**MERCK**

**Vaccine Biometrics Research** **DRAFT: November 1, 2001**

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|---|---|---|
| **TO:** | M. Morsy | WP75-200 |
| **FROM:** | J. M. Antonello | WP37C-305 |
| | B. H. Rich | 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

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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 pre-vaccination 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 re-classified 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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Table 1
Study KM-248 Phase III
Unanticipated ELISA Results for the Comparator Group

| | Original Titer (Ab Units) | | Retest Titer (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 |

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 (Ab 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

1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| | | |
|---|---|---|
| UNITED STATES OF AMERICA ex rel., STEPHEN A. KRAHLING and JOAN A. WLOCHOWSKI, Plaintiffs, | : | CIVIL ACTION NO. 2:10-04374(CDJ) |
| vs. | : | |
| MERCK & CO., INC., Defendant. | : | |
| IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION | : | Master File No. 2:12-cv-03555(CDJ) |
| THIS DOCUMENT RELATES TO: ALL ACTIONS | : | |

- - -

June 13, 2017

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

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Videotaped deposition of JOAN L. WLOCHOWSKI, taken at the offices of Morgan & Lewis, 1701 Market Street, Philadelphia, Pennsylvania 19103, beginning at 9:36 a.m., before LINDA ROSSI-RIOS, a Federally Approved RPR, CCR and Notary Public.

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VERITEXT LEGAL SOLUTIONS
MID-ATLANTIC REGION
1801 Market Street - Suite 1800
Philadelphia, PA 19103

APPEARANCES:

On behalf of the Private Payor Plaintiffs
SPECTOR ROSEMAN & KODROFF, P.C.
BY: DIANA J. ZINSER, ESQUIRE
1818 Market Street
Suite 2500
Philadelphia, PA 19103
215.496.0300
dzinser@srkw-law.com

On behalf of the Relators
CONSTANTINE CANNON LLP
BY: ROBERT L. BEGLEITER, ESQUIRE
and
MARLENE KOURY, ESQUIRE
335 Madison Avenue
New York, NY 10017
212-350-2700
rbegleiter@constantinecannon.com
mkoury@constantinecannon.com

On behalf of the Relators
KELLER GROVER LLP
BY: JEFFREY F. KELLER, ESQUIRE
1965 Market Street
San Francisco, CA 94103
415.543.1305
jfkeller@kellergrover.com





APPEARANCES (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
ldykstra@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
mfroberts@venable com

ALSO PRESENT:

TIMOTHY K HOWARD, ESQUIRE
Merck in-house counsel
DANIEL GRBICH, Videographer

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EXHIBITS







EXHIBITS (cont'd.)

DEPOSITION SUPPORT INDEX

DIRECTION TO WITNESS NOT TO ANSWER



REQUEST FOR PRODUCTION OF DOCUMENTS



STIPULATIONS



QUESTIONS MARKED







- - -

VIDEOGRAPHER: We are now on the record. Please note the microphones are sensitive and may pick up whispering and private conversations. Please turn off all cell phones and place them away from microphones as they can interfere with the deposition audio.

My name is Daniel Grbich, representing Veritext.

The date today is June 13, 2017. The time is approximately 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 Wlochowski.

At this time will the attorneys identify themselves and the parties they represent, after which our court





reporter, Linda Rossi of Veritext, will swear in the witness and we can proceed.

MR. KELLER: Jeffrey Keller from Keller Grover on behalf of the Relator.

MS. KOURY: Marlene Koury, Constantine Cannon, on behalf of the Relator.

MR. BEGLEITER: Robert Begleiter, Constantine Cannon, Relators.

MR. SANGIAMO: Dino Sangiamo from Venable on behalf of Merck.

MS. ROBERTS: Michaela Roberts from Venable on behalf of Merck.

MR. HOWARD: Timothy Howard, in-house counsel for Merck.

MS. DYKSTRA: Lisa Dykstra, Morgan Lewis for Merck.

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JOAN L. WLOCHOWSKI, after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. SANGIAMO:

Q. Good morning, ma'am. Could you state your name for the record, please?

A. Joan Wlochowski.

Q. Hello, Ms. Wlochowski. I'm Dino Sangiamo. I represent Merck in this matter.

You understand that you are here this morning to have your deposition taken. Correct?

A. Correct.

Q. You recognize that you are 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 flow today. First it's going to be important that all of your answers are audible. So a nod of the head or a shake of the head won't do. If you want to say yes or no, you have to say yes or no. Understood?

A. Understood.
Q. Another thing that you and I should both be on the lookout for is we should be sure to let each other finish. So you should not start answering a question until I've completed the question. And I will also undertake not to ask my next question until you have completed your answer. Fair enough?
A. Sounds good.
Q. If you don't understand any question I ask you, then, please, ask me to clarify and I'll do my best to restate it in a way that makes sense.
A. Okay.
Q. Are you under any medications that might impair your ability to testify today, as far as you know?
A. No.
Q. Any other reason you can think of why your ability to testify truthfully today might be impaired?
A. No.
Q. Ms. Wlochowski, could you tell us what you did to prepare for this



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?
A. Yes.
Q. Did you look at any documents that you selected on your own?
A. No.
Q. Did you also meet with your counsel?



A. Yes.
Q. Is that with Mr. Keller?
A. Yes.
Q. Others were present as well?
A. Yes.
Q. How many times would you say you met with Mr. Keller and other attorneys to prepare for the deposition?
A. Three days.
Q. Three full days?
A. Yes.
Q. Was Mr. Krahling in attendance at any of those meetings?
A. No.
Q. Have you spoken to Mr. Krahling at all about your deposition outside the presence of your attorneys?
A. No. About the deposition?
Q. Yes, ma'am.
A. I haven't spoken to him about the deposition.
Q. Understood. Your point is you may have spoken to him about other things but not the deposition. Correct?



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?
A. Correct.
Q. And you're married?
A. Correct.

Q. You have two children. Is that correct?
A. Correct.
Q. One is Jacob, approximately age 23 and one is Julia, approximately age 21. Is that accurate?
A. Correct.
Q. Have you -- strike that.
Did you have Jacob and Julia vaccinated --
MR. KELLER: Objection.
BY MR. SANGIAMO:
Q. -- with MMR?
MR. KELLER: Objection. I'm going to instruct you not to answer. Violates her right to privacy.
MR. SANGIAMO: I'm not agreeing with you, but I understand your objection and I'll move on.
BY MR. SANGIAMO:
Q. Have you advised either of them to get revaccinated with MMR based on concerns about the efficacy of the mumps component of MMR?



MR. KELLER: Hold on a second. You can answer.
THE WITNESS: No, I have not.
BY MR. SANGIAMO:
Q. Have you advised them to get their mumps titer checked based on concerns about the efficacy of MMR?
A. No, I have not.
Q. Do you have concerns about the efficacy of the mumps component of MMR?
A. I do.
Q. Is there any particular reason why you have not advised Jacob and Julia either to get revaccinated or to get their titers checked?
MR. KELLER: Objection to the form. You can answer.
THE WITNESS: I don't know that the -- by having the revaccination will actually help them at this point.
BY MR. SANGIAMO:
Q. And that explains why you have not advised them to get revaccinated. Is that the idea?



MR. KELLER: Objection to form.
THE WITNESS: Yes.
BY MR. SANGIAMO:
Q. Does it also explain why you have not advised them to get their titers checked?
MR. KELLER: Same objection.
BY MR. SANGIAMO:
Q. I didn't hear your answer?
A. Yes.
Q. I'm guessing the answer is no, but do you have any grandchildren?
A. No.
Q. Have you ever been a party to any other lawsuits?
A. No.
Q. Have you ever been named as an expert witness in any lawsuit?
A. No.
Q. Have you ever been approached about being an expert witness in any lawsuit?
A. No. Aside from this case.
Q. Have you ever contemplated bringing any whistleblower lawsuits other than



the one you have brought here?
MR. KELLER: Not knowing if anything -- if you filed any -- not commenting on whether or not you filed any other whistleblower lawsuits, if any of those lawsuits are under seal, you cannot breach that seal. So, therefore, to the extent that you can answer without breaching the seal, you can answer.
If there's a lawsuit, a whistleblower lawsuit that's filed under seal, not saying that there is one or not, she can't testify and breach that seal, so...
MR. SANGIAMO: I think the question so far is just whether she had ever contemplated filing. How about an answer to that precise question?
MR. KELLER: You can answer that.
THE WITNESS: I have not.
MR. KELLER: Dino, I'll let you ask if she's filed a lawsuit. Just

can't identify the content. If you want to do that.

MR. SANGIAMO: I'm guessing if she hasn't contemplated, she hasn't done it.

BY MR. SANGIAMO:

Q. Have you ever filed, again, another whistleblower lawsuit other than this one?

A. No.

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(Exhibits Wlochowski-1, Curriculum vitae, AMGEN_0007 and Wlochowski-2, Curriculum vitae, were marked for identification.)

- - -

BY MR. SANGIAMO:

Q. We've just had marked as Exhibits 1 and 2, two copies of a CV for you. In Exhibit 1 the most recent experience shown is your employment at Pfizer?

A. Uh-huh.

Q. And for Exhibit 2 the most recent experience shown is your employment at



Alexion?

A. Uh-huh.

Q. Are you able to give us an approximate date of when you created Exhibit 2?

A. It would have been between, I guess, between 2009 and -- let me just see this. Actually 2013 and 2016.

Q. I see. You can't pinpoint it any better than that?

A. No. I know it was before this year, but I don't know exactly when.

Q. I wanted to ask you some questions about your employment history. I may from time to time refer to Exhibits 1 and 2 in my questions. You should certainly feel free to refer to Exhibits 1 and 2 in your answers whether I ask about them or not, if that helps you, your memory.

Do I have it right that your first job out of college was working at Yale New Haven Hospital? Is that correct?

A. Correct.

Q. And you worked there from 1991 to 1998?



A. Yes. You said out of college, right? Is that what you said?

Q. I did, yes.

A. Okay. Yeah.

Q. And I have the years right of your employment?

A. Yes.

Q. Could you tell us what your positions were there?

A. I was a medical technologist in the virology laboratory.

Q. Was medical technologist your official title?

A. Yes.

Q. That was your title the whole time you were there?

A. Yes.

Q. Were there any promotions while you were there?

A. No, not that I recall.

Q. Now, do I have it right that New Haven Hospital is a hospital but it has some affiliation with Yale University Medical School? Is that right?



A. It does, yes.

Q. Were you employed by Yale Medical School or were you employed by New Haven Hospital?

A. New Haven Hospital.

Q. Did you engage in any research while you were at New Haven Hospital?

A. Can you explain what you mean by "research"?

Q. Why don't we come back to that and first you can tell me what it is that you did as a medical technologist and a virologist.

A. My primary responsibility was testing human samples from the hospital for viral detection; viral antibody titers.

Q. Looking for viral antibody titers for a diagnostic purpose, is that the idea?

A. Correct.

Q. The theory being that if there were antibodies to a particular virus present, then that might be one criterion for trying to evaluate whether the person was suffering from that disease?

A. Correct.
Q. Were there any particular diseases that you were focused on?
A. There were specific tests we did, but I wouldn't say that anything that we were focused on.
Q. What was your role specifically?
A. Again, to run the assays in the lab.
Q. I'm going to describe what it might have been, you tell me if this is accurate; and if not, how it's inaccurate. Was it the case that a serum sample would be brought to the lab where you worked. Is that right?
A. Correct.
Q. And then you would run the serum sample through the assay. Is that correct?
A. Correct.
MR. KELLER: Objection to form.
BY MR. SANGIAMO:
Q. And then you would report the results from running the sample through the



assay back to someone. Is that right?
MR. KELLER: Objection to form.
THE WITNESS: What do you mean by "report the results"?
BY MR. SANGIAMO:
Q. What would you do with the results?
A. The results would get entered into the file for the patient that was being tested.
Q. After that somebody other than you would evaluate the results?
A. Yes.
Q. Fair to say that you were not the person who ultimately decided whether clinically it appeared that the patient did or did not have the virus? True?
A. That is true.
Q. Did any of the tests -- these tests were, would you call them assays?
A. Yes.
Q. Did you run any assays at New Haven Hospital involving mumps?
A. We had the capability of



detecting mumps.
Q. Do you ever recall running one of those tests yourself?
A. We did viral cultures so any given sample that came in could potentially have been run for a screen for mumps.
Q. Could you describe what you mean by doing viral cultures?
A. We took the patient serum and/or patient culture, I should say, and inoculated into monolayers in a cell culture tube for growth of virus.
Q. What would you do next in the procedure?
A. So the culture tubes would get incubated to allow for virus growth.
Q. I'm sorry, to allow for what, virus growth?
A. Uh-huh. Replication.
Q. What would you do, then, to determine what viruses, if any, were present in the cultures?
A. The cultures were read at periodic times throughout the course of the



incubation and were read for cytopathic effect.
Q. Would reading for cytopathic effect enable you to determine what virus the person had?
A. No, then there would be identification following the CPE.
Q. And the identification would be a process involving the detection of antibodies?
A. It would be -- we would remove the cell monolayer to test the cells in the virus within the culture. So not, no, not necessarily running the titers.
Q. So how would you determine what viruses were present?
A. There were different immunoassays that would -- you would run through and have detection, either fluorescence detection or there were different types of -- it was an antibody against the virus that would detect and a signal that was confirmed that it was present.
Q. Would you run every sample through every immunoassay?

A. No.
Q. In other words, is it correct that the doctor would have had a suspicion as to what the disease might have been. Correct?
A. Yes.
Q. And then you would run the sample through the assays for those conditions?
A. Yes.
Q. And you were not the one who would decide --
A. Right.
Q. -- which conditions to run the assay through. Right?
A. That is correct.
Q. So do you recall ever running sample through the mumps assay?
A. I don't recall specifically.
Q. How many medical technicians were there in the New Haven Hospital virology lab at any given time?
A. I would say maybe five technicians.
Q. Did you run any assays while you were at New Haven Hospital that were designed to detect whether a particular



patient had an immune response to vaccination?
A. No, I did not.
Q. Did you run any assays at New Haven Hospital that were designed to detect whether a patient had an immune response to some other form of therapy?
MR. KELLER: Objection to form.
THE WITNESS: And I'm actually rethinking my previous answer because -- sorry, I apologize.
BY MR. SANGIAMO:
Q. Sure.
A. So we did test for rubella. We did do titer testing for -- which would be an indication of vaccination.
Q. Because if there was a rubella titer, that would suggest that the patient had been vaccinated, is that the idea?
A. Well, I guess it's -- it would be to determine whether or not the patient had antibodies. I don't know that the criteria was to see whether or not the patient had been vaccinated. So to clarify, it wasn't so much as to see whether or not the patient had been



vaccinated, just to confirm that the patient had immunity.
Q. Do you know how you would figure out if you saw rubella antibodies in a patient, whether that was a result of vaccination as opposed to being the result of active rubella disease or something else?
A. No.
Q. Would you consider that to be something beyond your expertise?
A. Yes.
Q. When you were at New Haven Hospital, did you run any assays in which you ran a patient sample prior to vaccination and ran a patient sample after vaccination in order to determine whether the patient had an immune response to vaccination?
A. I don't recall specifically that I had done one.
Q. If you look at Exhibit 1, there is a reference within the section on your time at Yale New Haven Hospital. In the fourth bullet point to performing "antiviral testing by plaque reduction assay."



Do you see that?
A. Uh-huh.
Q. What's that a reference to? Is that something different from what -- than what you just described to us today so far?
A. I believe so, yes.
Q. What is that a reference to?
A. So your question was whether or not I tested prior to being vaccinated and after being vaccinated. That was your original question?
Q. Yes.
A. And I don't believe that, at least to my knowledge, that I was given samples prior to vaccination and then following vaccination. I can't recall the specifics around the testing, but I -- I can't recall.
Q. I think I know what you're saying, but I just want to make sure the 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

plaque reduction assay," when you were at New Haven Hospital? Do you know what that's referring to?

A. That I did perform the plaque reduction assay. We were given samples to test and we ran that assay.

Q. What was that an assay for?

A. For the detection of antibodies against a virus.

Q. What is the reduction part?

A. The plaque reduction?

Q. Yes, ma'am.

A. So it's to basically -- if the antibodies were present, they would neutralize the virus and reduce the plaque count.

Q. Reduce it from what?

A. From the presence of not having antibodies.

Q. I'm sorry, I don't understand. So what would you -- so could you describe in more detail how that assay would work?

A. Again, I don't remember the specifics of running the assay. The methodology is that virus is added to plates.



If they're in the presence of no antibodies, there would be plaques that would form. If there were antibodies that were present, they would reduce the number of plaques. So typically a control is running the assay that would show the presence of no antibodies and what that would look like versus a positive control.

Q. Are there also plaque reduction assays for antiviral drugs, to your knowledge?

MR. KELLER: Objection to form.

THE WITNESS: I do not know.

BY MR. SANGIAMO:

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.

BY MR. SANGIAMO:

Q. Are you familiar with any assay



like that?

MR. KELLER: I apologize. You can answer.

THE WITNESS: Can you repeat that question again?

BY MR. SANGIAMO:

Q. Are you familiar with any plaque assays for antiviral drugs as distinguished from for vaccines?

A. So in this case, that was what I believe was not being tested versus a vaccination.

Q. So you think -- sorry.

A. So the patient response to the antiviral. Not the --

Q. If I understand your testimony correctly, then, your best recollection right now of the plaque reduction assay that you did when you were at New Haven Hospital was an assay to test patient response to antiviral therapies. Is that right?

A. That is my -- what I can recall.

Q. And you think that that testing



had nothing to do with immune response to vaccination based on your best recollection right now. Is that right?

A. Correct.

Q. But the antiviral therapy assay, which is what you now believe this was, did involve the counting of plaques?

A. Yes.

Q. Would you, yourself, count those plaques?

A. Yes.

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 question again?

BY MR. SANGIAMO:

Q. Do you recall that one of the plaque reduction assays referred to there in your CV from your time at New Haven Hospital was an assay for herpes simplex antiviral therapies? Do you recall that?

A. I can't remember which assay it

was, what it is that we were testing specifically.

Q. Do you know if the assay that was being used at New Haven Hospital was an off-the-shelf assay?

MR. KELLER: Objection to form.

THE WITNESS: What do you mean by "off-the-shelf"?

BY MR. SANGIAMO:

Q. Do you know if it was designed at New Haven Hospital?

A. I do not know if it was designed there.

Q. I gather you had nothing to do with designing the assay?

A. Correct.

Q. Can I assume from your answer that you don't know whether New Haven Hospital purchased it from a supplier?

A. I believe parts, components of it were purchased, but the entire assay I cannot say.

Q. Was there an SOP for that assay?

A. There was -- I can't remember



the test method that we ran it against, but there was a procedure in place that we would perform our test.

Q. A written SOP?

A. Again, I can't remember the documentation that was used for conducting those tests.

Q. Are you sure there was any?

A. That would -- we would have had procedures, yes, to run a method against.

Q. Well, are you sure you had a written procedure that you followed?

MR. KELLER: Objection. Asked and answered.

THE WITNESS: Yes.

BY MR. SANGIAMO:

Q. You are sure of that?

A. Yes.

Q. But you're just not sure whether it was an SOP?

MR. KELLER: Objection to form.

THE WITNESS: What do you mean by "SOP"?

BY MR. SANGIAMO:



Q. Do you have an understanding from your work in the industry of what an SOP is?

A. I do.

Q. And what is that?

A. It's a standard operating procedure. So working in the industry, the pharmaceutical industry, there's different requirements than working in a hospital laboratory.

Q. What are the requirements for an SOP in a hospital laboratory?

A. Again, I can't remember the exact methodology that they referred to. I believe we had binders of procedures that were kept that we would refer to.

Q. For the plaque reduction assays that you ran at New Haven Hospital for these antiviral therapies, was there ever any checking of plaque counts by a second scientist?

A. No.

Q. What was the nature of the training you received as regards counting of plaques, if any?



A. I was trained by my supervisor.

Q. What was the nature of that training?

A. The -- I mean, I can't remember the specifics around the training program, but he worked pretty closely with us as he trained us through the different tests within the laboratory.

Q. He was training you on all aspects of the assay?

A. Yes.

Q. And do you have any recollection of the nature of the portion of the training, if there was any, that was focused on the counting of plaques?

A. If I recall correctly, typically the trainer would count the plaques and the trainee would then count the plaques to determine if there was consistency in the plaque counts.

Q. Was there a rigid formula that would determine whether there was sufficient amount of consistency?

A. I don't recall the specific

formula.
Q. But there was one?
A. Yes.
Q. So it's not the case that the trainer could just kind of impressionistically assess whether the trainee's plaque counting was adequate, there was actually a mathematical formula?
MR. KELLER: Objection. Form.
THE WITNESS: Yeah. What do you mean by "mathematical formula"?
BY MR. SANGIAMO:
Q. Well, for example, was there a certain percentage that the trainee's plaque count had to be within the trainer's plaque count in order for the trainee to be deemed trained?
A. Typically that's the criteria for training and consistency, yes.
Q. Was it at New Haven Hospital?
A. I believe so.
Q. You're sure?
A. I can't remember the specifics, but, yes, I do believe that that is how we



were trained.
Q. Let me just make sure I understand your testimony. So your testimony is you do think that there was some percentage within which the trainee's plaque count had to come as compared to the trainer's plaque count for the trainee to be deemed adequately trained in plaque counting, but you just don't recall what that percentage is. Is that your testimony?
A. I don't recall what the percentage is. To the best of my recollection, there would be a percentage criteria that we would have to meet in order to show consistency.
Q. How many assays did you have to count in this comparison process before you could be deemed adequately trained?
A. I don't recall.
Q. More than one?
A. I don't recall. It would be my -- I don't recall.
Q. For this assay that you ran, the plaque reduction assay at New Haven



Hospital, were the plaques in wells?
A. Yes.
Q. And the wells were in plates, I assume?
A. Yes.
Q. Do you recall how many wells there were in any given assay run?
MR. KELLER: Objection. overbroad.
THE WITNESS: When you refer to wells in an assay run, can you be more specific?
BY MR. SANGIAMO:
Q. Do you have an understanding what I mean by "assay run"?
A. That -- if you could define assay run, yes, that's my question. Thank you.
Q. You'll have to tell me if my question makes sense because I expect you have a lot more expertise in this than I do. But I'm envisioning a certain number of plates that are run simultaneously through an assay. Does that make sense?



A. Yes.
Q. Does that sound like a reasonable definition of an assay run for our purposes right now?
A. Yes.
Q. Do you recall how many wells there would be in any given assay run for the plaque reduction assay that you ran at New Haven Hospital?
MR. KELLER: Objection. Overbroad.
THE WITNESS: So when -- can you repeat the question again?
BY MR. SANGIAMO:
Q. For the plaque reduction assay that you ran at New Haven Hospital, how many wells were there in any given assay run?
MR. KELLER: Objection. Overbroad.
THE WITNESS: So I believe per plate there were 24 wells. I do not know, remember how many plates we would run in a -- perform at the same time in a given run.

