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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1	Page 409	1	Page 411
1	A. From my understanding, yes.	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	information related to the testing of the
2	Q. What is the basis of that	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	protocol would have been reported to the FDA
3	understanding?	3	would be the only knowledge I would have
4	A. Going back to what I recollect,	4	that through that reporting and method
5	what the was documented in the development	5	validation that the FDA may have that
6	of the method, that document.	6	information.
7	Q. This is the document you	7	Q. I'm sorry, ma'am, I don't
8	referred to several times that Mr. Krahling	8	follow that. My question is, do you have
9	gave you?	9	firsthand knowledge of whether the FDA knew
10	A. Yes.	10	what virus was being used in the plaque
11	Q. Do you have the expertise to	11	reduction neutralization assay? Do you have
12	state whether the amount that it had been	12	firsthand knowledge of that?
13	passaged made it no longer wild type?	13	MR. KELLER: Objection. Vague
14	MR. KELLER: Objection. Lack	14	and ambiguous.
15	of foundation. Vague and ambiguous.	15	THE WITNESS: I have knowledge
16	THE WITNESS: I'm trying to	16	that they have received the completed
17	think through your question. So can	17	study, clinical study with the data
18	you repeat the question?	18	reported. Based on my knowledge, they
19	BY MR. SANGIAMO:	19	would also have the validation of the
20	Q. Let me ask this: Do you know	20	methodology and through that would be
21	how many times it was passaged?	21	what I would consider them to have
22	A. I do not recall.	22	information around what may or may not
23	Q. Do you have the expertise to	23	have been used as the virus used in the
24	assess whether that number of passages,	24	methodology.
	Page 410		Page 412
1	Page 410 whatever it is, was such that it is no longer	1	BY MR. SANGIAMO:
1 2		1 2	BY MR. SANGIAMO: Q. So it's your belief that they
	whatever it is, was such that it is no longer	-	BY MR. SANGIAMO: Q. So it's your belief that they had the validation. Right? Is that your
2	whatever it is, was such that it is no longer wild type?	2 3 4	BY MR. SANGIAMO: Q. So it's your belief that they had the validation. Right? Is that your testimony?
2 3	whatever it is, was such that it is no longer wild type? MR. KELLER: Objection. Lack of foundation. Vague and ambiguous. THE WITNESS: I cannot say. I	2 3	BY MR. SANGIAMO: Q. So it's your belief that they had the validation. Right? Is that your testimony? A. Yes.
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Appx6001

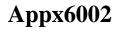
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1	Page 413	1	Page 415 through further on this?
$\begin{vmatrix} 1\\2 \end{vmatrix}$	that was used in the assay?	1	BY MR. SANGIAMO:
	A. I would have expected it to be, but I can't confirm that.	$\frac{2}{3}$	
3			Q. Absolutely.
4	Q. But if it was, that would be	4	MR. KELLER: You may want to
5	one means by which the FDA would have known	5	start at paragraph 33 to 39.
6	what virus was being used in the assay. Is	6	BY MR. SANGIAMO:
7	that your testimony?	7	Q. What paragraph are you on?
8	A. Yes.	8	A. I'm done.
9	Q. Do you have knowledge of	9	Q. So let's go back to paragraph 35
10	whether the FDA may have learned what virus	10	and the sentence, "The use of animal
11	was being used in the assay on other	11	antibodies in laboratory testing is not
12	occasions?	12	uncommon." I think the pending question is
13	MR. KELLER: Objection. Vague	13	whether you have an opinion as to whether that
14	and ambiguous. Overbroad.	14	is an accurate statement?
15	THE WITNESS: Not that I can	15	MR. KELLER: Objection. Seeks
16	recall.	16	a legal conclusion from a legal document.
17	BY MR. SANGIAMO:	17	Seeks expert opinion from a lay witness.
18	Q. You also mentioned the use of	18	You can answer.
19	antihuman IgG in the assay as a concern of	19	THE WITNESS: In my opinion,
20	yours about the design of the assay. Is that	20	yes, I have seen animal antibodies
21	a fair statement?	21	being used in laboratory testing,
22	A. Yes.	22	not which includes testing outside
23	Q. Could you turn to Exhibit 6,	23	of PRN methodology.
24	please, which is the Amended Complaint in this	24	BY MR. SANGIAMO:
	Page 414		Page 416
1	case. If you could turn, please, to	1	Q. Do you agree that it's not
2	paragraph 35. Are you there?	2	uncommon? You said you've seen it. I'm
3	A. Yes.	3	asking do you agree that it's not uncommon?
4	Q. If you go down five lines	4	MR. KELLER: Same objection.
5	within paragraph 35. Do you see the sentence,	5	THE WITNESS: I agree.
6	"The use of animal antibodies in laboratory	6	BY MR. SANGIAMO:
		7	
7	testing is not uncommon"? Do you see that?		
8	A. Yes.	8	not uncommon the fact that you've seen it
9	Q. Is the reference there to	9	yourself in other circumstances?
10		10	
11	IgG?	11	Q. Is there any other basis for
12	A. Yes.	12	your belief that it's not uncommon?
13	Q. Do you agree with that	13	MR. KELLER: Objection. If in
		14	order to answer that question you would
14	statement that the use of animal antibodies in		
15	laboratory testing is not uncommon?	15	have to disclose communications with
15 16	laboratory testing is not uncommon? MR. KELLER: Objection. Seeks	15 16	your counsel, I would instruct you not
15 16 17	laboratory testing is not uncommon? MR. KELLER: Objection. Seeks expert testimony from a lay witness.	15 16 17	your counsel, I would instruct you not to answer the question to the extent
15 16 17 18	laboratory testing is not uncommon? MR. KELLER: Objection. Seeks expert testimony from a lay witness. BY MR. SANGIAMO:	15 16 17 18	your counsel, I would instruct you not to answer the question to the extent that it will disclose communications
15 16 17 18 19	laboratory testing is not uncommon? MR. KELLER: Objection. Seeks expert testimony from a lay witness. BY MR. SANGIAMO: Q. Let me back it up a step to	15 16 17 18 19	your counsel, I would instruct you not to answer the question to the extent
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15 16 17 18 19 20 21	 laboratory testing is not uncommon? MR. KELLER: Objection. Seeks expert testimony from a lay witness. BY MR. SANGIAMO: Q. Let me back it up a step to accommodate Mr. Keller's objection. Do you have an opinion as to 	15 16 17 18 19 20 21	your counsel, I would instruct you not to answer the question to the extent that it will disclose communications with counsel. THE WITNESS: I cannot answer the question.

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1			
1	Page 417	1	Page 419 PV MP, SANGIAMO:
$\begin{vmatrix} 1\\2 \end{vmatrix}$	A. Right.Q you could not answer the	$\begin{vmatrix} 1\\2 \end{vmatrix}$	BY MR. SANGIAMO: Q. In connection with your
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Q you could not answer the question of whether there are other bases for	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Q. In connection with your employment at various places or just at New
4	your belief it's not uncommon. Do I have it	4	Haven?
5	right?	5	A. Various places.
6	A. Correct.	6	Q. Is there a way for you to
7	Q. How many assays have you seen	7	describe what the function is of the animal
8	animal antibodies used in?	8	antibodies in the ELISAs that you've seen?
9	A. What do you mean by "how many	9	MR. KELLER: Objection. Vague
10	assays"?	10	and ambiguous.
11	Q. Have you seen it referred to in	11	THE WITNESS: Can you restate
12	SOPs in other assays?	12	the question?
13	A. So you're talking about different	13	BY MR. SANGIAMO:
14	types of assays or how many different ELISAs		Q. If at any point you don't have
15	Is it just an ELISA and something else or is	15	the expertise to answer one of these
16	it number of ELISAs, that sort of thing?	16	questions, just say so.
17	Q. I understand your point. Have	17	A. Uh-huh.
18	you seen it in any assays other than ELISA	18	Q. Do you know what role the
19	assays and the plaque reduction neutralization	19	animal antibodies played in the operation of
20	assay that you ran at Merck?	20	the ELISAs in which you've seen animal
21	MR. KELLER: Objection. Lacks	21	antibodies used?
22	foundation.	22	MR. KELLER: Objection. Vague
23	THE WITNESS: So can you break	23	and ambiguous. Lack of foundation.
24	it down?	24	THE WITNESS: Again, it does
	Page 418		Page 420
1	BY MR. SANGIAMO:	1	help to enhance the reaction by
2	Q. Same problem?	2	allowing for more specific or not
3	A. Yes.	3	specific but more binding to what is
4			being tested.
1 1	Q. Have you seen it used in ELISAs?	4	being tested.
5	Q. Have you seen it used in ELISAs?A. Yes.	45	BY MR. SANGIAMO:
	A. Yes.		BY MR. SANGIAMO:
5	A. Yes.Q. How many different kinds of	5	BY MR. SANGIAMO:
5 6	A. Yes.	5 6	BY MR. SANGIAMO: Q. So does it make the assays more sensitive?
5 6 7	A. Yes.Q. How many different kinds ofELISAs have you seen animal antibodies used	5 6 7	BY MR. SANGIAMO: Q. So does it make the assays more
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5 6 7 8 9	A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack	5 6 7 8 9	BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous.
5 6 7 8 9 10	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. 	5 6 7 8 9 10	BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the
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5 6 7 8 9 10 11 12	A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds.	5 6 7 8 9 10 11 12	BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it
5 6 7 8 9 10 11 12 13	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: 	5 6 7 8 9 10 11 12 13	BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it
5 6 7 8 9 10 11 12 13 14	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? 	5 6 7 8 9 10 11 12 13 14	BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make
5 6 7 8 9 10 11 12 13 14 15	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. 	5 6 7 8 9 10 11 12 13 14 15	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive?
5 6 7 8 9 10 11 12 13 14 15 16	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. Q. More than ten? 	5 6 7 8 9 10 11 12 13 14 15 16	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive? A. Again, it could be used as much
5 6 7 8 9 10 11 12 13 14 15 16 17	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. Q. More than ten? A. Probably. 	5 6 7 8 9 10 11 12 13 14 15 16 17	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive? A. Again, it could be used as much in here as a highlighter, so there could be
5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. Q. More than ten? A. Probably. Q. Are these ELISAs that you ran 	5 6 7 8 9 10 11 12 13 14 15 16 17 18	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive? A. Again, it could be used as much in here as a highlighter, so there could be another function. I can't elaborate on it at
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. Q. More than ten? A. Probably. Q. Are these ELISAs that you ran at New Haven? 	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive? A. Again, it could be used as much in here as a highlighter, so there could be another function. I can't elaborate on it at this time. Just for my not having worked
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. Q. More than ten? A. Probably. Q. Are these ELISAs that you ran at New Haven? MR. KELLER: Objection. Lack 	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive? A. Again, it could be used as much in here as a highlighter, so there could be another function. I can't elaborate on it at this time. Just for my not having worked directly with it at the current time.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Yes. Q. How many different kinds of ELISAs have you seen animal antibodies used in? MR. KELLER: Objection. Lack of foundation. THE WITNESS: Many different kinds. BY MR. SANGIAMO: Q. More than five? A. Yes. Q. More than ten? A. Probably. Q. Are these ELISAs that you ran at New Haven? MR. KELLER: Objection. Lack of foundation. 	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 BY MR. SANGIAMO: Q. So does it make the assays more sensitive? MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: It depends on the assay. BY MR. SANGIAMO: Q. Is there any function it performs as far as you know other than to make the assay more sensitive? A. Again, it could be used as much in here as a highlighter, so there could be another function. I can't elaborate on it at this time. Just for my not having worked directly with it at the current time. Q. Why do you say at the current

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1	familiarity with it.	1	Q. I'm going to try to break that
2	Q. This is a topic that at one	2	down, but you tell me if I'm not doing it
3	time you would have felt comfortable	3	correctly. All right?
4	addressing but right now you do not. Do I	4	A. Yes.
5	have that right?	5	Q. I heard you testify that you
6	MR. KELLER: Mischaracterizes	6	believe that the reason why you were being
7	her testimony.	7	asked to recheck the pre-positives was because
8	THE WITNESS: That, I mean,	8	the antihuman IgG was being used in the assay
9	again, if I could refamiliarize myself	9	which was causing there to be more
10	at this time I could speak better to	10	pre-positives. Is that part of it right?
11	it.	11	A. It was causing an enhancement
12	BY MR. SANGIAMO:	12	across the assay.
13	Q. Did you have a concern about	13	Q. Including to the pre-vaccination
14	the use of antihuman IgG in the plaque	14	samples?
15	reduction neutralization assay at the time	15	A. Yes.
16	that you were working in Dr. Krah's lab?	16	Q. Which meant do I have it
17	MR. KELLER: Asked and answered.	17	right, which meant in your view it was
18	THE WITNESS: I was aware that	18	creating more pre-positives?
19	they had used it to enhance the	19	A. It would appear that it would.
20	reaction and so, yes.	20	Again, when based on paragraph 34 here,
21	BY MR. SANGIAMO:	21	there was the original PRN methodology which
22	Q. You're aware that they used it	22	had unsatisfactory seroconversion results
23	to enhance the reaction?	23	based on the objective of greater than a 95
24	A. Your question was did I have a	24	percent seroconversion rate. There was no
	Page 422		Page 424
1	concern while I was in Dave's lab. So the	1	explanation for why the methodology that was
2	answer is yes.	2	originally developed, the original PRN, why
3	Q. Yes, you had a concern, or yes,	3	that would have been abandoned and then moved
4	you were aware that they were using it to	4	on to the enhanced. Other than that, from the
5	enhance the reaction?	5	data that we've seen is that the enhanced gave
6	A. Yes, I was yes, I had a	6	a better seroconversion rate on the on
7	concern, yes.	7	those, at least if you exclude the
8	Q. Did you express that concern to	8	pre-positives, on their initial testing of the
9	anyone?	9	methodology is what they discovered.
10	A. Through the through my	10	Q. You weren't around when the
11	concern of what was occurring because of the	11	decision was made to use antihuman IgG in the
12	enhancement. We were also not only enhancing	12	assay. Correct?
13	the post-positive, but we were also enhancing	13	A. That is correct.
14	the pre-positive. So enhancing pre-vaccinated	14	MR. KELLER: Asked and answered.
15	serum at the same time you are enhancing the	15	BY MR. SANGIAMO:
16	post-vaccinated serum. The fact that we were	16	Q. So I guess what I'm trying to
17	getting a high level of pre-positives, that	17	get at is, whether the concerns that you had
18	was the concern. I basically had raised a	18	in 2001 when you were working in Dr. Krah's
19			lab were about the use of antihuman IgG itself
20	concern that, I guess sorry. I'm kind of	19	
	concern that, I guess sorry, I'm kind of rambling on.	19 20	-
	rambling on.	20	or whether the concerns were just that you
21	rambling on. I raised a concern that we were	20 21	or whether the concerns were just that you were being asked to check plaque counts?
21 22	rambling on. I raised a concern that we were being asked to recheck our counts on	20 21 22	or whether the concerns were just that you were being asked to check plaque counts? MR. KELLER: Objection. Asked
21	rambling on. I raised a concern that we were	20 21	or whether the concerns were just that you were being asked to check plaque counts?

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1			
1	Page 425	4	Page 427
1	believe I've answered it earlier is	1	that you don't know whether you had back in
2	based on the pre-positives, the	2	2001. Right?
3	increased pre-positives, my belief was	3	A. Correct. I can't recall if I
4	that the use of the animal antibodies	4	did.
5	enhance that rate and if we were	5	Q. So I assume you also do not
6	changing the pre-positives, we would	6	recall whether you expressed that concern to
7	have been falsely showing a greater	7	anyone back in 2001. Right?
8	greater seroconversion or a greater	8	A. Not specifically.
9	titer endpoint based on the	9	Q. Can you elaborate on what that
10	manipulation of the pre-positive data	10	concern is?
11	used against the post-vaccinated	11	A. If the control, if rabbit
12	samples.	12	antibodies were used in the mock control, it
13	BY MR. SANGIAMO:	13	would normalize against the data.
14	Q. Did you ever say to anyone in	14	Q. Do you know whether antihuman
15	2001 we should not be using antihuman IgG in	15	IgG was used in the mock control?
16	this assay?	16	A. I can't recall if it was or
17	A. I do not recall saying that.	17	wasn't. The data or the again, from the
18	Q. Do you remember thinking that	18	procedure, it's not clear whether or not it
19	in 2001?	19	was. But I yeah, I believe at the time
20	A. I remember thinking that we	20	that we reported this, we didn't recall that
21	shouldn't be recounting our original or	21	it was being used. We didn't
22	changing the data for the pre-positives.	22	Q. At the time when who reported
23	Q. But do you remember thinking in	23	what?
24	2001 that antihuman IgG should not be used in	24	A. When we filed the Complaint,
	Page 426		Page 428
1	the assay?	1	our statement within the Complaint is that
2	MR. KELLER: Objection. Asked	2	there was there was no proper control.
3	and answered. You can answer again.	3	Q. So what is the date of your
4	THE WITNESS: I'm trying to	4	knowledge right now as to whether antihuman
5	think how else I can explain it. If	5	IgG was used in the mock control?
6	the data I just want to go back to	6	MR. KELLER: Hold on a second.
7	something I looked at before.	7	You can answer that question if you can
8	So, again, you're asking about	8	answer without disclosing
9	in 2001.	9	communications you had with your
10	BY MR. SANGIAMO:	10	counsel. If in order to answer that
1.1			
11	Q. Yes, ma'am.	11	question you need to disclose
12	Q. Yes, ma'am.A. I think at the time in 2001 my	12	question you need to disclose communications you've had with your
12 13	Q. Yes, ma'am.A. I think at the time in 2001 my at least my basic belief would have been	12 13	question you need to disclose communications you've had with your counsel, I instruct you not to answer
12 13 14	Q. Yes, ma'am.A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine	12 13 14	question you need to disclose communications you've had with your
12 13 14 15	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, 	12 13 14 15	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel.
12 13 14 15 16	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently 	12 13 14 15 16	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your
12 13 14 15 16 17	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, 	12 13 14 15 16 17	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the procedure it does not state whether or
12 13 14 15 16	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently 	12 13 14 15 16	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the
12 13 14 15 16 17	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently against pre and post. I think the other 	12 13 14 15 16 17	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the procedure it does not state whether or
12 13 14 15 16 17 18	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently against pre and post. I think the other concern I have is that the there was no 	12 13 14 15 16 17 18	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the procedure it does not state whether or not animal antibodies are added to the
12 13 14 15 16 17 18 19	Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently against pre and post. I think the other concern I have is that the there was no control for the animal antibodies. I can't	12 13 14 15 16 17 18 19	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the procedure it does not state whether or not animal antibodies are added to the control. Beyond that, I cannot state
12 13 14 15 16 17 18 19 20	 Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently against pre and post. I think the other concern I have is that the there was no control for the animal antibodies. I can't recall if that was a concern of mine at the 	12 13 14 15 16 17 18 19 20	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the procedure it does not state whether or not animal antibodies are added to the control. Beyond that, I cannot state anything further that was discussed
12 13 14 15 16 17 18 19 20 21	Q. Yes, ma'am. A. I think at the time in 2001 my at least my basic belief would have been that if we at least were able to determine original counts or provide original counts, that at least we were measuring consistently against pre and post. I think the other concern I have is that the there was no control for the animal antibodies. I can't recall if that was a concern of mine at the time or, you know, current. I basically gave	12 13 14 15 16 17 18 19 20 21	question you need to disclose communications you've had with your counsel, I instruct you not to answer as to communications you had with your counsel. THE WITNESS: So in the procedure it does not state whether or not animal antibodies are added to the control. Beyond that, I cannot state anything further that was discussed with my counsel.

