

Vaccine Biometrics Research

DRAFT: November 1, 2001

MRK-KRA00760670

Appx5893

TO:	M. Morsy	WP75-200
FROM:	J. M. Antonello B. H. Rich	WP37C-305 WP16-118
	J. Hartzel	UNA-102

SUBJECT: Study KM-248 Phase III – Questionable ELISA Results in the Comparator Group

CC: J. Bramble, P. Burke, K. Chirgwin, N. Chirmule, T. Green, J. Heyse, H. Matthews, R. Mogg, F. Schodel, T. Schofield, M. Severino, BR, VBR, PF, Stat File, RIWP

Within Study KM-248 Phase III, the subjects in the Comparator group did not receive a mumps containing vaccine. Of the 106 subjects tested in the Comparator group, eleven subjects had Mumps ELISA titer results that were not consistent with clinical expectation in that seven of the subjects were pre-vaccination negative and post-vaccination positive, and four of the subjects were pre-vaccination positive and post-vaccination negative. Titer results for these eleven subjects are shown in Table 1. With the exception of Sample 183-362, whose pre-vaccination titer was 14.3 Ab units, the positive titers for these subjects were extremely low, ranging from 2.2 to 4.2 Ab Units.

Due to the nature of the assay, within a given assay run, there is the potential (1) for a small proportion of truly "negative" samples to be misclassified as "positive," where the response exceeds that of the cutoff by a small amount; and (2) for extremely low "positive" samples to be misclassified as "negative," where the response fails to exceed that of the cutoff. Therefore, with the exception of Sample 183-362, the results observed in this study are not considered highly atypical for this assay.

Samples 104-266 and 183-362 were retested in the assay. The results of the retest are also displayed in Table 1. The retest results suggest that Sample 104-266 is most-likely prevaccination negative and Sample 183-362 is most-likely post-vaccination positive. Although the retest results comport with clinical expectation, we recommend that the original results, and not the retest results, be used in the analyses since (1) with the exception of Sample 183-362, the results observed in this study are not highly atypical for this assay (note that for Sample 183-362, there is no difference between using the original result and the retest result since this sample would be excluded from the analysis in either case); (2) there is no justification for invalidating the original assay runs since the internal assay controls (positive and negative) behaved appropriately and there was no evidence of sample handling error (e.g., date mix up etc...); and (3) it is Merck's practice not to retest samples on the basis of clinical expectation since selective retesting would introduce bias and complete retesting would likely result in similar discrepancies based on assay variability.

To this point, all discussion has been limited to the Comparator Group, however, the potential for assay variability to influence measured titers within the M-M-R®II Group also exists. One might then question the potential impact of assay variability on the primary analysis, that being that the 95% lower bound on the M-M-R®II sero-conversion rate (SCR) exceed 85%. Using the measured assay results, the SCR (based on initially seronegative subjects) is 96.2% (177/184) with 95% lower bound 93.4%. To assess the potential impact of assay variability, a worst-case analysis was performed in which all subjects who were negative at baseline but <10 at 5 weeks

were re-classified as non-converters (assuming that they were above the cut-off because of assay variability), and all subjects who were positive at baseline, but <10 at 5-weeks were reclassified as negative at baseline and as non-converters (assuming their baseline and 5 week values were positive do to assay variability). In all, ten subjects such subjects were identified and these subjects are shown in Table 2. Given this extreme case, the SCR would be 90.9% (170/187) with a 95% lower bound of 86.8%. Thus, under this worst-case scenario, the lower bound of 85% would still be met, and therefore it can be concluded that the potential for misclassification due to assay variability is not sufficient to impact the primary study hypothesis.

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	Original Tite	er (Ab Units)	Retest Tite	r (Ab Units)
Sample ID (Pre-Post)	Pre	Post	Pre	Post
100-259	<2	2.2	NT	NT
81-290	<2	3.3	NT	NT
319-320	<2	2.4	NT	NT
199-342	<2	3.5	NT	NT
162-388	<2	3.4	NT	NT
385-526	<2	4.2	NT	NT
392-567	<2	3.7	NT	NT
3-69	3.5	<2	NT	NT
515-614	3.9	<2	NT	NT
104-266	2.1	<2	<2	<2
183-362	14.3	<2	17.5	18.3

Table 1
Study KM-248 Phase III
Unanticipated ELISA Results for the Comparator Group

NT - Not Tested

Table 2 Study KM-248 Phase III M-M-R®II Subjects Re-classified as Non-Converters Under the Worst-Case Scenario

	Titer (Al	b Units)	Subject (Classification
Sample ID (Pre-Post)	Pre	Post	Actual	Worst-Case
25-123	<2	5.7	+	-
73-240	<2	2.8	+	-
120-288	<2	9.3	+	-
275-464	<2	3.7	+	-
331-509	<2	9	+	-
419-542	<2	7.4	+	-
446-577	<2	9.8	+	-
159-340	4.3	4.6	NC	-
338-503	2.9	<2	NC	-
511-617	3.6	8.9	NC	-

NC – Not Classified due to pre-vaccination positive titer. +/- = Converter/Non Converter



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10/25/2019 Declaration of G. Reilly EXHIBIT 172

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1	IN THE UNITED STATES DISTRICT COURT	
	FOR THE EASTERN DISTRICT OF PENNSYLVANIA	
2		
	UNITED STATES OF AMERICA : CIVIL ACTION	
3	ex rel., STEPHEN A. : NO. 2:10-04374(C	DJ)
	KRAHLING and JOAN A. :	
4	WLOCHOWSKI, :	
	Plaintiffs, :	
5	:	
	vs. :	
6	:	
	MERCK & CO., INC., :	
7	Defendant. :	
8	IN RE: MERCK MUMPS : 2:12-cv-03555(CD	J)
	VACCINE ANTITRUST :	
9	LITIGATION :	
	:	
10	THIS DOCUMENT RELATES TO: :	
	ALL ACTIONS :	
11		
12	June 13, 2017	
13	HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY	
14		
15	Videotaped deposition of JOAN L.	
16	WLOCHOWSKI, taken at the offices of Morgan $\&$	
17	Lewis, 1701 Market Street, Philadelphia,	
18	Pennsylvania 19103, beginning at 9:36 a.m.,	
19	before LINDA ROSSI-RIOS, a Federally Approve	d
20	RPR, CCR and Notary Public.	
21		
22		
	VERITEXT LEGAL SOLUTIONS	
23	MID-ATLANTIC REGION	
	1801 Market Street - Suite 1800	
24	Philadelphia, PA 19103	

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9	On behalf of the Relators	10	 Bates AN Wlochowski-2 Ct 	IGEN_0007 urriculum vitae 18		
10	CONSTANTINE CANNON LLP BY: ROBERT L. BEGLEITER, ESQUIRE		Wlochowski-3 De	etection of Herpes 46		
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16	On behalf of the Relators	17		plied for job openings 119		
17	KELLER GROVER LLP BY: JEFFREY F. KELLER, ESQUIRE	18	3			
18	1965 Market Street	19		nended Complaint for 153 s of the		
	San Francisco, CA 94103		Federal F	alse Claims Act		
19	415.543.1305	20		lator Joan Wlochowski's 158		
20	jfkeller@kellergrover.com	21	Response	s and Objections		
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A P P E A R A N C E S (cont'd): On behalf of the Defendant, Merck & Co, Inc MORGAN LEWIS & BOCKIUS LLP BY: LISA C DYKSTRA, ESQUIRE and MARGARET ERIN RODGERS SCHMIDT, ESQUIRE 1701 Market Street Philadelphia, PA 19103 215-963-5000 Idykstra@morganlewis com margaret rodgers-schmidt@morganlewis com On behalf of the Defendant, Merck & Co, Inc VENABLE LLP BY: DINO s SANGIAMO, ESQUIRE and MICHAELA F ROBERTS, ESQUIRE 750 East Pratt Street Suite 900 Baltimore, MD 21202 410-244-7400 dssangiamo@venable com	Page 3	1 E X 2 Wlochowski disc 3 Batt 4 Wlochowski 6 Batt 000 7 Wlochowski 8 Batt 9 Wlochowski 8 Batt 9 Wlochowski 1 2 3 4 5 6 7 8 9	5 H I B I T S (cont'd.) -10 Outline for HR ussion \$\$ 00000273 -11 Work summary \$\$ 00000274 -12 E-mail exchange \$\$ 00048441 & 48442 - 13 E-Mail Exchange \$\$ 0000067 -14 E-mail exchange	236 266 273	Page 5
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Page 6		Page 8
6		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALIA8
DEPOSITION SUPPORT INDEX	1	reporter, Linda Rossi of Veritext, will
DIRECTION TO WITNESS NOT TO ANSWER		swear in the witness and we can
Page Line		proceed.
	4	MR. KELLER: Jeffrey Keller
83 13	5	from Keller Grover on behalf of the
126 3	6	Relator.
	7	MS. KOURY: Marlene Koury,
160 5	8	Constantine Cannon, on behalf of the
DECLIEST EOD DRODUCTION OF DOCUMENTS	9	Relator.
Page Line	10	MR. BEGLEITER: Robert Begleiter,
(None)	11	Constantine Cannon, Relators.
	12	MR. SANGIAMO: Dino Sangiamo
	13	from Venable on behalf of Merck.
STIPULATIONS	14	MS. ROBERTS: Michaela Roberts
Page Line	15	from Venable on behalf of Merck.
ruge Line	16	MR. HOWARD: Timothy Howard,
(None)	17	in-house counsel for Merck.
	18	MS. DYKSTRA: Lisa Dykstra,
QUESTIONS MARKED	19	Morgan Lewis for Merck.
Daga Ling	20	
Page Line	21	JOAN L. WLOCHOWSKI, after
(None)	22	having been duly sworn, was examined
	23	and testified as follows:
	24	
Page 7		Page 9
0		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALIA9
	1	EXAMINATION
VIDEOGRAPHER: We are now on		
the record. Please note the		BY MR. SANGIAMO:
		Q. Good morning, ma'am. Could you
		state your name for the record, please?
conversations. Please turn off all	6	A. Joan Wlochowski.
cell phones and place them away from	7	Q. Hello, Ms. Wlochowski. I'm
	8	Dino Sangiamo. I represent Merck in this
· ·	9	matter.
		You understand that you are
	11	here this morning to have your deposition
	12	taken. Correct?
	13	A. Correct.
2017. The time is approximately		
2017. The time is approximately 9:36 a.m. This deposition is being	14	Q. You recognize that you are
9:36 a.m. This deposition is being		
9:36 a.m. This deposition is being held at Morgan Lewis, located at 1701	14 15 16	under oath to tell the truth to the best of
9:36 a.m. This deposition is being held at Morgan Lewis, located at 1701 Market Street, Philadelphia,	15	
9:36 a.m. This deposition is beingheld at Morgan Lewis, located at 1701Market Street, Philadelphia,Pennsylvania. This is In Re: Merck's	15 16	under oath to tell the truth to the best of your ability. You understand that, right? A. I do.
9:36 a.m. This deposition is being held at Morgan Lewis, located at 1701 Market Street, Philadelphia, Pennsylvania. This is In Re: Merck's Mumps Vaccine Antitrust Litigation and	15 16 17 18	under oath to tell the truth to the best of your ability. You understand that, right? A. I do. Q. Let me just mention a couple of
 9:36 a.m. This deposition is being held at Morgan Lewis, located at 1701 Market Street, Philadelphia, Pennsylvania. This is In Re: Merck's Mumps Vaccine Antitrust Litigation and Wlochowski versus Merck & Company, Inc. 	15 16 17 18 19	under oath to tell the truth to the best of your ability. You understand that, right? A. I do. Q. Let me just mention a couple of ground rules that will facilitate a better
 9:36 a.m. This deposition is being held at Morgan Lewis, located at 1701 Market Street, Philadelphia, Pennsylvania. This is In Re: Merck's Mumps Vaccine Antitrust Litigation and Wlochowski versus Merck & Company, Inc. The name of the witness is Joan 	15 16 17 18	under oath to tell the truth to the best ofyour ability. You understand that, right?A. I do.Q. Let me just mention a couple ofground rules that will facilitate a betterflow today. First it's going to be important
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 9:36 a.m. This deposition is being held at Morgan Lewis, located at 1701 Market Street, Philadelphia, Pennsylvania. This is In Re: Merck's Mumps Vaccine Antitrust Litigation and Wlochowski versus Merck & Company, Inc. The name of the witness is Joan 	15 16 17 18 19 20 21	under oath to tell the truth to the best ofyour ability. You understand that, right?A. I do.Q. Let me just mention a couple ofground rules that will facilitate a betterflow today. First it's going to be important
	6 DEPOSITION SUPPORT INDEX DIRECTION TO WITNESS NOT TO ANSWER Page Line 12 14 64 1 83 13 126 3 127 18 154 18 160 5 REQUEST FOR PRODUCTION OF DOCUMENTS Page Line (None) STIPULATIONS Page Line (None) QUESTIONS MARKED Page Line (None) Page Line VIDEOGRAPHER: We are now on the record. Please note the microphones are sensitive and may pick up whispering and private	6 1 DIRECTION TO WITNESS NOT TO ANSWER 2 Page Line 3 12 14 4 83 13 5 126 3 5 127 18 6 154 18 7 160 5 8 REQUEST FOR PRODUCTION OF DOCUMENTS 9 Page Line 10 (None) 11 12 Page Line 12 (None) 12 13 Page Line 14 Page Line 12 (None) 13 14 Page Line 12 QUESTIONS MARKED 19 Page Line 20 (None) 21 VIDEOGRAPHER: We are now on 12 Microphones are sensitive and may pick 13 up whispering and private 5 conversations. Please turn off all 6

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	Page 10		Page 12
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI10		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI12
1	A. Understood.	1	A. Yes.
2	Q. Another thing that you and I	2	Q. Is that with Mr. Keller?
3	should both be on the lookout for is we should	3	A. Yes.
4	be sure to let each other finish. So you	4	Q. Others were present as well?
5	should not start answering a question until	5	A. Yes.
6	I've completed the question. And I will also	6	Q. How many times would you say
7	undertake not to ask my next question until	7	you met with Mr. Keller and other attorneys to
8	you have completed your answer. Fair enough?	8	prepare for the deposition?
9	A. Sounds good.	9	A. Three days.
10	Q. If you don't understand any	10	Q. Three full days?
11	question I ask you, then, please, ask me to	11	A. Yes.
12	clarify and I'll do my best to restate it in a	12	Q. Was Mr. Krahling in attendance
13	way that makes sense.	13	at any of those meetings?
14	A. Okay.	14	A. No.
15	Q. Are you under any medications	15	Q. Have you spoken to Mr. Krahling
16	that might impair your ability to testify	16	at all about your deposition outside the
17	today, as far as you know?	17	presence of your attorneys?
18	A. No.	18	A. No. About the deposition?
19	Q. Any other reason you can think	19	Q. Yes, ma'am.
20	of why your ability to testify truthfully	20	A. I haven't spoken to him about
21	today might be impaired?	21	the deposition.
22	A. No.	22	Q. Understood. Your point is you
23	Q. Ms. Wlochowski, could you tell	23	may have spoken to him about other things but
24	us what you did to prepare for this	24	not the deposition. Correct?
	Page 11		Page 13
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI11		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI13
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALIII deposition? And in answering my question,	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI13 A. Correct.
1 2		1 2	
	deposition? And in answering my question,		A. Correct.
2	deposition? And in answering my question, please don't disclose the content of any	2	A. Correct.Q. Have you discussed the
2 3	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys.	2 3	A. Correct.Q. Have you discussed the deposition with anyone besides your attorneys?
2 3 4	deposition? And in answering my question,please don't disclose the content of anyconversations you had with your attorneys.A. I reviewed the Complaint as	2 3 4	A. Correct.Q. Have you discussed thedeposition with anyone besides your attorneys?A. Aside from my husband and my
2 3 4 5	deposition? And in answering my question,please don't disclose the content of anyconversations you had with your attorneys.A. I reviewed the Complaint aswell as	2 3 4 5	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no.
2 3 4 5 6	 deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually 	2 3 4 5 6	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your
2 3 4 5 6 7	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose	2 3 4 5 6 7	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before?
2 3 4 5 6 7 8	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you	2 3 4 5 6 7 8	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No.
2 3 4 5 6 7 8 9	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you	2 3 4 5 6 7 8 9	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this
2 3 4 5 6 7 8 9 10	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did	2 3 4 5 6 7 8 9 10	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you
2 3 4 5 6 7 8 9 10 11	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did THE WITNESS: I looked at	2 3 4 5 6 7 8 9 10 11	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you spoken with Mr. Krahling outside the presence
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at documents. BY MR. SANGIAMO: Q. Those are documents that were provided to you by your counsel?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you spoken with Mr. Krahling outside the presence of your attorneys? A. Since the lawsuit was filed? Q. Yes. Which I think was approximately the fall of 2010. A. I have not spoken with Steve
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you spoken with Mr. Krahling outside the presence of your attorneys? A. Since the lawsuit was filed? Q. Yes. Which I think was approximately the fall of 2010. A. I have not spoken with Steve without my attorneys.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at documents. BY MR. SANGIAMO: Q. Those are documents that were provided to you by your counsel?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you spoken with Mr. Krahling outside the presence of your attorneys? A. Since the lawsuit was filed? Q. Yes. Which I think was approximately the fall of 2010. A. I have not spoken with Steve without my attorneys. Q. Since that time?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at MR. SANGIAMO: Q. Those are documents that were provided to you by your counsel? A. Yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you spoken with Mr. Krahling outside the presence of your attorneys? A. Since the lawsuit was filed? Q. Yes. Which I think was approximately the fall of 2010. A. I have not spoken with Steve without my attorneys. Q. Since that time? A. Since the case was filed, yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 deposition? And in answering my question, please don't disclose the content of any conversations you had with your attorneys. A. I reviewed the Complaint as well as Q. Actually MR. KELLER: Don't disclose what you looked at. Just say you looked at documents or what else you did THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at MR. KELLER: but don't disclose what you looked at. THE WITNESS: I looked at MR. SANGIAMO: Q. Those are documents that were provided to you by your counsel? A. Yes. Q. Did you look at any documents that you selected on your own? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Correct. Q. Have you discussed the deposition with anyone besides your attorneys? A. Aside from my husband and my immediate family and my children, no. Q. Have you ever had your deposition taken before? A. No. Q. Since the time that this lawsuit was filed, how many times have you spoken with Mr. Krahling outside the presence of your attorneys? A. Since the lawsuit was filed? Q. Yes. Which I think was approximately the fall of 2010. A. I have not spoken with Steve without my attorneys. Q. Since that time? A. Since the case was filed, yes. Q. We have it that you were born November of 1969. Is that right?

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			Page 14			Page 16
	JOAN L. WLOCHOWS	SKI -HIGHLY CONFIDENTA	ALI14	JOA	AN L. WLOCHOWSKI -HIGHLY CONFIDE	NTALI16
1	Q. You have two chi	ldren. Is that	1		MR. KELLER: Objection to form.	
2	correct?		2		THE WITNESS: Yes.	
3	A. Correct.		3	BY MF	R. SANGIAMO:	
4	Q. One is Jacob, app	roximately age	4	Q.	Does it also explain why you	
5	23 and one is Julia, approxi	mately age 21. Is	5	have no	advised them to get their titers	
6	that accurate?		6	checked	1?	
7	A. Correct.		7		MR. KELLER: Same objection.	
8	Q. Have you strike	e that.	8	BY MF	R. SANGIAMO:	
9	Did you have Jaco	b and Julia	9	Q.	I didn't hear your answer?	
10	vaccinated		10	А.	Yes.	
11	MR. KELLER: O	bjection.	11	Q.	I'm guessing the answer is no,	
12	BY MR. SANGIAMO:		12	but do	you have any grandchildren?	
13	Q with MMR?		13	А.	No.	
14	MR. KELLER: O	bjection. I'm	14	Q.	Have you ever been a party to	
15	going to instruct you no	ot to answer.	15	any oth	er lawsuits?	
16	Violates her right to pri	ivacy.	16	Α.	No.	
17	MR. SANGIAMO	: I'm not agreeing	17	Q.	Have you ever been named as an	
18	with you, but I understa		18	expert v	vitness in any lawsuit?	
19	objection and I'll move	on.	19	A.	No.	
20	BY MR. SANGIAMO:		20	Q.	Have you ever been approached	
21	Q. Have you advised	l either of them	21	about b	eing an expert witness in any lawsuit?	
22	to get revaccinated with MN	MR based on concerns	22	А.	No. Aside from this case.	
23	about the efficacy of the mu		23	Q.	Have you ever contemplated	
24	MMR?		24	bringin	g any whistleblower lawsuits other than	
			Page 15			Page 17
	IOAN L. WI OCHOWS	SKI -HIGHLY CONFIDENTA	0	IO	AN L. WLOCHOWSKI -HIGHLY CONFIDE	-
1	MR. KELLER: H		1		you have brought here?	
2	You can answer.	old off a second.	2	the one	MR. KELLER: Not knowing if	
3	THE WITNESS: 1	No. I have not	3	any	/thing if you filed any not	
4	BY MR. SANGIAMO:		4		nmenting on whether or not you filed	
5	Q. Have you advised	them to get	5		v other whistleblower lawsuits, if	
6	their mumps titer checked b	-	6		y of those lawsuits are under seal,	
7	about the efficacy of MMR		7		a cannot breach that seal. So,	
8	A. No, I have not.		8	•	refore, to the extent that you can	
9	Q. Do you have cond	cerns about the	9		wer without breaching the seal, you	
10	efficacy of the mumps com		10		answer.	
11	A. I do.	ponent of whyte:	10	cai	If there's a lawsuit, a	
11	Q. Is there any partic	ular reason	11	wh	istleblower lawsuit that's filed	
12	why you have not advised J		12		der seal, not saying that there is	
13	either to get revaccinated of		13		e or not, she can't testify and	
14	titers checked?		14		•	
16		hiection to the	15	ore	ach that seal, so	
	MR. KELLER: O	•			MR. SANGIAMO: I think the	
17	form. You can answer.		17	-	estion so far is just whether she had	
18	THE WITNESS: 1	t don't know that	18	eve	er contemplated filing. How about an	

22 THE WITNESS: I have not.
23 MR. KELLER: Dino, I'll let you
24 ask if she's filed a lawsuit. Just

MR. KELLER: You can answer

answer to that precise question?

5 (Pages 14 - 17)

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20

21

that.

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22

24 the idea?

the -- by having the revaccination will

Q. And that explains why you have

actually help them at this point.

23 not advised them to get revaccinated. Is that

21 BY MR. SANGIAMO:

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	Page 18		Page 20
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI18		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI20
1	can't identify the content. If you		A. Yes. You said out of college,
2	want to do that.	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	right? Is that what you said?
3	MR. SANGIAMO: I'm guessing if	3	Q. I did, yes.
4	she hasn't contemplated, she hasn't	4	A. Okay. Yeah.
5	done it.	5	Q. And I have the years right of
6	BY MR. SANGIAMO:	6	your employment?
7	Q. Have you ever filed, again,	7	A. Yes.
8	another whistleblower lawsuit other than this	8	Q. Could you tell us what your
9	one?	9	positions were there?
10	A. No.	10	A. I was a medical technologist in
11		11	the virology laboratory.
12	(Exhibits Wlochowski-1,	12	Q. Was medical technologist your
13	Curriculum vitae, AMGEN_0007 and	13	official title?
14	Wlochowski-2, Curriculum vitae, were	14	A. Yes.
15	marked for identification.)	15	Q. That was your title the whole
16		16	time you were there?
17	BY MR. SANGIAMO:	17	A. Yes.
18	Q. We've just had marked as	18	Q. Were there any promotions while
19	Exhibits 1 and 2, two copies of a CV for you.	19	you were there?
20	In Exhibit 1 the most recent experience shown	20	A. No, not that I recall.
21	is your employment at Pfizer?	21	Q. Now, do I have it right that
22	A. Uh-huh.	22	New Haven Hospital is a hospital but it has
23	Q. And for Exhibit 2 the most	23	some affiliation with Yale University Medical
24	recent experience shown is your employment at	24	School? Is that right?
	Page 19		Page 21
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI19		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI21
1	Alexion?	1	A. It does, yes.
2	A. Uh-huh.	2	Q. Were you employed by Yale
3	Q. Are you able to give us an	3	Medical School or were you employed by New
4	approximate date of when you created Exhibit 2?	4	Haven Hospital?
5	A. It would have been between, I	5	A. New Haven Hospital.
6	guess, between 2009 and let me just see	6	Q. Did you engage in any research
7	this. Actually 2013 and 2016.	7	while you were at New Haven Hospital?
8	Q. I see. You can't pinpoint it	8	A. Can you explain what you mean
9	any better than that?	9	by "research"?
10	A. No. I know it was before this	10	Q. Why don't we come back to that
11	year, but I don't know exactly when.	11	and first you can tell me what it is that you
12	Q. I wanted to ask you some	12	did as a medical technologist and a virologist.
13	questions about your employment history. I	13	A. My primary responsibility was
14	may from time to time refer to Exhibits 1 and	14	testing human samples from the hospital for
15	2 in my questions. You should certainly feel	15	viral detection; viral antibody titers.
16	free to refer to Exhibits 1 and 2 in your	16	Q. Looking for viral antibody
17	answers whether I ask about them or not, if	17	titers for a diagnostic purpose, is that the
18	that helps you, your memory.	18	idea?
19	Do I have it right that your	19	A. Correct.
20	first job out of college was working at Yale	20	Q. The theory being that if there
21	New Haven Hospital? Is that correct?	21	were antibodies to a particular virus present,
22	A. Correct.	22	then that might be one criterion for trying to
23	Q. And you worked there from 1991	23	evaluate whether the person was suffering from
24	to 1998?	24	that disease?

6 (Pages 18 - 21)

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	Page 22		Page 24
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL122		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI24
1	A. Correct.	1	detecting mumps.
2	Q. Were there any particular	2	Q. Do you ever recall running one
3	diseases that you were focused on?	3	of those tests yourself?
4	A. There were specific tests we	4	A. We did viral cultures so any
5	did, but I wouldn't say that anything that we	5	given sample that came in could potentially
6	were focused on.	6	have been run for a screen for mumps.
7	Q. What was your role specifically?	7	Q. Could you describe what you
8	A. Again, to run the assays in the	8	mean by doing viral cultures?
9	lab.	9	A. We took the patient serum
10	Q. I'm going to describe what it	10	and/or patient culture, I should say, and
11	might have been, you tell me if this is	11	inoculated into monolayers in a cell culture
12	accurate; and if not, how it's inaccurate.	12	tube for growth of virus.
13	Was it the case that a serum sample would be	13	Q. What would you do next in the
14	brought to the lab where you worked. Is that	14	procedure?
15	right?	15	A. So the culture tubes would get
16	A. Correct.	16	incubated to allow for virus growth.
17	Q. And then you would run the	17	Q. I'm sorry, to allow for what,
18	serum sample through the assay. Is that	18	virus growth?
19	correct?	19	A. Uh-huh. Replication.
20	A. Correct.	20	Q. What would you do, then, to
21	MR. KELLER: Objection to form.	21	determine what viruses, if any, were present
22	BY MR. SANGIAMO:	22	in the cultures?
23	Q. And then you would report the	23	A. The cultures were read at
24	results from running the sample through the	24	periodic times throughout the course of the

Page 23

	Page 23		Page 25
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI23		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI25
1	assay back to someone. Is that right?	1	incubation and were read for cytopathic
2	MR. KELLER: Objection to form.	2	effect.
3	THE WITNESS: What do you mean	3	Q. Would reading for cytopathic
4	by "report the results"?	4	effect enable you to determine what virus the
5	BY MR. SANGIAMO:	5	person had?
6	Q. What would you do with the	6	A. No, then there would be
7	results?	7	identification following the CPE.
8	A. The results would get entered	8	Q. And the identification would be
9	into the file for the patient that was being	9	a process involving the detection of antibodies?
10	tested.	10	A. It would be we would remove
11	Q. After that somebody other than	11	the cell monolayer to test the cells in the
12	you would evaluate the results?	12	virus within the culture. So not, no, not
13	A. Yes.	13	necessarily running the titers.
14	Q. Fair to say that you were not	14	Q. So how would you determine what
15	the person who ultimately decided whether	15	viruses were present?
16	clinically it appeared that the patient did or	16	A. There were different immunoassays
17	did not have the virus? True?	17	that would you would run through and have
18	A. That is true.	18	detection, either fluorescence detection or
19	Q. Did any of the tests these	19	there were different types of it was an
20	tests were, would you call them assays?	20	antibody against the virus that would detect
21	A. Yes.	21	and a signal that was confirmed that it was
22	Q. Did you run any assays at New	22	present.
23	Haven Hospital involving mumps?	23	Q. Would you run every sample
24	A. We had the capability of	24	through every immunoassay?

7 (Pages 22 - 25)

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		Page 26		Page 28
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDE	-		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI28
1	A. No.	1	1,	vaccinated, just to confirm that the patient
2	Q. In other words, is it correct	2	2 1	had immunity.
3	that the doctor would have had a suspicion as	3	3	Q. Do you know how you would
4	to what the disease might have been. Correct?	4	4 i	figure out if you saw rubella antibodies in a
5	A. Yes.	5		patient, whether that was a result of
6	Q. And then you would run the	6	6,	vaccination as opposed to being the result of
7	sample through the assays for those conditions?	7	7 :	active rubella disease or something else?
8	A. Yes.	8	8	A. No.
9	Q. And you were not the one who	ç	9	Q. Would you consider that to be
10	would decide	10	0 9	something beyond your expertise?
11	A. Right.	11	1	A. Yes.
12	Q which conditions to run the	12	2	Q. When you were at New Haven
13	assay through. Right?	13	3	Hospital, did you run any assays in which you
14	A. That is correct.	14	4 1	ran a patient sample prior to vaccination and
15	Q. So do you recall ever running	15	5 1	ran a patient sample after vaccination in
16	sample through the mumps assay?	16	6	order to determine whether the patient had an
17	A. I don't recall specifically.	17	7 i	immune response to vaccination?
18	Q. How many medical technicians	18	8	A. I don't recall specifically
19	were there in the New Haven Hospital virology	19	9 1	that I had done one.
20	lab at any given time?	20	0	Q. If you look at Exhibit 1, there
21	A. I would say maybe five technicians.	21	1 i	is a reference within the section on your time
22	Q. Did you run any assays while	22	2 a	at Yale New Haven Hospital. In the fourth
23	you were at New Haven Hospital that were	23	3 1	bullet point to performing "antiviral testing
24	designed to detect whether a particular	24	4 1	by plaque reduction assay."
		Page 27		Page 29
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDE	ENTALI27		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI29
1	patient had an immune response to vaccination?	1	1	Do you see that?
2	A. No, I did not.	2	2	A. Uh-huh.
3	Q. Did you run any assays at New	3	3	Q. What's that a reference to? Is
4	Haven Hospital that were designed to detect	4	4 1	that something different from what than
5	whether a patient had an immune response to	5	5	what you just described to us today so far?
6	some other form of therapy?	6	6	A. I believe so, yes.
7	MR. KELLER: Objection to form.	7	7	Q. What is that a reference to?
8	THE WITNESS: And I'm actually	8	8	A. So your question was whether or
9	rethinking my previous answer	ç	9 1	not I tested prior to being vaccinated and
10	because sorry, I apologize.	10	0 a	after being vaccinated. That was your
11	BY MR. SANGIAMO:	11	1 (original question?
12	Q. Sure.	12	2	Q. Yes.
13	A. So we did test for rubella. We	13	3	A. And I don't believe that, at
14	did do titer testing for which would be an	14	4	least to my knowledge, that I was given
15	indication of vaccination.	15	5 :	samples prior to vaccination and then
16	Q. Because if there was a rubella	16	6 1	following vaccination. I can't recall the
17	titer, that would suggest that the patient had	17	7 :	specifics around the testing, but I I can't
18	been vaccinated, is that the idea?	18	8 1	recall.

18 been vaccinated, is that the idea?
19 A. Well, I guess it's -- it would
20 be to determine whether or not the patient had

24

21 antibodies. I don't know that the criteria
22 was to see whether or not the patient had been
23 vaccinated. So to clarify, it wasn't so much

vaccinated. So to clarify, it wasn't so much23as to see whether or not the patient had been24

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Q. I think I know what you're

record is clear. Let me ask this question and

then you tell me your answer. Do you know

what your CV is referring to where it states

that you "Performed antiviral testing by

20 saying, but I just want to make sure the

^{8 (}Pages 26 - 29)

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	Page 30		Page 32
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI30		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI32
1	plaque reduction assay," when you were at New	1	like that?
2	Haven Hospital? Do you know what that's	2	MR. KELLER: I apologize. You
3	referring to?	3	can answer.
4	A. That I did perform the plaque	4	THE WITNESS: Can you repeat
5	reduction assay. We were given samples to	5	that question again?
6	test and we ran that assay.	6	BY MR. SANGIAMO:
7	Q. What was that an assay for?	7	Q. Are you familiar with any
8	A. For the detection of antibodies	8	plaque assays for antiviral drugs as
9	against a virus.	9	distinguished from for vaccines?
10	Q. What is the reduction part?	10	A. So in this case, that was what
11	A. The plaque reduction?	11	I believe was not being tested versus a
12	Q. Yes, ma'am.	12	vaccination.
13	A. So it's to basically if the	13	Q. So you think sorry.
14	antibodies were present, they would neutralize	14	A. So the patient response to the
15	the virus and reduce the plaque count.	15	antiviral. Not the
16	Q. Reduce it from what?	16	Q. If I understand your testimony
17	A. From the presence of not having	17	correctly, then, your best recollection right
18	antibodies.	18	now of the plaque reduction assay that you did
19	Q. I'm sorry, I don't understand.	19	when you were at New Haven Hospital was an
20	So what would you so could you describe in	20	assay to test patient response to antiviral
21	more detail how that assay would work?	21	therapies. Is that right?
22	A. Again, I don't remember the	22	A. That is my what I can
23	specifics of running the assay. The	23	recall.
24	methodology is that virus is added to plates.	24	Q. And you think that that testing
	Page 31		Page 33
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI31		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI33
1	If they're in the presence of no antibodies,	1	had nothing to do with immune response to
2	there would be plaques that would form. If	2	vaccination based on your best recollection
3	there were antibodies that were present, they	3	right now. Is that right?
4	would reduce the number of plaques. So	4	A. Correct.
5	typically a control is running the assay that	5	Q. But the antiviral therapy
6	would show the presence of no antibodies and	6	assay, which is what you now believe this was,
7	what that would look like versus a positive	7	did involve the counting of plaques?
8	control.	8	A. Yes.

9

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those plaques?

A. Yes.

9 Q. Are there also plaque reduction

10 assays for antiviral drugs, to your knowledge?

11 12 BY MR. SANGIAMO: 13

BY MR. SANGIAMO:

Q.

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MR. KELLER: Objection to form. THE WITNESS: I do not know.

Q. For example, could there be a plaque assay involving taking a clinical isolate and to see whether exposure to a particular antiviral therapy might have a cytopathic effect on whatever was in that isolate as a means of trying to evaluate what would be a good therapy for a given possible virus, for example, herpes simplex virus? MR. KELLER: Objection.

Are you familiar with any assay

18 BY MR. SANGIAMO: 19 Q. Do you recall that one of the plaque reduction assays referred to there in 20 21 your CV from your time at New Haven Hospital 22 was an assay for herpes simplex antiviral

question again?

23 therapies? Do you recall that?

> A. I can't remember which assay it

Q. Would you, yourself, count

Q. Do you recall there being an

antiviral therapy assay that you used at that

time for viruses other than herpes simplex?

MR. KELLER: Objection to form.

THE WITNESS: Can you ask the

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	Page 34		Page 36
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI34		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI36
1	was, what it is that we were testing	1	Q. Do you have an understanding
2	specifically.	2	from your work in the industry of what an SOP
3	Q. Do you know if the assay that	3	is?
4	was being used at New Haven Hospital was an	4	A. I do.
5	off-the-shelf assay?	5	Q. And what is that?
6	MR. KELLER: Objection to form.	6	A. It's a standard operating
7	THE WITNESS: What do you mean	7	procedure. So working in the industry, the
8	by "off-the-shelf"?	8	pharmaceutical industry, there's different
9	BY MR. SANGIAMO:	9	requirements than working in a hospital
10	Q. Do you know if it was designed	10	laboratory.
11	at New Haven Hospital?	11	Q. What are the requirements for
12	A. I do not know if it was	12	an SOP in a hospital laboratory?
13	designed there.	13	A. Again, I can't remember the
14	Q. I gather you had nothing to do	14	exact methodology that they referred to. I
15	with designing the assay?	15	believe we had binders of procedures that were
16	A. Correct.	16	kept that we would refer to.
17	Q. Can I assume from your answer	17	Q. For the plaque reduction assays
18	that you don't know whether New Haven Hospital	18	that you ran at New Haven Hospital for these
19	purchased it from a supplier?	19	antiviral therapies, was there ever any checking
20	A. I believe parts, components of	20	of plaque counts by a second scientist?
21	it were purchased, but the entire assay I	21	A. No.
22	cannot say.	22	O. What was the nature of the
23	Q. Was there an SOP for that assay?	23	training you received as regards counting of
24	A. There was I can't remember	24	plaques, if any?
	Page 35 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI35		Page 37 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI37
1	the test method that we ran it against, but	1	A. I was trained by my supervisor.
2	there was a procedure in place that we would	$\begin{vmatrix} 1\\2 \end{vmatrix}$	Q. What was the nature of that
3	perform our test.	3	training?
4	Q. A written SOP?	4	A. The I mean, I can't remember
5	A. Again, I can't remember the	5	the specifics around the training program, but
6	documentation that was used for conducting	6	he worked pretty closely with us as he trained
7	those tests.	7	us through the different tests within the
8	Q. Are you sure there was any?	8	laboratory.
9	A. That would we would have had	9	Q. He was training you on all
10	procedures, yes, to run a method against.	10	aspects of the assay?
10	Q. Well, are you sure you had a	10	A. Yes.
11	written procedure that you followed?	11	A. Tes.Q. And do you have any recollection
12	MR. KELLER: Objection. Asked	12	of the nature of the portion of the training,
13	and answered.	13	if there was any, that was focused on the
14	THE WITNESS: Yes.	14	counting of plaques?
	BY MR. SANGIAMO:		A. If I recall correctly,
16		16	•
17	Q. You are sure of that?	17	typically the trainer would count the plaques
18	A. Yes.	18	and the trainee would then count the plaques
19	Q. But you're just not sure	19	to determine if there was consistency in the
20	whether it was an SOP?	20	plaque counts.
21	MR. KELLER: Objection to form.	21	Q. Was there a rigid formula that
22	THE WITNESS: What do you mean	22	would determine whether there was sufficient
23	by "SOP"?	23	amount of consistency?
24	BY MR. SANGIAMO:	24	A. I don't recall the specific

10 (Pages 34 - 37)

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI38		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI40
	formula.	1	Hospital, were the plaques in wells?
2	Q. But there was one?	2	A. Yes.
;	A. Yes.	3	Q. And the wells were in plates, I
ŀ	Q. So it's not the case that the	4	assume?
5	trainer could just kind of impressionistically	5	A. Yes.
5	assess whether the trainee's plaque counting	6	Q. Do you recall how many wells
7	was adequate, there was actually a mathematical	7	there were in any given assay run?
8	formula?	8	MR. KELLER: Objection.
)	MR. KELLER: Objection. Form.	9	overbroad.
)	THE WITNESS: Yeah. What do	10	THE WITNESS: When you refer to
	you mean by "mathematical formula"?	11	wells in an assay run, can you be more
2	BY MR. SANGIAMO:	12	specific?
;	Q. Well, for example, was there a	13	BY MR. SANGIAMO:

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you. 18 19

Q. Do you have an understanding

A. That -- if you could define

assay run, yes, that's my question. Thank

Q. You'll have to tell me if my

I'm envisioning a certain number of plates that are run simultaneously through an assay.

question makes sense because I expect you have a lot more expertise in this than I do. But

what I mean by "assay run"?

Does that make sense?

13 Well, for example, was there a Q. certain percentage that the trainee's plaque 14 15 count had to be within the trainer's plaque 16 count in order for the trainee to be deemed 17 trained?

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18	А.	Typically that's the criteria
19	for traini	ing and consistency, yes.
20	Q.	Was it at New Haven Hospital?
21	А.	I believe so.
22	Q.	You're sure?
23	۸	I can't remember the specifics

23 Α. I can't remember the specifics, 24 but, yes, I do believe that that is how we

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	Page 39		Page 41
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI39		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI41
1	were trained.	1	A. Yes.
2	Q. Let me just make sure I	2	Q. Does that sound like a reasonable
3	understand your testimony. So your testimony	3	definition of an assay run for our purposes
4	is you do think that there was some percentage	4	right now?
5	within which the trainee's plaque count had to	5	A. Yes.
6	come as compared to the trainer's plaque count	6	Q. Do you recall how many wells
7	for the trainee to be deemed adequately	7	there would be in any given assay run for the
8	trained in plaque counting, but you just don't	8	plaque reduction assay that you ran at New
9	recall what that percentage is. Is that your	9	Haven Hospital?
10	testimony?	10	MR. KELLER: Objection.
11	A. I don't recall what the	11	Overbroad.
12	percentage is. To the best of my recollection,	12	THE WITNESS: So when can
13	there would be a percentage criteria that we	13	you repeat the question again?
14	would have to meet in order to show	14	BY MR. SANGIAMO:
15	consistency.	15	Q. For the plaque reduction assay
16	Q. How many assays did you have to	16	that you ran at New Haven Hospital, how many
17	count in this comparison process before you	17	wells were there in any given assay run?
18	could be deemed adequately trained?	18	MR. KELLER: Objection.
19	A. I don't recall.	19	Overbroad.
20	Q. More than one?	20	THE WITNESS: So I believe per
21	A. I don't recall. It would be	21	plate there were 24 wells. I do not
22	my I don't recall.	22	know, remember how many plates we would
23	Q. For this assay that you ran,	23	run in a perform at the same time in
24	the plaque reduction assay at New Haven	24	a given run.

11 (Pages 38 - 41)

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20 running the plaque reduction assay at New

A. So I -- can you ask the

Q. Did the antiviral therapies

21 Haven Hospital?

question again, sorry?

22

23

24

6 PRage 55077

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	Page 42		Page 44
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI42		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI44
1	MR. SANGIAMO: Jeff, why did	1	that were at issue when you were running the
2	you think it was overbroad? I'm going	2	plaque reduction assay at New Haven Hospital
3	to see if I can correct it.	3	work by generating antibodies to a virus?
4	MR. KELLER: Because you're	4	A. Not necessarily. It was an
5	talking about all assays she ran	5	immune response to the disease that the
6	instead of are you talking about	6	patient had.
7	when she was certified? Are you	7	Q. If there's simply a cytopathic
8	talking about you know, she ran	8	effect of the antiviral therapy on the isolate
9	different assays over time and she was	9	from the patient, is that an immune response?
10	at New Haven seven years. I don't know	10	MR. KELLER: Objection to form.
11	if the assays changed over time.	11	THE WITNESS: Can you repeat
12	That's why I objected, overbroad.	12	the question?
13	MR. SANGIAMO: Understood.	13	BY MR. SANGIAMO:
14	BY MR. SANGIAMO:	14	Q. If there's a cytopathic effect
15	Q. My question was directed at the	15	of the antiviral therapy on the isolate from
16	plaque reduction assay referred to on your CV	16	the patient, is that an antibody immune
17	as having been run at New Haven Hospital. You	17	response? Slightly different question but
17	understood that?		
		18	that's my question.
19	A. Yes.	19	MR. KELLER: Same objection.
20	Q. My sense of your recollection	20	THE WITNESS: Is a cytopathic
21	is that all that you recall about what that	21	effect an antibody immune response?
22	assay was is that it was an assay used not to	22	The question doesn't make sense to me.
23	evaluate response to vaccination or not even	23	I'm not the cytopathic effect is
24	to evaluate antibodies but used to evaluate	24	caused by the virus. The actual immune
	Page 43		Page 45
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI43		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI45
1	antiviral therapies. Is that right?	1	response would reduce the cytopathic
2	A. I believe it was their antibody	2	effect through neutralization of the
3	response to antiviral therapies. So it was	3	virus.
4	still detection of antibodies but after viral	4	BY MR. SANGIAMO:
5	therapies treatment.	5	Q. Can the antiviral therapy that
6	Q. You don't recall how many such	6	was being tested in the plaque reduction assay
7	assays there were. Right?	7	that you ran at New Haven Hospital accomplish
8	A. I believe there was only one	8	that by a means other than an antibody immune
9	that I recall and I can't remember I can't	9	response?
10	remember what the specific virus we were	10	MR. KELLER: Objection. Form.
11	testing it against.	11	THE WITNESS: I do not know the
12	Q. Do all antiviral therapies work	12	answer to that question.
13	by generating antibodies?	13	BY MR. SANGIAMO:
14	MR. KELLER: Objection.	14	Q. For sure the plaque reduction
15	Overbroad.	15	assay that you ran at New Haven Hospital was
16	THE WITNESS: I do not know.	16	not a plaque reduction neutralization assay.
17	BY MR. SANGIAMO:	17	Right?
18	Q. How about the antiviral	18	MR. KELLER: Objection to form.
19	therapies that were at issue when you were	19	THE WITNESS: Again, I can't
	- *		U /

20 remember the specifics of the assay. I21 do remember running a plaque assay.

²² BY MR. SANGIAMO:23 Q. You don't remember it well

²⁴ enough to answer my question just asked?

^{12 (}Pages 42 - 45)

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	Case 22322553 L	Loccioneent:t:/\$46	Haagge	e:55088 Ll2aatel-Heteld:1112026220233		
			Page 46		Page	
	JOAN L. WLOCHOWSKI	-HIGHLY CONFIDENTA	ALI46		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI48	
1	A. Correct.			1 1	helpful in trying to achieve whatever it is	
2				2 1	that's being described in this article. Is	
3	(Exhibit Wlochowski-	3, Detection of		3 1	that right?	
4	Herpes Simple Virus in Cl	inical Specimens by		4		
5	Cytospin-Enhanced Direct			5	Q. Was that Dr. Landry's idea?	
6	article, was marked for ide			6	-	
7				7	Q. Did you come up with the	
8	BY MR. SANGIAMO:			8 6	experimental design to test that hypothesis?	
9	Q. Ms. Wlochowski, you	u've just		9		
10	been handed a document marke		10	0 1	Dr. Landry and Dave Ferguson.	
11	Do you recognize this documer	nt?	1			
12	A. I do.		12			
13	Q. This is a medical jour	rnal	1			
14	article on which you are one of		14			
15	Right?		1:		-	
16	A. Correct.		1			
17	Q. Is it correct that there	are	1		1	
18	two such sorry, try that again		1			
19	Is it correct that you a		1		•	
20	listed as an author on two medi		20		-	
21	articles total?		2			
22	A. I believe so, yes.		2		-	
23	Q. Can you tell us what	this	2		1 61 5 6	
24	article is describing? And let n		24			
	IOAN I. WI OCHOWSKI		Page 47		Page	
1	JOAN L. WLOCHOWSKI			1 4	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI49	
	you what my ultimate question					
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	if that helps, is I wanted to find			2	5	
3	your personal role was in either			3	5	
	described here or the writing of	the article.		4 5 1	, , , , , , , , , , , , , , , , , , , ,	
5	A. Okay.	1.4				
6	MR. KELLER: There			6 7		
7	questions. I'm not sure wh	ich one you				
8	want her to answer.	Vall actuall-		8	2	
9	MR. SANGIAMO: W	-				
10	all I was doing just now, Je		10			
11	was trying to give her a litt		1			
12	guidance on how much she	e needs to look	11			
13	at that article.		1		,	
14	MR. KELLER: Okay		14			
15	MR. SANGIAMO: B	ut that's a	1:			
16	fair point.		10		11 2	
17	BY MR. SANGIAMO:		1			
18	Q. The first question I'll		1		1	
19	you, then, is what your role wa		1		<i>. . .</i>	
20	that is described in this article?		20			
21	A. My role was conduct		2			
22	testing of the samples in the art	icle.	22	2 0	earlier about some testimony earlier about	

23 being trained by a supervisor? 24 A. Uh-huh.