MR. SANGIAMO: Jeff, why did you think it was overbroad? I'm going to see if I can correct it.

MR. KELLER: Because you're talking about all assays she ran instead of -- are you talking about when she was certified? Are you talking about -- you know, she ran different assays over time and she was at New Haven seven years. I don't know if the assays changed over time. That's why I objected, overbroad.

MR. SANGIAMO: Understood.

BY MR. SANGIAMO:

Q. My question was directed at the plaque reduction assay referred to on your CV as having been run at New Haven Hospital. You understood that?

A. Yes.

Q. My sense of your recollection is that all that you recall about what that assay was is that it was an assay used not to evaluate response to vaccination or not even to evaluate antibodies but used to evaluate



antiviral therapies. Is that right?

A. I believe it was their antibody response to antiviral therapies. So it was still detection of antibodies but after viral therapies treatment.

Q. You don't recall how many such assays there were. Right?

A. I believe there was only one that I recall and I can't remember -- I can't remember what the specific virus we were testing it against.

Q. Do all antiviral therapies work by generating antibodies?

MR. KELLER: Objection. Overbroad.

THE WITNESS: I do not know.

BY MR. SANGIAMO:

Q. How about the antiviral therapies that were at issue when you were running the plaque reduction assay at New Haven Hospital?

A. So I -- can you ask the question again, sorry?

Q. Did the antiviral therapies



that were at issue when you were running the plaque reduction assay at New Haven Hospital work by generating antibodies to a virus?

A. Not necessarily. It was an immune response to the disease that the patient had.

Q. If there's simply a cytopathic effect of the antiviral therapy on the isolate from the patient, is that an immune response?

MR. KELLER: Objection to form.

THE WITNESS: Can you repeat the question?

BY MR. SANGIAMO:

Q. If there's a cytopathic effect of the antiviral therapy on the isolate from the patient, is that an antibody immune response? Slightly different question but that's my question.

MR. KELLER: Same objection.

THE WITNESS: Is a cytopathic effect an antibody immune response? The question doesn't make sense to me. I'm not -- the cytopathic effect is caused by the virus. The actual immune



response would reduce the cytopathic effect through neutralization of the virus.

BY MR. SANGIAMO:

Q. Can the antiviral therapy that was being tested in the plaque reduction assay that you ran at New Haven Hospital accomplish that by a means other than an antibody immune response?

MR. KELLER: Objection. Form.

THE WITNESS: I do not know the answer to that question.

BY MR. SANGIAMO:

Q. For sure the plaque reduction assay that you ran at New Haven Hospital was not a plaque reduction neutralization assay. Right?

MR. KELLER: Objection to form.

THE WITNESS: Again, I can't remember the specifics of the assay. I do remember running a plaque assay.

BY MR. SANGIAMO:

Q. You don't remember it well enough to answer my question just asked?

A. Correct.

- - -

(Exhibit Wlochowski-3, Detection of Herpes Simple Virus in Clinical Specimens by Cytospin-Enhanced Direct Immunofluorescence article, was marked for identification.)

- - -

BY MR. SANGIAMO:

Q. Ms. Wlochowski, you've just been handed a document marked as Exhibit 3. Do you recognize this document?

A. I do.

Q. This is a medical journal article on which you are one of the authors. Right?

A. Correct.

Q. Is it correct that there are two such -- sorry, try that again.

Is it correct that you are listed as an author on two medical journal articles total?

A. I believe so, yes.

Q. Can you tell us what this article is describing? And let me just tell



you what my ultimate question is going to be, if that helps, is I wanted to find out what your personal role was in either the research described here or the writing of the article.

A. Okay.

MR. KELLER: There's two questions. I'm not sure which one you want her to answer.

MR. SANGIAMO: Well, actually all I was doing just now, Jeff, is I was trying to give her a little guidance on how much she needs to look at that article.

MR. KELLER: Okay.

MR. SANGIAMO: But that's a fair point.

BY MR. SANGIAMO:

Q. The first question I'll ask you, then, is what your role was in the work that is described in this article?

A. My role was conducting the testing of the samples in the article.

Q. So you didn't come up with the hypothesis that cytocentrifugation could be



helpful in trying to achieve whatever it is that's being described in this article. Is that right?

A. That is correct.

Q. Was that Dr. Landry's idea?

A. Yes.

Q. Did you come up with the experimental design to test that hypothesis?

A. I believe I worked with both Dr. Landry and Dave Ferguson.

Q. Did they come up with the experimental design or was that you?

A. They advised the experimental design and I worked with them on that.

Q. You worked with them to implement it?

A. Yes.

Q. How about in the writing of the article, what was your role in that?

A. I don't recall my writing, if I was involved in the writing of the article other than providing probably the writing the data tables to the article.

Q. How did you get involved in



this?

MR. KELLER: Objection to form.

THE WITNESS: What do you mean by how did I get involved?

BY MR. SANGIAMO:

Q. How did you get involved in the work that's described in this article?

A. So my -- as I mentioned earlier, my primary responsibility was testing clinical samples within the laboratory, so routine samples that came in on a day-to-day basis. Based on, you know, learning the skill sets I had to do the routine work, I asked to be involved in additional studies that were going on in the laboratory as a development opportunity for me.

Q. To whom did you make that request?

A. Dave Ferguson was my manager at the time.

Q. You were giving some testimony earlier about -- some testimony earlier about being trained by a supervisor?

A. Uh-huh.

Q. Was that Dave Ferguson?
A. Correct.
Q. Do you know if he is still at Yale New Haven Hospital?
A. I do not know.
Q. How about this Dr. Landry, is she a pretty well reputed researcher, to your knowledge?
A. Yes, to my knowledge.
Q. She would be a pretty good source of virology expertise generally, would you say?
A. Yes.
MR. KELLER: Objection to form.
BY MR. SANGIAMO:
Q. Did you, in your discussions with, is it Dr. Ferguson?
A. Dave Ferguson.
Q. I don't want to disrespect him.
A. Yes.
Q. In your discussions with Dr. Landry or Mr. Ferguson about the design of the testing, did you make specific suggestions to them?



A. I don't recall.
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?
A. So there -- as you mentioned, there was another article, so I believe that also was another methodology, basically a



method. It depends on what you, again, mean by research. So -- but it was -- I did get involved in other activities outside of my routine testing.
Q. I don't want to misstate your testimony. I thought I heard you say before that you got involved in the work that's described in Exhibit 3 because you made it known to your supervisor that you were interested in other what I think you said was research opportunities for developmental purposes. Is that right?
A. I said development opportunities.
Q. Okay. Were there any other development opportunities that you pursued that you would consider to be research?
A. Yes, I do believe I did work on other methodology enhancements while I was there.
Q. Do you remember what those were?
A. I do not.
Q. Any of them involve mumps?
A. Not that I recall, no.



Q. Any of them involve vaccine 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?
A. I believe so. I can't recall.
MR. KELLER: Objection to form.
BY MR. SANGIAMO:

Q. How long were you at Charles River?
A. I think it was, I want to say maybe five months.
Q. Is it possible that it was -- strike that.
What did you do at Charles River?
A. I worked in their cell culture laboratory, so I maintained the cell lines. Charles -- yeah.
Q. Did you run any assays?
A. No, I did not.
Q. Were those cell lines used for just one purpose or were they used for many different purposes?
A. They were used for many different purposes.
Q. Clinical purposes?
MR. KELLER: Objection. Overbroad.
THE WITNESS: What do you mean by "clinical purposes"?
BY MR. SANGIAMO:



Q. Diagnostic purposes?
MR. KELLER: Same objection.
THE WITNESS: What do you mean by "diagnostic purposes"?
BY MR. SANGIAMO:
Q. To support assays or other testing intended to be used to diagnose conditions in humans.
A. I believe that was what they were used for. We prepared cell banks that were also for clients. So I can't say specifically what those clients were using them for.
Q. Did you encounter any issues there in the nature of group dynamic problems while you were working at Charles River?
A. No.
Q. Everybody seemed to get along fine with everybody else?
A. Yes.
Q. You got along fine with everybody?
A. To what I recall, yes.
Q. Do you have a recollection of



telling anybody anything different about your time at Charles River?
A. I do not.
Q. Is your recollection of your time at Charles River vivid enough that you could comfortably dismiss out of hand anyone who would say that you once said that you ran into problems at group dynamics there?
A. Meaning when I told somebody after I left Charles River or --
Q. Yes.
A. I do not recall saying that.
Q. Are you confident that that's something you just would not have said because of your recollection of your time at Charles River?
MR. KELLER: Objection. Asked and answered.
THE WITNESS: Am I confident that's something that I said because of what I recall now?
BY MR. SANGIAMO:
Q. Uh-huh.
A. I guess I could have said anything.



I mean, there's always dynamics between people so I can't say that I didn't necessarily say anything that was positive or negative either way.
Q. But right now you don't have any recollection of any dynamics problems at Charles River. Is that right?
A. Not specifically, no.
Q. Who was your supervisor at Charles River?
A. I don't remember his name.
Q. Your next position was at Merck?
A. Yes.
Q. Is there about a half year period there between when you left Charles River and when you started at Merck? Does that sound about right?
A. Yes.
Q. Were you employed at all during that time period?
A. No.
Q. Were you trying to get employment anywhere other than Merck during

that time period?
A. I can't recall. I may have been.
Q. How did you find out about -- strike that.
What prompted you to seek employment at Merck?
A. I was looking for a permanent position.
Q. Why Merck?
A. They were close to where I lived currently and they're a big reputable company in my mind at the time.
Q. Still today?
A. That -- based on my experience, I may not have the same opinion.
Q. What's your sense of Merck's reputation generally in the pharmaceutical industry?
MR. KELLER: Objection. Overbroad.
THE WITNESS: My sense in the pharmaceutical industry? Can you explain what you mean by that?
BY MR. SANGIAMO:



Q. When you were at Pfizer, did you hear people talk about Merck in any way?
A. When you're in the pharmaceutical industry, many people talk about many different companies. So, yes, I would have to -- I can't remember anything specifically.
Q. How about generally, reputationally, what do you remember about what people would say about Merck when you were at Pfizer?
MR. KELLER: Objection to form.
THE WITNESS: When you say -- so people at Pfizer that would -- can you repeat the question?
BY MR. SANGIAMO:
Q. What do you remember generally about what people would say about Merck's reputation while you were at Pfizer, if anything?
MR. KELLER: Objection. Lack of foundation.
THE WITNESS: I cannot remember.
BY MR. SANGIAMO:



Q. How about Amgen, same question at Amgen?
A. I cannot remember.
Q. How about at Alexion?
A. I don't recall anybody saying anything specific.
Q. When you applied for your positions at -- strike that.
When you applied for your position at Pfizer, did you get any impression from the interview process as to what the people interviewing you thought of Merck?
MR. KELLER: Objection as to form.
THE WITNESS: I cannot speak to what other people thought about Merck as I was being interviewed. I think the expectation is that I work in the pharmaceutical industry so I come with the experience that would carry across other pharmaceutical companies.
BY MR. SANGIAMO:
Q. Your work at Merck began in Dr. Krah's lab. Correct?



A. Correct.
Q. He's the one who interviewed you?
A. Correct.
Q. Did you interview with others as well?
A. I believe I interviewed with Mary Yagodich as well.
Q. Anyone else?
A. HR. I don't recall if I interviewed with others.
Q. Do you recall who it was at HR with whom you interviewed?
A. I want to say it was somebody named Naomi Yerkes.
Q. We'll talk obviously about your time in Dr. Krah's lab. But after you left Dr. Krah's lab, you went to a different lab. Right?
A. Correct.
Q. Whose lab was that?
A. Dr. Palker.
Q. What did you do in Dr. Palker's lab?

A. I was working with the DNA and RNA probes for -- and doing PCR testing while I was there.
Q. Was this vaccine-related work?
A. Yes.
Q. For any particular vaccines?
A. We were working on HPV.
Q. Anything else?
A. Probably, but I can't recall what it was.
Q. We're going to talk about some of the allegations of wrongdoing that you've made regarding Dr. Krah's lab.
Do you believe that there was any kind of wrongdoing in Dr. Palker's lab?
A. I do not.
MR. KELLER: We've been going about an hour, the next logical --
MR. SANGIAMO: I think we'll hit one in a moment.
- - -
(Exhibit Wlochowski-4, Protective efficacy of intranasal cold-adapted influenza A/New Caledonia/20/99 (H1N1)



vaccines article, was marked for identification.)
- - -
BY MR. SANGIAMO:
Q. Ms. Wlochowski, you've just been handed what's been marked as Exhibit 4, which is a journal article on which you're one of the listed authors. Right?
A. Yes.
Q. So this is the other journal article on which you are a listed author. Right?
A. Yes.
Q. This was written along with some co-authors from Merck. True?
A. Correct.
Q. It looks like there is about 14 or so total authors on there. Can you tell me what your role was in the work that's described in this paper?
A. I believe I performed some of the -- well, the laboratory testing as well as some of the animal studies that would support this.



Q. What was your role in the hypothesis being explored in this paper?
MR. KELLER: Objection to form.
If you need to read it to refresh your memory.
BY MR. SANGIAMO:
Q. Do you recall as you sit here today what -- whether this paper involved exploration of a particular hypothesis?
A. I do not recall.
Q. Whatever that hypothesis was, do you recall whether you developed the hypothesis?
A. No.
Q. Were you consulted about the development of a hypothesis?
A. I do not recall.
Q. Did you play any role in the experimental design?
A. Not that I recall, no.
Q. How about the writing of the article, what role did you play there, if any?
A. Again, I may have generated some of the data that was used to support that



I recall.
Q. Do you recall anything beyond that in the writing of the article?
A. I do not recall any other role in writing the article.
MR. SANGIAMO: Want to take a break?
MR. KELLER: Yes.
VIDEOGRAPHER: The time is now 10:40. Going off the video record.
- - -
(A recess was taken.)
- - -
VIDEOGRAPHER: The time is now 10:58. This begins disc two. You may proceed.
MR. SANGIAMO: I want to go back and clear up one thing, Jeff. I'm going to pose this question, but I can't remember whether you objected or instructed her not to answer.
BY MR. SANGIAMO:
Q. Ms. Wlochowski, did you have your children vaccinated with MMR?

MR. KELLER: Objection. I instruct her not to answer that question under right to privacy.

BY MR. SANGIAMO:

Q. Are you going to follow your counsel's instruction?

A. Yes.

Q. What did you think of Dr. Palker as a boss?

MR. KELLER: Objection as to form.

THE WITNESS: What do you mean by what do I think of him as a boss?

BY MR. SANGIAMO:

Q. Did you like working for him?

MR. KELLER: Same objection.

THE WITNESS: Explain what you mean by "like working for him."

BY MR. SANGIAMO:

Q. You don't know what that means, that concept has no meaning to you, to like working for somebody?

A. So --

MR. KELLER: Same objection.



THE WITNESS: There's, you know, different concepts of working for somebody. There's many aspects of that, so...

BY MR. SANGIAMO:

Q. What are they?

A. It could be a personal relationship with somebody versus the work or -- that is given. I guess I'm looking for you to explain what it is you're asking specifically about.

Q. Are you finished, I couldn't tell?

A. Yes.

Q. Did he seem like a nice man?

MR. KELLER: Same objection.

THE WITNESS: He seemed like a nice person.

BY MR. SANGIAMO:

Q. How would you describe your personal relationship with him?

A. He was my boss. That was my relationship with him.

Q. Do you think he respected your



work?

MR. KELLER: Objection. Calls for speculation.

THE WITNESS: I can't say what he thought of my work in general. The feedback he provided me was positive.

BY MR. SANGIAMO:

Q. Were there others who worked in his lab?

A. Yes.

Q. How would you describe the relationships amongst those people --

MR. KELLER: Objection. Vague.

BY MR. SANGIAMO:

Q. -- including yourself?

A. Again, what do you mean by "relationship"?

Q. You can interpret it however you like.

MR. KELLER: Same objection.

THE WITNESS: We were co-workers.

BY MR. SANGIAMO:

Q. Did you form any friendships?

A. I did have friends in the lab,



yes.

Q. Did you feel that there was a click that you were left out of in that lab?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: I don't -- as far as a click in the lab, I'm not sure what you would mean by that.

BY MR. SANGIAMO:

Q. Do you know what the term "click" means?

A. A group of people. There were only three of us at the time that reported in to Dr. Palker.

Q. Are you able to comment one way or the other on whether the three of you got along well or is that too vague a question from your perspective?

MR. KELLER: Objection. Argumentative.

THE WITNESS: Again, I, myself, feel that we got along fine.

BY MR. SANGIAMO:

Q. Why did you leave employment at

Merck?
A. We were moving back out of state.
Q. Where were you moving to?
A. Connecticut.
Q. All right. So where did you apply to work when you left Merck?
A. Pfizer.
Q. Is that the only place?
A. I can't recall. I believe so.
Q. You were at Pfizer for how long?
A. I would say about nine months.
Q. Why did you leave the position at Pfizer?
A. The position I had was moving to Kalamazoo, Michigan, and I did not -- that was not my family's choice to move to Kalamazoo, Michigan.
Q. Your CV that is Exhibit 1, in the first bullet reads: "Perform large-scale clinical assays (e.g. serum neutralization, virus isolation) using automated equipment such as Sci-Clone...," if I'm pronouncing that



correctly, "...BioMek and MultiMek in support of vaccine formulation trials." That says trials, plural. I take it there was more than one trial in which you performed those clinical assays?
A. I believe so, yes.
Q. How many trials were there?
A. I don't recall.
Q. Were all the trials for the same vaccine product?
MR. KELLER: Be careful not to disclose anything that would violate any agreement you had with Pfizer with respect to confidentiality. So if you want to testify, you can testify generally. If there is something specific you want to ask, we can cross that bridge, but start with that.
THE WITNESS: So you asked if there was more than one trial? Is that the question?
BY MR. SANGIAMO:
Q. I asked if all the trials were for the same vaccine product?



A. I don't think so. But, again, I don't recall.
MR. KELLER: Object to the form.
BY MR. SANGIAMO:
Q. Do you have an agreement with Pfizer that limits your ability to disclose certain things about your employment there?
A. Yes, I believe I have a confidentiality agreement with them.
Q. Do you intend to honor that agreement?
A. Yes.
Q. Are those agreements important?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: Again, which agreements? What do you mean by "important"?
BY MR. SANGIAMO:
Q. Why are you reluctant to answer that question, Ms. Wlochowski?
MR. KELLER: Argumentative. Important to who, to her, to the



company?
MR. SANGIAMO: She can testify.
THE WITNESS: Are you asking if it's important to me or are you asking if it's important to the company?
BY MR. SANGIAMO:
Q. I'm asking if they're important. You need to slice that up?
MR. KELLER: Objection. Overbroad.
THE WITNESS: Yes, they're important.
BY MR. SANGIAMO:
Q. Do you think it's okay to disregard those agreements? Is that okay in your view?
MR. KELLER: Objection. Form. Lack of foundation.
THE WITNESS: I don't think it's appropriate to violate those agreements, but I also -- it depends on the -- if the company themselves have violated any of their guidances as well.

BY MR. SANGIAMO:
Q. Any of their what?
A. The guidances or regulations that they're required to follow.
Q. So your view is if the company, in your opinion, has violated a guidance or regulation, then it's okay to go ahead and disclose their confidential information. Is that your view?
MR. KELLER: Objection. Mischaracterizes her testimony.
THE WITNESS: No, I'm not saying that specifically, but, again, in this case with Pfizer, the confidentiality agreement was important and it -- I agree with it in the case of Pfizer.
BY MR. SANGIAMO:
Q. So your view is each employee should decide for him or herself whether he or she wants to honor the confidentiality agreement when they leave an employer. Is that a fair summary?
MR. KELLER: Objection.



Argumentative. Vague and ambiguous.
MR. SANGIAMO: Jeff, the mere fact that she doesn't want to have to answer a question is not a basis to object to it.
MR. KELLER: You can ask your questions. I'll object as I deem appropriate.
THE WITNESS: So I -- again, in -- it depends, yes, I believe that it depends on the circumstances that surround that agreement.
BY MR. SANGIAMO:
Q. Have you told any of your subsequent employers after Merck that that's how you plan to go about honoring your confidentiality obligation?
A. No, I have not.
Q. Do you think they're entitled to know that?
A. I think they're entitled to be honest to me as I am to them.
Q. My question is, are they entitled to know that you're going to make



your own judgment about whether or not you have to honor the confidentiality agreements that you owe to them?
MR. KELLER: Objection. Form. Calls for speculation.
THE WITNESS: Right. I don't think that -- I can't say what they're entitled to know. So, yeah, it depends on the situation that occurs while I'm employed by them. The expectation is that they are -- you know, if they tell me they're running under GMP regulations, then that is their promise to me. My promise to them is I keep it confidential.
BY MR. SANGIAMO:
Q. Have you included that provision in any of your agreements with your subsequent employers?
MR. KELLER: Objection.
THE WITNESS: Again, that's a confidentiality agreement. I can't -- then I would be breaking the confidentiality agreement if I told you



what was in the agreement.
BY MR. SANGIAMO:
Q. So you're not going to answer? So you're saying that maybe you did include a provision in your agreements with your other employers about your compliance being conditioned upon them complying with the CGMP, maybe you did, you're just not going to tell us. Is that what you're saying?
MR. KELLER: Objection. Argumentative.
MR. SANGIAMO: Understood, Jeff, you made your objection.
THE WITNESS: Yes.
BY MR. SANGIAMO:
Q. Do you have copies of your confidentiality agreement with Wyeth -- I'm sorry, with Pfizer?
A. I believe I do, yes.
Q. And how about with Amgen?
A. I think I do. I can't confirm.
Q. Were the vaccines that were under study in the trials to which you refer in the first bullet point of your description

in Exhibit 1 of your work with Pfizer, were they already marketed by the time of those studies?

MR. KELLER: That's a yes or no. Overbroad. Objection. Overbroad.

MR. SANGIAMO: Overbroad how? Were they already marketed at the time of the studies, why is that overbroad?

MR. KELLER: There could be some that are marketed, some that aren't marketed. She hasn't said whether or not there was more than one vaccine and others, if you want to be precise. Object to the question.

THE WITNESS: I don't know, I think some were marketed at the time.

BY MR. SANGIAMO:

Q. Which ones?

A. I can't say which ones.

Q. Because you don't remember or because you think you're prohibited from doing so by your confidentiality agreement with Pfizer?

A. Again, I think probably a



little bit of both. That I wouldn't say which vaccines on top of -- I don't recall exactly which ones.

Q. So is it your belief that your confidentiality agreement with Pfizer precludes you from telling us about work you did on a clinical trial on a marketed product? Is that your recollection or understanding of your confidentiality agreement with Pfizer?