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1	Page 429		Page 431
1	mock controls? You said it would normalize	1	literature about whether an assay that is
2	it. What does that mean?	2	using antihuman IgG should use antihuman IgG
3	A. If there was non again, the	3	in the control?
4	pre and the post sera is calculated against	4	A. Not that I recall.
5	the mock control. So it would normalize	5	Q. Do you have any data to show
6	against that.	6	that the lack of use of antihuman IgG in the
7	Q. Is the concern that the	7	control in the assay that was used in Protocol
8	antihuman IgG might itself neutralize virus?	8	007 had an impact on the assay results?
9	A. It is a concern that it could	9	MR. KELLER: Objection. Vague
10	prevent let me just get this right. Not	10	and ambiguous. Overbroad. If
11	that it would necessarily neutralize virus but	11	requiring to answer that question would
12	impact the results of the plaques being	12	require you to disclose communications
13	formed.	13	with counsel, I instruct you not to
14	Q. How else could it impact the	14	answer. To the extent that you can
15	result of the plaque being form other than	15	answer independent of communications
16	neutralizing virus?	16	with counsel, you can answer.
17	A. I can't say that without having	17	THE WITNESS: I do not have, I
18	that information or that data to test through	18	specifically do not have data to say
19	a control. I don't know.	19	whether it does or whether it doesn't.
20	Q. Have you ever participated in	20	I also cannot answer specific to
21	the decision about whether to include	21	information discussed with my counsel.
22	antihuman IgG in the control in an assay?	22	
23	MR. KELLER: Objection.	23	(Exhibit Wlochowski-20,
24	Overbroad.	24	Sensitive Neutralization Test for Virus
	Page 430		Page 432
1	THE WITNESS: Could you restate	1	Antibody article, was marked for
2	the question?	2	identification.)
3	BY MR. SANGIAMO:	3	
4	Q. Have you ever strike that.	4	BY MR. SANGIAMO:
5	When an assay is being designed	5	Q. Ms. Wlochowski, you've just
6	someone needs to decide whether to include	6	been handed what has been marked as Exhibit 20
7	antihuman IgG in the control. Right?	7	which was among the documents that you
8	MR. KELLER: Objection. Lack	8	produced from your own files.
9	of foundation. Overbroad.	9	A. Okay.
10	THE WITNESS: When an assay is	10	Q. And as is evident here, this is
11	being designed, yes, somebody has to	11	a journal article entitled Sensitive
12	define what the parameters are as we	12	Neutralization Test For Virus Antibody. Do
12	called it before.	13	you see that?
13	BY MR. SANGIAMO:	14	A. Where are you referring to?
15			
15	Q. If an assay is going to be using an antihuman IgG, one of those	15 16	Q. I'm just looking at the title of the article.
17	parameters is whether the antihuman IgG is	17	
	going to be used in the control. Right?		A. Sorry. Yes.
18		18	Q. Do you know when it is that you
19	A. That is correct, yes.	19	obtained a copy of this article?
20	Q. Have you ever participated in	20	MR. KELLER: Objection. Lack
1 / 1	that decision of whether antihuman IgG should		of foundation.
21			
22	be used in the control?	22	MR. SANGIAMO: What is what?
1	A. Not that I recall, no. Q. Have you ever read any	22 23 24	BY MR. SANGIAMO: what is what? BY MR. SANGIAMO: Q. Did this document come from

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1	Page 433		Page 435
1	your files?	1	document speaks for itself.
2	A. I can't recall. It may have.	2	THE WITNESS: That's what the
3	MR. KELLER: It could have come	3	document is stating.
4	from Steve Krahling's files.	4	BY MR. SANGIAMO:
5	MR. SANGIAMO: According to	5	Q. Are you able to assess based on
6	what you told us, it came from her	6	this first several sentences whether this
7	files.	7	document represents researchers at the FDA
8	MR. KELLER: You haven't	8	describing a method of a mumps plaque
9	established a foundation. That's all	9	reduction neutralization assay that uses
10	I'm objecting to.	10	antihuman IgG?
11	BY MR. SANGIAMO:	11	MR. KELLER: Objection.
12	Q. Do you recall when you came	12	MR. SANGIAMO: I'm sorry.
13	into the possession of this document?	13	MR. BEGLEITER: I was reading.
14	A. If okay, let me think. I	14	I wasn't talking to anybody.
15	was	15	MR. KELLER: You need to read
16	MR. KELLER: If you need to	16	the whole article, feel free.
17	take time to review the document, you	17	BY MR. SANGIAMO:
18	can do that.	18	Q. You feel you would need to read
19	THE WITNESS: Without having	19	the whole article to figure out whether this
20	thoroughly gone through this, my guess	20	paper is describing the use of antihuman IgG
21	would be that	21	in a plaque reduction neutralization assay for
22	MR. KELLER: Don't guess.	22	mumps?
23	THE WITNESS: I can't you	23	MR. KELLER: Let her read it.
24	know, I can't say specifically when I	24	If you want to represent that is what
	Page 434		Page 436
1	got it without making a guess at when I	1	it says, you can represent it. But
2	got it.	2	it's fair to let her read a document if
3	BY MR. SANGIAMO:	3	you put it in front of her.
4	Q. Do you know if it was while you	4	MR. SANGIAMO: Go off the
5	were working at Merck?	5	record. You can read it.
6	A. Again, if I did, that would be	6	VIDEOGRAPHER: The time is
7	a guess.	7	2:10. Going off the video record.
8		0	
	Q. The first sentence of the paper	8	
9	Q. The first sentence of the paper says, "A sensitive mumps virus plaque	8 9	(A recess was taken.)
			(A recess was taken.)
	says, "A sensitive mumps virus plaque	9	(A recess was taken.) VIDEOGRAPHER: The time is
10	says, "A sensitive mumps virus plaque neutralization test has been developed based	9 10	·
10 11	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody	9 10 11	VIDEOGRAPHER: The time is
10 11 12	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins,	9 10 11 12	VIDEOGRAPHER: The time is 2:23. Back on the video record.
10 11 12 13	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)."	9 10 11 12 13	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO:
10 11 12 13 14	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that?	9 10 11 12 13 14 15 16	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a
10 11 12 13 14 15	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes.	9 10 11 12 13 14 15 16 17	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes. Q. Have you read it before?
10 11 12 13 14 15 16	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes. Q. "The enhanced neutralization	9 10 11 12 13 14 15 16	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes.
10 11 12 13 14 15 16 17	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes. Q. "The enhanced neutralization test was approximately 100 times more	9 10 11 12 13 14 15 16 17	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes. Q. Have you read it before?
10 11 12 13 14 15 16 17 18	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes. Q. "The enhanced neutralization test was approximately 100 times more sensitive than the conventional neutralization	9 10 11 12 13 14 15 16 17 18	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes. Q. Have you read it before? A. I can't recall if I have.
10 11 12 13 14 15 16 17 18 19	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes. Q. "The enhanced neutralization test was approximately 100 times more sensitive than the conventional neutralization test or the hemagglutination-inhibition test."	9 10 11 12 13 14 15 16 17 18 19 20 21	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes. Q. Have you read it before? A. I can't recall if I have. Q. As you were reading it just
10 11 12 13 14 15 16 17 18 19 20	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes. Q. "The enhanced neutralization test was approximately 100 times more sensitive than the conventional neutralization test or the hemagglutination-inhibition test." Did I read that correctly?	9 10 11 12 13 14 15 16 17 18 19 20 21 22	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes. Q. Have you read it before? A. I can't recall if I have. Q. As you were reading it just now, did you understand it? A. Yes. Q. What is it that these researchers
10 11 12 13 14 15 16 17 18 19 20 21	says, "A sensitive mumps virus plaque neutralization test has been developed based on the potentiation of virus-antibody complexes by heterologous anti-immunoglobins, (AIG)." Do you see that? A. Yes. Q. "The enhanced neutralization test was approximately 100 times more sensitive than the conventional neutralization test or the hemagglutination-inhibition test." Did I read that correctly? A. Yes.	9 10 11 12 13 14 15 16 17 18 19 20 21	VIDEOGRAPHER: The time is 2:23. Back on the video record. BY MR. SANGIAMO: Q. Ms. Wlochowski, you've had a chance to read the paper right now, Exhibit 20. A. Yes. Q. Have you read it before? A. I can't recall if I have. Q. As you were reading it just now, did you understand it? A. Yes.

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1	Page 437	1	Page 439
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	and ambiguous. Overbroad. The	1	Q. I asked the question of whether
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	document speaks for itself. Seeking	2	you disagreed with any of the conclusions in
3	expert testimony from a lay witness.	3	the paper. I'm not sure you answered that.
4	THE WITNESS: The document	4	Do you disagree? Is there anything in there
5	speaks for itself. There is a number	5	that you disagree with?
6	of statements made throughout the	6	MR. KELLER: Asked and answered.
7	document.	7	She has testified.
8	BY MR. SANGIAMO:	8	BY MR. SANGIAMO:
9	Q. Did they describe the use of	9	Q. Do you have anything to add to
10	antihuman IgG in a mumps neutralization assay		your prior answer in terms of whether there is
11	as a means of making the assay more sensitive?	11	anything in here that you disagree with?
12	MR. KELLER: Objection. The	12	MR. KELLER: Same objection.
13	document speaks for itself. Lack of	13	THE WITNESS: No.
14	foundation. Seeking expert testimony	14	BY MR. SANGIAMO:
15	from a lay witness.	15	Q. As you read this, did you feel
16	THE WITNESS: Again, I'll	16	that these FDA researchers were engaged in
17	repeat by saying that the document	17	data manipulation in describing this methodology?
18	speaks for itself. So I'll just leave	18	MR. KELLER: Objection. Lack
19	it at that. There is a lot of	19	of foundation.
20	conclusions drawn from the document.	20	THE WITNESS: I do not have
21	BY MR. SANGIAMO:	21	copies of their data. So I can't say
22	Q. Did you disagree with any of	22	whether they did or they didn't.
23	the conclusions?	23	BY MR. SANGIAMO:
24	A. There are statements that are	24	Q. Do you have any reason to
	Page 438		Page 440
1	made where it states, "The mechanism by which	1	believe that they did?
2	anti-immunoglobin enhances the neutralizing	2	MR. KELLER: Objection. Calls
3	capacity of immune sera is not fully	3	for speculation. Lack of foundation.
4	understood."	4	THE WITNESS: I can't speculate
5	So there are, again, some	5	on that.
6	conclusions drawn. However, there are some	6	BY MR. SANGIAMO:
7	statements made, for instance, "Studies on	7	
8			Q. Did you feel that the mere
0	cross-reactivity of antibody to viruses of the	8	Q. Did you feel that the mere methodology itself constitutes manipulation?
9	cross-reactivity of antibody to viruses of the paramyxovirus group with mumps virus in the	8 9	
9			methodology itself constitutes manipulation?
9	paramyxovirus group with mumps virus in the	9	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague
9 10	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress."	9 10	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.
9 10 11	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other	9 10 11	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a
9 10 11 12	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on	9 10 11 12	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation.
9 10 11 12 13	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document	9 10 11 12 13	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that
9 10 11 12 13 14	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not	9 10 11 12 13 14	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer
9 10 11 12 13 14 15	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small	9 10 11 12 13 14 15	methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that.
9 10 11 12 13 14 15 16	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small sample size used in the study.	9 10 11 12 13 14 15 16	 methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that. BY MR. SANGIAMO:
9 10 11 12 13 14 15 16 17	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small sample size used in the study. So there's so provides some	9 10 11 12 13 14 15 16 17	 methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that. BY MR. SANGIAMO: Q. Because you lack the expertise?
9 10 11 12 13 14 15 16 17 18	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small sample size used in the study. So there's so provides some information, but, again, it's a paper that the experts would have to that conducted the	9 10 11 12 13 14 15 16 17 18	 methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that. BY MR. SANGIAMO: Q. Because you lack the expertise? A. I
9 10 11 12 13 14 15 16 17 18 19	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small sample size used in the study. So there's so provides some information, but, again, it's a paper that the experts would have to that conducted the study would have to speak to.	9 10 11 12 13 14 15 16 17 18 19	 methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that. BY MR. SANGIAMO: Q. Because you lack the expertise? A. I MR. KELLER: Mischaracterizes
 9 10 11 12 13 14 15 16 17 18 19 20 	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small sample size used in the study. So there's so provides some information, but, again, it's a paper that the experts would have to that conducted the study would have to speak to. Q. Just the experts who conducted	9 10 11 12 13 14 15 16 17 18 19 20	 methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that. BY MR. SANGIAMO: Q. Because you lack the expertise? A. I MR. KELLER: Mischaracterizes her testimony. You can answer.
 9 10 11 12 13 14 15 16 17 18 19 20 21 	paramyxovirus group with mumps virus in the enhanced neut test are currently in progress." So it makes references to other studies as well as I want to say that based on the different studies throughout the document or different references it's making. I'm not sure, I thought I saw that there was a small sample size used in the study. So there's so provides some information, but, again, it's a paper that the experts would have to that conducted the study would have to speak to.	9 10 11 12 13 14 15 16 17 18 19 20 21	 methodology itself constitutes manipulation? MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Seeking expert witness testimony from a layperson. Calls for speculation. THE WITNESS: Again, to me that would be speculation for me to answer that. BY MR. SANGIAMO: Q. Because you lack the expertise? A. I MR. KELLER: Mischaracterizes her testimony. You can answer. THE WITNESS: Again, I haven't

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1	Page 441	1	Page 443
1	whether this article accurately describes the	1	testimony from a lay witness. Calls
2	underlying data from the researcher's work.	2	for speculation.
3	Right?	3	THE WITNESS: This question is
4	MR. KELLER: Objection.	4	different from the previous question in
5	Mischaracterizes her testimony.	5	that
6	THE WITNESS: Can you ask the	6	BY MR. SANGIAMO:
7	question again?	7	Q. Well, I'm trying to what I
8	BY MR. SANGIAMO:	8	can't tell, frankly, in your answers is
9	Q. Is the point you're making that	9	whether you are responding to my questions in
10	because you haven't seen the underlying data,	10	terms of whether the underlying data generated
11	you don't know if this article is accurately	11	in these tests is accurately described in the
12	describing the underlying data?	12	paper, whether you're talking about that, or
13	MR. KELLER: Objection.	13	whether you are talking about the methodology
14	Mischaracterizes her testimony. You're	14	itself. That's why I asked my follow-up
15	asking her to speculate about	15	question. I was trying to get that.
16	MR. SANGIAMO: I'm asking what	16	A. Maybe that's why I'm confused
17	her point was.	17	in answering. To me they go hand in hand.
18	MR. KELLER: No, you are	18	Q. Let's assume that the data are
19	recharacterizing	19	accurately described in the paper.
20	BY MR. SANGIAMO:	20	MR. KELLER: Objection. Seeks
21	Q. Did I state your point	21	a hypothetical.
22	accurately? If I didn't, just tell me I	22	BY MR. SANGIAMO:
23	didn't, that's fine.	23	Q. Then would you consider the
24	A. I keep losing track of your	24	methodology described in here to constitute
1	Page 442 actual question, sorry, because of the back	1	Page 444 manipulation?
2	and forth.	2	MR. KELLER: Objection. Vague
3	Q. Sure. Let me try it again.	3	and ambiguous as to manipulation.
4	A. Sorry.	4	Seeks an expert opinion from a lay
5	Q. That's fine.	5	witness. Overbroad. Lack of
6	Does the methodology described	6	foundation. Seeks a legal conclusion.
7	in here itself, the methodology itself,	7	THE WITNESS: I think I've
8		8	
	constitute manipulation in your opinion? MR. KELLER: Objection. Seeks	0 9	already answered.
9			
10			BY MR. SANGIAMO:
10	a legal conclusion. Seeks expert	10	Q. You've answered the best as you
11	a legal conclusion. Seeks expert opinion from a layperson. Calls for	10 11	Q. You've answered the best as you can?
11 12	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You	10 11 12	Q. You've answered the best as you can? A. Yes.
11 12 13	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer.	10 11 12 13	Q. You've answered the best as you can?A. Yes. MR. KELLER: We're at about an
11 12 13 14	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a	10 11 12 13 14	 Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break?
11 12 13 14 15	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was	10 11 12 13 14 15	 Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure.
11 12 13 14 15 16	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it	10 11 12 13 14 15 16	 Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now
11 12 13 14 15 16 17	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't.	10 11 12 13 14 15 16 17	 Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure.
11 12 13 14 15 16 17 18	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't. BY MR. SANGIAMO:	10 11 12 13 14 15 16 17 18	 Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now 2:32. Going off the video record.
11 12 13 14 15 16 17 18 19	a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't. BY MR. SANGIAMO: Q. Nothing in here suggested to	10 11 12 13 14 15 16 17 18 19	 Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now
11 12 13 14 15 16 17 18 19 20	 a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't. BY MR. SANGIAMO: Q. Nothing in here suggested to you that the process that they describe is 	10 11 12 13 14 15 16 17 18 19 20	Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now 2:32. Going off the video record.
11 12 13 14 15 16 17 18 19 20 21	 a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't. BY MR. SANGIAMO: Q. Nothing in here suggested to you that the process that they describe is inherently manipulative. True? 	10 11 12 13 14 15 16 17 18 19 20 21	Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now 2:32. Going off the video record. (A recess was taken.)
11 12 13 14 15 16 17 18 19 20 21 22	 a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't. BY MR. SANGIAMO: Q. Nothing in here suggested to you that the process that they describe is inherently manipulative. True? MR. KELLER: Objection. Lack 	10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now 2:32. Going off the video record. (A recess was taken.) UIDEOGRAPHER: The time is now 2:51. This begins disc four. You may
11 12 13 14 15 16 17 18 19 20 21	 a legal conclusion. Seeks expert opinion from a layperson. Calls for speculation. Lack of foundation. You can answer. THE WITNESS: I don't have a reason to believe that it was manipulated, but I cannot confirm if it has or it hasn't. BY MR. SANGIAMO: Q. Nothing in here suggested to you that the process that they describe is inherently manipulative. True? 	10 11 12 13 14 15 16 17 18 19 20 21	Q. You've answered the best as you can? A. Yes. MR. KELLER: We're at about an hour. Do you want to take break? MR. SANGIAMO: Sure. VIDEOGRAPHER: The time is now 2:32. Going off the video record. (A recess was taken.)