13 (Pages 46 - 49)

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23

Q. So you didn't come up with the

24 hypothesis that cytocentrifugation could be

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	Page 50		Page 52
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI50		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI52
1	Q. Was that Dave Ferguson?	1	method. It depends on what you, again, mean
2	A. Correct.	2	by research. So but it was I did get
3	Q. Do you know if he is still at	3	involved in other activities outside of my
4	Yale New Haven Hospital?	4	routine testing.
5	A. I do not know.	5	Q. I don't want to misstate your
6	Q. How about this Dr. Landry, is	6	testimony. I thought I heard you say before
7	she a pretty well reputed researcher, to your	7	that you got involved in the work that's
8	knowledge?	8	described in Exhibit 3 because you made it
9	A. Yes, to my knowledge.	9	known to your supervisor that you were
10	Q. She would be a pretty good	10	interested in other what I think you said was
11	source of virology expertise generally, would	11	research opportunities for developmental
12	you say?	12	purposes. Is that right?
13	A. Yes.	13	A. I said development opportunities.
14	MR. KELLER: Objection to form.	14	Q. Okay. Were there any other
15	BY MR. SANGIAMO:	15	development opportunities that you pursued
16	Q. Did you, in your discussions	16	that you would consider to be research?
17	with, is it Dr. Ferguson?	17	A. Yes, I do believe I did work on
18	A. Dave Ferguson.	18	other methodology enhancements while I was
19	Q. I don't want to disrespect him.	19	there.
20	A. Yes.	20	Q. Do you remember what those
21	Q. In your discussions with	21	were?
22	Dr. Landry or Mr. Ferguson about the design of	22	A. I do not.
23	the testing, did you make specific suggestions	23	Q. Any of them involve mumps?
24	to them?	24	A. Not that I recall, no.
	Page 51		Page 53
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI51		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI53
1	A. I don't recall.		
	ri. i don't locali.	1	Q. Any of them involve vaccine
2	Q. Your next employment, I	1 2	Q. Any of them involve vaccine development?
2 3			
	Q. Your next employment, I	2	development?
3	Q. Your next employment, I believe, was at Charles River. Is that right?	2 3	development? A. No. Q. Any of them involve vaccines in
3 4	Q. Your next employment, Ibelieve, was at Charles River. Is that right?A. Correct.	2 3 4	development? A. No.
3 4 5	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. 	2 3 4 5	development? A. No. Q. Any of them involve vaccines in any way? A. No.
3 4 5 6	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because 	2 3 4 5 6	development? A. No. Q. Any of them involve vaccines in any way?
3 4 5 6 7	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. 	2 3 4 5 6 7	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at
3 4 5 6 7 8	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? 	2 3 4 5 6 7 8	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that?
3 4 5 6 7 8 9 10	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of 	2 3 4 5 6 7 8 9	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000,
3 4 5 6 7 8 9 10 11	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. 	2 3 4 5 6 7 8 9 10	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right?
3 4 5 6 7 8 9 10 11 12	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. 	2 3 4 5 6 7 8 9 10 11 12	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes.
3 4 5 6 7 8 9 10 11 12 13	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven 	2 3 4 5 6 7 8 9 10 11 12 13	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a
3 4 5 6 7 8 9 10 11 12 13 14	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? 	2 3 4 5 6 7 8 9 10 11 12 13 14	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position?
3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary
3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. Q. I'm sorry, one of the questions 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position. Q. When you say "temporary position,"
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. Q. I'm sorry, one of the questions back at New Haven Hospital, did you get 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position. Q. When you say "temporary position," what do you mean specifically?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. Q. I'm sorry, one of the questions back at New Haven Hospital, did you get involved in any other research beyond what is 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position. Q. When you say "temporary position," what do you mean specifically? A. I believe, I can't recall, but
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. Q. I'm sorry, one of the questions back at New Haven Hospital, did you get involved in any other research beyond what is described in the article that is Exhibit 3 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position. Q. When you say "temporary position," what do you mean specifically? A. I believe, I can't recall, but I believe I was hired as a temporary employee.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. Q. I'm sorry, one of the questions back at New Haven Hospital, did you get involved in any other research beyond what is described in the article that is Exhibit 3 while you were at New Haven? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position. Q. When you say "temporary position," what do you mean specifically? A. I believe, I can't recall, but I believe I was hired as a temporary employee. Q. Serving as a contractor of sorts?
3 4 5 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. Your next employment, I believe, was at Charles River. Is that right? A. Correct. Q. I said Charles River because that's easier to say than the other word. What is the pronunciation of the other word? A. Tektagen. Q. Tektagen, okay. At the time, was that part of Charles River when you worked there? A. Yes. Q. Why did you leave New Haven Hospital? A. My husband took another job out of state. Q. I'm sorry, one of the questions back at New Haven Hospital, did you get involved in any other research beyond what is described in the article that is Exhibit 3 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	development? A. No. Q. Any of them involve vaccines in any way? A. No. Q. When you took your job at Charles River, are you good with that? A. Yep. Q. Which was around March of 2000, does that sound right? A. That sounds right, yes. Q. Was that intended to be a permanent position? A. I believe that was a temporary position. Q. When you say "temporary position," what do you mean specifically? A. I believe, I can't recall, but I believe I was hired as a temporary employee.

14 (Pages 50 - 53)

Q. Did you encounter any issues

while you were working at Charles River?

You got along fine with

To what I recall, yes.

Do you have a recollection of

there in the nature of group dynamic problems

Everybody seemed to get along

14

15

16

17

18

19

20

21

22

23

24

A. No.

Q.

Q.

everybody?

А.

Q.

fine with everybody else?

A. Yes.

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	Page 54		Page 56
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL154		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI56
1	Q. How long were you at Charles	1	telling anybody anything different about your
2	River?	2	time at Charles River?
3	A. I think it was, I want to say	3	A. I do not.
4	maybe five months.	4	Q. Is your recollection of your
5	Q. Is it possible that it was	5	time at Charles River vivid enough that you
6	strike that.	6	could comfortably dismiss out of hand anyone
7	What did you do at Charles	7	who would say that you once said that you ran
8	River?	8	into problems at group dynamics there?
9	A. I worked in their cell culture	9	A. Meaning when I told somebody
10	laboratory, so I maintained the cell lines.	10	after I left Charles River or
11	Charles yeah.	11	Q. Yes.
12	Q. Did you run any assays?	12	A. I do not recall saying that.
13	A. No, I did not.	13	Q. Are you confident that that's
14	Q. Were those cell lines used for	14	something you just would not have said because
15	just one purpose or were they used for many	15	of your recollection of your time at Charles
16	different purposes?	16	River?
17	A. They were used for many	17	MR. KELLER: Objection. Asked
18	different purposes.	18	and answered.
19	Q. Clinical purposes?	19	THE WITNESS: Am I confident
20	MR. KELLER: Objection.	20	that's something that I said because of
21	Overbroad.	21	what I recall now?
22	THE WITNESS: What do you mean	22	BY MR. SANGIAMO:
23	by "clinical purposes"?	23	Q. Uh-huh.
24	BY MR. SANGIAMO:	24	A. I guess I could have said anything.
	Page 55		Page 57
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL155		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI57
1	Q. Diagnostic purposes?	1	
2	MR. KELLER: Same objection.	2	so I can't say that I didn't necessarily say
3	THE WITNESS: What do you mean	3	anything that was positive or negative either
4	by "diagnostic purposes"?	4	way.
5	BY MR. SANGIAMO:	5	Q. But right now you don't have
6	Q. To support assays or other	6	any recollection of any dynamics problems at
7	testing intended to be used to diagnose	7	Charles River. Is that right?
8	conditions in humans.	8	A. Not specifically, no.
9	A. I believe that was what they	9	Q. Who was your supervisor at
10	were used for. We prepared cell banks that	10	Charles River?
10	were also for clients. So I can't say	10	A. I don't remember his name.
11	specifically what those clients were using	11	Q. Your next position was at
12	them for.	12	Merck?
1.5		13	

15 (Pages 54 - 57)

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A. Yes.

that sound about right?

A. Yes.

that time period?

A. No.

Q. Is there about a half year

16 period there between when you left Charles

Q. Were you trying to get

River and when you started at Merck? Does

Q. Were you employed at all during

employment anywhere other than Merck during

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	Page 58		Page 60
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI58		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI60
1	that time period?	1	Q. How about Amgen, same question
2	A. I can't recall. I may have been.	2	at Amgen?
3	Q. How did you find out about	3	A. I cannot remember.
4	strike that.	4	Q. How about at Alexion?
5	What prompted you to seek	5	A. I don't recall anybody saying
6	employment at Merck?	6	anything specific.
7	A. I was looking for a permanent	7	Q. When you applied for your
8	position.	8	positions at strike that.
9	Q. Why Merck?	9	When you applied for your
10	A. They were close to where I	10	position at Pfizer, did you get any impression
11	lived currently and they're a big reputable	11	from the interview process as to what the
12	company in my mind at the time.	12	people interviewing you thought of Merck?
13	Q. Still today?	13	MR. KELLER: Objection as to
14	A. That based on my experience,	14	form.
15	I may not have the same opinion.	15	THE WITNESS: I cannot speak to
16	Q. What's your sense of Merck's	16	what other people thought about Merck
17	reputation generally in the pharmaceutical	17	as I was being interviewed. I think
18	industry?	18	the expectation is that I work in the
19	MR. KELLER: Objection.	19	pharmaceutical industry so I come with
20	Overbroad.	20	the experience that would carry across
21	THE WITNESS: My sense in the	21	other pharmaceutical companies.
22	pharmaceutical industry? Can you	22	BY MR. SANGIAMO:
23	explain what you mean by that?	23	Q. Your work at Merck began in
24	BY MR. SANGIAMO:	24	Dr. Krah's lab. Correct?
	Page 59 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI59		Page 61 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI61
1	Q. When you were at Pfizer, did	1	A. Correct.
2	you hear people talk about Merck in any way?	2	Q. He's the one who interviewed
3	A. When you're in the	3	you?
4	pharmaceutical industry, many people talk	4	A. Correct.
5	about many different companies. So, yes, I	5	Q. Did you interview with others
6	would have to I can't remember anything	6	as well?
7	specifically.	7	A. I believe I interviewed with
8	Q. How about generally, reputationally,	8	Mary Yagodich as well.
9	what do you remember about what people would	9	Q. Anyone else?
10	say about Merck when you were at Pfizer?	10	A. HR. I don't recall if I
11	MR. KELLER: Objection to form.	11	interviewed with others.
11	THE WITNESS: When you say	12	Q. Do you recall who it was at HR
12	so people at Pfizer that would can	12	with whom you interviewed?
13	you repeat the question?	13	A. I want to say it was somebody
14	BY MR. SANGIAMO:	14	named Naomi Yerkes.
15	Q. What do you remember generally	16	Q. We'll talk obviously about your
	about what people would say about Merck's	17	time in Dr. Krah's lab. But after you left
17	reputation while you were at Pfizer, if	17	Dr. Krah's lab, you went to a different lab.
18	anything?		-
19		19	Right?
20	MR. KELLER: Objection. Lack	20	A. Correct.
21 22	of foundation.	21 22	Q. Whose lab was that?A. Dr. Palker.
	THE WITNESS: I cannot		
23	remember.	23	Q. What did you do in Dr. Palker's
24	BY MR. SANGIAMO:	24	lab?

16 (Pages 58 - 61)

		J	
	Page 62		Page 64
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI62		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI64
1	A. I was working with the DNA and	1	Q. What was your role in the
2	RNA probes for and doing PCR testing while	2	hypothesis being explored in this paper?
3	I was there.	3	MR. KELLER: Objection to form.
4	Q. Was this vaccine-related work?	4	If you need to read it to refresh your
5	A. Yes.	5	memory.
6	Q. For any particular vaccines?	6	BY MR. SANGIAMO:
7	A. We were working on HPV.	7	Q. Do you recall as you sit here
8	Q. Anything else?	8	today what whether this paper involved
9	A. Probably, but I can't recall	9	exploration of a particular hypothesis?
10	what it was.	10	A. I do not recall.
11	Q. We're going to talk about some	11	Q. Whatever that hypothesis was,
12	of the allegations of wrongdoing that you've	12	do you recall whether you developed the
13	made regarding Dr. Krah's lab.	13	hypothesis?
14	Do you believe that there was	14	A. No.
15	any kind of wrongdoing in Dr. Palker's lab?	15	Q. Were you consulted about the
16	A. I do not.	16	development of a hypothesis?
17	MR. KELLER: We've been going	17	A. I do not recall.
18	about an hour, the next logical	18	Q. Did you play any role in the
19	MR. SANGIAMO: I think we'll	19	experimental design?
20	hit one in a moment.	20	A. Not that I recall, no.
21		21	Q. How about the writing of the
22	(Exhibit Wlochowski-4, Protective	22	article, what role did you play there, if any?
23	efficacy of intranasal cold-adapted	23	A. Again, I may have generated
24	influenza A/New Caledonia/20/99 (H1N1)	24	some of the data that was used to support that
	Page 63		Page 65
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI63		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI65
1	vaccines article, was marked for	1	I recall.
2	identification.)	2	Q. Do you recall anything beyond
3		3	that in the writing of the article?
4	BY MR. SANGIAMO:	4	A. I do not recall any other role
5	Q. Ms. Wlochowski, you've just	5	in writing the article.
6	been handed what's been marked as Exhibit 4,	6	MR. SANGIAMO: Want to take a
7	which is a journal article on which you're one	7	break?
8	of the listed authors. Right?	8	MR. KELLER: Yes.
9	A. Yes.	9	VIDEOGRAPHER: The time is now
10	Q. So this is the other journal	10	10:40. Going off the video record.
11	article on which you are a listed author.	11	
12	Right?	12	(A recess was taken.)
13	A. Yes.	13	
14	Q. This was written along with	13	VIDEOGRAPHER: The time is now
14	some co-authors from Merck. True?	15	10:58. This begins disc two. You may
16	A. Correct.	16	proceed.
10	Q. It looks like there is about 14	17	MR. SANGIAMO: I want to go
18	or so total authors on there. Can you tell me	18	back and clear up one thing, Jeff. I'm
18 19	what your role was in the work that's	10	going to pose this question, but I
20 21	described in this paper?	20 21	can't remember whether you objected or
21	A. I believe I performed some of		instructed her not to answer.
22	the well, the laboratory testing as well as	22	BY MR. SANGIAMO:
23	some of the animal studies that would support	23	Q. Ms. Wlochowski, did you have
24	this.	24	your children vaccinated with MMR?

17 (Pages 62 - 65)

		F	Page 66	Page 68
	JOAN L. WLOCHOWS	SKI -HIGHLY CONFIDENTA	LI66	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI68
1	MR. KELLER: O	bjection. I	1	1 work?
2	instruct her not to answ	ver that	2	2 MR. KELLER: Objection. Calls
3	question under right to	privacy.	3	3 for speculation.
4	BY MR. SANGIAMO:		4	4 THE WITNESS: I can't say what
5	Q. Are you going to	follow your	5	5 he thought of my work in general. The
6	counsel's instruction?		e	6 feedback he provided me was positive.
7	A. Yes.		7	7 BY MR. SANGIAMO:
8	Q. What did you thir	hk of Dr. Palker	8	8 Q. Were there others who worked in
9	as a boss?		ç	9 his lab?
10	MR. KELLER: O	bjection as to	10	10 A. Yes.
11	form.		11	11 Q. How would you describe the
12	THE WITNESS: V	What do you mean	12	12 relationships amongst those people
13	by what do I think of h	im as a boss?	13	13 MR. KELLER: Objection. Vague.
14	BY MR. SANGIAMO:		14	14 BY MR. SANGIAMO:
15	Q. Did you like work	king for him?	15	15 Q including yourself?
16	MR. KELLER: Sa	•	16	16 A. Again, what do you mean by
17	THE WITNESS: 1		17	17 "relationship"?
18	mean by "like working	for him."	18	18 Q. You can interpret it however
19	BY MR. SANGIAMO:		19	19 you like.
20	Q. You don't know v	vhat that means,	20	20 MR. KELLER: Same objection.
21	that concept has no meaning	g to you, to like	21	21 THE WITNESS: We were co-workers.
22	working for somebody?		22	22 BY MR. SANGIAMO:
23	A. So		23	23 Q. Did you form any friendships?
24	MR. KELLER: Sa	me objection.	24	24 A. I did have friends in the lab,
			2000 67	
	IOAN I WI OCHOWS	SKI -HIGHLY CONFIDENTA	Page 67	Page 69 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI69
1	THE WITNESS: 7			1 yes.
2	know, different concep	•		2 Q. Did you feel that there was a
3	somebody. There's ma	e		3 click that you were left out of in that lab?
4	that, so	ity aspects of		4 MR. KELLER: Objection. Vague
5	BY MR. SANGIAMO:			5 and ambiguous.
6	O. What are they?			6 THE WITNESS: I don't as far
7	A. It could be a perso	onal		7 as a click in the lab, I'm not sure
8	relationship with somebody			8 what you would mean by that.
9	or that is given. I guess I			9 BY MR. SANGIAMO:
10	you to explain what it is you	-		10 Q. Do you know what the term
11	specifically about.	a re usking		11 "click" means?
12	Q. Are you finished,	I couldn't		12 A. A group of people. There were
13	tell?			13 only three of us at the time that reported in
14	A. Yes.			14 to Dr. Palker.
15	Q. Did he seem like	a nice man?		15 Q. Are you able to comment one way
16	MR. KELLER: Sa			16 or the other on whether the three of you got
17	THE WITNESS: 1	-		along well or is that too vague a question
18	nice person.	u		18 from your perspective?
	BY MR. SANGIAMO:			19 MR. KELLER: Objection.
1 19			13	·
19 20		lescribe your	20	20 Argumentative
20	Q. How would you d	•		 20 Argumentative. 21 THE WITNESS: Again, I. myself.
20 21	Q. How would you of personal relationship with h	im?	21	21 THE WITNESS: Again, I, myself,
20 21 22	Q. How would you of personal relationship with hA. He was my boss.	im?	21 22	 THE WITNESS: Again, I, myself, feel that we got along fine.
20 21	Q. How would you of personal relationship with h	im? That was my	21 22 23	21 THE WITNESS: Again, I, myself,

18 (Pages 66 - 69)

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THE WITNESS: So you asked if

there was more than one trial? Is that

Q. I asked if all the trials were

the question?

24 for the same vaccine product?

22 BY MR. SANGIAMO:

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			Page 70			Page 72
	JOAN L. WLOCHOWS	SKI -HIGHLY CONFIDENTA	ALI70		OAN L. WLOCHOWSKI -HIGHLY	CONFIDENTALI72
1	Merck?		1	l	A. I don't think so. But, again,	
2	A. We were moving	back out of	2	2 I de	n't recall.	
3	state.		3	3	MR. KELLER: Object to the	
4	Q. Where were you r	noving to?	4	1	form.	
5	A. Connecticut.		4	5 BY	MR. SANGIAMO:	
6	Q. All right. So whe	re did you	6	5	Q. Do you have an agreement with	
7	apply to work when you lef	t Merck?		7 Pfi	er that limits your ability to disclose	
8	A. Pfizer.		8	3 cer	in things about your employment ther	e?
9	Q. Is that the only pla	ace?	ģ)	A. Yes, I believe I have a	
10	A. I can't recall. I be	lieve so.	10) cor	identiality agreement with them.	
11	Q. You were at Pfize	er for how	11	l	Q. Do you intend to honor that	
12	long?		12	2 agr	ement?	
13	A. I would say about	nine months.	13	3	A. Yes.	
14	Q. Why did you leav	e the position	14	1	Q. Are those agreements important?	2
15	at Pfizer?		15	5	MR. KELLER: Objection. Vagu	e
16	A. The position I had	l was moving	16	5	and ambiguous.	
17	to Kalamazoo, Michigan, ar	nd I did not that	17	7	THE WITNESS: Again, which	
18	was not my family's choice	to move to	18	3	agreements? What do you mean by	
19	Kalamazoo, Michigan.		19)	"important"?	
20	Q. Your CV that is E	Exhibit 1, in	20) BY	MR. SANGIAMO:	
21	the first bullet reads: "Perfo	orm large-scale	21	l	Q. Why are you reluctant to answer	
22	clinical assays (e.g. serum n	eutralization,	22	2 tha	question, Ms. Wlochowski?	
23	virus isolation) using autom	ated equipment	23		MR. KELLER: Argumentative.	
24	such as Sci-Clone," if I'm	pronouncing that	24	1	Important to who, to her, to the	
			Page 71			Page 73
	JOAN L. WLOCHOWS	KI -HIGHLY CONFIDENTA	0		OAN L. WLOCHOWSKI -HIGHLY	•
1	correctly, "BioMek and M	IultiMek in support	1	l	company?	
2	of vaccine formulation trials	s." That says	2	2	MR. SANGIAMO: She can testif	ÿ.
3	trials, plural. I take it there	was more than		3	THE WITNESS: Are you asking	if
4	one trial in which you perfo	rmed those	4	1	it's important to me or are you asking	
5	clinical assays?		4	5	if it's important to the company?	
6	A. I believe so, yes.		e	5 BY	MR. SANGIAMO:	
7	Q. How many trials	were there?			Q. I'm asking if they're	
8	A. I don't recall.		8	3 im	prtant. You need to slice that up?	
9	Q. Were all the trials	for the	ç	,	MR. KELLER: Objection.	
10	same vaccine product?		10)	Overbroad.	
11	MR. KELLER: Be	e careful not to	11	l	THE WITNESS: Yes, they're	
12	disclose anything that v		12		important.	
13	any agreement you had		13		MR. SANGIAMO:	
14	respect to confidentialit		14		Q. Do you think it's okay to	
15	want to testify, you can	• •	15		egard those agreements? Is that okay i	n
16	generally. If there is so	-	10		view?	
17	specific you want to asl		17	•	MR. KELLER: Objection. Form	
18	that bridge, but start wi		18		Lack of foundation.	
10	strage, out built wi		10	-		

19 (Pages 70 - 73)

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well.

THE WITNESS: I don't think

agreements, but I also -- it depends on

the -- if the company themselves have

violated any of their guidances as

it's appropriate to violate those

16 how you plan to go about honoring your

Do you think they're entitled

A. I think they're entitled to be

Q. My question is, are they

entitled to know that you're going to make

confidentiality obligation?

Q.

to know that?

A. No, I have not.

honest to me as I am to them.

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		jge:	
	Page 74		Page 76
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI74		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI76
1	BY MR. SANGIAMO:	1	your own judgment about whether or not you
2	Q. Any of their what?	2	have to honor the confidentiality agreements
3	A. The guidances or regulations	3	that you owe to them?
4	that they're required to follow.	4	MR. KELLER: Objection. Form.
5	Q. So your view is if the company,	5	Calls for speculation.
6	in your opinion, has violated a guidance or	6	THE WITNESS: Right. I don't
7	regulation, then it's okay to go ahead and	7	think that I can't say what they're
8	disclose their confidential information. Is	8	entitled to know. So, yeah, it depends
9	that your view?	9	on the situation that occurs while I'm
10	MR. KELLER: Objection.	10	employed by them. The expectation is
11	Mischaracterizes her testimony.	11	that they are you know, if they tell
12	THE WITNESS: No, I'm not	12	me they're running under GMP
13	saying that specifically, but, again,	13	regulations, then that is their promise
14	in this case with Pfizer, the	14	to me. My promise to them is I keep it
15	confidentiality agreement was important	15	confidential.
16	and it I agree with it in the case	16	BY MR. SANGIAMO:
17	of Pfizer.	17	Q. Have you included that
18	BY MR. SANGIAMO:	18	provision in any of your agreements with your
19	Q. So your view is each employee	19	subsequent employers?
20	should decide for him or herself whether he or	20	MR. KELLER: Objection.
21	she wants to honor the confidentiality	21	THE WITNESS: Again, that's a
22	agreement when they leave an employer. Is	22	confidentiality agreement. I can't
23	that a fair summary?	23	then I would be breaking the
24	MR. KELLER: Objection.	24	confidentiality agreement if I told you
	Page 75	;	Page 77
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI75		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI77
1	Argumentative. Vague and ambiguous.	1	what was in the agreement.
2	MR. SANGIAMO: Jeff, the mere	2	BY MR. SANGIAMO:
3	fact that she doesn't want to have to	3	Q. So you're not going to answer?
4	answer a question is not a basis to	4	So you're saying that maybe you did include a
5	object to it.	5	provision in your agreements with your other
6	MR. KELLER: You can ask your	6	employers about your compliance being
7	questions. I'll object as I deem	7	conditioned upon them complying with the CGMP,
8	appropriate.	8	maybe you did, you're just not going to tell
9	THE WITNESS: So I again,	9	us. Is that what you're saying?
10	in it depends, yes, I believe that	10	MR. KELLER: Objection.
11	it depends on the circumstances that	11	Argumentative.
12	surround that agreement.	12	MR. SANGIAMO: Understood,
13	BY MR. SANGIAMO:	13	Jeff, you made your objection.
14	Q. Have you told any of your	14	THE WITNESS: Yes.
15	subsequent employers after Merck that that's	15	BY MR. SANGIAMO:
1	i i v		

20 (Pages 74 - 77)

Q. Do you have copies of your

And how about with Amgen?

I think I do. I can't confirm.

Were the vaccines that were

under study in the trials to which you refer

in the first bullet point of your description

17 confidentiality agreement with Wyeth -- I'm

I believe I do, yes.

sorry, with Pfizer?

A.

Q.

Α.

Q.

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	Page 78		Page 80
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL178		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL180
1	in Exhibit 1 of your work with Pfizer, were	1	going to stipulate now that she will
2	they already marketed by the time of those	2	testify?
3	studies?	3	MR. KELLER: I didn't stipulate
4	MR. KELLER: That's a yes or	4	anything. Ask your question. If you
5	no. Overbroad. Objection. Overbroad.	5	want to make a motion, make a motion.
6	MR. SANGIAMO: Overbroad how?	6	We're not under any obligation.
7	Were they already marketed at the time	7	BY MR. SANGIAMO:
8	of the studies, why is that overbroad?	8	Q. Can you describe whether any of
9	MR. KELLER: There could be	9	the serum neutralization assays involved
10	some that are marketed, some that	10	plaque reduction as a means of measuring an
11	aren't marketed. She hasn't said	11	immune response?
12	whether or not there was more than one	12	A. I don't think we performed
13	vaccine and others, if you want to be	13	plaque reduction.
14	precise. Object to the question.	14	Q. You understood my question just
15	THE WITNESS: I don't know, I	15	now was in reference to the work you did at
16	think some were marketed at the time.	16	Pfizer. Right?
17	BY MR. SANGIAMO:	17	A. Pfizer.
18	Q. Which ones?	18	Q. If not a plaque reduction serum
19	A. I can't say which ones.	19	neutralization assay, then what kind of serum
20	Q. Because you don't remember or	20	neutralization assay was it?
21	because you think you're prohibited from doing	21	A. I believe they were conducted
22	so by your confidentiality agreement with	22	on an ELISA format.
23	Pfizer?	23	Q. What was your role in running
24	A. Again, I think probably a	24	these ELISA serum neutralization assays?
	Page 79		Page 81
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL179		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI81
1	little bit of both. That I wouldn't say which	1	A. I performed the assays.
2	vaccines on top of I don't recall exactly	2	Q. Did you work in a lab that was
3	which ones.	3	running the assays?
4	Q. So is it your belief that your	4	A. Yes, I did.
5	confidentiality agreement with Pfizer	5	Q. How many other people were
		1	

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working in that lab?

Α.

Q.

A.

Q.

at Pfizer?

A.

0

A.

immune response?

Compound.

multiple trials?

I think two other people.

To my recollection, yes.

Did that lab run any plaque

reduction neutralization assays while you were

Were the serum neutralization

measuring the immune response to vaccination?

or were they measuring some other kind of

MR. KELLER: Objection.

Q. Were they measuring seroconversion

Not that I recall, no.

assays that you were running at Pfizer

Yes, I believe so.

Was the -- strike that.

I assume that lab ran assays on

confidentiality agreement with Pfizer 5 precludes you from telling us about work you 6 7 did on a clinical trial on a marketed product? Is that your recollection or understanding of 8 9 your confidentiality agreement with Pfizer? 10 MR. KELLER: Objection. Seeks 11 a legal conclusion, and I will instruct 12 you not to disclose any communications 13 you had with your counsel with respect 14 to anything that may be provided in 15 those confidentiality agreements to the 16 extent that you discussed them with 17 your counsel. 18 THE WITNESS: With the work 19 that's described within my CV to speak 20 to what I did on a particular product, 21 I wouldn't disclose that at this time. 22 MR. SANGIAMO: Do you plan to 23 have her to testify at trial about the

work she has done at Pfizer? Are you

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^{21 (}Pages 78 - 81)

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	Page 82 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI82		Page 84 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL184
1		1	
1	THE WITNESS: I don't recall	1	MR. SANGIAMO: Are you ready to
2	the specifics.	2	certify that would be a violation of
3	BY MR. SANGIAMO:	3	that confidentiality agreement?
4	Q. Do you recall the answer to my	4	MR. KELLER: I'm not certifying
5	question as to whether they were measuring	5	anything. You can ask your questions.
6	seroconversion as distinguished from some	6	I believe she answered it anyway.
7	other kind of immune response?	7	MR. SANGIAMO: You didn't let
8	MR. KELLER: Same objection.	8	her answer it.
9	THE WITNESS: I do recall your	9	MR. KELLER: I think she
10	question. I don't recall the intent of	10	answered it.
11	the assay that we were performing.	11	BY MR. SANGIAMO:
12	BY MR. SANGIAMO:	12	Q. Were any of the vaccines that
13	Q. It could have been either?	13	you worked on at Pfizer a mumps vaccine?
14	A. Uh-huh. I mean, I guess in the	14	MR. KELLER: You can answer.
15	case of you're saying neutralization, you're	15	THE WITNESS: No, they were
16	saying immune response which could be the	16	not.
17	same, could also be the same endpoint if	17	BY MR. SANGIAMO:
18	you're looking at end response and	18	Q. Did you design any of the
19	neutralization as an endpoint to detect it.	19	assays that you ran at Pfizer?
20	Q. My question was whether it was	20	A. What do you mean by design the
	seroconversion or some other kind of immune	21	assay?
		21	Q. Did you play any role in
21			Q. Did you play any fole in
22	response?		
22 23	A. Okay.	23	developing the assay methodology for any of
22	•		
22 23	A. Okay.	23	developing the assay methodology for any of
22 23	A. Okay.Q. I understand your answer to be	23	developing the assay methodology for any of those assays?
22 23	 A. Okay. Q. I understand your answer to be Page 83	23	developing the assay methodology for any of those assays? Page 8:
22 23 24	 A. Okay. Q. I understand your answer to be Page 83 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI83 	23 24	developing the assay methodology for any of those assays? Page 8: JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI85
22 23 24 1	A. Okay. Q. I understand your answer to be Page 83 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI83 you're not sure.	23 24 1	developing the assay methodology for any of those assays? Page 8: JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI85 A. I believe I worked on
22 23 24 1 2	 A. Okay. Q. I understand your answer to be Page 83 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI83 you're not sure. A. Right. 	23 24 1 2	developing the assay methodology for any of those assays? Page 8: JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI85 A. I believe I worked on developing assays while I was there.
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1	Page 86 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI86		Page 88 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI88
1	study samples per my description there.	1	
2	BY MR. SANGIAMO:	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	A. No.O. Where did you what other
3	Q. What's viremia?	3	kinds of work did you do at Pfizer?
4	A. Again, the I can't explain	4	A. Again, I was there for nine
5	to you the specifics of that right now.	5	months so what is listed on my CV is what I
6	Q. What is the definition of	6	conducted over that period.
7	viremia?	7	Q. Are you familiar with the term
8	A. Virus or viral infection in	8	"basic research" as used in the pharmaceutical
9	blood samples.	9	industry?
10	Q. So viremia can refer to many	10	A. Can you describe what you mean
11	different viruses?	11	by that?
12	A. Yes, it could.	12	Q. I was hoping you would. I'm
12	Q. It's not a definition of a	12	trying to come up with one summary way of
14	particular virus. Do I have that right?	14	describing what your work at Pfizer was and
15	A. Correct.	15	I'm asking if it was all in the nature of
16	Q. Was mumps among the viruses	16	basic research?
17	that were related to the PCR assay that you	17	A. It was part research; part, if
18	described there in your time at Pfizer?	18	we were supporting clinical trials, clinical
19	MR. KELLER: At this point I'm	19	work.
20	going to she's already testified	20	Q. Clinical work, namely serology
21	that she hasn't worked on a mumps	20	work. Right?
22	vaccine at Pfizer. You're getting into	21	A. Correct.
23	what specific work she's doing on	23	Q. Did you do any work while you
23	different products at Pfizer. She has	23	were at Pfizer that you would characterize as
	•	2.	· · · · · · · · · · · · · · · · · · ·
	Page 87		
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1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI87	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI89
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI87 a confidentiality agreement. You're	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI89 regulatory?
2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI87 a confidentiality agreement. You're trying to get her to breach that	2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI89 regulatory? A. The work conducting the studies
2 3	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI87 a confidentiality agreement. You're trying to get her to breach that confidentiality agreement, so I'm going	2 3	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI89 regulatory? A. The work conducting the studies for the clinical assays to support regulatory
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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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI87 a confidentiality agreement. You're trying to get her to breach that confidentiality agreement, so I'm going to instruct her not to answer that. MR. SANGIAMO: The thing she testified to, if I remember the testimony correctly, is that the vaccine trials that she for which she ran a large scale clinical assays that you referred to in the first bullet point in her CV about Pfizer, that those did not involve mumps vaccine. Right? Right now I'm asking her about a different part of her work at Pfizer, mainly the development of this PCR assay and whether any of that work was directed at mumps virus. MR. KELLER: I'm not trying to talk over you. Why don't you ask if she worked on mumps virus at all at Pfizer generally? BY MR. SANGIAMO:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI89 regulatory? A. The work conducting the studies for the clinical assays to support regulatory or could support anything that regulatory would use. Q. Was there anything else you did at Pfizer that you could say was regulatory in nature besides the work supporting the clinical studies? A. What is it that you're referring to by regulatory that I Q. Did any of your work at Pfizer involve you personally interacting with the FDA? A. No. Q. Did it involve you personally interacting with any other regulatory body? A. No. Q. Did it involve you authoring submissions to be made to the FDA? A. What do you mean by "authoring"? Q. Let's break that down. Did it
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI87 a confidentiality agreement. You're trying to get her to breach that confidentiality agreement, so I'm going to instruct her not to answer that. MR. SANGIAMO: The thing she testified to, if I remember the testimony correctly, is that the vaccine trials that she for which she ran a large scale clinical assays that you referred to in the first bullet point in her CV about Pfizer, that those did not involve mumps vaccine. Right? Right now I'm asking her about a different part of her work at Pfizer, mainly the development of this PCR assay and whether any of that work was directed at mumps virus. MR. KELLER: I'm not trying to talk over you. Why don't you ask if she worked on mumps virus at all at Pfizer generally?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 regulatory? A. The work conducting the studies for the clinical assays to support regulatory or could support anything that regulatory would use. Q. Was there anything else you did at Pfizer that you could say was regulatory in nature besides the work supporting the clinical studies? A. What is it that you're referring to by regulatory that I Q. Did any of your work at Pfizer involve you personally interacting with the FDA? A. No. Q. Did it involve you personally interacting with any other regulatory body? A. No. Q. Did it involve you authoring submissions to be made to the FDA? A. What do you mean by "authoring"?

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	Page 90 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI90		Page 92 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI92
1	A. Yes, potentially.	1	A. Correct.
2	Q. Did it include any other kind	$\begin{vmatrix} 1\\2 \end{vmatrix}$	Q. One more question on Pfizer.
3	of involvement on your part in an FDA	3	Did you have a single supervisor when you were
4	submission?	4	at Pfizer?
5	MR. KELLER: Objection. Vague and ambiguous. Overbroad.	5	A. Yes.O. Who was that?
6	THE WITNESS: What do you mean	6 7	
7	-		A. Jay Thompson.
8	by any other part besides generating	8	Q. First name Jay, J-A-Y?
9	data? What are you looking	9	A. Yes.
10	BY MR. SANGIAMO:	10	Q. Do you know if he's still at
11	Q. I'm asking about what you did.	11	Pfizer?
12	A. I can't think of anything	12	A. I do not.
13	besides the my work in the clinical	13	Q. Was the name of the group that
14	studies. Anything in basic research could	14	you were in biologics development?
15	potentially down the road be used for	15	A. Yes.
16	something further down development to support	16	Q. Your next stop was at Amgen.
17	regulatory. So as a whole, it is a vague	17	Correct?
18	question because as a whole there could be	18	A. Correct.
19	further development that leads into something	19	Q. Could you describe your work
20	that would be used in a regulatory submission	20	obligations at Amgen?
21	at a later point.	21	A. I worked in the analytical
22	Q. Do you know if that occurred in	22	laboratory at when I first started at Amgen
23	any of the basic research that you did?	23	for process development. I later moved to the
24	A. I do not.	24	product quality team where I provided
	Page 91		Page 93
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI91		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI93
1	Q. Did you provide any input into	1	oversight to the QC testing labs and
2	product labeling while you were at Pfizer?	2	monitoring and trending the data for the labs.
3	MR. KELLER: Objection. Vague	3	
1	and analytican and the form detion		Q. During the time that you were
4	and ambiguous. Lack of foundation.	4	Q. During the time that you were there, did Amgen make vaccines?
4 5	THE WITNESS: When you say	4 5	
	-		there, did Amgen make vaccines?
5	THE WITNESS: When you say	5	there, did Amgen make vaccines? A. No.
5 6	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning	5 6	there, did Amgen make vaccines?A. No.Q. Did you work on any vaccines in
5 6 7	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO:	5 6 7	there, did Amgen make vaccines?A. No.Q. Did you work on any vaccines in development while you were at Amgen?
5 6 7 8	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning	5 6 7 8	there, did Amgen make vaccines?A. No.Q. Did you work on any vaccines indevelopment while you were at Amgen?A. No.
5 6 7 8 9	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning to you, "input"?	5 6 7 8 9 10 11	 there, did Amgen make vaccines? A. No. Q. Did you work on any vaccines in development while you were at Amgen? A. No. Q. Did you work on any antiviral
5 6 7 8 9 10	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning to you, "input"? A. It could mean any number of	5 6 7 8 9 10	 there, did Amgen make vaccines? A. No. Q. Did you work on any vaccines in development while you were at Amgen? A. No. Q. Did you work on any antiviral products while you were at Amgen?
5 6 7 8 9 10 11	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning to you, "input"? A. It could mean any number of things. And I can say that, again,	5 6 7 8 9 10 11	 there, did Amgen make vaccines? A. No. Q. Did you work on any vaccines in development while you were at Amgen? A. No. Q. Did you work on any antiviral products while you were at Amgen? A. No.
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning to you, "input"? A. It could mean any number of things. And I can say that, again, potentially the work I performed in the clinical study would be used to support a label. Q. Did you review drafts of labeling? A. I did not. Q. Did you draft label language? A. I did not.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 there, did Amgen make vaccines? A. No. Q. Did you work on any vaccines in development while you were at Amgen? A. No. Q. Did you work on any antiviral products while you were at Amgen? A. No. Q. Did you work on any immunotherapy products while you were at Amgen? A. No. Q. Did you work on any immunotherapy products while you were at Amgen? A. When you say work on the products, what do you mean? Q. Was any of the work that you did related to such products? A. Yes, I believe so. Q. Did you do any work at Amgen
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE WITNESS: When you say "input," what are you looking for? BY MR. SANGIAMO: Q. Does that word have any meaning to you, "input"? A. It could mean any number of things. And I can say that, again, potentially the work I performed in the clinical study would be used to support a label. Q. Did you review drafts of labeling? A. I did not. Q. Did you draft label language? A. I did not. Q. Was your opinion solicited by co-workers regarding how wording should be	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 there, did Amgen make vaccines? A. No. Q. Did you work on any vaccines in development while you were at Amgen? A. No. Q. Did you work on any antiviral products while you were at Amgen? A. No. Q. Did you work on any immunotherapy products while you were at Amgen? A. No. Q. Did you work on any immunotherapy products while you were at Amgen? A. When you say work on the products, what do you mean? Q. Was any of the work that you did related to such products? A. Yes, I believe so. Q. Did you do any work at Amgen related to the mumps virus? A. No.

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	Page 94		Page 96
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL194		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI96
1	analytical laboratory for product development?	1	the product development.
2	Is that what you said?	2	Q. What kind of test methods did
3	A. Process development.	3	you run?
4	Q. Process development?	4	A. I would say mainly I performed
5	A. Yep.	5	the ELISAs.
6	Q. What does the analytical	6	Q. Anything else?
7	laboratory for process development at Amgen do	7	A. General test. PH, osmo, some
8	or what did it do at that time?	8	HPLC.
9	A. It was further developing the	9	Q. What was the purpose of the
10	process for one of their products.	10	I'm sorry, were you about to say something
11	Q. It was just a single product	11	else?
12	that you were working on when you were in the	12	A. SDS-page staining, Coomassie
13	analytical laboratory for process development?	13	staining.
14	A. Yes.	14	Q. What was the purpose of the
15	Q. What kind of product was that?	15	ELISAs that you were running?
16	MR. KELLER: Answer generally.	16	A. I can't remember.
17	Was it a drug? Was it a vaccine?	17	Q. Is it possible the purpose of
18	THE WITNESS: Biologic.	18	the ELISA was to detect the absence of
19	BY MR. SANGIAMO:	19	antibody development?
20	Q. Is it currently a marketed	20	MR. KELLER: Objection. Calls
21	product?	21	for speculation.
22	A. Yes.	22	THE WITNESS: No, because this
23	Q. What's the name of the product?	23	was a product that wasn't it was
24	MR. KELLER: You can answer	24	basically the detection of proteins.
	Page 95		Page 97
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL195		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTALI97
1	that.	1	BY MR. SANGIAMO:
2	THE WITNESS: Enbrel.	2	Q. That's what the ELISA was for?
3	BY MR. SANGIAMO:	3	A. Yes.
4	Q. What does it do?	4	Q. Detecting proteins by looking
5	A. It treats rheumatoid arthritis.	5	for antibodies to that protein?
6	Q. How does it do that?		for unitodies to that protein.
- 1		6	MR. KELLER: Objection. Lack
7	MR. KELLER: Objection.	6 7	-
8	MR. KELLER: Objection. Overbroad.		MR. KELLER: Objection. Lack
	·	7	MR. KELLER: Objection. Lack of foundation.
8	Overbroad.	7 8	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't
8 9	Overbroad. THE WITNESS: I can't explain	7 8 9	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the
8 9 10	Overbroad. THE WITNESS: I can't explain the mechanism.	7 8 9 10	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay.
8 9 10 11	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO:	7 8 9 10 11	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO:
8 9 10 11 12	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know?	7 8 9 10 11 12	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what?
8 9 10 11 12 13	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at	7 8 9 10 11 12 13	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the
8 9 10 11 12 13 14	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time.	7 8 9 10 11 12 13 14	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring.
8 9 10 11 12 13 14 15	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're	7 8 9 10 11 12 13 14 15	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to
8 9 10 11 12 13 14 15 16	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're saying you can't explain it because you don't	7 8 9 10 11 12 13 14 15 16	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to measure pH. Did I have that right?
8 9 10 11 12 13 14 15 16 17	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're saying you can't explain it because you don't know what it is. Is that your testimony?	7 8 9 10 11 12 13 14 15 16 17	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to measure pH. Did I have that right? A. Yes.
8 9 10 11 12 13 14 15 16 17 18	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're saying you can't explain it because you don't know what it is. Is that your testimony? A. I don't remember how the	7 8 9 10 11 12 13 14 15 16 17 18	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to measure pH. Did I have that right? A. Yes. Q. What was the purpose of that?
8 9 10 11 12 13 14 15 16 17 18 19	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're saying you can't explain it because you don't know what it is. Is that your testimony? A. I don't remember how the mechanism works. Yes.	7 8 9 10 11 12 13 14 15 16 17 18 19	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to measure pH. Did I have that right? A. Yes. Q. What was the purpose of that? A. The product needs to be
8 9 10 11 12 13 14 15 16 17 18 19 20	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're saying you can't explain it because you don't know what it is. Is that your testimony? A. I don't remember how the mechanism works. Yes. Q. And what specifically did you	7 8 9 10 11 12 13 14 15 16 17 18 19 20	MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to measure pH. Did I have that right? A. Yes. Q. What was the purpose of that? A. The product needs to be maintained within a certain pH.
8 9 10 11 12 13 14 15 16 17 18 19 20 21	Overbroad. THE WITNESS: I can't explain the mechanism. BY MR. SANGIAMO: Q. Because you don't know? A. Yeah, I can't explain it at this time. Q. I need clarification. You're saying you can't explain it because you don't know what it is. Is that your testimony? A. I don't remember how the mechanism works. Yes. Q. And what specifically did you do in the analytical laboratory for process	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MR. KELLER: Objection. Lack of foundation. THE WITNESS: Yeah, I can't remember the assay that was the intent of the assay. BY MR. SANGIAMO: Q. You can't remember what? A. I can't remember exactly the assay, what it was measuring. Q. You said you also ran assays to measure pH. Did I have that right? A. Yes. Q. What was the purpose of that? A. The product needs to be maintained within a certain pH. Q. And then you mentioned an HPLC

25 (Pages 94 - 97)

22

23

24

Q.

Α.

Enbrel.

there?

What product did you work on

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	Page 98		Page 100
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL198	JOA	N L. WLOCHOWSKI -HIGHLY CONFIDENTAL100
1	A. To identify the purity of the	1 A.	I'm not sure what you mean by
2	product.	2 what els	e did I provide.
3	Q. You mentioned something about	3 Q.	Did you provide was it your
4	Coomassie staining?	4 function	to provide organizational coordination
5	A. Yes.	5 as challe	enges were being encountered with
6	Q. What was the purpose of that?	6 methods	?
7	A. Also, I believe, purity.	7	MR. KELLER: Objection. Vague
8	Q. Was any of this in the nature	8 and	ambiguous.
9	of stability testing?	9	THE WITNESS: I'm not sure I
10	A. Not that I recall, no.	10 und	erstand. Can you ask the question
11	Q. How long were you in the	11 agai	n?
12	analytical laboratory for process development	12 BY MR.	SANGIAMO:
13	at Amgen?	13 Q.	Was it your responsibility to
14	A. Two years.	14 see to it	that the relevant portions of the
15	Q. I gather then 2005 is when you	15 product	quality team met appropriately to
16	moved to the product quality team?	16 resolve a	a particular issue that's an example
17	A. Correct.	17 of what	I'm talking about other than actual
18	Q. Did you work on more than one	18 subject r	natter expertise?
19	product while you were in the product quality	19 A.	Yes, there was a team that
20	team?	20 would m	neet to review the data and we would
21	A. No.	21 work tog	gether cross functionally.

Q. Looking at Exhibit 2, your

22 23 description of your time at Amgen has two 24 bullet points?

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	Page 99		Page 101
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL199		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL101
1	Q. What specifically was your	1	A. Uh-huh.
2	role?	2	Q. Is it the case that the work in
3	A. Again, the providing the	3	the analytical laboratory for process
4	oversight to the QC laboratories for their	4	development is what's described in the first
5	method development and transfer comparability	5	bullet point?
6	as well as trending and data that was	6	A. That is more based on the my
7	generated.	7	role in product quality.
8	Q. What is method development?	8	Q. Is your work in the analytical
9	A. It basically is developing a	9	laboratory for process development described
10	method based on an order to be able to test a	10	anywhere on this CV at Amgen?
11	specific criteria.	11	A. The second bullet is more
12	Q. In what way did you oversee the	12	relating to my analytical laboratory work.
13	QC lab? What was your job function?	13	Q. What's a site maturity model?
14	A. So if there were challenges	14	A. It's based on the performance
15	with method performance I would provide some	15	of the systems, the robustness of the systems.
16	oversight to investigate the issues around the	16	So they had a maturity model of where we were
17	performance and help to work with the analysts	17	at with developing the systems that managed
18	on the any further development or	18	our processes.
19	optimization that's needed for the performance	19	Q. Does your reference in that
20	of the assay.	20	first bullet point to validation, what is that
21	Q. Did you provide the subject	21	referring to?
22	matter expertise for that process?	22	A. Method validation.
23	A. Partially, yes.	23	Q. Can you describe what method
24	Q. What else did you provide?	24	validation amounts to?