MR. KELLER: Objection. Seeks a legal conclusion, and I will instruct you not to disclose any communications you had with your counsel with respect to anything that may be provided in those confidentiality agreements to the extent that you discussed them with your counsel.

THE WITNESS: With the work that's described within my CV to speak to what I did on a particular product, I wouldn't disclose that at this time.

MR. SANGIAMO: Do you plan to have her to testify at trial about the work she has done at Pfizer? Are you



going to stipulate now that she will testify?

MR. KELLER: I didn't stipulate anything. Ask your question. If you want to make a motion, make a motion. We're not under any obligation.

BY MR. SANGIAMO:

Q. Can you describe whether any of the serum neutralization assays involved plaque reduction as a means of measuring an immune response?

A. I don't think we performed plaque reduction.

Q. You understood my question just now was in reference to the work you did at Pfizer. Right?

A. Pfizer.

Q. If not a plaque reduction serum neutralization assay, then what kind of serum neutralization assay was it?

A. I believe they were conducted on an ELISA format.

Q. What was your role in running these ELISA serum neutralization assays?



A. I performed the assays.

Q. Did you work in a lab that was running the assays?

A. Yes, I did.

Q. How many other people were working in that lab?

A. I think two other people.

Q. I assume that lab ran assays on multiple trials?

A. To my recollection, yes.

Q. Did that lab run any plaque reduction neutralization assays while you were at Pfizer?

A. Not that I recall, no.

Q. Was the -- strike that.

Were the serum neutralization assays that you were running at Pfizer measuring the immune response to vaccination?

A. Yes, I believe so.

Q. Were they measuring seroconversion or were they measuring some other kind of immune response?

MR. KELLER: Objection.

Compound.

THE WITNESS: I don't recall the specifics.

BY MR. SANGIAMO:

Q. Do you recall the answer to my question as to whether they were measuring seroconversion as distinguished from some other kind of immune response?

MR. KELLER: Same objection.

THE WITNESS: I do recall your question. I don't recall the intent of the assay that we were performing.

BY MR. SANGIAMO:

Q. It could have been either?

A. Uh-huh. I mean, I guess in the case of you're saying neutralization, you're saying immune response which could be the same, could also be the same endpoint if you're looking at end response and neutralization as an endpoint to detect it.

Q. My question was whether it was seroconversion or some other kind of immune response?

A. Okay.

Q. I understand your answer to be



you're not sure.

A. Right.

Q. Were the vaccines live virus vaccines?

MR. KELLER: Hold on a second. You can answer.

THE WITNESS: I don't remember if they're a live virus or not.

BY MR. SANGIAMO:

Q. Do you remember whether any of the vaccines was a mumps vaccine?

A. No.

MR. KELLER: I instruct her not to answer that question.

MR. SANGIAMO: Right now you're asserting Pfizer's rights, is that what you're asserting?

MR. KELLER: I'm asserting, I don't want her to violate her confidentiality agreement.

MR. SANGIAMO: Have you seen the agreement?

MR. KELLER: I've reviewed the agreements.



MR. SANGIAMO: Are you ready to certify that would be a violation of that confidentiality agreement?

MR. KELLER: I'm not certifying anything. You can ask your questions. I believe she answered it anyway.

MR. SANGIAMO: You didn't let her answer it.

MR. KELLER: I think she answered it.

BY MR. SANGIAMO:

Q. Were any of the vaccines that you worked on at Pfizer a mumps vaccine?

MR. KELLER: You can answer.

THE WITNESS: No, they were not.

BY MR. SANGIAMO:

Q. Did you design any of the assays that you ran at Pfizer?

A. What do you mean by design the assay?

Q. Did you play any role in developing the assay methodology for any of those assays?



A. I believe I worked on developing assays while I was there.

Q. When you say you worked on developing assays while you were there, does that include the assays that were used in vaccine clinical trials as described on your CV?

A. Not that I recall, no.

Q. So you worked on developing other assays while you were at Pfizer. Is that the idea?

A. Correct.

Q. What kind of assays were those?

A. I have listed there that I developed a PCR assay, worked on that development in the -- that's all that I recall.

Q. What was that PCR assay used for?

MR. KELLER: You can describe it without identifying the products that it was used in.

THE WITNESS: It was used to measure proviral load and viremia in

study samples per my description there.
BY MR. SANGIAMO:
Q. What's viremia?
A. Again, the -- I can't explain to you the specifics of that right now.
Q. What is the definition of viremia?
A. Virus or viral infection in blood samples.
Q. So viremia can refer to many different viruses?
A. Yes, it could.
Q. It's not a definition of a particular virus. Do I have that right?
A. Correct.
Q. Was mumps among the viruses that were related to the PCR assay that you described there in your time at Pfizer?
MR. KELLER: At this point I'm going to -- she's already testified that she hasn't worked on a mumps vaccine at Pfizer. You're getting into what specific work she's doing on different products at Pfizer. She has



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:
Q. Did any of your work at Pfizer involve mumps virus?



A. No.
Q. Where did you -- what other kinds of work did you do at Pfizer?
A. Again, I was there for nine months so what is listed on my CV is what I conducted over that period.
Q. Are you familiar with the term "basic research" as used in the pharmaceutical industry?
A. Can you describe what you mean by that?
Q. I was hoping you would. I'm trying to come up with one summary way of describing what your work at Pfizer was and I'm asking if it was all in the nature of basic research?
A. It was part research; part, if we were supporting clinical trials, clinical work.
Q. Clinical work, namely serology work. Right?
A. Correct.
Q. Did you do any work while you were at Pfizer that you would characterize as



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 involve you generating data that was going to be included in a submission to the FDA?

A. Yes, potentially.
Q. Did it include any other kind of involvement on your part in an FDA submission?
MR. KELLER: Objection. Vague and ambiguous. Overbroad.
THE WITNESS: What do you mean by any other part besides generating data? What are you looking --
BY MR. SANGIAMO:
Q. I'm asking about what you did.
A. I can't think of anything besides the -- my work in the clinical studies. Anything in basic research could potentially down the road be used for something further down development to support regulatory. So as a whole, it is a vague question because as a whole there could be further development that leads into something that would be used in a regulatory submission at a later point.
Q. Do you know if that occurred in any of the basic research that you did?
A. I do not.



Q. Did you provide any input into product labeling while you were at Pfizer?
MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.
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 phrased in a label?
A. Not that I recall, no.
Q. After Pfizer you went to Amgen?



A. Correct.
Q. One more question on Pfizer. Did you have a single supervisor when you were at Pfizer?
A. Yes.
Q. Who was that?
A. Jay Thompson.
Q. First name Jay, J-A-Y?
A. Yes.
Q. Do you know if he's still at Pfizer?
A. I do not.
Q. Was the name of the group that you were in biologics development?
A. Yes.
Q. Your next stop was at Amgen. Correct?
A. Correct.
Q. Could you describe your work obligations at Amgen?
A. I worked in the analytical laboratory at -- when I first started at Amgen for process development. I later moved to the product quality team where I provided



oversight to the QC testing labs and monitoring and trending the data for the labs.
Q. During the time that you were 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. 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.
Q. My handwriting is too sloppy, I may not get this right. Do I have it right that you worked in the -- at first in the

analytical laboratory for product development?
Is that what you said?
A. Process development.
Q. Process development?
A. Yep.
Q. What does the analytical laboratory for process development at Amgen do or what did it do at that time?
A. It was further developing the process for one of their products.
Q. It was just a single product that you were working on when you were in the analytical laboratory for process development?
A. Yes.
Q. What kind of product was that?
MR. KELLER: Answer generally. Was it a drug? Was it a vaccine?
THE WITNESS: Biologic.
BY MR. SANGIAMO:
Q. Is it currently a marketed product?
A. Yes.
Q. What's the name of the product?
MR. KELLER: You can answer



that.
THE WITNESS: Enbrel.
BY MR. SANGIAMO:
Q. What does it do?
A. It treats rheumatoid arthritis.
Q. How does it do that?
MR. KELLER: Objection. 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 development?
A. I ran the test methods on the product that was being generated as part of



the product development.
Q. What kind of test methods did you run?
A. I would say mainly I performed the ELISAs.
Q. Anything else?
A. General test. PH, osmo, some HPLC.
Q. What was the purpose of the -- I'm sorry, were you about to say something else?
A. SDS-page staining, Coomassie staining.
Q. What was the purpose of the ELISAs that you were running?
A. I can't remember.
Q. Is it possible the purpose of the ELISA was to detect the absence of antibody development?
MR. KELLER: Objection. Calls for speculation.
THE WITNESS: No, because this was a product that wasn't -- it was basically the detection of proteins.



BY MR. SANGIAMO:
Q. That's what the ELISA was for?
A. Yes.
Q. Detecting proteins by looking for antibodies to that protein?
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 assay?
A. Uh-huh.
Q. What was the purpose of that?

A. To identify the purity of the product.
Q. You mentioned something about Coomassie staining?
A. Yes.
Q. What was the purpose of that?
A. Also, I believe, purity.
Q. Was any of this in the nature of stability testing?
A. Not that I recall, no.
Q. How long were you in the analytical laboratory for process development at Amgen?
A. Two years.
Q. I gather then 2005 is when you moved to the product quality team?
A. Correct.
Q. Did you work on more than one product while you were in the product quality team?
A. No.
Q. What product did you work on there?
A. Enbrel.



Q. What specifically was your role?
A. Again, the -- providing the oversight to the QC laboratories for their method development and transfer comparability as well as trending and data that was generated.
Q. What is method development?
A. It basically is developing a method based on an order to be able to test a specific criteria.
Q. In what way did you oversee the QC lab? What was your job function?
A. So if there were challenges with method performance I would provide some oversight to investigate the issues around the performance and help to work with the analysts on the -- any further development or optimization that's needed for the performance of the assay.
Q. Did you provide the subject matter expertise for that process?
A. Partially, yes.
Q. What else did you provide?



A. I'm not sure what you mean by what else did I provide.
Q. Did you provide -- was it your function to provide organizational coordination as challenges were being encountered with methods?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: I'm not sure I understand. Can you ask the question again?
BY MR. SANGIAMO:
Q. Was it your responsibility to see to it that the relevant portions of the product quality team met appropriately to resolve a particular issue that's an example of what I'm talking about other than actual subject matter expertise?
A. Yes, there was a team that would meet to review the data and we would work together cross functionally.
Q. Looking at Exhibit 2, your description of your time at Amgen has two bullet points?



A. Uh-huh.
Q. Is it the case that the work in the analytical laboratory for process development is what's described in the first bullet point?
A. That is more based on the -- my role in product quality.
Q. Is your work in the analytical laboratory for process development described anywhere on this CV at Amgen?
A. The second bullet is more relating to my analytical laboratory work.
Q. What's a site maturity model?
A. It's based on the performance of the systems, the robustness of the systems. So they had a maturity model of where we were at with developing the systems that managed our processes.
Q. Does your reference in that first bullet point to validation, what is that referring to?
A. Method validation.
Q. Can you describe what method validation amounts to?

A. It shows the method is suitable for its intended use, in this case an GMP environment. That it would be accurate, specific, precision and repeatability.

Q. Is there any validation work for any ELISA assays that you did? I'm sorry, let me try that question again.

Did you do any validation work on ELISA assays when you were at Amgen?

A. I do not -- I did not.

Q. Did you get along with your co-workers while you were at Amgen?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: Again, co-workers meaning who?

BY MR. SANGIAMO:

Q. So you feel you need to divide that up a little bit?

MR. KELLER: Same objection.

THE WITNESS: Yes.

BY MR. SANGIAMO:

Q. Were you ever told in your reviews that there was an issue about how you



were getting along with your co-workers?

A. There could have been an example of feedback of different -- working with different people throughout the company; yes.

Q. Did any of that feedback suggest that that was an area that you needed to work on, improving your relationships with co-workers?

A. Well, I think everybody needs to work on that because there are different personalities within an organization. So there could always be conflict between personalities.

Q. Were there such conflicts between personalities in your case when you were at Amgen?

A. None that impaired my work, no.

Q. But there was some that just didn't impair your work?

A. There was nothing that actually was detrimental to my performance.

Q. Why did you decide to leave Amgen?



A. Looking for a new opportunity.

Q. Were you asked to leave Amgen?

A. No.

Q. Did you apply to anyplace other than Alexion when you were deciding to leave Amgen?

A. I probably did. I don't recall.

Q. If we could talk a little about your work at Alexion --

A. Amgen had also a reduction in workforce. So they were going through a major reduction in their workforce which I was not part of. So I was still a part of Amgen at the time. As part of the, again, reason for leaving is the morale had dropped, so that was my reason for looking for a new opportunity.

Q. Morale had dropped and you attribute that drop in morale to reduction of force. Right?

A. Yes. Yes.

Q. If we could talk now about your work at Alexion. Are you currently employed there?

A. Yes.



Q. Has all of your work at Alexion been in the quality area?

A. Yes.

Q. What does that mean to say it was in the quality area?

A. I am overseeing compliance to GMP regulations for the specific areas I oversee.

Q. Does Alexion make any vaccines?

A. No.

Q. Does any of your work at Alexion ever involve vaccines?

A. No.

Q. Has it ever involved the mumps virus in any way?

A. No.

Q. Do you oversee compliance for GMP for a specific portion of Alexion?

A. Yes.

Q. What portion of that?

A. Are you asking for my current?

Q. Yes.

A. Okay. I oversee the manufacturing of clinical products as well as

the internal product development laboratories.
Q. Who do you report to?
A. I have an interim manager at the moment. I report to Brian Molloy.
Q. What's Brian Molloy's title?
A. Executive director of quality operations.
Q. Is there someone more senior than him within quality operations?
A. Currently we have chief of quality.
Q. Is he the only executive director of quality operations?
A. Yes.
Q. Are there other people who report directly to Brian Molloy besides yourself?
A. Yes.
Q. How many?
A. I want to say probably five others.
Q. How many products does Alexion manufacture?
A. Commercially?



Q. Yes.
A. Three.
Q. What are they just very generally?
A. They support rare diseases, blood disorders, that sort of thing.
Q. Does any of your work involve -- strike that.
Has any of your work at Alexion involved clinical trials?
A. Yes.
Q. In what way?
A. The manufacturing of the clinical product that we use are used in clinical trials.
Q. Used in clinical trials being performed by Alexion?
A. Yes.
Q. Have you had any other involvement in clinical trials while at Alexion other than your role related to the manufacturing of the product?
A. I'm trying to think how -- no, just as far as quality oversight for the



product is my role in clinical trials.
Q. That's quality oversight with regard to the manufacturing of the product?
A. Correct.
Q. When you were at Amgen, did you, yourself, interact with the FDA?
A. I don't think so.
Q. When you were at Pfizer, did you, yourself, interact with the CDC?
A. No.
Q. At Amgen did you interact with the CDC?
A. No.
Q. Do you interact with the FDA or have you -- strike that.
Have you interacted with the FDA during your time at Alexion?
A. Yes.
Q. How frequently?
A. I would say -- it depends on what you mean by interacting because I interact on different levels.
Q. What are they?
A. So I have been directly



involved in inspections by the FDA where I speak directly to the FDA. I currently support any data that's used to submit information to the FDA, so I do review documents that are submitted to the FDA. We do have responses, questions from the FDA that we have commitments to that I work towards as far as quality oversight, ensuring that those are completed.
Q. So that's three different thing you just described? I couldn't tell whether I was dividing them up.
A. Yeah, in general -- that's in general what I do.
Q. Have there been any 483s issued in any of these inspections at Alexion when you've been interacting with the FDA?
MR. KELLER: If any of those 483s are public, you can testify to it. If they're not public, then you cannot pursuant to your confidentiality agreement with Alexion.
THE WITNESS: For the inspections that I supported directly

we were not issued 483s for the GMP manufacturing.

BY MR. SANGIAMO:

Q. Were there 483s that you were involved indirectly in that were issued as a result of FDA inspections at Alexion?

MR. KELLER: Again, the caveat is if that 483 is publicly available, you can answer. If it's not publicly available, I instruct you not to answer pursuant to your confidentiality.

THE WITNESS: I do not know the status. And, you know, as far as, I guess indirectly is pretty broad. I work for the company.

BY MR. SANGIAMO:

Q. It was your term.

A. So I can't say to the status of the answer of that question based on confidentiality, whether or not it's public.

Q. So the 483 is issued but you can't describe them because you don't know whether they are public. Is that a fair summary of what you're saying? Yes?



A. Yes.

Q. A second area of FDA-related work that you identified at Alexion was supporting data used to submit information to the FDA. Right?

A. Yes.

Q. What's the nature of that data support work?

A. The manufacturing process. So we would describe the manufacturing process of the product. The support is reviewing the data that's submitted related to the manufacturing.

Q. You also referred to questions and then responses -- strike that.

You referred to questions from the FDA and responses to the FDA. That would also be about the manufacturing processes?

A. Correct.

Q. Are Alexion's products biologics?

A. Yes.

Q. Do you have any involvement in stability programs at Alexion -- sorry, try it again.



Have you had any responsibility for stability programs at Alexion?

MR. KELLER: Objection to form.

THE WITNESS: What do you mean by "responsibility"?

BY MR. SANGIAMO:

Q. Have you had any involvement in stability programs at Alexion?

MR. KELLER: Same objection.

THE WITNESS: Can you elaborate on "involvement"?

BY MR. SANGIAMO:

Q. What are some of the aspects of the stability program at Alexion?

A. What are some of the aspects?

Q. And then if you could tell me which ones of those you were involved in, that would be helpful?

A. So the -- I provide quality oversight for the testing that is conducted in support of stability.

Q. What does it mean to provide quality oversight of that testing?

A. So that I ensure that any



stability data -- or my team ensures that any stability data that's generated is reviewed, quality reviewed. Any events that occur during the testing, stability testing, would be documented within a deviation and we provide quality oversight for that. Any changes to the stability program would be submitted through change control and provide quality oversight for that as well.

Q. Do you play a role in defining the terms of the stability program?

MR. KELLER: Objection.

THE WITNESS: What role are you referring to?

BY MR. SANGIAMO:

Q. Any role.

A. The stability program, the definition or the parameters that are set by the stability, for stability is proposed by the subject matter experts and the information or criteria being presented is reviewed by quality.

Q. Do you participate in that review?

A. Yes.
Q. What's the nature of your participation?
A. We verify that the data being submitted would provide the appropriate justification for the parameters.
Q. Is that a team of people in quality who review the proposals from the subject matter experts?
A. Yes.
Q. You're one member of that team?
A. Yes.
Q. How many people are on that team?
A. There -- you're just speaking specifically to quality members?
Q. I'm speaking to quality members who review the proposals from the subject matter experts about the parameters of the stability program.
A. I can't say that it's defined how many members. There's at least two quality representatives. Actually it would then -- it depends, again, upon the extent of



the review. It would go up to the chief of quality for anything that's submitted for any changes in the parameters of the program.
Q. Are there people other than those in quality who review changes in parameters of the stability programs?
A. Yes. It would be the head of the product development team as well as regulatory would be part of the cross functional team.
Q. How does the approval of changes in the parameters for the stability program ultimately get decided, is that by consensus of this team?
A. Yes, I would say so.
Q. How many times in your tenure at Alexion have you participated in this kind of review of the parameters of the stability program?
A. Are we talking about new parameters or changes to parameters?
Q. Either. Or both I should say.
A. I'm trying to think. I would say -- so the question is how many times



during my time at Alexion?
Q. Yes.
A. I would say maybe a dozen times.
Q. Have you ever interacted with the CDC during your time at Alexion?
A. No.
MR. SANGIAMO: Jeff, now would be a good time to break from my perspective.
MR. KELLER: It's been an hour. Let's take a break.
VIDEOGRAPHER: The time is now 11:58. Going off the video record.
- - -
(A recess was taken.)
- - -
VIDEOGRAPHER: The time is now 12:13. This begins disc three. You may proceed.
BY MR. SANGIAMO:
Q. Ms. Wlochowski, your CV describing your time at Alexion refers several times to product disposition. What does that mean?



A. I released the product to the market or to the clinical sites.
Q. You said "I released the product," you mean --
A. Release or reject.
Q. Your group does?
A. Yes.
Q. Did you attempt in 2004 about a year into your tenure at Amgen to get rehired by Pfizer?
A. Check on the dates. I may have applied to a position there.
Q. Did you get rejected?
A. I didn't get called for an interview, if that's what you're referring to.
Q. Do you know -- strike that.
Do you recall what the position was that you were applying for?
A. No, I do not.
Q. Was there any particular reason you wanted to leave Amgen at that time?
A. Because I was commuting an hour to Amgen.
Q. You got no response from Pfizer

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 commute to Alexion?



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 applied for a position with Pfizer in 2013 I thought I would show it to you.
A. Okay.
MR. KELLER: What's the question -- before you go on, I have a question. Have you ever produced this



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



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 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 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 for now. I'll just ask you, Ms. Wlochowski about your recollection of applying for a 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, did you?

A. According to this document, that's what it's showing here.
Q. Do you have a recollection of that?
A. It's likely that this job description would be something that -- or job title would be something that I would be interested in and apply to.
Q. Do you recall what happened after you applied for that position?
A. I do not recall.
Q. Do you recall why you applied for it?
A. Again, it's a job description title that I would have been interested in.
Q. Are you presently seeking a new job?
A. I currently am not, no. I have not applied.
Q. Have you had any discussions about the mumps vaccine with anyone from the federal government?
A. Have I had discussions with them?



Q. Yes.
MR. KELLER: Objection. Overbroad.
THE WITNESS: Can you clarify discussions?
BY MR. SANGIAMO:
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 vaccine?
A. I have not had any direct conversations with the CDC about the mumps vaccine.



Q. Do you believe you may have had some indirect conversations with the CDC about the mumps vaccine?
A. I believe I may have had indirect input to information provided to the CDC.
Q. When did that occur?
A. While I was at Merck.
Q. How about as regards the FDA, do you believe you may have had indirect input to information that was provided to the FDA?
A. Yes.
Q. And if that were to have occurred, would that have occurred while you were at Merck?
A. Yes.
Q. How about since you have left Merck, have you had any communication, direct or indirect, with the federal government about the mumps vaccine?
MR. KELLER: All agencies of the federal government?
MR. SANGIAMO: Yes.
MR. KELLER: Lack of



foundation. Vague and ambiguous.
THE WITNESS: So all agencies of the federal government, have I had direct or indirect information provided to them regarding the mumps vaccine is 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?
A. I don't recall any other conversations with the government agencies.
Q. What can you tell us about the

discussion you had with the Department of Justice?

MR. KELLER: I object. Her discussion with the Department of Justice -- give us a second.

You can ask her generally about when she spoke with the DOJ, who was at that meeting, how many times she met at that meeting, but I'm going to instruct her not to answer any questions regarding what was discussed at that meeting with the Department of Justice.