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	JOAN E. WEOCHOWSKI -		
	Page 445		Page 447
1	Q. Ms. Wlochowski, you gave	1	A. Yes.
2	testimony on several occasions over the course	2	Q. When you refer to him having
3	of your deposition about plaque counts being	3	given that direction, do you have in mind him
4	changed to pre-positive samples. Do you	4	giving the direction to the lab as a group or
5	recall that?	5	are you referring to instances where he may
6	A. Yes.	6	have said that to individual lab members or
7	Q. What do you recall Dr. Krah	7	something else?
8	A. I'm sorry, can you repeat	8	MR. KELLER: Objection.
9	again I said yes before I think I heard	9	Overbroad.
10	something different.	10	THE WITNESS: Since he gave it
11	Q. I just wanted to orient you to	11	on different occasions, I recall him
12	your prior testimony on the topic of plaque	12	saying it to me. I recall him saying
13	counts being changed on samples that were	13	it to other staff members. I, myself,
14	pre-positive. There was no actual question	14	at a staff meeting, you know, brought
15	other than to orient you.	15	up the fact that, you know, the changes
16	A. I'm sorry. Didn't mean to say	16	were being made on focusing on
17	question. Yes.	17	pre-positives which is falsifying data.
18	Q. What do you recall Dr. Krah	18	Making the statement that we're not
19	saying as regards plaque count changes to	19	blinded so, therefore, being selective
20	pre-positive samples?	20	over what we're going back to recount
21	MR. KELLER: Objection. Asked	21	based on what the expectation is.
22	and answered. You can answer again.	22	BY MR. SANGIAMO:
23	THE WITNESS: From my previous	23	Q. Can you give me the most
24	responses, again, his indication to us	24	specific recollection you have of how he
	Page 446		Page 448
1	was that the it is not expected to	1	described what it is that you were supposed to
2	have pre-positives in unvaccinated	2	do if you did encounter a pre-positive?
3	population, that although it does	3	A. He would ask us to check our
4	occur, it doesn't you know, it's not	4	results.
5	occurring often. I'm not quoting him	5	Q. Okay. To go back and check to
6	on that, but that is the direction he	6	make sure the count was accurate. Is that how
7	gave the lab.	7	he would say it?
8	BY MR. SANGIAMO:	8	A. Again, I don't recall his
9	Q. Well, so far all you've said is	9	specific words, but I believe that is what he
10	that he said it was not expected to have	10	was implying.
11	pre-positives in an unvaccinated population.	11	Q. That is what you understood him
12	And that it does occur but not very often. I	12	to be saying?
12	realize you were not quoting him directly.	12	A. Yes.
13	But then was there some kind of direction he	13 14	MR. KELLER: Could I get the
14	gave to the lab in light of that?	14	last question and answer back? Two
16	A. Based on that, yes, he has on	15 16	last question and answer back? Two
17	occasion asked to go back and recheck counts	10 17	hast questions and answers.
17	where it resulted in a pre-positive.	17 18	(The court reporter read the
18		18 19	(The court reporter read the pertinent part of the record.)
			pertinent part of the fectora.)
20 21	heard him say?	20	PV MD SANGIAMO:
	A. Yes.	21	BY MR. SANGIAMO:
22	Q. How many times?	22	Q. You described a staff meeting
23	A. I would say it was quite often.	23	in your testimony a moment ago where, as I
24	Q. More than five?	24	understood it, you brought up that changes

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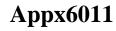
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	JOAN E. WEOCHOWSKI -		
	Page 449		Page 451
1	were being made to pre-positives and you	1	fraud.
2	considered that to be falsification I think is	2	BY MR. SANGIAMO:
3	the words you used in your testimony just now?	3	Q. You just referred to changing
4	A. Yes.	4	data, and I gather what you were referring to
5	Q. And do you think that is the	5	there was going back to check a count and then
6	word you used at that staff meeting?	6	changing it if you came up with if you
7	A. I believe I stated that it was	7	counted a different number of plaques on that
8	fraud.	8	count as compared to what was counted on the
9	Q. You think fraud is the word	9	first count. Do I have that right?
10	that is used?	10	A. That's correct.
11	A. Yes.	11	Q. Do you agree that strike
12	Q. Why is that fraud? Why is it	12	that.
13	fraud to check the pre-positives?	13	Do you have an opinion as to
14	A. Because you're only selectively	14	whether a pre-positive is to be expected or
15	checking your pre-positives. You're not	15	not?
16	checking the entire assay. Again, if the	16	MR. KELLER: Objection.
17	method was validated and analysts were	17	BY MR. SANGIAMO:
18	qualified, then the original results should	18	Q. Do you have an opinion on that?
19	serve to provide a result.	19	MR. KELLER: Objection. Vague
20	Q. So you thought it was fraud in	20	and ambiguous. Seeks expert opinion
21	the sense that if only the pre-positives were	21	from a layperson. Lack of foundation
22	checked, that would bias the results?	22	and overbroad.
23	A. I'm trying to think. So the	23	THE WITNESS: I would defer to
24	MR. KELLER: Objection.	24	an expert opinion on that.
	Page 450		Page 452
1	Overbroad. You can answer.	1	BY MR. SANGIAMO:
2	THE WITNESS: Can you provide,	2	Q. I'm going to ask a slightly
3	I guess provide a different way of	3	different question using a term you may or may
4	asking the questions. I'm not quite	4	not have encountered in your assay work. Do
5	sure	5	you have an opinion on whether a pre-positive
6	BY MR. SANGIAMO:	6	would be considered an abhorrent result?
7	Q. I asked you why it's fraud to	7	MR. KELLER: Objection. Vague
8	check only the pre-positives, and part of your	8	and ambiguous. Overbroad. Lack of
9	response was because you're only selectively	9	foundation.
10	checking I'm paraphrasing, selectively	10	THE WITNESS: My opinion on
11	checking pre-positives, you're not checking	11	abhorrent results is that it could be
12	the whole assay. I'm trying to get at why	12	seen in both a positive or a negative
13	that amounts to fraud. Can you elaborate at	13	in either the pre- or the
14	all on why that is fraud?	14	post-vaccination.
15	MR. KELLER: Objection to form.	15	BY MR. SANGIAMO:
16	BY MR. SANGIAMO:	16	Q. What does an abhorrent result
17	Q. And I suggested to you that	17	mean to you? What does that term mean to you?
18	perhaps it's a matter of biasing the results,	18	A. I guess I would refer to it as
19	but that's for you to say, not me.	19	an unexpected result. Let me think if I can
20	MR. KELLER: Same objection.	20	further define that. Yeah, an unexpected
21	THE WITNESS: Yes, in my	21	result.
22	opinion, if you are selectively	22	MR. KELLER: Let me interpose
23	changing data to reach a desired	23	an objection, lack of foundation.
24	outcome, then I would consider that	24	BY MR. SANGIAMO:

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1	Page 453	1	Page 455
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Q. To your knowledge, based on	1	because it may not be a count, but it's
2	assays that you've worked with, are abhorrent	2	basically trying to bring your
3	results ever excluded from final testing	3	abhorrent result into I guess,
4	results?	4	testing into what you want it to be
5	MR. KELLER: Objection.	5	versus taking the abhorrent result or
6	Overbroad. Lack of foundation. Seeks	6	at that point to me it would be
7	expert opinion from a lay witness.	7	considered invalid sample result and,
8	You can answer.	8	therefore, the whole sample would be
9	THE WITNESS: In my experience,	9	repeated.
10	I have seen defined in methods what is	10	So in other words, I've never
11	an abhorrent result and how they may or	11	seen, in my experience, it's either the
12	may not be excluded based on certain	12	single result out of the replicates is
13	criteria.	13	excluded based on certain criteria or
14	BY MR. SANGIAMO:	14	if it goes beyond a single result and
15	Q. Is it ever, in your experience,	15	it's abhorrent as a whole, you wouldn't
16	done that abhorrent results would be retested?	16	be taking that data that you had gotten
17	MR. KELLER: Objection.	17	on that abhorrent result and
18	Overbroad. Lack of foundation.	18	manipulated and changed it to come into
19	MR. SANGIAMO: Let me rephrase	19	something that is not abhorrent.
20	that. Are you done, Jeff?	20	BY MR. SANGIAMO:
21	MR. KELLER: If you're going to	21	Q. And as applied here, "manipulated
22	strike the question and start over,	22	and changed it" would be to check the accuracy
23	then I can stop objecting. But if	23	of the plaque count. Right?
24	you're not, I'll keep going.	24	MR. KELLER: Objection. Vague
	Page 454		Page 456
1	MR. SANGIAMO: We can have an	1	and ambiguous. Unintelligible.
2	agreement when you object to the next	2	Overbroad. Lacks foundation. Seeks an
3	question we'll carry over your	3	expert opinion from a lay witness.
4	objections to the next question so you	4	THE WITNESS: I have a
5	don't have to repeat that.	5	difficult time and, again, an expert
6	BY MR. SANGIAMO:	6	witness can expand on this, but I have
7	Q. In your experience in running	7	a difficult time saying that you would
8	assays with which you're familiar, are	8	check the accuracy of a result on a
9	abhorrent results ever subjected to retest?	9	method that is validated.
9 10	MR. KELLER: Objection.	9 10	BY MR. SANGIAMO:
	Ũ		
11	Overbroad. Lack of foundation.	11	Q. The counting of plaques can be
12	THE WITNESS: I can give you an	12	subjective. Right?
13	example in my experience, but I would	13	A. It can be, yes.
14	not limit it to just this example	14	Q. You could look at a plaque
15	because I'm sure there are other expert	15	count one day and then look at it another day
16	explanations for it as well. But in my	16	and get a different count the second day.
17	experience, if there is replicate	17	Agreed?
18	testing, there may be a criteria for	18	MR. KELLER: Objection. Calls
19	exclusion of a particular result out of	19	for speculation. Lack of foundation.
20	those replicates. If I've never	20	THE WITNESS: Any either a
21	seen, that I can recall, an abhorrent	21	plaque count or any result really could
22	result in itself being recounted. I	22	have variability within itself. But,
23 24	would expect to see it recounted in that you were looking at the data again	23 24	again, that should be factored into the precision of the methodology. So in

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1	Page 457	1	Page 459
1	this case, if you're speaking to	1	that the number of, whether you want to
2	variability between analysts, you know,	2	call it rechecks or recounts, basically
3	counting versus variability between	3	in the end changes were made to
4	analyst themselves, I would refer back	4	pre-positives that occurred within the
5	to not just accuracy but repeatability	5	data within a portion of the data
6	and precision of the methodology.	6	set more often than it basically
7	BY MR. SANGIAMO:	7	occurred on a good portion of the
8	Q. There is variability in	8	sorry. Chopping up my words.
9	determining plaque count data points that is	9	There was a portion of that
10	greater than, say, the variability in reading	10	data set that I had reviewed, just to
11	ELISA results. Agreed?	11	say it like that, that showed that
12	A. Yes.	12	there were changes made to pre-positive
13	Q. Do you have any experience in	13	data on a significant number of the
14	the validation of a plaque assay?	14	assays that were performed.
15	MR. KELLER: Objection.	15	BY MR. SANGIAMO:
16	THE WITNESS: I potentially may	16	Q. I want to make sure I
17	have during the course again, I'm	17	understand what you mean when you talk about
18	not sure exactly when the completion of	18	changes being made to pre-positive data. Do
19	the enhanced PRN that was being	19	you mean changes to plaque counts on samples
20	conducted at Merck, when that	20	that on original count were pre-positive that
21	completed. So I cannot say if I was a	21	resulted in a change to pre-negative or do you
22	part of that. But I guess I would also	22	just mean any change, any change to a
23	add that because there is variability	23	pre-positive?
24	in something like a cell-based assay,	24	A. Any change made to it was
	Page 458		Page 460
			c
1	you are running replicate wells. So in	1	changes from a pre-positive to a pre-negative.
$\begin{vmatrix} 1\\2 \end{vmatrix}$	you are running replicate wells. So in this instance, in this enhanced PRN.		changes from a pre-positive to a pre-negative. O. And you're saving that that
2	this instance, in this enhanced PRN,	2	Q. And you're saying that that
2 3	this instance, in this enhanced PRN, it's run in triplicate wells. So that	2 3	Q. And you're saying that that occurred more frequently than a change to a
2 3 4	this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to	2 3 4	Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample
2 3 4 5	this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either	2 3 4 5	Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct.
2 3 4 5 6	this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the	2 3 4 5 6	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go
2 3 4 5 6 7	this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted.	2 3 4 5 6 7	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is
2 3 4 5 6 7 8	this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO:	2 3 4 5 6 7 8	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying?
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2 3 4 5 6 7 8 9 10	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever 	2 3 4 5 6 7 8 9 10	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples.
2 3 4 5 6 7 8 9 10 11	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque 	2 3 4 5 6 7 8 9 10 11	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to
2 3 4 5 6 7 8 9 10 11 12	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? 	2 3 4 5 6 7 8 9 10 11 12	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no
2 3 4 5 6 7 8 9 10 11 12 13	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. 	2 3 4 5 6 7 8 9 10 11 12 13	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do
2 3 4 5 6 7 8 9 10 11 12 13 14	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I 	2 3 4 5 6 7 8 9 10 11 12 13 14	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is,
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only plaque counts that were checked in Protocol 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome? A. The latter. So it was no
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only plaque counts that were checked in Protocol 007 were those for pre-positives?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome? A. The latter. So it was no changes were made to the results, no
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only plaque counts that were checked in Protocol 007 were those for pre-positives? MR. KELLER: Objection. Lack 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome? A. The latter. So it was no changes were made to the results, no pre-negative no pre-negatives were changed
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only plaque counts that were checked in Protocol 007 were those for pre-positives? MR. KELLER: Objection. Lack of foundation. Overbroad. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome? A. The latter. So it was no changes were made to the results, no pre-negative no pre-negatives were changed to pre-positives. No post negatives or
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only plaque counts that were checked in Protocol 007 were those for pre-positives? MR. KELLER: Objection. Lack of foundation. Overbroad. THE WITNESS: I cannot say that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome? A. The latter. So it was no changes were made to the results, no pre-negative no pre-negatives were changed to pre-positives were changed to the opposite.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 this instance, in this enhanced PRN, it's run in triplicate wells. So that would be the intent of that is to account for the variability in either the well, in many aspects of the assay being conducted. BY MR. SANGIAMO: Q. Outside of what you just referred to regarding Merck, have you ever participated in the validation of a plaque assay? MR. KELLER: Asked and answered. THE WITNESS: Not that I recall, no. BY MR. SANGIAMO: Q. Is it your belief that the only plaque counts that were checked in Protocol 007 were those for pre-positives? MR. KELLER: Objection. Lack of foundation. Overbroad. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. And you're saying that that occurred more frequently than a change to a post-vaccination sample A. Correct. Q that would cause it to go from positive to negative or vice versa? Is that what you're saying? A. If I recall correctly, there was no changes made to the post samples. Q. When you say no changes made to the post samples, you mean there were no plaque count changes to any post sample or do you mean something more specific; that is, there were no plaque count changes that resulted in a different seroconversion outcome? A. The latter. So it was no changes were made to the results, no pre-negative no pre-negatives were changed to pre-positives. No post negatives or

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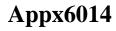
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	JOAN E. WEOCHOWSKI -		
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1	negatives or pre-negatives, but they just	1	requested to do that and check that. And
2	weren't enough to convert them to a different	2	really for me it was a matter of
3	status that would impact whether that sample	3	understanding, well, if it didn't seem to be a
4	had seroconverted. Do I have that right?	4	big deal, then let's just look at the data and
5	A. That could be the case. Yeah,	5	see what it's telling us. So that was my
6	I don't remember if there were or were not any	6	intent of looking at the data and seeing if
7	changes made in the data set.	7	there was a bias that occurred.
8		8	Q. You were testifying earlier
9	(Exhibit Wlochowski-21,	9	about Dr. Krah telling people to check the
10	Handwritten document, RELATOR_00001025	10	plaque counts for pre-positives. When he did
11	& 26, was marked for identification.)	11	that, would he make the request in general
12		12	terms or in your experience was it a matter of
13	BY MR. SANGIAMO:	13	him pointing to a particular sample and asking
14	Q. Ms. Wlochowski, you've just	14	the analyst to go recheck that sample?
15	been handed what has been marked as	15	A. As far as I can recall, it was
16	Exhibit 21. Do you recognize that document?	16	a particular sample.
17	A. I do.	17	Q. And that's how it occurred in
18	Q. What is it?	18	your case? By your case, I mean the times
19	A. It is how to describe it.	19	when he asked you to check pre-positives?
20	It is a summary of a data set from different	20	A. Yes.
21	experiments that were run just to summarize	21	Q. Is that what you witnessed with
22	the results, the results of pre-positives and	22	others?
23	whether or not they were changed.	23	A. Yes.
24	Q. In your testimony a few minutes	24	Q. Is it your testimony that you
	Page 462		Page 464
1	ago you referred to a subset of the data that	1	have no recollection of him asking you to
2	you had looked at. Is the subset of the data	2	recheck anything other than a pre-positive?
3	to which you're referring described here in	3	A. I can't say that he didn't ask
4	this Exhibit 21?	4	that. Yeah, I can't say that that was the
5	A. Yes, I believe so.	5	case.
6	Q. Who performed the analysis that	6	Q. Is that because you don't
7	led to the creation of this document?	7	recall whether he did or he didn't, or is that
8	A. It was jointly performed by	8	because you remember that he did ask you to
9	myself and Steve Krahling.	9	check other plates?
10	Q. To make it easier for us to	10	A. I can say more in the lines
11	talk about this, can we call this an audit?	11	that sometimes there were questionable results
12	A. Sure.	11	or, again, going back to what you were talking
12	Q. Whose idea was it to perform	12	
14	that audit?		about, what you would consider an abhorrent
14		14	result. The replicates didn't align, or if
	A. I believe it was my idea.Q. What do you recall about the	15	there were some anomalies with the monolayers,
16		16	things like that. So I wouldn't exclude it.
17	initial discussion between you and	17	Q. Do you know whether there was
18	Mr. Krahling about this audit?	18	checking of plaque counts by others in the lab
19	A. Just that, you know, again, I	19	on samples that were not pre-positive? Do you
20	was questioning about being asked to recheck	20	have knowledge of that?
21	plates based on pre-negatives as were	21	MR. KELLER: Objection. Vague
22	sorry, pre-positives, as were others. And	22	and ambiguous. Overbroad.
23	basically getting no I don't know how to	23	THE WITNESS: Can you repeat
24	explain it. You know, continuing to be	24	the question?