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		F	Page 102		Page 104
	JOAN L. WLOCHOWS	SKI -HIGHLY CONFIDENTA	AL102	JOA	N L. WLOCHOWSKI -HIGHLY CONFIDENTAL104
1	A. It shows the meth	od is suitable	1	А.	Looking for a new opportunity.
2	for its intended use, in this	case an GMP	2	Q.	Were you asked to leave Amgen?
3	environment. That it would	l be accurate,	3	А.	No.
4	specific, precision and repe	atability.	4	Q.	Did you apply to anyplace other
5	Q. Is there any valid	ation work	5	than Ale	exion when you were deciding to leave
6	for any ELISA assays that y	you did? I'm sorry,	6	Amgen?	,
7	let me try that question agai	in.	7	А.	I probably did. I don't recall.
8	Did you do any val	lidation work	8	Q.	If we could talk a little about
9	on ELISA assays when you	were at Amgen?	9	your wo	rk at Alexion
10	A. I do not I did no	-	10	А.	Amgen had also a reduction in
11	Q. Did you get along	g with your	11	workfor	ce. So they were going through a major
12	co-workers while you were		12		n in their workforce which I was not
13	MR. KELLER: O		13	part of.	So I was still a part of Amgen at
14	and ambiguous.	j	14	-	. As part of the, again, reason for
15	THE WITNESS:	Again, co-workers	15		is the morale had dropped, so that was
16	meaning who?	-8, · · · · · · · · · · · ·	16	U	on for looking for a new opportunity.
17	BY MR. SANGIAMO:		17	0.	Morale had dropped and you
18	Q. So you feel you n	eed to divide	18		that drop in morale to reduction of
19	that up a little bit?		19	force. R	
20	MR. KELLER: Sa	ame objection	20	A.	Yes. Yes.
20	THE WITNESS: `	•	20	Q.	If we could talk now about your
21	BY MR. SANGIAMO:	103.	21		Alexion. Are you currently employed
22	Q. Were you ever to	ld in your	22	there?	Alexion. Are you currently employed
23 24	reviews that there was an is	•	23	A.	Yes.
24				A.	
	IOAN I WI OCHOWS	۲ SKI -HIGHLY CONFIDENT	Page 103	IOA	Page 105 N L. WLOCHOWSKI -HIGHLY CONFIDENTAL105
1			1		Has all of your work at Alexion
1 2	A. There could have		2		the quality area?
					· ·
3	example of feedback of diff		3	A.	Yes.
4	with different people throug	gnout the company;	4	Q.	What does that mean to say it
5	yes.	11 1	5		he quality area?
6	Q. Did any of that fe		6		I am overseeing compliance to
7	suggest that that was an are	•	7		gulations for the specific areas I
8	to work on, improving your	r relationships with	8	oversee.	
9	co-workers?		9	Q.	Does Alexion make any vaccines?
10	A. Well, I think ever		10		No.
11	to work on that because the		11	Q.	Does any of your work at
12	personalities within an orga		12	Alexion	ever involve vaccines?
13	there could always be confl	ict between	13	А.	No.
14	personalities.		14		Has it ever involved the mumps
15	Q. Were there such a	conflicts	15	virus in	any way?
16	between personalities in you	ur case when you	16	А.	No.
17	were at Amgen?		17	Q.	Do you oversee compliance for
18	A. None that impaire	ed my work, no.	18	GMP for	r a specific portion of Alexion?
19	Q. But there was son	ne that just	19	Α.	Yes.
• •					

20 20 didn't impair your work? What portion of that? Q. 21 A. There was nothing that actually Are you asking for my current? А. 22 was detrimental to my performance. 22 Yes. Q. Why did you decide to leave 23 Q. A. Okay. I oversee the 24 Amgen? 24 manufacturing of clinical products as well as

21

23

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	Page 106		Page 108
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL106		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL108
1	the internal product development laboratories.	1	product is my role in clinical trials.
2	Q. Who do you report to?	2	Q. That's quality oversight with
3	A. I have an interim manager at	3	regard to the manufacturing of the product?
4	the moment. I report to Brian Molloy.	4	A. Correct.
5	Q. What's Brian Molloy's title?	5	Q. When you were at Amgen, did
6	A. Executive director of quality	6	you, yourself, interact with the FDA?
7	operations.	7	A. I don't think so.
8	Q. Is there someone more senior	8	Q. When you were at Pfizer, did
9	than him within quality operations?	9	you, yourself, interact with the CDC?
10	A. Currently we have chief of	10	A. No.
11	quality.	11	Q. At Amgen did you interact with
12	Q. Is he the only executive	12	the CDC?
13	director of quality operations?	13	A. No.
14	A. Yes.	14	Q. Do you interact with the FDA or
15	Q. Are there other people who	15	have you strike that.
16	report directly to Brian Molloy besides	16	Have you interacted with the
17	yourself?	17	FDA during your time at Alexion?
18	A. Yes.	18	A. Yes.
19	Q. How many?	19	Q. How frequently?
20	A. I want to say probably five	20	A. I would say it depends on
21	others.	21	what you mean by interacting because I
22	Q. How many products does Alexion	22	interact on different levels.
23	manufacture?	23	Q. What are they?
24	A. Commercially?	24	A. So I have been directly
	Page 107		Page 109
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL107		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL109
1	Q. Yes.	1	involved in inspections by the FDA where I
2	A. Three.	2	speak directly to the FDA. I currently
3	Q. What are they just very	3	support any data that's used to submit
4	generally?	4	information to the FDA, so I do review
5	A. They support rare diseases,	5	documents that are submitted to the FDA. We
6	blood disorders, that sort of thing.	6	do have responses, questions from the FDA that
7	Q. Does any of your work	7	we have commitments to that I work towards as
8	involve strike that.	8	far as quality oversight, ensuring that those
9	Has any of your work at Alexion	9	are completed.
10	involved clinical trials?	10	Q. So that's three different thing
11	A. Yes.	11	you just described? I couldn't tell whether I
12	Q. In what way?	12	was dividing them up.
13	A. The manufacturing of the	13	A. Yeah, in general that's in
14	clinical product that we use are used in	14	general what I do.
15	clinical trials.	15	Q. Have there been any 483s issued
16	Q. Used in clinical trials being	16	in any of these inspections at Alexion when
17	performed by Alexion?	17	you've been interacting with the FDA?
18	A. Yes.	18	MR. KELLER: If any of those
19	Q. Have you had any other	19	483s are public, you can testify to it.
20	involvement in clinical trials while at	20	If they're not public, then you cannot
21	Alexion other than your role related to the	21	pursuant to your confidentiality
22	manufacturing of the product?	22	agreement with Alexion.
23	A. I'm trying to think how no,	23	THE WITNESS: For the
24	just as far as quality oversight for the	24	inspections that I supported directly
L		1	

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	Case 28328533 LDCCOMBERINT: / 440	Haagee:	52244 LL2128ECTHEBERCIIII2/2/0220223
	Pag	ge 110	Page 112
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	.110	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL112
1	we were not issued 483s for the GMP	1	Have you had any responsibility
2	manufacturing.	2	for stability programs at Alexion?
3	BY MR. SANGIAMO:	3	MR. KELLER: Objection to form.
4	Q. Were there 483s that you were	4	THE WITNESS: What do you mean
5	involved indirectly in that were issued as a	5	by "responsibility"?
6	result of FDA inspections at Alexion?	6	BY MR. SANGIAMO:
7	MR. KELLER: Again, the caveat	7	Q. Have you had any involvement in
8	is if that 483 is publicly available,	8	stability programs at Alexion?
9	you can answer. If it's not publicly	9	MR. KELLER: Same objection.
10	available, I instruct you not to answer	10	THE WITNESS: Can you elaborate
11	pursuant to your confidentiality.	11	on "involvement"?
12	THE WITNESS: I do not know the	12	BY MR. SANGIAMO:
13	status. And, you know, as far as, I	13	Q. What are some of the aspects of
14	guess indirectly is pretty broad. I	14	the stability program at Alexion?
15	work for the company.	15	A. What are some of the aspects?
16	BY MR. SANGIAMO:	16	Q. And then if you could tell me
17	Q. It was your term.	17	which ones of those you were involved in, that
18	A. So I can't say to the status of	18	would be helpful?
19	the answer of that question based on	19	A. So the I provide quality
20	confidentiality, whether or not it's public.	20	oversight for the testing that is conducted in
21	Q. So the 483 is issued but you	21	support of stability.
22	can't describe them because you don't know	22	Q. What does it mean to provide
23	whether they are public. Is that a fair	23	quality oversight of that testing?
24	summary of what you're saying? Yes?	24	A. So that I ensure that any
	Pag	ge 111	Page 113
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	.111	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL113
1	A. Yes.	1	stability data or my team ensures that any
2	Q. A second area of FDA-related	2	stability data that's generated is reviewed,
3	work that you identified at Alexion was	3	quality reviewed. Any events that occur
4	supporting data used to submit information to	4	during the testing, stability testing, would
5	the FDA. Right?	5	be documented within a deviation and we
6	A. Yes.	6	provide quality oversight for that. Any
7	Q. What's the nature of that data	7	changes to the stability program would be
8	support work?	8	submitted through change control and provide
9	A. The manufacturing process. So	9	quality oversight for that as well.
10	we would describe the manufacturing process of	10	Q. Do you play a role in defining
11	the product. The support is reviewing the	11	the terms of the stability program?
12	data that's submitted related to the	12	MR. KELLER: Objection.
13	manufacturing.	13	THE WITNESS: What role are you
14	Q. You also referred to questions	14	referring to?
15	and then responses strike that.	15	BY MR. SANGIAMO:
16	You referred to questions from	16	Q. Any role.
17	the FDA and responses to the FDA. That would	17	A. The stability program, the
18	also be about the manufacturing processes?	18	definition or the parameters that are set by
19	A. Correct.	19	the stability, for stability is proposed by
20	Q. Are Alexion's products biologics?	20	the subject matter experts and the information
21	A. Yes.	21	or criteria being presented is reviewed by
22	Q. Do you have any involvement in	22	quality.
23	stability programs at Alexion sorry, try it	23	Q. Do you participate in that
24	again.	24	review?

29 (Pages 110 - 113)

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	Pag	ge 114		Page 116
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	_114	JOAN	L. WLOCHOWSKI -HIGHLY CONFIDENTAL116
1	A. Yes.	1	during my	time at Alexion?
2	Q. What's the nature of your	2	Q. 1	Zes.
3	participation?	3	A. I	would say maybe a dozen times.
4	A. We verify that the data being	4	Q. I	Have you ever interacted with
5	submitted would provide the appropriate	5	the CDC d	uring your time at Alexion?
6	justification for the parameters.	6	A. 1	No.
7	Q. Is that a team of people in	7	M	R. SANGIAMO: Jeff, now would
8	quality who review the proposals from the	8	be a g	bod time to break from my
9	subject matter experts?	9	perspe	ctive.
10	A. Yes.	10) M	R. KELLER: It's been an hour.
11	Q. You're one member of that team?	11	Let's t	ake a break.
12	A. Yes.	12	v v	IDEOGRAPHER: The time is now
13	Q. How many people are on that	13	11:58.	Going off the video record.
14	team?	14		
15	A. There you're just speaking	15	; (A	recess was taken.)
16	specifically to quality members?	16	,	
17	Q. I'm speaking to quality members	17		IDEOGRAPHER: The time is now
18	who review the proposals from the subject	18		This begins disc three. You
19	matter experts about the parameters of the	19		roceed.
20	stability program.	20	• •	ANGIAMO:
21	A. I can't say that it's defined	21		As. Wlochowski, your CV
22	how many members. There's at least two	22		your time at Alexion refers several
23	quality representatives. Actually it would	23		oduct disposition. What does that
24	then it depends, again, upon the extent of	24		
		115		D 117
		ge 115	IOAN	Page 117
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL			L. WLOCHOWSKI -HIGHLY CONFIDENTAL117
1	the review. It would go up to the chief of	1		released the product to the
2	quality for anything that's submitted for any	2		o the clinical sites.
3	changes in the parameters of the program.	3		You said "I released the
4	Q. Are there people other than	4		ou mean
5	those in quality who review changes in	5		Release or reject.
6	parameters of the stability programs?	6		Your group does?
7	A. Yes. It would be the head of	7		Zes.
8	the product development team as well as	8		Did you attempt in 2004 about a
9	regulatory would be part of the cross	9	• •	our tenure at Amgen to get rehired
10	functional team.	10		
11	Q. How does the approval of	11		Check on the dates. I may have
12	changes in the parameters for the stability	12		a position there.
13	program ultimately get decided, is that by	13		Did you get rejected?
14	consensus of this team?	14		didn't get called for an
15	A. Yes, I would say so.	15	interview,	if that's what you're referring to.
16	Q. How many times in your tenure	16	6 Q. I	Do you know strike that.
17	at Alexion have you participated in this kind	17	D	o you recall what the position
18	of review of the parameters of the stability	18	was that ye	ou were applying for?
19	program?	19	A. 1	Jo, I do not.
20	A. Are we talking about new	20) Q. Y	Vas there any particular reason
. .				

A. Are we talking about new 20 Q. Was there any particular reason 21 parameters or changes to parameters? 21 you wanted to leave Amgen at that time? Q. Either. Or both I should say. 22 A. Because I was commuting an hour A. I'm trying to think. I would 23 to Amgen. 24 say -- so the question is how many times 24 Q. You got no response from Pfizer

22

23

30 (Pages 114 - 117)

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D 110		D 100
Page 118		Page 120
	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL120
		document to us pursuant to your obligations?
-		MR. SANGIAMO: I assume we
-		have, but I can't I'm not
		MR. KELLER: We've never seen
-		this document based on my
		understanding. Anybody here can
		confirm this has been produced to us
		pursuant to our agreements? There's
		four lawyers here.
		MS. DYKSTRA: Do you want me to
		confirm whether this has been produced
		to you similar to the documents that
-		you provided to us that haven't been
-		produced to us? I'm not sure
		MR. SANGIAMO: We've all agreed
-		to produce third-party discovery to
		each other. So we've asked you
		specifically to produce all documents
		regarding any third-party subpoenas
		you've issued. Is this produced
		voluntarily or pursuant to a
		third-party subpoena?
		MS. DYKSTRA: I don't personally
		· · ·
-		Page 121 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL121
	1	
-		know, I'll have to find out. Sitting here today at this moment, I don't
		know.
		MR. KELLER: Are there any
-		other documents that you plan to use
		with her that haven't been produce to
		us? It's certainly unfair to our
(Exhibit Wlochowski-5, Applied		witness to get documents pursuant to
		agreement to provide them to us and not
		provide them to us in preparation for a
		client's a witness' deposition. So
BY MR. SANGIAMO:		if you're going to produce any other
		documents that you have from Pfizer
-		that you haven't provided to us, we'd
		like to know and have an opportunity to
		look at it.
		BY MR. SANGIAMO:
-		Q. We'll set aside the document
applied for a position with Pfizer in 2013 I	19	for now. I'll just ask you, Ms. Wlochowski
	20	about your recollection of applying for a
thought I would show it to you	_ 20	about your reconcerion or apprying for a
thought I would show it to you.	21	position at Pfizer in 2013 Do you know
A. Okay.	21 22	position at Pfizer in 2013. Do you know whether you did? A moment ago I think you
	21 22 23	position at Pfizer in 2013. Do you know whether you did? A moment ago I think you said you're unsure. My question to you is,
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL118 other than just they didn't get back to you. Is that right? A. I don't know if they sent me a response. Q. You have no recollection of the reason they offered for not pursuing it further with you. Is that right? A. That's right. Q. Did you apply to Pfizer again in October of 2007? A. I could have. Q. What happened that time? A. Again, same reason. I'm still commuting. I think I would as far as I recall be the reason I would have applied again. Q. How long was that commute when you were working at Amgen? A. It was an hour. Q. How long was the Pfizer commute? A. 20 minutes. Q. How long was the Pfizer commute? A. 20 minutes. Q. How long was the commute to Alexion? Page 119 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL119 A. Currently it's half-hour. Q. Did you apply to Pfizer again in 2013? A. Potentially I could have. Q. You're not sure? A. No, I don't recall. (Exhibit Wlochowski-5, Applied for job openings, was marked for identification.) BY MR. SANGIAMO: Q. Ms. Wlochowski, I've shown you a document that has been marked as Exhibit 5 which was produced to us by Pfizer. And I have no reason to believe that you've seen this document, but to the extent it might refresh your recollection about whether you	other than just they didn't get back to you.1Is that right?2A. I don't know if they sent me a3response.4Q. You have no recollection of the5reason they offered for not pursuing it6further with you. Is that right?7A. That's right.8Q. Did you apply to Pfizer again9in October of 2007?10A. I could have.11Q. What happened that time?12A. Again, same reason. I'm still13commuting. I think I would as far as I14recall be the reason I would have applied15again.16Q. How long was that commute when17you were working at Amgen?18A. It was an hour.19Q. How long was the Pfizer20commute?21A. 20 minutes.22Q. How long was the Commute to23Alexion?24JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL1191A. Potentially I could have.4Q. You're not sure?3A. Potentially I could have.4Q. You're not sure?5A. No, I don't recall.67(Exhibit Wlochowski-5, Applied611BY MR. SANGIAMO:12Q. Ms. Wlochowski, I've shown you13a document that has been marked as Exhibit 514which was produced to us by Pfizer. And I16this document, but to the extent it might

31 (Pages 118 - 121)

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1	5		
	Page 122		Page 124
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL122		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL124
1	A. According to this document,	1	Q. Do you believe you may have had
2	that's what it's showing here.	2	some indirect conversations with the CDC about
3	Q. Do you have a recollection of	3	the mumps vaccine?
4	that?	4	A. I believe I may have had
5	A. It's likely that this job	5	indirect input to information provided to the
6	description would be something that or job	6	CDC.
7	title would be something that I would be	7	Q. When did that occur?
8	interested in and apply to.	8	A. While I was at Merck.
9	Q. Do you recall what happened	9	Q. How about as regards the FDA,
10	after you applied for that position?	10	do you believe you may have had indirect input
11	A. I do not recall.	11	to information that was provided to the FDA?
12	Q. Do you recall why you applied	12	A. Yes.
13	for it?	13	Q. And if that were to have
14	A. Again, it's a job description	14	occurred, would that have occurred while you
15	title that I would have been interested in.	15	were at Merck?
16	Q. Are you presently seeking a new	16	A. Yes.
17	job?	17	Q. How about since you have left
18	A. I currently am not, no. I have	18	Merck, have you had any communication, direct
19	not applied.	19	or indirect, with the federal government about
20	Q. Have you had any discussions	20	the mumps vaccine?
21	about the mumps vaccine with anyone from the	21	MR. KELLER: All agencies of
22	federal government?	22	the federal government?
23	A. Have I had discussions with	23	MR. SANGIAMO: Yes.
24	them?	24	MR. KELLER: Lack of
	D 100		
	Page 123		Page 125
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL123	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL125
1	Q. Yes.	1	foundation. Vague and ambiguous.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	MR. KELLER: Objection.	2	THE WITNESS: So all agencies
3	Overbroad.	3	of the federal government, have I had
4	THE WITNESS: Can you clarify	4	direct or indirect information provided
5	discussions?		
6		5	to them regarding the mumps vaccine is
	BY MR. SANGIAMO:	6	what you stated?
7	Q. A conversation where you spoke	6 7	what you stated? BY MR. SANGIAMO:
8	Q. A conversation where you spoke words to a representative of the federal	6 7 8	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question
8 9	Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine.	6 7 8 9	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any
8 9 10	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. 	6 7 8 9 10	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom
8 9 10 11	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think 	6 7 8 9 10 11	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps
8 9 10 11 12	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about 	6 7 8 9 10 11 12	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm
8 9 10 11 12 13	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. 	6 7 8 9 10 11 12 13	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about?
8 9 10 11 12 13 14	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? 	6 7 8 9 10 11 12 13 14	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form.
8 9 10 11 12 13 14 15	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. 	6 7 8 9 10 11 12 13	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I
8 9 10 11 12 13 14	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. Q. You qualified your answer as to 	6 7 8 9 10 11 12 13 14 15 16	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I did meet with a Department of Justice
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8 9 10 11 12 13 14 15 16 17	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. Q. You qualified your answer as to the FDA by saying directly. Do you need that 	6 7 8 9 10 11 12 13 14 15 16 17	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I did meet with a Department of Justice about the mumps vaccine.
8 9 10 11 12 13 14 15 16 17 18	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. Q. You qualified your answer as to the FDA by saying directly. Do you need that same qualification for the CDC or can you say 	6 7 8 9 10 11 12 13 14 15 16 17 18	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I did meet with a Department of Justice about the mumps vaccine. BY MR. SANGIAMO:
8 9 10 11 12 13 14 15 16 17 18 19	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. Q. You qualified your answer as to the FDA by saying directly. Do you need that same qualification for the CDC or can you say without that qualification you have not had 	6 7 8 9 10 11 12 13 14 15 16 17 18 19	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I did meet with a Department of Justice about the mumps vaccine. BY MR. SANGIAMO: Q. All right. Any other
8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. Q. You qualified your answer as to the FDA by saying directly. Do you need that same qualification for the CDC or can you say without that qualification you have not had any conversations with the CDC about the mumps 	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I did meet with a Department of Justice about the mumps vaccine. BY MR. SANGIAMO: Q. All right. Any other conversations besides the one with the
8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. A conversation where you spoke words to a representative of the federal government about the mumps vaccine. A. I don't I'm trying to think. I can't recall a conversation. I don't think that I have had a conversation directly about the mumps with directly with the FDA. Q. How about with the CDC? A. No, I have not. Q. You qualified your answer as to the FDA by saying directly. Do you need that same qualification for the CDC or can you say without that qualification you have not had any conversations with the CDC about the mumps with experiment. 	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	what you stated? BY MR. SANGIAMO: Q. Yes, all as in the question encompasses all agencies. So if there is any agency of the federal government with whom you've had conversations about the mumps vaccine since you left Merck, that's what I'm asking about? MR. KELLER: Objection to form. THE WITNESS: I have so I did meet with a Department of Justice about the mumps vaccine. BY MR. SANGIAMO: Q. All right. Any other conversations besides the one with the Department of Justice?

32 (Pages 122 - 125)

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	Page 126		Page 128
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL126		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL128
1	discussion you had with the Department of	1	that right?
2	Justice?	2	A. Yes.
3	MR. KELLER: I object. Her	3	Q. What was your degree in?
4	discussion with the Department of	4	A. Medical technology.
5	Justice give us a second.	5	Q. That's a Bachelor of Arts degree?
6	You can ask her generally about	6	A. Yes.
7	when she spoke with the DOJ, who was at	7	Q. Did you ever apply to graduate
8	that meeting, how many times she met at	8	school?
9	that meeting, but I'm going to instruct	9	A. No.
10	her not to answer any questions	10	Q. Did you ever think about
11	regarding what was discussed at that	11	applying to graduate school?
12	meeting with the Department of Justice.	12	A. No.
13	BY MR. SANGIAMO:	13	Q. Do you know if Mr. Krahling
14	Q. How many times have you met	14	ever applied to graduate school?
15	with the Department of Justice?	15	A. I do not know.
16	A. I met with them once.	16	Q. You have something called a
17	Q. When was that?	17	medical technologist certification from the
18	A. Between 2010 and 2012, I think	18	American Society for Clinical Pathology. Is
19	it was. I think it was 2012. I can't	19	that right?
20	remember.	20	A. Correct.
21	Q. Who was present at the meeting?	21	Q. When did you get that?
22	A. Actually I guess it was	22	A. When I at the time I
23	yeah, I guess it was more yeah, okay. I	23	graduated I took that certification.
24	can't recall the date, but between 2010 and	24	Q. Does that entitle you to do
	Page 127		Page 129
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL127		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL129
1	2012.	1	anything in particular that you could not do
2	Q. Who was present at the meeting?	2	without the certification?
3	A. My legal counsel was present as	3	A. Yes, I believe the
4	well as a representative from the DOJ.	4	certification allows you to be a medical
5	Q. You say your legal counsel was	5	technologist level versus without it you
6	present. Is that Mr. Keller?	6	would, I think the at least at the time I
7	A. Yes.	7	was working in that field, I think they called
8	Q. Who was the representative from	8	it a medical laboratory technician. So an MLT
9	the DOJ, if you remember?	9	versus an MT. There's different without
10	A. Joel was his first name.	10	the certification, it's a lower level position
11	Q. Anyone else present?	11	that you can perform in the lab.
12	A. I don't there were a room of	12	Q. Is that a matter of state
13	people. I don't remember who they were.	13	licensing requirements or is that just
14	Q. Were they lawyers?	14	something else?
15	A. That's my understanding, yes.	15	A. I think it's just based on I
16	Q. What was discussed at the	16	don't know the licensing requirements. It was
17	meeting?	17	just a certification that the hiring staff
18	MR. KELLER: I'm going to	18	would be looking for.
19	instruct the witness not to answer.	19	Q. We've been talking a lot this
20	Attorney-client privilege, work	20	morning about what you did and did not do at
21	product. Prosecution.	21	your prior jobs. I want to see if I've got it
22	BY MR. SANGIAMO:	22	right on a few specific points. Is it correct
23	Q. Ms. Wlochowski, do I have it	23	that other than at Merck, you have never run a
23	right that you are a college graduate? Is	24	plaque reduction neutralization assay to test

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	Pag	e 130		Page 13
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	130	JOA	AN L. WLOCHOWSKI -HIGHLY CONFIDENTAL132
1	response to vaccination?	1	I've	e had?
2	A. That's correct.	2	BY MR	R. SANGIAMO:
3	Q. Other than at Merck, you have	3	Q.	Yes.
4	never run any assay to test response to	4	А.	I guess I might be a little
5	vaccination other than the ELISA assay that	5		about that. So if I was at Merck,
6	you ran at Pfizer. Is that correct?	6		gain, the testing I was performing at
7	A. Correct.	7		would could potentially be used to
8	Q. At none of your jobs have you	8	• •	a product labeling.
9	interacted with the CDC. Is that correct?	9		Did anyone, while you were at
10	A. Correct. Directly.	10		ask you to review the labeling as part
11	Q. Subject to the limitation you	11	-	job function?
12	described a few minutes ago?	12		Specifically the document
13	A. Correct.	13		
14	Q. And your only direct interactions	14	~	Yes.
15	with the FDA at any job have been related to	15		No.
16	manufacturing issues. Is that fair?	16		Did I hear you testify that you
17	A. Correct.	17		viewed some draft labeling at one of
18	Q. I asked you some questions	18		bs? Is that right?
19	specific to one of your jobs, and honestly	19		
20	right now I can't remember which one it was,	20		Which job was that?
21	about any role in product labeling. Let me	21		Alexion.
22	just ask you more generally, for any of the	22		What was the draft labeling
23	positions that you have held at any	23		a reviewed?
24	pharmaceutical company, have you reviewed	24	A.	What was it?
	•	e 131		Page 13
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL			AN L. WLOCHOWSKI -HIGHLY CONFIDENTAL133
1	drafts of labeling?	1		Yes.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. Yes.	2		The product insert as well as
3	Q. Were any of the drafts of	3		on and the label.
4	labeling that you reviewed related to labeling	4	Q.	What were the circumstances of
6	for vaccine efficacy?	-		
7	A. No.Q. Were any of them related to			I provide quality oversight for roval of the changes that are made in
8	labeling for vaccine effectiveness?	8		6
9	A. No.	9		What do you mean by providing
10	Q. Were any of them related to	10		oversight for that?
11	labeling for vaccine immunogenicity?	11		The again, the changes that
12	A. No.	12		ng made would be supported by other
12	Q. Have you, as part of your work,	13		entation that would allow for the change.
14	ever been called upon to decide strike	14		build verify that the information is
15	that.	15		ed and that the content is correct.
16	Have you, as part of your work,	16		Did any of those changes
17	ever been called upon to review vaccine	17		product efficacy?
18	labeling on any topic?	18		I can't recall. I don't recall
19	A. Have I been called upon to	19		re was a specific change for efficacy.
20	review vaccine labeling on any topic?	20		There wouldn't be any reason
21	MR. KELLER: As part of her job	21	-	in your position to review label
22	duties?	22		related to product efficacy, would
23	MR. SANGIAMO: Yes.	23		t Alexion?
24		24		
24	THE WITNESS: In any job that	24	ļ	MR. KELLER: Objection. Calls

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	D 104		P 126
	Page 134		Page 136
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL134	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL136
1	for speculation.		So it's my basic knowledge of requirements for
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	THE WITNESS: So at the time	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	a label.
3	that I did have oversight for the	3	Q. What are those regulations as
4	labels, I would provide a review of any	4	they pertain to descriptions of vaccine
5	label change from a quality perspective.	5	efficacy, if you know?
6	BY MR. SANGIAMO:	6	A. I don't I mean, I don't know
7	Q. Would you be involved in a	7	the specific CFRs. I do know that there is
8	decision as to whether efficacy information in	8	GMP requirements to ensure that your label is
9	a label accurately described the efficacy of	9	an accurate representation of the product.
10	the product?	10	Q. Is it your testimony that GMP
11	MR. KELLER: If that was the	11	requirements are applicable to descriptions of
12	label change that was going to happen?	12	efficacy on vaccine labeling?
13	THE WITNESS: Can you repeat	13	A. Yes.
14	that again? Sorry.	14	Q. What section do you know the
15	BY MR. SANGIAMO:	15	section of the code that imposes that
16	Q. Would you be involved in a	16	obligation?
17	decision as to whether efficacy information in	17	A. Not off the top of my head, no.
18	a label accurately described the efficacy of	18	Q. Do you have any training in
19	the product?	19	your view that would qualify you to opine on
20	MR. KELLER: Again, the same.	20	the cause of an outbreak?
21	It's vague and ambiguous.	21	А. То
22	THE WITNESS: If the label	22	MR. KELLER: Objection as to
23	change was for efficacy, you're asking	23	form.
24	if I would be involved in the decision,	24	THE WITNESS: So you're asking
	Page 135		Page 137
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL135		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL137
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL135 whether that was acceptable?	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL137 if I could determine the cause of an
1 2		1 2	
	whether that was acceptable?		if I could determine the cause of an
2	whether that was acceptable? BY MR. SANGIAMO:	2	if I could determine the cause of an outbreak?
2 3	whether that was acceptable? BY MR. SANGIAMO: Q. Yes.	2 3	if I could determine the cause of an outbreak? BY MR. SANGIAMO:
2 3 4	whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there	2 3 4	if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any
2 3 4 5	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight 	2 3 4 5	if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to
2 3 4 5 6	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and 	2 3 4 5 6	if I could determine the cause of an outbreak?BY MR. SANGIAMO:Q. I'm asking if you had any training that would put you in a position to make those determinations?
2 3 4 5 6 7	whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made.	2 3 4 5 6 7	if I could determine the cause of an outbreak?BY MR. SANGIAMO:Q. I'm asking if you had any training that would put you in a position to make those determinations?MR. KELLER: Same objection.
2 3 4 5 6 7 8	whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with	2 3 4 5 6 7 8	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had
2 3 4 5 6 7 8 9	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? 	2 3 4 5 6 7 8 9	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an
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2 3 4 5 6 7 8 9 10 11	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, 	2 3 4 5 6 7 8 9 10 11	if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to
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2 3 4 5 6 7 8 9 10 11 12 13	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. 	2 3 4 5 6 7 8 9 10 11 12 13	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a
2 3 4 5 6 7 8 9 10 11 12 13 14	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the 	2 3 4 5 6 7 8 9 10 11 12 13 14	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the regulations that govern descriptions of efficacy on vaccine labeling? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that. BY MR. SANGIAMO: Q. If you had that information, do
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the regulations that govern descriptions of efficacy on vaccine labeling? A. I am not currently familiar 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that. BY MR. SANGIAMO: Q. If you had that information, do you have the training in order to make the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the regulations that govern descriptions of efficacy on vaccine labeling? A. I am not currently familiar with the specific regulations. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that. BY MR. SANGIAMO: Q. If you had that information, do you have the training in order to make the assessment?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the regulations that govern descriptions of efficacy on vaccine labeling? A. I am not currently familiar with the specific regulations. Q. You once were? A. I do have knowledge of some, 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that. BY MR. SANGIAMO: Q. If you had that information, do you have the training in order to make the assessment? MR. KELLER: Same objection.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the regulations that govern descriptions of efficacy on vaccine labeling? A. I am not currently familiar with the specific regulations. Q. You once were? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that. BY MR. SANGIAMO: Q. If you had that information, do you have the training in order to make the assessment? MR. KELLER: Same objection. THE WITNESS: That is not I do not hold a role that would make
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 whether that was acceptable? BY MR. SANGIAMO: Q. Yes. A. The as far as yes, there would be some element of a quality oversight to ensure that the data was verified and supported the change that was being made. Q. Did that ever happen with regard to an efficacy label change? A. I think that you had asked that question previously that I didn't wasn't, that I can recall, involved in any label change with regard to efficacy. Q. Are you familiar with the regulations that govern descriptions of efficacy on vaccine labeling? A. I am not currently familiar with the specific regulations. Q. You once were? A. I do have knowledge of some, you know, regulations that require that the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 if I could determine the cause of an outbreak? BY MR. SANGIAMO: Q. I'm asking if you had any training that would put you in a position to make those determinations? MR. KELLER: Same objection. THE WITNESS: Have I had training to determine the cause of an outbreak? I basically wouldn't have I don't have any information related to an outbreak to be able to determine what it is. It's not I'm not in a position to do that. BY MR. SANGIAMO: Q. If you had that information, do you have the training in order to make the assessment? MR. KELLER: Same objection. THE WITNESS: That is not I

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	Page 138		Page 14
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL138		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL140
1	BY MR. SANGIAMO:	1	for purposes of a vaccine?
2	Q. Do you have any training that	2	A. Would I have to understand what
3	would position you to determine the efficacy	3	the requirements were by the FDA? I' sorry, I
4	of a vaccine?	4	missed the first part of the question.
5	MR. KELLER: Objection. Vague	5	Q. At any job, would it have been
6	and ambiguous. Overbroad.	6	part of your job responsibilities to be aware
7	THE WITNESS: Do I have	7	of how the FDA defines efficacy for a vaccine?
8	training to determine the efficacy of a	8	MR. KELLER: Lack of foundation.
9	vaccine?	9	THE WITNESS: Is it a
10	BY MR. SANGIAMO:	10	requirement of my job, is that what
11	Q. Uh-huh.	11	you're asking me?
12	MR. KELLER: Same objection.	12	BY MR. SANGIAMO:
13	THE WITNESS: I guess I would	13	Q. Okay. Yes.
14	ask to elaborate on that because	14	A. I don't know that it would be
15	there's, as far as being able to	15	the for a vaccine, the requirement of my
16	generate data to determine efficacy, I	16	job to know that at the time. Basically the
17	do have training around that.	17	only time I would be doing that would be at
18	BY MR. SANGIAMO:	18	Merck. It wasn't the expectation of the level
19	Q. What methodology would you use	19	that I was performing the work that I would
20	to determine a vaccine efficacy rate?	20	have that understanding of what the FDA
21	MR. KELLER: Objection.	21	defined as efficacy.
22	THE WITNESS: So I guess	22	Q. The same question as to the
23	MR. KELLER: Wait. Let me	23	CDC, at any job would it have been a
23	finish the objection.	24	requirement for you to have an understanding
	•	24	
	Page 139		Page 14
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL139		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL141
1	THE WITNESS: I'm sorry.	1	of how the CDC defines vaccine efficacy?
2	MR. KELLER: Objection. Vague	2	MR. KELLER: Objection. Lack
3	and ambiguous. Lack of foundation.	3	of foundation.
4	Overbroad. You can answer.	4	THE WITNESS: So, again, my
5	BY MR. SANGIAMO:	5	only work with vaccines was while I was
6	Q. Mr. Keller makes a good point,	6	at Merck as well as Pfizer, and the
7	that did lack foundation.	7	it was not, based on the work I was
8	Do you know the methodologies	8	performing in the laboratory, not a
9	that are used to determine the efficacy of a	9	requirement for me to have that
10	vaccine?	10	understanding or the knowledge of the
11	MR. KELLER: Again, objection.	11	definition defined by CDC.
10		1.1.2	DV MD CANCIAMO

11 definition defined by CDC.

clinical significance, meaning? Can

iii iiii iiii iiii iiii iiiii iiiiiiii	The dominion domined by CDC.
12 Vague and ambiguous. Overbroad.	12 BY MR. SANGIAMO:
13 THE WITNESS: So in your	13 Q. You've given testimony today
14 question with efficacy, can you define	14 describing your experiences as running
15 what you're referring to as efficacy?	15 serology tests. Correct?
16 BY MR. SANGIAMO:	16 A. Correct.
17 Q. Efficacy as the FDA would	17 Q. Has any part of your job duties
18 define it, do you know what that is?	18 including evaluating the clinical significance
19 A. I do not have that in front of	19 of the results of those serology results at
20 me at this time, so I do not, can't explain	20 any job?
21 it.	21 MR. KELLER: Objection. Vague
22 Q. Have you ever as part of your	22 and ambiguous. Lack of foundation.
23 job responsibilities at any employer had to be	23 THE WITNESS: When you say

24 cognizant of how the FDA would define efficacy

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL142		JOAN	L. WLOCHOWSKI -HIGHLY CONFIDENTAL144
1	you elaborate on that?	1	A. Y	es, I understand what the
2	BY MR. SANGIAMO:	2	different re	sults would mean in the clinical
3	Q. Implications for the relationship	3	setting.	
4	between the serology findings and human disease.	4	Q. Y	You have training in that?
5	A. Was it my responsibility between	5	A. I	have basic training for
6	serology to define or understand the	6	understand	ing what the methods are that we
7	serology findings sorry, I'm getting	7	were perfo	rming.
8	confused. And	8	Q. V	What the methods of the assays
9	I'm sorry. Can you repeat it	9	were?	
10	again?	10	А. У	/es.
11	Q. I was asking you earlier today	11	Q. I	Do you have any training in
12	about your work at New Haven Hospital.	12	understand	ing strike that.
13	A. Yes.	13	De	o you have any training in
14	Q. And you were describing tests	14	evaluating	what the clinical significance is
15	that you ran on clinical samples. I think I	15	of the resul	Its of those methods?
16	asked you whether it was up to you or up to	16	A. E	Based on training that I was
17	the doctor to figure out what those test	17	provided p	otentially by my supervisor or
18	results implied for disease. Right?	18	information	n that was provided to me during the
19	A. Yes.	19	course of c	onducting the studies, I have been
20	Q. I think you told me that was	20	trained in t	hat sense.
21	told by the doctor?	21	Q. 1	That was information that was
22	A. Correct.	22	provided to	you not in order for you to do
23	Q. I'm asking the same kind of	23	your job, jı	ast provided to you as additional
24	question now for your other jobs, as to	24	information	n. Is that right?

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	Page 143		Page 145
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL143		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL145
1	whether it's your role in any job to determine	1	MR. KELLER: Objection.
2	what the clinical significance was from a	2	Overbroad.
3	human disease perspective	3	THE WITNESS: I mean, there are
4	A. I got you.	4	requirements of me to be trained in
5	Q of the serology work that	5	order to do my job as well as any
6	you did?	6	information that was provided to me
7	A. No, I was not the decision-maker	7	while I was at my job.
8	on the output of the data that was provided	8	BY MR. SANGIAMO:
9	from the testing that we performed in the	9	Q. But your job consisted of
10	laboratory.	10	running the serology. Right?
11	Q. You wouldn't be qualified to do	11	A. That was my responsibility at
12	that. Right?	12	the time, yes.
13	A. I wouldn't	13	MR. KELLER: Are we just
14	MR. KELLER: Objection. Vague	14	talking about Yale, or are we I'm
15	and ambiguous.	15	confused.
16	THE WITNESS: I mean, I do have	16	MR. SANGIAMO: No, we're
17	qualifications, I have a basic	17	talking about all of her involvement.
18	understanding of what the outputs mean.	18	I think she understands.
19	But it wasn't my responsibility at that	19	BY MR. SANGIAMO:
20	level to be doing that.	20	Q. You've been answering for all
21	BY MR. SANGIAMO:	21	your jobs. Right?
22	Q. Do you have any training in	22	A. Yes.
23	understanding what the clinical significance	23	Q. Would you know a methodology to
24	is of serology results?	24	use if were you were trying to evaluate what

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23 the general protocol that would be used with

24 different types of measures and outcomes to --

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	Page 146		Page 148
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL146		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL148
1	the clinical significance was of, say, a	1	because there is also that that's involved.
2	seroconversion rates from a vaccine clinical	2	Q. If you run a serology test, you
3	trial?	3	get information about the serum that was
4	MR. KELLER: Objection. Vague	4	tested from that individual. Right?
5	and ambiguous. Lack of foundation.	5	MR. KELLER: Objection. Vague
6	Overbroad.	6	and ambiguous. Lack of foundation.
7	THE WITNESS: Yeah, I mean, it	7	THE WITNESS: I guess
8	depends on what you're trying to	8	information is very general there. So
9	measure. So there's no different types	9	it's very limited information.
10	of methodology. Different types of	10	BY MR. SANGIAMO:
11	methodology works better for one	11	Q. That's the point. Whatever the
12			
	vaccine or virus versus the other,	12	information you get, it's about the serum.
13	SO	13	Right?
14	BY MR. SANGIAMO:	14	MR. KELLER: Same objections.
15	Q. Can you provide some examples?	15	THE WITNESS: On the the
16	MR. KELLER: Objection. Calls	16	serum is typically a number that
17	for speculation. Overbroad. Lack of	17	identifies the serum.
18	foundation.	18	BY MR. SANGIAMO:
19	THE WITNESS: I mean, again,	19	Q. And what that information about
20	even just within the plaque assay	20	the serum means clinically for the patient is
21	itself we could be seeing different	21	a different question entirely. Right?
22	strains of virus. There could be, you	22	MR. KELLER: You guys are
23	know, any type of other assay that, you	23	talking past each other. Vague and
24	know, whether it's hemagglutination	24	ambiguous. Lack of foundation.
	Page 147		Page 149
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL147		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL149
1	assay or some other type of assay that,	1	THE WITNESS: What the serum
2	you know, would be tacting [ph] based	2	means for the patient?
3	on the different type of virus.	3	BY MR. SANGIAMO:
4	BY MR. SANGIAMO:	4	Q. What the information about the
5	Q. You've just described different	5	serum means clinically for the patient is an
6	ways in which an assay could be run. Correct?	6	entirely different question. Correct?
7	A. Or different assays.	7	MR. KELLER: Vague and
8	Q. Or different assays. My	8	C
		9	ambiguous. Overbroad.
9	question is, what methodology would you use to		THE WITNESS: Once we test the
10	determine what the clinical significance was	10	serum
11	of the output of those assays?	11	BY MR. SANGIAMO:
12	MR. KELLER: Objection. Vague	12	Q. Yes.
13	and ambiguous.	13	A the results are does
14	THE WITNESS: When you say	14	relate back to the patient. I guess I'm not
15	"methodology," you're not referring	15	understanding what you're trying to ask
16	to so, I guess, define methodology	16	specifically.
17	in your sentence there.	17	Q. Have you ever undertaken to
18	BY MR. SANGIAMO:	18	figure out whether a certain antibody level
19	Q. Do you not know what a	19	correlates with protection from disease?
20	methodology would be in order to determine the	20	MR. KELLER: Objection.
21	clinical significance of serology results?	21	Overbroad. Vague and ambiguous.
22	A. I mean, are we talking about	22	THE WITNESS: I have been I
		1	

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have been involved in running assays

that would help to determine the

14

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18

19

20

21

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23

24

that you have you learned from counsel,

question, any communications with your

I instruct you not to answer the

counsel. To the extent you have

information that's independent of

can answer.

BY MR. SANGIAMO:

discussions you had with counsel, you

Q. So the question is, do you know

anything about the CDC's decision-making

process regarding the purchasing of vaccines

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	Page 150		Page 152
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL150		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL152
1	correlation of the antibody, yes, level	1	but you should exclude from your answer
2	in a serum.	2	anything that you've learned from your
3	BY MR. SANGIAMO:	3	counsel?
4	Q. Have you ever been involved in	4	A. Do I know anything is the
5	the determination of whether those antibody	5	question?
6	levels, whatever they are, are correlated with	6	Q. Yes.
7	protection from disease?	7	A. Right, I do.
8	A. In the sense that I perform the	8	Q. Where did you learn that other
9	assay, that's my involvement.	9	than from your counsel?
10	Q. Any other involvement?	10	A. I know that the label is
11	A. Not that I can think of, no.	11	public, so that information is available to
12	Q. Have you ever designed a	12	the CDC in determining a decision on whether
13	clinical trial?	13	or not to purchase a product.
14	A. No.	14	Q. Anything else?
15	Q. Do you know anything about the	15	A. I think that's it.
16	CDC's decision-making process when it decides	16	Q. Do you know whether the CDC, in
17	whether to purchase a vaccine?	17	fact, looks to the label in order to determine
18	MR. KELLER: Objection.	18	whether to purchase the product?
19	Overbroad.	19	MR. KELLER: Objection. Vague
20	THE WITNESS: I know that I	20	and ambiguous.
21	know that they would	21	THE WITNESS: I cannot say what
22	BY MR. SANGIAMO:	22	the CDC does.
23	Q. It's a yes or no question. Do	23	BY MR. SANGIAMO:
24	you know?	24	Q. Because you just don't know.
	Page 151		Page 153
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL151		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL153
1	A. All right. Can you state the	1	Right?
2	question again?	2	MR. KELLER: Same objection.
3	Q. Do you know anything about the	3	BY MR. SANGIAMO:
4	CDC's decision-making process regarding the	4	Q. Right?
5	purchasing of vaccines?	5	A. Yes.
6	A. Yes.	6	
7	Q. What's your basis of that	7	(Exhibit Wlochowski-6, Amended
8	knowledge?	8	Complaint for Violations of the Federal
9	A. I know that they receive	9	False Claims Act, was marked for
10	Q. What's your basis?	10	identification.)
11	A. What's my basis?	11	
12	MR. KELLER: Vague. Argumentative.	12	BY MR. SANGIAMO:
13	And the extent that the information	13	Q. Ms. Wlochowski, you've been
14		14	

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14 handed what's been marked as Exhibit 6. Are

be very careful now when you answer my

invade the attorney-client privilege.

questions because I want to make sure I don't

need to make sure to give Mr. Keller a chance

This is a copy of the Complaint.

Did you play any -- you should

Right now my question is -- you

15 you familiar with that document?

What is it?

A. Yes.

Q.

Α.