BY MR. SANGIAMO:

Q. How many times have you met with the Department of Justice?

A. I met with them once.

Q. When was that?

A. Between 2010 and 2012, I think it was. I think it was 2012. I can't remember.

Q. Who was present at the meeting?

A. Actually I guess it was -- yeah, I guess it was more -- yeah, okay. I can't recall the date, but between 2010 and



2012.

Q. Who was present at the meeting?

A. My legal counsel was present as well as a representative from the DOJ.

Q. You say your legal counsel was present. Is that Mr. Keller?

A. Yes.

Q. Who was the representative from the DOJ, if you remember?

A. Joel was his first name.

Q. Anyone else present?

A. I don't -- there were a room of people. I don't remember who they were.

Q. Were they lawyers?

A. That's my understanding, yes.

Q. What was discussed at the meeting?

MR. KELLER: I'm going to instruct the witness not to answer. Attorney-client privilege, work product. Prosecution.

BY MR. SANGIAMO:

Q. Ms. Wlochowski, do I have it right that you are a college graduate? Is



that right?

A. Yes.

Q. What was your degree in?

A. Medical technology.

Q. That's a Bachelor of Arts degree?

A. Yes.

Q. Did you ever apply to graduate school?

A. No.

Q. Did you ever think about applying to graduate school?

A. No.

Q. Do you know if Mr. Krahling ever applied to graduate school?

A. I do not know.

Q. You have something called a medical technologist certification from the American Society for Clinical Pathology. Is that right?

A. Correct.

Q. When did you get that?

A. When I -- at the time I graduated I took that certification.

Q. Does that entitle you to do



anything in particular that you could not do without the certification?

A. Yes, I believe the certification allows you to be a medical technologist level versus without it you would, I think the -- at least at the time I was working in that field, I think they called it a medical laboratory technician. So an MLT versus an MT. There's different -- without the certification, it's a lower level position that you can perform in the lab.

Q. Is that a matter of state licensing requirements or is that just something else?

A. I think it's just based on -- I don't know the licensing requirements. It was just a certification that the hiring staff would be looking for.

Q. We've been talking a lot this morning about what you did and did not do at your prior jobs. I want to see if I've got it right on a few specific points. Is it correct that other than at Merck, you have never run a plaque reduction neutralization assay to test

response to vaccination?
A. That's correct.
Q. Other than at Merck, you have never run any assay to test response to vaccination other than the ELISA assay that you ran at Pfizer. Is that correct?
A. Correct.
Q. At none of your jobs have you interacted with the CDC. Is that correct?
A. Correct. Directly.
Q. Subject to the limitation you described a few minutes ago?
A. Correct.
Q. And your only direct interactions with the FDA at any job have been related to manufacturing issues. Is that fair?
A. Correct.
Q. I asked you some questions specific to one of your jobs, and honestly right now I can't remember which one it was, about any role in product labeling. Let me just ask you more generally, for any of the positions that you have held at any pharmaceutical company, have you reviewed



drafts of labeling?
A. Yes.
Q. Were any of the drafts of labeling that you reviewed related to labeling for vaccine efficacy?
A. No.
Q. Were any of them related to labeling for vaccine effectiveness?
A. No.
Q. Were any of them related to labeling for vaccine immunogenicity?
A. No.
Q. Have you, as part of your work, ever been called upon to decide -- strike that.
Have you, as part of your work, ever been called upon to review vaccine labeling on any topic?
A. Have I been called upon to review vaccine labeling on any topic?
MR. KELLER: As part of her job duties?
MR. SANGIAMO: Yes.
THE WITNESS: In any job that



I've had?
BY MR. SANGIAMO:
Q. Yes.
A. I guess I might be a little unclear about that. So if I was at Merck, the -- again, the testing I was performing at Merck would -- could potentially be used to support a product labeling.
Q. Did anyone, while you were at Merck, ask you to review the labeling as part of your job function?
A. Specifically the document itself?
Q. Yes.
A. No.
Q. Did I hear you testify that you have reviewed some draft labeling at one of your jobs? Is that right?
A. Yes.
Q. Which job was that?
A. Alexion.
Q. What was the draft labeling that you reviewed?
A. What was it?



Q. Yes.
A. The product insert as well as the carton and the label.
Q. What were the circumstances of that review?
A. I provide quality oversight for the approval of the changes that are made in the document.
Q. What do you mean by providing quality oversight for that?
A. The -- again, the changes that are being made would be supported by other documentation that would allow for the change. So I would verify that the information is supported and that the content is correct.
Q. Did any of those changes involve product efficacy?
A. I can't recall. I don't recall that there was a specific change for efficacy.
Q. There wouldn't be any reason for you in your position to review label change related to product efficacy, would there, at Alexion?
MR. KELLER: Objection. Calls

for speculation.
THE WITNESS: So at the time that I did have oversight for the labels, I would provide a review of any label change from a quality perspective.
BY MR. SANGIAMO:
Q. Would you be involved in a decision as to whether efficacy information in a label accurately described the efficacy of the product?
MR. KELLER: If that was the label change that was going to happen?
THE WITNESS: Can you repeat that again? Sorry.
BY MR. SANGIAMO:
Q. Would you be involved in a decision as to whether efficacy information in a label accurately described the efficacy of the product?
MR. KELLER: Again, the same. It's vague and ambiguous.
THE WITNESS: If the label change was for efficacy, you're asking if I would be involved in the decision,



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 data that is being generated should be represented on the label. So the label should be an accurate representation of the product.



So it's my basic knowledge of requirements for a label.
Q. What are those regulations as they pertain to descriptions of vaccine efficacy, if you know?
A. I don't -- I mean, I don't know the specific CFRs. I do know that there is GMP requirements to ensure that your label is an accurate representation of the product.
Q. Is it your testimony that GMP requirements are applicable to descriptions of efficacy on vaccine labeling?
A. Yes.
Q. What section -- do you know the section of the code that imposes that obligation?
A. Not off the top of my head, no.
Q. Do you have any training in your view that would qualify you to opine on the cause of an outbreak?
A. To --
MR. KELLER: Objection as to form.
THE WITNESS: So you're asking



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 me -- so basically I'm not, in that sense, trained to do a role that would be determining that.

BY MR. SANGIAMO:
Q. Do you have any training that would position you to determine the efficacy of a vaccine?
MR. KELLER: Objection. Vague and ambiguous. Overbroad.
THE WITNESS: Do I have training to determine the efficacy of a vaccine?
BY MR. SANGIAMO:
Q. Uh-huh.
MR. KELLER: Same objection.
THE WITNESS: I guess I would ask to elaborate on that because there's, as far as being able to generate data to determine efficacy, I do have training around that.
BY MR. SANGIAMO:
Q. What methodology would you use to determine a vaccine efficacy rate?
MR. KELLER: Objection.
THE WITNESS: So I guess --
MR. KELLER: Wait. Let me finish the objection.



THE WITNESS: I'm sorry.
MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Overbroad. You can answer.
BY MR. SANGIAMO:
Q. Mr. Keller makes a good point, that did lack foundation.
Do you know the methodologies that are used to determine the efficacy of a vaccine?
MR. KELLER: Again, objection. Vague and ambiguous. Overbroad.
THE WITNESS: So in your question with efficacy, can you define what you're referring to as efficacy?
BY MR. SANGIAMO:
Q. Efficacy as the FDA would define it, do you know what that is?
A. I do not have that in front of me at this time, so I do not, can't explain it.
Q. Have you ever as part of your job responsibilities at any employer had to be cognizant of how the FDA would define efficacy



for purposes of a vaccine?
A. Would I have to understand what the requirements were by the FDA? I' sorry, I missed the first part of the question.
Q. At any job, would it have been part of your job responsibilities to be aware of how the FDA defines efficacy for a vaccine?
MR. KELLER: Lack of foundation.
THE WITNESS: Is it a requirement of my job, is that what you're asking me?
BY MR. SANGIAMO:
Q. Okay. Yes.
A. I don't know that it would be the -- for a vaccine, the requirement of my job to know that at the time. Basically the only time I would be doing that would be at Merck. It wasn't the expectation of the level that I was performing the work that I would have that understanding of what the FDA defined as efficacy.
Q. The same question as to the CDC, at any job would it have been a requirement for you to have an understanding



of how the CDC defines vaccine efficacy?
MR. KELLER: Objection. Lack of foundation.
THE WITNESS: So, again, my only work with vaccines was while I was at Merck as well as Pfizer, and the -- it was not, based on the work I was performing in the laboratory, not a requirement for me to have that understanding or the knowledge of the definition defined by CDC.
BY MR. SANGIAMO:
Q. You've given testimony today describing your experiences as running serology tests. Correct?
A. Correct.
Q. Has any part of your job duties including evaluating the clinical significance of the results of those serology results at any job?
MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.
THE WITNESS: When you say clinical significance, meaning? Can

you elaborate on that?
BY MR. SANGIAMO:
Q. Implications for the relationship between the serology findings and human disease.
A. Was it my responsibility between serology -- to define or understand the serology findings -- sorry, I'm getting confused. And --
I'm sorry. Can you repeat it again?
Q. I was asking you earlier today about your work at New Haven Hospital.
A. Yes.
Q. And you were describing tests that you ran on clinical samples. I think I asked you whether it was up to you or up to the doctor to figure out what those test results implied for disease. Right?
A. Yes.
Q. I think you told me that was told by the doctor?
A. Correct.
Q. I'm asking the same kind of question now for your other jobs, as to



whether it's your role in any job to determine what the clinical significance was from a human disease perspective --
A. I got you.
Q. -- of the serology work that you did?
A. No, I was not the decision-maker on the output of the data that was provided from the testing that we performed in the laboratory.
Q. You wouldn't be qualified to do that. Right?
A. I wouldn't --
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: I mean, I do have qualifications, I have a basic understanding of what the outputs mean. But it wasn't my responsibility at that level to be doing that.
BY MR. SANGIAMO:
Q. Do you have any training in understanding what the clinical significance is of serology results?



A. Yes, I understand what the different results would mean in the clinical setting.
Q. You have training in that?
A. I have basic training for understanding what the methods are that we were performing.
Q. What the methods of the assays were?
A. Yes.
Q. Do you have any training in understanding -- strike that.
Do you have any training in evaluating what the clinical significance is of the results of those methods?
A. Based on training that I was provided potentially by my supervisor or information that was provided to me during the course of conducting the studies, I have been trained in that sense.
Q. That was information that was provided to you not in order for you to do your job, just provided to you as additional information. Is that right?



MR. KELLER: Objection. Overbroad.
THE WITNESS: I mean, there are requirements of me to be trained in order to do my job as well as any information that was provided to me while I was at my job.
BY MR. SANGIAMO:
Q. But your job consisted of running the serology. Right?
A. That was my responsibility at the time, yes.
MR. KELLER: Are we just talking about Yale, or are we -- I'm confused.
MR. SANGIAMO: No, we're talking about all of her involvement. I think she understands.
BY MR. SANGIAMO:
Q. You've been answering for all your jobs. Right?
A. Yes.
Q. Would you know a methodology to use if were you were trying to evaluate what

the clinical significance was of, say, a seroconversion rates from a vaccine clinical trial?

MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Overbroad.

THE WITNESS: Yeah, I mean, it depends on what you're trying to measure. So there's no different types of methodology. Different types of methodology works better for one vaccine or virus versus the other, so...

BY MR. SANGIAMO:

Q. Can you provide some examples?

MR. KELLER: Objection. Calls for speculation. Overbroad. Lack of foundation.

THE WITNESS: I mean, again, even just within the plaque assay itself we could be seeing different strains of virus. There could be, you know, any type of other assay that, you know, whether it's hemagglutination



assay or some other type of assay that, you know, would be tacting [ph] based on the different type of virus.

BY MR. SANGIAMO:

Q. You've just described different ways in which an assay could be run. Correct?

A. Or different assays.

Q. Or different assays. My question is, what methodology would you use to determine what the clinical significance was of the output of those assays?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: When you say "methodology," you're not referring to -- so, I guess, define methodology in your sentence there.

BY MR. SANGIAMO:

Q. Do you not know what a methodology would be in order to determine the clinical significance of serology results?

A. I mean, are we talking about the general protocol that would be used with different types of measures and outcomes to --



because there is also that that's involved.

Q. If you run a serology test, you get information about the serum that was tested from that individual. Right?

MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.

THE WITNESS: I guess information is very general there. So it's very limited information.

BY MR. SANGIAMO:

Q. That's the point. Whatever the information you get, it's about the serum. Right?

MR. KELLER: Same objections.

THE WITNESS: On the -- the serum is typically a number that identifies the serum.

BY MR. SANGIAMO:

Q. And what that information about the serum means clinically for the patient is a different question entirely. Right?

MR. KELLER: You guys are talking past each other. Vague and ambiguous. Lack of foundation.



THE WITNESS: What the serum means for the patient?

BY MR. SANGIAMO:

Q. What the information about the serum means clinically for the patient is an entirely different question. Correct?

MR. KELLER: Vague and ambiguous. Overbroad.

THE WITNESS: Once we test the serum --

BY MR. SANGIAMO:

Q. Yes.

A. -- the results are -- does relate back to the patient. I guess I'm not understanding what you're trying to ask specifically.

Q. Have you ever undertaken to figure out whether a certain antibody level correlates with protection from disease?

MR. KELLER: Objection. Overbroad. Vague and ambiguous.

THE WITNESS: I have been -- I have been involved in running assays that would help to determine the

correlation of the antibody, yes, level in a serum.

BY MR. SANGIAMO:

Q. Have you ever been involved in the determination of whether those antibody levels, whatever they are, are correlated with protection from disease?

A. In the sense that I perform the assay, that's my involvement.

Q. Any other involvement?

A. Not that I can think of, no.

Q. Have you ever designed a clinical trial?

A. No.

Q. Do you know anything about the CDC's decision-making process when it decides whether to purchase a vaccine?

MR. KELLER: Objection. Overbroad.

THE WITNESS: I know that -- I know that they would --

BY MR. SANGIAMO:

Q. It's a yes or no question. Do you know?



A. All right. Can you state the question again?

Q. Do you know anything about the CDC's decision-making process regarding the purchasing of vaccines?

A. Yes.

Q. What's your basis of that knowledge?

A. I know that they receive --

Q. What's your basis?

A. What's my basis?

MR. KELLER: Vague. Argumentative. And the extent that the information that you have you learned from counsel, I instruct you not to answer the question, any communications with your counsel. To the extent you have information that's independent of discussions you had with counsel, you can answer.

BY MR. SANGIAMO:

Q. So the question is, do you know anything about the CDC's decision-making process regarding the purchasing of vaccines



but you should exclude from your answer anything that you've learned from your counsel?

A. Do I know anything is the question?

Q. Yes.

A. Right, I do.

Q. Where did you learn that other than from your counsel?

A. I know that the label is public, so that information is available to the CDC in determining a decision on whether or not to purchase a product.

Q. Anything else?

A. I think that's it.

Q. Do you know whether the CDC, in fact, looks to the label in order to determine whether to purchase the product?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: I cannot say what the CDC does.

BY MR. SANGIAMO:

Q. Because you just don't know.



Right?

MR. KELLER: Same objection.

BY MR. SANGIAMO:

Q. Right?

A. Yes.

- - -

(Exhibit Wlochowski-6, Amended Complaint for Violations of the Federal False Claims Act, was marked for identification.)

- - -

BY MR. SANGIAMO:

Q. Ms. Wlochowski, you've been handed what's been marked as Exhibit 6. Are you familiar with that document?

A. Yes.

Q. What is it?

A. This is a copy of the Complaint.

Q. Did you play any -- you should be very careful now when you answer my questions because I want to make sure I don't invade the attorney-client privilege.

Right now my question is -- you need to make sure to give Mr. Keller a chance

to object.

My question is, did you play any role in the drafting of this Complaint?

A. Yes.

Q. Did you draft any of the original language in the Complaint?

MR. KELLER: You can answer it yes or no.

I'm going to object. Vague and ambiguous. Objection.

THE WITNESS: I guess by original I did provide information that was used in the drafting of this Complaint.

BY MR. SANGIAMO:

Q. Do you recall what information you provided?

MR. KELLER: Objection. I'm going to instruct you not to answer.

BY MR. SANGIAMO:

Q. Did you review that Complaint prior to -- sorry, strike that.

Did you review a final version of that Complaint prior to it being filed?



A. Yes.

Q. Was there anything in there that appeared to be inaccurate to you?

A. With the exception of the initial of my first name, no.

MR. KELLER: Take full responsibility for that.

THE WITNESS: I should say my middle initial.

BY MR. SANGIAMO:

Q. Other than that?

MR. KELLER: Color it out.

THE WITNESS: No, I didn't see anything inaccurate.

BY MR. SANGIAMO:

Q. Can you vouch for the accuracy of everything that is in there?

MR. KELLER: Objection. Vague and ambiguous.

BY MR. SANGIAMO:

Q. Do you understand how it's different from the last question I asked you?

A. Yes.

Q. So there are certain sections



of the Complaint that refers to information provided by Steve Krahling that I can only say that it's accurate based on what he has provided.

MR. KELLER: I assume you're going to ask her if she understands the legal jargon that's also in this Complaint, as to the accuracy of the legal jargon as well? Are you asking about the facts or are you asking --

BY MR. SANGIAMO:

Q. I'm asking about the facts, and I heard your answer which I understood to be that there are some things in there factually that you know to be true. There are other things in there factually that to the extent you know anything about them, you know it from Mr. Krahling. Is that right?

A. Correct.

Q. Could you identify what portions of the Complaint fall into that latter category?

MR. KELLER: Do we have a week to do that? Sure.



MR. SANGIAMO: Is it all from Krahling?

MR. KELLER: Excuse me?

MR. SANGIAMO: So much of it was from Krahling that it would take a long time to identify?

MR. KELLER: There's how many paragraphs in this Complaint? It's your deposition. If you want to ask her questions as to every line that -- of information that she knows, can verify herself.

BY MR. SANGIAMO:

Q. Are there any that you know of that fall into that latter category?

MR. KELLER: Feel free to review the Complaint.

BY MR. SANGIAMO:

Q. I'm not asking for an exhaustive list. If there are any that come to mind.

MR. KELLER: Objection.

THE WITNESS: Not that I know of offhand without looking through the

document.
BY MR. SANGIAMO:
Q. You just have a recollection of having looked at it previously and seeing there were some things in there that Krahling knew about, but you, yourself, didn't know about. Is that fair?
A. The only way I knew about it was through Krahling, yes.
- - -
(Exhibit Wlochowski-7, Relator Joan Wlochowski's Responses and Objections to Merck's Revised First Set of Interrogatories, was marked for identification.)
- - -
BY MR. SANGIAMO:
Q. Ms. Wlochowski, you've been handed what's been marked as Exhibit 7. My question to you is whether you recognize that document?
A. Yes, I do recognize this document.
Q. What is that document?



A. This is the Interrogatories that were submitted that we have responded to.
Q. If you go to the second to the last page, you see there is a verification there.
A. Yes.
Q. Is that your signature?
A. Yes.
Q. When you signed that, did you review the final version prior to signing?
A. Yes.
Q. Is everything in the final version accurate?
A. Yes. According to my signature and, again, according to what I know from Steve.
Q. Where there was information in these answers that derived from Steve, did you make that evident, the substance of the answer?
A. I would have to go back and look at that.
Q. You just don't have a recollection one way or the other?



A. Right.
Q. Did your attorneys draft these answers and then you approved them or did you draft the answers?
MR. KELLER: Objection. It's vague and ambiguous. Overbroad. Invades work product. I'm going to instruct the witness not to answer that question.
MR. SANGIAMO: On the basis of attorney-client privilege?
MR. KELLER: And work product, yes.
BY MR. SANGIAMO:
Q. Did anyone other than you and your attorneys participate in drafting these answers?
A. So the --
MR. KELLER: His question is, did anybody other than you and your attorneys draft this without telling him who drafted each of the two groups or together?
THE WITNESS: So there were two



sets of Interrogatories, as I recall, one was for myself and one was for Steve. Most of the questions were the same. So we did a --
MR. KELLER: I want you to be very careful. Do not describe -- his question to you is did anybody other than your lawyers and yourself prepare these responses. He's asking for anybody else.
MR. SANGIAMO: Exhibit 7.
MR. KELLER: Yes. Not anything about what was written down. Do you understand the question?
THE WITNESS: Yes. I guess it's a little, you know -- so Steve was involved in discussions but as far as the responses, that was my agreement, my signature on this document.
BY MR. SANGIAMO:
Q. Steve was involved in discussions about what the content of the answer should be. Is that correct?
A. In the instances where it

applied to both of us.
MR. KELLER: His question was -- the answer is that Steve Krahling was involved in responding to these interrogatories as well. Correct?
THE WITNESS: When --
MR. SANGIAMO: Yes or no. Very specific because it's a privilege question. Yes or no.
THE WITNESS: Yes for the questions that referred -- that were posed to both of us.
BY MR. SANGIAMO:
Q. Could we look at Interrogatory Number 5 which is on page 10. This is an Interrogatory that is directed at you, not to both of you. Right?
A. Right.
Q. Did Mr. Krahling provide any of the information that went into the response to Interrogatory Number 5?
MR. KELLER: Hold on a second. I'll let you answer that.



THE WITNESS: So the answer is no, Steve did not. The only response -- the response to Question Number 5 -- 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 full document?
MS. DYKSTRA: Yes.
MR. KELLER: It wasn't Bates numbered, so it's hard for me to tell --



MS. DYKSTRA: It's how we received it.
MR. KELLER: Thank you.
VIDEOGRAPHER: The time is 1:08. Off the video record.
- - -
(A recess was taken.)
- - -
VIDEOGRAPHER: The time is now 2:08. This begins disc four. You may proceed.
BY MR. SANGIAMO:
Q. Ms. Wlochowski, is it your belief that there has been significantly diminished efficacy for the mumps component of the MMR?
MR. KELLER: Objection. Overbroad.
THE WITNESS: So in the sense you're referring to efficacy in which definition?
BY MR. SANGIAMO:
Q. I'm asking you if those words reflect your belief, do they or not?



MR. KELLER: Objection. Vague and ambiguous. Overbroad. Lack of 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?
MR. KELLER: Objection. Overbroad. Lack of foundation. Vague and ambiguous.
THE WITNESS: If you're referring to the efficacy component of the mumps

vaccine, whether or not it's effective in protecting against mumps, based on my experience working in Dave Krah's lab, I did see that the testing that was conducted while I was there showed results that were not aligned with what's being reported in the label currently.

BY MR. SANGIAMO:

Q. So is it your belief that there has been a significantly diminished efficacy of the mumps component of MMR?

MR. KELLER: Objection. Asked and answered. Vague and ambiguous. Overbroad.

THE WITNESS: So, again, the -- based on the data and information that was provided while I was working in Dave Krah's lab, it did show that there was less than what's being reported in the label.