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	Page 465	1	Page 467
1	BY MR. SANGIAMO:	1	Mischaracterizes her testimony.
2	Q. Do you have knowledge of	2	THE WITNESS: What would be
3	whether there was checking of plaque counts by	3	entered is the crossed out number.
4	others in the lab to samples other than	4	BY MR. SANGIAMO:
5	pre-positives?	5	Q. And this you would create a
6	MR. KELLER: Objection. Vague	6	brand new worksheet for this assay? In other
7	and ambiguous. Overbroad.	7	words, would you enter in every data point for
8	THE WITNESS: My knowledge	8	the assay when you were conducting this audit?
9	would just be drawn from that if he	9	MR. KELLER: Overbroad.
10	guided me to do that, he would guide	10	THE WITNESS: Repeat the
11	others based on applying the same	11	question.
12	rationale what I just described in my	12	BY MR. SANGIAMO:
13	previous question.	13	Q. When you were conducting the
14	BY MR. SANGIAMO:	14	audit for a given assay, would you enter every
15	Q. So that's an assumption on your	15	data point for that assay?
16	part. Right?	16	A. Every data point, yes, on the
17	A. Yes.	17	counting sheet. So with the what we just
18	Q. If we look at Exhibit 21, which	18	described, so the crossed out, not yes, so
19	is the documentation of the audit, the audit	19	the crossed out results.
20	you and Mr. Krahling performed, you see the	20	Q. I got you. And then did you
21	results. What was the nature of the	21	save that?
22	underlying data for this?	22	A. I did not save it myself. I
23	A. I want to say it was the cell	23	don't recall if that was saved by Steve.
24	count sheets.	24	Q. Did you print it out?
	Page 466		Page 468
1	Q. What did you do with the cell	1	A. I don't recall if he printed it
2	count sheets?	2	out.
3	A. If I remember correctly, we	3	Q. But you didn't?
4	took that and entered into the Excel workbook	4	A. I'm sorry?
5	to populate the data.	5	Q. You did not print it out. Right?
6	Q. You would populate the Excel	6	A. Correct.
7	workbook with the data originally counted? Is	7	Q. If we take a look at, let's
8	that the idea?	8	say, the third row down, and reading across we
9	A. So in this instance, original	9	see MKY under the column titled "counted by"
10	count would mean what was written on the	10	Right?
11	counting sheet. Again, whether or not there	11	A. Yes.
12	were changes between the plates and what was	12	Q. That indicates that the person
13	entered on the counting sheet, we didn't go	13	with the initials MKY did the original count
14	back to the plates, we only went back to the	14	on that?
15	point of the counting sheets. So as there was	15	A. Correct.
16	a cross out on the counting sheet, we would	16	Q. Reading across to the right you
17	factor that into the calculation in the	17	say assay number 758-00. Correct?
18	workbook.	18	A. Correct.
19	Q. If you encountered a data point	19	Q. Then it says three pre-positives.
20	that had been crossed out in the counting	20	Right?
21	sheet, then what you would enter into the	21	A. Correct.
22	workbook was the crossed out number, not the	22	Q. And then there is a blank next
23	new number. Is that right?	23	to that which in the case of this particular

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1	Page 469		Page 471
1	were changed. Right?	1	subset of the data. So we did not, at
2	MR. KELLER: Objection.	2	least I did not, I don't recall that
3	Overbroad.	3	there was anything that Steve had done
4	THE WITNESS: What it means is	4	to calculate that.
5	that none of the pre-positives, based	5	BY MR. SANGIAMO:
6	on either were not changed or the	6	Q. So, for example, if you look at
7	result of changing them still resulted	7	the assay that we were looking at a moment
8	in three pre-positives.	8	ago, 759-00 which had six pre-positives and
9	BY MR. SANGIAMO:	9	two pre-positives were changed to
10	Q. And then if we go to the next	10	pre-negative, you didn't, and as far as you
11	line, we see an assay that was counted by JD	11	know, Steve didn't try and determine whether
12	and that was assay 759-00. In that instance,	12	those two that were changed were seroconverters.
13	there were six pre-positives. Right?	13	Right?
14	A. Uh-huh.	14	A. Not to my recollection.
15	Q. And what we see is that for two	15	Q. If they hadn't been seroconverters,
16	of those six, there were changes to the plaque	16	then that would actually be detrimental to the
17	count that resulted in them becoming	17	overall seroconversion rate in the assay.
18	pre-negative. Right?	18	Right?
19	A. Correct.	19	MR. KELLER: Objection. Lack
20	Q. And for the other four, either	20	of foundation. Calls for speculation.
21	there were no changes at all or whatever	21	THE WITNESS: I can't answer
22	changes there were did not cause it to convert	22	that in the overall set of data
23	from being pre-positive to pre-negative?	23	because, again, it was just a portion
$\frac{23}{24}$	A. Correct.	24	of the data.
		27	
1	Page 470 Q. Now, do you have any way of	1	Page 472 BY MR. SANGIAMO:
2	addressing the question of why it is that	2	Q. It would have been detrimental,
3	those four pre-positives in 759-00 that did	3	you don't know how detrimental, but it would
4	not convert to pre-negative and the three	4	have been detrimental?
5	pre-positives in 758 that did not convert to	5	MR. KELLER: Objection. Vague
6	pre-negative, why it is that those were not	6	and ambiguous. Lack of foundation.
7	changed to pre-negative?	7	Argumentative.
8	MR. KELLER: Objection. Lack	8	THE WITNESS: I'm trying to
9	of foundation. Calls for speculation.	9	think through the so it may or may
10	THE WITNESS: It would be a	10	not have been, just based on the fact
111			-
11	speculation that no additional plaques	11	that, again, that either if
12	speculation that no additional plaques were able to be identified, or if they	11 12	that, again, that either if pre-positives were excluded from the
12 13	speculation that no additional plaques were able to be identified, or if they were didn't change the results.	11 12 13	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases
12 13 14	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO:	11 12 13 14	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having
12 13 14 15	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in	11 12 13 14 15	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them
12 13 14 15 16	speculation that no additional plaqueswere able to be identified, or if theywere didn't change the results.BY MR. SANGIAMO:Q. Did you and Mr. Krahling inconducting this audit attempt to determine	11 12 13 14 15 16	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other
12 13 14 15 16 17	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from	11 12 13 14 15 16 17	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your
12 13 14 15 16 17 18	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from pre-positive to pre-negative on the overall	11 12 13 14 15 16 17 18	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your sample size. So really I can't speak
12 13 14 15 16 17 18 19	 speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from pre-positive to pre-negative on the overall assay sorry, on the overall seroconversion 	11 12 13 14 15 16 17 18 19	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your sample size. So really I can't speak to whether or not it would have been
12 13 14 15 16 17 18 19 20	 speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from pre-positive to pre-negative on the overall assay sorry, on the overall seroconversion rate? 	11 12 13 14 15 16 17 18 19 20	that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your sample size. So really I can't speak to whether or not it would have been detrimental overall.
12 13 14 15 16 17 18 19 20 21	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from pre-positive to pre-negative on the overall assay sorry, on the overall seroconversion rate? MR. KELLER: Objection. Vague	11 12 13 14 15 16 17 18 19 20 21	 that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your sample size. So really I can't speak to whether or not it would have been detrimental overall. BY MR. SANGIAMO:
12 13 14 15 16 17 18 19 20 21 22	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from pre-positive to pre-negative on the overall assay sorry, on the overall seroconversion rate? MR. KELLER: Objection. Vague and ambiguous. Overbroad. Lacks	11 12 13 14 15 16 17 18 19 20 21 22	 that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your sample size. So really I can't speak to whether or not it would have been detrimental overall. BY MR. SANGIAMO: Q. How is seroconversion
12 13 14 15 16 17 18 19 20 21	speculation that no additional plaques were able to be identified, or if they were didn't change the results. BY MR. SANGIAMO: Q. Did you and Mr. Krahling in conducting this audit attempt to determine what the impact was of these conversions from pre-positive to pre-negative on the overall assay sorry, on the overall seroconversion rate? MR. KELLER: Objection. Vague	11 12 13 14 15 16 17 18 19 20 21	 that, again, that either if pre-positives were excluded from the study, and so, therefore, it decreases your overall sample size, versus having two more results, maybe one of them gave you a seroconversion, the other one didn't, at least it increased your sample size. So really I can't speak to whether or not it would have been detrimental overall. BY MR. SANGIAMO:

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1	Page 473	1	Page 475
1	of foundation. Overbroad.	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	at the time?
2	THE WITNESS: Can you elaborate	2	MR. KELLER: Objection. Vague
3	on that?	3	and ambiguous. Overbroad. Lack of
4	BY MR. SANGIAMO:	4	foundation.
5	Q. I'm not sure I can. Do you	5	THE WITNESS: I can't recall.
6	know what formula was used to calculate a	6	BY MR. SANGIAMO:
7	seroconversion rate in Protocol 007?	7	Q. If you didn't know how the
8	MR. KELLER: Objection.	8	seroconversion rate was calculated at the
9	BY MR. SANGIAMO:	9	time, then did you have any means of
10	Q. If you don't know, you don't	10	evaluating what the impact would be of
11	know.	11	conversions from pre-positive to pre-negative
12	A. I'm not clear that I would	12	on the seroconversion rates in the study?
13	know.	13	MR. KELLER: Objection.
14	Q. You don't know?	14	Argumentative. Seeking expert
15	A. I'm trying to think this	15	testimony from a lay witness. Vague
16	through. In the protocol, I mean, I don't	16	and ambiguous. Overbroad.
17	know the specific of the calculation in the	17	THE WITNESS: I will defer to
18	protocol. Protocol 007 is what you're	18	an expert witness for fully answering
19	referring to?	19	that question. Again, my intent here
20	Q. Yes. You don't know it today.	20	is to, with this audit, was also to
21	Right?	21	provide information around data that
22	MR. KELLER: As she's sitting	22	was being changed and whether or not
23	here today?	23	there was a pattern of changing results
24	BY MR. SANGIAMO:	24	in a pre-positive readout.
			• •
1	Page 474 Q. Is that what your testimony was	1	Page 476 BY MR. SANGIAMO:
2	Q. Is that what your testimony was a moment ago?	$\begin{vmatrix} 1\\2 \end{vmatrix}$	
2 3		$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Q. Did you have any intent beyond that?
4	again, I would have to go back and refer to	4	A. It was it was basically to
5	documents because, yeah, I don't know it as	5	confirm that there were changes that were
6	I'm sitting here today.	6	being made on a biased basis that in my view
7	Q. Did you know it at the time you	7	would impact the outcome of the study.
8	were working in Dr. Krah's lab?	8	Q. Why did you think they would
9	A. My interpretation of a	9	impact the outcome of the study?
10	seroconversion as a at the time that I	10	MR. KELLER: Asked and answered
11	worked in Dave Krah's lab is if it went from	11	a half a dozen times, but answer again.
12	pre-negative to pre-positive, it was a	12	THE WITNESS: Because it's not
		13	the original data results. And, again,
	seroconversion sorry, I think I said it		•
13 14	seroconversion sorry, I think I said it wrong. Pre-negative to post-positive is a	14	going back to the validation of the
14 15	wrong. Pre-negative to post-positive is a seroconversion.	14 15	going back to the validation of the method, should provide the information
14 15	wrong. Pre-negative to post-positive is a	14	going back to the validation of the
14 15 16	wrong. Pre-negative to post-positive is a seroconversion.	14 15	going back to the validation of the method, should provide the information
14 15 16 17	wrong. Pre-negative to post-positive is a seroconversion. Q. Did it matter what the titer	14 15 16	going back to the validation of the method, should provide the information around what would be the actual data
14 15 16 17 18	wrong. Pre-negative to post-positive is a seroconversion.Q. Did it matter what the titer was on the post-positive?	14 15 16 17	going back to the validation of the method, should provide the information around what would be the actual data results that should be reported.
	 wrong. Pre-negative to post-positive is a seroconversion. Q. Did it matter what the titer was on the post-positive? A. That, I can't recall. Q. So that's how you would figure 	14 15 16 17 18	going back to the validation of the method, should provide the information around what would be the actual data results that should be reported. BY MR. SANGIAMO:
14 15 16 17 18 19	 wrong. Pre-negative to post-positive is a seroconversion. Q. Did it matter what the titer was on the post-positive? A. That, I can't recall. Q. So that's how you would figure out whether an individual sample had 	14 15 16 17 18 19	going back to the validation of the method, should provide the information around what would be the actual data results that should be reported. BY MR. SANGIAMO: Q. Do you agree there would be changes to data that would not necessarily
14 15 16 17 18 19 20	 wrong. Pre-negative to post-positive is a seroconversion. Q. Did it matter what the titer was on the post-positive? A. That, I can't recall. Q. So that's how you would figure 	14 15 16 17 18 19 20 21	going back to the validation of the method, should provide the information around what would be the actual data results that should be reported. BY MR. SANGIAMO: Q. Do you agree there would be changes to data that would not necessarily impact the outcome of the study?
14 15 16 17 18 19 20 21	 wrong. Pre-negative to post-positive is a seroconversion. Q. Did it matter what the titer was on the post-positive? A. That, I can't recall. Q. So that's how you would figure out whether an individual sample had seroconverted. Right? 	14 15 16 17 18 19 20	going back to the validation of the method, should provide the information around what would be the actual data results that should be reported. BY MR. SANGIAMO: Q. Do you agree there would be changes to data that would not necessarily

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

Page 479Page 4791THE WITNESS: Again, I would1you referring to?2defer to an expert witness, but I would3earlier where we were doing testing of high3also add that the outcome of a study3earlier where we were doing testing of high4should include the original data, test4and low passage cell lines.5data integrity should be maintained in5Q. You think that was improper?6A. I do because you're generatingadditional date on those test articles that8Q. So are you able to answer the8could also influence your results.9question of whether there could be changes to9Q. How would that happen?10data that would no impact the outcome of the11comparison to the results or try to draw11study? Are you able to answer tha?11comparison to the results or try to draw12MR. KELLER: Asked and answered.13Q. I'm sorry, could you spell that14question.15THE WITNESS: I guess I can1615THE WITNESS: I guess I can16testing of the mumps neutralization assay for16read data is and I think that as a19supplemental assay and then saw something19scientist we all should want to know18ad then if you ran two other assays and a19study. I would want to know24A. I do not know if that happened?21what the real data is that would be21results in the assay that was being tested for <t< th=""><th></th><th></th><th></th><th>JHL I CONFIDENTIAL</th></t<>				JHL I CONFIDENTIAL
2 A. Thewhat I spoke about 3 also add that the outcome of a study 3 4 should include the original data, the 4 5 data integrity should be maintained in 6 6 the study. 6 7 BY MR. SANGIAMO: 7 8 Q. So are you able to answer the 9 9 question of whether there could be changes to 9 10 data that would not impact the outcome of the 11 11 study? Are you able to answer that? 11 12 MR. KELLER: Asked and answered. 12 13 She just answered the exact same 13 Q. I'm sorry, could you spell that 14 question. 14 out? I don't understand. 15 THE WTINESS: I guess I can 15 A. If during the course of the 16 restate my answer in saying I wouldn't 16 testing of the mumps neutralization assay for 17 want to know if the changes impacted 17 the frequidata is and I think that as a 19 20 scientist we all should want to know 20 different, it may make you question your <		C C		6
3 also add that the outcome of a study 3 carlier where we were doing testing of high 4 should include the original data, the 4 and low passage cell lines. 6 data integrity should be maintained in 6 A. I do because you're generating 7 BY MR. SANGIAMO: 7 additional data on those test articles that 9 question of whether there could be changes to 9 Q. How would that happen? 10 data that would not impact the outcome of the 10 A. If somebody would make a 11 stud? Are you able to answer tht? 11 comparison to the results or try to draw 12 MR. KELLER: Asked and answered. 12 comparison to the results or the assay for 13 stud? Are you able to answer the simpacted 14 out? I don't understand. 14 question. 14 out? I don't understand. 15 THE WITNESS: I guess I can 16 testing of the mumps neutralization assay for 16 the study. what the real data is and 1 think that as a 19 udifferent, i may make you question your 21 what the real data is that would be 21 results in the assay that was being tested for	1	-		
4 should include the original data, the 4 and low passage cell lines. 5 data integrity should be maintained in 5 Q. You think that was improper? 6 the study. 7 BY MR, SANGIAMO: 7 7 BY MR, SANGIAMO: 7 additional data on those test articles that 8 Q. So are you able to answer the 9 Q. How would that happen? 10 data that would not impact the outcome of the 10 A. If somebody would make a 11 study? Are you able to answer that? 11 conclusions from that. 12 MR, KELLER: Asked and answered. 12 conclusions from that. 13 She just answered the exact same 13 Q. If during the course of the 14 question. 14 out? I don't understand. 15 THE WITNESS: I guess I can 15 A. If during the course of the 16 restate my answer in saying I wouldn't 18 and then if you ran two other assays and a 20 scientist we all should want to know 20 different, it may make you question your 21 what the real data is and I think that as a 19 supplemental				-
5data integrity should be maintained in the study.5Q. You think that was improper?6A. I do because you're generating a dditional data on those test articles that7BY MR, SANGIAMO:99question of whether there could be changes to data that would not impact the outcome of the910data that would on' impact the outcome of the1111study? Are you able to answer that?1212MR, KELLER: Asked and answerd question.1313She just answered the exact same1414question.1515THE WITNESS: I guess I can1516restate my answer in saying I wouldn't17want to know if the changes impacted1718the study. I would want to know1820scientist we all should want to know2021reported in the study.2022reported in the study.2323BY MR. SANGIAMO:2424Q. Why wouldn't you want to know2425believe that it did happen?26ywphemental assay and the nasway something27whether the changes impacted the outcome of 128Why wouldn't you want to know2429With the changes impacted the outcome of 220Why wouldn't you want to know21whether the changes impacted the outcome of 43A. Because this is not a research4or a developmental study. This is a study5Has again, being		•		
6 the study. 6 A. I do because you're generating additional data on those test articles that 7 BY MR. SANGIAMO: 7 additional data on those test articles that 9 question of whether there could be changes to 9 Q. How would that happen? 10 data that would not impact the outcome of the 10 A. If somebody would make a 11 study? Are you able to answer that? 10 A. If somebody would make a 13 She just answered the exact same 13 Courlaisons from that. 14 14 question. 14 out? I don't understand. 15 A. If during the course of the 16 restate my answer in saying I wouldn't 16 testing of the mumps neutralization assay for 16 testing of the mumps neutralization assay or 17 want to know what 19 the real data is and I think that as a 19 supplemental assay and then assay and a 20 scientist we all should want to know 10 trans make you question your 1 results in the assay and then says as and a 21 whet we all should want to know 20 Ifferent, it may make you question your 1 <td></td> <td>•</td> <td></td> <td></td>		•		
7 BY MR. SANGIAMO: 7 additional data on those test articles that 8 Q. So are you able to answer the 8 could also influence your results. 9 question of whether there could be changes to 9 Q. How would that happen? 10 data that would not impact the outcome of the 10 A. If somebody would make a 11 study? Are you able to answer that? 11 comparison to the results or try to draw 12 MR. KELLER: Asked and answerd. 12 conclusions from that. 13 She just answered the exact same 14 out? I don't understand. 14 question. 15 A. If during the course of the 16 restate my answer in saying I wouldn't 16 testing of the murps neutralization assay for 17 want to know if the changes impacted 17 the real data is and I think that as a 19 supplemental assay and then saw something 20 scientist we all should want to know 21 results in the assay that was being tested for 22 21 reported in the study. 22 Q. Do you know if that happened? 2 Q. Do you know if that happened? 24 Q. Why wouldn't you		•		
8 Q. So are you able to answer the 9 question of whether there could be changes to 10 data that would not impact the outcome of the 11 study? Are you able to answer tha? 9 Q. How would make a 11 study? Are you able to answer tha? 11 study? Are you able to answer tha? 11 comparison to the results or try to draw 12 MR. KELLER: Asked and answered. 13 She just answered the exact same 14 question. 12 O. Im sorry, could you spell that 14 14 question. 13 O. If during the course of the 16 The WITNESS: I guess I can 16 16 16 restate my answer in saying I wouldn't 17 want to know what 18 18 the study. I would want to know what 19 18 18 and then if you ran two other assays and a supplemental assay and then saw something 20 supplemental assay and then saw something 20 21 results in the assay that was being tested for 21 Protocol 007, you, say, saw a seroconversion 22 23 BY MR. SANGIAMO: 24 23 Q. Do you know if that happened? 24 Q. Why wouldn't you want to know 24 A. I do not know if that happened? 24 A. Because this is not a research 4 or a developmental study. This is a study 4 MR. KELLER: Lack of foundation. 4 4 or a developmental study. This is a study 4 5 MR. KAGIAMO: 4		•	-	
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10serum which is not part of, as far as I10believe that it did or didn't happen. Again,11understand, the clinical study. The clinical11the test articles, I would just expect it to,12study, the testing should only be conducted on12you know, be used in what it was intended to13what was stated in the clinical study until13be used in at the time for Protocol 007.14the clinical study was closed and completed.14Q. Do you even know that the15Q. Did you say you had an15supplemental testing involved serum from16understanding that there were additional16Protocol 007?17assays being conducted on the clinical trial17A. I recall Dave Krah asking us to18serum that were not part of the clinical19testing as their, I think, again, not wanting20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail		•••		
11understand, the clinical study. The clinical11the test articles, I would just expect it to,12study, the testing should only be conducted on12you know, be used in what it was intended to13what was stated in the clinical study until13be used in at the time for Protocol 007.14the clinical study was closed and completed.14Q. Do you even know that the15Q. Did you say you had an15supplemental testing involved serum from16understanding that there were additional16Protocol 007?17assays being conducted on the clinical trial17A. I recall Dave Krah asking us to18serum that were not part of the clinical18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail	9	were being tested using the clinical trial	9	A. I do not have any reason to
12study, the testing should only be conducted on 1312you know, be used in what it was intended to 1313what was stated in the clinical study until the clinical study was closed and completed.13be used in at the time for Protocol 007.14the clinical study was closed and completed.14Q. Do you even know that the15Q. Did you say you had an understanding that there were additional15supplemental testing involved serum from16understanding that there were additional serum that were not part of the clinical17A. I recall Dave Krah asking us to18serum that were not part of the clinical trial?18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A. There were the supplemental testing, I believe, utilized the serum that was generated or obtained as part of the20me at the time of the timing of his e-mail	10	serum which is not part of, as far as I	10	believe that it did or didn't happen. Again,
13what was stated in the clinical study until13be used in at the time for Protocol 007.14the clinical study was closed and completed.14Q. Do you even know that the15Q. Did you say you had an14Q. Do you even know that the16understanding that there were additional15supplemental testing involved serum from17assays being conducted on the clinical trial16Protocol 007?18serum that were not part of the clinical17A. I recall Dave Krah asking us to19trial?19testing as their, I think, again, not wanting20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail		understand, the clinical study. The clinical		
14the clinical study was closed and completed.14Q.Do you even know that the15Q.Did you say you had an15supplemental testing involved serum from16understanding that there were additional16Protocol 007?17assays being conducted on the clinical trial17A.I recall Dave Krah asking us to18serum that were not part of the clinical18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A.There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail	12		12	you know, be used in what it was intended to
15Q. Did you say you had an15supplemental testing involved serum from16understanding that there were additional16Protocol 007?17assays being conducted on the clinical trial17A. I recall Dave Krah asking us to18serum that were not part of the clinical18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail	13	what was stated in the clinical study until	13	be used in at the time for Protocol 007.
16understanding that there were additional16Protocol 007?17assays being conducted on the clinical trial17A.I recall Dave Krah asking us to18serum that were not part of the clinical18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A.There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail	14			-
17assays being conducted on the clinical trial17A. I recall Dave Krah asking us to18serum that were not part of the clinical18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail				
18serum that were not part of the clinical18hold performing any additional supplemental19trial?19testing as their, I think, again, not wanting20A.There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail		Ū		
19trial?19testing as their, I think, again, not wanting20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail		assays being conducted on the clinical trial		•
20A. There were the supplemental20to generate additional results on the test21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail		-		hold performing any additional supplemental
21testing, I believe, utilized the serum that21sera. So I, again, may be speculation, but to22was generated or obtained as part of the22me at the time of the timing of his e-mail		trial?	19	
22 was generated or obtained as part of the 22 me at the time of the timing of his e-mail	20	A. There were the supplemental	20	to generate additional results on the test
		testing, I believe, utilized the serum that		sera. So I, again, may be speculation, but to
23 trial. 23 after the FDA inspection would lead me to	22	was generated or obtained as part of the		me at the time of the timing of his e-mail
	23	trial.		-
24 Q. What supplemental testing are 24 believe that those were the test articles for	24	Q. What supplemental testing are	24	believe that those were the test articles for