Q.

		ge .	
	Page 154		Page 156
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL154		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL156
1	to object.	1	of the Complaint that refers to information
2	My question is, did you play	2	provided by Steve Krahling that I can only say
3	any role in the drafting of this Complaint?	3	that it's accurate based on what he has
4	A. Yes.	4	provided.
5	Q. Did you draft any of the	5	MR. KELLER: I assume you're
6	original language in the Complaint?	6	going to ask her if she understands the
7	MR. KELLER: You can answer it	7	legal jargon that's also in this
8	yes or no.	8	Complaint, as to the accuracy of the
9	I'm going to object. Vague and	9	legal jargon as well? Are you asking
10	ambiguous. Objection.	10	about the facts or are you asking
11	THE WITNESS: I guess by	11	BY MR. SANGIAMO:
12	original I did provide information that	12	Q. I'm asking about the facts, and
13	was used in the drafting of this	13	I heard your answer which I understood to be
14	Complaint.	14	that there are some things in there factually
15	BY MR. SANGIAMO:	15	that you know to be true. There are other
16	Q. Do you recall what information	16	things in there factually that to the extent
17	you provided?	17	you know anything about them, you know it from
18	MR. KELLER: Objection. I'm	18	Mr. Krahling. Is that right?
19	going to instruct you not to answer.	19	A. Correct.
20	BY MR. SANGIAMO:	20	Q. Could you identify what
21	Q. Did you review that Complaint	21	portions of the Complaint fall into that
22	prior to sorry, strike that.	22	latter category?
23	Did you review a final version	23	MR. KELLER: Do we have a week
24	of that Complaint prior to it being filed?	24	to do that? Sure.
	Page 155		Page 157
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL155		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL157
1	A. Yes.	1	MR. SANGIAMO: Is it all from
2	Q. Was there anything in there	2	Krahling?
3	that appeared to be inaccurate to you?	3	MR. KELLER: Excuse me?
4	A. With the exception of the	4	MR. SANGIAMO: So much of it
5	initial of my first name, no.	5	was from Krahling that it would take a
6	MR. KELLER: Take full	6	long time to identify?
7	responsibility for that.	7	MR. KELLER: There's how many
		1	

	Page 155		Page 157
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL155		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL157
1	A. Yes.	1	MR. SANGIAMO: Is it all from
2	Q. Was there anything in there	2	Krahling?
3	that appeared to be inaccurate to you?	3	MR. KELLER: Excuse me?
4	A. With the exception of the	4	MR. SANGIAMO: So much of it
5	initial of my first name, no.	5	was from Krahling that it would take a
6	MR. KELLER: Take full	6	long time to identify?
7	responsibility for that.	7	MR. KELLER: There's how many
8	THE WITNESS: I should say my	8	paragraphs in this Complaint? It's
9	middle initial.	9	your deposition. If you want to ask
10	BY MR. SANGIAMO:	10	her questions as to every line that
11	Q. Other than that?	11	of information that she knows, can
12	MR. KELLER: Color it out.	12	verify herself.
13	THE WITNESS: No, I didn't see	13	BY MR. SANGIAMO:
14	anything inaccurate.	14	Q. Are there any that you know of
15	BY MR. SANGIAMO:	15	that fall into that latter category?
16	Q. Can you vouch for the accuracy	16	MR. KELLER: Feel free to
17	of everything that is in there?	17	review the Complaint.
18	MR. KELLER: Objection. Vague	18	BY MR. SANGIAMO:
19	and ambiguous.	19	Q. I'm not asking for an
20	BY MR. SANGIAMO:	20	exhaustive list. If there are any that come
21	Q. Do you understand how it's	21	to mind.
22	different from the last question I asked you?	22	MR. KELLER: Objection.
23	A. Yes.	23	THE WITNESS: Not that I know
24	Q. So there are certain sections	24	of offhand without looking through the

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	Page 158		Page 160
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL158		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL160
1	document.	1	A. Right.
2	BY MR. SANGIAMO:	2	Q. Did your attorneys draft these
3	Q. You just have a recollection of	3	answers and then you approved them or did you
4	having looked at it previously and seeing	4	draft the answers?
5	there were some things in there that Krahling	5	MR. KELLER: Objection. It's
6	knew about, but you, yourself, didn't know	6	vague and ambiguous. Overbroad.
7	about. Is that fair?	7	Invades work product. I'm going to
8	A. The only way I knew about it	8	instruct the witness not to answer that
9	was through Krahling, yes.	9	question.
10		10	MR. SANGIAMO: On the basis of
11	(Exhibit Wlochowski-7, Relator	11	attorney-client privilege?
12	Joan Wlochowski's Responses and	12	MR. KELLER: And work product,
13	Objections to Merck's Revised First Set	13	yes.
14	of Interrogatories, was marked for	14	BY MR. SANGIAMO:
15	identification.)	15	Q. Did anyone other than you and
16		16	your attorneys participate in drafting these
17	BY MR. SANGIAMO:	17	answers?
18	Q. Ms. Wlochowski, you've been	18	A. So the
19	handed what's been marked as Exhibit 7. My	19	MR. KELLER: His question is,
20	question to you is whether you recognize that	20	did anybody other than you and your
21	document?	21	attorneys draft this without telling
22	A. Yes, I do recognize this	22	him who drafted each of the two groups
23	document.	23	or together?
24	Q. What is that document?	24	THE WITNESS: So there were two
	Page 159		Page 161
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL159		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL161
1	A. This is the Interrogatories	1	sets of Interrogatories, as I recall,
2	that were submitted that we have responded to.	2	one was for myself and one was for
3	Q. If you go to the second to the	3	Steve. Most of the questions were the
4	last page, you see there is a verification	4	same. So we did a
5	there.	5	MR. KELLER: I want you to be
6	A. Yes.	6	very careful. Do not describe his
7	Q. Is that your signature?	7	question to you is did anybody other
8	A. Yes.	8	than your lawyers and yourself prepare
9	Q. When you signed that, did you	9	these responses. He's asking for
10	review the final version prior to signing?	10	anybody else.
11	A. Yes.	11	MR. SANGIAMO: Exhibit 7.
12	Q. Is everything in the final	12	MR. KELLER: Yes. Not anything
13	version accurate?	13	about what was written down. Do you
14	A. Yes. According to my signature	14	understand the question?
15	and, again, according to what I know from	15	THE WITNESS: Yes. I guess
16	Steve.	16	it's a little, you know so Steve was
17	Q. Where there was information in	17	involved in discussions but as far as
18	these answers that derived from Steve, did you	18	the responses, that was my agreement,
19	make that evident, the substance of the	19	my signature on this document.
20	answer?	20	BY MR. SANGIAMO:
21	A. I would have to go back and	21	Q. Steve was involved in discussions
22	look at that.	22	about what the content of the answer should
23	Q. You just don't have a	23	be. Is that correct?
24	recollection one way or the other?	24	A. In the instances where it
24			

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1	Page 162		Page 164
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL162		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL164
1	applied to both of us.	1	MS. DYKSTRA: It's how we
2	MR. KELLER: His question	2	received it.
3	was the answer is that Steve	3	MR. KELLER: Thank you.
4	Krahling was involved in responding to	4	VIDEOGRAPHER: The time is
5	these interrogatories as well.	5	1:08. Off the video record.
6	Correct?	6	
7	THE WITNESS: When	7	(A recess was taken.)
8	MR. SANGIAMO: Yes or no. Very	8	
9	specific because it's a privilege	9	VIDEOGRAPHER: The time is now
10	question. Yes or no.	10	2:08. This begins disc four. You may
11	THE WITNESS: Yes for the	11	proceed.
12	questions that referred that were	12	BY MR. SANGIAMO:
13	posed to both of us.	13	Q. Ms. Wlochowski, is it your
14	BY MR. SANGIAMO:	14	belief that there has been significantly
15	Q. Could we look at Interrogatory	15	diminished efficacy for the mumps component of
16	Number 5 which is on page 10. This is an	16	the MMR?
17	Interrogatory that is directed at you, not to	17	MR. KELLER: Objection.
18	both of you. Right?	18	Overbroad.
19	A. Right.	19	THE WITNESS: So in the sense
20	Q. Did Mr. Krahling provide any of	20	you're referring to efficacy in which
21	the information that went into the response to	21	definition?
22	Interrogatory Number 5?	22	BY MR. SANGIAMO:
23	MR. KELLER: Hold on a second.	23	Q. I'm asking you if those words
24	I'll let you answer that.	24	reflect your belief, do they or not?
	Page 163		Page 165
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL163		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL165
1	THE WITNESS: So the answer is	1	MR. KELLER: Objection. Vague
2	no, Steve did not. The only response	2	and ambiguous. Overbroad. Lack of
3	the response to Question Number 5		
		3	foundation.
4	sorry, it's been a while. The response	3	
4 5	sorry, it's been a while. The response		foundation. THE WITNESS: So again.
		4	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree
5	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO:	4 5	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection.
5 6	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from	4 5 6	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree
5 6 7	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling?	4 5 6 7	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me.
5 6 7 8 9	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting	4 5 6 7 8	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last
5 6 7 8 9 10	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response.	4 5 6 7 8 9 10	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection.
5 6 7 8 9 10 11	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood.	4 5 6 7 8 9 10 11	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying
5 6 7 8 9 10 11 12	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going	4 5 6 7 8 9 10 11 12	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused.
5 6 7 8 9 10 11 12 13	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for	4 5 7 8 9 10 11 12 13	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to
5 6 7 8 9 10 11 12 13 14	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for lunch now. Before we do that, I just	4 5 7 8 9 10 11 12 13 14	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to the question is whether the mumps
5 6 7 8 9 10 11 12 13 14 15	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for lunch now. Before we do that, I just want to mention that there was some	4 5 6 7 8 9 10 11 12 13 14 15	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to the question is whether the mumps did you say mumps vaccine?
5 6 7 8 9 10 11 12 13 14 15 16	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for lunch now. Before we do that, I just want to mention that there was some discussion earlier about Exhibit 5 and	4 5 6 7 8 9 10 11 12 13 14 15 16	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to the question is whether the mumps did you say mumps vaccine? BY MR. SANGIAMO:
5 6 7 8 9 10 11 12 13 14 15 16 17	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for lunch now. Before we do that, I just want to mention that there was some discussion earlier about Exhibit 5 and whether it had been produced, and looks	4 5 6 7 8 9 10 11 12 13 14 15 16 17	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to the question is whether the mumps did you say mumps vaccine? BY MR. SANGIAMO: Q. Yes, the mumps component of
5 6 7 8 9 10 11 12 13 14 15 16 17 18	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for lunch now. Before we do that, I just want to mention that there was some discussion earlier about Exhibit 5 and whether it had been produced, and looks like it was produced on March 20, 2017.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to the question is whether the mumps did you say mumps vaccine? BY MR. SANGIAMO: Q. Yes, the mumps component of MMR, has it had a significantly diminished
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	sorry, it's been a while. The response to Question Number 5 was by myself. BY MR. SANGIAMO: Q. With no contribution from Mr. Krahling? A. Correct. During the drafting of the response. Q. Right. Understood. MR. SANGIAMO: Jeff, I'm going to suggest we go ahead and break for lunch now. Before we do that, I just want to mention that there was some discussion earlier about Exhibit 5 and whether it had been produced, and looks like it was produced on March 20, 2017. MR. BEGLEITER: Is this the	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	foundation. THE WITNESS: So again. MR. SANGIAMO: Definitely agree with that last objection. MR. KELLER: Excuse me. MR. SANGIAMO: I said I definitely agree with that last objection. MR. KELLER: Are you testifying now? Is that a question? I'm confused. THE WITNESS: So going back to the question is whether the mumps did you say mumps vaccine? BY MR. SANGIAMO: Q. Yes, the mumps component of MMR, has it had a significantly diminished efficacy, in your view?
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1	Page 166		Page 168
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL166		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL168
1	vaccine, whether or not it's effective	1	controlled field trials which demonstrated a
2	in protecting against mumps, based on	2	high degree of protected efficacy afforded by
3	my experience working in Dave Krah's	3	the individual components, and it references
4	lab, I did see that the testing that	4	studies that were done with the original
5	was conducted while I was there showed	5	approval of the mumps component of the product
6	results that were not aligned with	6	back in 1967 in support of that statement.
7	what's being reported in the label	7	And then there is another statement within the
8	currently.	8	label that says that the MMR II is highly
9	BY MR. SANGIAMO:	9	immunogenic and generally well tolerated. And
10	Q. So is it your belief that there	10	the studies for that showed that there was
11	has been a significantly diminished efficacy	11	mumps neutralizing antibody in 96 percent of
12	of the mumps component of MMR?	12	vaccinees. I should say yes, sorry, of the
13	MR. KELLER: Objection. Asked	13	susceptible persons in that statement.
14	and answered. Vague and ambiguous.	14	Q. Is it your belief that the
15	Overbroad.	15	information there about the detection of mumps
16	THE WITNESS: So, again, the	16	neutralizing antibodies in 96 percent of
17	based on the data and information that	17	susceptible persons, so that's a statement
18	was provided while I was working in	18	about efficacy?
19	Dave Krah's lab, it did show that there	19	A. In my definition of efficacy it
20	was less than what's being reported in	20	shows is how well, how effective the
21	the label.	21	product is and in neutralizing antibodies does
22		22	correlate with an immune response in a patient.
23	(Exhibit Wlochowski-8, MMR II	23	Q. What do you base that last
24	label, was marked for identification.)	24	statement on?
	· ,		
	Page 167 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL167		Page 169 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL169
1	JOAN E. WEOCHOWSKI-HIGHET CONFIDENTALIO/	1	
1			A. The assay is designed to
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	BY MR. SANGIAMO: Q. Ms. Wlochowski, you've been	2	it's a biological assay so it's designed to
3	Q. Ms. Wlochowski, you've been		
		3	replicate what would happen as far as the
4	handed Exhibit 8 and that is a copy of the	4	vaccine or the human antibody being able to
5	handed Exhibit 8 and that is a copy of the MMR II label. Right?	45	vaccine or the human antibody being able to neutralize the virus.
5 6	handed Exhibit 8 and that is a copy of theMMR II label. Right?A. Yes. From it appears that	4 5 6	vaccine or the human antibody being able to neutralize the virus. Q. Does it?
5 6 7	handed Exhibit 8 and that is a copy of theMMR II label. Right?A. Yes. From it appears thatit's from the 2009 let's see. 2000 it	4 5 6 7	vaccine or the human antibody being able to neutralize the virus. Q. Does it? A. Does it?
5 6 7 8	handed Exhibit 8 and that is a copy of theMMR II label. Right?A. Yes. From it appears thatit's from the 2009 let's see. 2000 itwas issued December 2010.	4 5 6	vaccine or the human antibody being able to neutralize the virus. Q. Does it?
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5 6 7 8	 handed Exhibit 8 and that is a copy of the MMR II label. Right? A. Yes. From it appears that it's from the 2009 let's see. 2000 it was issued December 2010. Q. Where are you reading that from? A. The page 12. 	4 5 6 7 8	 vaccine or the human antibody being able to neutralize the virus. Q. Does it? A. Does it? MR. KELLER: Objection. BY MR. SANGIAMO: Q. It was designed for that
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 handed Exhibit 8 and that is a copy of the MMR II label. Right? A. Yes. From it appears that it's from the 2009 let's see. 2000 it was issued December 2010. Q. Where are you reading that from? A. The page 12. Q. Is it your belief that what you witnessed in Dr. Krah's lab showed that there was efficacy below what's described in the label? A. So I need to take a look at this version of the label. And then your question again was? Q. Let me first ask you, what does the label say about efficacy? A. So the label currently has what 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 vaccine or the human antibody being able to neutralize the virus. Q. Does it? A. Does it? MR. KELLER: Objection. BY MR. SANGIAMO: Q. It was designed for that purpose, does it do that? A. The assay that I performed while I was in Dave Krah's lab had also an addition of animal antibodies which wouldn't be the same as what would happen in a human. It's enhanced. Q. Do you have MR. KELLER: Let me interpose an objection. I object that the label speaks for itself.
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22

23

Uh-huh.

Does it correlate with

24 protection, seroconversion, does it correlate

A.

Q.

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		Page 1	70	Page 172
		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL170		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL172
	1	protection from disease?	1	with protection?
	2	MR. KELLER: Objection. Vague	2	MR. KELLER: Objection. Vague
	3	and ambiguous. Overbroad.	3	and ambiguous. Lack of foundation.
	4	THE WITNESS: Do I have the	4	THE WITNESS: Does it correlate
	5	expertise? I have so I do know that	5	with protection?
	6	you're reporting the neutralizing	6	BY MR. SANGIAMO:
	7	antibodies here as a means to say that	7	Q. Yes.
	8	it's highly immunogenic. And so based	8	A. Against the mumps virus?
	9	on even what's written in the label, it	9	Q. Against disease, mumps disease.
	10	suggests that the neutralizing antibody	10	MR. KELLER: Are you asking
	11	supports immunogenicity.	11	about the label or are you asking just
	12	MR. KELLER: Objection. Lack	12	in general?
	13	of foundation as well.	13	MR. SANGIAMO: I'm asking if it
	14	BY MR. SANGIAMO:	14	correlates with protection.
	15	Q. My question is, do you have the	15	MR. KELLER: Same objections.
	16	expertise do assess whether seroconversion as	16	THE WITNESS: Again, I think my
	17	measured in a neutralization assay correlates	17	understanding, my answer to that was
	18	with protection from disease. What's your	18	that based on having neutralizing
	19	answer to that question?	19	antibodies, that it would correlate to
	20	MR. KELLER: Objection. Asked	20	some extent in protection.
	21	and answered. Lack of foundation.	21	BY MR. SANGIAMO:
	22	Vague and ambiguous. Overbroad.	22	Q. Have you ever studied that
	23	THE WITNESS: So as part of my	23	issue of whether neutralizing antibody to
	24	experience working in Dave Krah's lab,	24	mumps correlates to protection in disease?
				* *
		Page 1'	1	Page 173
	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL171	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL173
	1	we were running the neutralization	1	MR. KELLER: Objection. Vague
	2	assay to show seroconversion rates and	2	and ambiguous.
	3	that the results of what we performed	3	THE WITNESS: What do you mean
	4	during the testing was an indication of	4	by study the issue?
	5	seroconversion in a patient.	5	BY MR. SANGIAMO:
	6	BY MR. SANGIAMO:	6	Q. Read literature on it.
	7	Q. Does that seroconversion	7	A. I have read some literature.
	8	correlate with protection from disease as	8	Q. Was it ever a part of your job
	9	measured in that assay?	9	responsibility anywhere to figure out whether
	10	MR. KELLER: Same objections.	10	seroconversion in a mumps neutralization assay
	11	THE WITNESS: It provides the	11	correlates with protection from disease?
	12	information about how effective the	12	A. That was not part of my job
	13	vaccine, it provides some information	13	description.
	14	about how effective the vaccine is at	14	Q. What is the most you can tell
	15	neutralizing the virus. Which would	15	me about your training that would show you to
	16	indicate that it's providing information	16	have the expertise in order to assess whether
	17	around how well the product is	17	seroconversion in a mumps neutralization assay
	18	protecting against the virus.	18	correlates with protection from disease?
	19	BY MR. SANGIAMO:	19	MR. KELLER: Let me just
	20	Q. I think you said provides some	20	MR. SANGIAMO: Don't testify,
	21	information, is that what you said?	21	Jeff. Let her answer the question.
- 1			1	

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23

24

MR. KELLER: Protect my

In answering this question, you

privilege, Dino. Excuse me.

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	Page 174		Page 176
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL174		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL176
1	can answer to the extent that you don't	1	component was significantly diminished from
2	disclose any communication you had with	2	this high degree of protective efficacy?
3	your counsel. You don't disclose any	3	A. I believe that the data was
4	information that was provided to you in	4	showing from running the plaque reduction
5	part of those communications in	5	neutralization assay that the results did not
6	answering his question. So other than	6	reflect the actual seroconversion rates that
7	communications that you had with	7	were occurring in the patient population.
8	counsel or information that you	8	And
9	received from counsel regarding this	9	Q. I'm sorry, the results of the
10	issue, you can answer.	10	neutralization assay did not reflect the
11	THE WITNESS: So the training	11	actual
12	I've had to determine whether or not	12	A. Correct, because they were
13	this correlates to seroconversion	13	being changed. So the original results that
14	correlates to protection against the	14	we had generated by performing the assay were
15	mumps disease. So I do have training	15	being changed to provide information that
16	in basic science, so I have an	16	basically the testing was biased and the
17	understanding of how that works. And,	17	results for pre-positive sample would be
18	again, my understanding based on my	18	changed in order to represent something that
19	training and documents that I've seen	19	was pre-negative. So that it showed a
20	is that there is a correlation between	20	different rate of seroconversion than what
21	antibody response and protection	21	would have been reported out with the original
22	against disease.	22	results.
23	BY MR. SANGIAMO:	23	Q. What was the difference in the
24	Q. What documents?	24	rate?
	Page 175		Page 177
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL175		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL177
1	MR. KELLER: Other than	1	A. I do not know the actual
2	documents that you've reviewed or were	2	difference in the rate.
3	provided to you by counsel.	3	Q. Did you ever calculate it?
4	BY MR. SANGIAMO:	4	A. I did not calculate the entire
5	Q. Were the documents that you	5	study, no.
6	referred to in your last answer strictly	6	Q. Did you ever calculate the

	1 uge 175		1450 177
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL175		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL177
1	MR. KELLER: Other than	1	A. I do not know the actual
2	documents that you've reviewed or were	2	difference in the rate.
3	provided to you by counsel.	3	Q. Did you ever calculate it?
4	BY MR. SANGIAMO:	4	A. I did not calculate the entire
5	Q. Were the documents that you	5	study, no.
6	referred to in your last answer strictly	6	Q. Did you ever calculate the
7	documents that were provided to you by	7	difference in the seroconversion rate that
8	counsel?	8	resulted from whatever these practices are to
9	MR. KELLER: Answer yes or no.	9	which you take exception in the running of the
10	THE WITNESS: No.	10	assay?
11	BY MR. SANGIAMO:	11	A. Did I ever calculate the
12	Q. Okay. Which documents were you	12	difference in I was aware of data that
13	referring to that were not provided to you by	13	showed that there was a percentage of the
14	counsel?	14	portion that we looked at that was different
15	A. So I can't think off the top of	15	than the original results.
16	my head.	16	Q. Seroconversion rate was
17	Q. Now, the label does mention	17	different?
18	efficacy itself as you pointed out on page 2	18	A. That the pre-positive rate was
19	here of Exhibit 8.	19	different so which would lead to either those
20	A. Uh-huh.	20	results being those results, you know,
21	Q. And it refers to a high degree	21	being excluded from a seroconversion rate.
22	of protective efficacy. Is it your testimony	22	Q. What was the impact on the
23	that when you were in Dr. Krah's lab, you	23	seroconversion rate, did you ever calculate
24	learned that the efficacy of the mumps	24	that?

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL178		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL180
1	A. No. I don't believe, no. I	1	PRN using the anti-rabbit or the rabbit
2	don't believe we calculated the difference in	2	anti-IgG antibodies. They performed different
3	the seroconversion rate.	3	studies to determine an appropriate dilution
4	Q. So even if we accept your	4	to use with the rabbit antibodies and the
5	premise that seroconversion rate correlates	5	challenge with the development of that was as
6	with efficacy, how do you know that anything	6	they were trying to reach the desired outcome
7	you saw in the lab suggests that the efficacy	7	of the greater than 95 percent seroconversion,
8	has been significantly diminished from a,	8	the enhancement was also causing greater than
9	quote, high degree of protective efficacy?	9	10 percent of pre-positive rate which, from
10	MR. KELLER: Objection. Lack	10	what I've been told, in the general population
11	of foundation. Vague and ambiguous.	11	the expectation is around a 10 percent
12	Overbroad.	12	pre-positive. So going above that would is
13	THE WITNESS: So the results	13	not expected.
14	were if the results the original	14	So after conducting a few
15	results are used, the actual	15	studies they reached conclusion on the optimal
16	seroconversion and the titer or the	16	dilution to use with the rabbit antibodies,
17	neutralizing titer would be higher	17	and that would obtained their desired outcome
18	based on the enhancement of using	18	of having a greater than 95 percent
19	rabbit antibodies in the assay.	19	seroconversion and less than 10 percent
20	Previous studies during the assay	20	pre-positive rate.
21	development also showed a lower rate of	21	Q. Do you have the strike that.
22	seroconversion which would indicate	22	Do you consider yourself to
23	that there is also some other issues	23	have the expertise to evaluate which of
24	with the seroconversion rate that would	24	several assay designs for a mumps
	Page 179		Page 181
		1	

	Page 179		Page 181	
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL179		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL181	
1	make it make the product less	1	neutralization assay would better correlate	
2	effective.	2	with protection from disease?	
3	BY MR. SANGIAMO:	3	MR. KELLER: Objection.	
4	Q. Did you participate in those	4	Overbroad.	
5	earlier studies?	5	THE WITNESS: So which	
6	A. I did not.	6	methodology would have a better	
7	Q. How did you hear about them?	7	correlation to the disease?	
8	A. I was provided a document, a	8	BY MR. SANGIAMO:	
9	Merck document, a copy of a Merck document	9	Q. To protection from disease.	
10	that showed information from those previous	10	A. Protection from disease?	
11	studies.	11	Again, I believe that biological assays such	
12	Q. Who gave it to you?	12	as the plaque reduction assay would correlate	
13	A. Steve gave it to me, Steve	13	better to protection from the disease than an	
14	Krahling.	14	ELISA.	
15	Q. When did he give it to you?	15	Q. How about as between two	
16	A. Probably in the spring of 2001.	16	different biological assays, do you have the	
17	Q. What do you remember about the	17	expertise to short out which of those two	
18	content of that document besides what you've	18	would yield a seroconversion rate that	
19	already told us?	19	correlates better to protection from disease?	
20	A. That the original assay that	20	MR. KELLER: Objection. Vague	
21	was being performed itself didn't meet the	21	and ambiguous. Overbroad. Lack of	
22	desired outcome of a 95 percent seroconversion	22	foundation.	
23	rate. It was lower. And in that case a new	23	THE WITNESS: My expertise at	
24	method was developed to with the enhanced	24	least would point me towards that if	

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	Page 18	2	Page 184
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL182		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL184
1	you were developing an assay, you would	1	foundation.
2	look to have a known control that would	2	THE WITNESS: So the actual
3	lead you to demonstrate a correlation	3	response in the assay of an antibody
4	against a known population.	4	neutralizing the virus on its own
5	BY MR. SANGIAMO:	5	versus having an enhanced rabbit
6	Q. Correlation of protection from	6	antibody that wouldn't be present,
7	disease?	7	rabbit antibody potentially giving
8	A. Yes.	8	nonspecific neutralization in the assay
9	Q. And is there such a thing for	9	would indicate to me that it wouldn't
10	mumps?	10	provide the same correlation that it
11	A. I'm not aware.	11	would without.
12	Q. Then how could you form an	12	BY MR. SANGIAMO:
13	opinion that one assay format was better than	13	Q. That sounds like your logic. I
14	the other	14	understand what your argument is. My question
15	MR. KELLER: Objection.	15	is, what is it about your experience that
16	Argumentative.	16	would support that?
17	BY MR. SANGIAMO:	17	MR. KELLER: She's already
18	Q if you don't know that	18	testified about her experience
19	fundamental piece of information?	19	BY MR. SANGIAMO:
20	MR. KELLER: Objection.	20	Q. You referred to your experience
21	Argumentative. Lack of foundation.	21	being a basis for your conclusion. Now I'm
22	Overbroad.	22	asking what is your experience that you're
23	THE WITNESS: Again, I'm not	23	referring to?
24	my experience, I've not seen the use of	24	MR. KELLER: Asked and
	Page 18	3	Page 185
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL183		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL185
1	rabbit antibodies in a biological assay	1	answered. This is like the fifth time
2	to enhance the reaction. And based on	2	around. If you want to answer it
3	that, the rabbit antibody wouldn't be	3	again, you can answer it again.
4	present in a human reaction. It	4	THE WITNESS: I do have
5	doesn't necessarily correlate to	5	experience performing other
6	protection against the disease.	6	performing ELISAs where rabbit anti
7	BY MR. SANGIAMO:	7	sorry, rabbit antibody is used. I have
8	Q. You've been involved in one	8	performed other plaque assays. We
9	plaque reduction neutralization assay in your	9	haven't used animal antibody. So
10	life. Right?	10	that's the basis of my response.
11	A. When you say "involved," you	11	BY MR. SANGIAMO:
12	mean performed in the assay?	12	Q. Do you have a belief as to what
13	Q. Yes.	13	the efficacy rate is for the mumps component
14	A. That would be yes, that is	14	of the MMR?
15	probably correct, yes.	15	MR. KELLER: Objection.
16	Q. And that one assay used rabbit	16	Overbroad. Lack of foundation.
17	antihuman IgG. Right?	17	THE WITNESS: I believe that
18	A. Yes.	18	the true efficacy rate has not been
19	Q. So what is it about your	19	reported based on the current
20	experience that would suggest to you that an	20	information that's been generated from
20	assay would correlate better if it did not use	21	Dave Krah's lab.
21		1	
	rabbit antihuman IgG?	22	BY MR. SANGIAMO:
21	rabbit antihuman IgG? MR. KELLER: Objection. Asked	22 23	BY MR. SANGIAMO: Q. What's the information from

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	Page 186		Pag	ge 188
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL186		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	.188
1	affect the efficacy rate?	1	that what's being reported in the label	
2	A. So	2	is that there's 96 percent neutralizing	
3	MR. KELLER: Objection. Asked	3	antibodies in a study that was in a	
4	and answered. You can answer again.	4	different study that was done. And	
5	THE WITNESS: So while I was at	5	what what has not been reported is	
6	Dave Krah's lab, we performed testing	6	how effective the product is with the	
7	related to what was referred to as	7	results that were coming out of the	
8	Protocol 007 which is the clinical	8	Protocol 007 study.	
9	study to determine the seroconversion	9	BY MR. SANGIAMO:	
10	rates in different strengths of the	10	Q. Can you show me where in the	
11	vaccine, of the mumps vaccine. And	11	label it says that the efficacy rate is 95	
12	based on that information and that	12	percent?	
13	protocol being completed and data being	13	A. The label says that there's	
14	generated, the what I believe to be	14	96 percent mumps neutralizing antibodies and	
15	the end result of that study has not	15	96 percent from that study that was done. And	
16	been reported as how effective the	16	which is which to me is a demonstration of	
17	product is even at a decreased	17	the effectiveness of product and, therefore,	
18	strength.	18	based on newer data that we have about the	
19	BY MR. SANGIAMO:	19	effectiveness and the neutralizing antibodies,	
20	Q. So it's your belief that the	20	that data is not represented here.	
21	end result of that study has not been	21	Q. And, of course, you don't know	
22	reported? Is that what you just said?	22	whether the FDA would also interpret that	
23	A. I believe that the well, I	23	96 percent as representative of the efficacy	
24	know that the original data was being changed	24	of the product because I know you testified	
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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL187		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL189
1	as we were performing the testing. There was	1	this morning that you don't know how the FDA
2	data that's been destroyed and, therefore,	2	defines efficacy. Right?
3	what hasn't been reported is the original	3	MR. KELLER: Objection. Lack
4	results that should have come out of that	4	of calls for speculation. Lack of
5	study.	5	foundation.
6	Q. If you turn to Exhibit 6 which	6	BY MR. SANGIAMO:
7	is the Complaint. If you look at the bottom	7	Q. Right, ma'am?
8	of the first page. Paragraph 2 reads:	8	MR. KELLER: Let me finish my
9	"Specifically, in an effort to maintain its	9	objection, Dino. I give you the
10	exclusive license to sell the vaccine and its	10	courtesy of letting you ask finish
11	monopoly of the U.S. market for mumps vaccine,	11	your questions.
12	Merck has fraudulently represented and	12	You can answer.
13	continues to falsely represent in its labeling	13	THE WITNESS: I do know that
14	and elsewhere that its mumps vaccine has an	14	the label says 96 percent neutralizing
15	efficacy rate of 95 percent or higher."	15	antibodies which is not the percentage
16	Can you show me where on the	16	of neutralizing antibodies that would
17	label Merck says that the efficacy rate is 95	17	be concluded based on the assay that
18	percent or higher?	18	the PRN that was being performed as
19	MR. KELLER: Objection. Seeks	19	part of Protocol 007.
20	a legal conclusion. You're having her	20	BY MR. SANGIAMO:
21	interpret a legal document. You can	21	Q. My question is, you don't know
22	answer.	22	whether the FDA would interpret that
23	THE WITNESS: So in terms of	23	96 percent seroconversion rate as being
24	I guess I can answer just in the fact	24	representative of the efficacy rate because I

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	Pag	ge 190	Page	192
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	.190	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL1	92
1	think you testified this morning you don't	1	or guardians could make a decision on	
2	know how the FDA defines efficacy. Right?	2	the basis of the data that is available	
3	MR. KELLER: Objection. Lack	3	for the product.	
4	of foundation. Calls for speculation.	4	BY MR. SANGIAMO:	
5	THE WITNESS: And in the	5	Q. How did you think this lawsuit	
6	Complaint I didn't say that this was	6	was going to accomplish that?	
7	the FDA's definition of efficacy.	7	MR. KELLER: Objection. You	
8	BY MR. SANGIAMO:	8	can answer that question as long as you	
9	Q. So whose definition is it?	9	don't disclose any communications with	
10	A. It's based on what we filed,	10	your counsel. To the extent that you	
11	myself and Steve who filed the Complaint, is	11	can answer the question without	
12	the effectiveness of the product.	12	disclosing communications with your	
13	Q. So it's your definition?	13	counsel, you can answer. If you	
14	MR. KELLER: Objection. Calls	14	cannot, do not answer that question.	
15	for a legal conclusion. Calls for	15	THE WITNESS: That's a lot of	
16	speculation. Lack of foundation.	16	information.	
17	Seeks an expert opinion from a lay	17	I guess in the simplest form is	
18	witness. You can answer now.	18	that if we raise a complaint to	
19	THE WITNESS: Yes, based on how	19	identify something that's wrong, it's	
20	the Complaint was written.	20	my belief that it would be that the	
21	BY MR. SANGIAMO:	21	just thing would be accomplished and it	
22	Q. Why did you file this lawsuit?	22	would be corrected.	
23	MR. KELLER: Objection. Vague	23	BY MR. SANGIAMO:	
24	and ambiguous. You can answer.	24	Q. Now, you're seeking recovery	
	Pag	ge 191	Page	193
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL	.191	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL1	93
1	THE WITNESS: I filed it	1	for losses that you say the CDC incurred.	
2	because based on what I saw in Dave	2	Right?	
3	Krah's lab of falsifying data and	3	MR. KELLER: Objection. Seeks	
4	knowing that that was wrong, knowing	4	a legal conclusion. You can answer.	
5	that the protocol was conducted and	5	THE WITNESS: That is what is	
6	completed, that protocol supported a	6	filed in the Complaint, yes.	
7	label change to reduce to allow for	7	BY MR. SANGIAMO:	
8	a reduction in the strength of end	8	Q. You're not out of pocket any	
9	expiry of the product. And that was	9	money based on what's alleged here in this	
10	what was being measured as a part of	10	Complaint. Right?	
11	the protocol during my time in Dave	11	A. Correct.	
12	Krah's lab.	12	Q. Why didn't you just go tell the	
		1		

13 CDC? BY MR. SANGIAMO: Q. What did you hope to accomplish 14 MR. KELLER: Objection. Calls by filing the lawsuit? 15 for speculation. I will, again, MR. KELLER: Objection. Vague 16 instruct you not to disclose any and ambiguous. Calls for speculation. 17 communications you had with counsel Lack of foundation. Seeks a legal 18 that you would have to disclose in conclusion. You can answer. 19 order to answer that question. If you THE WITNESS: So I wanted to be 20 can answer the question without able to bring awareness to the fact 21 disclosing communications you had with that the data that was found was not 22 counsel, you can. 23 being reported so that the children who THE WITNESS: I don't know if I are being vaccinated and their parents 24 thought about it much. I mean, it

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	D 104		D 107
	Page 194 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL194		Page 196 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL196
1	wasn't about what the CDC was doing but	1	
2	more about what Merck was doing. So I	2	laboratory. I wasn't aware of what was being done with the data after I had
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	wanted to be able to address it	3	left.
4	directly with Merck.	4	BY MR. SANGIAMO:
	•		
5	BY MR. SANGIAMO:	5	Q. Now, if you had simply told the
6	Q. When did you first contact a	6	CDC what you knew, then that wouldn't lead to
7 8	lawyer about filing this lawsuit? A. I want to say 2009, 2010.	7 8	any financial benefit for you. Right?
	•	8	MR. KELLER: Objection. Lack
9		10	of foundation. You can answer.
10	2004, 2005 where all these parents you said were not able to make an informed decision and		THE WITNESS: Again, I don't
11		11	know what it would have led to, but as
12	you had all this information, why didn't you	12	far as making the implication that I
13	just disclose it then?	13	would be getting financial I guess
14	MR. KELLER: Objection. Calls	14	in settling the case, getting a
15	for you can answer. Objection to	15	financial, I want to call it
16	form.	16	reimbursement or whatnot, that's not
17	THE WITNESS: When my time that	17	the reason I filed the case.
18	I worked at Merck, while I was there, I	18	BY MR. SANGIAMO:
19	did raise and elevated the issue within	19	Q. That played no role in your
20	Merck. After I had left Merck, I still	20	thought process. Right?
21	was working full time, raising a	21	A. No. Again, I work in the
22	family. At the time when the label	22	industry so I'm really putting myself out
23	change came out in 2007, which is,	23	there by being a part of this case.
24	again, based on the Protocol 007 being	24	Q. What do you mean when you say
	Page 195		Page 197
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL 195		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL197
1	the information that was available at	1	you're putting yourself out there by being
2	the time of the submission, the that	2	part of this case?
3	drawing the conclusion of allowing for	3	A. The fact that I would raise a
4	the label change based on that data led	4	concern or an issue to a lawsuit is something
5	me to raising the case at that point.	5	that could be viewed by others as I guess
6	BY MR. SANGIAMO:	6	could question my I don't know what to
7	Q. 2007?	7	say my loyalty to a company. It depends on
8	A. Yeah, after 2007.	8	the company or the way that they view it
9	Q. I thought it was in 2001 when	9	versus I can't say what others would think,
10	you discovered that as a result of what you	10	but I do know that it does allow an
11	were seeing in the lab, that the vaccine had	11	opportunity for others to make judgment.
12	significantly diminished efficacy. Isn't that	12	Q. Has anyone made such judgments,
13	what you told me before?	13	to your knowledge?
14	A. Yes.	14	A. No.
15	Q. So why didn't you let the CDC	15	Q. So the reason you think you're
16	know at that time?	16	putting yourself out there is based on
17	MR. KELLER: Objection. Lack	17	speculation that somebody might make such a
18	of foundation.	18	judgment. Is that a fair statement?
	THE WITNESS: At that time the	19	A. Yes.
19		- C	
19 20	FDA was contacted, not the CDC.	20	MR. KELLER: Objection.
19 20 21	FDA was contacted, not the CDC. BY MR. SANGIAMO:	21	BY MR. SANGIAMO:
19 20 21 22	FDA was contacted, not the CDC. BY MR. SANGIAMO: Q. How about after that?	21 22	BY MR. SANGIAMO: Q. If you go to page 7 I'm
19 20 21	FDA was contacted, not the CDC. BY MR. SANGIAMO:	21	BY MR. SANGIAMO:

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL 198		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL200
1	"Relator had multiple communications with	1	times it was the two of you along with some
2	Relator Krahling about topics relating to	2	other people from the lab at Merck?
3	allegations in the Complaint regarding the	3	A. Yes.
4	mumps vaccine between 2001 and 2010. Most of	4	Q. Do you remember who those other
5	these communications took place in person at	5	people were?
6	Merck's facility where they worked in	6	A. I would say, I believe, Frank
7	West Point, Pennsylvania. In particular,	7	Kennedy was there, Suzanne Maahs and Jon
8	Relator recalls having discussions with	8	Gombola.
9	Relator Krahling while they were both employed	9	Q. Is that it?
10	at Merck regarding the fraudulent methods	10	A. That's all I recall.
11	mandated by Krah for the Protocol 007 testing	11	Q. If you have to provide an
12	and ways of avoiding compliance with these	12	approximation of the dates of those two
13	mandates. Relator also met with Relator	13	meetings, what would your best approximation
14	Krahling at Relator's home in Pennsylvania	14	be?
15	after Krahling left Merck, and several times	15	A. I would say the meeting, the
16	at her home in Connecticut after they both	16	first meeting with a group of people was
17	left Merck."	17	either late 2001 or it was probably late
18	That's the end of that quote	18	2001, I'm thinking. When I met with Steve
19	which is from your response to Interrogatory	19	when he came to my house in Connecticut
20	Number 5, not the entire response, but it's a	20	sometime I'm going to say after 2007, prior to
21	portion of the response.	21	2009 around.
22	A. Uh-huh.	22	Q. Have you ever been represented
23	Q. How many times in total do you	23	in this litigation by a man named James Moody?
24	think you met with Mr. Krahling after he left	24	A. Not that I no.
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	Page 199		Page 201
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL199		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL201
1	Merck?	1	Q. When Mr. Krahling came to visit
2	A. In person?	2	you in 2007, was that a meeting that was at
3	Q. Yes.	3	his suggestion or your suggestion?
4	A. I would say a handful of times,	4	A. At his suggestion.
5	if that.	5	Q. Had the two of you spoken at
6	Q. Five or less, is that fair?	6	all between that 2001 meeting at your house
7	A. Yes.	7	and the 2007 meeting at your house in
8	Q. Was anyone else present at any	8	Connecticut?
9	of those meetings?	9	A. Not that I recall, no.
10	A. So the first couple of times	10	Q. Had you exchanged e-mails?
11	that we met while I was still in Pennsylvania.	11	A. No.
12	Or at least there was at least one instance	12	Q. Did he just call you in 2007
13	where there were other co-workers from Dave	13	and suggest that you meet?
14	Krah's lab who were in attendance. After	14	A. Yes.
15	that, we didn't meet again until he came to my	15	Q. Did he say why?
16	house in Connecticut and he came I believe	16	A. He talked about the what we
17	he came by himself one time and then came with	17	experienced, again, in Dave Krah's lab with
18	my legal counsel.	18	the falsification of the data, and we talked
19	Q. You met twice with him after he	19	about the protocol being completed and also to
20	left Merck prior to him appearing with legal	20	discuss the label change as well.
21	counsel. Is that right?	21	Q. What else do you recall about
22	A. Yes.	22	those discussions?
23	Q. One of those two times it was	23	A. I don't recall much. I know
24	just the two of you, and one of those two	24	that I basically told them I still supported

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	Page 202		Page 204
	Page 202 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL202		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL204
1	what I did when I was there, that it was wrong	1	attorney had told him about the viability of
2	what was being conducted in the laboratory.	2	any lawsuit?
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Q. Did he tell you that he was	3	A. No.
4	contemplating a lawsuit?	4	Q. How much time between when you
5	A. Yes.	5	had that meeting at your house and when he
6	Q. Did he tell you that he had	6	subsequently met with you with legal counsel?
7	been contemplating that for some time?	7	A. Again, it was in the span of
8	A. I don't recall.	8	between 2007 to 2009.
9	Q. Did he give you any indication	9	Q. Would it be fair to say that
10	at all about how long he had been contemplating	10	Mr. Krahling persuaded you to join this
11	that?	11	lawsuit?
12	A. I know he was following	12	MR. KELLER: Objection.
12	information around the vaccine. That's all I	12	BY MR. SANGIAMO:
13	know.	13	
14	Q. I thought you said a minute ago	14	Q. Would that be a fair characterization in your view?
15 16	he was contemplating a lawsuit?	15	A. I wouldn't characterize it as
10	MR. KELLER: Objection.	10	A. I would t characterize it as persuasion, as informing me of the
17	Mischaracterizes her testimony.	17	developments. As far as whether or not I
18 19	BY MR. SANGIAMO:	18	wanted to participate was my decision.
20		20	
20 21	Q. Did you have any basis for thinking he was contemplating filing a lawsuit	20	Q. Did you have discussions about that outside the presence of counsel?
21	besides the fact that he was following the	21	MR. KELLER: With whom?
22	vaccine?	22	THE WITNESS: Right.
23 24	A. Just following the vaccine does	23	BY MR. SANGIAMO:
24	-	24	
	Page 203		Page 205
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL203		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL205
1	not necessarily mean he would file a lawsuit.	1	Q. With Mr. Krahling.
2	Q. I thought you had perhaps I	2	A. I can't recall.
3	got it wrong. I thought you had said that	3	Q. Do you recall Mr. Krahling
4	your impression when you met with him in 2007	4	identifying any pros, advantages for you if
5	was that he had been contemplating filing a	5	you joined the lawsuit?
6	lawsuit?	6	A. No.
7	A. At that time, yes, versus what	7	MR. KELLER: How long have we
8	he had been doing prior to that.	8	been going? Whenever you get to a
9	Q. What did he tell you about that	9	comfortable change, just a restroom
10	effort to file a lawsuit or that contemplation	10	break. We've been going an hour.
11	of filing a lawsuit?	11	MR. SANGIAMO: At this time, we
12	MR. KELLER: Objection. Lack	12	can do it right now.
13	of foundation.	13	VIDEOGRAPHER: The time is
14	THE WITNESS: That he was	14	3:02. Going off the video record.
15	looking into finding legal representation.	15	
16	BY MR. SANGIAMO:	16	(A recess was taken.)
17	Q. Did he tell you he had been	17	
18	trying to do that?	18	VIDEOGRAPHER: The time is now
19	A. I don't know if he might have	19	3:21. This begins disc five. You may
	mentioned that he reached out to somebody else	20	proceed.
20	-		LENC NALE STANIC TANACY.
21	previously. I think that's what he said.	21	BY MR. SANGIAMO:
21 22	previously. I think that's what he said. Q. To another attorney?	22	Q. Ms. Wlochowski, in general
21	previously. I think that's what he said.		

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		Page 206		Page 208
		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL206		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL208
	1	A. General terms, I worked on	1	THE WITNESS: I'm trying to
	2	testing for Protocol 007 as well as I was	2	think.
	3	conducting some supplemental testing for the	3	BY MR. SANGIAMO:
	4	mumps neutralization assay. I also conducted	4	Q. I can make this easier for you,
	5	some assays for VZV studies, and I believe	5	Ms. Wlochowski. Was it while you were working
	6	that was that I can recall what I worked on	6	at Merck?
	7	generally.	7	A. Yes.
	8	Q. What was the supplemental	8	Q. Was it while you were in
	9	testing for the mumps neutralization assay?	9	Dr. Krah's lab?
	10	A. There were some different	10	A. Yes.
	11	from what I can remember, there were some	11	Q. How did you hear about that?
	12	different testing we did on passage, whether	12	A. The part of the I'm trying
	13	it was high or low passage of the cell lines	13	to recall. Part of the information that
	14	that we were using. That's all I can remember	14	talked about the development of the PRN also
	15	at this point.	15	talked about the ELISA.
	16	Q. The Protocol 007 testing that	16	Q. You just said part of the
	17	you referred to, that's a reference to running	17	information that talked about the development
	18	the plaque reduction neutralization assay?	18	of the PRN. Are you referring there to the
	19	A. Correct. As well as the	19	document that you testified about earlier that
	20	supplemental testing.	20	Mr. Krahling showed you?
	21	Q. You did not work on the mumps	21	A. Correct.
	22	ELISA assay during your time at Merck. Correct?	22	Q. Did that document say that the
	23	MR. KELLER: Objection. Vague	23	correlation had actually occurred?
	24	and ambiguous.	24	A. No.
F		Page 207		Page 209
		Tage 207		Tage 209

Page 207

	Page 207		Page 209
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL207		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL209
1	THE WITNESS: Can you define	1	Q. That wouldn't make any sense,
2	what you mean by work on the ELISA	2	right?
3	assay?	3	A. Right.
4	BY MR. SANGIAMO:	4	Q. Because you hadn't run the
5	Q. Is there some sense of the	5	plaque reduction neutralization yet?
6	meaning of the term "work on" that would fit	6	A. Right.
7	what you did on the ELISA assay?	7	Q. So do you know if that
8	A. So the ELISA assay was based,	8	correlation ever occurred?
9	the development was based on correlation to	9	MR. KELLER: Objection.
10	the PRN assay that I performed. So to the	10	Overbroad.
11	extent that the correlation was based on the	11	THE WITNESS: While I was at
12	work I did, was my involvement with the ELISA	12	Merck?
13	assay at that time.	13	BY MR. SANGIAMO:
14	Q. Your involvement, then, with	14	Q. Right now the question is do
15	the ELISA assay consisted of running of the	15	you know?
16	plaque reduction neutralization assay.	16	MR. KELLER: Overbroad.
17	Correct?	17	THE WITNESS: Currently I do
18	A. Correct.	18	know.
19	Q. When is it that you came into	19	BY MR. SANGIAMO:
20	the belief that the ELISA assay was correlated	20	Q. When did you learn that?
21	to the plaque reduction neutralization assay?	21	A. As part of the case.
22	MR. KELLER: Hold on a sec.	22	Q. So you learned that in
23	Objection to form. Lack of foundation.	23	conjunction with this lawsuit? Yes?
24	You can answer.	24	A. Yes.

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22 this document?

