-
		VIDEOGRAPHER: The time is now
		10:33. This begins disc two. You may
-		proceed.
_		BY MR. SCHNELL:
		Q. Dr. Krah, in terms of the
		interim analysis, taking us back to the flow
· ·		of the plaque counting process, in terms of
		the interim analysis, when you were reviewing
- 1		the spreadsheet which had the data that
		derived from the plaque counting, and you were
-		looking for criteria to confirm accuracy, was
		that something that you were directed to do?
-		A. I would say the single positive
-		dilution aspect, as best I recall, was
form.	25	something in reviewing the data with Emilio
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		Emini that he, I wouldn't say directed, but
		pointed out that those were ones that he
		thought were worthy of verifying plaque
		counts. So I wouldn't call it a directive,
		but in doing that and realizing that some of
		the counts were not accurate became somethin
*		that seemed appropriate to continue, from my
		interpretation to continue doing. So one
- ·		point it is a directive but something that
		came out of initial discussions with Emilio.
		Q. When you say that in reviewing
		this and you finding out that the plaque
		counts weren't accurate in this regard, how
•		did you confirm that they weren't accurate?
_		A. Well, not the original
		counters were, as I indicated, I can't I
		don't recall in each case the original counter
		was the one that verified it, but I had
		confidence that the person doing the recheck
assay, so I don't	20	was taking an accurate count. I would point
BY MR. SCHNELL:	21	out that not all of them some were accurate
Q. You don't know what controls, if	22	and some weren't. So it wasn't always in
any, they used?	23	each case where there was a check, it did not
	sure that the neutralization results you were getting in the AIGENT testing was specific, 100 percent specific to not to mumps neutralizing antibodies? MR. SANGIAMO: Object to the form. THE WITNESS: Again, going back to the validation study, as best I recall, those the results of the validation study were presented both to Merck and to CBER. They did not raise concerns over that specificity. My conclusion from that was that the assay was specific, demonstrated to be specific for mumps. BY MR. SCHNELL: Q. If you had used a non-immune serum, a non-immune control, meaning non-immune serum in the control, and anti-IgG, wouldn't that have told you exactly whether or not there was neutralizing antibodies caused by the anti-IgG that were not mumps neutralizing antibodies? MR. SANGIAMO: Object to the form. Page 467 THE WITNESS: No. That has one major caveat to my understanding in that negative serum is, from my understanding, not an absolute value, meaning it depends on the assay that's used to show that it's devoid of antibodies to mumps. BY MR. SCHNELL: Q. Didn't you use it for the ELISA testing? MR. SANGIAMO: Object to the form. BY MR. SCHNELL: Q. Wasn't that critical to the ELISA testing? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not familiar with the ELISA it's a different	sure that the neutralization results you were getting in the AIGENT testing was specific, 100 percent specific to not to mumps neutralizing antibodies? MR. SANGIAMO: Object to the form. THE WITNESS: Again, going back to the validation study, as best I recall, those the results of the validation study were presented both to Merck and to CBER. They did not raise concerns over that specificity. My conclusion from that was that the assay was specific, demonstrated to be specific for mumps. BY MR. SCHNELL: Q. If you had used a non-immune serum, a non-immune control, meaning non-immune serum in the control, and anti-IgG, wouldn't that have told you exactly whether or not there was neutralizing antibodies caused by the anti-IgG that were not mumps 22 neutralizing antibodies? MR. SANGIAMO: Object to the form. Page 467 THE WITNESS: No. That has one major caveat to my understanding in that negative serum is, from my understanding, not an absolute value, meaning it depends on the assay that's used to show that it's devoid of antibodies to mumps. BY MR. SCHNELL: Q. Didn't you use it for the ELISA testing? MR. SANGIAMO: Object to the form. BY MR. SCHNELL: Q. Wasn't that critical to the ELISA testing? MR. SANGIAMO: Object to the form. THE WITNESS: I'm not familiar with the ELISA it's a different