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Appx6018

Veritext Legal Solutions $215\text{-}241\text{-}1000 \sim 610\text{-}434\text{-}8588 \sim 302\text{-}571\text{-}0510 \sim 202\text{-}803\text{-}8830$ Case: 23-2553 Document: 45 Page: 118 Date Filed: 11/01/2023

HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	Page 481		Page 483
1	Protocol 007.	1	Q. Can you tell me your best
2	Q. You inferred that the supplemental	2	recollection of what it is that Dr. Krah said?
3	testing on the other passages was being done	3	MR. KELLER: Do you want to
4	on serum from Protocol 007 because after the	4	take a minute to read the entire
5	FDA inspection, Dr. Krah told you to stop	5	paragraph?
6	doing the additional testing. Do I have it	6	THE WITNESS: Yes.
7	right?	7	Your question again was?
8	A. And that he also stated that	8	BY MR. SANGIAMO:
9	there may be some concerns with generating	9	Q. Can you give me your best
10	additional data on the test sera.	10	recollection of what it is that Dr. Krah said
11	Q. But he didn't tell you that the	11	in what is referred to in the second sentence
12	test sera were Protocol 007 test sera. Right?	12	of this paragraph?
13	A. Not at the time and, again, I	13	A. I don't think I can elaborate
14	can't confirm whether it was or it wasn't.	14	more than what was said here. That's my best
15	But, again, based on the information that I	15	recollection.
16	reviewed, it leads me to question that.	16	Q. Do you have a recollection of
17		17	what he meant by the assay needing to be
18	(Exhibit Wlochowski-22, Assay	18	thrown out?
19	Counts, Bates RELATOR_00001014 to 1024,	19	A. So, again, the assay wouldn't
20	was marked for identification.)	20	the assay results would not be used. So the
21		21	assay would be discarded.
22	BY MR. SANGIAMO:	22	Q. You don't recall what words he
23	Q. Ms. Wlochowski, you've just	23	used to communicate what you interpreted to be
24	been handed what has been marked as	24	him saying that the assay would need to be
	Page 482		Page 484
1	Exhibit 22. I'd ask you to take a look at	1	discarded?
2	that, please.	2	A. I do not.
3	Have you looked it over?		
1	•	3	Q. Is it your recollection that he
4	A. Okay. Yes, I've looked it	4	was saying that the assay would need to be
5	A. Okay. Yes, I've looked it over.	4 5	was saying that the assay would need to be discarded because there was a tear in the cell
5 6	A. Okay. Yes, I've looked itover.Q. Are you familiar with that	4 5 6	was saying that the assay would need to be discarded because there was a tear in the cell monolayer?
5 6 7	A. Okay. Yes, I've looked it over.Q. Are you familiar with that document?	4 5 6 7	was saying that the assay would need to be discarded because there was a tear in the cell monolayer?A. Yes.
5 6 7 8	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. 	4 5 6 7 8	was saying that the assay would need to be discarded because there was a tear in the cell monolayer?A. Yes.Q. Would that be a reason to
5 6 7 8 9	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at 	4 5 6 7 8 9	was saying that the assay would need to be discarded because there was a tear in the cell monolayer?A. Yes.Q. Would that be a reason to discard an entire assay?
5 6 7 8 9 10	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's 	4 5 6 7 8 9 10	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock
5 6 7 8 9 10 11	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And 	4 5 6 7 8 9 10 11	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all
5 6 7 8 9 10 11 12	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. 	4 5 6 7 8 9 10 11 12	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on.
5 6 7 8 9 10 11 12 13	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph 	4 5 6 7 8 9 10 11 12 13	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a
5 6 7 8 9 10 11 12 13 14	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator 	4 5 6 7 8 9 10 11 12 13 14	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the
5 6 7 8 9 10 11 12 13 14 15	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for 	4 5 6 7 8 9 10 11 12 13 14 15	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay?
5 6 7 8 9 10 11 12 13 14 15 16	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." 	4 5 6 7 8 9 10 11 12 13 14 15 16	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you
5 6 7 8 9 10 11 12 13 14 15 16 17	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? 	4 5 6 7 8 9 10 11 12 13 14 15 16 17	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer
5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? A. Yes. 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer right?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? A. Yes. Q. It says, "Krah was claiming 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer right? Q. Would a tear in a single well
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? A. Yes. Q. It says, "Krah was claiming that the assay needed to be thrown out because 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer right? Q. Would a tear in a single well in a
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? A. Yes. Q. It says, "Krah was claiming that the assay needed to be thrown out because the cell monolayer was torn and there was a 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer right? Q. Would a tear in a single well in the mock control require discarding the entire assay?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? A. Yes. Q. It says, "Krah was claiming that the assay needed to be thrown out because the cell monolayer was torn and there was a low plaque count." 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer right? Q. Would a tear in a single well in the mock control require discarding the entire assay? A. It don't think we had requirements
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Okay. Yes, I've looked it over. Q. Are you familiar with that document? A. I'm not certain what it is. Q. Could you take a look at Exhibit 7 which is your Answers to Merck's Revised First Set of Interrogatories? And could you turn to page 18, please. The third full paragraph begins, "Once, Relator Krahling asked Relator and Jon Gombola to review his plaque count for the mock control for one of his assays." Do you see that? A. Yes. Q. It says, "Krah was claiming that the assay needed to be thrown out because the cell monolayer was torn and there was a 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 was saying that the assay would need to be discarded because there was a tear in the cell monolayer? A. Yes. Q. Would that be a reason to discard an entire assay? A. If it occurred in the mock control, the mock control is what you base all your results on. Q. So a tear in a single well in a mock control would require discarding the entire assay? A. It wouldn't require can you ask your question again to make sure I answer right? Q. Would a tear in a single well in the mock control require discarding the entire assay?

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	JOAN L. WLOCHOWSKI -		
	Page 485		Page 487
1	count? Did Dr. Krah say it was a low plaque	1	right now of how many wells Dr. Krah said were
2	count and that that was part of the reason	2	torn in this particular assay. Right?
3	that the assay would have to be discarded?	3	A. No. Maybe the wording is
4	A. Well, if the monolayer is torn,	4	misleading just to say it's a torn monolayer
5	as he said, then the plaque count would be	5	and that would indicate one well, but it could
6	you know, you wouldn't be able to provide a	6	mean across the plate.
7	you wouldn't have the full count for a	7	Q. Are you asserting that that is
8	confluent monolayer.	8	what he said?
9	Q. How many wells were there for	9	MR. KELLER: Mischaracterizes
10	the mock?	10	her testimony.
11	A. I don't recall.	11	MR. SANGIAMO: I'm trying to
12	Q. Could you take a look at	12	get to the bottom of this, Jeff.
13	Exhibit 16, please, which is the plate layout	13	MR. KELLER: She just testified
14	sheet for assay 211. Right?	14	she doesn't recall.
15	A. Yes.	15	MR. SANGIAMO: She put something
16	Q. Does that show how many plates	16	in verified Answers to Interrogatories
17	were used for the mock?	17	accusing Dr. Krah of wrongdoing. I
18	A. It shows that there was one	18	need to find out what Dr. Krah said.
19	plate.	19	MR. KELLER: To be fair to the
20	Q. How many wells on a plate?	20	witness, she signed the Verification
21	A. Going to get this right.	21	May 20, 2015. So two years ago.
22	Q. If it helps you any, you might	22	BY MR. SANGIAMO:
23	want to look at Exhibit 19. I don't know if	23	Q. Ms. Wlochowski, yesterday I
24	it will help you any.	24	asked you which of these Interrogatories
	Page 486		Page 488
1	A. So it was 12 wells per plate.	1	Mr. Krahling had input into. Did Mr. Krahling
2	Q. 12 wells per plate, is that	2	have any input into this paragraph?
3	what you said, Ms. Wlochowski?	3	A. No.
4	A. Yes.	4	Q. This was all your writing with
5	Q. Is it your recollection there	5	your counsel?
6	was a tear in one of those 12 wells, the assay	6	A. Yes.
7	would have to be discarded?	7	Q. And so what is your best
8	A. Sometimes if there is a tear,	8	recollection of what Dr. Krah said that you're
9	it could occur across a plate, across wells.	9	trying to capture there in the second sentence
10	So if you're as you're, you know, dumping	10	of this paragraph?
11	out the stain or the media, the aspirate, the	11	A. It's just exactly that. That
12	media, but it could be a trigger that occurs	12	the cell monolayer was torn. Whether he's
13	across the plate.	13	indicating one or multiple wells, I don't
14	Q. Across all 12 wells?	14	know.
15	A. Not across 12 wells, but it	15	Q. You also don't know what it is
16	could. Sometimes as you're fixing the edges	16	that he said in terms of what needed to be
17	of the monolayers across the plate, it could	17	done with the assay other than you've captured
18	start to come off. It depends on, you know	18	here him saying it needed to be thrown out.
19	again, going back to the variability within	19	Is that right?
20	cell-based assays, that could occur, or it	20	A. Yes.
21	could be something during the course of	21	Q. Ms. Wlochowski, when I looked
22	running the assay that could cause that to	22	at that paragraph and when I looked at what
23	occur.	23	was marked as Exhibit 22 that raised a
24	Q. But you don't have a recollection	24	question in my mind which I'm going to ask you

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	Page 489	1	Page 491
1	now to address if you could, whether there is	1	whether what is contained here in Exhibit 22
2	any relationship between the events described	2	relates to what is described on page 18 of
3	in the paragraphs and what is captured in	3	your Answers to Interrogatories?
4	Exhibit 22?	4	A. I cannot confirm that. I do
5	MR. KELLER: For the record,	5	not know.
6	give her chance to look at Exhibit 22.	6	Q. Now, I think I when I first
7	MR. SANGIAMO: She spent a few	7	asked you if you recognized this document, you
8	minutes looking at it previously.	8	said something like I'm not certain if I
9	THE WITNESS: So you want to	9	recognize it.
10	you're asking me if what is in the	10	A. Yes.
11	paragraph relates to what is in	11	Q. You now looked at it a little
12	Exhibit 22?	12	more. Do you recognize it at all?
13	BY MR. SANGIAMO:	13	A. I do not remember what this
14	Q. Yes, I am. If I could direct	14	document is for. It looks like there was a
15	your attention to 1017 of Exhibit 22 using the	15	comparison done, but I do not remember the
16	Bates numbers in the bottom right-hand corner?	16	intent of the data that is being presented
17	A. Okay.	17	here.
18	Q. You may note that this purports	18	Q. Have you seen the document
19	to describe counts done by you, Mr. Gombola,	19 20	before? MR. KELLER: Asked and answered.
20 21	Dr. Krah and Mr. Krahling. Right?	20	BY MR. SANGIAMO:
$\begin{vmatrix} 21\\22 \end{vmatrix}$	A. Not necessarily.Q. Page 1017 does not	$\frac{21}{22}$	Q. Don't tell me if you saw it in
22	Q. Page 1017 does notA. Oh, sorry. So page 1017 refers	22	your meetings with counsel, but other than
23	to can you repeat your question?	23	that, have you seen it before?
24		24	-
1	Page 490		Page 492
1		1	A Vac hasses Island it
1 2	Q. I was trying to direct your	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	A. Yes, because I signed it.
2	attention to the fact that page 1017 purports	2	Q. Are you sure you signed it?
3	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola,	2 3	Q. Are you sure you signed it? Your signature appears there.
3 4	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with	2 3 4	Q. Are you sure you signed it?Your signature appears there.A. Yes, my signature.
3 4 5	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that?	2 3 4 5	Q. Are you sure you signed it?Your signature appears there.A. Yes, my signature.Q. Do you recall signing it?
3 4 5 6	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes.	2 3 4 5 6	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can
3 4 5 6 7	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes. Q. And the paragraph in your	2 3 4 5 6 7	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can answer.
3 4 5 6 7 8	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes. Q. And the paragraph in your Answers to Interrogatories on page 18, as I	2 3 4 5 6 7 8	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can answer. THE WITNESS: I don't remember
3 4 5 6 7 8 9	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes. Q. And the paragraph in your Answers to Interrogatories on page 18, as I read it, is describing an instance in which a	2 3 4 5 6 7 8 9	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can answer. THE WITNESS: I don't remember if I signed it, but I believe that to
3 4 5 6 7 8 9 10	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes. Q. And the paragraph in your Answers to Interrogatories on page 18, as I read it, is describing an instance in which a certain mock was looked at by you, Mr. Gombola,	2 3 4 5 6 7 8 9 10	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can answer. THE WITNESS: I don't remember if I signed it, but I believe that to be my signature.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes. Q. And the paragraph in your Answers to Interrogatories on page 18, as I read it, is describing an instance in which a certain mock was looked at by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Right? A. Correct. Q. And if we go back to page 1017 it appears that in one of the 12 wells in the data as reported by Dr. Krah the word "torn" appears. Right? A. Correct. Q. And in the corresponding wells in the counts as done by you, Mr. Gombola and Mr. Krahling, there is no indication of a tear. Right? A. Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can answer. THE WITNESS: I don't remember if I signed it, but I believe that to be my signature. BY MR. SANGIAMO: Q. Well, do you have any way of assessing whether it's a photocopy of your signature as opposed to your original signature? A. I mean, it is a photocopy here today. Q. Right. A. That I don't have any reason to believe that it's not my signature. Q. Do you remember doing a count of mocks under these special circumstances
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	attention to the fact that page 1017 purports to show counts being done by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Do you agree with that? A. Yes. Q. And the paragraph in your Answers to Interrogatories on page 18, as I read it, is describing an instance in which a certain mock was looked at by you, Mr. Gombola, Dr. Krah and Mr. Krahling. Right? A. Correct. Q. And if we go back to page 1017 it appears that in one of the 12 wells in the data as reported by Dr. Krah the word "torn" appears. Right? A. Correct. Q. And in the corresponding wells in the counts as done by you, Mr. Gombola and Mr. Krahling, there is no indication of a tear. Right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. Are you sure you signed it? Your signature appears there. A. Yes, my signature. Q. Do you recall signing it? MR. KELLER: Are you you can answer. THE WITNESS: I don't remember if I signed it, but I believe that to be my signature. BY MR. SANGIAMO: Q. Well, do you have any way of assessing whether it's a photocopy of your signature as opposed to your original signature? A. I mean, it is a photocopy here today. Q. Right. A. That I don't have any reason to believe that it's not my signature. Q. Do you remember doing a count