A. I was seeing things in the

24 laboratory that I wasn't comfortable with,

23

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		Page 21	0			Page 212
	JOAN L. WLOCHOWS	SKI -HIGHLY CONFIDENTAL210		JOA	N L. WLOCHOWSKI -HIGHLY CONFIDE	-
1	Q. What specifically	did you do on	1	that in n	ny work experience had not been	
2	the plaque reduction neutra	lization assay in	2	exposed	to before and I wanted to document the	
3	Dr. Krah's lab other than the	e supplemental	3	activitie	s that were occurring.	
4	testing that you were descri	bing related to	4	Q.	And that's what this document	
5	the passaging of cell lines?		5	does. R	ight?	
6	A. I believe I perform	med the assay	6	А.	Correct.	
7	in its entirety so I set up the	e serum	7	Q.	Did you end up showing this	
8	dilutions, I inoculated the p	lates. I fixed	8	docume	nt to anybody?	
9	and stained the plates and I	performed	9	А.	While I was at Merck?	
10	counting on the plates.		10	Q.	Yes.	
11			11	А.	No.	
12	(Exhibit Wlochow	ski-9,	12	Q.	Did you intend to show it to	
13	Documentation of Wor	k Activities,	13	someon	e when you first created it?	
14	00000272, was marked	for identification.)	14	А.	My intent was really my record	
15			15	when I c	created this.	
16	BY MR. SANGIAMO:		16	Q.	Why did you want a record?	
17	Q. Ms. Wlochowski,	, you've just	17	А.	So, again, I could keep track	
18	been handed what's been m	arked as Exhibit 9.	18	of the ac	tivities because I felt like there	
19	Do you recognize this docu	ment?	19	were thi	ngs that were being done wrong in the	
20	A. Yes, I do.		20	lab and	I wanted at least to have information	
21	Q. What is it?		21	around t	hat.	
22	A. This is just a docu	ument I	22	Q.	Were you contemplating filing a	
23	created for myself to outline	e the activities	23	lawsuit	based on what's described here in this	
24	of work that I conducted in	the lab from my	24	docume	nt?	
		Page 21	1			Page 213
	JOAN L. WLOCHOWS	SKI -HIGHLY CONFIDENTAL211		JOA	N L. WLOCHOWSKI -HIGHLY CONFIDE	ENTAL213
1	start date in January throug	h April.	1	А.	No.	
2	Q. Are you sure that	you created	2	Q.	Maybe we can go through some of	
3	it strike that.		3	the conc	erns you express in the document. At	
4	Do you know when	n you created	4	the top t	here is a section that begins with	
5	it?		5	"Start da	te," and the first entry there reads:	
6	A. I don't recall exac	ctly when,	6	"offered	no direction or training." I gather	
7	but based on the last date en	ntry there, it's	7	that's a s	tatement that neither Dr. Krah nor	
8	April 11th, it's around that	time frame.	8	anyone	else in the lab provided you with what	
9	Q. I'm sorry, I don't	mean to	9	you con	sider to be the adequate direction or	
10	nitpick on this. But do you	have a basis to	10	training	?	
11	believe it was around April	11th other than	11	А.	I believe it was more geared	
12	seeing that date there?		12	towards	receiving no training from my	
13	A. If there if it was	s late	13	supervis	or which was Dave Krah.	
14	well, obviously if it was ear	rlier, I couldn't	14	Q.	Did you receive training from	
15	have written the other dates	s, but if it was	15	others?		
16	later in time, I would have	likely filled in	16	А.	From what I can recall, I	
17	more information up to the	date that it was	17	received	training from, when I first started	
18	being documented.		18	there, fr	om another co-worker in the	
19	Q. Why is it that you	a wanted to	19	laborato	ry.	
20	document your work activit	ties from your start	20	Q.	Who is that?	
21	date until whenever it was t	hat you prepared	21	А.	Frank Kennedy.	
22	11 1 10		0	0		

A. When I first started workingthere, we were maintaining cell lines,

What did he train you on?

Q.

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22

23 does that mean?

A. There were, I guess, certain --

24

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	Page 214 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL214		Page 216 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL216
1	passaging cell lines, so he trained me on	1	I'm just trying to think about the timeline.
$\begin{vmatrix} 1\\2 \end{vmatrix}$	that.	2	Basically there was certain relationships in
3	Q. Were you working on anything	3	the lab where people were seemed to receive
4	else when you first started working there?	4	more information or different items such as
5	A. I can't recall. My recollection	5	gifts or exchanges of things that I wouldn't
6	is mainly working on the passaging and	6	necessarily expect to occur in a workplace.
7	maintaining of cell lines. I also, I think,	7	That kind of from my perspective felt like I
8	was involved in performing the VZV assays. I	8	wasn't being treated the same as my co-workers.
9	originally was not involved in performing the	9	Q. So the concerns about the
10	mumps assays because when I joined Merck, I	10	social dynamic were in the nature of people
10	was tested for mumps antibody titers and I	11	getting more information than you and people
11	was I didn't have the seroconversion needed	11	receiving gifts that you weren't receiving?
13 14	for to be able to work with the virus so I needed to receive a booster of the vaccine.	13	Right? You mentioned those two things?
14		14	A. Yup.
15 16	Q. Did you start working on the	15	Q. Was there anything else?
16	VZV assays right when you arrived at Merck in	16	A. That's yeah, again, people
17	January?	17	weren't in my opinion, people weren't all
18	A. I cannot recall when I started	18	being treated the same.
19	conducting those assays.	19	Q. Can you give me an example of
20	Q. So it's possible that the only	20	information that you perceived that was being
21	thing you were actually working on at the	21	withheld from you?
22	beginning of your tenure at Merck was just	22	A. So there were instances, from
23	maintaining the cell lines. Right?	23	what I understand, that the procedure related
24	A. It's possible, yes.	24	to the assays were being provided to certain
	Page 215		Page 217
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL215		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL217
1	Q. You did receive training on	1	people that worked in the laboratory,
2	that, but it was your belief that the training	2	background on the assays that were being
3	should have come from Dr. Krah, not from	3	performed were being provided to certain
4	Mr. Kennedy. Is that a fair statement, fair	4	people in the laboratory as well.
5	summary of your view?	5	Q. You said that was your
6	A. That the training should have	6	understanding. What was that understanding
7	come from him?	7	based on?
8	Q. Uh-huh.	8	A. I had some conversations with
9	A. I think that it wasn't that he	9	Steve Krahling and others in the laboratory.
10	needed to train me on that specific duty, but	10	I would, you know, discover somebody got
11	to provide more guide I would have expected	11	something and yeah.
12	more guidance from my manager at the time.	12	Q. Who else besides Mr. Krahling?
13	Q. Do you feel that you were	13	A. Probably Jill DeHaven. I
14	adequately trained on maintaining the cell	14	you know, it's a small laboratory. Overhearing
15	lines?	15	conversations with different people, whether
16	A. As far yes, I mean, that	16	it's Colleen Barr, people like that.
17	basic yes.	17	Q. I think you said, tell me if I
18	Q. That was right in your	18	have it wrong, I think you said that two
19	wheelhouse, wasn't it?	19	examples of the information were procedures
20	A. Yes.	20	about certain experiments and background on
21	Q. The next line reads: work	21	assays?
	hindowed by again! dynamics in the lab. What	22	A. Uh-huh.
22	hindered by social dynamics in the lab. What	24	A. On-hun.

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23

Q. Are you referring there

24 specifically to the mumps PRN assay?

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	Page 218		Page 220
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL218		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL220
1	A. Yes.	1	clinical trials prior to.
2	Q. For both of those?	2	Q. That's pretty indirect, isn't
3	A. Yes.	3	it?
4	Q. You were not actually running	4	MR. KELLER: Objection. Vague
5	the mumps PRN assay at the time. Right?	5	and ambiguous.
6	MR. KELLER: Objection. Vague	6	THE WITNESS: It still follows
7	and ambiguous.	7	regulations.
8	THE WITNESS: It depends on	8	BY MR. SANGIAMO:
9	what timeline you are referring to. I	9	Q. Can you give me some examples
10	believe at a certain point in time I	10	of these gifts that some were receiving that
11	was performing the counting of the	11	you didn't get?
12	mumps assays.	12	A. From what I was told, you know,
13	BY MR. SANGIAMO:	13	jelly beans or Easter baskets were being given
14	Q. Was it your view that you	14	to people within the laboratory. I don't I
15	needed to see the SOP for how the assay was	15	don't know more than that.
16	run in order to perform the counting?	16	Q. Presumably that didn't happen
17	A. I did not need to see the SOP	17	until April, I would imagine?
18	to perform the counting. However, it would be	18	A. Correct.
19	beneficial for me to have an understanding of	19	Q. So then as of January, the only
20	the method that I am generating results for.	20	social dynamics issue in the lab was just that
21	Q. Would it make for I'm sorry.	21	people were receiving information about the
22	A. With that, the SOP does speak	22	PRN assay that you weren't getting. Is that
23	to how you report the results, whether it's,	23	fair?
24	you know, document where, you know, the I'm	24	A. So you said that the only thing
	Page 219		Page 221
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL219		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL221
1	not sure about the documentation, but	1	that was hindering my work in the lab was the
2	basically that there is an Excel spreadsheet	2	fact that I didn't get the procedure. Is that
3	file that's utilized in calculating the final	3	correct?
4	results. And so it's all the results are	4	Q. Yes, but I was being slightly
5	part of the method. So, therefore, I should	5	more specific than that. I was saying the
6	have had them in my hand.	6	only thing related to this work being hindered
7	Q. Well, you can do the counting	7	by social dynamics in the lab was the fact
8	without knowing what was done with the	8	that you didn't get the procedures and the
9	counting output. Right?	9	background for the PRN assay.
10	A. I could do the counting, but I	10	A. And the overall guidance that
11	should know what I should be doing with that	11	I, you know, would again, going back to the
12	data once I generate that data, especially	12	direction provided by my supervisor.
13	since the data is being generated for a	13	Q. Anything else by way of the
14	clinical trial protocol; that there should be	14	social dynamics in the lab at the start of
15	more oversight and control of the data so that	15	your tenure there?
16	original data is not lost.	16	A. Meaning what time frame?
17	Q. You had never worked on a	17	Q. January let's say.
17		18	A. Just the again, going back
17	clinical trial at that stage of your career.	10	
	-	19	to not being treated the same as everybody
18	clinical trial at that stage of your career.		to not being treated the same as everybody else basically.
18 19	clinical trial at that stage of your career. Right?	19	
18 19 20	clinical trial at that stage of your career. Right? A. Not directly, no.	19 20	else basically.
18 19 20 21	clinical trial at that stage of your career. Right? A. Not directly, no. Q. Indirectly you did?	19 20 21	else basically. Q. Because you didn't get those

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	Page 22	2	Page	224
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL222		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL2	24
1	Q. Were people being nasty to you?	1	1 A. Uh-huh.	
2	A. I guess it depends on it was	2	2 Q. Is that a complaint?	
3	more of an exclusion than being nasty.	3	A. That's, again, just my	
4	Q. Were there certain people in	4	4 documentation to myself that typically when	
5	particular that you thought were excluding you	5	5 your manager is out of the office for an	
6	more than other people were?	6	6 extended time, you're notified in advance of	
7	A. I guess I look at it the	7	7 that just in case you need to prepare or ask	
8	opposite way and there was more people	8	8 about preparing for anything while they're	
9	there was people that I was more	9	9 out. So that was my reason for that	
10	interacting more with or felt comfortable	10	0 documentation.	
11	interacting more than others.	11	1 Q. Do you think he told other	
12	Q. Who were they?	12	2 people?	
13	A. So Jill DeHaven sat next to me	13	A. That I do not know.	
14	and I was comfortable working with her.	14	4 Q. Would that have been adequate	
15	The as far as how we operated within the	15	5 if he had told other people in the lab? Would	
16	laboratory, typically we worked in if we	16	6 that have addressed your concerns?	
17	were in working in a BSC, we were typically	17	7 MR. KELLER: Objection. Calls	
18	working in pairs together so we would be in a	18	8 for speculation.	
19	small room together and I was typically paired	19	9 THE WITNESS: No, because I	
20	up with either Frank Kennedy or Steve Krahling	20	0 really unless he told those people	
21	based on the fact that I worked, as well as	21	1 to tell me. But, again, I don't think	
22	they did, five days a week, eight-hour shifts.	22	2 that as a manager, again, should treat	
23	So we were on the same shifts. So typically	23	3 his staff equally and informed all	
24	we were paired together. So I also felt	24	4 staff the same.	
	Page 22	3	Page	225

	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL223		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL225
1	comfortable with them. When we had we had	1	BY MR. SANGIAMO:
2	a couple of interns that had started and also	2	Q. When you say he sent an e-mail
3	felt comfortable with them as well.	3	during that time period stating there would be
4	Q. Those were Jon Gombola and	4	no vacation allowed until after August
5	Suzie Maahs?	5	A. Correct.
6	A. Correct.	6	Q is your concern there that
7	Q. Were there others in the lab	7	there was not going to be any vacation allowed
8	who worked five days a week, eight-hour shifts	8	until after August or was your concern that he
9	besides the people you've mentioned?	9	was sending such an e-mail while he, himself,
10	A. Well, Dave Krah worked full	10	was on vacation?
11	time. He came in typically later than	11	A. A little bit of both.
12	everybody else. He worked kind of odd hours.	12	Q. There's then a reference in the
13	But as far as 8:00 to 4:30, from what I	13	next paragraph, if you will, about requesting
14	recall, five days a week was myself, Steve and	14	error reports from you for aspiration of media
15	Frank as well as the interns.	15	from the wrong assay tray which does not
16	Q. Did Colleen Barr work a	16	adversely affect results. Do you remember
17	five-day-a-week schedule?	17	that incident?
18	A. She had a different schedule	18	A. I do vaguely recall it, yes.
19	based on a family need.	19	Q. Only vaguely?
20	Q. Did you find that irksome?	20	A. Again, I don't recall the
21	A. No.	21	actual event itself, but I recall the context
22	Q. Continuing on in the document	22	around the event.
23	under March it says, "Dave went on vacation	23	Q. Do you remember being angry
24	unannounced for 2 weeks."	24	about it?

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	D 004		P 220
	Page 226		Page 228
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL226		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL228
	A. To myself internally, yeah.	1	the lab?
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Again, I felt like I was being signaled out or	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. That was my feeling just based
3	treated differently than others in the	3	on walking, you know, into a room and the mood
4	laboratory.	4	changing, yes.
5	Q. How so?	5	Q. Were there certain people in
6	A. Because there were there are	6	particular who would be in the room in that
7	incidents of people making errors including	7	kind of circumstance where the mood would
8	Dave Krah where I didn't see the same type of	8	change when you walked in? A. Yeah, there were certain
9	report having to be done. Again, this was	9	· · · · · · · · · · · · · · · · · · ·
10	something that was just instituted at this	10	incidents of particular people aside from the
11	time, was, you know, people make mistakes in	11	people that I mentioned previously that were I worked with and was comfortable
12	conducting laboratory work so to think that	12	with.
13	this wasn't in place prior to that was a	13	
14	little the timing, I guess, again, felt like I was being singled out.	14	Q. So who were those people where those incidents occurred?
15 16	6 6	15 16	A. So Colleen Barr would be one of
17	Q. Did you ever form any belief as to why Dr. Krah was singling you out this way?	17	them. Again, nothing I don't have anything
17	A. I do not know why, no.	17	against her, but I'm just, again, telling you
19	Q. I know you don't know because	10	my observation of what I saw when I walked in
20	that would be speculation. Right?	20	the room. She would mostly in the lab space
20	A. Correct.	20	area that we worked in, Jenny Kriss would also
21	Q. Did you ever form a suspicion?	$\begin{vmatrix} 21 \\ 22 \end{vmatrix}$	be in the room there, too.
22	MR. KELLER: Same objection.	22	Q. Did you have anything against
23	Calls for speculation.	23	Jenny Kriss?
		21	seniry miss.
	Page 227		Page 229
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227 THE WITNESS: Isn't that the	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229 A. No.
2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227 THE WITNESS: Isn't that the same?	2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229A. No.Q. Do you think the same standards
2 3	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227 THE WITNESS: Isn't that the same? BY MR. SANGIAMO:	2 3	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229 A. No. Q. Do you think the same standards about error reports ought to apply to the lab
2 3 4	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227 THE WITNESS: Isn't that the same? BY MR. SANGIAMO: Q. I'm not asking you to state	2 3 4	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229 A. No. Q. Do you think the same standards about error reports ought to apply to the lab supervisor as it would apply to people working
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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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227 THE WITNESS: Isn't that the same? BY MR. SANGIAMO: Q. I'm not asking you to state definitively what his motivation was. I'm asking if you have a suspicion as to what his motivation was? MR. KELLER: Again, that calls for speculation. MR. SANGIAMO: Calls for speculation as to whether she, in fact, had a suspicion? BY MR. SANGIAMO: Q. Don't speculate about whether you had a suspicion. Just did you have a suspicion, that's my question? A. I don't know if it was based on what other people said about me. I mean, that's the only thing that I don't know if that's speculation, but that's the only thing. Q. Was it your impression that people were saying derogatory things about you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229 A. No. Q. Do you think the same standards about error reports ought to apply to the lab supervisor as it would apply to people working the lab? A. Yes. Q. Reading down further it says you were left a note on your desk that you had entered an incorrect lot number on a worksheet. Do you see that? A. Yes. Q. You did make that mistake. Right? A. Correct. Q. And yet you thought that that was I don't want to put words in your mouth. Did you think it was an injustice that he had left that note on your desk? A. Based on the fact that there were other errors made by other people, again, it would suggest that I'm being singled out. Q. Down at the bottom there is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL227 THE WITNESS: Isn't that the same? BY MR. SANGIAMO: Q. I'm not asking you to state definitively what his motivation was. I'm asking if you have a suspicion as to what his motivation was? MR. KELLER: Again, that calls for speculation. MR. SANGIAMO: Calls for speculation as to whether she, in fact, had a suspicion? BY MR. SANGIAMO: Q. Don't speculate about whether you had a suspicion. Just did you have a suspicion, that's my question? A. I don't know if it was based on what other people said about me. I mean, that's the only thing that I don't know if that's speculation, but that's the only thing. Q. Was it your impression that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL229 A. No. Q. Do you think the same standards about error reports ought to apply to the lab supervisor as it would apply to people working the lab? A. Yes. Q. Reading down further it says you were left a note on your desk that you had entered an incorrect lot number on a worksheet. Do you see that? A. Yes. Q. You did make that mistake. Right? A. Correct. Q. And yet you thought that that was I don't want to put words in your mouth. Did you think it was an injustice that he had left that note on your desk? A. Based on the fact that there were other errors made by other people, again, it would suggest that I'm being singled out.

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL230		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL232
1	A. Yes.	1	reported the way it was being reported
2	Q. First thing there is "mumps	2	would be fraudulent.
3	protocol." Is that a reference to what we	3	BY MR. SANGIAMO:
4	were discussing earlier about you not getting	4	Q. It was your opinion that the
5	the SOP until later than you thought you	5	data being reported was fraudulent?
6	should have gotten it?	6	A. If it was yes, if the intent
7	A. I think that that may have also	7	was to use the data for the trial, then it
8	referred to the experience I had witnessing	8	would be fraud, yes.
9	changes to data while I was conducting the PRN	9	Q. You knew that the intent was to
10	or performing the counting of the PRN assay.	10	use the data for the trial. Right?
11	Q. That's what that refers to?	11	A. It was my assumption, that's my
12	A. Yes.	12	expectation.
13	Q. When did you write that?	13	Q. The way you captured is very
14	A. Again, going back to after	14	serious strike that.
15	April time frame.	15	You agree that that's quite
16	Q. But you don't know when?	16	serious, isn't it, if you're using data
17	A. No.	17	fraudulently for a clinical trial?
18	Q. Did you think there was	18	A. Yes.
19	research fraud going on at the time?	19	Q. Extraordinarily serious, isn't
20	A. Research fraud?	20	it?
21	Q. Yes.	21	A. Yes.
22	MR. KELLER: Objection. Vague	22	Q. So the way you captured it on
23	and ambiguous.	23	this document was you wrote the words "mumps
24	THE WITNESS: What do you mean	24	protocol?
	Page 231		Page 233
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL231		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL233
1	by "research fraud"?	1	A. Yes.
2	BY MR. SANGIAMO:	2	Q. Is that your testimony?
3	Q. Did you think that what was	3	MR. KELLER: Asked and
4	going on at the time fit the description of	4	answered. Argumentative.
5	what you would have called research fraud?	5	THE WITNESS: Yes.
6	MR. KELLER: Same objection.	6	BY MR. SANGIAMO:
7	Lack of foundation.	7	Q. Right above where you wrote the
8	THE WITNESS: I don't know that	8	thing about the jelly bean?
9	I would call something research fraud.	9	A. Yes.
10	The data was being falsified.	10	Q. Why didn't you provide more
11	BY MR. SANGIAMO:	11	detail about the fraud that you say you were
12	Q. So data could be falsified but	12	witnessing?
13	that might not be fraud, is that what you're	13	A. So this document, again, was an
14	saying?	14	outline of my activities that I was
1		1.5	conducting. I believed I used this as part of
15	MR. KELLER: Objection.	15	8
15 16	MR. KELLER: Objection. Mischaracterizes her testimony. Lack	15	my to provide some background into a
	5		
16	Mischaracterizes her testimony. Lack	16	my to provide some background into a
16 17	Mischaracterizes her testimony. Lack of foundation. Seeks a legal conclusion.	16 17	my to provide some background into a discussion that I was raising internally with
16 17 18	Mischaracterizes her testimony. Lack of foundation. Seeks a legal conclusion. THE WITNESS: So to, I guess,	16 17 18	my to provide some background into a discussion that I was raising internally with HR about my work in the laboratory with the
16 17 18 19	Mischaracterizes her testimony. Lack of foundation. Seeks a legal conclusion. THE WITNESS: So to, I guess, make the clarification between fraud	16 17 18 19	my to provide some background into a discussion that I was raising internally with HR about my work in the laboratory with the treatment of the treatment from my
16 17 18 19 20	Mischaracterizes her testimony. Lack of foundation. Seeks a legal conclusion. THE WITNESS: So to, I guess, make the clarification between fraud and data falsification which you're	16 17 18 19 20	my to provide some background into a discussion that I was raising internally with HR about my work in the laboratory with the treatment of the treatment from my supervisor and amongst my co-workers.
16 17 18 19 20 21	Mischaracterizes her testimony. Lack of foundation. Seeks a legal conclusion. THE WITNESS: So to, I guess, make the clarification between fraud and data falsification which you're referring to, I guess my interpretation	16 17 18 19 20 21	 my to provide some background into a discussion that I was raising internally with HR about my work in the laboratory with the treatment of the treatment from my supervisor and amongst my co-workers. Q. What is this here about acetone

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19

20

23

Did you testify that you

21 looking at, in preparation for a meeting with

A. I think maybe not in the

24 initial intent of creating the document but as

22 HR or did I get that wrong?

created this document, the one we were just

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL234		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL236
1	reference to?	1	I kept the log or kept this information or
2	A. Again, being not being	2	defined this outline, I believe that I used
3	treated the same as the others in the laboratory.	3	this as a supporting document when I went to
4	Q. So that wasn't strike that.	4	have a discussion with HR.
5	Did you have in mind gender-based	5	
6	discrimination?	6	(Exhibits Wlochowski-10,
7	A. No.	7	Outline for HR discussion, 00000273 and
8	Q. Is there some other group that	8	Wlochowski-11, Work summary, 00000274,
9	you feel that you're a part of that was	9	were marked for identification.)
0	discriminated against as a group in the lab or	10	
1	was this just discrimination as to you	11	BY MR. SANGIAMO:
2	personally?	12	Q. Ms. Wlochowski, you've just
3	A. I guess the if I could use	13	been handed documents marked as Exhibits 10
4	the word "click" as you had before, maybe	14	and 11. And I'm just going to go through them
5	discrimination of being in the click or not	15	with you. Before we do that, I just wonder if
6	the click.	16	you could shed any light on something. The
17	Q. This is a click consisting of	17	documents have these numbers we call Bates
8	whom?	18	numbers down at the corner that the lawyers
9	A. Those who Dave seemed to	19	put on before they produce documents.
0	interact with on a regular basis versus those	20	A. Okay.
21	who didn't.	21	Q. These two are sequential.
22	Q. Who were they?	22	Exhibit 10 is 273 and Exhibit 11 is 274. And
23	A. Mary Yagodich, Colleen Barr,	23	then Exhibit 11 down in the bottom right
24	Jenny Kriss. That's kind of, I guess, the	24	sorry, bottom left-hand corner says, "Page 2
	Page 235		Page 23
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL235		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL237
1	extent.	1	of 2." Do you think that these two pages were
2	Q. Right below discrimination it	2	part of the same document?
3	says, "hostile." Is that referring to	3	A. I don't I don't think so. I
4	anything other than what we've been talking	4	think they were independent of each other. I
5	about?	5	think the page number is it's not
6	A. No.	6	representative of any other page to this
7	Q. What's the word underneath	7	document. Meaning that there was no other
8	that?	8	there was no page 1.
9	A. It says I think it says,	9	
	"injust."		Q. Did you create these documents on your home computer or did you create them
1		10	
1	Q. What's that a reference to?	11	in work? And by "these," I mean Exhibits 9, 10 and 11.
2	A. I can't remember. I don't	12	
13	know.	13	A. I believe I created them at
14	Q. I apologize, Ms. Wlochowski. I	14	home, my home computer.
15	think but I'm not sure that your testimony	15	Q. Did you create them all at one
6	might have been inconsistent on this, but	16	sitting or did you revise them from time to
17	ultimately the transcript will tell us. But	17	time? What do you recall in that regard?
18	I'll nevertheless ask again just so I'm clear.	18	A. No, I think they were under

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happening.

separate documents at separate times. Part of

what I was going through in the laboratory or

kind of my internal feelings was to write

things down and keep a log of what was

Q. Is it fair to say you were very

	Case 22325533 Document: 7946 Pag	ge :	556 6	D2aeeFiilieed:1112026220223
	Page 238			Page 240
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL238		JOAN	NL. WLOCHOWSKI -HIGHLY CONFIDENTAL240
1	unhappy during your time at Merck during these	1	Q.	Questions about things you
2	first three months that were three and a	2	might hav	ve done wrong?
3	half months that were described in Exhibit 9?	3	А.	No.
4	A. Unhappy in what regard?	4	Q.	Questions about things you
5	Q. I'm sorry, unhappy about your	5	might hav	ve been accused of?
6	job.	6	А.	No, just no, not about me.
7	A. Unhappy about my job?	7	Q.	If we look at Exhibit 10, the
8	MR. KELLER: Objection. Vague	8	first section	on is called "Poor Management." Is
9	and ambiguous.	9	that a refe	erence to Dr. Krah?
10	BY MR. SANGIAMO:	10	А.	Yes, at the time I worked for
11	Q. Do you know what unhappy means?	11	Dave Kra	h.
12	A. Yes, I know what unhappy means.	12	Q.	You felt you were getting a
13	Yes, I think that it was a challenge to be in	13	lack of re	spect and recognition. Is that
14	this environment. So for me, I also I took	14	right?	
15	my job very seriously and wanted to be	15	А.	I did feel that way, yes.
16	recognized for the work that I do. So part of	16	Q.	You felt that he was a poor
17	this I, again, felt like there was a threat to	17	communi	cator?
18	my position there. So part of it was	18	А.	Yes.
19	documentation if there ever came some other	19	Q.	It says, "lack of trust (does a
20	information that was in conflict with what I	20	lot of lab	work himself)." Was it your belief
21	perceived as my performance in the laboratory.	21	that he di	d not trust any of the people in the
22	Q. You were worried about getting	22	lab or jus	t that he didn't trust you?
23	fired. Is that what you're saying?	23	А.	Both. I think there were
24	A. I don't know that I was worried	24	things that	t he conducted on his own to have

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	Page 239		Page 241
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL239		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL241
1	about being fired so much as my reputation in	1	that, I guess, just direct interaction with it
2	the workplace.	2	versus, you know, also it seemed to be as far
3	Q. Your reputation at Merck, is	3	as what he delegated for me to work on was
4	that what you mean?	4	also less than what he, you know, would assign
5	A. At the time, yes. Or for my	5	to other people in the lab.
6	career in general. If there were things that	6	Q. You found the work assignments
7	were going to be documented about me in my	7	you were getting degrading. Is that right?
8	file, my employee file, could be impact	8	MR. KELLER: Objection.
9	future, my career.	9	THE WITNESS: I felt that I
10	Q. Had you done this at other	10	wasn't being challenged.
11	jobs, make a record of the things that you	11	BY MR. SANGIAMO:
12	found dissatisfactory about the job during	12	Q. You considered them degrading,
13	your first few months there?	13	didn't you?
14	A. As far as this, no, I have not	14	MR. KELLER: Asked and
15	done documentation outlined like this.	15	answered. This is harassing.
16	Q. Have you done anything similar	16	MR. SANGIAMO: She didn't
17	to that?	17	answer.
18	A. I've saved e-mails, exchanges.	18	THE WITNESS: I don't
19	Q. In connection with other jobs?	19	MR. KELLER: She's answered.
20	A. Yes.	20	THE WITNESS: If you interpret
21	Q. Saved them for what purpose?	21	not being challenged as degrading,
22	A. If questions came up in the	22	yeah.
23	future, that I would be able to refer back to	23	BY MR. SANGIAMO:
24	an e-mail.	24	Q. Would you use that term to

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	Page 242		Page 244
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL242		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL244
1	describe it?	1	
2	A. To the extent that of the	2	Q. Is the correct interpretation
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	work that I was assigned to do, yeah, at	3	what is written there that you felt that
4		4	Dr. Krah was leaving you out of the loop in
	times, yes. Q. Did you think that you were		order to protect others who feel threatened by
5	Q. Did you think that you were more skilled than the other people in the lab?	5	your experience?
6	A. No, I didn't think that I was	6 7	A. That was my feeling at the time.
8	or I wasn't. I felt them my equivalence.	8	
9		9	Q. Who were the others?A. Those that potentially those
10	Q. You felt you were as skilled as the other people in the lab but not more	10	that were considered part of his click.
10	skilled. Is that fair?		-
		11	Q. What made you think that they
12	A. Yes, I felt like yes.O. Under "Favoritism" back on	12	felt threatened by your experience?
13		13	A. It was just, again, the
14	Exhibit 10, it says, "unable to separate	14	perception I had based on that there wasn't
15	social versus professional relationship with	15	that interaction between myself and my
16	certain employees." It says, "i.e. birthday	16	co-workers to say, to help me get oriented in
17	luncheon, gifts, etc."	17	the lab as I started working there. Typically
18	Gifts, is that the thing for	18	when, you know, I'm used to working in an
19	the Easter baskets and jelly beans?	19	environment with others who will provide you
20	A. Yes.	20	guidance because you just started. Basically
21	Q. Where it says, "birthday	21	to show you the ropes of what we were all
22	luncheon," what's that mean?	22	working together as a team to do.
23	A. He would take certain staff	23	Q. A couple of lines down it says,
24	members, when it was their birthday, take them	24	ERROR REPORTS specifically designed with
	Page 243		Page 245
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL243		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL245
1	out to lunch with other staff members.	1	the intent to facilitate your departure. Do
2	Q. How many times did that happen?	2	you see that?
3	A. I can't recall how many times.	3	A. Yes.
4	Q. More than one?	4	Q. Did you believe that the error
5	A. Not that I can recall.	5	report policy was specifically designed with
6	Q. Just one you can recall?	6	the intent to facilitate your departure from
7	A. Yes.	7	Merck?
8	Q. And what happened, you didn't	8	A. Based on my discussion with
9	get invited to that?	9	others in the laboratory.
10	A. Me and others didn't get	10	Q. That was your belief?
11	invited.	11	A. Uh-huh.
12	Q. Did you find that insulting?	12	Q. What were those discussions
13	A. As coming from a manager, yes.	13	that you were just referring to?
14	Q. Then under "Discrimination,"	14	A. That they were set up to have
15	there are, looks like, five starred items and	15	me basically to have to get rid of me as
16	within the first one there are two bullets, if	16	a worker within the laboratory.
17	you will, the second of which reads: "left	17	Q. Who told you that?
18	out of the loop to protect others who feel	18	A. Steve had the conversation
19	threatened by my experience." There's no	19	because he was also involved in the
19	subject in that sentence. Were you saying	20	conversation with the others in the
20			
	that Dr. Krah left you out of the loop in	21	laboratory. So Steve had discussed it with
20	that Dr. Krah left you out of the loop in order to protect others who feel threatened by	22	myself as well as Frank.
20 21	that Dr. Krah left you out of the loop in		-

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	Page 246	_	Page 248
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL246		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL248
1	facilitate your departure?	1	MR. KELLER: Objection. Calls
2	A. My departure. I can't remember	2	for speculation. Lack of foundation.
3	if he also told Frank it was also focused on	3	THE WITNESS: Again, just based
4	him as well.	4	on different discussions within the
5	Q. How would that facilitate your	5	laboratory about people saying,
6	respective departures? By creating a record	6	admitting that they wouldn't have to do
7	of you having made mistakes, is that the idea?	7	that report when I would.
8	A. Yes.	8	BY MR. SANGIAMO:
9	Q. Did anyone else tell you that	9	Q. How many times did that happen?
10	that was Dr. Krah's intent besides Mr. Krahling?	10	A. I can remember once specifically.
10	A. Again, I saw comments being	11	
			Q. Any others?
12	made by Dave how I made this error, but, you	12	A. Not that I can recall.
13	know, I'm not going to have to do an error	13	Q. The next line says or the
14	report. So it basically, you know, suggested	14	next star says, "degrading work, restricted
15	to me, again, that this was singling me out in	15	from running assays." So the fact that you
16	the laboratory just based on what I heard from	16	were restricted from running assays, you
17	others within the laboratory that, you know,	17	consider to be degrading. Right?
18	there's a the laboratory itself had a high	18	A. Yes.
19	turnover rate for people that worked there.	19	Q. You felt you were above the
20	So this wasn't, you know, just this type of	20	work of whatever it was that you were doing,
21	treatment wasn't like something new to other	21	the maintaining the cell lines?
22	people who had worked in the laboratory.	22	MR. KELLER: Objection.
23	Q. You felt that Dr. Krah set up	23	THE WITNESS: I felt like I had
24	the error report policy to facilitate your	24	more to offer and contribute to the
	Page 247		Page 249
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL247		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL249
1	departure based on the fact that Mr. Krahling	1	laboratory as a whole.
2	told you that's why Dr. Krah did it, and the	2	BY MR. SANGIAMO:
3	fact that other people did not have to write	3	Q. Isn't maintaining cell lines
4	up error reports under circumstances similar	4	exactly what you were doing at your last job?
5	to yours when you had to write up error	5	A. For the temporary position, yes.
6	reports. Right?	6	Q. Weren't you running the VZV
7	A. Uh-huh.	7	assay at the beginning of your tenure at
8	MR. KELLER: Mischaracterizes	8	Merck?
9	her testimony. Go ahead. Sorry, you	9	A. Again, I don't recall when I
10	weren't finished.	10	started running them, but I do know that the
11	BY MR. SANGIAMO:	11	workload was not the same, the assignments of
12	Q. Anything else?	12	the workload was not the same across the other
13	MR. KELLER: Mischaracterizes	13	workers in the laboratory.
14	her testimony.	14	Q. Do you take issue with the
15	THE WITNESS: Not that I can	15	policy of you not being allowed to work with
16	recall at this time.	16	the mumps virus for the plaque reduction
17	BY MR. SANGIAMO:	17	neutralization assay until you had
18	Q. Did Dr. Krah ever try to put	18	demonstrated a positive titer?
19	you on probation?	19	A. No.
20	A. No.	20	Q. You think that's a good policy?
20	Q. How do you rate the possibility	20	A. Yes.
$\begin{vmatrix} 21\\22 \end{vmatrix}$	that Mr. Krahling was lying to you when he	21	Q. Then you have a section
22	told you that that was Dr. Krah's intent with	22	"Injustice/Hostile Work Environment."
1 23	-	23 24	Do you see that?
24	regard to the error report policy?		

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	Page 250			Page 252
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL250		JOA	N L. WLOCHOWSKI -HIGHLY CONFIDENTAL252
1	A. I'm sorry?	1	that, did	you say that kind of thing?
2	Q. Do you see that section?	2	А.	Yes.
3	A. Yes.	3	Q.	She did say that. She affirmed
4	Q. The second starred item there	4	what Mr	. Krahling was saying about Dr. Krah
5	is "unacceptable behavior as a supervisor."	5	having r	nade derogatory comments about you?
6	Under that you have ridiculed past employees,	6	А.	Yes.
7	has made derogatory comments about, quote,	7	Q.	But sitting here, you don't
8	myself, which is a reference to you,	8	recall w	hat any of those derogatory comments
9	Ms. Wlochowski. Right?	9	were that	it were reported to you. Right?
10	A. Uh-huh.	10	А.	Right.
11	Q. What were the derogatory	11	Q.	You said he "readily gives out
12	comments he had made about you?	12	confider	tial information about employees."
13	A. I don't recall what he made	13	What's t	hat?
14	about me, what comments he made about me.	14	А.	That, I can't remember what
15	Q. How did you know that he had	15	specifics	s were around that.
16	made them?	16	Q.	Are you the one who heard him
17	A. So I know that, again, in my	17	A.	Yes.
18	discussions with Steve but also going back to	18	Q.	giving out confidential
19	the previous point of ridicules past	19	informat	tion about employees?
20	employees, I, myself have heard him, you know,	20	A.	Yes.
21	make comments about other employees who have	21	Q.	Do you remember what
22	worked there. So for me that was, you know,	22	A.	No.
23	again, not something that I have observed with	23	Q.	Do you remember what category
24	previous or employers or, you know,	24	of confid	dential information you had in mind
				· · · · · · · · · · · · · · · · · · ·
	Page 251 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL251		IOA	Page 253 N L. WLOCHOWSKI -HIGHLY CONFIDENTAL253
1		1	there?	N L. WLOCHOWSKI-HIGHLI CONFIDENTAL255
	current. That I wouldn't expect a supervisor to be talking about his employees to other	$\begin{vmatrix} 1\\2 \end{vmatrix}$	A.	No, I do not.
2	staff members.	3		Now, this document was written,
4		4	Q. Exhibit	10 here was written sometime after
	Q. But did I hear you to say that your basis for believing that he had made			2001. Does that sound right? I can
5	derogatory comments about you is Mr. Krahling	5		why I say that if it speeds things up
6		6	-	why I say that if it speeds things up
7	had told you that?	7	at all. A.	Tall ma why you gay it
8	A. Yes, Mr. Krahling told me that.	8		Tell me why you say it.
9	And, again, I also have had conversations with	9	Q.	There's a reference in the
10	Jill and, you know, she would also acknowledge	10		of the document right around the
11	that as well.	11		nination" section which says, "RECEIVED
12	Q. Ms. DeHaven told you that	12		NE OF HOW TO DO MUMPS ASSAYJULY 26,
13	Dr. Krah had made derogatory comments about	13	2001!!!!	
14	you?	14	A.	Okay.
15	A. She would be part of conversations	15	Q.	Does seeing that enable you to
16	with myself and Steve where she would	16		any more when it is that you may have
17	acknowledge that as well.	17	written t	his document?

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A. Probably shortly after that

HR at the end of July.

because I believe I did have a discussion with

Q. Did you present this document

don't think I have provided this copy. It was

to HR when you had that discussion?

A. Again, not that I recall. I

18

19

20

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24

Q. Could you explain what you mean

we had and Steve made comments about, I spoke

Said, yes, I heard Dr. Krah say

A. Any as far as discussions that

by "she would acknowledge that"?

about derogatory comments, Jill also

acknowledged them.

Q.

		90~	
	Page 254		Page 256
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL254		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL256
1	just my thoughts in my head for a discussion	1	feeling that that was part of his plan, so I
2	with HR.	2	felt compelled to defend myself and stand up
3	Q. You didn't come into that	3	for myself. I, again, wouldn't define that
4	meeting with any documents?	4	into hatred as much as, you know, disrespect
5	A. I don't believe I did.	5	for what he, you know, I felt should have been
6	Q. Was this a meeting with Bob	6	doing as a supervisor of a staff.
7	Suter?	7	Q. Well, you also thought he was
8	A. Yes.	8	making derogatory comments about you. Right?
9	Q. Was anyone else present at that	9	A. Uh-huh.
10	meeting?	10	Q. You thought he was giving you
11	A. Not that I recall.	11	degrading assignments. Right?
12	Q. If you take a look at	12	A. Uh-huh.
13	Exhibit 11. Do you know when that document	13	Q. And you thought he was
14	was prepared? Can you approximate that?	14	facilitating your social exclusion from the
15	A. Again, just going on the	15	lab. Right?
16	timeline that this goes through, September, I	16	A. Yes.
17	would say at the end of September.	17	Q. And whatever you felt in
18	Q. Towards the end of the first	18	response to that stopped short of hatred or
19	paragraph which is describing events of	19	was it hatred?
20	January and February, the last two sentences	20	MR. KELLER: Objection. Asked
21	read well, last three sentences read: "I	21	and answered. Argumentative.
22	tried to keep an open mind about the situation	22	THE WITNESS: I would say
23	and maintain a respectful professional	23	stopped short of hatred.
24	relationship with everyone. This however was	24	BY MR. SANGIAMO:
			D 257
	Page 255 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL255		Page 257 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL257
1	to no avail since far too many premature	1	Q. Did you feel anger?
2	judgments were made against me. The demands	2	MR. KELLER: Same objection.
3	for social acceptance outweighed any asset I	3	THE WITNESS: Uh-huh. As I
4	could bring to the table career wise."	4	mentioned before, I was you know,
5	What are the premature	5	internally, yes, I had some anger.
6	judgments that you're referring to there?	6	internativ, yes, i had some anger.
7		0	MR KELLER. Let's take a
		7	MR. KELLER: Let's take a
	A. I think just from the start I felt as though I wasn't accepted right into	7	break. It's been an hour.
8	felt as though I wasn't accepted right into	8	break. It's been an hour. VIDEOGRAPHER: The time is now
9	felt as though I wasn't accepted right into the lab and working with others. So I don't	8 9	break. It's been an hour.
9 10	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the	8 9 10	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record.
9 10 11	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think	8 9 10 11	break. It's been an hour. VIDEOGRAPHER: The time is now
9 10 11 12	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with	8 9 10 11 12	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.)
9 10 11 12 13	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers.	8 9 10 11 12 13	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is
9 10 11 12 13 14	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred	8 9 10 11 12 13 14	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may
9 10 11 12 13 14 15	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred of Dr. Krah for the way he was treating you?	8 9 10 11 12 13 14 15	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may proceed.
9 10 11 12 13 14 15 16	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred of Dr. Krah for the way he was treating you? A. I don't think I would call it	8 9 10 11 12 13 14 15 16	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may proceed. BY MR. SANGIAMO:
9 10 11 12 13 14 15 16 17	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred of Dr. Krah for the way he was treating you? A. I don't think I would call it hatred.	8 9 10 11 12 13 14 15 16 17	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may proceed. BY MR. SANGIAMO: Q. Ms. Wlochowski, when you were
9 10 11 12 13 14 15 16 17 18	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred of Dr. Krah for the way he was treating you? A. I don't think I would call it hatred. Q. Well, you felt he was trying to	8 9 10 11 12 13 14 15 16 17 18	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may proceed. BY MR. SANGIAMO: Q. Ms. Wlochowski, when you were working in Dr. Krah's lab, was there an
9 10 11 12 13 14 15 16 17 18 19	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred of Dr. Krah for the way he was treating you? A. I don't think I would call it hatred. Q. Well, you felt he was trying to get you fired. Right?	8 9 10 11 12 13 14 15 16 17 18 19	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may proceed. BY MR. SANGIAMO: Q. Ms. Wlochowski, when you were working in Dr. Krah's lab, was there an occasion when you requested an adjustment in
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 9 10 11 12 13 14 15 16 17 18 19 20 21 	felt as though I wasn't accepted right into the lab and working with others. So I don't know, to this day I don't know what the judgments are against me, but, again, I think it just prevented a working relationship with my co-workers. Q. Did you develop a personal hatred of Dr. Krah for the way he was treating you? A. I don't think I would call it hatred. Q. Well, you felt he was trying to get you fired. Right? A. Well, yes, and I know you asked me that question previously and I saw that, I	8 9 10 11 12 13 14 15 16 17 18 19 20 21	break. It's been an hour. VIDEOGRAPHER: The time is now 4:26. Going off the video record. (A recess was taken.) VIDEOGRAPHER: The time is 4:42. This begins disc six. You may proceed. BY MR. SANGIAMO: Q. Ms. Wlochowski, when you were working in Dr. Krah's lab, was there an occasion when you requested an adjustment in your work hours? A. Yes, I did.

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL258		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL260
1	Q. That is what I was saying. Is	1	work on the weekends other than that schedules
2	that your recollection?	2	were rearranged to accommodate weekend
3	A. I don't recall that, no.	3	coverage.
4	Q. You just recall one?	4	Q. Did he request volunteers to
5	A. Yes.	5	work on the weekend, to your recollection?
6	Q. Do you recall what the	6	A. I believe so.
7	precipitating event was for that one request?	7	Q. Did you ever volunteer to work
8	A. Based on sorry, what, why I	8	on the weekends?
9	needed different hours?	9	A. I do not recall.
10	Q. Yes.	10	Q. You don't recall ever
11	A. So my husband was taking	11	volunteering or you don't recall whether you
12	classes at the time so I wanted to be able to	12	ever volunteered? Do you see the distinction
13	fit my work schedule around being able to be	13	I'm drawing?
14	home for my children.	14	A. No.
15	Q. Did Dr. Krah accommodate that?	15	Q. You do not have a recollection
16	A. He did not immediately. There	16	of having volunteered. Right?
17	was not an immediate response to the request,	17	A. I do not recall if I volunteered
18	as far as I can recall.	18	or not.
19	Q. How long did it take him to	19	Q. Do you recall other members of
20	respond to the request?	20	the lab complaining to you about you making
21	A. I believe he had me submit some	21	sexually inappropriate comments? Do you
22	different documentation around that. I can't	22	remember that?
23	remember the details.	23	A. No.
24	Q. Didn't he grant the request	24	Q. Do you have a recollection of
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JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL259		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL261
while the documentation was being submitted	1	telling Dr. Krah at one point that you were
and evaluated?	2	uncertain if you were counting plaques
A. I would I can't remember off	3	correctly?
the top of my head.	4	A. I don't recall making that
Q. You just don't remember one way	5	statement that I was uncertain.
or the other?	6	Q. Did you ever seek his guidance
A. Yes.	7	for counting plaques?
Q. The other request for a change	8	A. I don't know if I sought out
in your hours that I was recalling was several	9	his guidance as he would provide guidance.
years I'm sorry, several months prior to	10	Q. So just to be clear, you don't
what you were just describing. Does that jog	11	have a recollection of you ever seeking out
your does my saying that jog your	12	his guidance. Right?
recollection in any way?	13	A. On plaque counting?
A. No.	14	Q. Correct.
Q. Is it the case that others in	15	A. I guess it depends on guidance
Dr. Krah's lab were working on weekends? Do	16	because if there was a particular assay that
you recall that?	17	had a different look to it, I would bring it
A. There were some time required	18	to his attention.
for others for the lab to work on weekends,	19	Q. When you were at New Haven
yes.	20	Hospital, did you ever have an occasion where
Q. I'm sorry, I don't understand	21	you were uncertain about a plaque count when
that.	22	you were running the plaque reduction assay
A. I don't recall that there was	23	for the antiviral therapies?
anybody scheduled, you know, as a routine to	24	A. I don't recall if I did.
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL259 while the documentation was being submitted and evaluated? A. I would I can't remember off the top of my head. Q. You just don't remember one way or the other? A. Yes. Q. The other request for a change in your hours that I was recalling was several years I'm sorry, several months prior to what you were just describing. Does that jog your does my saying that jog your recollection in any way? A. No. Q. Is it the case that others in Dr. Krah's lab were working on weekends? Do you recall that? A. There were some time required for others for the lab to work on weekends, yes. Q. I'm sorry, I don't understand that. A. I don't recall that there was	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL259while the documentation was being submitted1and evaluated?2A. I would I can't remember off3the top of my head.4Q. You just don't remember one way5or the other?6A. Yes.7Q. The other request for a change8in your hours that I was recalling was several9years I'm sorry, several months prior to10what you were just describing. Does that jog11your does my saying that jog your12recollection in any way?13A. No.14Q. Is it the case that others in15Dr. Krah's lab were working on weekends? Do16your recall that?17A. There were some time required18for others for the lab to work on weekends,19yes.20Q. I'm sorry, I don't understand21that.22A. I don't recall that there was23

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	Page 262		Page 264
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL262		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL264
1	Q. Was there a procedure in place	1	Q. Do you feel that your aptitude
2	for what you were to do at New Haven Hospital	2	as a plaque counter for the mumps plaque
3	in that circumstance?	3	reduction neutralization assay improved over
4	A. If I had a question about a	4	the time period that you worked at Merck?
5	plaque count, about a procedure about that? I	5	A. Yes, like any skill, your
6	don't know if there was a procedure about	6	aptitude would improve. I do know, though,
7	questions about plaque counts, but essentially	7	that there were many others in the laboratory
8	in my work experience, if there is something	8	that also conducted plaque counts that would
9	that I see that I have a question about or	9	raise questions, it still would continue to

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A. So Dave would, you know, look

at the plates, be in the lab when we were

various members within the laboratory.

counting. So he would provide guidance to

Q. Did you get that training from

the mumps plaque reduction neutralization

him before you did your first plaque counts on

	that i bee that i have a question about of	1	Taise questions, it bin would continue to
10	think is an issue, I would raise it to my	10	raise questions on plaque counts. As a
11	manager.	11	general rule, as we were counting plaques in
12	Q. Would you include plaque counts	12	the laboratory, it was known across the lab
13	within that category of the kind of thing that	13	staff that anything that we found pre-positive
14	you would raise with your manager if you had a	14	was unexpected. And so there was, you know, a
15	question?	15	feeling across the lab members that if the
16	MR. KELLER: Objection. Calls	16	results of the plaque counting would give you
17	for speculation.	17	something that would generate a pre-positive
18	THE WITNESS: Yeah, I guess,	18	result, they would continue to look for
19	again, when you say raise a question	19	plaques to find additional plaques in order to
20	about a plaque count, can you be more	20	get the result that was expected as far as not
21	specific?	21	having a pre-positive. The statement that,
22	BY MR. SANGIAMO:	22	you know, Krah explained that I recall during
23	Q. Did you ever have uncertainty	23	my training is that, you know, in the patient
24	as to whether the well you were looking at	24	population you wouldn't expect that people
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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL263		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL265
1	had, for example, seven plaques versus six	1	would have that there isn't that level of
2	plaques? I'm referring now to the work you	2	having antibodies to mumps prior to
3	did at New Haven Hospital.	3	vaccination, at least in, you know, a majority
4	A. I don't recall. Again, my	4	of the population and, therefore, it's not
5	experience, I would be trained to perform	5	expected to see that result. That's what I
6	something during my training period. Yes, I	6	recall as part of my training.
7	would have questions that I would rely on	7	Q. When did you get this training?
8	either my co-workers or my management to	8	A. Again, it was part of it was
9	provide me feedback on any questions that I	9	throughout the course of us conducting the
10	would have.	10	plaque counting in the laboratory.
11	Q. Were the plaques for the plaque	11	Q. Did you get it I'm sorry.