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Page 472 second count was more accurate than the first post-vaccination serum that made that sample 2 count. Correct? result invalid, the pair would be retested. 3 That's my best recollection, 3 We always tested the sera as a pair in the A. 4 4 same assay. Which the point there being that yes. 5 Q. What's that based on? 5 if, for example, one of the serum -- like a My confidence -- it's based on 6 pre-vaccination serum result was valid, a my confidence in the first count plaques were post-vaccination serum was not valid, we would 8 miscounted, the person realized that in the 8 retest the pair together. To get a valid recount and then had a -- in some cases, not 9 result, you needed a valid pre- and 10 all the cases resulted in a change, but that 10 post-vaccination serum result. their recount verified whether the original 11 11 Q. So what were the circumstances that would lead to a pre- or post-vaccination 12 result was accurate or the correction was 12 accurate and that recount, the recheck gave me 13 sample being invalid? 14 confidence that the person verified the 14 A. In the first third, I don't recall the specific example. The second third 15 accurate plaque count. 15 16 So these were criteria for 16 and third third, for example, there were, I 17 checking views to determine whether or not 17 believe, what was described in the workbook as there should be recounts. Correct? That's 18 an invalid dilution, meaning a -- for example, 19 what we've been talking about, this criteria 19 if for a given serum dilution we have 20 for the interim analysis was the criteria that 20 triplicate wells, the samples are inoculated 21 you were guided by in determining whether or 21 in triplicate wells, we need at least two --22 not there should be recounts? 22 values for two of those wells to have a valid 23 MR. SANGIAMO: Object to the 23 result for that well; meaning that if we only 24 form. 24 had one result out of the three replicates, 25 THE WITNESS: I'm not sure I 25 that would be an invalid dilution. So there Page 471 Page 473 1 understand the question. 1 would be no opportunity to determine whether 2 BY MR. SCHNELL: 2 that serum was neutralizing or not. 3 Q. So the four criteria you 3 Q. Any other examples? 4 A. No. We had cases where, besides 4 outlined, positive neutralization single 5 5 dilution, erratic neutralization, plaques and the extra -- there was extra -- extra 6 unaffected cell control and pre-positives to 6 variability criteria was part of that. And in 7 post-negatives, those were criteria that you 7 some assays we're having, for want of a better identified before that you looked at to 8 description, tearing of the monolayers, they 9 determine whether or not you were going to 9 need some healing of the cells that prevented 10 10 direct a recount? getting an accurate count for those wells. 11 A. Those were conditions in which 11 Those would then result in, from my 12 we looked at the plates and did a recount to 12 interpretation, a similar invalid dilution. 13 verify the accuracy of the counts. 13 There may be other cases. Those are two that 14 Q. So what about for retesting, was 14 comes to mind. 15 15 So with the extra variability there also a set of criteria that you were Q. governing -- that you were looking towards to 16 criteria, what would that entail? 17 determine whether or not a retest was 17 That -- as best I understand it, Α 18 it was a value established by our 18 appropriate? 19 A. There was a criteria for --19 statistician. It's not an area I'm fluent in. 20 there was a criteria for retest that involved 20 My general understanding is that it looked at 21 an invalid result for -- in the first part I 21 the variability between the triplicate well 22 don't recall if this applies. The point I was 22 values or having duplicate wells would still 23 trying to -- I was thinking I was trying to 23 be valid. So looking at variability between 24 make is that in one of the -- if there was an 24 the duplicate and triplicate wells. And then 25 aspect to our pre-vaccination serum or a there was a calculation involved to, as best I

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Page 476 recall, identify a range that is statistically number, the count number for that well yet. 2 acceptable between, as best I recall, the high 2 Q. So you recall instances at least 3 and the low value in that range. So my 3 where you were counting where you would do a 4 understanding it's basically looking to see if 4 count, and you'd mark it on the plate and then 5 the numbers, if the replicate values are 5 you would check your count and get a different unusually unlike each other. 6 number? 6 7 Was positive neutralization in a 7 It's not a -- I wouldn't A. 8 single dilution ever used as a criteria for 8 characterize it as a check. As part of the 9 9 retesting? routine counting, after I put spots in the 10 A. Positivity of a single dilution 10 plate, I tilt the plate back and forth to make 11 was used, not specifically for pre-positive. sure that I wasn't missing something. So it's 11 12 So that was also used as a 12 not a recount or a check but a verification 13 criteria for retesting? 13 that something wasn't being missed. 14 14 As best I can recall, a single Q. So you didn't double check your 15 positive dilution was flagged for not 15 work, you would just count once, give it a necessarily -- I'm sorry, not for retesting. 16 little look and that's that. Right? 17 For plaque count as a first check, not --17 MR. SANGIAMO: Object to the 18 there are some samples that were tested, 18 form. And asked and answered. 19 retested as part of an understanding the assay 19 THE WITNESS: As best -- as far 20 20 and monitoring the assay. There were single as -- I don't recall doing -- unless it 21 positive dilutions. But in those cases, the 21 was part of a recheck of additional 22 22 result of the original test was always assay plates later, I would not recheck 23 23 reported if the original result was valid. or recount that particular plate. 24 So getting back to the interim 24 BY MR. SCHNELL: 25 analysis, I want to make sure I understand the 25 And you didn't direct your staff Page 475 Page 477 path. So the counter would first look at the 1 to either? plate, count the plaques, and each time they 2 No. A. 3 Would that have made the 3 counted the plaque, they would mark somewhere Q. 4 on the plate a dot for each plaque they 4 counting more accurate? 5 counted. Correct? 5 A. From a statistical criteria, I A. That's my understanding and 6 can't say whether it would have. My 6 7 7 recollection of the -- how they were counted. understanding was that when we're doing the 8 Q. Then the plaque count, would 8 plaque count qualification, it's typically a 9 9 they double check that? person counts the plate, set of plates, 10 A. Not that I'm aware of. From my 10 another person counts the set of plates. We 11 own personal experience, as part of the 11 were doing the plaque count comparison with a counting of the plate, I would mark the spots single round of counting. So whether or not a 12 12 and then give a second look, not recheck, but 13 second round of counting would have had an 14 look to see that I didn't miss something. 14 impact, I don't have a thought. 15 Q. And were there instances where 15 Q. Do you recall during the 16 you missed something? 16 counting process that you would on occasion go 17 A. I recall cases where the 17 to some of your counters while they were 18 plates -- occasionally the plaques aren't 18 counting and help them count? 19 visible. It may be like -- hard to describe, 19 I recall some counters when they 20 20 but they could be at the corner of the well so were counting saying I'm having trouble seeing 21 you need to tilt the plate back and forth a 21 these plaques, they look kind of faint or bit to make sure that you're seeing all the 22 they're not readily visible, can you take a surface of the wells. But I considered that 23 look at this and verify that I'm counting 24 not a recheck but part of the original 24 accurately. counting. Because I hadn't finalized the 25 Q. Do you recall finding that there

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