- - -

(Exhibit Wlochowski-8, MMR II label, was marked for identification.)



- - -

BY MR. SANGIAMO:

Q. Ms. Wlochowski, you've been 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 I would consider two indications of efficacy. There's a general statement that says the efficacy of measles, mumps and rubella vaccine was established in a series of double blind



controlled field trials which demonstrated a high degree of protected efficacy afforded by the individual components, and it references studies that were done with the original approval of the mumps component of the product back in 1967 in support of that statement. And then there is another statement within the label that says that the MMR II is highly immunogenic and generally well tolerated. And the studies for that showed that there was mumps neutralizing antibody in 96 percent of vaccinees. I should say -- yes, sorry, of the susceptible persons in that statement.

Q. Is it your belief that the information there about the detection of mumps neutralizing antibodies in 96 percent of susceptible persons, so that's a statement about efficacy?

A. In my definition of efficacy it shows -- is how well, how effective the product is and in neutralizing antibodies does correlate with an immune response in a patient.

Q. What do you base that last statement on?



A. The assay is designed to -- it's a biological assay so it's designed to replicate what would happen as far as the 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.

BY MR. SANGIAMO:

Q. Do you have the expertise to assess whether seroconversion as measured in a neutralization assay correlates with

protection from disease?
MR. KELLER: Objection. Vague and ambiguous. Overbroad.
THE WITNESS: Do I have the expertise? I have -- so I do know that you're reporting the neutralizing antibodies here as a means to say that it's highly immunogenic. And so based on even what's written in the label, it suggests that the neutralizing antibody supports immunogenicity.
MR. KELLER: Objection. Lack of foundation as well.
BY MR. SANGIAMO:
Q. My question is, do you have the expertise do assess whether seroconversion as measured in a neutralization assay correlates with protection from disease. What's your answer to that question?
MR. KELLER: Objection. Asked and answered. Lack of foundation. Vague and ambiguous. Overbroad.
THE WITNESS: So as part of my experience working in Dave Krah's lab,



we were running the neutralization assay to show seroconversion rates and that the results of what we performed during the testing was an indication of seroconversion in a patient.
BY MR. SANGIAMO:
Q. Does that seroconversion correlate with protection from disease as measured in that assay?
MR. KELLER: Same objections.
THE WITNESS: It provides the information about how effective the vaccine, it provides some information about how effective the vaccine is at neutralizing the virus. Which would indicate that it's providing information around how well the product is protecting against the virus.
BY MR. SANGIAMO:
Q. I think you said provides some information, is that what you said?
A. Uh-huh.
Q. Does it correlate with protection, seroconversion, does it correlate



with protection?
MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.
THE WITNESS: Does it correlate with protection?
BY MR. SANGIAMO:
Q. Yes.
A. Against the mumps virus?
Q. Against disease, mumps disease.
MR. KELLER: Are you asking about the label or are you asking just in general?
MR. SANGIAMO: I'm asking if it correlates with protection.
MR. KELLER: Same objections.
THE WITNESS: Again, I think my understanding, my answer to that was that based on having neutralizing antibodies, that it would correlate to some extent in protection.
BY MR. SANGIAMO:
Q. Have you ever studied that issue of whether neutralizing antibody to mumps correlates to protection in disease?



MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: What do you mean by study the issue?
BY MR. SANGIAMO:
Q. Read literature on it.
A. I have read some literature.
Q. Was it ever a part of your job responsibility anywhere to figure out whether seroconversion in a mumps neutralization assay correlates with protection from disease?
A. That was not part of my job description.
Q. What is the most you can tell me about your training that would show you to have the expertise in order to assess whether seroconversion in a mumps neutralization assay correlates with protection from disease?
MR. KELLER: Let me just --
MR. SANGIAMO: Don't testify, Jeff. Let her answer the question.
MR. KELLER: Protect my privilege, Dino. Excuse me.
In answering this question, you

can answer to the extent that you don't disclose any communication you had with your counsel. You don't disclose any information that was provided to you in part of those communications in answering his question. So other than communications that you had with counsel or information that you received from counsel regarding this issue, you can answer.

THE WITNESS: So the training I've had to determine whether or not this correlates to -- seroconversion correlates to protection against the mumps disease. So I do have training in basic science, so I have an understanding of how that works. And, again, my understanding based on my training and documents that I've seen is that there is a correlation between antibody response and protection against disease.

BY MR. SANGIAMO:

Q. What documents?



MR. KELLER: Other than documents that you've reviewed or were provided to you by counsel.

BY MR. SANGIAMO:

Q. Were the documents that you referred to in your last answer strictly documents that were provided to you by counsel?

MR. KELLER: Answer yes or no.

THE WITNESS: No.

BY MR. SANGIAMO:

Q. Okay. Which documents were you referring to that were not provided to you by counsel?

A. So I can't think off the top of my head.

Q. Now, the label does mention efficacy itself as you pointed out on page 2 here of Exhibit 8.

A. Uh-huh.

Q. And it refers to a high degree of protective efficacy. Is it your testimony that when you were in Dr. Krah's lab, you learned that the efficacy of the mumps



component was significantly diminished from this high degree of protective efficacy?

A. I believe that the data was showing from running the plaque reduction neutralization assay that the results did not reflect the actual seroconversion rates that were occurring in the patient population. And --

Q. I'm sorry, the results of the neutralization assay did not reflect the actual --

A. Correct, because they were being changed. So the original results that we had generated by performing the assay were being changed to provide information that basically the testing was biased and the results for pre-positive sample would be changed in order to represent something that was pre-negative. So that it showed a different rate of seroconversion than what would have been reported out with the original results.

Q. What was the difference in the rate?



A. I do not know the actual difference in the rate.

Q. Did you ever calculate it?

A. I did not calculate the entire study, no.

Q. Did you ever calculate the difference in the seroconversion rate that resulted from whatever these practices are to which you take exception in the running of the assay?

A. Did I ever calculate the difference in -- I was aware of data that showed that there was a percentage of the portion that we looked at that was different than the original results.

Q. Seroconversion rate was different?

A. That the pre-positive rate was different so which would lead to either those results being -- those results, you know, being excluded from a seroconversion rate.

Q. What was the impact on the seroconversion rate, did you ever calculate that?

A. No. I don't believe, no. I don't believe we calculated the difference in the seroconversion rate.

Q. So even if we accept your premise that seroconversion rate correlates with efficacy, how do you know that anything you saw in the lab suggests that the efficacy has been significantly diminished from a, quote, high degree of protective efficacy?

MR. KELLER: Objection. Lack of foundation. Vague and ambiguous. Overbroad.

THE WITNESS: So the results were -- if the results -- the original results are used, the actual seroconversion and the titer or the neutralizing titer would be higher based on the enhancement of using rabbit antibodies in the assay. Previous studies during the assay development also showed a lower rate of seroconversion which would indicate that there is also some other issues with the seroconversion rate that would



make it -- make the product less effective.

BY MR. SANGIAMO:

Q. Did you participate in those earlier studies?

A. I did not.

Q. How did you hear about them?

A. I was provided a document, a Merck document, a copy of a Merck document that showed information from those previous studies.

Q. Who gave it to you?

A. Steve gave it to me, Steve Krahling.

Q. When did he give it to you?

A. Probably in the spring of 2001.

Q. What do you remember about the content of that document besides what you've already told us?

A. That the original assay that was being performed itself didn't meet the desired outcome of a 95 percent seroconversion rate. It was lower. And in that case a new method was developed to -- with the enhanced



PRN using the anti-rabbit -- or the rabbit anti-IgG antibodies. They performed different studies to determine an appropriate dilution to use with the rabbit antibodies and the challenge with the development of that was as they were trying to reach the desired outcome of the greater than 95 percent seroconversion, the enhancement was also causing greater than 10 percent of pre-positive rate which, from what I've been told, in the general population the expectation is around a 10 percent pre-positive. So going above that would -- is not expected.

So after conducting a few studies they reached conclusion on the optimal dilution to use with the rabbit antibodies, and that would obtained their desired outcome of having a greater than 95 percent seroconversion and less than 10 percent pre-positive rate.

Q. Do you have the -- strike that.

Do you consider yourself to have the expertise to evaluate which of several assay designs for a mumps



neutralization assay would better correlate with protection from disease?

MR. KELLER: Objection. Overbroad.

THE WITNESS: So which methodology would have a better correlation to the disease?

BY MR. SANGIAMO:

Q. To protection from disease.

A. Protection from disease? Again, I believe that biological assays such as the plaque reduction assay would correlate better to protection from the disease than an ELISA.

Q. How about as between two different biological assays, do you have the expertise to short out which of those two would yield a seroconversion rate that correlates better to protection from disease?

MR. KELLER: Objection. Vague and ambiguous. Overbroad. Lack of foundation.

THE WITNESS: My expertise at least would point me towards that if

you were developing an assay, you would look to have a known control that would lead you to demonstrate a correlation against a known population.

BY MR. SANGIAMO:

Q. Correlation of protection from disease?

A. Yes.

Q. And is there such a thing for mumps?

A. I'm not aware.

Q. Then how could you form an opinion that one assay format was better than the other --

MR. KELLER: Objection. Argumentative.

BY MR. SANGIAMO:

Q. -- if you don't know that fundamental piece of information?

MR. KELLER: Objection. Argumentative. Lack of foundation. Overbroad.

THE WITNESS: Again, I'm not -- my experience, I've not seen the use of



rabbit antibodies in a biological assay to enhance the reaction. And based on that, the rabbit antibody wouldn't be present in a human reaction. It doesn't necessarily correlate to protection against the disease.

BY MR. SANGIAMO:

Q. You've been involved in one plaque reduction neutralization assay in your life. Right?

A. When you say "involved," you mean performed in the assay?

Q. Yes.

A. That would be -- yes, that is probably correct, yes.

Q. And that one assay used rabbit antihuman IgG. Right?

A. Yes.

Q. So what is it about your experience that would suggest to you that an assay would correlate better if it did not use rabbit antihuman IgG?

MR. KELLER: Objection. Asked and answered. Overbroad. Lack of



foundation.

THE WITNESS: So the actual response in the assay of an antibody neutralizing the virus on its own versus having an enhanced rabbit antibody that wouldn't be present, rabbit antibody potentially giving nonspecific neutralization in the assay would indicate to me that it wouldn't provide the same correlation that it would without.

BY MR. SANGIAMO:

Q. That sounds like your logic. I understand what your argument is. My question is, what is it about your experience that would support that?

MR. KELLER: She's already testified about her experience --

BY MR. SANGIAMO:

Q. You referred to your experience being a basis for your conclusion. Now I'm asking what is your experience that you're referring to?

MR. KELLER: Asked and



answered. This is like the fifth time around. If you want to answer it again, you can answer it again.

THE WITNESS: I do have experience performing other -- performing ELISAs where rabbit anti -- sorry, rabbit antibody is used. I have performed other plaque assays. We haven't used animal antibody. So that's the basis of my response.

BY MR. SANGIAMO:

Q. Do you have a belief as to what the efficacy rate is for the mumps component of the MMR?

MR. KELLER: Objection. Overbroad. Lack of foundation.

THE WITNESS: I believe that the true efficacy rate has not been reported based on the current information that's been generated from Dave Krah's lab.

BY MR. SANGIAMO:

Q. What's the information from Dave Krah's lab that you say if reported would

affect the efficacy rate?
A. So --
MR. KELLER: Objection. Asked and answered. You can answer again.
THE WITNESS: So while I was at Dave Krah's lab, we performed testing related to what was referred to as Protocol 007 which is the clinical study to determine the seroconversion rates in different strengths of the vaccine, of the mumps vaccine. And based on that information and that protocol being completed and data being generated, the -- what I believe to be the end result of that study has not been reported as how effective the product is even at a decreased strength.
BY MR. SANGIAMO:
Q. So it's your belief that the end result of that study has not been reported? Is that what you just said?
A. I believe that the -- well, I know that the original data was being changed



as we were performing the testing. There was data that's been destroyed and, therefore, what hasn't been reported is the original results that should have come out of that study.
Q. If you turn to Exhibit 6 which is the Complaint. If you look at the bottom of the first page. Paragraph 2 reads: "Specifically, in an effort to maintain its exclusive license to sell the vaccine and its monopoly of the U.S. market for mumps vaccine, Merck has fraudulently represented and continues to falsely represent in its labeling and elsewhere that its mumps vaccine has an efficacy rate of 95 percent or higher."
Can you show me where on the label Merck says that the efficacy rate is 95 percent or higher?
MR. KELLER: Objection. Seeks a legal conclusion. You're having her interpret a legal document. You can answer.
THE WITNESS: So in terms of -- I guess I can answer just in the fact



that what's being reported in the label is that there's 96 percent neutralizing antibodies in a study that was -- in a different study that was done. And what -- what has not been reported is how effective the product is with the results that were coming out of the Protocol 007 study.
BY MR. SANGIAMO:
Q. Can you show me where in the label it says that the efficacy rate is 95 percent?
A. The label says that there's 96 percent mumps neutralizing antibodies and 96 percent from that study that was done. And which is -- which to me is a demonstration of the effectiveness of product and, therefore, based on newer data that we have about the effectiveness and the neutralizing antibodies, that data is not represented here.
Q. And, of course, you don't know whether the FDA would also interpret that 96 percent as representative of the efficacy of the product because I know you testified



this morning that you don't know how the FDA defines efficacy. Right?
MR. KELLER: Objection. Lack of -- calls for speculation. Lack of foundation.
BY MR. SANGIAMO:
Q. Right, ma'am?
MR. KELLER: Let me finish my objection, Dino. I give you the courtesy of letting you ask -- finish your questions.
You can answer.
THE WITNESS: I do know that the label says 96 percent neutralizing antibodies which is not the percentage of neutralizing antibodies that would be concluded based on the assay that the PRN that was being performed as part of Protocol 007.
BY MR. SANGIAMO:
Q. My question is, you don't know whether the FDA would interpret that 96 percent seroconversion rate as being representative of the efficacy rate because I

think you testified this morning you don't know how the FDA defines efficacy. Right?

MR. KELLER: Objection. Lack of foundation. Calls for speculation.

THE WITNESS: And in the Complaint I didn't say that this was the FDA's definition of efficacy.

BY MR. SANGIAMO:

Q. So whose definition is it?

A. It's based on what we filed, myself and Steve who filed the Complaint, is the effectiveness of the product.

Q. So it's your definition?

MR. KELLER: Objection. Calls for a legal conclusion. Calls for speculation. Lack of foundation. Seeks an expert opinion from a lay witness. You can answer now.

THE WITNESS: Yes, based on how the Complaint was written.

BY MR. SANGIAMO:

Q. Why did you file this lawsuit?

MR. KELLER: Objection. Vague and ambiguous. You can answer.



THE WITNESS: I filed it because based on what I saw in Dave Krah's lab of falsifying data and knowing that that was wrong, knowing that the protocol was conducted and completed, that protocol supported a label change to reduce -- to allow for a reduction in the strength of end expiry of the product. And that was what was being measured as a part of the protocol during my time in Dave Krah's lab.

BY MR. SANGIAMO:

Q. What did you hope to accomplish by filing the lawsuit?

MR. KELLER: Objection. Vague and ambiguous. Calls for speculation. Lack of foundation. Seeks a legal conclusion. You can answer.

THE WITNESS: So I wanted to be able to bring awareness to the fact that the data that was found was not being reported so that the children who are being vaccinated and their parents



or guardians could make a decision on the basis of the data that is available for the product.

BY MR. SANGIAMO:

Q. How did you think this lawsuit was going to accomplish that?

MR. KELLER: Objection. You can answer that question as long as you don't disclose any communications with your counsel. To the extent that you can answer the question without disclosing communications with your counsel, you can answer. If you cannot, do not answer that question.

THE WITNESS: That's a lot of information.

I guess in the simplest form is that if we raise a complaint to identify something that's wrong, it's my belief that it would be -- that the just thing would be accomplished and it would be corrected.

BY MR. SANGIAMO:

Q. Now, you're seeking recovery



for losses that you say the CDC incurred. Right?

MR. KELLER: Objection. Seeks a legal conclusion. You can answer.

THE WITNESS: That is what is filed in the Complaint, yes.

BY MR. SANGIAMO:

Q. You're not out of pocket any money based on what's alleged here in this Complaint. Right?

A. Correct.

Q. Why didn't you just go tell the CDC?

MR. KELLER: Objection. Calls for speculation. I will, again, instruct you not to disclose any communications you had with counsel that you would have to disclose in order to answer that question. If you can answer the question without disclosing communications you had with counsel, you can.

THE WITNESS: I don't know if I thought about it much. I mean, it

wasn't about what the CDC was doing but more about what Merck was doing. So I wanted to be able to address it directly with Merck.

BY MR. SANGIAMO:

Q. When did you first contact a lawyer about filing this lawsuit?

A. I want to say 2009, 2010.

Q. What were you doing 2002, 2003, 2004, 2005 where all these parents you said were not able to make an informed decision and you had all this information, why didn't you just disclose it then?

MR. KELLER: Objection. Calls for -- you can answer. Objection to form.

THE WITNESS: When my time that I worked at Merck, while I was there, I did raise and elevated the issue within Merck. After I had left Merck, I still was working full time, raising a family. At the time when the label change came out in 2007, which is, again, based on the Protocol 007 being



the information that was available at the time of the submission, the -- that drawing the conclusion of allowing for the label change based on that data led me to raising the case at that point.

BY MR. SANGIAMO:

Q. 2007?

A. Yeah, after 2007.

Q. I thought it was in 2001 when you discovered that as a result of what you were seeing in the lab, that the vaccine had significantly diminished efficacy. Isn't that what you told me before?

A. Yes.

Q. So why didn't you let the CDC know at that time?

MR. KELLER: Objection. Lack of foundation.

THE WITNESS: At that time the FDA was contacted, not the CDC.

BY MR. SANGIAMO:

Q. How about after that?

MR. KELLER: Same objection.

THE WITNESS: I had left the



laboratory. I wasn't aware of what was being done with the data after I had left.

BY MR. SANGIAMO:

Q. Now, if you had simply told the CDC what you knew, then that wouldn't lead to any financial benefit for you. Right?

MR. KELLER: Objection. Lack of foundation. You can answer.

THE WITNESS: Again, I don't know what it would have led to, but as far as making the implication that I would be getting financial -- I guess in settling the case, getting a financial, I want to call it reimbursement or whatnot, that's not the reason I filed the case.

BY MR. SANGIAMO:

Q. That played no role in your thought process. Right?

A. No. Again, I work in the industry so I'm really putting myself out there by being a part of this case.

Q. What do you mean when you say



you're putting yourself out there by being part of this case?

A. The fact that I would raise a concern or an issue to a lawsuit is something that could be viewed by others as -- I guess could question my -- I don't know what to say -- my loyalty to a company. It depends on the company or the way that they view it versus -- I can't say what others would think, but I do know that it does allow an opportunity for others to make judgment.

Q. Has anyone made such judgments, to your knowledge?

A. No.

Q. So the reason you think you're putting yourself out there is based on speculation that somebody might make such a judgment. Is that a fair statement?

A. Yes.

MR. KELLER: Objection.

BY MR. SANGIAMO:

Q. If you go to page 7 -- I'm sorry, Exhibit 7, page 16, third paragraph down, I'm going to read it into the record,

"Relator had multiple communications with Relator Krahling about topics relating to allegations in the Complaint regarding the mumps vaccine between 2001 and 2010. Most of these communications took place in person at Merck's facility where they worked in West Point, Pennsylvania. In particular, Relator recalls having...discussions with Relator Krahling while they were both employed at Merck regarding the fraudulent methods mandated by Krah for the Protocol 007 testing and ways of avoiding compliance with these mandates. Relator also met with Relator Krahling at Relator's home in Pennsylvania after Krahling left Merck, and several times at her home in Connecticut after they both left Merck."

That's the end of that quote which is from your response to Interrogatory Number 5, not the entire response, but it's a portion of the response.

A. Uh-huh.

Q. How many times in total do you think you met with Mr. Krahling after he left



Merck?

A. In person?

Q. Yes.

A. I would say a handful of times, if that.

Q. Five or less, is that fair?

A. Yes.

Q. Was anyone else present at any of those meetings?

A. So the first couple of times that we met while I was still in Pennsylvania. Or at least there was at least one instance where there were other co-workers from Dave Krah's lab who were in attendance. After that, we didn't meet again until he came to my house in Connecticut and he came -- I believe he came by himself one time and then came with my legal counsel.

Q. You met twice with him after he left Merck prior to him appearing with legal counsel. Is that right?

A. Yes.

Q. One of those two times it was just the two of you, and one of those two



times it was the two of you along with some other people from the lab at Merck?

A. Yes.

Q. Do you remember who those other people were?

A. I would say, I believe, Frank Kennedy was there, Suzanne Maahs and Jon Gombola.

Q. Is that it?

A. That's all I recall.

Q. If you have to provide an approximation of the dates of those two meetings, what would your best approximation be?

A. I would say the meeting, the first meeting with a group of people was either late 2001 or -- it was probably late 2001, I'm thinking. When I met with Steve when he came to my house in Connecticut sometime I'm going to say after 2007, prior to 2009 around.

Q. Have you ever been represented in this litigation by a man named James Moody?

A. Not that I -- no.



Q. When Mr. Krahling came to visit you in 2007, was that a meeting that was at his suggestion or your suggestion?

A. At his suggestion.

Q. Had the two of you spoken at all between that 2001 meeting at your house and the 2007 meeting at your house in Connecticut?

A. Not that I recall, no.

Q. Had you exchanged e-mails?

A. No.

Q. Did he just call you in 2007 and suggest that you meet?

A. Yes.

Q. Did he say why?

A. He talked about the -- what we experienced, again, in Dave Krah's lab with the falsification of the data, and we talked about the protocol being completed and also to discuss the label change as well.

Q. What else do you recall about those discussions?

A. I don't recall much. I know that I basically told them I still supported

what I did when I was there, that it was wrong what was being conducted in the laboratory.

Q. Did he tell you that he was contemplating a lawsuit?

A. Yes.

Q. Did he tell you that he had been contemplating that for some time?

A. I don't recall.

Q. Did he give you any indication at all about how long he had been contemplating that?

A. I know he was following information around the vaccine. That's all I know.

Q. I thought you said a minute ago he was contemplating a lawsuit?

MR. KELLER: Objection. Mischaracterizes her testimony.

BY MR. SANGIAMO:

Q. Did you have any basis for thinking he was contemplating filing a lawsuit besides the fact that he was following the vaccine?

A. Just following the vaccine does



not necessarily mean he would file a lawsuit.

Q. I thought you had -- perhaps I got it wrong. I thought you had said that your impression when you met with him in 2007 was that he had been contemplating filing a lawsuit?

A. At that time, yes, versus what he had been doing prior to that.

Q. What did he tell you about that effort to file a lawsuit or that contemplation of filing a lawsuit?

MR. KELLER: Objection. Lack of foundation.