12 reduction assay that you counted -- sorry, 13 strike that. 14 Were the plaques for the plaque 15 reduction assay that you ran at New Haven 16 Hospital easier to count than the plaques in the mumps plaque reduction neutralization 17 18 assay, harder to count or roughly the same? 19 MR. KELLER: Objection. Vague 20 and ambiguous. 21

22

23

24

19 assay? 20 A. I don't recall. THE WITNESS: I don't know if I 21 Q. Now, I'm going to have to reask can make a comparison. They were 22 a question I asked you a moment ago, because different. you gave a long answer, but it didn't -- I'm 23 BY MR. SANGIAMO: 24 not sure I got the answer to the very specific

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	Page 266		Page 268
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL266		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL268
1	question I asked you, which is, do you feel	1	as the context for this first paragraph here?
2	that your aptitude as a plaque counter	2	A. Discussed at the meeting. I
3	improved as regards to mumps plaque reduction	3	don't recall exactly what was discussed at the
4	neutralization assay over the course of your	4	meeting. I believe that my discussion with
5	time at Merck?	5	him would be about being able to complete the
6	A. Yes.	6	amount of work that was assigned in the
7	MR. KELLER: Asked and answered.	7	eight-hour day and being able to leave on
8		8	time.
9	(Exhibit Wlochowski-12, E-mail	9	Q. This is your boss here offering
10	exchange, 00048441 & 00048442, was	10	to complete any projects
11	marked for identification.)	11	A. Right.
12		12	Q that you may not be able to
12	BY MR. SANGIAMO:	12	complete in the workday. Right?
13	Q. Ms. Wlochowski, you've just	13	A. Yes.
15	been handed what has been marked as	14	Q. That's a pretty generous thing
15	Exhibit 12, which is an e-mail exchange	16	for a boss to do, don't you agree?
17	between you and Dr. Krah.	17	A. I agree. I think that, you
17	MR. KELLER: Take a minute to		know, it was not my intent for him to complete
10	read the e-mail.	18 19	•
20	MR. SANGIAMO: I'm sorry, what	20	my work in the middle of me performing something. So, you know, again, it's yeah,
$\begin{vmatrix} 20\\21 \end{vmatrix}$	did you say, Jeff?		
		21	it's a generous offer for him to do that.
22	MR. KELLER: I'm asking her to	22	However, that was not the intent of what I was
23	review the e-mail if you're going to	23	asking for.
24	ask questions about it.	24	Q. Did you thank him for it in
	Page 267		Page 269
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL267		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL269
1	BY MR. SANGIAMO:	1	your response?
2	Q. You've read it?	2	A. Not in this particular response, no.
3	A. Yes.	3	
4			Q. Down at the bottom of his
I .	Q. Do you have a recollection of	4	e-mail, four lines from the bottom he says,
5	this e-mail exchange?	4 5	e-mail, four lines from the bottom he says, "Some reports, such as the one that you
6	this e-mail exchange? A. Yes. Because I read it.	5 6	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed
6 7	this e-mail exchange?A. Yes. Because I read it.Q. I'm sorry?	5 6 7	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I
6 7 8	this e-mail exchange?A. Yes. Because I read it.Q. I'm sorry?A. Because I read it, yes.	5 6 7 8	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to
6 7 8 9	this e-mail exchange?A. Yes. Because I read it.Q. I'm sorry?A. Because I read it, yes.Q. If we look at the first e-mail	5 6 7 8 9	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone."
6 7 8	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, 	5 6 7 8 9 10	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct.
6 7 8 9 10 11	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's 	5 6 7 8 9 10 11	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there
6 7 8 9 10 11 12	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that 	5 6 7 8 9 10	 e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that
6 7 8 9 10 11	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that if you need to leave early or if any of the 	5 6 7 8 9 10 11	 e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that he did not pass along the rest of the lab? Is
6 7 8 9 10 11 12	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that if you need to leave early or if any of the work is going over the regular hours for our 	5 6 7 8 9 10 11 12 13 14	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that he did not pass along the rest of the lab? Is that correct?
6 7 8 9 10 11 12 13	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that if you need to leave early or if any of the work is going over the regular hours for our mumps Nt assays and you need or want to leave 	5 6 7 8 9 10 11 12 13	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that he did not pass along the rest of the lab? Is that correct? A. I think my questions were
6 7 8 9 10 11 12 13 14	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that if you need to leave early or if any of the work is going over the regular hours for our 	5 6 7 8 9 10 11 12 13 14	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that he did not pass along the rest of the lab? Is that correct? A. I think my questions were you know, in my response there was more around
6 7 8 9 10 11 12 13 14 15	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that if you need to leave early or if any of the work is going over the regular hours for our mumps Nt assays and you need or want to leave 	5 6 7 8 9 10 11 12 13 14 15	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that he did not pass along the rest of the lab? Is that correct? A. I think my questions were
6 7 8 9 10 11 12 13 14 15 16	 this e-mail exchange? A. Yes. Because I read it. Q. I'm sorry? A. Because I read it, yes. Q. If we look at the first e-mail from Dr. Krah to you dated June 20th at 4:04, it begins with. "As follow-up from today's meeting I wanted to be sure that you knew that if you need to leave early or if any of the work is going over the regular hours for our mumps Nt assays and you need or want to leave for the day, please let me know and we can 	5 6 7 8 9 10 11 12 13 14 15 16	e-mail, four lines from the bottom he says, "Some reports, such as the one that you generated, did not provide a proposed suggestion of steps to avoid occurrence, so I did not feel that there was information to pass along to anyone." A. Correct. Q. I gather the background there is that you had written an error report that he did not pass along the rest of the lab? Is that correct? A. I think my questions were you know, in my response there was more around
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of foundation.

BY MR. SANGIAMO:

THE WITNESS: That is an

appropriate e-mail response, yes.

Q. Did you identify -- strike that.

Did you take him up on his

24 offer to identify other reports that should

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	JOAN L. WLOCHOWSKI -HIGHLY COM	NFIDENTAL270		JOA	N L. WLOCHOWSKI -HIGHLY CONFIDENTAL272
1	error that you had made?		1	have bee	en written?
2	A. I don't know if he didn't pass		2	А.	I did not in this e-mail response.
3	it along. He said he didn't feel the need to		3	Q.	Did you ever?
4	pass it along, but I don't know if he did or		4	А.	I may have verbally based on my
5	did not pass it along to other people in the		5	notes.	
6	laboratory.		6	Q.	But you don't have a recollection
7	Q. Do you have a recollection of		7	of that?	
8	finding out that it was passed along?		8	А.	I do not.
9	A. I do not recall.		9	Q.	He responds to your e-mail and
10	Q. Well, if he didn't		10	at the be	ginning he says, "Please feel free at
11	A. I do know that others were		11		to ask about any questions that come
12	aware that I was being made to write an error		12	up."	
13	report.		13	A.	Uh-huh.
14	Q. Well, there were two error		14	Q.	Did you take him up on that
15	reports. Right?		15		a general proposition?
16	A. Yes.		16	А.	Yes, I did.
17	Q. That you had to write?		17	Q.	Did he engage when you would
18	A. That I recall, yes.		18	-	juestions to him?
19	Q. Do you know if others were made		19	A.	Typically he would respond to
20	aware of this particular error report that,		20		s that I had. It wasn't always an
21	from the way Dr. Krah's e-mail is phrased, it		21		te response, but, yes, he did respond
22	sounds like he did not circulate to the lab?		22		ons I had. He also makes note that,
23	A. He again, if everybody		23	-	w, here he did confirm that he passed
24	already knew what the error was and that I was		24		nation to certain members of the lab
<u> </u>					
		Page 271			Page 273
	JOAN L. WLOCHOWSKI -HIGHLY CON	NFIDENTAL271			N L. WLOCHOWSKI -HIGHLY CONFIDENTAL273
1	required to write a report for it, they did		1	• •	it had stated that he may have missed
2	know that.		2	-	g it to me. You know, so that's just
3	Q. But you don't know whether the		3		example of him providing certain
4	error report that he's referring to there is		4	-	f information to certain pieces
5	an error report that was made known to the		5		eople within the laboratory and just
6	entire lab. Right?		6		you know, I left you out. And just,
7	A. Right.		7		w, in general from, again, all this
8	Q. Then his next sentence says,		8		on between myself and Dave and
9	"Again, if you feel that there are other		9		ah and the laboratory, based on the
10	reports that should have been written, please		10		10, in addition to the other
11	let me know and I will either request one or		11		ion that I documented for my outline
12	clarify why one is not needed."		12		ssion with HR, I also documented
13	Looking at this now, would you		13		know, manipulation of data was also
14	say that that's an appropriate and responsible		14		g at that time. So a mix of the
15	response by the boss to an inquiry from a		15	interacti	ons with his unprofessional behavior
16	member of his staff?		16	the way	I saw it with the other events that
17	MR. KELLER: Objection. Lack		17	were hap	opening in the laboratory, had, you
1 10					

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know, had played into my responses and

I guess what I'll do is I'll move to strike

that answer and then I'll just ask you the

Q. Okay. I'm going to need to --

Would he engage when you would

interactions with Dave Krah.

question again.

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL274		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL276
1	present questions to him?	1	prepared and, you know, put together in
2	A. And I believe I answered that	2	preparation for the discussion.
3	question.	3	Q. But you don't remember what you
4	Q. I know but then you inserted	4	said to him at the discussion?
5	some other things about manipulation of data	5	A. I don't remember the conversation,
6	so I need to and including that in some	6	no.
7	prior documents. I need a clean answer to my	7	Q. How long do you remember how
8	question, which was would he engage when you	8	long it lasted?
9	would present questions to him?	9	A. I do not. I do not.
10	A. Again, he would engage with a	10	Q. Do you recall what it was that
11	delayed response.	11	you were hoping to accomplish in the
12	MR. SANGIAMO: Dino, you don't	12	discussion?
13	like her answers, I know you selectively	13	A. I just wanted to again, I
14	are picking things out of exhibits,	14	felt that as if there were any documentation
15	but, you know, if you want to make a	15	that or records that Dave was Dave Krah
16	motion to strike, this is not the	16	was maintaining on me, I also wanted to put on
17	appropriate venue. You can do that in	17	record my experience in the laboratory.
18	front of a judge who can get the full	18	Q. Fair to say it was a defensive
19	record in front of you. She testified	19	action on your part to protect yourself should
20	and answered your question. Appreciate	20	it be the case that you were at risk of some
21	you didn't like her answer, but we	21	sort of adverse action being taken against
22	don't agree with your motion to strike.	22	you? Is that fair?
23	If you want to make that motion, bring	23	A. I don't know if it was, you
24	it before the court.	24	know, defensive, but also part of it making a
	Page 275		Daga 277
	Page 275		Page 277 IOAN I. WI OCHOWSKI HIGHI Y CONFIDENTAL 277
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL275	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL277
1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL275 BY MR. SANGIAMO:	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL277 statement about the professionalism and the
2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL275 BY MR. SANGIAMO: Q. In looking at the third	2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL277 statement about the professionalism and the handling of the data within the laboratory.
23	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL275 BY MR. SANGIAMO: Q. In looking at the third sentence or, I'm sorry, his 8:54 response, he	2 3	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL277 statement about the professionalism and the handling of the data within the laboratory. Q. Do you recall whether Mr. Suter
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL275 BY MR. SANGIAMO: Q. In looking at the third sentence or, I'm sorry, his 8:54 response, he says "Regarding the report that you provided, I fully," underlined, "appreciate and accept that it was an accident." Do you question whether he fully appreciated and accepted that it was an accident? A. I questioned the reason I would be called out on an accident if other accidents occur in the laboratory and, again, I don't see a consistency in what requires an error report versus what doesn't. So that was my question back to him. Q. You said you had a meeting with Bob Suter which you thought was on July 31, 2001. Is that right? A. The end of July. Q. The end of July. Can you tell me what you recall about that meeting? A. I don't recall much about the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL277 statement about the professionalism and the handling of the data within the laboratory. Q. Do you recall whether Mr. Suter gave you any particular guidance? A. I don't recall that he gave me any guidance at that time. Q. Do you recall if he ever gave you any guidance? MR. KELLER: Overbroad. THE WITNESS: What I do recall is that, you know, shortly after this time period there were some exchanges of Bob Suter arranging for me to interview and transfer to another laboratory within Merck. BY MR. SANGIAMO: Q. Do you recall if there was a subsequent meeting between you and Mr. Suter after January 31, 2001? A. I do not recall a specific meeting. I know we exchanged some a discussion about whether or not, you know, at

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1	Page 278		Page 280
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL278		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL280
1	in setting up an interview or how that occurred.	1	about a finding of data manipulation. You're
2	Q. In particular I gather you	2	just talking about you having questioned Dave
3	don't recall whether any of his activities in	3	regarding your view that there was data
4	that regard were done by e-mail versus meeting	4	manipulation? Is that what you're referring
5	versus telephone? Is that accurate?	5	to?
6	A. I believe that I had e-mailed	6	A. Yes. Yep.
7	him about the actual transfer itself. There	7	А. тех. тер.
8	was an e-mail, but as far as phone call	8	(Exhibit Wlochowski-13, E-mail
9	discussions or anything further than that, I	9	exchange, 00000067, was marked for
10	don't recall.	10	identification.)
10	Q. Did you form an impression of		identification.)
		11	DV MD SANCIAMO.
12	Mr. Suter as a professional?	12	BY MR. SANGIAMO:
13	MR. KELLER: Objection. Vague	13	Q. So Ms. Wlochowski, you've been
14	and ambiguous.	14	handed what has been marked as Exhibit 13. Is
15	THE WITNESS: I don't have an	15	that correct?
16	opinion about him one way or the other.	16	A. Yes.
17	BY MR. SANGIAMO:	17	Q. This is an e-mail exchange
18	Q. Is it your recollection that he	18	between you and Mr. Suter?
19	handled the conversation with you responsibly?	19	A. Yes.
20	MR. KELLER: Same objection.	20	Q. Down at the bottom of the
21	THE WITNESS: I don't recall	21	e-mail we see sorry, mark this as 14.
22	that there was much action after my	22	
23	discussion with him immediately, but,	23	(Exhibit Wlochowski-14, E-mail
24	you know, the circumstances following	24	exchange, 00000072, was marked for
	Page 279		Page 281
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL279		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL281
1	that, there was, you know, actions that	1	identification.)
2	were that occurred based on the	2	
3	additional findings of data	3	BY MR. SANGIAMO:
4	manipulation within the laboratory.	4	Q. Strike the question I was just
5	BY MR. SANGIAMO:	5	
6	Q. You just referred to some		asking. Sorry, I've generated some exhibit
	-	6	asking. Sorry, I've generated some exhibit confusion here. What I was hoping you would
7	finding of data manipulation.	6 7	
8	finding of data manipulation. A. I guess not necessarily		confusion here. What I was hoping you would look at, Ms. Wlochowski, is the document that has the Bates number that ends in 72, which I
	finding of data manipulation. A. I guess not necessarily findings, but reporting of manipulation of	7	confusion here. What I was hoping you would look at, Ms. Wlochowski, is the document that has the Bates number that ends in 72, which I think is Exhibit 14. Do you have that?
8	finding of data manipulation. A. I guess not necessarily findings, but reporting of manipulation of data within the laboratory.	7 8	confusion here. What I was hoping you would look at, Ms. Wlochowski, is the document that has the Bates number that ends in 72, which I think is Exhibit 14. Do you have that? A. Yes.
8 9	finding of data manipulation. A. I guess not necessarily findings, but reporting of manipulation of	7 8 9	 confusion here. What I was hoping you would look at, Ms. Wlochowski, is the document that has the Bates number that ends in 72, which I think is Exhibit 14. Do you have that? A. Yes. Q. Down at the bottom of that
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8 9 10 11 12 13 14 15 16 17 18 19	 finding of data manipulation. A. I guess not necessarily findings, but reporting of manipulation of data within the laboratory. Q. What do you mean reporting of manipulation of data within the laboratory? A. Maybe, sorry, I'm not being clear. So the going back to counting of plaques, again, the what I experienced while I was there is that people were recounting the plaques on the plates and focused on counting the pre-positives because, again, it was not the expected and did not 	7 8 9 10 11 12 13 14 15 16 17 18 19	 confusion here. What I was hoping you would look at, Ms. Wlochowski, is the document that has the Bates number that ends in 72, which I think is Exhibit 14. Do you have that? A. Yes. Q. Down at the bottom of that e-mail there's an e-mail exchange, there's an e-mail from you to Mr. Suter, dated August 13, 2001. And it refers to having met with him on July 31, 2001. Do you see that? A. Yes. Q. And that's the meeting that you were describing in your testimony a few minutes ago. Right?
8 9 10 11 12 13 14 15 16 17 18 19 20	 finding of data manipulation. A. I guess not necessarily findings, but reporting of manipulation of data within the laboratory. Q. What do you mean reporting of manipulation of data within the laboratory? A. Maybe, sorry, I'm not being clear. So the going back to counting of plaques, again, the what I experienced while I was there is that people were recounting the plaques on the plates and focused on counting the pre-positives because, again, it was not the expected and did not lead to the desired outcome. And based on 	7 8 9 10 11 12 13 14 15 16 17 18 19 20	 confusion here. What I was hoping you would look at, Ms. Wlochowski, is the document that has the Bates number that ends in 72, which I think is Exhibit 14. Do you have that? A. Yes. Q. Down at the bottom of that e-mail there's an e-mail exchange, there's an e-mail from you to Mr. Suter, dated August 13, 2001. And it refers to having met with him on July 31, 2001. Do you see that? A. Yes. Q. And that's the meeting that you were describing in your testimony a few minutes ago. Right? A. Yes.
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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL282		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL284
1	aspects of your situation are on hold pending	1	Q. Did Mr. Krahling ever say to
2	resolution of their investigation. I'll keep	2	you that Mr. Suter told him that he would go
3	you informed."	3	to jail if he were to call the FDA?
4	Do you see that?	4	A. He did tell me that, yes.
5	A. Yes.	5	Q. Do you know if anyone was a
6	Q. And then you then got back to	6	witness to that alleged statement by Mr. Suter?
7	him on September 6th asking if there's any new	7	A. I do not know if anyone was a
8	information?	8	witness.
9	A. Correct.	9	Q. Does that ring true to you?
10	Q. Then he replied to you that day	10	MR. KELLER: Objection. Vague
11	on that occasion, he replied to you the same	11	and ambiguous.
12	day asking if you were free to talk that	12	THE WITNESS: What do you mean
13	morning?	13	by "does that ring true"?
14	A. Correct.	14	BY MR. SANGIAMO:
15	Q. Is the gap in time between	15	Q. You've been in the pharmaceutical
16	July 31st and, say, September 6th, is that the	16	industry for almost two decades, I guess.
17	delay, I don't know if that's the word you	17	Does that sound right, that an HR representative
18	used, but the delay in him responding to you	18	in the pharmaceutical industry would threaten
19	in following up after the meeting that I think	19	someone they're going to go to jail if they
20	you referred to in your testimony?	20	call the FDA?
21	A. Yes.	21	MR. KELLER: Objection. Calls
22	Q. Now, I think when that line of	22	for speculation. Vague and ambiguous.
23	questioning began, I had asked you whether you	23	Lack of foundation.
24	felt that Mr. Suter had responded strike	24	THE WITNESS: To me, I don't
	Page 283		Page 285
	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL283		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL285
1	that.	1	to answer, I would not expect HR to say
2	I think when that line of	2	that, but I also would not necessarily
3	questioning began, I asked if you thought that	3	use HR as the primary decision-maker on
4	Mr. Suter had acted in a responsible manner in	4	whether or not information needed to be
5	his meeting with you on July 31st.	5	reported to the FDA.
6	A. Uh-huh.	6	MR. SANGIAMO: Okay. Jeff,
7	Q. I think you in your answer	7	could we take a break now, I want to
8	you mentioned this delay, I believe. But	8	talk to the team here.
9	other than that, do you feel that he handled	9	VIDEOGRAPHER: The time is now
10	the meeting with you in a responsible manner?	10	5:23. Going off the video record.
11	MR. KELLER: Objection.	11	
12	Mischaracterizes her testimony. Go	12	(A recess was taken.)
13	ahead and answer.	13	
14			VIDEOCD ADLIED. The time is now
	THE WITNESS: Again, I don't	14	VIDEOGRAPHER: The time is now
15	THE WITNESS: Again, I don't recall exactly what he did with the	14 15	5:28. Back on the video record.
16	-		
16 17	recall exactly what he did with the	15	5:28. Back on the video record.
16 17 18	recall exactly what he did with the information that I presented to him at that meeting. There were other things that transpired between my meeting with	15 16 17 18	5:28. Back on the video record. MR. SANGIAMO: We have more
16 17	recall exactly what he did with the information that I presented to him at that meeting. There were other things	15 16 17	5:28. Back on the video record. MR. SANGIAMO: We have more questions to cover with Ms. Wlochowski,
16 17 18 19 20	recall exactly what he did with the information that I presented to him at that meeting. There were other things that transpired between my meeting with him on July 31st until September 6th that if, you know, had not occurred,	15 16 17 18 19 20	5:28. Back on the video record.MR. SANGIAMO: We have more questions to cover with Ms. Wlochowski, but we have up to two days for deposition,
16 17 18 19 20 21	recall exactly what he did with the information that I presented to him at that meeting. There were other things that transpired between my meeting with him on July 31st until September 6th	15 16 17 18 19 20 21	 5:28. Back on the video record. MR. SANGIAMO: We have more questions to cover with Ms. Wlochowski, but we have up to two days for deposition, so we're going to suspend for the day and resume tomorrow morning. Thank you. VIDEOGRAPHER: The time is now
 16 17 18 19 20 21 22 	recall exactly what he did with the information that I presented to him at that meeting. There were other things that transpired between my meeting with him on July 31st until September 6th that if, you know, had not occurred,	15 16 17 18 19 20	5:28. Back on the video record.MR. SANGIAMO: We have more questions to cover with Ms. Wlochowski, but we have up to two days for deposition, so we're going to suspend for the day and resume tomorrow morning. Thank you.
16 17 18 19 20 21	recall exactly what he did with the information that I presented to him at that meeting. There were other things that transpired between my meeting with him on July 31st until September 6th that if, you know, had not occurred, may not have had the same result. I	15 16 17 18 19 20 21	 5:28. Back on the video record. MR. SANGIAMO: We have more questions to cover with Ms. Wlochowski, but we have up to two days for deposition, so we're going to suspend for the day and resume tomorrow morning. Thank you. VIDEOGRAPHER: The time is now

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	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL286		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL288
1	(Witness excused.)	1	INSTRUCTIONS TO WITNESS
2	(WHILESS CACUSCA.)	2	Please read your deposition over
3	(Deposition concluded at	3	carefully and make any necessary corrections.
4	5:28 p.m.)	4	You should state the reason in the appropriate
5	5.26 p.m.)	5	space on the errata sheet for any corrections
6		6	that are made.
7		7	
		8	After doing so, please sign the errata sheet and date it.
8		8 9	You are signing same subject to the
9		-	
10		10	changes you have noted on the errata sheet,
11		11	which will be attached to your deposition.
12		12	It is imperative that you return the
13		13	original errata sheet to the deposing attorney
14		14	within thirty (30) days of receipt of the
15		15	deposition transcript by you. If you fail to
16		16	do so, the deposition transcript may be deemed
17		17	to be accurate and may be used in court.
18		18	
19		19	
20		20	
21		21	
22		22	
23		23	
24		24	
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,	JOAN L WLOCHOWSKI -HIGHLY CONFIDENTAL287		Page 289 JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289
1 2		1	C C
	JOAN L WLOCHOWSKI -HIGHLY CONFIDENTAL287 CERTIFICATE	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289
2 3	JOAN L WLOCHOWSKI -HIGHLY CONFIDENTAL287 C E R T I F I C A T E I do hereby certify that I am a Notary	1	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289
2 3	JOAN L WLOCHOWSKI -HIGHLY CONFIDENTAL287 CERTIFICATE		JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289 E R R A T A
2 3	JOAN L WLOCHOWSKI -HIGHLY CONFIDENTAL287 CERTIFICATE I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that	2	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289 E R R A T A
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2 3 4 5 6 7 8 9 10 11 12 13 14	JOAN L WLOCHOWSKI-HIGHLY CONFIDENTAL287 CERTIFICATE I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly swom to tell the truth, the whole truth, and nothing but the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof WITNESS my hand and official seal this 20th day of June, 2017	2 3 4 5 6 7 8 9 10 11 12 13 14	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289 E R R A T A PAGE LINE CHANGE Reason for Change:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	JOAN L WLOCHOWSKI-HIGHLY CONFIDENTAL287 CERTIFICATE I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof WITNESS my hand and official seal this 20th day of June, 2017 Mamaman Linda Rossi-Rios, RPR, CSR	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289 E R R A T A FINITE CHANGE FAGE LINE CHANGE Reason for Change: FREASON for Change: FR
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	JOAN L WLOCHOWSKI-HIGHLY CONFIDENTAL287 CERTIFICATE I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof WITNESS my hand and official seal this 20th day of June, 2017 Mamaman Linda Rossi-Rios, RPR, CSR	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	JOAN L. WLOCHOWSKI -HIGHLY CONFIDENTAL289 E R R A T A PAGE LINE CHANGE Reason for Change:
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		F	Page 290	
	JOAN L. WLOCHOWS	KI -HIGHLY CONFIDENT	AL290	
1	ACKNOWLEDGMEN	T OF DEPONENT		
2	I,			
3	hereby certify that I have re	ad the foregoing		
4	pages and that the same is a			
5	transcription of the answers			
6	the questions therein proport			
7	the corrections or changes in			
8	substance, if any, noted in the	he attached		
9	Errata Sheet.			
10				
11				
12	DATE SIGNAT	URE		
13		с <u>л</u> :		
14	Subscribed and sworn to be			
15 16	day of	, 2017.		
17	My commission expires:			
18	wry commission expires.			
19				
20	Notary Public			
21				
22				
23	Assignment: PA 2632736			
24	0			

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HIGHLY CONFIDENTIAL

Page 292 1 IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA 2 UNITED STATES OF AMERICA : CIVIL ACTION ex rel., STEPHEN A. : NO. 2:10-04374(CDJ) 3 KRAHLING and JOAN A. : 4 WLOCHOWSKI, Plaintiffs, 5 vs. б MERCK & CO., INC., 7 Defendant. ___ : Master File No. IN RE: MERCK MUMPS 8 : 2:12-cv-03555(CDJ) VACCINE ANTITRUST : 9 LITIGATION 10 THIS DOCUMENT RELATES TO: : ALL ACTIONS : 11 12 June 14, 2017 13 HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY 14 15 Continued videotaped deposition of JOAN L. WLOCHOWSKI, taken at the offices of 16 17 Morgan & Lewis, 1701 Market Street, 18 Philadelphia, Pennsylvania 19103, beginning at 19 9:30 a.m., before LINDA ROSSI-RIOS, a 20 Federally Approved RPR, CCR and Notary Public. 21 VERITEXT LEGAL SOLUTIONS 22 MID-ATLANTIC REGION 1801 Market Street - Suite 1800 23 Philadelphia, PA 19103 24

HIGHLY CONFIDENTIAL

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1 2	A P P E A R A N C E S :	1 INDEX WITNESS PAGE
3		2
	On behalf of the Relators	JOAN L WLOCHOWSKI
4	CONSTANTINE CANNON LLP	By Mr Sangiamo 296
5	BY: ROBERT L BEGLEITER, ESQUIRE and	4 By Mr Keller 556 5
6	MARLENE KOURY, ESQUIRE	EXHIBITS
-	335 Madison Avenue	6 MARKED DESCRIPTION PAGE
7	New York, NY 10017 212-350-2700	MARKED DESCRIPTION PAGE 7
8	rbegleiter@constantinecannon com	Wlochowski-15Mumps AIGENT Processing 362
0	mkoury@constantinecannon com	8 Workbook, Bates RELATOR_00000716 to 721
9 10		9
10	On behalf of the Relators	Wlochowski-16Plate Layout Sheet, 364 10 Bates MRK-KRA00680674
11		11 Wlochowski-17Virus & Cell Biology 369
12	KELLER GROVER LLP BY: JEFFREY F KELLER, ESQUIRE	Research Procedure, Bates 12 MRK-KRA00064382 to 4391
12	1965 Market Street	13 Wlochowski-18Notebook page, Bates 373
13	San Francisco, CA 94103	MRK-KRA00680669 & 670 14
14	415 543 1305 jfkeller@kellergrover com	Wlochowski-19Counting sheet, 375
14 15	Jikener @ Kenergi Over Colli	15 Bates MRK-KRA00680676 16 Wlochowski-20Sensitive Neutralization 431
16	On behalf of the Defendant, Merck & Co,	16 Wiocnowski-20Sensitive Neutralization 431 Test for Virus Antibody
17	Inc	17 article 18 Wlachowski 21 Handwitten document 461
1/	MORGAN LEWIS & BOCKIUS LLP	18 Wlochowski-21Handwritten document, 461 Bates RELATOR_00001025 & 26
18	BY: LISA C DYKSTRA, ESQUIRE	19
19	1701 Market Street	Wlochowski-22Assay Counts, Bates 481 20 RELATOR_00001014 to 1024
19	Philadelphia, PA 19103 215-963-5000	21 Wlochowski-23Handwritten document, 523
20	ldykstra@morganlewis com	Bates RELATOR_00000707 22
21		Wlochowski-24Responses and Objections 530
22 23		23 to Merck's First Set of Interrogatories
24		24
		Page 294 Page 296
1	A P P E A R A N C E S (cont'd):	1
2		
	On behalf of the Defendant, Merck & Co,	2 VIDEOGRAPHER: We are now on
3	Inc	3 the record. The date today is June 14,
4	VENABLE LLP	4 2017. This begins disc one of the
E	BY: DINO s SANGIAMO, ESQUIRE	5 continuation of the deposition of Joan
5	and MICHAELA F ROBERTS, ESQUIRE	6 Wlochowski. You may proceed.
6	750 East Pratt Street	7
0	Suite 900	
7	Baltimore, MD 21202	8 JOAN L. WLOCHOWSKI, after
	410-244-7400	9 having been previously sworn, was
8	dssangiamo@venable com	10 examined and testified as follows:
-	mfroberts@venable com	11
9		12 EXAMINATION
10	ALSO PRESENT:	
11	ALSO INESENI.	13
12	DANIEL GRBICH, Videographer	14 BY MR. SANGIAMO:
		15 Q. Good morning, Ms. Wlochowski.
13		
13		16 A. Good morning.
14		16 A. Good morning.
14 15		17 Q. You understand that you are
14 15 16		17Q.You understand that you are18still under oath from yesterday. Right?
14 15 16 17		17 Q. You understand that you are18 still under oath from yesterday. Right?19 A. I do.
14 15 16 17 18		17Q.You understand that you are18still under oath from yesterday. Right?
14 15 16 17 18 19		 17 Q. You understand that you are 18 still under oath from yesterday. Right? 19 A. I do. 20 Q. Did you have an understanding
14 15 16 17 18		 17 Q. You understand that you are 18 still under oath from yesterday. Right? 19 A. I do. 20 Q. Did you have an understanding 21 at the time that you were working in
14 15 16 17 18 19 20		 17 Q. You understand that you are 18 still under oath from yesterday. Right? 19 A. I do. 20 Q. Did you have an understanding 21 at the time that you were working in 22 Dr. Krah's lab of what the purpose was of
14 15 16 17 18 19 20 21		 17 Q. You understand that you are 18 still under oath from yesterday. Right? 19 A. I do. 20 Q. Did you have an understanding 21 at the time that you were working in

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	JOAN L. WLOCHOWSKI -		
1	Page 297	1	Page 299
1	MR. KELLER: Objection. Vague	1	Krah's lab?
2	and ambiguous.	2	A. No.
3	THE WITNESS: Can you elaborate	3	Q. Has it changed since?
4	on the plaque reduction assay?	4	A. There are yeah, there's
5	BY MR. SANGIAMO:	5	different information that I'm aware of now
6	Q. Was there more than one plaque	6	that Protocol 007 was used to support. I do,
7	reduction neutralization assay that you were	7	I guess, have additional information about Protocol 007.
8	running in Dr. Krah's lab?	8	
9	A. There were different versions	9	Q. Is that information that you
10	of different purposes for running the	10	got after your departure from Merck? A. Yes.
11	plaque reduction neutralization assay.	11	
12	Q. Okay. What were they?	12	Q. Is that information that you
13	A. So in regards to mumps	13 14	got in connection with this lawsuit?
14	Q. I'm sorry, this is I'm		A. Prior to and with connection
15	asking about your understanding at the time	15 16	with the lawsuit. Q. What is the information that
16 17	that you were working in the lab.	-	-
	A. Okay. In regards to the mumps	17 18	you got prior to the lawsuit that indicated to
18	neutralization plaque sorry, PRN, the	10	you that Protocol 007 had additional purposes? A. What information I received
19	multiple purposes we were running it for was	20	
20	for Protocol 007 testing as well as there were	20	prior to is that I was aware that there was a
21 22	some supplemental assays that we were running for looking at different passage levels of	$\frac{21}{22}$	label change for Protocol 007 which supported an end expiry claim with decreased strength of
22	cell lines. And for Protocol 007, the	22	the product.
23	intention, again, was to try to achieve	23	Q. Did you have an understanding
24		27	Q. Did you have an understanding
1	Page 298	1	Page 300
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	greater than 95 percent seroconversion rate	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	while you were working in Dr. Krah's lab of
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	while maintaining also a less than 10 percent	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	what the purpose of Protocol 007 was?
34	pre-positive rate.	3	MR. KELLER: Asked and answered.
	Q. What was the source of your		Vague and ambiguous.
5 6	understanding that the purpose of running the assay was to support Protocol 007?	5	THE WITNESS: Again, to the
1	• • • • • • • • • • • • • • • • • • • •	6	extent that I explained what I knew of
7 8	A. The there was multiple sources. So there was a document that	7	the protocol in the previous questions. BY MR. SANGIAMO:
9	provided some history on the development of	9	
10	the assay and what the desired outcome was.	-	Q. The previous questions you were
10	-	10	telling me what you understood the purpose of
$11 \\ 12$	Dave Krah himself had told us on multiple occasions that we were also to that the	11 12	running the assay was, and I think you testified that the purpose was one of the
12	pre-positive results are unexpected and not a	12	purposes was to support Protocol 007. Right?
13	desired outcome for as a result of the	13	A. Correct.
14			
15	assay. Q. Is it that document to which	15 16	Q. And now I'm asking you what your understanding was at the time, if you had
17	you just referred that told you that the	17	an understanding while you were working in the
17	purpose of the running the assay was to	17	lab, of what the purpose of Protocol 007 was?
10	support Protocol 007?	18	A. I don't believe I had a full
20	A. Our lab, our laboratory	20	understanding of what Protocol 007 was at the
$\frac{20}{21}$	notebooks would refer to Protocol 007.	20	time I was in the lab.
$\begin{vmatrix} 21 \\ 22 \end{vmatrix}$	Q. Did your understanding of the	21	Q. Did you have a partial understanding?
22	purpose of running the assay change at all	22	A. I did have a partial understanding.
23	during the course of your time within Dr.	23	Q. What was the source of that
~ +	during the course of your time within Di.	²⁴	2. What was the source of that

3 (Pages 297 - 300)

	D 201		P 202
1	Page 301 partial understanding?	1	Page 303 A. Multiple.
2	A. Again, the original outcome or	2	Q. More than five?
3	the results of the assay was to determine	3	A. Yes.
4	seroconversion, and we were testing pediatric	4	Q. More than ten?
5	sera.	5	A. Yes.
6	Q. Did you have any understanding	6	Q. Are you familiar with the
7	of the purpose of Protocol 007 at the time you	7	notion of a clinical study having an objective?
8	were working in Dr. Krah's lab beyond what you	8	A. Yes.
9	just said?	9	Q. Do you know what the did you
10	A. That we were basically	10	have an understanding when you were working in
11	again, with seroconversion, that we were	11	Dr. Krah's lab what the objective was of
12	testing pediatric sera for pre- and post-	12	Protocol 007?
13	vaccinated children. So to basically, you	13	A. I don't believe I had full
14	know, to test the effectiveness of the vaccine.	14	understanding of the objective.
15	Q. To test the effectiveness of	15	Q. Did you have any understanding
16	the vaccine?	16	of the objective beyond what you already
17	A. Yes.	17	testified to this morning?
18	Q. What was the basis of that part	18	A. Not that I recall, no.
19	of your understanding?	19	Q. Did you have any understanding
20	A. So a seroconversion would show	20	at the time you worked in Dr. Krah's lab of
21	that the vaccine is an indicator that the	21	what the hypothesis to be tested in Protocol
22	vaccine is effective.	22	007 was?
23	Q. In your opinion?	23	MR. KELLER: Objection. Vague
24	A. Yes.	24	and ambiguous. Lack of foundation.
	Page 302		Page 304
1	Q. Was your opinion the only	1	BY MR. SANGIAMO:
2	source of your understanding that the purpose	2	Q. Ma'am, are you familiar with the
3	of Protocol 007 was to test the effectiveness	3	notion of a clinical study having a hypothesis?
4	of the vaccine?	4	A. Yes.
5	A. Again, from our direction from	5	Q. Did you have an understanding
6	Dave Krah who would also reiterate to us about		at the time that you were working in Dr.
7	the testing of what is expected when you	7	Krah's lab of what the hypothesis was for
8	vaccinate a child that they are pre-negative	8	Protocol 007?
9	and convert to pre-positive based on dosing	9	A. I can't recall if I had at that
10	with the vaccine.	10	time the understanding of what the hypothesis
11	Q. Is that the entirety of the	11	was beyond what I've already told you.
12	information you had regarding the purpose of	12	Q. Are you familiar with the notion
13	Protocol 007 at the time you worked in Dr.	13	of clinical trials often having different arms?
14	Krah's lab?	14	A. Yes.
15	A. I believe so.	15	Q. What does that mean?
16	Q. Did you know what the study	16	A. There's different study groups
17	objectives were for Protocol 007 at the time	17	within the clinical protocol.
18	you were working in Dr. Krah's lab?	18	Q. Did you have an understanding
19	MR. KELLER: Objection. Vague	19	at the time that you were working in Dr.
20	and ambiguous.	20	Krah's lab of what the different study groups
21	BY MR. SANGIAMO:	21	were that were being evaluated in Protocol
22	Q. How many clinical studies have	22	007?
23	you been involved with to your knowledge over	:23	A. I don't recall if I had the
24	your career?	24	knowledge of the different study groups.

4 (Pages 301 - 304)

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Page 305 1 Q. Did you know, at the time that 2 you were working in Dr. Krah's lab, how many 3 study groups there were? 4 A. Again, I don't think I did have Page 305 1 BY MR. SANGIAMO: 2 Q. Who told you that there 3 linkage between Protocol 007 ar 4 change?	
2you were working in Dr. Krah's lab, how many2Q.Who told you that then3study groups there were?3linkage between Protocol 007 and	Page 307
3 study groups there were? 3 linkage between Protocol 007 ar	
4 A. Again, I don't think I did have 4 change?	nd the label
5 that knowledge at that time. 5 A. Again, in my initial di	
6 Q. Did you know at the time that 6 with Steve, we talked about that	
7 you were working in Dr. Krah's lab whether 7 only protocol currently that was	reported
8 there was more than one study group? 8 completed at the time.	
9 A. No, I don't think so. 9 Q. How did you know?	
10 Q. Have you, since your departure 10 A. This was just through	my
11 from Dr. Krah's lab, developed more of a sense 11 initial discussion with Steve.	
12 of what the objective of Protocol 007 was? 12 Q. Did Steve tell you?	
13 A. Yes, I have a sense of the 13 A. Yes.	
14 objective, yes. 14 Q. Were you reluctant to	tell me
15 Q. And do you have a sense 15 that Steve told you? I don't under	erstand.
16 developed since you left Dr. Krah's lab of 16 A. Yes, at that time my k	nowledge
17 what the study groups were in Protocol 007? 17 was through my initial discussion	on with Steve.
18 A. Yes, I do. 18 Q. Because he told you?	
19 Q. And what is your current 19 A. Yes, he told me.	
20 understanding of what the objective was in 20 Q. You didn't have any se	ource of
21 Protocol 007? 21 that knowledge at that time othe	
22 A. To determine the end expiry 22 Mr. Krahling. Right?	
23 claim for the product. 23 A. Correct.	
24 Q. Did you testify, correct me if 24 Q. Have you had any sou	rce of that
Page 306	Page 308
1 I'm wrong, did you testify that you learned of 1 knowledge since then other than Mr	
2 that purpose in conjunction with hearing about 2 or what you've heard from your atto	
3 a label change? 3 A. It's posted on the	incys.
4 A. Yes. 4 clinicaltrial.gov website.	
5Q.Could you be more specific4Could you check I'n5Q.When did you check I'n	n
	11
6 about what it was that you were told that 6 corry did you finish your answer?	
6 about what it was that you were told that 7 linked the label change to Protocol 007? 7 A Vac	and see
7 linked the label change to Protocol 007? 7 A. Yes.	
7linked the label change to Protocol 007?7A.Yes.8A.At the time, Protocol 007 was8Q.When did you check that a	
7linked the label change to Protocol 007?7A.Yes.8A.At the time, Protocol 007 was8Q.When did you check that a9the only protocol, clinical trial protocol9that it was posted there?	
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the	
 7 linked the label change to Protocol 007? 8 A. At the time, Protocol 007 was 9 the only protocol, clinical trial protocol 10 that would support the seroconversion of 11 patients with a lower potency product. 7 A. Yes. 8 Q. When did you check that a 9 that it was posted there? 10 A. I can't recall. During the 11 course of the case it was 	
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan	ding of
 7 linked the label change to Protocol 007? 8 A. At the time, Protocol 007 was 9 the only protocol, clinical trial protocol 10 that would support the seroconversion of 11 patients with a lower potency product. 12 Q. Who told you that? 13 MR. KELLER: I'm going to 7 A. Yes. 8 Q. When did you check that a second protocol of the case it was 12 Q. Do you have an understant of the case it was 13 MR. KELLER: I'm going to 	ding of ypothesis of
 7 linked the label change to Protocol 007? 8 A. At the time, Protocol 007 was 9 the only protocol, clinical trial protocol 10 that would support the seroconversion of 11 patients with a lower potency product. 12 Q. Who told you that? 13 MR. KELLER: I'm going to 14 instruct the witness not to disclose 7 A. Yes. 8 Q. When did you check that a series of the case it was 12 Q. Do you have an understant of the immunogenicity of the mumps of the mumps	ding of ypothesis of
 7 linked the label change to Protocol 007? 8 A. At the time, Protocol 007 was 9 the only protocol, clinical trial protocol 9 that it was posted there? 10 that would support the seroconversion of 11 patients with a lower potency product. 12 Q. Who told you that? 13 MR. KELLER: I'm going to 14 instruct the witness not to disclose 15 any communications she may have had 7 A. Yes. 8 Q. When did you check that is 9 that it was posted there? 10 A. I can't recall. During the 11 course of the case it was 12 Q. Do you have an understant 13 MR. KELLER: I'm going to 14 the immunogenicity of the mumps of 15 MMR at various potencies? 	iding of hypothesis of component of
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what time	iding of hypothesis of component of
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.	iding of hypothesis of component of ne?
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.18will instruct her not to answer. If18MR. KELLER: Again, I de	iding of hypothesis of component of ne? on't
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.18will instruct her not to answer. If18MR. KELLER: Again, I de19you can answer the question without19want you to disclose any comm	iding of hypothesis of component of ne? on't unications
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that if9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.18will instruct her not to answer. If18MR. KELLER: Again, I de19you can answer the question without19want you to disclose any comm20disclosing communications you had with20you had with your counsel. To	iding of hypothesis of component of ne? on't unications
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.11course of the case it was12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.18will instruct her not to answer. If18MR. KELLER: Again, I de19you can answer the question without19want you to disclose any comm20disclosing communications you had with20you had with your counsel. To21counsel, you may answer.21extent you can answer without	iding of aypothesis of component of ne? on't unications the
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that at9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.10A. I can't recall. During the12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.18will instruct her not to answer. If18MR. KELLER: Again, I de19you can answer the question without19want you to disclose any comm20disclosing communications you had with20you had with your counsel. To21counsel, you may answer.21extent you can answer without22THE WITNESS: In my initial22disclosing communications you	iding of hypothesis of component of me? on't unications the had with
7linked the label change to Protocol 007?7A. Yes.8A. At the time, Protocol 007 was8Q. When did you check that a9the only protocol, clinical trial protocol9that it was posted there?10that would support the seroconversion of10A. I can't recall. During the11patients with a lower potency product.10A. I can't recall. During the12Q. Who told you that?12Q. Do you have an understan13MR. KELLER: I'm going to13why Merck decided to explore the h14instruct the witness not to disclose14the immunogenicity of the mumps of15any communications she may have had15MMR at various potencies?16with counsel. If she learned this16A. Can you define at what tin17through communications with counsel, I17Q. Currently.18will instruct her not to answer. If18MR. KELLER: Again, I de19you can answer the question without19want you to disclose any comm20disclosing communications you had with20you had with your counsel. To21counsel, you may answer.21extent you can answer without	iding of hypothesis of component of me? on't unications the had with

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		~	
	Page 309		Page 311
1	the question again, then?	1	tossed out, changed, manipulated, you know,
2	BY MR. SANGIAMO:	2	all tied into likely the reason between myself
3	Q. Other than anything that you	3	and me questioning Dave Krah as to why maybe I
4	heard from your attorneys, do you have an	4	was given limited information at the time I
5	understanding currently of why Merck decided	5	was working in the laboratory.
6	to explore the hypothesis regarding	6	Q. Do I have it right that you did
7	immunogenicity of the mumps component of MMR	7	not have an understanding of why Merck was
8	at various potencies?	8	running the assays that are described in that
9	A. Other than what I discussed	9	document at the time that you were working in
10	with counsel, going back to the information I	10	Dr. Krah's lab?
11	had at the time when I was in the laboratory,	11	A. Again
12	that they had conducted studies for the	12	MR. KELLER: Objection. Vague
13	development of the assay. They were finding	13	and ambiguous.
14	seroconversion rates that were much lower than	14	THE WITNESS: Again, that
15	what was reported in the label. So that at	15	was that predated me. Steve had
16	that time, before my discussions with counsel,	16	worked in the lab before I did, so he
17	was my understanding of running additional	17	had more knowledge about information
18	studies to determine what the current	18	and discussions. Before I joined the
19	seroconversion rate is.	19	lab, Steve Dave Krah spoke to Steve
20	Q. What is the source of that	20	regularly and provided him all
21	understanding?	21	background information. So, you know,
22	A. The documentation regarding the	22	based on just my interactions with
23	development of the assay.	23	Steve, I felt that he was very
24	Q. You said documentation. Was	24	informative. I trusted the information
27		24	
1	Page 310	1	Page 312
	that just one document?	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	that he was providing. There was, you
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. Yes.	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	know, legitimate information that he
3	Q. And was that document provided	3	was providing over to me. It wasn't
4	to you by Mr. Krahling?	4	just that he was telling me information
5	A. Yes, it was.	5	and I was, you know, using that as the
6	Q. Was that document that was	6	basis of the basis of my belief.
7	provided to you by Mr. Krahling, is that the	7	BY MR. SANGIAMO:
8	entirety of the source of your understanding?	8	Q. Did Mr. Krahling tell you his
9	A. Yes, it was.	9	understanding of why it is that Merck was
10	Q. Did you have an understanding	10	running those assays that were described in
11	of why Merck was running those assays that are	11	that document?
12	described in that document?	12	A. I can't recall, I can't recall
13	A. I did not have an understanding.	13	if it was even outlined in the development
14	That was before my time. Again, my knowledge	14	document at that time. I can't recall what I
15	in the lab as to what we were doing is very	15	knew at that time. It's blurred with what I
16	limited. My discussions with Dave Krah was	16	know now.
17	very limited. So basically I was running the	17	Q. Understood. Do you recall
18	assay. I did know, again, during the course	18	whether Mr. Krahling said anything to you
19	of running the assay we weren't getting the	19	about why Merck was running those assays?
1	· · · · · · · ·	20	A. No, I don't recall.
20	desired results. People were told to recheck	20	
20 21	desired results. People were told to recheck counts. People were changing data in order to	20	Q. I believe you may have answered
	-		
21	counts. People were changing data in order to meet the results of what the desired outcome	21	Q. I believe you may have answered this in response to an earlier question, but I
21 22	counts. People were changing data in order to	21 22	Q. I believe you may have answered

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	JOAN L. WLOCHOWSKI -		
1	Page 313	1	Page 315
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Protocol 007?	1	A. No.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	MR. KELLER: Objection. Vague	2	Q. What was your understanding at
3	and ambiguous.	3 4	the time that you left Dr. Krah's lab
4	THE WITNESS: Again, to what		regarding whether seroconversion rates had
5	I've already explained about the	5	been calculated for the subjects in Protocol
6	seroconversion rates, that's all I can	6	007?
7	recall at this time.	7	A. They had been calculated to the
8	BY MR. SANGIAMO:	8 9	extent that there was an Excel workbook that
9	Q. And specifically what is it	-	we could enter results of the plaque count into to tell whether or not there was a
10	that you heard from Dr. Krah regarding the	10	
11	seroconversion rates?	11	positive or a negative result.
12	A. What was expected was that the	12	Q. That would tell you whether
13	pre-vaccinated samples would be negative,	13	there was a positive or negative result for
14	seronegative and we were looking for the	14	any one subject. Right?
15	endpoints in the vaccinated samples.	15	A. Correct.
16	Q. What did he say about	16	Q. And did you have an
17	seroconversion rates?	17	understanding at the time that you were
18	A. That the pre-positives were	18	working in Dr. Krah's lab of whether a
19	expected to be less than 10 percent.	19	cumulative or aggregate seroconversion rate
20	Q. Do you have anything else to	20	was going to be calculated in Protocol 007?
21	tell me about what he said to you about	21	A. Can you repeat that? I missed
22	seroconversion rates?	22	parts of that question.
23	A. I don't think so.	23	Q. I tried to set the question up,
24	Q. At the time that you left Dr.	24	perhaps unsuccessfully, by asking you, and I
	Page 314		Page 316
1	Krah's lab, had the assay testing for Protocol	1	think you agreed, that the Excel worksheet
2	007 been completed? I'm sorry, strike that.	2	would show whether any individual patient
3	Let me ask that question again.	3	seroconverted?
4	Do you know what sera samples	4	A. Correct.
5	serum samples were supposed to be tested	5	Q. Did you have an understanding
6	beyond the fact that some were pre-vaccination		as to whether there was going to be a
7	and some were post-vaccination at the time you		calculation of a seroconversion rate that was
8	worked in Dr. Krah's lab?	8	designed to capture the aggregate of all of
9	MR. KELLER: Objection. Vague	9	the patients in Protocol 007?
10	and ambiguous.	10	A. The result of the aggregate?
11	THE WITNESS: Can you repeat	11	Did I have an understanding of the result of
12	that question?	12	the aggregate?
13	BY MR. SANGIAMO:	13	Q. Okay. Yes.
14	Q. It's your understanding that	14	A. Is that the question?
15	the subjects of Protocol 007 had blood draws	15	Q. Yes.
16	done prior to vaccination and post-vaccination.	16	A. I did not have an understanding
17	Correct?	17	of the result of the aggregate at the time
18	A. Correct.	18	because the testing was not completed when I
	Q. Do you know whether there was	19	left the laboratory. Again, my feeling, my
19	more than one blood draw done after	20	strong feelings about this is that not all the
19 20	more than one blood draw done after		
	vaccination for the subjects in Protocol 007?	21	data that was not all of the serum that was
20		21 22	data that was not all of the serum that was tested did have data reported on it. So
20 21	vaccination for the subjects in Protocol 007?		