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Veritext Legal Solutions



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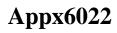
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1	Page 493	1	Page 495
1	A. I cannot remember doing this,	1	those counts?
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	no.	2	A. Again, I don't recall Steve
3	Q. This is an unusual kind of	3	asking me to count I'm trying to respond
4	thing, isn't it?	4	correctly. So I don't recall him asking me to
5	A. Yes.	5	recount both of these assays I guess is
6	MR. KELLER: Objection.	6	what or both of these mock plates is what
7	BY MR. SANGIAMO:	7	you're saying.
8	Q. There is no particular reason	8	Q. That's what I'm asking. You
9	why the running of the assay, you and Jill	9	don't recall that?
10	DeHaven and Dr. Krah and Mr. Krahling would	10	A. Him asking me to count
11	have all counted the mocks for two assays.	11	specifically both plates.
12	Right?	12	Q. Do you recall him ever asking
13	MR. KELLER: And Jon Gombola,	13	you to count plates?
14	you forgot him.	14	A. Based on what I have here, yes.
15	BY MR. SANGIAMO:	15	Q. Other than that?
16	Q. Jon Gombola, one of the other	16	A. Again, when we say count, it's
17	ones. Right?	17	taking a look at what somebody else reported.
18	A. Your question again was?	18	I'm not saying that my if he asked me to
19	Q. It would be unusual for you and	19	look at something, that it was something that
20	Jill DeHaven and Dr. Krah and Mr. Krahling all	20	changed any results that were being reported.
21	to count the mocks for one assay and for you	21	But as we agreed to here, we talked about how
22	and Mr. Gombola and Dr. Krah and Mr. Krahling	22	we wanted to keep a record of what we were
23	all to count the mocks for another assay.	23	counting at that time.
24	Right?	24	Q. But you don't recall him saying
	Page 494		Page 496
1	Page 494 A. Well, again, it depends on what	1	Page 496 to you, hey, Joan, could you, please, count
	A. Well, again, it depends on what	1 2	to you, hey, Joan, could you, please, count
2	A. Well, again, it depends on what you consider unusual. This wouldn't be		to you, hey, Joan, could you, please, count the mock for this assay and tell me what
2 3	A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of	2	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get?
2 3 4	A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there	2 3	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked
2 3 4 5	A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the	2 3 4 5	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it
2 3 4 5 6	A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for	2 3 4 5 6	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again.
2 3 4 5 6 7	A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007.	2 3 4 5 6 7	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as
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2 3 4 5 6 7 8 9 10 11 12	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? 	2 3 4 5 6 7 8 9 10 11 12	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were
2 3 4 5 6 7 8 9 10 11 12 13	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? 	2 3 4 5 6 7 8 9 10 11 12 13	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't
2 3 4 5 6 7 8 9 10 11 12 13 14	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat the question? Q. Do you agree that Exhibit 22 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we take a break. MR. KELLER: We've been going
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat the question? Q. Do you agree that Exhibit 22 appears to indicate that you counted all 12 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we take a break. MR. KELLER: We've been going an hour or so.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat the question? Q. Do you agree that Exhibit 22 appears to indicate that you counted all 12 wells for the mock for assay 170 and that you 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we take a break. MR. KELLER: We've been going an hour or so. VIDEOGRAPHER: The time is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat the question? Q. Do you agree that Exhibit 22 appears to indicate that you counted all 12 wells for the mock for assay 170 and that you also counted all 12 wells for the mock for 	$ \begin{array}{r} 2 \\ 3 \\ 4 \\ 5 \\ 6 \\ 7 \\ 8 \\ 9 \\ 10 \\ 11 \\ 12 \\ 13 \\ 14 \\ 15 \\ 16 \\ 17 \\ 18 \\ 19 \\ 20 \\ \end{array} $	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we take a break. MR. KELLER: We've been going an hour or so.
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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. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat the question? Q. Do you agree that Exhibit 22 appears to indicate that you counted all 12 wells for the mock for assay 170 and that you also counted all 12 wells for the mock for assay 179? Do you agree with that? A. Based on this, yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we take a break. MR. KELLER: We've been going an hour or so. VIDEOGRAPHER: The time is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Well, again, it depends on what you consider unusual. This wouldn't be something that we would conduct as part of I guess in Protocol 007 we wouldn't there wouldn't be four different people counting the same plates for every assay that we tested for Protocol 007. Q. Do you recall Mr. Krahling asking you to do a count of all 12 plates I'm sorry, all 12 wells for the mock in two different assays for some reason unrelated to actual data for the clinical trial? A. Mr. Krahling? Q. Yes. A. Asking me to can you repeat the question? Q. Do you agree that Exhibit 22 appears to indicate that you counted all 12 wells for the mock for assay 170 and that you also counted all 12 wells for the mock for assay 179? Do you agree with that? 	$\begin{array}{c} 2 \\ 3 \\ 4 \\ 5 \\ 6 \\ 7 \\ 8 \\ 9 \\ 10 \\ 11 \\ 12 \\ 13 \\ 14 \\ 15 \\ 16 \\ 17 \\ 18 \\ 19 \\ 20 \\ 21 \\ 22 \\ 23 \end{array}$	to you, hey, Joan, could you, please, count the mock for this assay and tell me what numbers you get? MR. KELLER: Objection. Asked and answered like six times. Answer it again. THE WITNESS: Yeah, I mean, as I stated earlier, he did ask me to look at a mock. Now, whether or not that mock is this mock, whether or not he asked me to look at that and there was additional plates or counts that were being conducted anyways, I can't recall. MR. SANGIAMO: Why don't we take a break. MR. KELLER: We've been going an hour or so. VIDEOGRAPHER: The time is 4:09. Going off the video record.

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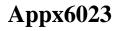
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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1	Page 497	1	Page 499
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	4:31. Back on the video record.	1	you looking at the Answers to Interrogatories.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	BY MR. SANGIAMO:	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	I'm asking for your recollection right now.
3	Q. Ms. Wlochowski, if you could	3	A. My recollection right now is I
4	take out Exhibit 7, please. And turn to	4	don't recall. I believe I did.
5	page 18. And turn if you look at the top	5	Q. I'm having a hard time. You
6	of page 18, these are your revised Answers to	6	don't recall but you believe you did?
	Interrogatories and the particular paragraph	7	A. I believe that I saw him but
8	at the top of page 18 begins with, "One	8 9	again, to the best of my recollection, I saw him do that.
9 10	morning in early August 2001, Relator witnessed Krah taking plates from completed		
10	•••••••••••••••••••••••••••••••••••••••	10 11	Q. What time of day was this?A. This was early in the morning.
	assays and disposing them in biohazard bags.	11	,
12	She told Relator Krahling immediately.		Q. Around what time, do you recall?
13	Relator and Relator Krahling discussed how	13	A. Maybe around 8:00.
14	unusual this was because they had never seen	14	Q. Was it the case that you walked
15	Krah dispose of any plates before and Krah was		into the room and that is how you saw it or did you see it through a window or how did you
16 17	intentionally destroying the evidence of raw data that was being manipulated in an ongoing	16	see it?
17	clinical trial."	17 18	A. I walked into the room.
10	Where in the lab was Dr. Krah	10	
20			Q. Was there anyone else in the room at the time?
20	when you witnessed him taking the plates from completed assays and disposing them in	20	A. I don't think so.
$ ^{21}_{22}$	biohazard bags?	$\frac{21}{22}$	Q. You were arriving I'm sorry,
22	A. So I'll have to explain. I	22	strike that.
23	don't know what you know about the lab setup.	23	Did you and Dr. Krah say
24		24	
1	Page 498 Q. Was he in his office?	1	Page 500 anything to each other at that point?
$\begin{vmatrix} 1\\2 \end{vmatrix}$	A. No, he was not in his office.	$\begin{vmatrix} 1\\2 \end{vmatrix}$	A. Not that I recall, no.
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Q. What room? Is there a name for	3	Q. Did you remain in the room?
1	the room he was in?	4	A. No, because I went to discuss
45		5	with Steve.
6	A. They have room numbers. And I can't remember which room number was which.	6	Q. How long were you in the room
7	So his office was attached to one of the labs	7	before you then left to go discuss it with
8	and then across the hall there was a second	8	Steve? A moment?
9	lab. So he was across the hall in that second	9	A. Not a moment. Again, I believe
	lab, not the one that is next to his office.	-	I was just coming in for the day and dropped
11	So in that second lab is where I would say the	11	my stuff off at the desk. So I can't say if I
12	majority, if not all, I can't recall if there	12	stayed there five minutes or ten minutes. I
12	is any counting done in the other lab, but the	12	can't remember.
13	lab where my desk is, there was a big island	13	Q. Did Dr. Krah see you?
15	typically that we sat there to count the	15	A. I believe so, yes.
16	plates and there were stacks of plates in the	16	Q. Do you have any way of
17	middle of the island against the wall. So he	17	estimating how many plates he was putting in
18	was taking those plates and putting them into	18	the biohazard bag?
	a biohazard bag to be destroyed.	19	MR. KELLER: Objection. Lack
119	a oronazara oug to be abbitoyea.	20	of foundation.
19 20	O Well you saw him putting them		or roundation.
20	Q. Well, you saw him putting them in a biohazard bag. Right?		THE WITNESS. I do not
20 21	in a biohazard bag. Right?	21	THE WITNESS: I do not. BY MR_SANGIAMO [.]
20 21 22	in a biohazard bag. Right? A. I can't remember if I saw him	21 22	BY MR. SANGIAMO:
20 21	in a biohazard bag. Right?	21	

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	Page 501	1	Page 503
1	take the first step in discarding?	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Q. What did he say? I'm sorry,
2	A. Again, I've never seen what	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	continue.
3	how I have never seen him do this before	3	A. I was going to say he was in
4	so	4	shock he was doing it. Your question?
5	Q. So you don't know whether that	5	Q. Do you recall what words
6	is the appropriate first step to take to	6	Mr. Krahling spoke?
7	MR. KELLER: Objection.	7	A. I do not recall.
8	Mischaracterizes the testimony.	8	Q. Do you know what the process
9	BY MR. SANGIAMO:	9	was generally for discarding the plates that
10	Q to discard plates?	10	were used in Protocol 007?
11	MR. KELLER: Lack of foundation.	11	A. I do not know what the process
12	THE WITNESS: Again, I don't	12	was that I can recall.
13	recall any method that we had for	13	Q. Have you had any involvement in
14	disposing them.	14	the discarding of plates strike that.
15	BY MR. SANGIAMO:	15	Have you had any involvement in
16	Q. Do you know whether plates had	16	the discarding of test samples that contain a
17	been disposed of earlier in the clinical	17	live virus in your career?
18	trial?	18	A. Yes.
19	A. I do not other than because	19	Q. Is that at Pfizer?
20	this was, like I said, the first time I had	20	A. At Yale. I can't remember if
21	seen him do this. There were many, many	21	at Pfizer. And there may have been other
22	plates that were stacked up in the laboratory.	22	instances, but I can say at Yale that I did it.
23	They were covered with dust. Seemed like they	23	Q. Do you have any recollection of
24	had been there for quite some time.	24	what the procedure was for discarding the test
	Page 502		Page 504
1	Q. What do you mean covered with	1	samples containing live virus at New Haven?
2	dust?	2	A. We discarded into a biohazard
3	A. They had been there for some	3	waste container.
4	time. There was a number of plates.	4	Q. Would you do that right after
5	Q. Do you mean literally covered	5	the testing?
6	with dust or are you using that figuratively?	6	A. When the test was complete, yes.
7	A. That's what I recall, yes.	7	Q. As I understand your testimony
8	Q. What was strike that.	8	sitting here right now, you don't have a
9	Did Dr. Krah alter his conduct	9	recollection of being involved in the
10	when he saw you?	10	discarding of test samples containing a live
11	A. I don't think so.	11	virus in your time at Pfizer or Amgen. Right?
12	Q. You said you left the room to	12	A. I'm not excluding it, but I
13	then go talk to Mr. Krahling?	13	don't recall.
14	A. I did.	14	Q. Could you flip back to page 14,
15	Q. Was it unusual for Mr. Krahling	15	please, of Exhibit 7? I want to direct your
16	to be in at that hour?	16	attention to the first paragraph on that page.
17	A. He was typically in before Dave	17	In particular, I was going to ask you about
18	was.	18	the sentence in the fifth line that reads,
19	Q. Okay. And 8:00, that was your	19	"Kennedy agreed that there was fraud in the
20	arrival time at that time. Right?	20	lab regarding Protocol 007, but he did not
21	A. Yes.	21	want to be a part of taking a stand against it
22	Q. What was Mr. Krahling's	22	as he did not want to lose his job."
23	reaction when you told him what you saw?	23	My question is going to be your
24	A. I think he was somewhat shocked.	24	best recollection of exactly what it is that
<u>~</u> ¬	11. I think he was some what shocked.		sest reconcerton of exactly what it is that

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	JOAN E. WEOCHOWSKI -		
	Page 505		Page 507
1	Mr. Kennedy said. If you feel you need to	1	conversation with him would have been
2	read the whole paragraph to answer that	2	around the fact that Dave Krah was
3	question, that's fine.	3	asking us to look to identify more
4	A. I would like to read that	4	plaques where on pre-positives
5	paragraph.	5	because, again, it's not expected and
6	Q. Sure.	6	that there were people he agreed in the
7	A. Your question again was?	7	lab that would do that based on Dave
8	Q. Just for your best recollection	8	Krah's direction.
9	of the words Mr. Kennedy spoke that you are	9	BY MR. SANGIAMO:
10	referring to in the sentence that begins on	10	Q. Could you turn to page 15,
11	line 5 that reads, "Kennedy agreed that there	11	please. And if you look at the paragraph at
12	was fraud in the lab regarding Protocol 007,	12	the bottom of page 15, it reads, In July of
13	but he did not want to be a part of taking a	13	2001, at a laboratory meeting involving all
14	stand against it as he did not want to lose	14	members of the laboratory, Relator accused
15	his job."	15	Krah of "cheating." She stated that when the
16	A. Again, not being able to quote	16	testers are not blinded as to whether samples
17	exactly what he said at that time, that was	17	are pre- or post-vaccination, it is wrong to
18	the conversations that we had exchanged was	18	recount and adjust a pre-vaccination sample
19	that is what he had indicated, he did not want	19	only because it is found to be seropositive,
20	to lose his job.	20	Krah responded to this accusation with an
21	Q. Did he use the word "fraud"?	21	awkward silence.
22	A. I don't recall if he used the	22	Have you already described for
23	word "fraud" himself. But, again, in our	22	us today that event?
23	discussions with it, or surrounding the events	23	A. Yes.
24	discussions with it, or surrounding the events	24	
1	Page 506		Page 508
1	that occurred in the laboratory, he was in	1	Q. If you turn to page 17, the
2	agreement that data was being manipulated and		last paragraph reads, On one occasion,
3	falsified.	3	Relator, DeHaven, Kennedy, Gombola and Suzanne
4	Q. Did he use the word "manipulated"?	4	Maahs learned of Emini's planned audit from
5	A. I can't recall what word he	5	Relator Krahling. Relator, Gombola and Maahs
6	used. I mean, it was more likely that I	6	agreed to stick together and explain to the
7	stated something and he agreed with it.	7	Merck auditors exactly what was going on in
8	Q. Do you recall what it is that	8	the lab. DeHaven and Kennedy opted to take a
9	you stated when he agreed?	9	neutral stance with Emini's auditors. They
10	A. I do not recall exactly what I	10	agreed not to lie but said that they would not
11	stated to him other than what we described,	11	volunteer information unless asked.
12	you know, the events that we described here	12	What specifically do you recall
13	today about changing the data and that it was	13	Mr. Gombola and Ms. Maahs saying as you
14	wrong, and he agreed with that.	14	characterized here as them agreeing to stick
15	Q. And is it possible you said to	15	together?
16	him, Dr. Krah is having us focus counting	16	A. Again, I think to the extent of
17	checks on pre-positives. And he said, yes, I	17	what I have documented here is my recollection
18	agree?	18	of, you know, there was multiple discussions
19	MR. KELLER: Objection. Lack	19	with all these different people in the
20	of foundation. Argumentative.	20	laboratory about what was going on, this group
20	THE WITNESS: Again, I it is	20	here in particular. So to remember the exact
22	I'm trying to think of another way	22	words of what was discussed at that time,
	to say it. He agreed that in the	22	because it was carried out over multiple
	to say it. The agreed that III the	123	because it was carried but over illultiple
23 24	course of our discussions, my	24	conversations, but as it relates to the audit,

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	JUAN L. WLUCHUWSKI -	піс	JILI CONFIDENTIAL
	Page 509		Page 511
1	again, Suzanne and Jon were willing to they	1	Q. Is that the entirety of what
2	were more willing to speak up in the audit if	2	you have to say to me in terms of whether he
3	there was opportunity as, again, Jill and	3	was ever told that he might lose his job if he
4	Frank were, although they agreed, they weren't	4	answered the questions at the audit?
5	going to they weren't going to volunteer	5	A. Yes.
6	that information.	6	MR. KELLER: Objection. Lack
7	Q. Weren't going to volunteer what	7	of foundation. Interpose an objection.
8	information?	8	Lack of foundation.
9	A. Of, again, the data changes	9	BY MR. SANGIAMO:
10	that were occurring on the pre-positives.	10	Q. If you turn to page 20 of your
11	Q. Did they express any reluctance	11	Answers to Interrogatories. The last full
12	to reveal it?	12	paragraph on that page reads, "Relator had
13	A. They were reluctant based on	13	multiple communications with Alan Shaw about
14	the what we went over previously with my	14	topics relating to allegations in the
15	response to Frank. Again, his reluctance was	15	complaint regarding the mumps vaccine. These
16	around potentially losing his job for	16	communications took place in person at Merck's
17	providing information.	17	facility where they worked in West Point,
18	Q. Is that what he said?	18	Pennsylvania between January and September 2001.
19	MR. KELLER: Objection. Asked	19	Relator specifically recalls the day that Shaw
20	and answered.	20	came into the lab to tell the team that the
21	BY MR. SANGIAMO:	21	FDA was on site. Shaw was white as a ghost
22	Q. Did he say if I tell the truth	22	and left quickly after making the
23	I might lose my job?	23	announcement. Relator does not know Shaw's
24	A. Again, in the general sense, yes.	24	current or last known address or place of
	Page 510		Page 512
1	Q. Did he indicate that anyone	1	employment."
2	ever told him that that was so?	2	When you say Shaw was white as
3	MR. KELLER: I'm sorry, can you	3	a ghost, that is colorful phrasing. Do you
4	read that question back?	4	mean his natural complexion was different than
5	BY MR. SANGIAMO:	5	what it usually is?
6	Q. Did he indicate that anyone	6	A. Yes.
7	ever told him that was so?	7	Q. Was his complexion pretty pale
8	A. When he had he had indicated	8	to begin with?
9	he, himself, also felt isolated from the lab	9	A. It is, but his my impression
10	group and, you know, he didn't want to put	10	of Alan Shaw is he always carried himself with
11	anything, any additional stresses on his	11	confidence. This particular day, was it
12	acceptance and maintaining his job.	12	was as they came in, he had a look of
13	Q. Did anyone ever indicate to	13	trying to find the right word. I guess a look
14	Mr. Kennedy that he might lose his job if he	14	of concern.
15	answered the questions of the auditor at the	14	Q. As one would expect a
16	audit?	16	pharmaceutical executive to have if there was
17	MR. KELLER: Objection. Asked	17	an FDA inspection. Right?
18	and answered.	18	MR. KELLER: Objection.
19	THE WITNESS: Again, if you are	19	Objection. Lack of foundation. Calls
20	being targeted and don't feel	19 20	for speculation.
20	comfortable with something that could	20 21	THE WITNESS: Pharmaceutical
21	-	21 22	
22	put your job at risk, then that was his	22 23	companies are, you know, inspected
23	feeling. BY MR. SANGIAMO:	23 24	regularly. So those who are seasoned are used to handling this handling
		24	are used to nanoning this nanoning