THE WITNESS: That he was looking into finding legal representation.

BY MR. SANGIAMO:

Q. Did he tell you he had been trying to do that?

A. I don't know if he might have mentioned that he reached out to somebody else previously. I think that's what he said.

Q. To another attorney?

A. Yes.

Q. Did he tell you what that



attorney had told him about the viability of any lawsuit?

A. No.

Q. How much time between when you had that meeting at your house and when he subsequently met with you with legal counsel?

A. Again, it was in the span of between 2007 to 2009.

Q. Would it be fair to say that Mr. Krahling persuaded you to join this lawsuit?

MR. KELLER: Objection.

BY MR. SANGIAMO:

Q. Would that be a fair characterization in your view?

A. I wouldn't characterize it as persuasion, as informing me of the developments. As far as whether or not I wanted to participate was my decision.

Q. Did you have discussions about that outside the presence of counsel?

MR. KELLER: With whom?

THE WITNESS: Right.

BY MR. SANGIAMO:



Q. With Mr. Krahling.

A. I can't recall.

Q. Do you recall Mr. Krahling identifying any pros, advantages for you if you joined the lawsuit?

A. No.

MR. KELLER: How long have we been going? Whenever you get to a comfortable change, just a restroom break. We've been going an hour.

MR. SANGIAMO: At this time, we can do it right now.

VIDEOGRAPHER: The time is 3:02. Going off the video record.

- - -

(A recess was taken.)

- - -

VIDEOGRAPHER: The time is now 3:21. This begins disc five. You may proceed.

BY MR. SANGIAMO:

Q. Ms. Wlochowski, in general terms, what projects did you work on in Dr. Krah's lab?

A. General terms, I worked on testing for Protocol 007 as well as I was conducting some supplemental testing for the mumps neutralization assay. I also conducted some assays for VZV studies, and I believe that was -- that I can recall what I worked on generally.

Q. What was the supplemental testing for the mumps neutralization assay?

A. There were some different -- from what I can remember, there were some different testing we did on passage, whether it was high or low passage of the cell lines that we were using. That's all I can remember at this point.

Q. The Protocol 007 testing that you referred to, that's a reference to running the plaque reduction neutralization assay?

A. Correct. As well as the supplemental testing.

Q. You did not work on the mumps ELISA assay during your time at Merck. Correct?

MR. KELLER: Objection. Vague and ambiguous.



THE WITNESS: Can you define what you mean by work on the ELISA assay?

BY MR. SANGIAMO:

Q. Is there some sense of the meaning of the term "work on" that would fit what you did on the ELISA assay?

A. So the ELISA assay was based, the development was based on correlation to the PRN assay that I performed. So to the extent that the correlation was based on the work I did, was my involvement with the ELISA assay at that time.

Q. Your involvement, then, with the ELISA assay consisted of running of the plaque reduction neutralization assay. Correct?

A. Correct.

Q. When is it that you came into the belief that the ELISA assay was correlated to the plaque reduction neutralization assay?

MR. KELLER: Hold on a sec. Objection to form. Lack of foundation. You can answer.



THE WITNESS: I'm trying to think.

BY MR. SANGIAMO:

Q. I can make this easier for you, Ms. Wlochowski. Was it while you were working at Merck?

A. Yes.

Q. Was it while you were in Dr. Krah's lab?

A. Yes.

Q. How did you hear about that?

A. The part of the -- I'm trying to recall. Part of the information that talked about the development of the PRN also talked about the ELISA.

Q. You just said part of the information that talked about the development of the PRN. Are you referring there to the document that you testified about earlier that Mr. Krahling showed you?

A. Correct.

Q. Did that document say that the correlation had actually occurred?

A. No.



Q. That wouldn't make any sense, right?

A. Right.

Q. Because you hadn't run the plaque reduction neutralization yet?

A. Right.

Q. So do you know if that correlation ever occurred?

MR. KELLER: Objection. Overbroad.

THE WITNESS: While I was at Merck?

BY MR. SANGIAMO:

Q. Right now the question is do you know?

MR. KELLER: Overbroad.

THE WITNESS: Currently I do know.

BY MR. SANGIAMO:

Q. When did you learn that?

A. As part of the case.

Q. So you learned that in conjunction with this lawsuit? Yes?

A. Yes.

Q. What specifically did you do on the plaque reduction neutralization assay in Dr. Krah's lab other than the supplemental testing that you were describing related to the passaging of cell lines?

A. I believe I performed the assay in its entirety so I set up the serum dilutions, I inoculated the plates. I fixed and stained the plates and I performed counting on the plates.

- - -

(Exhibit Wlochowski-9, Documentation of Work Activities, 00000272, was marked for identification.)

- - -

BY MR. SANGIAMO:

Q. Ms. Wlochowski, you've just been handed what's been marked as Exhibit 9. Do you recognize this document?

A. Yes, I do.

Q. What is it?

A. This is just a document I created for myself to outline the activities of work that I conducted in the lab from my



start date in January through April.

Q. Are you sure that you created it -- strike that.

Do you know when you created it?

A. I don't recall exactly when, but based on the last date entry there, it's April 11th, it's around that time frame.

Q. I'm sorry, I don't mean to nitpick on this. But do you have a basis to believe it was around April 11th other than seeing that date there?

A. If there -- if it was late -- well, obviously if it was earlier, I couldn't have written the other dates, but if it was later in time, I would have likely filled in more information up to the date that it was being documented.

Q. Why is it that you wanted to document your work activities from your start date until whenever it was that you prepared this document?

A. I was seeing things in the laboratory that I wasn't comfortable with,



that in my work experience had not been exposed to before and I wanted to document the activities that were occurring.

Q. And that's what this document does. Right?

A. Correct.

Q. Did you end up showing this document to anybody?

A. While I was at Merck?

Q. Yes.

A. No.

Q. Did you intend to show it to someone when you first created it?

A. My intent was really my record when I created this.

Q. Why did you want a record?

A. So, again, I could keep track of the activities because I felt like there were things that were being done wrong in the lab and I wanted at least to have information around that.

Q. Were you contemplating filing a lawsuit based on what's described here in this document?



A. No.

Q. Maybe we can go through some of the concerns you express in the document. At the top there is a section that begins with "Start date," and the first entry there reads: "offered no direction or training." I gather that's a statement that neither Dr. Krah nor anyone else in the lab provided you with what you consider to be the adequate direction or training?

A. I believe it was more geared towards receiving no training from my supervisor which was Dave Krah.

Q. Did you receive training from others?

A. From what I can recall, I received training from, when I first started there, from another co-worker in the laboratory.

Q. Who is that?

A. Frank Kennedy.

Q. What did he train you on?

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

passaging cell lines, so he trained me on that.

Q. Were you working on anything else when you first started working there?

A. I can't recall. My recollection is mainly working on the passaging and maintaining of cell lines. I also, I think, was involved in performing the VZV assays. I originally was not involved in performing the mumps assays because when I joined Merck, I was tested for mumps antibody titers and I was -- I didn't have the seroconversion needed for -- to be able to work with the virus so I needed to receive a booster of the vaccine.

Q. Did you start working on the VZV assays right when you arrived at Merck in January?

A. I cannot recall when I started conducting those assays.

Q. So it's possible that the only thing you were actually working on at the beginning of your tenure at Merck was just maintaining the cell lines. Right?

A. It's possible, yes.



Q. You did receive training on that, but it was your belief that the training should have come from Dr. Krah, not from Mr. Kennedy. Is that a fair statement, fair summary of your view?

A. That the training should have come from him?

Q. Uh-huh.

A. I think that it wasn't that he needed to train me on that specific duty, but to provide more guide -- I would have expected more guidance from my manager at the time.

Q. Do you feel that you were adequately trained on maintaining the cell lines?

A. As far -- yes, I mean, that basic -- yes.

Q. That was right in your wheelhouse, wasn't it?

A. Yes.

Q. The next line reads: work hindered by social dynamics in the lab. What does that mean?

A. There were, I guess, certain --



I'm just trying to think about the timeline. Basically there was certain relationships in the lab where people were -- seemed to receive more information or different items such as gifts or exchanges of things that I wouldn't necessarily expect to occur in a workplace. That kind of from my perspective felt like I wasn't being treated the same as my co-workers.

Q. So the concerns about the social dynamic were in the nature of people getting more information than you and people receiving gifts that you weren't receiving? Right? You mentioned those two things?

A. Yup.

Q. Was there anything else?

A. That's -- yeah, again, people weren't -- in my opinion, people weren't all being treated the same.

Q. Can you give me an example of information that you perceived that was being withheld from you?

A. So there were instances, from what I understand, that the procedure related to the assays were being provided to certain



people that worked in the laboratory, background on the assays that were being performed were being provided to certain people in the laboratory as well.

Q. You said that was your understanding. What was that understanding based on?

A. I had some conversations with Steve Krahling and others in the laboratory. I would, you know, discover somebody got something and -- yeah.

Q. Who else besides Mr. Krahling?

A. Probably Jill DeHaven. I -- you know, it's a small laboratory. Overhearing conversations with different people, whether it's Colleen Barr, people like that.

Q. I think you said, tell me if I have it wrong, I think you said that two examples of the information were procedures about certain experiments and background on assays?

A. Uh-huh.

Q. Are you referring there specifically to the mumps PRN assay?

A. Yes.
Q. For both of those?
A. Yes.
Q. You were not actually running the mumps PRN assay at the time. Right?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: It depends on what timeline you are referring to. I believe at a certain point in time I was performing the counting of the mumps assays.
BY MR. SANGIAMO:
Q. Was it your view that you needed to see the SOP for how the assay was run in order to perform the counting?
A. I did not need to see the SOP to perform the counting. However, it would be beneficial for me to have an understanding of the method that I am generating results for.
Q. Would it make for -- I'm sorry.
A. With that, the SOP does speak to how you report the results, whether it's, you know, document where, you know, the -- I'm



not sure about the documentation, but basically that there is an Excel spreadsheet file that's utilized in calculating the final results. And so it's all -- the results are part of the method. So, therefore, I should have had them in my hand.
Q. Well, you can do the counting without knowing what was done with the counting output. Right?
A. I could do the counting, but I should know what I should be doing with that data once I generate that data, especially since the data is being generated for a clinical trial protocol; that there should be more oversight and control of the data so that original data is not lost.
Q. You had never worked on a clinical trial at that stage of your career. Right?
A. Not directly, no.
Q. Indirectly you did?
A. If I was maintaining cell lines for other clients, yes, I could have potentially indirectly been supporting



clinical trials prior to.
Q. That's pretty indirect, isn't it?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: It still follows regulations.
BY MR. SANGIAMO:
Q. Can you give me some examples of these gifts that some were receiving that you didn't get?
A. From what I was told, you know, jelly beans or Easter baskets were being given to people within the laboratory. I don't -- I don't know more than that.
Q. Presumably that didn't happen until April, I would imagine?
A. Correct.
Q. So then as of January, the only social dynamics issue in the lab was just that people were receiving information about the PRN assay that you weren't getting. Is that fair?
A. So you said that the only thing



that was hindering my work in the lab was the fact that I didn't get the procedure. Is that correct?
Q. Yes, but I was being slightly more specific than that. I was saying the only thing related to this work being hindered by social dynamics in the lab was the fact that you didn't get the procedures and the background for the PRN assay.
A. And the overall guidance that I, you know, would -- again, going back to the direction provided by my supervisor.
Q. Anything else by way of the social dynamics in the lab at the start of your tenure there?
A. Meaning what time frame?
Q. January let's say.
A. Just the -- again, going back to not being treated the same as everybody else basically.
Q. Because you didn't get those procedures?
A. As far as communication and, yeah, interaction.

Q. Were people being nasty to you?
A. I guess it depends on -- it was more of an exclusion than being nasty.
Q. Were there certain people in particular that you thought were excluding you more than other people were?
A. I guess I look at it the opposite way and there was more people -- there was people that I was more -- interacting more with or felt comfortable interacting more than others.
Q. Who were they?
A. So Jill DeHaven sat next to me and I was comfortable working with her. The -- as far as how we operated within the laboratory, typically we worked in -- if we were in working in a BSC, we were typically working in pairs together so we would be in a small room together and I was typically paired up with either Frank Kennedy or Steve Krahling based on the fact that I worked, as well as they did, five days a week, eight-hour shifts. So we were on the same shifts. So typically we were paired together. So I also felt



comfortable with them. When we had -- we had a couple of interns that had started and also felt comfortable with them as well.
Q. Those were Jon Gombola and Suzie Maahs?
A. Correct.
Q. Were there others in the lab who worked five days a week, eight-hour shifts besides the people you've mentioned?
A. Well, Dave Krah worked full time. He came in typically later than everybody else. He worked kind of odd hours. But as far as 8:00 to 4:30, from what I recall, five days a week was myself, Steve and Frank as well as the interns.
Q. Did Colleen Barr work a five-day-a-week schedule?
A. She had a different schedule based on a family need.
Q. Did you find that irksome?
A. No.
Q. Continuing on in the document under March it says, "Dave went on vacation unannounced for 2 weeks."



A. Uh-huh.
Q. Is that a complaint?
A. That's, again, just my documentation to myself that typically when your manager is out of the office for an extended time, you're notified in advance of that just in case you need to prepare or ask about preparing for anything while they're out. So that was my reason for that documentation.
Q. Do you think he told other people?
A. That I do not know.
Q. Would that have been adequate if he had told other people in the lab? Would that have addressed your concerns?
MR. KELLER: Objection. Calls for speculation.
THE WITNESS: No, because I really -- unless he told those people to tell me. But, again, I don't think that as a manager, again, should treat his staff equally and informed all staff the same.



BY MR. SANGIAMO:
Q. When you say he sent an e-mail during that time period stating there would be no vacation allowed until after August --
A. Correct.
Q. -- is your concern there that there was not going to be any vacation allowed until after August or was your concern that he was sending such an e-mail while he, himself, was on vacation?
A. A little bit of both.
Q. There's then a reference in the next paragraph, if you will, about requesting error reports from you for aspiration of media from the wrong assay tray which does not adversely affect results. Do you remember that incident?
A. I do vaguely recall it, yes.
Q. Only vaguely?
A. Again, I don't recall the actual event itself, but I recall the context around the event.
Q. Do you remember being angry about it?

A. To myself internally, yeah. Again, I felt like I was being signaled out or treated differently than others in the laboratory.
Q. How so?
A. Because there were -- there are incidents of people making errors including Dave Krah where I didn't see the same type of report having to be done. Again, this was something that was just instituted at this time, was, you know, people make mistakes in conducting laboratory work so to think that this wasn't in place prior to that was a little -- the timing, I guess, again, felt like I was being singled out.
Q. Did you ever form any belief as to why Dr. Krah was singling you out this way?
A. I do not know why, no.
Q. I know you don't know because that would be speculation. Right?
A. Correct.
Q. Did you ever form a suspicion?
MR. KELLER: Same objection. Calls for speculation.



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 behind your back in this, let's say, the first three months that you were working there in the lab?



A. That was my feeling just based on walking, you know, into a room and the mood changing, yes.
Q. Were there certain people in particular who would be in the room in that kind of circumstance where the mood would change when you walked in?
A. Yeah, there were certain incidents of particular people aside from the people that I mentioned previously that were -- I worked with and was comfortable with.
Q. So who were those people where those incidents occurred?
A. So Colleen Barr would be one of them. Again, nothing -- I don't have anything against her, but I'm just, again, telling you my observation of what I saw when I walked in the room. She would mostly in the lab space area that we worked in, Jenny Kriss would also be in the room there, too.
Q. Did you have anything against Jenny Kriss?



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 some handwritten comments. Is that your handwriting?

A. Yes.
Q. First thing there is "mumps protocol." Is that a reference to what we were discussing earlier about you not getting the SOP until later than you thought you should have gotten it?
A. I think that that may have also referred to the experience I had witnessing changes to data while I was conducting the PRN or performing the counting of the PRN assay.
Q. That's what that refers to?
A. Yes.
Q. When did you write that?
A. Again, going back to after April time frame.
Q. But you don't know when?
A. No.
Q. Did you think there was research fraud going on at the time?
A. Research fraud?
Q. Yes.
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: What do you mean



by "research fraud"?
BY MR. SANGIAMO:
Q. Did you think that what was going on at the time fit the description of what you would have called research fraud?
MR. KELLER: Same objection. Lack of foundation.
THE WITNESS: I don't know that I would call something research fraud. The data was being falsified.
BY MR. SANGIAMO:
Q. So data could be falsified but that might not be fraud, is that what you're saying?
MR. KELLER: Objection. 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 at that time is this data, again, was being conducted as part of a clinical trial that if the data that was



reported the way it was being reported would be fraudulent.
BY MR. SANGIAMO:
Q. It was your opinion that the data being reported was fraudulent?
A. If it was -- yes, if the intent was to use the data for the trial, then it would be fraud, yes.
Q. You knew that the intent was to use the data for the trial. Right?
A. It was my assumption, that's my expectation.
Q. The way you captured is very serious -- strike that.
You agree that that's quite serious, isn't it, if you're using data fraudulently for a clinical trial?
A. Yes.
Q. Extraordinarily serious, isn't it?
A. Yes.
Q. So the way you captured it on this document was you wrote the words "mumps protocol?



A. Yes.
Q. Is that your testimony?
MR. KELLER: Asked and answered. Argumentative.
THE WITNESS: Yes.
BY MR. SANGIAMO:
Q. Right above where you wrote the thing about the jelly bean?
A. Yes.
Q. Why didn't you provide more detail about the fraud that you say you were witnessing?
A. So this document, again, was an outline of my activities that I was conducting. I believed I used this as part of 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 log, what's that?
A. I don't remember.
Q. Discrimination, what's that a

reference to?
A. Again, being -- not being treated the same as the others in the laboratory.
Q. So that wasn't -- strike that.
Did you have in mind gender-based discrimination?
A. No.
Q. Is there some other group that you feel that you're a part of that was discriminated against as a group in the lab or was this just discrimination as to you personally?
A. I guess the -- if I could use the word "click" as you had before, maybe discrimination of being in the click or not the click.
Q. This is a click consisting of whom?
A. Those who Dave seemed to interact with on a regular basis versus those who didn't.
Q. Who were they?
A. Mary Yagodich, Colleen Barr, Jenny Kriss. That's kind of, I guess, the



extent.
Q. Right below discrimination it says, "hostile." Is that referring to anything other than what we've been talking about?
A. No.
Q. What's the word underneath that?
A. It says -- I think it says, "injust."
Q. What's that a reference to?
A. I can't remember. I don't know.
Q. I apologize, Ms. Wlochowski. I think but I'm not sure that your testimony might have been inconsistent on this, but ultimately the transcript will tell us. But I'll nevertheless ask again just so I'm clear.
Did you testify that you created this document, the one we were just looking at, in preparation for a meeting with HR or did I get that wrong?
A. I think maybe not in the initial intent of creating the document but as



I kept the log or kept this information or defined this outline, I believe that I used this as a supporting document when I went to have a discussion with HR.
- - -
(Exhibits Wlochowski-10, Outline for HR discussion, 00000273 and Wlochowski-11, Work summary, 00000274, were marked for identification.)
- - -
BY MR. SANGIAMO:
Q. Ms. Wlochowski, you've just been handed documents marked as Exhibits 10 and 11. And I'm just going to go through them with you. Before we do that, I just wonder if you could shed any light on something. The documents have these numbers we call Bates numbers down at the corner that the lawyers put on before they produce documents.
A. Okay.
Q. These two are sequential. Exhibit 10 is 273 and Exhibit 11 is 274. And then Exhibit 11 down in the bottom right -- sorry, bottom left-hand corner says, "Page 2



of 2." Do you think that these two pages were part of the same document?
A. I don't -- I don't think so. I think they were independent of each other. I think the page number is -- it's not representative of any other page to this document. Meaning that there was no other -- there was no page 1.
Q. Did you create these documents on your home computer or did you create them in work? And by "these," I mean Exhibits 9, 10 and 11.
A. I believe I created them at home, my home computer.
Q. Did you create them all at one sitting or did you revise them from time to time? What do you recall in that regard?
A. No, I think they were under 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 happening.
Q. Is it fair to say you were very

unhappy during your time at Merck during these first three months that were -- three and a half months that were described in Exhibit 9?

A. Unhappy in what regard?

Q. I'm sorry, unhappy about your job.

A. Unhappy about my job?

MR. KELLER: Objection. Vague and ambiguous.

BY MR. SANGIAMO:

Q. Do you know what unhappy means?

A. Yes, I know what unhappy means. Yes, I think that it was a challenge to be in this environment. So for me, I also -- I took my job very seriously and wanted to be recognized for the work that I do. So part of this I, again, felt like there was a threat to my position there. So part of it was documentation if there ever came some other information that was in conflict with what I perceived as my performance in the laboratory.

Q. You were worried about getting fired. Is that what you're saying?

A. I don't know that I was worried about being fired so much as my reputation in the workplace.



Q. Your reputation at Merck, is that what you mean?

A. At the time, yes. Or for my career in general. If there were things that were going to be documented about me in my file, my employee file, could be -- impact future, my career.

Q. Had you done this at other jobs, make a record of the things that you found dissatisfactory about the job during your first few months there?

A. As far as this, no, I have not done documentation outlined like this.

Q. Have you done anything similar to that?

A. I've saved e-mails, exchanges.

Q. In connection with other jobs?

A. Yes.

Q. Saved them for what purpose?

A. If questions came up in the future, that I would be able to refer back to an e-mail.



Q. Questions about things you might have done wrong?

A. No.

Q. Questions about things you might have been accused of?

A. No, just -- no, not about me.

Q. If we look at Exhibit 10, the first section is called "Poor Management." Is that a reference to Dr. Krah?

A. Yes, at the time I worked for Dave Krah.

Q. You felt you were getting a lack of respect and recognition. Is that right?

A. I did feel that way, yes.

Q. You felt that he was a poor communicator?

A. Yes.

Q. It says, "lack of trust (does a lot of lab work himself)." Was it your belief that he did not trust any of the people in the lab or just that he didn't trust you?

A. Both. I think there were things that he conducted on his own to have



that, I guess, just direct interaction with it versus, you know, also it seemed to be as far as what he delegated for me to work on was also less than what he, you know, would assign to other people in the lab.

Q. You found the work assignments you were getting degrading. Is that right?

MR. KELLER: Objection.

THE WITNESS: I felt that I wasn't being challenged.

BY MR. SANGIAMO:

Q. You considered them degrading, didn't you?

MR. KELLER: Asked and answered. This is harassing.

MR. SANGIAMO: She didn't answer.

THE WITNESS: I don't --

MR. KELLER: She's answered.

THE WITNESS: If you interpret not being challenged as degrading, yeah.