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	JOINTE: WEDEND WEIG		
1	Page 317	1	Page 319
1	that were not representative of what was the	1	A. So, again, it was to determine
2	actual testing or the actual yeah, the	2	the zero it was to determine the end expiry
3	actual results of the sera that was tested.	3	claim of different yeah, that's basically
4	Q. Had the seroconversion rate for	4	what it was for the objective.
5	the aggregate of the patients in the study	5	Q. Do you know what the criteria
6	been calculated at the time you left the lab?	6	strike that.
7	A. No.	7	Was it your understanding
8	Q. Do you have a current understanding	8	that strike that again.
9	of what the seroconversion rates that were	9	Is it your current understanding
10	determined in Protocol 007 are?	10	that each of the study arms represented
11	A. I do.	11	different potencies of the mumps component of
12	Q. What were those rates?	12	MMR?
13	A. I may not remember the numbers	13	A. Yes.
14	exactly, but I believe two of the study groups	14	Q. Was it your understanding
15	had a level that was higher than the target	15	strike that.
16	based on what was reported. But, again, I	16	Is it your current understanding
17	feel as though the information that was	17	that two of those study arms were being
18	reported is not the whole story or the whole	18	tested, being compared to the third study arm
19	information.	19	as a control study arm? Is that your current
20	Q. How many study groups were	20	understanding?
21	there in total?	21	A. That is not my current
22	A. Three. To my understanding.	22	understanding.
23	Q. So I gather one of the study	23	Q. Is it your current understanding
24	groups did not reach the target. Right?	24	that there was no control study arm?
1	Page 318	1	Page 320
1	A. Yes.	1	A. It was my understanding that
2	A. Yes.Q. Do you know what that target	2	A. It was my understanding that there were three study groups.
2 3	A. Yes. Q. Do you know what that target was?	2 3	A. It was my understanding that there were three study groups.Q. With no control?
2 3 4	A. Yes. Q. Do you know what that target was? MR. KELLER: Today or	2 3 4	A. It was my understanding that there were three study groups.Q. With no control?A. That I
2 3 4 5	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. 	2 3 4 5	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague
2 3 4 5 6	A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO:	2 3 4 5 6	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous.
2 3 4 5 6 7	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO: Q. Do you have a current understanding 	2 3 4 5 6 7	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: Yeah, can you
2 3 4 5 6 7 8	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO: Q. Do you have a current understanding of what that target was? 	2 3 4 5 6 7 8	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: Yeah, can you explain what you mean by the control
2 3 4 5 6 7 8 9	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO: Q. Do you have a current understanding of what that target was? A. I have an understanding. I 	2 3 4 5 6 7 8 9	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: Yeah, can you explain what you mean by the control group?
2 3 4 5 6 7 8 9 10	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO: Q. Do you have a current understanding of what that target was? A. I have an understanding. I can't remember, I can't give you the exact 	2 3 4 5 6 7 8 9 10	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: Yeah, can you explain what you mean by the control group? BY MR. SANGIAMO:
2 3 4 5 6 7 8 9 10 11	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO: Q. Do you have a current understanding of what that target was? A. I have an understanding. I can't remember, I can't give you the exact number off the top of my head. I would have 	2 3 4 5 6 7 8 9 10 11	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: Yeah, can you explain what you mean by the control group? BY MR. SANGIAMO: Q. Are you familiar with clinical
2 3 4 5 6 7 8 9 10 11 12	 A. Yes. Q. Do you know what that target was? MR. KELLER: Today or objection. Overbroad. BY MR. SANGIAMO: Q. Do you have a current understanding of what that target was? A. I have an understanding. I can't remember, I can't give you the exact number off the top of my head. I would have to refer back. 	2 3 4 5 6 7 8 9 10 11 12	 A. It was my understanding that there were three study groups. Q. With no control? A. That I MR. KELLER: Objection. Vague and ambiguous. THE WITNESS: Yeah, can you explain what you mean by the control group? BY MR. SANGIAMO: Q. Are you familiar with clinical trials sometimes having a control group?
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1	being tested was adequate?	1	A. Yes.
2	MR. KELLER: Objection. Vague	2	Q. Why is it that you think
3	and ambiguous. Are you talking today	3	strike that.
4	or are you talking in the past?	4	When you say that, are you
5	MR. SANGIAMO: I'm asking for	5	referring to the data that were reported to
6	her current understanding.	6	the FDA?
7	THE WITNESS: My current	7	A. The data that was reported as
8	understanding, and, again, my	8	part of the clinical protocol.
9	understanding, I would have to go back	9	Q. Reported to the FDA?
10	and check the data, I believe it was to	10	A. It was reported, yes, to the
11	be greater than 90 percent seroconversion.	11	FDA. Or as through the clinical study report.
12	BY MR. SANGIAMO:	12	Q. What is the basis of your
13	Q. So if the seroconversion rate	13	knowledge that a clinical study report was
14	within a study arm was greater than 90	14	reported to the FDA?
15	percent, your current understanding, subject	15	MR. KELLER: Again, I'm going
16	to you having to go back and check the data,	16	to
17	then that would be deemed successful. Is that	17	BY MR. SANGIAMO:
18	it?	18	Q. Other than what you've learned
19	A. Yes.	19	from your attorneys.
20	Q. Based on your current understanding,	20	A. Then I can't elaborate on that.
21	was there also a criterion for success that	21	Q. Let's try this.
22	entailed the seroconversion rate of a study	22	A. Other than
23	arm being comparable to the seroconversion	23	Q. Other than what you have
24	rate of another study arm?	24	learned from your attorneys, do you know
	Page 322		Page 324
1	MR. KELLER: Objection. Vague	1	whether a clinical study report was submitted
2	and ambiguous. Do you want to show her	2	to the FDA?
3	the protocol? You're asking her	3	A. I do know that the report
4	questions about a very, very technical	4	was the protocol was completed. I do know
4 5	questions about a very, very technical document, to be fair, but you can	4 5	was the protocol was completed. I do know that Protocol 007 was referenced in, I
5	document, to be fair, but you can	5	that Protocol 007 was referenced in, I
5 6	document, to be fair, but you can answer if you can.	5 6	that Protocol 007 was referenced in, I believe, the EMA submission.
5 6 7	document, to be fair, but you can answer if you can. THE WITNESS: I don't have the	5 6 7 8 9	that Protocol 007 was referenced in, I believe, the EMA submission. That's the extent of my knowledge without other than what I've discussed with my counsel.
5 6 7 8	document, to be fair, but you can answer if you can. THE WITNESS: I don't have the information in front of me to be able	5 6 7 8	that Protocol 007 was referenced in, I believe, the EMA submission. That's the extent of my knowledge without other than what I've
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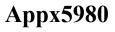
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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1			
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	performing the assay would be qualified to run	1	piece is that because the data was
2	that validated method and be able to generate	2	being manipulated or changed, that the
3	validated results. That would be withheld to	3	results that are being reported are not
4	data integrity standards.	4	accurate. Again, going back to if the
5	Q. Does the fact that data was	5	method was validated prior to running
6	discarded, you say, mean that the data that	6	testing on human subjects, the accuracy
7	were reported were inaccurate?	7	of the method would already be defined
8	A. If there was no reason to go	8	and there would be parameters for which
9	back and retest or recount plaques, then, yes,	9	we would follow in order to either
10	if the original raw data is being discarded	10	reject or accept a test or counts that
11	and not used as an original result, then the	11	were being performed at the time.
12	data is flawed in that there is data that is	12	MR. KELLER: Interpose an
13	being omitted from the study.	13	objection. Compound.
14	Q. So your concern there as regards	14	BY MR. SANGIAMO:
15	accuracy is not the fact that data were	15	Q. If an assay was counted
16	discarded, it's the fact that the original	16	accurately and that accurate count was
17	results were not being reported. Do I have	17	reported to the FDA, would it matter in terms
18	that right?	18	of the accuracy that the FDA received if the
19	MR. KELLER: Objection.	19	well plate was discarded?
20	Mischaracterizes her testimony.	20	A. The well plate is the original
21	MR. BEGLEITER: Argumentative.	21	data in this case. It would be a means to
22	MR. KELLER: Argumentative.	22	preserve the original raw data, maintain it
23	MR. SANGIAMO: Good objection,	23	through the end of the study. So, in my
24	Bob. I don't agree with the objection.	24	experience, while working in Dave Krah's lab,
	Page 326		Page 328
1	Please answer the question.	1	I did see him discard plates which had been
2	MR. KELLER: I do.	2	sitting there since I had started in January
3	THE WITNESS: So it all	3	through July after some escalations had
4	right. Repeat the question again?	45	happened internally. The very next day after
	Sorry.	<u> </u>	
5	DV MD CANCIAMO.		being told that an internal audit would occur,
6	BY MR. SANGIAMO:	6	Dave Krah came into the laboratory early in
6 7	Q. I was asking you questions	6 7	Dave Krah came into the laboratory early in the morning, which he never does, I was in,
6 7 8	Q. I was asking you questions about your contention that original data were	6 7 8	Dave Krah came into the laboratory early in the morning, which he never does, I was in, taking plates and putting them in the
6 7 8 9	Q. I was asking you questions about your contention that original data were discarded and what the implications were for	6 7 8 9	Dave Krah came into the laboratory early in the morning, which he never does, I was in, taking plates and putting them in the autoclave and getting rid of them, which was
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1	Page 329	1	Page 331
1	controlled counting sheets. So unlike	1	themselves could, once the plaques were
2	the laboratory notebook, which was	2	counted, the plaque counts could be
3	controlled pages where you could see if	3	erased from the plate and recounted and
4	data was omitted, the counting sheets	4	then transcribed to a counting sheet.
5	were a blank piece of paper that an	5	So, therefore, again, I can't
6	analyst could write on the paper and if	6	claim that there was accuracy on any
7	they didn't like it because they made	7	given counting sheet at any time. If
8	too many cross-outs, would be able to	8	the method had described what the
9	toss out that piece of paper and	9	requirements were for reporting plaque
10	rewrite their results.	10	counts, and the criteria for which it
11	BY MR. SANGIAMO:	11	was acceptable to perform an additional
12	Q. Suppose an assay was counted	12	count, may have given some more
13	and for a given well a determination was made	13	information around that. The procedure
14	that there were 15 plaques, and suppose that	14	itself did not have that information
15	the data were reported to the FDA that way	15	until the FDA had audited where there
16 17	with 15 plaques in that well, would that count	16 17	were revisions around the procedures to
	of 15 plaques in that well become inaccurate		put some more definitions around what
18 19	if the well plate were discarded? MR. KELLER: Objection. Vague	18 19	the criteria would be. But by that time the majority of Protocol 007 had
20		19 20	already been executed.
20	and ambiguous. Calls for speculation. THE WITNESS: That well count	20 21	BY MR. SANGIAMO:
$\frac{21}{22}$	would not be able to be confirmed	21	Q. You just referred to the
22	against its original raw data point.	22	procedure itself. Are you referring to the
23	BY MR. SANGIAMO:	23 24	SOP?
		21	501.
1	Page 330 O Would it be inaccurate?	1	Page 332
$\begin{vmatrix} 1\\ 2 \end{vmatrix}$	Q. Would it be inaccurate?	1	A. Correct.
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1	THE WITNESS: I cannot answer	1	necessarily need to have expertise on
2	the question.	2	plaque reduction neutralization assays
3	BY MR. SANGIAMO:	3	in order to make that statement.
4	Q. Did you know anything about the	4	Again, appropriate method validation
5	timing of the validation of the assay at the	5	should be able to demonstrate
6	time that you were working in Dr. Krah's lab?	6	robustness, reputability, precision,
7	A. The development information	7	accuracy that would allow for that.
8	that was provided spoke to concurrent	8	BY MR. SANGIAMO:
9	validation with running the human test sera.	9	Q. What is it that qualifies you
10	Q. What information was this?	10	to make that statement as it pertains to
11	A. In the development presentation	11	plaque reduction neutralizations?
12	information or document.	12	MR. KELLER: Asked and answered.
13	Q. Is it the same document we've	13	THE WITNESS: I believe I've
14	been talking about	14	already answered that.
15	A. Yes.	15	BY MR. SANGIAMO:
16	Q that you got from Mr. Krahling?	16	Q. You've told me what qualifies
17	A. Yes.	17	you for that?
18	Q. That told you what was planned	18	A. My experience in working in the
19	for validation?	19	industry and as an analyst performing method
20	A. It stated that there would be	20	validation, that that is what gives me the
20	concurrent validation to testing of the sera.	20	basis for that response.
$ ^{21}_{22}$	Q. Do you know if that is, in	22	Q. Is it your experience that
23	fact, what happened?	22	strike that.
23	A. I cannot.	23 24	
24	A. I calliot.	24	Have you ever seen an SOP for a
1	Page 334	1	Page 336
1	Q. Strike that. Did you know at	1	
	1'' D V 11 11		plaque reduction neutralization assay other
2	the time you were working in Dr. Krah's lab	2	than the one that was run in Dr. Krah's lab?
2 3	whether that is, in fact, what happened?	2 3	than the one that was run in Dr. Krah's lab?A. I can't recall that I have.
2 3 4	whether that is, in fact, what happened?A. I did not know that at the time	2 3 4	than the one that was run in Dr. Krah's lab?A. I can't recall that I have.Q. So, therefore, you have no idea
2 3 4 5	whether that is, in fact, what happened?A. I did not know that at the timeI was working in the laboratory.	2 3 4 5	than the one that was run in Dr. Krah's lab?A. I can't recall that I have.Q. So, therefore, you have no idea whether SOPs for plaque reduction
2 3 4 5 6	whether that is, in fact, what happened?A. I did not know that at the timeI was working in the laboratory.Q. You said a few minutes ago that	2 3 4 5 6	than the one that was run in Dr. Krah's lab?A. I can't recall that I have.Q. So, therefore, you have no ideawhether SOPs for plaque reductionneutralization assays typically do or do not
2 3 4 5 6 7	whether that is, in fact, what happened?A. I did not know that at the timeI was working in the laboratory.Q. You said a few minutes ago thatcounts should never have to be rechecked in an	2 3 4 5 6 7	 than the one that was run in Dr. Krah's lab? A. I can't recall that I have. Q. So, therefore, you have no idea whether SOPs for plaque reduction neutralization assays typically do or do not address the question of whether it's
2 3 4 5 6 7 8	whether that is, in fact, what happened?A. I did not know that at the timeI was working in the laboratory.Q. You said a few minutes ago thatcounts should never have to be rechecked in an assay such as the one being run in Dr. Krah's	2 3 4 5 6 7 8	 than the one that was run in Dr. Krah's lab? A. I can't recall that I have. Q. So, therefore, you have no idea whether SOPs for plaque reduction neutralization assays typically do or do not address the question of whether it's appropriate to check plaque counts. Right?
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$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array}$	 whether that is, in fact, what happened? A. I did not know that at the time I was working in the laboratory. Q. You said a few minutes ago that counts should never have to be rechecked in an assay such as the one being run in Dr. Krah's lab. Right? A. I believe what I stated was I believe that if the assay was validated, the robustness of the assay should allow for a single plaque count, again, based on validation and training qualification of the analyst performing the assay. Q. Now, you've never run strike that. You've never been part of a plaque reduction neutralization assay in your entire career other than what you did in Dr. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	than the one that was run in Dr. Krah's lab? A. I can't recall that I have. Q. So, therefore, you have no idea whether SOPs for plaque reduction neutralization assays typically do or do not address the question of whether it's appropriate to check plaque counts. Right? MR. KELLER: Can you read the question back? (The court reporter read the pertinent part of the record.) MR. KELLER: You can answer that question. THE WITNESS: Again, I stated previously if there were to be a reason to have to recheck, my expectation is that that would be defined in the SOP
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$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \end{array}$	 whether that is, in fact, what happened? A. I did not know that at the time I was working in the laboratory. Q. You said a few minutes ago that counts should never have to be rechecked in an assay such as the one being run in Dr. Krah's lab. Right? A. I believe what I stated was I believe that if the assay was validated, the robustness of the assay should allow for a single plaque count, again, based on validation and training qualification of the analyst performing the assay. Q. Now, you've never run strike that. You've never been part of a plaque reduction neutralization assay in your entire career other than what you did in Dr. Krah's lab. Right? MR. KELLER: Objection. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	than the one that was run in Dr. Krah's lab? A. I can't recall that I have. Q. So, therefore, you have no idea whether SOPs for plaque reduction neutralization assays typically do or do not address the question of whether it's appropriate to check plaque counts. Right? MR. KELLER: Can you read the question back? (The court reporter read the pertinent part of the record.) MR. KELLER: You can answer that question. THE WITNESS: Again, I stated previously if there were to be a reason to have to recheck, my expectation is that that would be defined in the SOP based on the validation. BY MR. SANGIAMO:
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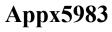
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1	reduction neutralization assays. Right?	1	dozen?
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. I cannot recall that I've seen	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. Yes.
3	another SOP.	3	Q. Who did you see destroy a
4	Q. You've made some comments about	4	counting sheet?
5	the plaque counting sheets not being controlled.	5	A. I'm trying to remember who it
6	Right? A. Correct.	6	was. I don't recall who exactly it was. Q. Was it a man or a woman?
7		7	
8	Q. And your point was that the	8	MR. KELLER: Objection.
9	that by not being controlled, the data, in	9	Compound. Or both.
10	your view, is compromised in some way. Right?	10	THE WITNESS: I'm trying to
11	MR. KELLER: Objection.	11	remember. I believe I saw Colleen Barr
12	Mischaracterizes strike that.	12	and Jen Kriss. I believe I was told to
13	You can answer.	13	discard an assay as well.
14	THE WITNESS: Can you repeat	14	BY MR. SANGIAMO:
15	the question?	15	Q. Did you witness someone else
16	BY MR. SANGIAMO:	16	destroying counting sheets other than Colleen
17	Q. Is it your view that because	17	Barr and Jenny Kriss?
18	you say the plaque counting sheets are not	18	A. I can't remember.
19	controlled, the data is, therefore,	19	Q. Did you see them doing it
20	compromised in some way?	20	together?
21	MR. KELLER: Objection to form.	21	A. No.
22	THE WITNESS: The data can be	22	Q. How many occasions did you see
23	compromised. There is no way of	23	this happen?
24	ensuring that it hasn't been	24	MR. KELLER: Asked and answered.
	Page 338		Page 340
1	compromised.	1	THE WITNESS: Yes, I
2	BY MR. SANGIAMO:	2	BY MR. SANGIAMO:
3	Q. Why is that?	3	Q. Before you testified that you
4	MR. KELLER: Asked and answered.	4	think it happened between five and a dozen
5	THE WITNESS: The as I	5	times. Does that mean somewhere between five
6	explained earlier, the laboratory	6	and a dozen counting sheets or would that mean
7	notebook pages are all numbered. You	7	something else?
8	can tell if there is missing	8	A. Five and a dozen counting
9	information. The counting sheet is not	9	sheets, yes.
10	in any way controlled with a numbering.	10	Q. Did that all occur on one
11	It can be generated and destroyed	11	single occasion?
12	without anybody knowing.	12	A. No.
13	BY MR. SANGIAMO:	13	Q. How many occasions?
14	Q. Did you witness any counting	14	A. The same amount of occasions.
1 4 -	sheets being destroyed?	15	Q. So one counting sheet on 5 to
15	• •		
16	A. I did.	16	12 occasions. Do I have it right?
16 17	• •	16 17	A. Yes.
16 17 18	A. I did.Q. How many times?A. Several times.		
16 17 18 19	A. I did.Q. How many times?	17	A. Yes.
16 17 18	A. I did.Q. How many times?A. Several times.	17 18	A. Yes.Q. How did they destroy them?
16 17 18 19	 A. I did. Q. How many times? A. Several times. Q. What is your best estimate? A. I would say maybe less than a dozen times. 	17 18 19	A. Yes.Q. How did they destroy them?A. In some cases it was just a
16 17 18 19 20	A. I did.Q. How many times?A. Several times.Q. What is your best estimate?A. I would say maybe less than a	17 18 19 20	A. Yes.Q. How did they destroy them?A. In some cases it was just a matter of the sheet became messy, so it was
16 17 18 19 20 21	 A. I did. Q. How many times? A. Several times. Q. What is your best estimate? A. I would say maybe less than a dozen times. 	17 18 19 20 21	A. Yes.Q. How did they destroy them?A. In some cases it was just a matter of the sheet became messy, so it was just a transcription of what their end results

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Case 22328553 Document: 7946 Plage 5883 Date Filed 1120262223

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	JOAN E. WEOCHOWSKI -		
1	Page 341	1	Page 343
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	assay based on the results being faint when I	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	A. Yes.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	read the after I completed reading the	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Q. On the occasion that you saw
3	entire assay.	3	Colleen do it, where were you in relation to
4	Q. Let's continue to focus on the	4	Colleen?
5	occasions when you saw Colleen Barr and Jenny	5	A. We sit in the same area so I
6	Kriss discard a counting sheet. I think you	6	was sitting near her in the laboratory.
7	said that actually, let's focus in on the	7	Q. Did she throw it in the garbage
8	ones that Colleen Barr discarded. Okay?	8	can? Is that how she discarded it?
9	A. [Witness nods.]	9	A. Yes.
10	Q. Were some of the ones that they	10	Q. Was this an instance of the
11	discarded based on the fact that the original	11	count sheet that ultimately got discarded
12	counting sheet was messy?	12	being too messy?
13	A. Yes.	13	A. Yes.
14	Q. All of them?	14	Q. How do you know that?
15	A. I can't recall because sometimes	15	A. Just because she was
16	it wasn't necessarily me seeing them but	16	transcribing it from one to the other.
17	conversations that were had in the laboratory.	17	Q. Did she say something that led
18	Q. So sometimes you saw it happen?	18	you to believe that it was an issue of
19	A. Uh-huh.	19	messiness?
20	Q. When you refer you have to	20	A. I could see that the counting
21	say yes.	21	sheet had many cross-outs on it.
22	A. Yes.	22	Q. Do you know anything about the
23	Q. When you refer to 5 to 12	23	accuracy of the transcription done by Colleen
24	occasions previously, which I understand was	24	from the prior counting sheet to the newer
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1	your estimate, those were 5 to 12 times when	1	counting sheet?
2	you saw it happen?	2	A. I do not.
3	A. Between seeing it happen and	3	Q. So as far as you know, the
4	hearing about it happen.	4	transcription was accurate. Fair statement?
5	Q. How many times did you see it	5	MR. KELLER: Objection.
6	happen?	6	Argumentative.
7	A. I would have to say, from what	7	THE WITNESS: I do not know if
8	I recall, less than five times from what I	8	it's accurate or not accurate.
9	recall.	9	BY MR. SANGIAMO:
10	Q. Less than three?	10	Q. How about on the one occasion
11	A. At most it was three I can	11	where you saw Jenny Kriss discard a counting
12	think of. Three.	12	sheet, where were you in relation to Ms. Kriss?
13	Q. You said you can think of three?	13	A. Again, in the laboratory. She
14	A. Yeah.	14	sits across from me.
15	Q. Who did it on those three	15	Q. How did she discard it?
16	occasions, was it just Colleen, just Jenny or	16	A. She, I believe, also discarded
17	both.	17	it in the trash.
18	A. The three that I the three	18	Q. What information do you have
19	examples I provided previously. Colleen,	19	about why she discarded it?
20	Jenny and myself.	20	A. I don't know why she discarded
21	Q. So in terms of others discarding	21	it.
22	counting sheets, you've seen it happen twice	22	Q. I think you said you also heard
23	that you can recall, once by Colleen and once	23	conversations about people discarding counting
24	by Jenny. Right?	24	sheets. Is that right?
·	- ,,B	- ·	

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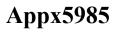
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1	A. Yeah, conversations about just,	1	counting sheet to another counting sheet.
2	again, transcribing or making the data	2	Right?
3	cleaner. And I guess transcribe it to a	3	A. Yes.
4	different data sheet.	4	Q. You are inferring that that
5	Q. I'm asking about conversations	5	means that they discounted the earlier
6	about discarding counting sheets?	6	counting sheet. Right?
7	A. Okay.	7	A. Yes.
8	MR. KELLER: Objection. Form.	8	Q. But you did not actually hear
9	Mischaracterizes her testimony.	9	them say that they discarded the earlier
10	MR. SANGIAMO: Let's back up.	10	counting sheet?
11	BY MR. SANGIAMO:	11	A. Not that I recall.
12	Q. You testified to an occasion	12	Q. Who is it that you heard say
13	when you saw Colleen Barr discard a counting	13	these things about transcribing data from one
14	sheet. Correct?	14	counting sheet to another counting sheet?
15	A. Correct.	15	A. I can't say that I can pinpoint
16	Q. On another occasion you saw	16	it. It was just conversations within the
17	Jenny Kriss discard a counting sheet? Correct?	17	laboratory.
18	A. Correct.	18	Q. Now, is this a situation where
19	Q. Your belief is there were more	19	Mr. Krahling told you he heard this or did
20	discarding of counting sheets beyond those two	20	you, yourself, hear these conversations?
21	occasions and whatever the occasion was	21	A. Myself.
22	regarding yourself which we'll get to shortly.	22	Q. Do you recall the gender of the
23	Right?	23	person who was making these statements?
24	A. Right.	24	A. There was both men and women in
	Page 346		Page 348
1	Page 346 Q. You think in total, some number,	1	6
1 2		1 2	Page 348 the laboratory. Again, we all sat in a general area and so I can't I just can't
	Q. You think in total, some number,		the laboratory. Again, we all sat in a
2	Q. You think in total, some number, you estimate between 5 and 12 counting sheets	2	the laboratory. Again, we all sat in a general area and so I can't I just can't
2 3	Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right?	2 3	the laboratory. Again, we all sat in a general area and so I can't I just can't recall.
2 3 4	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief 	2 3 4	the laboratory. Again, we all sat in a general area and so I can't I just can't recall. Q. I gather on those occasions
2 3 4 5	Q. You think in total, some number,you estimate between 5 and 12 counting sheetswere discarded. Right?A. Correct.	2 3 4 5	the laboratory. Again, we all sat in a general area and so I can't I just can't recall.Q. I gather on those occasions that you heard about people transcribing data from one counting sheet to another counting
2 3 4 5 6	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief that there was additional discarding of 	2 3 4 5 6	the laboratory. Again, we all sat in a general area and so I can't I just can't recall.Q. I gather on those occasions that you heard about people transcribing data
2 3 4 5 6 7	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief that there was additional discarding of counting sheets beyond what you witnessed 	2 3 4 5 6 7	the laboratory. Again, we all sat in a general area and so I can't I just can't recall.Q. I gather on those occasions that you heard about people transcribing data from one counting sheet to another counting sheet, you have no information about whether
2 3 4 5 6 7 8	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief that there was additional discarding of counting sheets beyond what you witnessed Ms. Kriss do and beyond what you witnessed Ms. 	2 3 4 5 6 7 8	 the laboratory. Again, we all sat in a general area and so I can't I just can't recall. Q. I gather on those occasions that you heard about people transcribing data from one counting sheet to another counting sheet, you have no information about whether the transcription was accurate. Right?
2 3 4 5 6 7 8 9	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief that there was additional discarding of counting sheets beyond what you witnessed Ms. Kriss do and beyond what you witnessed Ms. Barr do and beyond what you, yourself, did is 	2 3 4 5 6 7 8 9	 the laboratory. Again, we all sat in a general area and so I can't I just can't recall. Q. I gather on those occasions that you heard about people transcribing data from one counting sheet to another counting sheet, you have no information about whether the transcription was accurate. Right? A. Right. That's correct.
2 3 4 5 6 7 8 9 10	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief that there was additional discarding of counting sheets beyond what you witnessed Ms. Kriss do and beyond what you witnessed Ms. Barr do and beyond what you, yourself, did is conversations you heard. Correct? 	2 3 4 5 6 7 8 9 10	 the laboratory. Again, we all sat in a general area and so I can't I just can't recall. Q. I gather on those occasions that you heard about people transcribing data from one counting sheet to another counting sheet, you have no information about whether the transcription was accurate. Right? A. Right. That's correct. Q. Now, you, yourself, discarded a
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. You think in total, some number, you estimate between 5 and 12 counting sheets were discarded. Right? A. Correct. Q. And the basis for your belief that there was additional discarding of counting sheets beyond what you witnessed Ms. Kriss do and beyond what you witnessed Ms. Barr do and beyond what you, yourself, did is conversations you heard. Correct? A. Correct. Q. Please tell me what those conversations were in which people talked about discarding counting sheets? A. Again, the transcription of the data into a clean counting sheet was what I recall, which the data itself or data packet would be basically would maintain one counting sheet. So, therefore, and maybe this is an assumption, drawing a conclusion that if it was transcribed, the original was being destroyed. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the laboratory. Again, we all sat in a general area and so I can't I just can't recall. Q. I gather on those occasions that you heard about people transcribing data from one counting sheet to another counting sheet, you have no information about whether the transcription was accurate. Right? A. Right. That's correct. Q. Now, you, yourself, discarded a counting sheet once? A. From what I recall, yes. I recall a specific assay that I ran that was I completed, I counted the entire assay, had valid results from the counting. The staining was faint on that but I was still able to count and get a valid result. So that assay had a high pre-positive rate on the original counts that I had conducted, and based on that, Dave Krah had made a statement that the assay was no good and to discard it. Q. What is it that Dr. Krah told

15 (Pages 345 - 348)

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Page 351Page 3512remember exactly what he said, but I believeQ. Did you discard the counting3Q. You discarded the plates and34the counts?35A. The I did not discard the56plates.Q. Who discarded the plates?7A. The I did not discard the66plates.Q. Who discarded the plates?7A. Ta chor to know. If they99Q. How do you know sorry.910A. I can't confirm if they were?1011discarded.1112Q. Do you think they were?1213A. I think they were, but I don't1314know.1415Q. What is the basis of your1516thiking that?1417A. That just the basis that he1318had said to discard it.1719Q. Didn't you just tell me you2020don't remember what he said?2121to as far as discarding.2222skeed me if he said exactly what he told me to if23skeed me if he said exactly what he was referring2424MR. KELLER: Argumentative.325MR. KELLER: Argumentative.426So you don't know whether he336Gon't know whether he337sense., Jeff. I'm just trying tog tto738MR. KELLER: Argumentative.339		JOINTE. WEGGING WORK		
2 we discarded the plates and the counts. 2 sheet? 3 Q. You discarded the plates and the counts? 3 A. I believe so. 4 the counts? 5 A. The I did not discard the 5 A. I believe so. 6 plates. 7 Q. Who discarded the plates? 7 A. I believe so. 7 Q. Who discarded the plates? A. I believe so. 6 Q. What was the procedure in the 7 Q. How do you know sory. 9 sorry, once the assay was counted? Do you 10 understand my question? That wasn't phrased 11 discarded. 12 A. That just the basis of your 13 that? 14 Mow. That just the basis of your 16 that? 14 Q. Transking about the process 15 Q. Didn't you just tell me you 10 complete the counting sheet, what would you 11 asseci free ing to the plate? 14 Q. Transking about the process 15 for documentation or plaque countis when 16 unknex LLER: Asid be you 16 sepcifically was supposed to be, after you 20 do you want me to explain what we as analystste 24 did? <t< th=""><th></th><th>6</th><th></th><th></th></t<>		6		
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1 0	19 20 21	You can answer the question. THE WITNESS: He asked me to discard, discard the assay. Based on	20 21	as far as I can recall. Q. If you continued an assay, are
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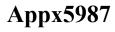
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Appx5986

	Page 353		Page 355
1	Overbroad.	1	BY MR. SANGIAMO:
2	THE WITNESS: From what I	2	Q. Where was this file physically
3	recall, I did enter some. I don't know	3	in relation to where you entered the
4	that all of the data was entered by the	4	information into the Excel worksheet?
5	analyst who conducted the testing. Or	5	A. It was next to my desk.
6	sorry, conducted the counting.	6	Q. Was it a single repository for
7	BY MR. SANGIAMO:	7	all the assays or was it just limited to the
8	Q. Again, I'm just referring to	8	assays that you were counting?
9	your practice.	9	MR. KELLER: Objection.
10	A. Okay.	10	Compound.
11	Q. Did I hear you to say that	11	THE WITNESS: Can you repeat
12	sometimes if you did the count of the assay,	12	that question?
13	you would then enter the numbers into the	13	BY MR. SANGIAMO:
14	Excel worksheet?	14	Q. I'm trying to figure out the
15	A. Correct.	15	location of the file into which you would put
16	Q. But sometimes you wouldn't?	16	the counting sheet. I think you said it was
17	A. I want to say that there were	17	right next to your desk?
18	occasions that somebody else would enter it as	18	A. Yes.
19	far as I recall.	19	Q. What I'm trying to figure out
20	Q. Was the place where you would	20	is, whether that thing that was right next to
21	enter the data into the Excel worksheet, was	21	your desk simply held the files for the assays
22	that right at your desk?	22	that you were counting or did it hold the
23	A. Yes.	23	files for all the assays no matter who counted
24	Q. Was it the same place where you	24	them or what?
	Page 354		Page 356
1	would do the plaque counts?	1	A. It would contain all the files.
2	would do the plaque counts? A. Right near it, yes.	1 2	A. It would contain all the files.Q. On this occasion when Dr. Krah
2 3	would do the plaque counts?A. Right near it, yes.Q. So after you entered the data		A. It would contain all the files.Q. On this occasion when Dr. Krah told you to discard something in connection
2 3 4	would do the plaque counts?A. Right near it, yes.Q. So after you entered the datainto the Excel worksheet, what would you do	2	A. It would contain all the files.Q. On this occasion when Dr. Krah told you to discard something in connection with the assay that you were counting, what is
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2 3 4 5 6	would do the plaque counts?A. Right near it, yes.Q. So after you entered the datainto the Excel worksheet, what would you dowith the counting sheet?A. Again, from what I recall, it	2 3 4	 A. It would contain all the files. Q. On this occasion when Dr. Krah told you to discard something in connection with the assay that you were counting, what is your best recollection of how much time elapsed between when you entered the data into
2 3 4 5 6 7	 would do the plaque counts? A. Right near it, yes. Q. So after you entered the data into the Excel worksheet, what would you do with the counting sheet? A. Again, from what I recall, it would get entered into the file for the 	2 3 4 5 6 7	 A. It would contain all the files. Q. On this occasion when Dr. Krah told you to discard something in connection with the assay that you were counting, what is your best recollection of how much time elapsed between when you entered the data into the Excel worksheet and when you had this
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	Page 357		Page 359
1	Q. When you were the one to enter	1	revised first set of Interrogatories. I
2	the information into the Excel worksheet,	2	wonder if I could ask you to turn to page 18.
3	would you do that immediately after completing	3	And I'd like to direct your attention to the
4	the count?	4	paragraph at the bottom of page 18 that
5	MR. KELLER: Objection. Compound.	5	carries over to page 19. I'm going to start
6	THE WITNESS: Yeah, I don't	6	to read that into the record.
7	know what your definition of	7	"On another occasion, Relator
8	"immediately" is. But I don't I	8	was working in the back laboratory next to
9	don't think that it was consistent, the	9	Relator Krahling. She showed Relator Krahling
10	time of entry for different plaque	10	her counting sheet that contained 11
11	counting.	11	pre-positives. Relator Krahling calculated
12	BY MR. SANGIAMO:	12	this equaled an 84 percent pre-positive rate.
13	Q. Even within your own practice	13	Relator joked sarcastically about the unlikely
14	it was not consistent?	14	possibility the data would survive the day.
15	A. As far as I recall.	15	Krah overheard their conversation and came
16	MR. KELLER: Dino, we've been	16	over to look at the plates. He told Relator
17	going about an hour. Can we take a	17	that the plaques were too faint to count and
18	break?	18	ordered her to throw away her counting sheet
19	MR. SANGIAMO: Give me one or	19	because he intended to retest the entire
20	two more, Jeff.	20	assay. Relator protested that the plaques
21	BY MR. SANGIAMO:	21	were not too faint to count, citing as
22	Q. I asked you before whether you	22	evidence the fact that she had already counted
23	would do it immediately, and you appropriately	23	them. Krah ordered her again to throw out the
24	asked for what would one mean by immediately.	24	counting sheet and she complied."
1	Page 358 I guess I meant would it be the next thing on	1	Page 360 That's the end of the quote
$\begin{vmatrix} 1\\2 \end{vmatrix}$	your to-do list?	2	from the Interrogatory answer. Is what is
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	•	3	described in that paragraph that I just read
	MR. KELLER: Objection. THE WITNESS: I'm trying to	4	
4	•••		the incident about which you were testifying
5	think. As far as I can recall, it	5 6	just before the break? A. Yes.
6	would be the next thing, yes.		
7	MR. SANGIAMO: Okay. Take a	7	Q. When you prepared the answer to
8	break now.	8	this Interrogatory, how did you know that the
9	VIDEOGRAPHER: The time is now	9	number of pre-positives from that assay run
10	10:43. Off the video record.	10	was 11?
11		11	MR. KELLER: Objection. Strike
12	(A recess was taken.)	12	my objection. In answering this
13		13	question do not disclose any
14	VIDEOGRAPHER: The time is now	14	communications you had with your
15	11:02. This begins disc two. You may	15	counsel or any communications that may
16	proceed.	16	have occurred in order to answer this
17	BY MR. SANGIAMO:	17	question. So if you can answer the
18	Q. Ms. Wlochowski, before the	18	question without disclosing
19	break we were talking about an occasion on	19	communication you had with your
20	which you discarded a counting sheet. I	20	counsel, by all means do so. If you
21	wonder if I could ask you to take a look at	21	can't, then I instruct you not to
22	Exhibit 7 which is one of the exhibits we	22	answer.
23	looked at yesterday from that stack right	23	THE WITNESS: Can you repeat
24	there. Exhibit 7 is your Answers to Merck's	24	the question, please?