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	Page 513		Page 515
1	an inspection and typically there is a	1	at the company?
2	different I guess it does put you on	2	Q. Yes. For example. How many
3	guard, but, again, it's not he	3	FDA inspections were there at Amgen while you
4	seemed to be a bit more concerned than	4	were working at Amgen, added to the number of
5	I would expect him.	5	FDA inspections at Pfizer while you were
6	BY MR. SANGIAMO:	6	working at Pfizer, added to the number of FDA
7	Q. Inspections are usually of	7	inspections at Alexion while you were working
8	manufacturing facilities by the FDA?	8	at Alexion.
9	MR. KELLER: Objection.	9	A. Again, those are global companies
10	Foundation. Overbroad.	10	so
11	BY MR. SANGIAMO:	11	MR. KELLER: Objection.
12	Q. Do you know?	12	Overbroad. Lack of foundation.
13	A. I do know that it goes beyond	13	BY MR. SANGIAMO:
14	manufacturing facilities.	14	Q. The ones you know of.
15	Q. How many inspections do you	15	MR. KELLER: Still overbroad.
16	have knowledge of in your career, FDA	16	Lack of foundation.
17	inspections?	17	THE WITNESS: If you are asking
18	A. What do you mean do I have	18	me maybe I can make it easier.
19	knowledge of?	19	BY MR. SANGIAMO:
20	Q. That you're aware of. That is	20	Q. Sure.
21	a fair question. How many inspections are you		A. So typically there would be an
22	aware of that have occurred at pharmaceutical	22	annual or biannual inspection. There could be
23	companies while you were working there?	23	a follow-up inspection. But FDA inspections
24	A. That's pretty broad, too.	24	are usually unannounced, but pharmaceutical
1	Page 514 MR. KELLER: That's very broad.	1	Page 516 companies typically have an indication of when
2	BY MR. SANGIAMO:	2	they expect the next visit to occur. The
3	Q. FDA inspections.	3	exception would be if there was a for-cause
4	MR. KELLER: Same.	4	audit that the FDA could come in on that
5	THE WITNESS: I worked for	5	non-routine schedule to inspect.
6	multiple pharmaceutical companies. I	6	Q. You say in your the
7	guess I'm not	7	paragraph in your Answers to Interrogatories
8	BY MR. SANGIAMO:	8	that we were just reading that you had
9		9	multiple communications with Alan Shaw about
10	Q. So you think it could be more than 50 or something?	10	topics relating to allegations in the
	-		
11	A. Are you saying at the company	11	Complaint regarding the mumps vaccine. Were
12	that I worked at?	12	any of those one-on-one conversations between
13	Q. Uh-huh.	13	you and Dr. Shaw?
14	A. And over the course of what	14	A. I don't recall one-on-one
15	I guess I'm again, it's still very broad to	15	conversations.
16	me.	16	Q. What do you recall about the
17	Q. When you were working there.	17	context of the communications that are
18	A. When I was working where?	18	referred to in that response?
19	Q. At the various pharmaceutical	19	A. I believe when we had when
20	companies that you've worked at?	20	we had the meeting with Emilio, I believe that
21	A. And you're asking the question,	21	Alan was present. So this was the meeting
22	again, about the	22	where Emilio was enforcing the importance of
23	Q. Number of FDA inspections.	23	the lab being able to complete the testing in,
24	A. The number of FDA inspections	24	I guess, an expedited manner and that bonuses

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	JUAN L. WLUCHUWSKI -		
	Page 517		Page 519
1	would be given for completion of the testing.	1	attendees, but was it multiple labs?
2	I'm trying to remember other examples. That's	2	A. From what I recall, yes, I
3	all I can remember at this time specifically.	3	think it was the whole department of virus and
4	Q. That's all you can remember by	4	cell biology.
5	way of occasions in which Dr. Shaw	5	Q. Did anyone else speak at this
6	communicated with you about the topics related	6	meeting?
7	to allegations in the Complaint regarding	7	A. I can't recall.
8	mumps vaccine?	8	Q. What did Dr. Emini say about
9	A. Yes.	9	next steps?
10	Q. What do you recall Dr. Shaw	10	A. So that, again, I would have
11	saying at that meeting?	11	to to the best of my recollection, I
12	A. I don't recall if he said	12	believe there was a statement around the
13	anything at that meeting.	13	application of I can't remember. I know I
14	Q. Do you recall having any	14	have a summary of it.
15	communications with Dr. Emini other than at	15	Q. You said you know you have a
16	the meeting you just described?	16	summary of it?
17	A. Not directly, no.	17	A. Yes.
18	Q. Okay. Make sure I understand	18	Q. You mean in writing?
19	what that means. Does that mean that	19	A. Yes.
20	actually, what does that mean?	20	Q. But other than that summary,
21	A. I mean, it doesn't make sense,	21	you don't have a recollection?
22	I guess. So I did not have a conversation	22	A. Because, again, it's getting
23	with Emilio. I know that through Bob Suter	23	blurred with other information. I know we had
24	that one of the exhibits that we looked at the	24	some after the FDA inspection, we had
	Page 518		Page 520
1	other day was after my talking to Bob, Bob	1	training, other presentation information that
2	talked to Emilio. So that's the extent.	2	was given to us on I'm just blurring on
3	Q. I see. You just now said	3	what his direction was.
4	you just now spoke in terms of conversations	4	Q. You gave some testimony earlier
5	with Emilio. Make sure I have a full	5	about the meeting attended by Dr. Emini and
6	understanding. Do you recall any other kind	6	Dr. Shaw during which Dr. Emini mentioned the
7	of direct communication with Emilio other than	7	importance of completing the study and the
8	the one meeting that you described?	8	bonuses to the lab if this study was completed
9	A. So I believe there was a	9	on a certain schedule?
10	departmental meeting that Emilio had provided	10	A. Yes.
11	following the FDA inspection. That's what I	11	Q. Do you recall anything else
12	recall.	12	about what Dr. Emini said at that meeting?
13	Q. Anything else?	13	A. I do not.
14	A. I can't recall at this time.	14	Q. Was it a short meeting?
15	Q. What do you recall about the	15	A. To the best I can recall, yes.
16	departmental meeting following the FDA	16	Q. If you had to estimate the
17	inspection in terms of what Dr. Emini said?	17	length of the meeting, what would be your best
18	A. I want to say he gave a summary	18	estimate?
19	of the 483 responses.	19	A. Not more than a half an hour.
20	Q. Okay. Did he talk about next	20	Q. Could you turn to page 8 of the
21	steps?	21	Answers to Interrogatories, please. If you
22	A. Yes, I believe so.	22	look at the paragraph under the heading 1, do
23	Q. Who was at this departmental	23	you see that?
24	meeting, I'm not asking for a roster of all	24	A. Yes.
	6		

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1	Page 521	1	Page 523
1	Q. It says, "Relator Krahling told	1	THE WITNESS: So I can't I
2	Relator what he learned from Krah of numerous	2	don't think I can answer that question
3	communications both written and verbal	3	based on what I've discussed with legal
4	that Merck had with the FDA in the 1999-2001	4	counsel.
5	time frame in connection with its Protocol 007	5	BY MR. SANGIAMO:
6	testing. Relator knows these communications	6	Q. Right. So you don't know
7	occurred and that these communications did not	7	anything about that other than what you have
8	disclose what Merck knew about the	8	discussed with counsel. Is that a fair
9	significantly diminished efficacy of the	9	statement?
10	vaccine and the steps it was taking to conceal	10	A. To the extent of my knowledge,
11	this from the FDA." That's the end of the	11	beyond what counsel has told me, I know that,
12	quote.	12	again, the what is currently reported in
13	How is it that you know that	13	the label is referencing to the original data
14	these communications occurred and that these	14	that was generated from the approval of the
15	communications did not disclose what Merck	15	vaccine when it was first approved. This is
16	knew about the significant diminished efficacy	16	because I guess I'll let you hook that into
17	of the vaccine and the steps it was taking to	17	my response.
18	conceal this from the FDA?	18	MR. KELLER: Let me interpose
19	MR. KELLER: I object. The	19	an objection. Asked and answered this
20	responses to Interrogatories were	20	question previously.
21	written by both lawyers and the	21	
22	verifier. And I object as a legal	22	(Exhibit Wlochowski-23,
23	conclusion to that question. To the	23	Handwritten document, Bates RELATOR_
24	extent you can answer it. And to the	24	00000707, was marked for identification.)
	Page 522		Page 524
1	extent the question is compound, I	1	
2	object to that as well.	2	BY MR. SANGIAMO:
3	THE WITNESS: Can I read the	3	Q. Ms. Wlochowski, you've been
4	context of the question?	4	handed what has been marked as Exhibit 23. A
5	BY MR. SANGIAMO:	5	few minutes ago you were giving testimony
6	Q. Sure. I may be able to	6	about a meeting that you attended in which Dr.
7	simplify this for you. Do you have any	7	Emini discussed the inspection and the next
8	personal knowledge of what is stated there in	8	steps after the inspection. I believe while
9	the second sentence of the response under	9	you were giving that testimony you indicated
10	paragraph number 1 on page 8 of your Answers	10	you had documentation of what was discussed at
11	to Interrogatories, the sentence that begins,	11	that meeting. Is that right?
12	"Relator knows these communications	12	A. Yes.
13	occurred," and so forth?	13	Q. Exhibit 23, is that the
14	MR. KELLER: Objection.	14	documentation you were referring to?
15	Overbroad.	15	A. Yes.
16	THE WITNESS: Can you define	16	Q. Down at the very bottom of the
17	what you mean by personal knowledge	17	page it says, "human subject must be GMP."
18	here?	18	Right?
19	BY MR. SANGIAMO:	19	A. Yes.
20	Q. What is the basis of your	20	Q. And there is a little mark of
21	knowledge supporting that statement? Let's	21	some sort just to the left of human. Do you
22	try that question.	22	know what that is?
23	MR. KELLER: Again, seeks a	23	A. That's a star, an asterisk.
24	legal conclusion.	24	Q. Do you recall exactly what it
_ _	<u> </u>		

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	JOAN E. WEOCHOWSKI -		
	Page 525		Page 527
1	is that Dr. Emini said in that regard, and in	1	some cases that the analyst that counted the
2	particular I'd ask you to focus on whether he	2	plate originally, the data was changed by a
3	was saying that that is what the FDA said or	3	different analyst. So it didn't go back to
4	was he saying that that was his belief, or	4	the original person who counted the assay.
5	what was he saying to the best of your belief?	5	Q. Did Jon Gombola use the word
6	MR. KELLER: Objection. Lack	6	"fraud"?
7	of foundation. You can answer.	7	A. I don't recall if he used the
8	THE WITNESS: I don't recall	8	word "fraud."
9	what was his reasoning for stating	9	Q. Did he use the word "manipulation"?
10	that.	10	A. I don't recall.
11	BY MR. SANGIAMO:	11	Q. Is he a college student?
12	Q. Okay. If we could go back to	12	A. Yes.
13	Exhibit 7, please. Turn to page 13. The	13	Q. Turning to page 14, please.
14	first paragraph reads: "Relator had multiple	14	The paragraph at the bottom begins, "On one
15	communications with Jon Gombola about topics	15	occasion, Krah instructed Relator to perform
16	relating to allegations in the complaint	16	recounts of her data. Relator was not
17	regarding the mumps vaccine. These	17	provided information regarding the methodology
18	communications took place in person at Merck's	18	of the study, so initially she thought Krah
19	facility where they worked in West Point,	19	Was teaching her how to find plaques correctly
20	Pennsylvania between January and September 2001.		and this was part of the learning curve of
21	Gombola was an intern working in Krah's lab	21	plaque identification. Later, however, after
22	for the summer who was planning to go on to	22	Relator Krahling gave her a copy of the
23	med school. Gombola expressed he did not want	23	Enhanced Assay methodology and after more
24	to be a part of the fraud occurring in the	24	experience counting plaques, she began to
	Page 526		Page 528
1	lab. He agreed with Relators and Maahs to	1	question Krah's motives. Krah requested
2	make copies of counting sheets and countersign	2	recounts of plaques after the data was
3	the sheets which Relator Krahling would	3	assessed." And then the paragraph continues.
4	collect for safe-keeping. Relator, feeling	4	My question to you is just
5	bad that an intern had to be exposed to fraud,	5	whether you can describe the document that
6	told Gombola that this is an example of what	6	you're referring to in this answer where you
7	not to do and it is not like this everywhere	7	say "Enhanced Assay methodology"?
8	you go. Relator does not know Gombola's	8	MR. KELLER: If you need to
9	current or last known address or place of	9	read the entire paragraph, feel free to
10	employment."	10	do that.
11	I want to focus on the sentence	11	THE WITNESS: I believe in this
12	that reads, "Gombola expressed he did not want		statement here the Enhanced Assay
13	to be a part of the fraud occurring in the	13	methodology refers to the I want to
14	lab." I want to ask you your best	14	make sure I get it right.
15	recollection of the words Gombola spoke?	15	I believe in this instance here
16	A. Again, there were a number of	16	the reference is back to the document
17	us that at a certain point in time when we	17	for the development of the assay.
18	were being asked to go back and find more	18	BY MR. SANGIAMO:
19	plaques on pre-positives, felt that we had	19	Q. I see. Okay. At the end of
20	enough experience to count the plates so we	20	that paragraph it states, "On another occasion,
21	did not make any changes. And, you know, an		Krah directed Relator and others in the lab on
22	example of the I guess just going back to	22	a procedure to avoid invalidating assays
23	Exhibit 21, just looking at who the plates	23	that should have been discarded because the
24	were originally counted by, you can see in	24	lab was under pressure to complete all testing

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1	Page 529	1	Page 531
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	by an August deadline."	1	Q. You've just been handed what
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	What was the procedure to avoid	2	has been marked as Exhibit 24. These are your
3	invalidating assays?	3	Answers to Merck's First Set of Interrogatories.
4	MR. KELLER: If you need to	4	Right? If you're wondering what the relationship
5	read the entire paragraph	5	is between
6 7	MR. SANGIAMO: I thought she did.	6 7	A. They look very similar.Q. They are. It looks like Jeff
8	MR. KELLER: I wasn't sure if	8	is about to tell you.
9	she did.	9	MR. KELLER: One is revised,
10	BY MR. SANGIAMO:	10	one is original.
11	Q. Have you read that paragraph	11	THE WITNESS: So the one we
12	already?	11	were looking at first is the revised
12	A. I didn't finish. Repeat your	12	but this is the first set.
14	question.	14	BY MR. SANGIAMO:
15	Q. My question is, what is the	14	Q. Yes.
16	procedure to which you are referring in the	16	A. So they're in reverse.
17	last sentence of that paragraph?	17	Q. Yes. Exactly.
18	A. In the sense that I don't think	18	I was going to ask you to turn
19	procedure means an SOP document as, again,	19	to page 14, please, where there is a paragraph
20	similar to let's see if I can get an	20	at the top that reads as follows: "Relator
20	example. So similar to above where Krah had	20	was working in David Krah's lab on August 6,
22	explained that a sample would be recounted, if	21	2001, along with Stephen Krahling and others.
23	it was determined to show a pre-positive	22	Alan Shaw came in to Krah's lab and told
24	result. He also had advised on a procedure	24	Relator that the FDA was 'here.' Relator
	result. The unso had advised on a procedure		Relator that the PDPP was here. Relator
1	Page 530	1	Page 532
1	that I shouldn't say a procedure, but he	1	continued to go about her work while the FDA
2	that I shouldn't say a procedure, but he had also advised the same for assays which may	2	continued to go about her work while the FDA representative was in Krah's lab. Relator saw
2 3	that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck	2 3	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where
2 3 4	that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well.	2 3 4	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative
2 3 4 5	that I shouldn't say a procedure, but hehad also advised the same for assays which mayhave resulted in invalid assays, to recheckthose as well.Q. To recheck those to make sure	2 3 4 5	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office.
2 3 4 5 6	 that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately 	2 3 4 5 6	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that
2 3 4 5 6 7	 that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed 	2 3 4 5 6 7	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA
2 3 4 5 6 7 8	that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed to an accurate count, an invalid assay would	2 3 4 5 6 7 8	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA representative, Krah and Shaw on August 6,
2 3 4 5 6 7 8 9	 that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed to an accurate count, an invalid assay would become valid? 	2 3 4 5 6 7 8 9	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA representative, Krah and Shaw on August 6, 2001 described in Relators' complaint."
2 3 4 5 6 7 8 9 10	 that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed to an accurate count, an invalid assay would become valid? A. To recheck the count to see if 	2 3 4 5 6 7 8 9 10	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA representative, Krah and Shaw on August 6, 2001 described in Relators' complaint." Did you, yourself, hear what
2 3 4 5 6 7 8 9 10 11	 that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed to an accurate count, an invalid assay would become valid? A. To recheck the count to see if you could either find more plaques because 	2 3 4 5 6 7 8 9 10 11	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA representative, Krah and Shaw on August 6, 2001 described in Relators' complaint." Did you, yourself, hear what was said between Dr. Krah and the FDA on
2 3 4 5 6 7 8 9 10 11 12	that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed to an accurate count, an invalid assay would become valid? A. To recheck the count to see if you could either find more plaques because that would make it positive or less plaques	2 3 4 5 6 7 8 9 10 11 12	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA representative, Krah and Shaw on August 6, 2001 described in Relators' complaint." Did you, yourself, hear what was said between Dr. Krah and the FDA on August 6, 2001?
2 3 4 5 6 7 8 9 10 11 12 13	that I shouldn't say a procedure, but he had also advised the same for assays which may have resulted in invalid assays, to recheck those as well. Q. To recheck those to make sure that the plaques are counted accurately because if they weren't, and they were changed to an accurate count, an invalid assay would become valid? A. To recheck the count to see if you could either find more plaques because that would make it positive or less plaques because I'm sorry, find more plaques	2 3 4 5 6 7 8 9 10 11 12 13	continued to go about her work while the FDA representative was in Krah's lab. Relator saw Mr. Krahling sitting at his desk near where Krah, Shaw and the FDA representative were talking in Mr. Krah's office. Thereafter, Mr. Krahling informed Relator that he overheard the conversations between the FDA representative, Krah and Shaw on August 6, 2001 described in Relators' complaint." Did you, yourself, hear what was said between Dr. Krah and the FDA on August 6, 2001? MR. KELLER: Objection. Asked
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Appx6031