BY MR. SANGIAMO:

Q. Would you use that term to

describe it?
A. To the extent that -- of the work that I was assigned to do, yeah, at times, yes.
Q. Did you think that you were more skilled than the other people in the lab?
A. No, I didn't think that I was or I wasn't. I felt them my equivalence.
Q. You felt you were as skilled as the other people in the lab but not more skilled. Is that fair?
A. Yes, I felt like -- yes.
Q. Under "Favoritism" back on Exhibit 10, it says, "unable to separate social versus professional relationship with certain employees." It says, "i.e. birthday luncheon, gifts, etc."
Gifts, is that the thing for the Easter baskets and jelly beans?
A. Yes.
Q. Where it says, "birthday luncheon," what's that mean?
A. He would take certain staff members, when it was their birthday, take them



out to lunch with other staff members.
Q. How many times did that happen?
A. I can't recall how many times.
Q. More than one?
A. Not that I can recall.
Q. Just one you can recall?
A. Yes.
Q. And what happened, you didn't get invited to that?
A. Me and others didn't get invited.
Q. Did you find that insulting?
A. As coming from a manager, yes.
Q. Then under "Discrimination," there are, looks like, five starred items and within the first one there are two bullets, if you will, the second of which reads: "left out of the loop to protect others who feel threatened by my experience." There's no subject in that sentence. Were you saying that Dr. Krah left you out of the loop in order to protect others who feel threatened by your experience?
A. So can you repeat the question?



Sorry.
Q. Is the correct interpretation what is written there that you felt that Dr. Krah was leaving you out of the loop in order to protect others who feel threatened by your experience?
A. That was my feeling at the time.
Q. Who were the others?
A. Those that -- potentially those that were considered part of his click.
Q. What made you think that they felt threatened by your experience?
A. It was just, again, the perception I had based on that there wasn't that interaction between myself and my co-workers to say, to help me get oriented in the lab as I started working there. Typically when, you know, I'm used to working in an environment with others who will provide you guidance because you just started. Basically to show you the ropes of what we were all working together as a team to do.
Q. A couple of lines down it says, ERROR REPORTS -- specifically designed with



the intent to facilitate your departure. Do you see that?
A. Yes.
Q. Did you believe that the error report policy was specifically designed with the intent to facilitate your departure from Merck?
A. Based on my discussion with others in the laboratory.
Q. That was your belief?
A. Uh-huh.
Q. What were those discussions that you were just referring to?
A. That they were set up to have me -- basically to have -- to get rid of me as a worker within the laboratory.
Q. Who told you that?
A. Steve had the conversation because he was also involved in the conversation with the others in the laboratory. So Steve had discussed it with myself as well as Frank.
Q. So Steve told you and Frank that the error report policy was set up to

facilitate your departure?
A. My departure. I can't remember if he also told Frank it was also focused on him as well.
Q. How would that facilitate your respective departures? By creating a record of you having made mistakes, is that the idea?
A. Yes.
Q. Did anyone else tell you that that was Dr. Krah's intent besides Mr. Krahling?
A. Again, I saw comments being made by Dave how I made this error, but, you know, I'm not going to have to do an error report. So it basically, you know, suggested to me, again, that this was singling me out in the laboratory just based on what I heard from others within the laboratory that, you know, there's a -- the laboratory itself had a high turnover rate for people that worked there. So this wasn't, you know, just this type of treatment wasn't like something new to other people who had worked in the laboratory.
Q. You felt that Dr. Krah set up the error report policy to facilitate your



departure based on the fact that Mr. Krahling told you that's why Dr. Krah did it, and the fact that other people did not have to write up error reports under circumstances similar to yours when you had to write up error reports. Right?
A. Uh-huh.
MR. KELLER: Mischaracterizes her testimony. Go ahead. Sorry, you weren't finished.
BY MR. SANGIAMO:
Q. Anything else?
MR. KELLER: Mischaracterizes her testimony.
THE WITNESS: Not that I can recall at this time.
BY MR. SANGIAMO:
Q. Did Dr. Krah ever try to put you on probation?
A. No.
Q. How do you rate the possibility that Mr. Krahling was lying to you when he told you that that was Dr. Krah's intent with regard to the error report policy?



MR. KELLER: Objection. Calls for speculation. Lack of foundation.
THE WITNESS: Again, just based on different discussions within the laboratory about people saying, admitting that they wouldn't have to do that report when I would.
BY MR. SANGIAMO:
Q. How many times did that happen?
A. I can remember once specifically.
Q. Any others?
A. Not that I can recall.
Q. The next line says -- or the next star says, "degrading work, restricted from running assays." So the fact that you were restricted from running assays, you consider to be degrading. Right?
A. Yes.
Q. You felt you were above the work of whatever it was that you were doing, the maintaining the cell lines?
MR. KELLER: Objection.
THE WITNESS: I felt like I had more to offer and contribute to the



laboratory as a whole.
BY MR. SANGIAMO:
Q. Isn't maintaining cell lines exactly what you were doing at your last job?
A. For the temporary position, yes.
Q. Weren't you running the VZV assay at the beginning of your tenure at Merck?
A. Again, I don't recall when I started running them, but I do know that the workload was not the same, the assignments of the workload was not the same across the other workers in the laboratory.
Q. Do you take issue with the policy of you not being allowed to work with the mumps virus for the plaque reduction neutralization assay until you had demonstrated a positive titer?
A. No.
Q. You think that's a good policy?
A. Yes.
Q. Then you have a section "Injustice/Hostile Work Environment."
Do you see that?

A. I'm sorry?
Q. Do you see that section?
A. Yes.
Q. The second starred item there is "unacceptable behavior as a supervisor." Under that you have ridiculed past employees, has made derogatory comments about, quote, myself, which is a reference to you, Ms. Wlochowski. Right?
A. Uh-huh.
Q. What were the derogatory comments he had made about you?
A. I don't recall what he made about me, what comments he made about me.
Q. How did you know that he had made them?
A. So I know that, again, in my discussions with Steve but also going back to the previous point of ridicules past employees, I, myself have heard him, you know, make comments about other employees who have worked there. So for me that was, you know, again, not something that I have observed with previous or -- employers or, you know,



current. That I wouldn't expect a supervisor to be talking about his employees to other staff members.
Q. But did I hear you to say that your basis for believing that he had made derogatory comments about you is Mr. Krahling had told you that?
A. Yes, Mr. Krahling told me that. And, again, I also have had conversations with Jill and, you know, she would also acknowledge that as well.
Q. Ms. DeHaven told you that Dr. Krah had made derogatory comments about you?
A. She would be part of conversations with myself and Steve where she would acknowledge that as well.
Q. Could you explain what you mean by "she would acknowledge that"?
A. Any as far as discussions that we had and Steve made comments about, I spoke about derogatory comments, Jill also acknowledged them.
Q. Said, yes, I heard Dr. Krah say



that, did you say that kind of thing?
A. Yes.
Q. She did say that. She affirmed what Mr. Krahling was saying about Dr. Krah having made derogatory comments about you?
A. Yes.
Q. But sitting here, you don't recall what any of those derogatory comments were that were reported to you. Right?
A. Right.
Q. You said he "readily gives out confidential information about employees." What's that?
A. That, I can't remember what specifics were around that.
Q. Are you the one who heard him --
A. Yes.
Q. -- giving out confidential information about employees?
A. Yes.
Q. Do you remember what --
A. No.
Q. Do you remember what category of confidential information you had in mind



there?
A. No, I do not.
Q. Now, this document was written, Exhibit 10 here was written sometime after July 26, 2001. Does that sound right? I can tell you why I say that if it speeds things up at all.
A. Tell me why you say it.
Q. There's a reference in the middle of the document right around the "Discrimination" section which says, "RECEIVED OUTLINE OF HOW TO DO MUMPS ASSAY...JULY 26, 2001!!!!!!"
A. Okay.
Q. Does seeing that enable you to pinpoint any more when it is that you may have written this document?
A. Probably shortly after that because I believe I did have a discussion with HR at the end of July.
Q. Did you present this document to HR when you had that discussion?
A. Again, not that I recall. I don't think I have provided this copy. It was

just my thoughts in my head for a discussion with HR.

Q. You didn't come into that meeting with any documents?

A. I don't believe I did.

Q. Was this a meeting with Bob Suter?

A. Yes.

Q. Was anyone else present at that meeting?

A. Not that I recall.

Q. If you take a look at Exhibit 11. Do you know when that document was prepared? Can you approximate that?

A. Again, just going on the timeline that this goes through, September, I would say at the end of September.

Q. Towards the end of the first paragraph which is describing events of January and February, the last two sentences read -- well, last three sentences read: "I tried to keep an open mind about the situation and maintain a respectful professional relationship with everyone. This however was



to no avail since far too many premature judgments were made against me. The demands for social acceptance outweighed any asset I could bring to the table career wise."

What are the premature judgments that you're referring to there?

A. I think just from the start I 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 guess, you know, looking now, I didn't think that, but I did write that at the time. So, yes, I was -- had that -- I guess I had that



feeling that that was part of his plan, so I felt compelled to defend myself and stand up for myself. I, again, wouldn't define that into hatred as much as, you know, disrespect for what he, you know, I felt should have been doing as a supervisor of a staff.

Q. Well, you also thought he was making derogatory comments about you. Right?

A. Uh-huh.

Q. You thought he was giving you degrading assignments. Right?

A. Uh-huh.

Q. And you thought he was facilitating your social exclusion from the lab. Right?

A. Yes.

Q. And whatever you felt in response to that stopped short of hatred or was it hatred?

MR. KELLER: Objection. Asked and answered. Argumentative.

THE WITNESS: I would say stopped short of hatred.

BY MR. SANGIAMO:



Q. Did you feel anger?

MR. KELLER: Same objection.

THE WITNESS: Uh-huh. As I mentioned before, I was -- you know, internally, yes, I had some anger.

MR. KELLER: Let's take a 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.

Q. That happened twice. Right?

A. I don't recall. Are you saying there's two separate adjustments or --

Q. That is what I was saying. Is that your recollection?
A. I don't recall that, no.
Q. You just recall one?
A. Yes.
Q. Do you recall what the precipitating event was for that one request?
A. Based on -- sorry, what, why I needed different hours?
Q. Yes.
A. So my husband was taking classes at the time so I wanted to be able to fit my work schedule around being able to be home for my children.
Q. Did Dr. Krah accommodate that?
A. He did not immediately. There was not an immediate response to the request, as far as I can recall.
Q. How long did it take him to respond to the request?
A. I believe he had me submit some different documentation around that. I can't remember the details.
Q. Didn't he grant the request



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 anybody scheduled, you know, as a routine to



work on the weekends other than that schedules were rearranged to accommodate weekend coverage.
Q. Did he request volunteers to work on the weekend, to your recollection?
A. I believe so.
Q. Did you ever volunteer to work on the weekends?
A. I do not recall.
Q. You don't recall ever volunteering or you don't recall whether you ever volunteered? Do you see the distinction I'm drawing?
A. No.
Q. You do not have a recollection of having volunteered. Right?
A. I do not recall if I volunteered or not.
Q. Do you recall other members of the lab complaining to you about you making sexually inappropriate comments? Do you remember that?
A. No.
Q. Do you have a recollection of



telling Dr. Krah at one point that you were uncertain if you were counting plaques correctly?
A. I don't recall making that statement that I was uncertain.
Q. Did you ever seek his guidance for counting plaques?
A. I don't know if I sought out his guidance as he would provide guidance.
Q. So just to be clear, you don't have a recollection of you ever seeking out his guidance. Right?
A. On plaque counting?
Q. Correct.
A. I guess it depends on guidance because if there was a particular assay that had a different look to it, I would bring it to his attention.
Q. When you were at New Haven Hospital, did you ever have an occasion where you were uncertain about a plaque count when you were running the plaque reduction assay for the antiviral therapies?
A. I don't recall if I did.

Q. Was there a procedure in place for what you were to do at New Haven Hospital in that circumstance?

A. If I had a question about a plaque count, about a procedure about that? I don't know if there was a procedure about questions about plaque counts, but essentially in my work experience, if there is something that I see that I have a question about or think is an issue, I would raise it to my manager.

Q. Would you include plaque counts within that category of the kind of thing that you would raise with your manager if you had a question?

MR. KELLER: Objection. Calls for speculation.

THE WITNESS: Yeah, I guess, again, when you say raise a question about a plaque count, can you be more specific?

BY MR. SANGIAMO:

Q. Did you ever have uncertainty as to whether the well you were looking at



had, for example, seven plaques versus six plaques? I'm referring now to the work you did at New Haven Hospital.

A. I don't recall. Again, my experience, I would be trained to perform something during my training period. Yes, I would have questions that I would rely on either my co-workers or my management to provide me feedback on any questions that I would have.

Q. Were the plaques for the plaque reduction assay that you counted -- sorry, strike that.

Were the plaques for the plaque reduction assay that you ran at New Haven Hospital easier to count than the plaques in the mumps plaque reduction neutralization assay, harder to count or roughly the same?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: I don't know if I can make a comparison. They were different.

BY MR. SANGIAMO:



Q. Do you feel that your aptitude as a plaque counter for the mumps plaque reduction neutralization assay improved over the time period that you worked at Merck?

A. Yes, like any skill, your aptitude would improve. I do know, though, that there were many others in the laboratory that also conducted plaque counts that would raise questions, it still would continue to raise questions on plaque counts. As a general rule, as we were counting plaques in the laboratory, it was known across the lab staff that anything that we found pre-positive was unexpected. And so there was, you know, a feeling across the lab members that if the results of the plaque counting would give you something that would generate a pre-positive result, they would continue to look for plaques to find additional plaques in order to get the result that was expected as far as not having a pre-positive. The statement that, you know, Krah explained that I recall during my training is that, you know, in the patient population you wouldn't expect that people



would have -- that there isn't that level of having antibodies to mumps prior to vaccination, at least in, you know, a majority of the population and, therefore, it's not expected to see that result. That's what I recall as part of my training.

Q. When did you get this training?

A. Again, it was part of -- it was throughout the course of us conducting the plaque counting in the laboratory.

Q. Did you get it -- I'm sorry.

A. So Dave would, you know, look at the plates, be in the lab when we were counting. So he would provide guidance to various members within the laboratory.

Q. Did you get that training from him before you did your first plaque counts on the mumps plaque reduction neutralization assay?

A. I don't recall.

Q. Now, I'm going to have to reask a question I asked you a moment ago, because you gave a long answer, but it didn't -- I'm not sure I got the answer to the very specific

question I asked you, which is, do you feel that your aptitude as a plaque counter improved as regards to mumps plaque reduction neutralization assay over the course of your time at Merck?

A. Yes.

MR. KELLER: Asked and answered.

- - -

(Exhibit Wlochowski-12, E-mail exchange, 00048441 & 00048442, was marked for identification.)

- - -

BY MR. SANGIAMO:

Q. Ms. Wlochowski, you've just been handed what has been marked as Exhibit 12, which is an e-mail exchange between you and Dr. Krah.

MR. KELLER: Take a minute to read the e-mail.

MR. SANGIAMO: I'm sorry, what did you say, Jeff?

MR. KELLER: I'm asking her to review the e-mail if you're going to ask questions about it.



BY MR. SANGIAMO:

Q. You've read it?

A. Yes.

Q. Do you have a recollection of 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 cover the balance of the work with the remaining people, or I would be happy to cover this myself. This applies to everyone in the lab."

Do you remember what it is that you had -- strike that.

Do you remember what it is that had been discussed at the meeting that served



as the context for this first paragraph here?

A. Discussed at the meeting. I don't recall exactly what was discussed at the meeting. I believe that my discussion with him would be about being able to complete the amount of work that was assigned in the eight-hour day and being able to leave on time.

Q. This is your boss here offering to complete any projects --

A. Right.

Q. -- that you may not be able to complete in the workday. Right?

A. Yes.

Q. That's a pretty generous thing for a boss to do, don't you agree?

A. I agree. I think that, you know, it was not my intent for him to complete my work in the middle of me performing something. So, you know, again, it's -- yeah, it's a generous offer for him to do that. However, that was not the intent of what I was asking for.

Q. Did you thank him for it in



your response?

A. Not in this particular response, no.

Q. Down at the bottom of his 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 that he didn't distribute another error report made by somebody else to the rest of the lab where a suggestion of how we could prevent the issue was made. So, again, I was not informed of a change in our practices.

Q. But is it the case that you had written an error report that he did not distribute to the rest of the lab about an

error that you had made?
A. I don't know if he didn't pass it along. He said he didn't feel the need to pass it along, but I don't know if he did or did not pass it along to other people in the laboratory.
Q. Do you have a recollection of finding out that it was passed along?
A. I do not recall.
Q. Well, if he didn't --
A. I do know that others were aware that I was being made to write an error report.
Q. Well, there were two error reports. Right?
A. Yes.
Q. That you had to write?
A. That I recall, yes.
Q. Do you know if others were made aware of this particular error report that, from the way Dr. Krah's e-mail is phrased, it sounds like he did not circulate to the lab?
A. He -- again, if everybody already knew what the error was and that I was



required to write a report for it, they did know that.
Q. But you don't know whether the error report that he's referring to there is an error report that was made known to the entire lab. Right?
A. Right.
Q. Then his next sentence says, "Again, if you feel that there are other reports that should have been written, please let me know and I will either request one or clarify why one is not needed."
Looking at this now, would you say that that's an appropriate and responsible response by the boss to an inquiry from a member of his staff?
MR. KELLER: Objection. Lack of foundation.
THE WITNESS: That is an appropriate e-mail response, yes.
BY MR. SANGIAMO:
Q. Did you identify -- strike that.
Did you take him up on his offer to identify other reports that should



have been written?
A. I did not in this e-mail response.
Q. Did you ever?
A. I may have verbally based on my notes.
Q. But you don't have a recollection of that?
A. I do not.
Q. He responds to your e-mail and at the beginning he says, "Please feel free at all times to ask about any questions that come up."
A. Uh-huh.
Q. Did you take him up on that offer as a general proposition?
A. Yes, I did.
Q. Did he engage when you would present questions to him?
A. Typically he would respond to questions that I had. It wasn't always an immediate response, but, yes, he did respond to questions I had. He also makes note that, you know, here he did confirm that he passed on information to certain members of the lab



group but had stated that he may have missed providing it to me. You know, so that's just another example of him providing certain pieces of information to certain pieces -- certain people within the laboratory and just saying, you know, I left you out. And just, you know, in general from, again, all this interaction between myself and Dave and -- Dave Krah and the laboratory, based on the Exhibit 10, in addition to the other information that I documented for my outline for discussion with HR, I also documented that, you know, manipulation of data was also occurring at that time. So a mix of the interactions with his unprofessional behavior the way I saw it with the other events that were happening in the laboratory, had, you know, had played into my responses and interactions with Dave Krah.
Q. Okay. I'm going to need to -- I guess what I'll do is I'll move to strike that answer and then I'll just ask you the question again.
Would he engage when you would

present questions to him?
A. And I believe I answered that question.
Q. I know but then you inserted some other things about manipulation of data so I need to -- and including that in some prior documents. I need a clean answer to my question, which was would he engage when you would present questions to him?
A. Again, he would engage with a delayed response.
MR. SANGIAMO: Dino, you don't like her answers, I know you selectively are picking things out of exhibits, but, you know, if you want to make a motion to strike, this is not the appropriate venue. You can do that in front of a judge who can get the full record in front of you. She testified and answered your question. Appreciate you didn't like her answer, but we don't agree with your motion to strike. If you want to make that motion, bring it before the court.



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 discussion other than the information that was presented in Exhibit 10 was what I had



prepared and, you know, put together in preparation for the discussion.
Q. But you don't remember what you said to him at the discussion?
A. I don't remember the conversation, no.
Q. How long -- do you remember how long it lasted?
A. I do not. I do not.
Q. Do you recall what it was that you were hoping to accomplish in the discussion?
A. I just wanted to -- again, I felt that as if there were any documentation that -- or records that Dave was -- Dave Krah was maintaining on me, I also wanted to put on record my experience in the laboratory.
Q. Fair to say it was a defensive action on your part to protect yourself should it be the case that you were at risk of some sort of adverse action being taken against you? Is that fair?
A. I don't know if it was, you know, defensive, but also part of it making a



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 least setting up or arranging for the transfer. I can't recall if he was involved

in setting up an interview or how that occurred.
Q. In particular I gather you don't recall whether any of his activities in that regard were done by e-mail versus meeting versus telephone? Is that accurate?
A. I believe that I had e-mailed him about the actual transfer itself. There was an e-mail, but as far as phone call discussions or anything further than that, I don't recall.
Q. Did you form an impression of Mr. Suter as a professional?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: I don't have an opinion about him one way or the other.
BY MR. SANGIAMO:
Q. Is it your recollection that he handled the conversation with you responsibly?
MR. KELLER: Same objection.
THE WITNESS: I don't recall that there was much action after my discussion with him immediately, but, you know, the circumstances following



that, there was, you know, actions that were -- that occurred based on the additional findings of data manipulation within the laboratory.
BY MR. SANGIAMO:
Q. You just referred to some 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 that, the -- I had, you know, questioned Dave about the data manipulation that was occurring in the laboratory.
Q. So before you said something



about a finding of data manipulation. You're just talking about you having questioned Dave regarding your view that there was data manipulation? Is that what you're referring to?
A. Yes. Yep.
- - -
(Exhibit Wlochowski-13, E-mail exchange, 00000067, was marked for identification.)
- - -
BY MR. SANGIAMO:
Q. So Ms. Wlochowski, you've been handed what has been marked as Exhibit 13. Is that correct?
A. Yes.
Q. This is an e-mail exchange between you and Mr. Suter?
A. Yes.
Q. Down at the bottom of the e-mail we see -- sorry, mark this as 14.
- - -
(Exhibit Wlochowski-14, E-mail exchange, 00000072, was marked for



identification.)
- - -
BY MR. SANGIAMO:
Q. Strike the question I was just asking. Sorry, I've generated some exhibit 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.
Q. And then he responds to you a week later after your e-mail in which he says, "I meet...," I guess he meant I met, "...with Emilio on Friday. Per direction of Legal, all

aspects of your situation are on hold pending resolution of their investigation. I'll keep you informed."

Do you see that?

A. Yes.

Q. And then you then got back to him on September 6th asking if there's any new information?

A. Correct.

Q. Then he replied to you that day on that occasion, he replied to you the same day asking if you were free to talk that morning?

A. Correct.

Q. Is the gap in time between July 31st and, say, September 6th, is that the delay, I don't know if that's the word you used, but the delay in him responding to you in following up after the meeting that I think you referred to in your testimony?

A. Yes.

Q. Now, I think when that line of questioning began, I had asked you whether you felt that Mr. Suter had responded -- strike



that.

I think when that line of questioning began, I asked if you thought that Mr. Suter had acted in a responsible manner in his meeting with you on July 31st.

A. Uh-huh.

Q. I think you -- in your answer you mentioned this delay, I believe. But other than that, do you feel that he handled the meeting with you in a responsible manner?