18 (Pages 357 - 360)

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	JOINTE. WEDENOWSKI		
	Page 361		Page 363
1	BY MR. SANGIAMO:	1	BY MR. SANGIAMO:
2	Q. Let me come at it a different	2	Q. Ms. Wlochowski, you've just
3	way. If you take a look at the second to the	3	been handed what has been marked as
4	last page of Exhibit 7, we see your Verification		Exhibit 15. This is what is this document?
5	there. Right?	5	A. This is the Excel worksheet
6	A. Correct.	6	that was used to calculate the titers.
7	Q. And in that Verification you	7	Q. This was contained in the
8	say that you certify under the penalty of	8	production of documents that we received from
9	perjury that you've reviewed these responses	9	the Relators. We're checking our records to
10	and the content is true and correct to the	10	confirm, but I'll just ask you, do you know if
11	best of your knowledge. Right?	11	this document was in your possession as
12	A. Correct.	12	distinguished from Mr. Krahling's possession
13	Q. When you did that review, were	13	at the time the litigation began?
14	you also certifying to the accuracy of the	14	A. I'm sorry, I didn't hear.
15	fact that there were 11 pre-positives on the	15	Q. This document was either in
16	particular assay that we've been discussing?	16	your possession or Mr. Krahling's possession
17	A. Yes.	17	at the time the litigation began. We're
18	Q. Are you sure it was 11?	18	trying to confirm right now, but if you know,
19	MR. KELLER: Objection.	19	it will save us a minute or two.
20	Argumentative. Vague and ambiguous.	20	A. I can't remember.
21	THE WITNESS: Based on the	21	Q. I believe based on the
22	information that I had at that time,	22	information we've been provided by your
23	yes.	23	attorneys, this was in Mr. Krahling's
24	BY MR. SANGIAMO:	24	possession, not in your possession, at the
	Page 362		Page 364
1	Q. At the time you certified?	1	time we requested documents in this
2	A. Yes.	2	litigation. That's all background, providing
3	Q. What was that information?	3	that information.
4	MR. KELLER: Do not disclose	4	This particular assay run shows
5	any communications with counsel. If	5	nine pre-positives if I'm reading this correctly.
6	you can answer without disclosing	6	Would you be able to confirm that easily? I
7	communications with counsel, you may do	7	don't want to take up a whole bunch of time.
8	so.	8	MR. KELLER: Take the time.
9	THE WITNESS: I cannot provide	9	Are you representing there is nine
10	additional information on that.	10	pre-positives?
11	BY MR. SANGIAMO:	11	MR. SANGIAMO: I am. You know
12	Q. Did you have any documents that	12	what, let's
13	associated with this assay at the time that	13	MR. KELLER: I don't disagree
14	you verified?	14	with you, but I haven't taken the time
15			• ·
15	A. I cannot remember.	15	to
		15 16	to MR. SANGIAMO: I counted nine,
15 16 17	A. I cannot remember.		MR. SANGIAMO: I counted nine,
16 17	A. I cannot remember. (Exhibit Wlochowski-15, Mumps	16	
16 17 18	A. I cannot remember. (Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates	16 17	MR. SANGIAMO: I counted nine, but perhaps it's better if Ms.
16 17 18 19	A. I cannot remember. (Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates RELATOR_00000716 to 721, was marked for	16 17 18 19	MR. SANGIAMO: I counted nine, but perhaps it's better if Ms. Wlochowski confirms. MR. KELLER: You don't have the
16 17 18 19 20	A. I cannot remember. (Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates	16 17 18 19 20	MR. SANGIAMO: I counted nine, but perhaps it's better if Ms. Wlochowski confirms. MR. KELLER: You don't have the counting sheets for this?
16 17 18 19 20 21	A. I cannot remember. (Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates RELATOR_00000716 to 721, was marked for identification.)	16 17 18 19 20 21	MR. SANGIAMO: I counted nine, but perhaps it's better if Ms. Wlochowski confirms. MR. KELLER: You don't have the counting sheets for this? MR. SANGIAMO: I'm about to
16 17 18 19 20 21 22	A. I cannot remember. (Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates RELATOR_00000716 to 721, was marked for identification.) MR. KELLER: What exhibit	16 17 18 19 20	MR. SANGIAMO: I counted nine, but perhaps it's better if Ms. Wlochowski confirms. MR. KELLER: You don't have the counting sheets for this?
16 17 18 19 20 21	A. I cannot remember. (Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates RELATOR_00000716 to 721, was marked for identification.)	16 17 18 19 20 21 22	MR. SANGIAMO: I counted nine, but perhaps it's better if Ms. Wlochowski confirms. MR. KELLER: You don't have the counting sheets for this? MR. SANGIAMO: I'm about to

19 (Pages 361 - 364)

Appx5989

	Page 365		Page 367
1	Layout Sheet, Bates MRK-KRA00680674,		MR. KELLER: It's blue ink.
2	was marked for identification.)	2	THE WITNESS: Okay.
3		3	BY MR. SANGIAMO:
4	BY MR. SANGIAMO:	4	Q. I suggest you put a check mark
5	Q. You've just been handed what	5	next to each one that is pre-positive.
6	has been marked as Exhibit 16. Ms.	6	
7	Wlochowski, do you recognize that document?	7	(A discussion off the record
8	A. Yes.	8	occurred.)
9	Q. What is that?	9	
10	A. That is the plate layout sheet	10	THE WITNESS: I am like
11	with the corresponding serum IDs.	11	having I would have to go back and
12	Q. If you take a moment, can you	12	refer to our procedures for counting
13	see that the assay being referred to in both	13	because I'm having trouble recalling
14	Exhibit 16 and Exhibit 15 is Assay 211? Do	14	the calculation for figuring out which
15	you see that?	15	one is which.
16	A. Yes.	16	BY MR. SANGIAMO:
17	Q. With the aid of the plate	17	Q. When you say which one is
18	layout sheet, Exhibit 16, can you now tell me	18	which, what do you mean?
19	how many pre-positives you believe are	19	A. Again, the numbers are just
20	reflected on Exhibit 15, the Excel workbook?	20	confusing me as far as reporting the outcome.
21	Ms. Wlochowski, we have a ruler	21	Q. Why don't we walk through a
22	here. Will that help at all?	22	couple of these, see if that helps any. If we
23	A. Yes. Thank you.	23	look at Exhibit 16 which is the plate layout
24	MR. KELLER: Do you have the	24	sheet
			D 200
1	Page 366	1	Page 368
$\begin{vmatrix} 1\\ 2 \end{vmatrix}$	actual counting sheets?	1	A. Correct.
2	actual counting sheets? MR. SANGIAMO: She said she	2	A. Correct.Q the first row in which there
2 3	actual counting sheets? MR. SANGIAMO: She said she discarded it.	2 3	A. Correct.Q the first row in which thereis handwriting underneath the case number
2 3 4	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you	2 3 4	A. Correct. Q the first row in which there is handwriting underneath the case number column
2 3 4 5	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that	2 3 4 5	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh.
2 3 4 5 6	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm	2 3 4 5 6	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the
2 3 4 5 6 7	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out.	2 3 4 5 6 7	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right?
2 3 4 5 6 7 8	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting	2 3 4 5 6 7 8	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes.
2 3 4 5 6 7 8 9	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to	2 3 4 5 6 7 8 9	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it
2 3 4 5 6 7 8 9 10	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all.	2 3 4 5 6 7 8 9 10	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right?
2 3 4 5 6 7 8 9 10 11	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting	2 3 4 5 6 7 8 9 10 11	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. A. Yes.
2 3 4 5 6 7 8 9 10 11 12	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining	2 3 4 5 6 7 8 9 10 11 12	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across
2 3 4 5 6 7 8 9 10 11 12 13	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes	2 3 4 5 6 7 8 9 10 11 12 13	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181
2 3 4 5 6 7 8 9 10 11 12 13 14	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out.	2 3 4 5 6 7 8 9 10 11 12 13 14	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO:	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or what to call this, but is it correct that it	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to plate 182 and 181. Right?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or what to call this, but is it correct that it would essentially alternate by	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to plate 182 and 181. Right? A. Correct. A. Correct.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or what to call this, but is it correct that it would essentially alternate by A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to plate 182 and 181. Right? A. Correct. Q. Then if you look over to the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or what to call this, but is it correct that it would essentially alternate by A. Yes. Q. And if it helps you to put a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to plate 182 and 181. Right? A. Correct. Q. Then if you look over to the right, right next to the column that says
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or what to call this, but is it correct that it would essentially alternate by A. Yes. Q. And if it helps you to put a little check mark after you've identified each	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to plate 182 and 181. Right? A. Correct. Q. Then if you look over to the right, right next to the column that says "Titer"?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	actual counting sheets? MR. SANGIAMO: She said she discarded it. MR. KELLER: Are you representing this is the assay that MR. SANGIAMO: That's what I'm trying to find out. To be clear, I have a counting sheet for an assay. But I'm trying to have her help me understand it all. THE WITNESS: I'm just getting confused because the data is not lining up. I'm not seeing it right. My eyes are bugging out. BY MR. SANGIAMO: Q. Ms. Wlochowski, can I I don't know whether to call it a suggestion or what to call this, but is it correct that it would essentially alternate by A. Yes. Q. And if it helps you to put a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Correct. Q the first row in which there is handwriting underneath the case number column A. Uh-huh. Q it says 1452. That's the case number. Right? A. Yes. Q. And then right next to that it says "pre." Right? A. Yes. Q. If you continue to read across to the right, you come to plate numbers 181 and 182. Right? A. Correct. Q. SO then if we look at Exhibit 15, we see the corresponding reference there to plate 182 and 181. Right? A. Correct. Q. Then if you look over to the right, right next to the column that says

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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	D 260		D 271
1	Page 369 A. Yes.	1	Page 371 A. Yes.
2	Q. Is what so that would be a	$\begin{vmatrix} 1\\2 \end{vmatrix}$	Q. Was the data set more than just
3	pre-positive. Correct?	3	a printout from the Excel spreadsheet?
4	A. Again, I'm trying to go through	4	A. I can't remember.
5	in my head. I don't want to get it backwards.	5	Q. The Answers to Interrogatories
6	So, again, I can't	6	were verified some 15 years or so after the
7	Q. Ms. Wlochowski, I'm going to	7	assay was actually counted.
8	suggest something to you and see if it jogs	8	A. Yes.
9	your memory at all. What I'm going to suggest	9	Q. With that in mind, I'm just
10	to you is that a titer was considered positive	10	trying to gauge your level of certainty as
11	if it was 32 or greater. Does that sound	11	regards 11 being the number of pre-positives
12	right to you?	12	in that particular assay. Could you comment
13	MR. KELLER: Objection. Lack	13	on that?
14	of foundation. Do you want to show her	14	MR. KELLER: Objection.
15	the protocol?	15	Argumentative. Vague and ambiguous.
16	THE WITNESS: Again, I would	16	You can answer.
17	need to go back to the protocol.	17	THE WITNESS: If I recall, I
18		18	would have had the data to confirm
19	(Exhibit Wlochowski-17, Virus &	19	that.
20	Cell Biology Research Procedure, Bates	20	BY MR. SANGIAMO:
21	MRK-KRA00064382 to 4391, was marked for	21	Q. Would you very confidently
22	identification.)	22	exclude the possibility that there are
23		23	actually 9 pre-positives in that assay?
24	BY MR. SANGIAMO:	24	MR. KELLER: Objection.
	Page 370		Page 372
1	Q. Ms. Wlochowski, I've just	1	Argumentative. Vague and ambiguous.
2	handed you what has been marked as Exhibit 17.	2	Calls for speculation.
3	Do you recognize that document?	3	THE WITNESS: I can't say.
4	A. Yes. That is the SOP.	4	BY MR. SANGIAMO:
5	MR. KELLER: Take your time to	5	Q. The Answer to Interrogatory
6	review that.	6	says that you were working in the back
7	BY MR. SANGIAMO:	7	laboratory next to Relator Krahling. Is that
8	Q. Ms. Wlochowski, I'm going to	8	different from your desk?
9	suggest an alternative approach to this. If	9	A. Where are you referring to?
10	you could look back again to Exhibit 15 which	10	Sorry.
10	you could look back again to Exhibit 15 which	10	-
11	is the workbook printout?	11	Q. On page 18.
		11 12	Q. On page 18.A. Okay. Got it. That wouldn't
11	is the workbook printout? A. Uh-huh. Q. Do you know whether you	11 12 13	Q. On page 18.A. Okay. Got it. That wouldn't be at my desk but near my desk.
11 12	is the workbook printout?A. Uh-huh.Q. Do you know whether youreferred to that document when you were	11 12 13 14	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you
11 12 13	is the workbook printout?A. Uh-huh.Q. Do you know whether youreferred to that document when you wereverifying your Answers to Interrogatories?	11 12 13 14 15	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet
11 12 13 14 15 16	is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack	11 12 13 14 15 16	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at
11 12 13 14 15 16 17	is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation.	11 12 13 14 15 16 17	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as
11 12 13 14 15 16 17 18	is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation. THE WITNESS: I believe that I	11 12 13 14 15 16 17 18	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as to what the titers were for the sample in the
11 12 13 14 15 16 17 18 19	 is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation. THE WITNESS: I believe that I referred to a data set in order to come 	11 12 13 14 15 16 17 18 19	Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as to what the titers were for the sample in the assay?
11 12 13 14 15 16 17 18 19 20	 is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation. THE WITNESS: I believe that I referred to a data set in order to come up with the number at the time. 	11 12 13 14 15 16 17 18 19 20	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as to what the titers were for the sample in the assay? A. They may have been, but they
11 12 13 14 15 16 17 18 19 20 21	 is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation. THE WITNESS: I believe that I referred to a data set in order to come up with the number at the time. BY MR. SANGIAMO: 	11 12 13 14 15 16 17 18 19 20 21	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as to what the titers were for the sample in the assay? A. They may have been, but they it was also at that time easier for us to
11 12 13 14 15 16 17 18 19 20 21 22	 is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation. THE WITNESS: I believe that I referred to a data set in order to come up with the number at the time. BY MR. SANGIAMO: Q. When you say at the time, you 	11 12 13 14 15 16 17 18 19 20 21 22	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as to what the titers were for the sample in the assay? A. They may have been, but they it was also at that time easier for us to eyeball the difference between the mock
11 12 13 14 15 16 17 18 19 20 21	 is the workbook printout? A. Uh-huh. Q. Do you know whether you referred to that document when you were verifying your Answers to Interrogatories? MR. KELLER: Objection. Lack of foundation. THE WITNESS: I believe that I referred to a data set in order to come up with the number at the time. BY MR. SANGIAMO: 	11 12 13 14 15 16 17 18 19 20 21	 Q. On page 18. A. Okay. Got it. That wouldn't be at my desk but near my desk. Q. The next sentence says you showed Relator Krahling your counting sheet that contained 11 pre-positives. I gather at that point the determination had been made as to what the titers were for the sample in the assay? A. They may have been, but they it was also at that time easier for us to

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Case 22322553 Document: 7946 Plage 5591 Date Filed 1120262223

HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

1	Page 373	1	Page 375
1	A. You could eyeball it.	1	Q. And that reads, "Large amount
2	Q. You could eyeball it?	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	of plates in assay showed faint staining. See
3	A. Meaning that it's a comparison	3	counting sheet for details. This assay will
4	of the reduction against the control, the mock	4	be repeated per Dave Krah's request." And
5	control. So just based on the number of	5	it's signed by you. Right?
6	plaques in the control, and the number you	6	A. Yes.
7	were counting as a pre-positive, it was at	7	Q. Do you think this assay 211 is
8	the time you were counting could have a feel	8	the one that you were describing in your
9	for whether it was going to be pre-positive or	9	Answers to Interrogatories at page 18?
10	not.	10	A. This could be the one, yes.
11	Q. You could have a feel for it,	11	Q. And you have a vivid recollection
12	but you could be off by a little bit. Right?	12	of discarding the counting sheet for that
13	A. Yes.	13	assay. Right?
14	Q. Do you recall any occasions	14	A. I recall being told to discard
15	other than this one when Dr. Krah told you	15	it. Yes.
16	that an assay needed to be rerun because the	16	Q. Did you discard it?
17	plaques were too faint?	17	A. To the best of my recollection.
18	A. I can't recall, no.	18	
19		19	(Exhibit Wlochowski-19,
20	(Exhibit Wlochowski-18,	20	Counting sheet, Bates MRK-KRA00680676,
21	Notebook page, Bates MRK-KRA00680669 &	21	was marked for identification.)
22	670, was marked for identification.)	22	
23		23	BY MR. SANGIAMO:
24	MR. SANGIAMO: That is 18, I	24	Q. Ms. Wlochowski, you've just
	Page 374		Page 376
1	believe.	1	been handed what has been marked as
2	BY MR. SANGIAMO:	2	Exhibit 19. Do you recognize that document?
3	Q. Do you recognize Exhibit 18,	3	A. That is a counting sheet.
4	Ms. Wlochowski?	4	Q. Counting sheet for which assay?
5	A. Yes. It is a page from the	5	A. For 211-01.
6	laboratory notebook.	6	Q. Do you see a reference to very
7	Q. And what assays are you	7	faint plaques on the counting sheet?
8	referring to?	8	A. I do.
9	A. It is referring to the mumps	9	Q. Is that your handwriting?
10	AIGENT assay for Protocol 007.	10	A. Yes.
11	Q. What assay number?	11	Q. Does that mean that on or
12	- · ·	12	around the time that you were counting plaques
	A. The MMRV-211-01.		
13	A. The MMRV-211-01. COURT REPORTER: Could you keep		
13 14	COURT REPORTER: Could you keep	13	for this assay you noted that the plaques were
14	COURT REPORTER: Could you keep your voice up, please?	13 14	for this assay you noted that the plaques were very faint?
14 15	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01.	13 14 15	for this assay you noted that the plaques were very faint? A. That yes.
14 15 16	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO:	13 14 15 16	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that
14 15 16 17	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we	13 14 15 16 17	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is
14 15 16 17 18	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we were looking at the Excel spreadsheet there in	13 14 15 16 17 18	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is it your best belief that the assay being
14 15 16 17 18 19	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we were looking at the Excel spreadsheet there in Exhibit 15. Right?	13 14 15 16 17 18 19	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is it your best belief that the assay being referred to in your Answers to Interrogatories
14 15 16 17 18 19 20	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we were looking at the Excel spreadsheet there in Exhibit 15. Right? A. Yes.	13 14 15 16 17 18 19 20	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is it your best belief that the assay being referred to in your Answers to Interrogatories on page 18 is assay 211?
14 15 16 17 18 19 20 21	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we were looking at the Excel spreadsheet there in Exhibit 15. Right? A. Yes. Q. And then if you take a look on	13 14 15 16 17 18 19 20 21	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is it your best belief that the assay being referred to in your Answers to Interrogatories on page 18 is assay 211? MR. KELLER: Objection.
14 15 16 17 18 19 20 21 22	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we were looking at the Excel spreadsheet there in Exhibit 15. Right? A. Yes. Q. And then if you take a look on the first page of Exhibit 18 there is an entry	 13 14 15 16 17 18 19 20 21 22 	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is it your best belief that the assay being referred to in your Answers to Interrogatories on page 18 is assay 211? MR. KELLER: Objection. Mischaracterizes her testimony.
14 15 16 17 18 19 20 21	COURT REPORTER: Could you keep your voice up, please? THE WITNESS: The MMRV-211-01. BY MR. SANGIAMO: Q. That was the assay for which we were looking at the Excel spreadsheet there in Exhibit 15. Right? A. Yes. Q. And then if you take a look on	13 14 15 16 17 18 19 20 21	for this assay you noted that the plaques were very faint? A. That yes. Q. Based on the documents that have been presented to you, as of right now is it your best belief that the assay being referred to in your Answers to Interrogatories on page 18 is assay 211? MR. KELLER: Objection.

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1	Page 377		Page 379
	It could be.	1	Q. The next sentence reads, "The
2	BY MR. SANGIAMO:	2	faint plaque appearance was not described
3	Q. How would you describe the fact	3	specifically in the SOP for the assay as a
4	that we have this counting sheet if you	4	reason to invalidate a sample or the assay.
5	discarded it?	5	There were no documented technical errors
6	MR. KELLER: Objection.	6	during the," next word is hard to read,
7	Argumentative.	7	"to account for the faint plaquesTherefore,
8	THE WITNESS: I don't know if	8	the assay and the individual sample results
9	it is the one that was being referred	9	are considered valid." Right?
10	to at the time.	10	MR. KELLER: That's not exactly
11	BY MR. SANGIAMO:	11	what it reads, but you can answer. The
12	Q. I'm sorry?	12	document speaks for itself.
13	A. I don't know if this is the	13	THE WITNESS: Yes. So the
14	assay that we were referring to in the	14	assay was repeated in June of 2001 and
15	Complaint.	15	the entry that was entered by Dave Krah
16	Q. In the Answers to Interrogatories,	16	about the assay being valid and
17	is that what you meant? Just now you said	17	reporting to the results to the
18	Complaint.	18	clinical database was made in 2002, a
19	A. Sorry, yes. The Interrogatories,	19	year later.
20	yes.	20	BY MR. SANGIAMO:
21	Q. If you go back to Exhibit 18,	21	Q. And sitting here right now, you
22	do you see down at the bottom of the page	22	don't know whether the results that were
23	there is an entry dated July 23, 2002. Do you	23	submitted to the clinical database were the
24	see that?	24	results from the running of the assay as
	Page 378		Page 380
			rage 380
1	A. Yes.	1	counted by you or the running of the assay
1 2	A. Yes.Q. It reads, "See assay results,"	1 2	5
2		2	counted by you or the running of the assay
2 3	Q. It reads, "See assay results,"	2	counted by you or the running of the assay subsequently. Right?
2 3	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained	2 3	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because
2 3 4 5	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template."	2 3 4	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248
2 3 4 5 6	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word	2 3 4 5	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what
2 3 4 5 6 7 8	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all	2 3 4 5 6	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results.
2 3 4 5 6 7 8	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right?	2 3 4 5 6 7	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know,
2 3 4 5 6 7 8	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all	2 3 4 5 6 7 8	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right?
2 3 4 5 6 7 8 9 10 11	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation.	2 3 4 5 6 7 8 9 10 11	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack
2 3 4 5 6 7 8 9 10 11	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack	2 3 4 5 6 7 8 9 10	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right?
2 3 4 5 6 7 8 9 10 11	Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation.	2 3 4 5 6 7 8 9 10 11 12 13	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack of foundation. Argumentative. Calls for speculation.
2 3 4 5 6 7 8 9 10 11 12 13 14	 Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation. BY MR. SANGIAMO: Q. Is that how it reads? A. Yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack of foundation. Argumentative. Calls for speculation. THE WITNESS: That is correct,
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation. BY MR. SANGIAMO: Q. Is that how it reads? A. Yes. Q. "Results are being reported to 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack of foundation. Argumentative. Calls for speculation. THE WITNESS: That is correct, I do not know what was reported into
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation. BY MR. SANGIAMO: Q. Is that how it reads? A. Yes. Q. "Results are being reported to the clinical database." Do you see that? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack of foundation. Argumentative. Calls for speculation. THE WITNESS: That is correct, I do not know what was reported into the clinical database.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation. BY MR. SANGIAMO: Q. Is that how it reads? A. Yes. Q. "Results are being reported to the clinical database." Do you see that? A. I see that, yes. Q. Now, this happened after you 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack of foundation. Argumentative. Calls for speculation. THE WITNESS: That is correct, I do not know what was reported into the clinical database. BY MR. SANGIAMO: Q. You gave testimony about
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. It reads, "See assay results," maybe the next word is "summary." "Obtained using Mumps AIGENT Processing Template." Not confident I read every word correctly in that sentence. Some of the handwriting is hard to read. But the next sentence reads, "The assay is valid (all controls are valid)." Right? MR. KELLER: Objection. Lack of foundation. BY MR. SANGIAMO: Q. Is that how it reads? A. Yes. Q. "Results are being reported to the clinical database." Do you see that? A. I see that, yes. Q. Now, this happened after you had left the lab. Right? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	counted by you or the running of the assay subsequently. Right? A. Right. I don't know because there is a different assay number here for 248 for the repeat assay, so I don't know what happened to those results. Q. Right. So as far as you know, you just don't know one way or the other, the results of assay 211 could have been reported to the clinical database. Right? MR. KELLER: Objection. Lack of foundation. Argumentative. Calls for speculation. THE WITNESS: That is correct, I do not know what was reported into the clinical database. BY MR. SANGIAMO: Q. You gave testimony about discarding of counting sheets which we've gone
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1			
1	Page 381	1	Page 383
1	THE WITNESS: When I had	1 2	Q. Can you give me your best
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	mentioned earlier about the discarding	2 3	approximation?
3	of the plates is an example of not		MR. KELLER: Objection to form.
4	retaining the original data as well as	4	THE WITNESS: I cannot because there's instances of discussions as
5	when analysts would read or count the	5	
6	plaques, there were instances of wiping	6	well as, you know, somebody actually
7	out the original plaque counts on the	7	doing it. There was, you know, alcohol
8	plate and repeating the plaque counts.	8 9	wipe in the lab and you could easily
9	So, therefore, again, I consider that the original data was not maintained.	9 10	just wipe off the counts. BY MR. SANGIAMO:
10 11	BY MR. SANGIAMO:	10	Q. And, of course, that's standard
11		11	
12	Q. Did you witness that occurring?A. Yes.	12 13	practice for when you want to check a count in
13		13 14	a plaque reduction neutralization assay. Right?
14	Q. Did you, yourself, do that?A. I believe in the beginning I	14	MR. KELLER: Objection. Lack
15	may have done that, yes.	15 16	of foundation.
17	Q. How many times did you do it?	10	BY MR. SANGIAMO:
18	Just to be clear my question is unclear.	17	Q. Do you know whether that is
19	What I had in mind was how many times did you	10 19	standard practice when you want to check a
20	wipe the plate clean and then do the count	20	count in a plaque reduction neutralization
20	over again?	20	assay?
21	A. I can't recall how many times.	22	MR. KELLER: Same objection.
22	Q. More than five?	22	THE WITNESS: I would go back
23	A. I can't recall.	23 24	to my original statement that, again,
		21	
1	Page 382	1	Page 384
$\begin{vmatrix} 1\\2 \end{vmatrix}$	Q. How many times did you see it done by others?	2	the assay should be validated to be able to read a plate and generate the
	-	-	able to read a plate and generate the
	A I don't know Again conversations	3	
3	A. I don't know. Again, conversations	3	results.
3 4	in the lab of people questioning their own	4	results. BY MR. SANGIAMO:
3 4 5	in the lab of people questioning their own results, going back and, you know, either	4 5	results. BY MR. SANGIAMO: Q. So your belief about wiping
3 4 5 6	in the lab of people questioning their own results, going back and, you know, either starting over and trying again or an instance	4 5 6	results. BY MR. SANGIAMO: Q. So your belief about wiping plates clean is based on two different kinds
3 4 5 6 7	in the lab of people questioning their own results, going back and, you know, either starting over and trying again or an instance where the data is being reviewed by Dave Krah	4 5 6 7	results. BY MR. SANGIAMO: Q. So your belief about wiping plates clean is based on two different kinds of information, what you saw and what you
3 4 5 6 7 8	in the lab of people questioning their own results, going back and, you know, either starting over and trying again or an instance where the data is being reviewed by Dave Krah and he comes back and he asks analysts to	4 5 6 7 8	results. BY MR. SANGIAMO: Q. So your belief about wiping plates clean is based on two different kinds of information, what you saw and what you heard discussions about. Correct?
3 4 5 6 7 8 9	in the lab of people questioning their own results, going back and, you know, either starting over and trying again or an instance where the data is being reviewed by Dave Krah and he comes back and he asks analysts to count plates. An instance where Suzie Maahs	4 5 6 7 8 9	results. BY MR. SANGIAMO: Q. So your belief about wiping plates clean is based on two different kinds of information, what you saw and what you heard discussions about. Correct? A. Correct.
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1know, basis of the plaque counting,1On that occasion, do you know2what I was, you know, conducting in thealb at that time I was not comfortable2whether the person had already recorded the3lab at that time I was not comfortable3plaque counts on a counting sheet?4with. I, you know again, this may5be some of the reason why there were66different people who conformed who6that you may remember?7agreed, yes, we'll count again, we'll8Jenny Kriss.9to what is pre-vaccination versus9Q. So you remember that?10post-vaccination and able to change those11Q. Now, you said you also heard12determination and able to change those12clean. Right?14were just given prepared serum and15Gidn't know what was pre and post, I1516think our you know, what we16that discussed?17conducted in the lab would be handled a17A. Again, I can't give you a18lot differently. We would not be18number. We all sat in the same laboratory, we19targeting specific, specific plaque20people, a group of staff in the laboratory, we20counts to go back and recheck based on21there's different conversations going on. I21it was not expected.23saying I can't find more plaques, you know,23that answer.23saying I can't find more24Q. Ma'am, how many times di you<	1know, basis of the plaque counting,1On that occasion, do you know2what I was, you know, conducting in thewhat I was, you know, conducting in the2whether the person had already recorded th3lab at that time I was not comfortablewith. I, you know again, this may2whether the person had already recorded th4with. I, you know again, this may2whether the person had already recorded th5be some of the reason why there were6different people who conformed who7agreed, yes, we'll count again, we'll4A. I do not know.8change our results, we are not blinded7A. I would have to say it was9to what is pre-vaccination versus9Q. So you remember?10post-vaccination sera so we could, you10A. Yes.11know, go back and make that11Q. Now, you said you also heard12determination and able to change those13results. If we didn't know if we13results. If we didn't know what was pre and post, I15Q. How many times did you hear16think our you know, what we15Q. How many times did you hear17conducted in the lab would be handled a18lot differently. We would not be18lot differently. We would not be18number. We all sat in the same laboratory,19targeting specific, specific plaque20people, a group of staff in the laboratory,21it was not expected.22MR. SANGIAMO:2	1 know, basis of the plaque counting, what I was, you know, conducting in the lab at that time I was not comfortable 1 On that occasion, do you know whether the person had already reco plaque counts on a counting sheet? 3 lab at that time I was not comfortable A. I do not know. 4 with. I, you know, - again, this may seed, yes, we'll count again, we'll A. I do not know. 5 be some of the reason why there were different people who conformed who 7 A. I would have to say it was seed, yes, we'll count again, we'll 8 change our results, we are not blinded 9 to what is pre-vaccination versus 10 Post-vaccination sera so we could, you 11 10 post-vaccination and able to change those 12 determination and able to change those 13 results. If we didn't know if we 14 Now, you said you also he 12 11 were just given prepared serum and 15 G. How many times did you 16 that discussed? 16 think our you know, what we 17 conducted in the lab would be handled a 18 17 A. Again, I can't give you a 18 19 targeting specific, specific plaque 20 counts to go back and recheck based on 21 17 A. Again, I can't give you a 18 24 BY MR. SANGIAMO: 24 asking somebody else to look at it. 7 Q. Did you definitely see it, 8 <th></th> <th></th> <th></th> <th></th>				
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25 (Pages 385 - 388)

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Appx5995

1	Page 389	1	Page 391
1	A. I'm sorry, can you repeat that		BY MR. SANGIAMO:
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	question?	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Q. Do you have anything to add to
3	Q. On the occasions when you heard	3	your last answer?
4	people commenting on wiping the plate clean,	4	A. No.
5	did they say anything one way or the other	5	Q. Is it your testimony that
6	whether they had already recorded the plaque	6	because there could possibly be transcription
7	counts on the counting sheet at the time they	7	errors, we can't know what the original data
8	wiped the plate clean?	8	was?
9	A. I cannot recall, no.	9	MR. KELLER: Objection.
10	Q. Do you have an understanding as	10	Overbroad. Argumentative.
11	to whether the data that Merck used in support	11	THE WITNESS: That is part
12	of its submission for Protocol 007 was the	12	of yes, not knowing the original
13	data as originally counted versus the data as	13	data.
14	it stood after recounts had been done?	14	BY MR. SANGIAMO:
15	MR. KELLER: Objection. Vague	15	Q. Are there any other reasons why
16	and ambiguous. Overbroad.	16	we wouldn't know what the original data is?
17	THE WITNESS: I cannot say	17	MR. KELLER: Objection. Asked
18	whether original data was submitted.	18	and answered. You can answer.
19	If it was, it would be very difficult	19	THE WITNESS: Again, if
20	to determine what original data was.	20	there if plates are being tossed
21	In some cases there could be	21	out, if data is being changed before
22	transcription errors on a counting	22	it's entered onto the sheet, if data
23	sheet that if you went back to the	23	if the sheet itself is not the original
24	original data, then you would be	24	sheet, it would be very difficult to
	Page 390		Page 392
1	accounting for a transcription error.	1	say if you would be able to provide
2	So, you know, if that was the case,	2	original data.
3	then the reliability of the results,	3	BY MR. SANGIAMO:
4	again, would be questioned.	4	Q. Would there always be a risk of
5	BY MR. SANGIAMO:	5	a transcription error?
6	Q. So is it the case that you have	6	MR. KELLER: Objection.
7	no understanding as to whether the data as	7	Overbroad. Lack of foundation.
8			
-	submitted by Merck to the FDA in support of	8	
9	submitted by Merck to the FDA in support of Protocol 007 was the data as originally	8	Argumentative.
9 10	Protocol 007 was the data as originally	9	Argumentative. THE WITNESS: I'm not sure what
10	Protocol 007 was the data as originally counted versus the data as it stood after the	9 10	Argumentative. THE WITNESS: I'm not sure what you mean by that.
10 11	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed?	9 10 11	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO:
10 11 12	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked	9 10 11 12	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by
10 11 12 13	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that	9 10 11 12 13	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors?
10 11 12 13 14	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous.	9 10 11 12 13 14	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count
10 11 12 13 14 15	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what	9 10 11 12 13 14 15	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the
10 11 12 13 14 15 16	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw	9 10 11 12 13 14 15 16	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number
10 11 12 13 14 15 16 17	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription	9 10 11 12 13 14 15 16 17	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the
10 11 12 13 14 15 16 17 18	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription errors. Do you have an understanding,	9 10 11 12 13 14 15 16 17 18	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the wrong line. That type of transcription error.
10 11 12 13 14 15 16 17 18 19	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription errors. Do you have an understanding, that's my question.	9 10 11 12 13 14 15 16 17 18 19	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the wrong line. That type of transcription error. Q. Is it your view that there
10 11 12 13 14 15 16 17 18 19 20	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription errors. Do you have an understanding, that's my question. MR. KELLER: Not having defined	9 10 11 12 13 14 15 16 17 18 19 20	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the wrong line. That type of transcription error. Q. Is it your view that there should have been some check to assure the
10 11 12 13 14 15 16 17 18 19 20 21	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription errors. Do you have an understanding, that's my question. MR. KELLER: Not having defined what original is. She testified as to	9 10 11 12 13 14 15 16 17 18 19 20 21	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the wrong line. That type of transcription error. Q. Is it your view that there should have been some check to assure the transcription errors did not occur?
10 11 12 13 14 15 16 17 18 19 20 21 22	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription errors. Do you have an understanding, that's my question. MR. KELLER: Not having defined what original is. She testified as to you have a different definition of	9 10 11 12 13 14 15 16 17 18 19 20 21 22	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the wrong line. That type of transcription error. Q. Is it your view that there should have been some check to assure the transcription errors did not occur? MR. KELLER: Objection to form.
10 11 12 13 14 15 16 17 18 19 20 21	Protocol 007 was the data as originally counted versus the data as it stood after the counts had been changed? MR. KELLER: Objection. Asked and answered. She just answered that question. Vague and ambiguous. MR. SANGIAMO: I asked her what her understanding was. She then threw in some stuff about transcription errors. Do you have an understanding, that's my question. MR. KELLER: Not having defined what original is. She testified as to	9 10 11 12 13 14 15 16 17 18 19 20 21	Argumentative. THE WITNESS: I'm not sure what you mean by that. BY MR. SANGIAMO: Q. What did you mean by transcription errors? A. If somebody is taking the count off of a plate and entering it into the counting sheet, they could write the number incorrectly, they could enter it into the wrong line. That type of transcription error. Q. Is it your view that there should have been some check to assure the transcription errors did not occur?

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	JOAN E. WEOCHOWSKI -		
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1	documented as a transcription error,	1	of executing the testing. Originally
2	then it would be detectable. If it's	2	while I was there, originally the assay
3	not documented that that is what the	3	was to be transferred and outsourced,
4	cross out is, then it's not necessarily	4	so transferred to an outside laboratory
5	detectable.	5	which I believe may have been set up to
6	BY MR. SANGIAMO:	6	conduct this type of study in a
7	Q. If Merck submitted the data as	7	controlled manner. That didn't occur
8	originally counted in support of the label	8	as far as I knew because the transfer,
9	change application associated with Protocol	9	we could not transfer it. It didn't
10	007, then who has been harmed as a result of a	10	qualify in that laboratory. So, to me,
11	plaque recounts having been done?	11	that's I would just, as a matter of
12	MR. KELLER: Objection. Calls	12	compliance, question it.
13	for expert opinion. Calls for	13	BY MR. SANGIAMO:
14	speculation. Lack of foundation.	14	Q. Can you identify a party that
15	Incomplete hypothetical. Vague and	15	has been misled as a result of the counting
16	ambiguous. Legal conclusion.	16	rechecks and the recounts?
17	THE WITNESS: Can you repeat	17	MR. KELLER: Objection. Seeks
18	the question?	18	a legal conclusion. Vague and
19	BY MR. SANGIAMO:	19	ambiguous. Lack of foundation.
20	Q. If Merck submitted the data in	20	Seeking expert testimony from a lay
21	support of the label change associated with	21	witness. Vague and ambiguous.
22	Protocol 007 based on the plaques as	22	Overbroad. Objection to form.
23	originally counted rather than the counts as	23	THE WITNESS: I would say from
24	recounted, who has been harmed as a result of	24	being there, I was misled.
	Page 394		Page 396
1	the recounts?	1	BY MR. SANGIAMO:
2	MR. KELLER: Objection. Same	2	Q. Anybody else?
3	objection as the last question.	3	A. Everybody that was in that lab
4	THE WITNESS: Again, I guess I	4	was misled.
5	would question the methodology that is	5	Q. Anyone else?
6	being employed, that there would be a	6	
7			-
	recount being done and all that time	7	MR. KELLER: Same objections. THE WITNESS: It can go on from
8	recount being done and all that time spent on recounts based on guidance by		MR. KELLER: Same objections. THE WITNESS: It can go on from
8 9	spent on recounts based on guidance by	7	MR. KELLER: Same objections.
9	spent on recounts based on guidance by Dave Krah and then coming back a year	7 8 9	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO:
9 10	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to	7 8	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else?
9 10 11	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we	7 8 9 10	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections.
9 10 11 12	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data.	7 8 9 10 11	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative.
9 10 11	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was	7 8 9 10 11 12	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections.
9 10 11 12 13 14	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question	7 8 9 10 11 12 13	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is
9 10 11 12 13 14 15	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't	7 8 9 10 11 12 13 14 15	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know,
9 10 11 12 13 14 15 16	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to	7 8 9 10 11 12 13 14 15 16	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out
9 10 11 12 13 14 15 16 17	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just	7 8 9 10 11 12 13 14 15 16 17	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know,
9 10 11 12 13 14 15 16 17 18	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just wasn't realtime conducting the	7 8 9 10 11 12 13 14 15 16 17 18	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out for vaccination of children. BY MR. SANGIAMO:
9 10 11 12 13 14 15 16 17 18 19	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just wasn't realtime conducting the methodology that should have been	7 8 9 10 11 12 13 14 15 16 17 18 19	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out for vaccination of children. BY MR. SANGIAMO: Q. Did the public know about the
9 10 11 12 13 14 15 16 17 18 19 20	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just wasn't realtime conducting the methodology that should have been employed from the start. So it's hard	7 8 9 10 11 12 13 14 15 16 17 18 19 20	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out for vaccination of children. BY MR. SANGIAMO: Q. Did the public know about the recounts to your knowledge?
9 10 11 12 13 14 15 16 17 18 19 20 21	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just wasn't realtime conducting the methodology that should have been employed from the start. So it's hard to say whether or not there was control	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out for vaccination of children. BY MR. SANGIAMO: Q. Did the public know about the recounts to your knowledge? MR. KELLER: Objection.
9 10 11 12 13 14 15 16 17 18 19 20 21 22	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just wasn't realtime conducting the methodology that should have been employed from the start. So it's hard to say whether or not there was control over the study as a whole, if you	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out for vaccination of children. BY MR. SANGIAMO: Q. Did the public know about the recounts to your knowledge? MR. KELLER: Objection. THE WITNESS: That's why I'm
9 10 11 12 13 14 15 16 17 18 19 20 21	spent on recounts based on guidance by Dave Krah and then coming back a year later to say we're going to go back to what we can find as, or what we consider to be, the original data. During the time that this was happening, I did, you know, question Dave Krah about it. So it wasn't corrected at the time. So for it to come back at a later time, to me just wasn't realtime conducting the methodology that should have been employed from the start. So it's hard to say whether or not there was control	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. KELLER: Same objections. THE WITNESS: It can go on from there. BY MR. SANGIAMO: Q. Who else? MR. KELLER: Same objections. Argumentative. THE WITNESS: In general, to allow this practice to occur is misleading to the public for, you know, a product that you're distributing out for vaccination of children. BY MR. SANGIAMO: Q. Did the public know about the recounts to your knowledge? MR. KELLER: Objection.

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	JOAN E. WEOCHOWSKI -		
1	Page 397	1	Page 399
1	an objection. Lack of foundation.	1	A. Yes.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Argumentative.	2	Q. Did Dr. Krah tell you exactly
3	BY MR. SANGIAMO:	3	what testing that lab was going to do?
4	Q. So do you believe the public	4	A. I believe, to the best of my
5	was misled by the recounts?	5	knowledge, that he was referring to the PRN
6	A. Yes.	6	assay.
7	Q. And do you have any knowledge	7	Q. In which samples, did he say?
8	of the public knowing about the recounts other	8	A. For Protocol 007.
9	than you having filed this lawsuit?	9	Q. Was he any more specific than
10	A. What I have	10	that?
11	MR. KELLER: Objection. Lack	11	A. No.
12	of foundation. Overbroad. Calls for	12	MR. KELLER: We've been going
13	speculation.	13	about an hour. Do you want to take a
14	THE WITNESS: What I have	14	break?
15	knowledge of is it would be the	15	MR. SANGIAMO: Why don't we
16	public's expectation that the	16	finish up this. I don't think it will
17	manufacturing site would be complying	17	take long.
18	with the regulations set forth by the	18	BY MR. SANGIAMO:
19	health authorities.	19	Q. Did you have an understanding
20	BY MR. SANGIAMO:	20	at the time that you worked in Dr. Krah's lab
21	Q. You gave some testimony about	21	regarding why Dr. Ward's lab was not going to
22	another lab that was supposed to run the assay	22	run any assay samples?
23	at one point. What lab was that?	23	A. While I was in Dr. Krah's lab,
24	A. It was a lab out in Ohio. I	24	I don't I didn't have an understanding why
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1	believe it was Dr. Ward's lab.	1	it wasn't going it wasn't carried out.
2	Q. When did you first learn about	2	Q. Have you developed an understanding
3	the idea of Dr. Ward's lab running the assay?	3	since then?
4	A. I can't remember. I believe it	4	A. I can't recall.
5	was springtime or early on while I was there.	5	Q. Do you have a current
6	Q. You're referring to 2001?	6	understanding of why there was
7	A. Yes.	7	A. I can't recall if it's
8	Q. Who did you hear that from?	8	speculation or based on information that I
9	A. I want to I do know that it	9	know today. So I don't want to say. My
10	was part of a document that again, about	10	belief is, again, that it didn't they
11	the development of the assay. I want to say	11	weren't able to transfer it, they weren't able
12	that Dave was had also discussed and	12	to qualify it in that laboratory. There
13	provided information that it was going to be	13	were we were held to, you know, a very
14	transferred. I do know from discussions	14	strict timeline to complete Protocol 007 by
15	within the laboratory that Colleen Barr was	15	August. We were being, you know, told that if
16	I can't remember if she had already gone out	16	we were able to complete it by August, that we
17	there or was going out there, but I do	17	would get bonuses for completion of that work
18	remember her being part of that.	18	on time. So I think it was a matter of being
19	Q. So the basis for your knowledge	19	able to meet the timeline and having the assay
20	that it was going to be transferred is the	20	qualified in the laboratory, the outsourced
	document to which you previously referred that		laboratory.
21	document to which you previously referred that		-
			Q. What is the basis of your
21 22 23	you got from Mr. Krahling, statements that Dr.	22	
22		22	Q. What is the basis of your belief that there was a problem with the outside laboratory, namely Dr. Ward's lab

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1	Page 401	1	Page 403
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	being qualified?	1	THE WITNESS: Can you elaborate
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. That's the piece I can't	2	on that?
3	recall, can't confirm.	3	BY MR. SANGIAMO:
4	Q. Would it be fair to say that	4	Q. Do you have an understanding
5	you simply don't know why it is that the assay	5	what the word design might mean in the context
6	was not performed in Dr. Ward's lab?	6	of an assay?
7	MR. KELLER: Objection. Asked	7	A. Can you define what you mean by
8	and answered. Argumentative.	8	that?
9	You can try to answer again. THE WITNESS: If it was a	9	Q. Suppose I were to use the term
10		10	parameters, the parameters for the assay,
11	matter of timing in order to complete	11	would that have any better meaning for you?
12	the assay transfer and complete the	12	MR. KELLER: Same objection.
13	testing in that timeline, that would	13	THE WITNESS: Again, do you
14	be that would suggest that that was	14	want to describe which parameters
15	part of the reason.	15	you're referring to?
16	BY MR. SANGIAMO:	16	BY MR. SANGIAMO:
17	Q. Is it your testimony that that	17	Q. What term would you use to
18	was part of the reason? I'm just trying to	18	describe the methodology of an assay as well
19	understand your testimony, ma'am.	19	as the reagents to be used in the assay?
20	MR. KELLER: Objection. Asked	20	MR. KELLER: Objection.
21	and answered. She just testified to	21	THE WITNESS: So I think I know
22	it.	22	what you're referring to as far as
23	THE WITNESS: I truly don't	23	design. I guess to me that would be
24	know as I sit here today. I can't	24	the procedure itself that has already
	Page 402		Page 404
1	confirm one way or the other.	1	been defined.
2	BY MR. SANGIAMO:	2	been defined. BY MR. SANGIAMO:
2 3	BY MR. SANGIAMO: Q. As to what the reason was that	2 3	been defined. BY MR. SANGIAMO: Q. And that would be distinct from
2 3 4	BY MR. SANGIAMO: Q. As to what the reason was that Dr. Ward's lab did not run any testing on the	2 3 4	been defined. BY MR. SANGIAMO: Q. And that would be distinct from the running of the assay?
2 3	BY MR. SANGIAMO: Q. As to what the reason was that Dr. Ward's lab did not run any testing on the assay. Right?	2 3 4 5	been defined. BY MR. SANGIAMO: Q. And that would be distinct from the running of the assay? A. Not sure.
2 3 4 5 6	BY MR. SANGIAMO: Q. As to what the reason was that Dr. Ward's lab did not run any testing on the assay. Right? A. Yes.	2 3 4 5 6	been defined. BY MR. SANGIAMO: Q. And that would be distinct from the running of the assay? A. Not sure. MR. KELLER: Objection. Vague
2 3 4 5 6 7	BY MR. SANGIAMO: Q. As to what the reason was that Dr. Ward's lab did not run any testing on the assay. Right? A. Yes. MR. SANGIAMO: Why don't we	2 3 4 5 6 7	been defined. BY MR. SANGIAMO: Q. And that would be distinct from the running of the assay? A. Not sure. MR. KELLER: Objection. Vague and ambiguous. I think the problem is
2 3 4 5 6 7 8	BY MR. SANGIAMO: Q. As to what the reason was that Dr. Ward's lab did not run any testing on the assay. Right? A. Yes. MR. SANGIAMO: Why don't we take a break.	2 3 4 5 6 7 8	been defined. BY MR. SANGIAMO: Q. And that would be distinct from the running of the assay? A. Not sure. MR. KELLER: Objection. Vague and ambiguous. I think the problem is you're missing multiple steps in the
2 3 4 5 6 7 8 9	BY MR. SANGIAMO: Q. As to what the reason was that Dr. Ward's lab did not run any testing on the assay. Right? A. Yes. MR. SANGIAMO: Why don't we take a break. VIDEOGRAPHER: The time is now	2 3 4 5 6 7 8 9	been defined. BY MR. SANGIAMO: Q. And that would be distinct from the running of the assay? A. Not sure. MR. KELLER: Objection. Vague and ambiguous. I think the problem is you're missing multiple steps in the development of an assay. There's
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HIGHLY CONFIDENTIAL JOAN L. WLOCHOWSKI - HIGHLY CONFIDENTIAL

	JOAN E. WEOCHOWSKI -		
	Page 405		Page 407
1	A. I think we also talked about	1	Q. Have you ever run an assay that
2	the use of what was called a wild type	2	used a wild type virus?
3	actually being the vaccine strain as a concern	3	A. I cannot recall.
4	as well.	4	Q. Does the wild type virus have
5	Q. Any others?	5	to be passaged before it can be used in a
6	A. Let me think. So I think that	6	plaque reduction neutralization assay?
7	those are the key points with the addition of	7	MR. KELLER: Objection. Lack
8	concerns over the assay not being fully	8	of foundation.
9	validated before it was being used in testing.	9	THE WITNESS: Does a wild type
10	Q. Anything else?	10	virus have to be passaged before it can
11	A. Can I look at one of my SOPs	11	be used in an assay. Is that your
12	that's here?	12	question?
13	Q. Yes.	13	BY MR. SANGIAMO:
14	A. I guess in general, as I sit	14	Q. Yes.
15	here today, when I look through the way the	15	MR. KELLER: Same objection.
16	procedure is written, in some areas it's not	16	THE WITNESS: I don't know that
17	very clear what exactly is being conducted.	17	it has to be. Typically it's my
18	And in some cases, you know, it calls out not	18	understanding that typically it would
19	used for routine testing. So it kind of lays	19	be.
20	it open to what you mean by routine testing,	20	BY MR. SANGIAMO:
21	but yes, it was in a procedure that was used	21	Q. That it would be passaged?
22	for testing in the clinical protocol.	22	A. Yes.
23	In this procedure, at least I'm	23	Q. Before it could be used in an
24	not seeing it right now, as I look at it	24	assay?
	Page 406		Page 408
1	doesn't describe the methodology for	1	A. That it would be.
2	performing the counting. That's my overview	2	Q. How many times can a virus be
3	of the methodology.	3	passaged before it is no longer a wild type
4	Q. Do you have any other concerns	4	virus?
5	about the methodology other than what you've	5	MR. KELLER: Objection. Lack
6	just told us?	6	of foundation. Seeks testimony from a
7	MR. KELLER: Objection.	7	lay witness.
8	Overbroad. Vague and ambiguous.	8	BY MR. SANGIAMO:
9	THE WITNESS: Based on	9	Q. Do you have the expertise to
10	MR. KELLER: Sorry. Lack of	10	answer that question?
11	foundation. Seeking testimony from a	11	A. I do not.
12	lay witness.	12	Q. Was the virus that was used in
13	THE WITNESS: Based on what I	13	the plaque reduction neutralization assay in
14	looked at, at this time, that those are	14	Protocol 007 a wild type virus?
15	the key points.	15	MR. KELLER: Objection. Lack
16	BY MR. SANGIAMO:	16	of foundation. Seeks expert
17	Q. So you can't think of any	17	BY MR. SANGIAMO:
18	others right now. Is that a fair statement?	18	Q. If you don't have the expertise
19	A. Yes.	19	to answer that, just say so.
$\frac{1}{20}$	Q. Let's talk about the virus that	20	A. It was a strain of virus that
$\frac{20}{21}$	was used in the assay. What is a wild type	20	at one point was a wild type virus in my
$ ^{21}_{22}$	virus? What does that mean?	$\frac{21}{22}$	understanding.
22	A. It's the strain that would be	22	Q. Had it been passaged since that
	in the population. Different types of strains.	23	time?
24		1 4 T	

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