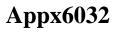
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	JOAN E. WEOCHOWSKI -		
	Page 533		Page 535
1	were inside Dr. Krah's office. Is that right?	1	confirm or deny, but there were other things
2	A. Yes.	2	in Exhibit 6 that you did know based on your
3	Q. Is there a door on Dr. Krah's	3	own personal knowledge. Right?
4	office?	4	A. Yes.
5	A. Yes.	5	Q. I just want to go through some
6	Q. Was the door closed to your	6	of the paragraphs or sentence within Exhibit 6
7	recollection?	7	to get a sense of which portions of the
8	A. I don't recall.	8	Amended Complaint fall into each of those two
9	Q. How close was Mr. Krahling to	9	categories?
10	where Dr. Krah and Dr. Shaw and the FDA	10	MR. KELLER: You got to be
11	representative were talking?	11	kidding me.
12	MR. KELLER: Objection. Lack	12	BY MR. SANGIAMO:
13	of foundation.	13	Q. If you go to paragraph 3.
14	MR. SANGIAMO: I'm sorry?	14	A. Yes.
15	MR. KELLER: Lack of foundation.	15	Q. And the last sentence in
16	THE WITNESS: So the wall of	16	paragraph 3 reads: In fact, their superiors
17	Steve's office where he would sit or	17	and senior Merck management pressured them to
18	his desk, I should say, was the wall	18	participate in the fraud and subsequent
19	for Dave Krah's office. So he was	19	cover-up when Relators objected to and tried
20	right next to his office.	20	to stop it.
21	BY MR. SANGIAMO:	21	Do you have personal knowledge
22	Q. Do you know firsthand whether	22	of your superiors and senior Merck management
23	if one is at the location that Mr. Krahling	23	pressuring you to participate in the fraud?
24	was at, as you just described it, one could	24	MR. KELLER: Objection.
	Page 534		Page 536
1	hear what is being discussed inside Dr. Krah's	1	Overbroad.
2	office?	2	THE WITNESS: Your question was
3	A. I do not know.	3	if I had personal knowledge?
4	Q. Do you have any knowledge as to	4	BY MR. SANGIAMO:
5	whether there were any follow-up visits from	5	Q. Uh-huh.
6	the FDA in connection with the August 6, 2001,	6	A. From the
7	inspection?	7	MR. KELLER: The answer is yes
8	A. I do not not that I can	8	or no.
9	recall. I do not I'm not aware of any	9	THE WITNESS: Yes.
10	follow-up visits.	10	BY MR. SANGIAMO:
11	Q. Could you take out Exhibit 6,	11	Q. What is that pressure that
12	please? Could you turn to page 2 of	12	you're referring to there in that sentence of
12	Exhibit 6, please? Exhibit 6, by the way, is	12	the Complaint?
13	the Amended Complaint in this case. Right?	13	MR. KELLER: Objection. Seeks
14	A. Yes.	14	legal conclusion. You can answer.
15	A. Yes.Q. We testified you testified	15	THE WITNESS: From the
17	yesterday about your knowledge of what is	17	discussions we had earlier, from some
17	contained within Exhibit 6. Do you remember	17	of the responses I had provided earlier
18	that?	10	
		20	was that Dave Krah was asking us to change data. The meeting with Emilio
20	A. Yes.		6
21	Q. And I think you indicated that	21	was asking us to, you know, expedite
22	there were some things in Exhibit 6 that were	22	the testing and complete the testing,
23	not based on your own knowledge and,	23	offering us bonuses. So in my personal
24	therefore, you personally would not be able to	24	knowledge, that was being pressured to

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Page 337Page 3391participate in the fraud.1Vague and ambiguous.2BY MR, SANGIAMO:2THE WITNESS: It is a pretty3Q. You said Dr. Krah was asking3broad statement. 1 think that the -4you to change data. You're referring to the4based on what I've already spoke to.6and check the plaque counts for the6BY MR. SANGIAMO:7pre-positives that you testified about7Q. Do you have anything else to8earlier. Right?9M. KELLER: Same objection.10Q. And you say that Dr. Emini10THE WITNESS: Again, there is a11offered bonuses. He offered bonuses for11Iot of documentation that we have, so I12completing the work under a certain schedule.12think I have highlighted the key points13Right?14BY MR. SANGIAMO:1414A. Yes.19W MR. SANGIAMO:1615Q. Did he describe any other15Q. That would support that Merck16condition for the bonus?10WR. SANGIAMO:17A. I don't recall him describing17MR. KELLER: Skede and answered.18any other conditions.18THE WITNESS: Yes.19Q. And then that sentence also19BY MR. SANGIAMO:20refers to a subsequent coveru p. What are youQ. Yes?21refers to a subsequent coveru p. What are you20Q. Yes?22MR. KELLER: Are you going to1 </th <th>1</th> <th></th> <th>1</th> <th></th>	1		1	
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3 Q. You said Dr. Krah was asking 3 broad statement. I think that the 4 you to change data. You're referring to the 5 supports that paragraph. 6 and check the plaque counts for the 5 support if? 7 re-positives that you testified about 7 Q. Do you have anything else to 8 support if? 9 MR. KELLER: Same objection. 10 Q. And you say that Dr. Emini 10 THE WTINESS: Again, there is a 11 offered bonuses. He offered bonuses for 11 lot of documentation that we have, so I 12 completing the work under a certain schedule. 12 think I have highlighted the key points 13 Right? 13 that would support that. 14 14 A. Yes. 13 BY MR. SANGIAMO: 15 15 Q. Did he describe any other 15 Q. That would support that Merck 18 any other conditions. 18 may other conditions. 18 21 referris to a subsequent cover up. What are you 20 Q. Yees? 21 21 referring to there? 21 A. Yees. 24	1			
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Page 541 Page 541 1 Do you see that? 1 MR. KELLER: Thank you. 2 A. Yes. 2 BY MR. SANGIAMO: 3 Q. Is that something you have 3 Q. Paragraph 23, first sentence, 4 knowledge of? 4 "Without demonstrating that its mumps vaccine 5 MR. KELLER: Objection. Seeks 5 continued to be 95 percent effective, Merck 6 al egal conclusion. Overbroad. 7 sale of the mumps vaccine in the U.S." 8 BY MR. SANGIAMO: 8 Is that something that you have 9 Q. Had Merck made that prediction? 9 (Mark ELLER: Objection. Seeks a legal conclusion. And if you can 11 A. Yes. 10 maswering the question, please do not 15 disclosing communications with counsel, the please do not. 16 those communications. you may. 16 then please do not. 17 17 THE WTINESS: I cannot disclose 20 it would open up the doors for a 20 THE WTINESS: I cannot disclose 21 competitor to be able to provide a 21				
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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1			
1	Page 545	1	Page 547
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Q. Okay. This refers to preliminary	$\begin{vmatrix} 1\\2 \end{vmatrix}$	MR. KELLER: Employed. Okay. THE WITNESS: Yes.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	testing which involved testing blood samples	-	
3	of approximately 60 to 100 children? A. Yes.	3	BY MR. SANGIAMO:
4		4	Q. What is the basis of your
5	Q. Is that a reference to something	5	knowledge about why it was employed?
6	in Protocol 007 or a reference to something else? A. That is a reference to the	6	A. Can I refer back to one of my exhibits?
7			
8	development of the, again, the document for	8	
9	the development of protocol I should say of the PRN.	9	A. I just want to confirm again.
10		10	Looked at so much information.
11	Q. So your knowledge is based on	11	Based on Exhibit 17, I believe
12	that document?	12	that the data calculation spreadsheet is
13	A. And with additional information	13	reference to the Excel spreadsheet in that
14	from counsel.	14	bullet.
15	Q. The third sentence says,	15	Q. So is it fair to say that your
16	"He," meaning Dr. Krah, "also admitted	16	knowledge about why the Excel spreadsheet was
17	that the efficacy of Merck's vaccine had	17	employed is based on the SOP that is at
18	declined over time, explaining that the	18	Exhibit 17?
19	constant passaging of virus to make more	19	A. That is knowledge that there is
20	vaccine for distribution had degraded the	20	the Excel spreadsheet for conducting
21	product and that because of this, mumps	21	calculations. It was also something that we
22	outbreaks will increase over time."	22	had, myself had access to enter data into as
23	Did you ever hear Dr. Krah say	23	well. And the spreadsheet would highlight, if
24	any of those things?	24	I recall correctly, it would highlight the
	Page 546		Page 548
1	A. I do not recall Dave Krah	1	pre-positives upon entry.
2	stating that.	2	Q. Highlight how?
3	Q. Turn to page 17, please. The	3	A. Again, my recollection is that
4	third bullet says that "Krah instituted	4	it would highlight the cell yellow.
5	several measures to isolate the pre-positive	5	Q. Was your departure from Dr.
6	samples, facilitate their 'recount' and	6	Krah's lab at your request?
7	consequent conversion to pre-negatives. For		
		7	A. I don't recall that I requested
8	example, when manually changing original	8	to leave his lab, but I did agree to it when
9	example, when manually changing original counting sheets proved too time-consuming,	8 9	to leave his lab, but I did agree to it when offered.
9 10	example, when manually changing original counting sheets proved too time-consuming, Krah employed an Excel spreadsheet which would	8 9 10	to leave his lab, but I did agree to it when offered. Q. Were you told that you had no
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9 10 11 12 13 14 15 16 17 18 19 20 21	example, when manually changing original counting sheets proved too time-consuming, Krah employed an Excel spreadsheet which would automatically highlight the undesirable pre-positives so that they could be targeted more efficiently. The data was entered, highlighted and changed before it was ever saved." My first question is, do you have personal knowledge about why the Excel spreadsheet was employed? MR. KELLER: Could I get the question back?	8 9 10 11 12 13 14 15 16 17 18 19 20 21	to leave his lab, but I did agree to it when offered. Q. Were you told that you had no choice but to leave his lab? A. I don't recall being told that I had no choice. Again, I agreed to it. As discussed previously, you know, it was very uncomfortable working there. Based on the dynamics, in addition more importantly the manipulation of the data was not something that I wanted to be a part of. So when I was given an opportunity to work elsewhere, I took the opportunity. It was a very good experience for me working in the other lab.

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	Page 549		Page 551
1	When I started working in the other lab, I	1	Q. Who was it that said you're no
2	felt more at ease in that surprisingly the	2	longer part of Dave's harem?
3	even though I believe it was in a separate	3	A. I would I believe it was Kim
4	building, the people from that lab knew about	4	Johnstone.
5	Dave Krah and were actually supportive of me	5	Q. Did she elaborate on what she
6	in the move. They're as one person stated,	6	meant by that?
7	you're not part of Dave Krah's harem is the	7	A. I don't think so.
8	terminology that they used. So it made me	8	Q. Do you have any knowledge of
9	think it wasn't, again, just me thinking that.	9	whether Mr. Krahling signed a separation
10	There was something that was recognized	10	agreement with Merck?
11	outside of his laboratory.	11	MR. KELLER: I'm going to ask
12	Q. Ma'am, were you told you had no	12	you you can answer that question yes
13	choice but to leave Dr. Krah's lab?	13	or no.
14	MR. KELLER: Asked and answered.	14	THE WITNESS: Yes.
15	Come on. Argumentative.	15	BY MR. SANGIAMO:
16	MR. SANGIAMO: She doesn't get	16	Q. Did he discuss the separation
17	to do this, Jeff. She has to answer	17	agreement with you in 2001?
18	the question. She doesn't get to make	18	A. What do you mean by discuss the
19	a speech after that.	19	agreement?
20	MR. KELLER: You're not	20	Q. Did he mention to you anything
21	entitled to badger the witness and	21	about a possibility of a separation agreement
22	harass her. Ask your question again,	22	between him and Merck?
23	she'll answer again. It's getting	23	MR. KELLER: Objection. Lack
24	harassing at this point, Dino.	24	of foundation.
	Page 550		Page 552
1	Page 550 THE WITNESS: As I had already	1	Page 552 THE WITNESS: I want to say
1 2	6	1 2	0
	THE WITNESS: As I had already		THE WITNESS: I want to say
2	THE WITNESS: As I had already responded in the previous question, no,	2	THE WITNESS: I want to say that he actually mentioned it but it
2 3	THE WITNESS: As I had already responded in the previous question, no, I was not told I had no choice.	2 3	THE WITNESS: I want to say that he actually mentioned it but it was never confirmed. I didn't know at
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2 3 4 5 6	THE WITNESS: As I had already responded in the previous question, no, I was not told I had no choice. BY MR. SANGIAMO: Q. You said something in your last answer about you said you felt embarrassed	2 3 4 5 6	THE WITNESS: I want to say that he actually mentioned it but it was never confirmed. I didn't know at that time if he actually did from my recollection. BY MR. SANGIAMO:
2 3 4 5 6 7	THE WITNESS: As I had already responded in the previous question, no, I was not told I had no choice. BY MR. SANGIAMO: Q. You said something in your last answer about you said you felt embarrassed by it because I felt like it was arranged just	2 3 4 5 6 7	THE WITNESS: I want to say that he actually mentioned it but it was never confirmed. I didn't know at that time if he actually did from my recollection. BY MR. SANGIAMO: Q. When he mentioned it to you,
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1			
1	Page 553	1	Page 555 MR. SANGIAMO: She's not
2	BY MR. SANGIAMO:	$\begin{vmatrix} 1\\2 \end{vmatrix}$	
1	Q. How frequently did you see	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	answering, Jeff. Let's get an answer.
34	Mr. Krahling in September of 2001, if you recall?	4	MR. KELLER: Objection to form. THE WITNESS: So if you're
5	A. I don't recall when he left		•
1	A. I don't fecan when he left Merck.	5	asking physically safe, I can't say
6 7		6	that I felt that, felt that I was
8	Q. When you say when he left Merck, that's a reference to his last day of	7 8	physically threatened. I can't say
	•		that it wouldn't happen, but it was,
9	work at Merck? Do you understand what I'm	9	yeah, it was not, you know like I
10	saying?	10	said, it's a stretch.
11	A. I do. I don't know when his	11	BY MR. SANGIAMO:
12	last day of work was at Merck.	12	Q. So you did not feel physically
13	Q. Did you have discussions with	13	threatened. Right?
14	him about the separation agreement after he	14	MR. KELLER: Asked and answered.
15	had stopped working there? A. I can't remember if it was	15	This is the third time now. I know you
16		16	don't like her answer, but you can
17	prior or I want to say after he left Merck,	17	answer again.
18	no.	18	THE WITNESS: What I said
19	Q. Did Mr. Krahling ever tell you	19	previously was that I did not feel
20	that he thought his life was in danger?	20	physically threatened because it was a
21	A. He may have stated something	21	stretch, and but I can't say that's
22	around that, you know, and based on what we	22	something that wouldn't have happened.
23	were going through at the time, it's again,	23	You never know.
24	it's a stretch but it's also part of what we	24	BY MR. SANGIAMO:
	Page 554		Page 556
1	were feeling. We were up it's almost as	1	Q. You never told anybody that you
	though we were up against the world. At least		
2		2	felt physically threatened. Right?
3	for me, that's how I felt as well.	3	A. I can't recall.
3 4	for me, that's how I felt as well. It was very clear to me that	3 4	A. I can't recall. MR. SANGIAMO: Give me a second
3 4 5	for me, that's how I felt as well. It was very clear to me that there was data being changed to reach a	3 4 5	 A. I can't recall. MR. SANGIAMO: Give me a second here. No further questions.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	for me, that's how I felt as well. It was very clear to me that there was data being changed to reach a desired outcome. We had discussed it, addressed it. We had raised it internally. We had contacted the FDA. It was a difficult thing to do to raise something at a big company like Merck. It's scary. Q. Did you think your life was in danger? A. I don't I can tell you I had nightmares. It's not a good feeling. Q. Did you fear for your safety? MR. KELLER: Asked and answered. THE WITNESS: That was my feeling. I was scared. So if scared is part of being having feelings against feeling safe and comfortable. BY MR. SANGIAMO:	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I can't recall. MR. SANGIAMO: Give me a second here. No further questions. MR. KELLER: I've just got a couple of questions. EXAMINATION BY MR. KELLER: Q. Could you take a look at Exhibit 7, your revised Interrogatories, particularly page 18? COURT REPORTER: I can't hear you. BY MR. KELLER: Q. Could you take a look at Exhibit 7, your revised Interrogatories, particularly page 18? I could you take a look at Exhibit 7, your revised Interrogatories, particularly page 18? In the fourth paragraph where

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Veritext Legal Solutions

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1	Page 557	1	Page 559
1	the plaques that were too faint to count were	1	times, but he is a very knowledgeable
2	just a was it more than one cell plate or	2	and trustworthy person. I, again,
3	was it the entire assay that was too faint to	3	don't believe everything I hear, so,
4	count, if you recall?	4	you know, my opinions about the data
5	MR. SANGIAMO: Object to form.	5	falsification are my own opinions.
6	THE WITNESS: And just to	6	Again, I wouldn't put myself in this
7	clarify, I think that you're referring	7	position to be here today if I didn't
8	to the third paragraph?	8	feel myself that this occurrence was
9	BY MR. KELLER:	9	true.
10	Q. The bottom paragraph.	10	MR. KELLER: I have no further
11	A. The bottom paragraph. From	11	questions.
12	what I recall of that reference was that the	12	MR. SANGIAMO: Nothing further.
13	entire assay had the same staining. And that	13	VIDEOGRAPHER: The time is now
14	they were faint.	14	6:18. This concludes the video
15	Q. If you go back to Exhibit 19	15	deposition.
16	which is the counting sheet that was put in	16	
17	front of you and asked whether or not this	17	(Witness excused.)
18	counting sheet referenced those particular	18	
19	the assay identified at page 18 of Exhibit 7,	19	(Deposition concluded at 6:18
20	here in Exhibit 19 only a couple of the plates	20	p.m.)
21	were, in fact, faint. Correct?	21	r · · ·
22	MR. SANGIAMO: Object to the	22	
23	form.	23	
24	THE WITNESS: Yes, some of the	24	
1	Page 558		Page 560 CERTIFICATE
1	Page 558 plates but not all.	1 2	Page 560 CERTIFICATE
2	Page 558 plates but not all. BY MR. KELLER:	1	CERTIFICATE
2 3	Page 558 plates but not all. BY MR. KELLER: Q. Would that lead you to believe	1 2	
2 3 4	Page 558 plates but not all. BY MR. KELLER: Q. Would that lead you to believe that this assay 211-1 was not the assay that	1 2 3 4	CERTIFICATE I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to
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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1	Page 561 INSTRUCTIONS TO WITNESS	1	Page 563
2	Please read your deposition over	2	
3	carefully and make any necessary corrections.	3	ACKNOWLEDGMENT OF DEPONENT
4	You should state the reason in the appropriate	4	I,, do
5	space on the errata sheet for any corrections	5	hereby certify that I have read the foregoing
6	that are made.	6	pages and that the same is a correct
7	After doing so, please sign the errata	7	transcription of the answers given by me to
8	sheet and date it.	8	the questions therein propounded, except for
9	You are signing same subject to the	9	the corrections or changes in form or
10	changes you have noted on the errata sheet,	10	substance, if any, noted in the attached
11	which will be attached to your deposition.	10	Errata Sheet.
11	It is imperative that you return the	11	Errata Sheet.
12	original errata sheet to the deposing attorney	12	
14	within thirty (30) days of receipt of the	13	DATE SIGNATURE
14	deposition transcript by you. If you fail to	14 15	DATE SIGNATURE
16	do so, the deposition transcript may be deemed		Subscribed and sworn to before me this
17	to be accurate and may be used in court.	17	day of, 2017.
18	to be accurate and may be used in court.	17	, 2017.
19		19	My commission expires:
20		20	My commission expires
20		21	
22		22	Notary Public
23		23	
24		24	Assignment: 2632763
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