MR. KELLER: Objection. Mischaracterizes her testimony. Go ahead and answer.

THE WITNESS: Again, I don't 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 don't know if that influenced the actions taken after our meeting.

BY MR. SANGIAMO:



Q. Did Mr. Krahling ever say to you that Mr. Suter told him that he would go to jail if he were to call the FDA?

A. He did tell me that, yes.

Q. Do you know if anyone was a witness to that alleged statement by Mr. Suter?

A. I do not know if anyone was a witness.

Q. Does that ring true to you?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: What do you mean by "does that ring true"?

BY MR. SANGIAMO:

Q. You've been in the pharmaceutical industry for almost two decades, I guess. Does that sound right, that an HR representative in the pharmaceutical industry would threaten someone they're going to go to jail if they call the FDA?

MR. KELLER: Objection. Calls for speculation. Vague and ambiguous. Lack of foundation.

THE WITNESS: To me, I don't --



to answer, I would not expect HR to say that, but I also would not necessarily use HR as the primary decision-maker on whether or not information needed to be reported to the FDA.

MR. SANGIAMO: Okay. Jeff, could we take a break now, I want to talk to the team here.

VIDEOGRAPHER: The time is now 5:23. Going off the video record.

- - -

(A recess was taken.)

- - -

VIDEOGRAPHER: The time is now 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 5:28. This concludes the video deposition.

- - -

(Witness excused.)

- - -

(Deposition concluded at 5:28 p.m.)



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

Linda Rossi-Rios, RPR, CSR
Notary Public



INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.



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ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

DATE SIGNATURE

Subscribed and sworn to before me this

_____ day of _____, 2017.

My commission expires: _____

_____

Notary Public

Assignment: PA 2632736

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| | | |
|---|---|---|
| UNITED STATES OF AMERICA ex rel., STEPHEN A. KRAHLING and JOAN A. WLOCHOWSKI, Plaintiffs, | : | CIVIL ACTION NO. 2:10-04374(CDJ) |
| vs. | : | |
| MERCK & CO., INC., Defendant. | : | |
| IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION | : | Master File No. 2:12-cv-03555(CDJ) |
| THIS DOCUMENT RELATES TO: ALL ACTIONS | : | |

- - -

June 14, 2017

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

- - -

Continued videotaped deposition of JOAN L. WLOCHOWSKI, taken at the offices of Morgan & Lewis, 1701 Market Street, Philadelphia, Pennsylvania 19103, beginning at 9:30 a.m., before LINDA ROSSI-RIOS, a Federally Approved RPR, CCR and Notary Public.

- - -

VERITEXT LEGAL SOLUTIONS
MID-ATLANTIC REGION
1801 Market Street - Suite 1800
Philadelphia, PA 19103

APPEARANCES:

On behalf of the Relators

CONSTANTINE CANNON LLP
BY: ROBERT L BEGLEITER, ESQUIRE
and
MARLENE KOURY, ESQUIRE
335 Madison Avenue
New York, NY 10017
212-350-2700
rbegleiter@constantinecannon com
mkoury@constantinecannon com

On behalf of the Relators

KELLER GROVER LLP
BY: JEFFREY F KELLER, ESQUIRE
1965 Market Street
San Francisco, CA 94103
415 543 1305
jfkeller@kellergrover com

On behalf of the Defendant, Merck & Co , Inc

MORGAN LEWIS & BOCKIUS LLP
BY: LISA C DYKSTRA, ESQUIRE
1701 Market Street
Philadelphia, PA 19103
215-963-5000
ldykstra@morganlewis com



APPEARANCES (cont'd ):

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
mfroberts@venable com

ALSO PRESENT:

DANIEL GRBICH, Videographer

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EXHIBITS





- - -

VIDEOGRAPHER: We are now on the record. The date today is June 14, 2017. This begins disc one of the continuation of the deposition of Joan Wlochowski. You may proceed.

- - -

JOAN L. WLOCHOWSKI, after having been previously sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. SANGIAMO:

Q. Good morning, Ms. Wlochowski.

A. Good morning.

Q. You understand that you are still under oath from yesterday. Right?

A. I do.

Q. Did you have an understanding at the time that you were working in Dr. Krah's lab of what the purpose was of running the plaque reduction neutralization assay?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: Can you elaborate on the plaque reduction assay?

BY MR. SANGIAMO:

Q. Was there more than one plaque reduction neutralization assay that you were running in Dr. Krah's lab?

A. There were different versions of -- different purposes for running the plaque reduction neutralization assay.

Q. Okay. What were they?

A. So in regards to mumps --

Q. I'm sorry, this is -- I'm asking about your understanding at the time that you were working in the lab.

A. Okay. In regards to the mumps neutralization plaque -- sorry, PRN, the multiple purposes we were running it for was for Protocol 007 testing as well as there were some supplemental assays that we were running for looking at different passage levels of cell lines. And for Protocol 007, the intention, again, was to try to achieve



greater than 95 percent seroconversion rate while maintaining also a less than 10 percent pre-positive rate.

Q. What was the source of your understanding that the purpose of running the assay was to support Protocol 007?

A. The -- there was multiple sources. So there was a document that provided some history on the development of the assay and what the desired outcome was. Dave Krah himself had told us on multiple occasions that we were also to -- that the pre-positive results are unexpected and not a desired outcome for -- as a result of the assay.

Q. Is it that document to which you just referred that told you that the purpose of the running the assay was to support Protocol 007?

A. Our lab, our laboratory notebooks would refer to Protocol 007.

Q. Did your understanding of the purpose of running the assay change at all during the course of your time within Dr.



Krah's lab?

A. No.

Q. Has it changed since?

A. There are -- yeah, there's different information that I'm aware of now that Protocol 007 was used to support. I do, I guess, have additional information about Protocol 007.

Q. Is that information that you got after your departure from Merck?

A. Yes.

Q. Is that information that you got in connection with this lawsuit?

A. Prior to and with connection with the lawsuit.

Q. What is the information that you got prior to the lawsuit that indicated to you that Protocol 007 had additional purposes?

A. What information I received prior to is that I was aware that there was a label change for Protocol 007 which supported an end expiry claim with decreased strength of the product.

Q. Did you have an understanding



while you were working in Dr. Krah's lab of what the purpose of Protocol 007 was?

MR. KELLER: Asked and answered. Vague and ambiguous.

THE WITNESS: Again, to the extent that I explained what I knew of the protocol in the previous questions.

BY MR. SANGIAMO:

Q. The previous questions you were telling me what you understood the purpose of running the assay was, and I think you testified that the purpose was -- one of the purposes was to support Protocol 007. Right?

A. Correct.

Q. And now I'm asking you what your understanding was at the time, if you had an understanding while you were working in the lab, of what the purpose of Protocol 007 was?

A. I don't believe I had a full understanding of what Protocol 007 was at the time I was in the lab.

Q. Did you have a partial understanding?

A. I did have a partial understanding.

Q. What was the source of that

partial understanding?
A. Again, the original outcome or the results of the assay was to determine seroconversion, and we were testing pediatric sera.
Q. Did you have any understanding of the purpose of Protocol 007 at the time you were working in Dr. Krah's lab beyond what you just said?
A. That we were basically -- again, with seroconversion, that we were testing pediatric sera for pre- and post-vaccinated children. So to basically, you know, to test the effectiveness of the vaccine.
Q. To test the effectiveness of the vaccine?
A. Yes.
Q. What was the basis of that part of your understanding?
A. So a seroconversion would show that the vaccine -- is an indicator that the vaccine is effective.
Q. In your opinion?
A. Yes.



Q. Was your opinion the only source of your understanding that the purpose of Protocol 007 was to test the effectiveness of the vaccine?
A. Again, from our direction from Dave Krah who would also reiterate to us about the testing of what is expected when you vaccinate a child that they are pre-negative and convert to pre-positive based on dosing with the vaccine.
Q. Is that the entirety of the information you had regarding the purpose of Protocol 007 at the time you worked in Dr. Krah's lab?
A. I believe so.
Q. Did you know what the study objectives were for Protocol 007 at the time you were working in Dr. Krah's lab?
MR. KELLER: Objection. Vague and ambiguous.
BY MR. SANGIAMO:
Q. How many clinical studies have you been involved with to your knowledge over your career?



A. Multiple.
Q. More than five?
A. Yes.
Q. More than ten?
A. Yes.
Q. Are you familiar with the notion of a clinical study having an objective?
A. Yes.
Q. Do you know what the -- did you have an understanding when you were working in Dr. Krah's lab what the objective was of Protocol 007?
A. I don't believe I had full understanding of the objective.
Q. Did you have any understanding of the objective beyond what you already testified to this morning?
A. Not that I recall, no.
Q. Did you have any understanding at the time you worked in Dr. Krah's lab of what the hypothesis to be tested in Protocol 007 was?
MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.



BY MR. SANGIAMO:
Q. Ma'am, are you familiar with the notion of a clinical study having a hypothesis?
A. Yes.
Q. Did you have an understanding at the time that you were working in Dr. Krah's lab of what the hypothesis was for Protocol 007?
A. I can't recall if I had at that time the understanding of what the hypothesis was beyond what I've already told you.
Q. Are you familiar with the notion of clinical trials often having different arms?
A. Yes.
Q. What does that mean?
A. There's different study groups within the clinical protocol.
Q. Did you have an understanding at the time that you were working in Dr. Krah's lab of what the different study groups were that were being evaluated in Protocol 007?
A. I don't recall if I had the knowledge of the different study groups.

Q. Did you know, at the time that you were working in Dr. Krah's lab, how many study groups there were?
A. Again, I don't think I did have that knowledge at that time.
Q. Did you know at the time that you were working in Dr. Krah's lab whether there was more than one study group?
A. No, I don't think so.
Q. Have you, since your departure from Dr. Krah's lab, developed more of a sense of what the objective of Protocol 007 was?
A. Yes, I have a sense of the objective, yes.
Q. And do you have a sense developed since you left Dr. Krah's lab of what the study groups were in Protocol 007?
A. Yes, I do.
Q. And what is your current understanding of what the objective was in Protocol 007?
A. To determine the end expiry claim for the product.
Q. Did you testify, correct me if



I'm wrong, did you testify that you learned of that purpose in conjunction with hearing about a label change?
A. Yes.
Q. Could you be more specific about what it was that you were told that linked the label change to Protocol 007?
A. At the time, Protocol 007 was the only protocol, clinical trial protocol that would support the seroconversion of patients with a lower potency product.
Q. Who told you that?
MR. KELLER: I'm going to instruct the witness not to disclose any communications she may have had with counsel. If she learned this through communications with counsel, I will instruct her not to answer. If you can answer the question without disclosing communications you had with counsel, you may answer.
THE WITNESS: In my initial discussion with Steve we talked about the label change.



BY MR. SANGIAMO:
Q. Who told you that there was a linkage between Protocol 007 and the label change?
A. Again, in my initial discussion with Steve, we talked about that this was the only protocol currently that was reported completed at the time.
Q. How did you know?
A. This was just through my initial discussion with Steve.
Q. Did Steve tell you?
A. Yes.
Q. Were you reluctant to tell me that Steve told you? I don't understand.
A. Yes, at that time my knowledge was through my initial discussion with Steve.
Q. Because he told you?
A. Yes, he told me.
Q. You didn't have any source of that knowledge at that time other than Mr. Krahling. Right?
A. Correct.
Q. Have you had any source of that



knowledge since then other than Mr. Krahling or what you've heard from your attorneys?
A. It's posted on the clinicaltrial.gov website.
Q. When did you check -- I'm sorry, did you finish your answer?
A. Yes.
Q. When did you check that and see that it was posted there?
A. I can't recall. During the course of the case it was --
Q. Do you have an understanding of why Merck decided to explore the hypothesis of the immunogenicity of the mumps component of MMR at various potencies?
A. Can you define at what time?
Q. Currently.
MR. KELLER: Again, I don't want you to disclose any communications you had with your counsel. To the extent you can answer without disclosing communications you had with your counsel, you may answer.
THE WITNESS: Can you repeat

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the question again, then?
BY MR. SANGIAMO:
Q. Other than anything that you heard from your attorneys, do you have an understanding currently of why Merck decided to explore the hypothesis regarding immunogenicity of the mumps component of MMR at various potencies?
A. Other than what I discussed with counsel, going back to the information I had at the time when I was in the laboratory, that they had conducted studies for the development of the assay. They were finding seroconversion rates that were much lower than what was reported in the label. So that -- at that time, before my discussions with counsel, was my understanding of running additional studies to determine what the current seroconversion rate is.
Q. What is the source of that understanding?
A. The documentation regarding the development of the assay.
Q. You said documentation. Was

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that just one document?
A. Yes.
Q. And was that document provided to you by Mr. Krahling?
A. Yes, it was.
Q. Was that document that was provided to you by Mr. Krahling, is that the entirety of the source of your understanding?
A. Yes, it was.
Q. Did you have an understanding of why Merck was running those assays that are described in that document?
A. I did not have an understanding. That was before my time. Again, my knowledge in the lab as to what we were doing is very limited. My discussions with Dave Krah was very limited. So basically I was running the assay. I did know, again, during the course of running the assay we weren't getting the desired results. People were told to recheck counts. People were changing data in order to meet the results of what the desired outcome was as outlined in the original development of the assay. There was data that was being

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tossed out, changed, manipulated, you know, all tied into likely the reason between myself and me questioning Dave Krah as to why maybe I was given limited information at the time I was working in the laboratory.
Q. Do I have it right that you did not have an understanding of why Merck was running the assays that are described in that document at the time that you were working in Dr. Krah's lab?
A. Again --
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: Again, that was -- that predated me. Steve had worked in the lab before I did, so he had more knowledge about information and discussions. Before I joined the lab, Steve -- Dave Krah spoke to Steve regularly and provided him all background information. So, you know, based on just my interactions with Steve, I felt that he was very informative. I trusted the information

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that he was providing. There was, you know, legitimate information that he was providing over to me. It wasn't just that he was telling me information and I was, you know, using that as the basis of -- the basis of my belief.
BY MR. SANGIAMO:
Q. Did Mr. Krahling tell you his understanding of why it is that Merck was running those assays that were described in that document?
A. I can't recall, I can't recall if it was even outlined in the development document at that time. I can't recall what I knew at that time. It's blurred with what I know now.
Q. Understood. Do you recall whether Mr. Krahling said anything to you about why Merck was running those assays?
A. No, I don't recall.
Q. I believe you may have answered this in response to an earlier question, but I want to make sure I have it right. Did Dr. Krah ever tell what you the purpose was of

Protocol 007?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: Again, to what I've already explained about the seroconversion rates, that's all I can recall at this time.
BY MR. SANGIAMO:
Q. And specifically what is it that you heard from Dr. Krah regarding the seroconversion rates?
A. What was expected was that the pre-vaccinated samples would be negative, seronegative and we were looking for the endpoints in the vaccinated samples.
Q. What did he say about seroconversion rates?
A. That the pre-positives were expected to be less than 10 percent.
Q. Do you have anything else to tell me about what he said to you about seroconversion rates?
A. I don't think so.
Q. At the time that you left Dr.



Krah's lab, had the assay testing for Protocol 007 been completed? I'm sorry, strike that. Let me ask that question again.
Do you know what sera samples -- serum samples were supposed to be tested beyond the fact that some were pre-vaccination and some were post-vaccination at the time you worked in Dr. Krah's lab?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: Can you repeat that question?
BY MR. SANGIAMO:
Q. It's your understanding that the subjects of Protocol 007 had blood draws done prior to vaccination and post-vaccination. Correct?
A. Correct.
Q. Do you know whether there was more than one blood draw done after vaccination for the subjects in Protocol 007?
A. Currently, I do.
Q. Did you know at the time you were working in Dr. Krah's lab?



A. No.
Q. What was your understanding at the time that you left Dr. Krah's lab regarding whether seroconversion rates had been calculated for the subjects in Protocol 007?
A. They had been calculated to the extent that there was an Excel workbook that we could enter results of the plaque count into to tell whether or not there was a positive or a negative result.
Q. That would tell you whether there was a positive or negative result for any one subject. Right?
A. Correct.
Q. And did you have an understanding at the time that you were working in Dr. Krah's lab of whether a cumulative or aggregate seroconversion rate was going to be calculated in Protocol 007?
A. Can you repeat that? I missed parts of that question.
Q. I tried to set the question up, perhaps unsuccessfully, by asking you, and I



think you agreed, that the Excel worksheet would show whether any individual patient seroconverted?
A. Correct.
Q. Did you have an understanding as to whether there was going to be a calculation of a seroconversion rate that was designed to capture the aggregate of all of the patients in Protocol 007?
A. The result of the aggregate? Did I have an understanding of the result of the aggregate?
Q. Okay. Yes.
A. Is that the question?
Q. Yes.
A. I did not have an understanding of the result of the aggregate at the time because the testing was not completed when I left the laboratory. Again, my feeling, my strong feelings about this is that not all the data that was -- not all of the serum that was tested did have data reported on it. So whether -- in conclusion of the study, I feel like it was inconclusive or it showed results

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that were not representative of what was the actual testing or the actual -- yeah, the actual results of the sera that was tested.

Q. Had the seroconversion rate for the aggregate of the patients in the study been calculated at the time you left the lab?

A. No.

Q. Do you have a current understanding of what the seroconversion rates that were determined in Protocol 007 are?

A. I do.

Q. What were those rates?

A. I may not remember the numbers exactly, but I believe two of the study groups had a level that was higher than the target based on what was reported. But, again, I feel as though the information that was reported is not the whole story or the whole information.

Q. How many study groups were there in total?

A. Three. To my understanding.

Q. So I gather one of the study groups did not reach the target. Right?

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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.

Q. When you say a target, are you talking about a seroconversion rate target?

A. I was actually referring to the strength of the product. But both, you know, as far as numbers of results of seroconversion rates versus the strength target. Or I shouldn't say target, but what was used in the study.

Q. Could you give me your best current understanding of what the objective was for Protocol 007? I think that might facilitate me understanding your last answer.

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A. So, again, it was to determine the zero -- it was to determine the end expiry claim of different -- yeah, that's basically what it was for the objective.

Q. Do you know what the criteria -- strike that.

Was it your understanding that -- strike that again.

Is it your current understanding that each of the study arms represented different potencies of the mumps component of MMR?

A. Yes.

Q. Was it your understanding -- strike that.

Is it your current understanding that two of those study arms were being tested, being compared to the third study arm as a control study arm? Is that your current understanding?

A. That is not my current understanding.

Q. Is it your current understanding that there was no control study arm?

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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?

A. Yes.

Q. That is practically every clinical trial you are familiar with had a control group. Right?

A. Yes.

Q. Based on your understanding of Protocol 007, was there a control group?

A. I don't know which one was the control group in the study.

Q. What were the criteria for success for Protocol 007 that would enable one to determine whether one of the potencies

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being tested was adequate?
MR. KELLER: Objection. Vague and ambiguous. Are you talking today or are you talking in the past?
MR. SANGIAMO: I'm asking for her current understanding.
THE WITNESS: My current understanding, and, again, my understanding, I would have to go back and check the data, I believe it was to be greater than 90 percent seroconversion.
BY MR. SANGIAMO:
Q. So if the seroconversion rate within a study arm was greater than 90 percent, your current understanding, subject to you having to go back and check the data, then that would be deemed successful. Is that it?
A. Yes.
Q. Based on your current understanding, was there also a criterion for success that entailed the seroconversion rate of a study arm being comparable to the seroconversion rate of another study arm?

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MR. KELLER: Objection. Vague and ambiguous. Do you want to show her the protocol? You're asking her questions about a very, very technical 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 to answer that.
BY MR. SANGIAMO:
Q. So as of now, you don't have any knowledge of there being a comparability criterion of success? Did I state it accurately?
MR. KELLER: Objection. Mischaracterizes her testimony.
THE WITNESS: I don't have that without having the protocol.
BY MR. SANGIAMO:
Q. You said maybe a couple of times that you don't think that the data that were reported, I believe was the term you used, for Protocol 007 were accurate. Did I say that right or no?

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A. Yes.
Q. Why is it that you think -- strike that.
When you say that, are you referring to the data that were reported to the FDA?
A. The data that was reported as part of the clinical protocol.
Q. Reported to the FDA?
A. It was reported, yes, to the FDA. Or as through the clinical study report.
Q. What is the basis of your knowledge that a clinical study report was reported to the FDA?
MR. KELLER: Again, I'm going to --
BY MR. SANGIAMO:
Q. Other than what you've learned from your attorneys.
A. Then I can't elaborate on that.
Q. Let's try this.
A. Other than --
Q. Other than what you have learned from your attorneys, do you know

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whether a clinical study report was submitted to the FDA?
A. I do know that the report was -- the protocol was completed. I do know 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.
Q. Is it correct that the reason why you think that the data that Merck reported to the FDA in connection with Protocol 007 was inaccurate is that plaque counts had been changed when the assay was being run?
A. Correct. As well as original data being discarded. Again, this is a Phase III clinical trial. The data integrity is an important piece of any clinical trial that is being run on human subjects. You know, the expectation is that the method itself would be validated prior to running any testing on human subjects and, therefore, any following validation of an assay, the analysts that are

performing the assay would be qualified to run that validated method and be able to generate validated results. That would be withheld to data integrity standards.

Q. Does the fact that data was discarded, you say, mean that the data that were reported were inaccurate?

A. If there was no reason to go back and retest or recount plaques, then, yes, if the original raw data is being discarded and not used as an original result, then the data is flawed in that there is data that is being omitted from the study.

Q. So your concern there as regards accuracy is not the fact that data were discarded, it's the fact that the original results were not being reported. Do I have that right?

MR. KELLER: Objection. Mischaracterizes her testimony.

MR. BEGLEITER: Argumentative.

MR. KELLER: Argumentative.

MR. SANGIAMO: Good objection, Bob. I don't agree with the objection.



Please answer the question.

MR. KELLER: I do.

THE WITNESS: So it -- all right. Repeat the question again? Sorry.

BY MR. SANGIAMO:

Q. I was asking you questions about your contention that original data were discarded and what the implications were for the accuracy of what was reported to the FDA. Right?

A. Correct.

Q. Your concern as regards accuracy in that regard is not that the data were discarded, per se, but it's that you claim that the data being reported were not the original data. Is that right?

MR. KELLER: Mischaracterizes her testimony. You can answer.

THE WITNESS: My concern as a scientist working in the laboratory is that, first, a concern over data integrity, that the original data set is not being maintained. The second



piece is that because the data was being manipulated or changed, that the results that are being reported are not accurate. Again, going back to if the method was validated prior to running testing on human subjects, the accuracy of the method would already be defined and there would be parameters for which we would follow in order to either reject or accept a test or counts that were being performed at the time.

MR. KELLER: Interpose an objection. Compound.

BY MR. SANGIAMO:

Q. If an assay was counted accurately and that accurate count was reported to the FDA, would it matter in terms of the accuracy that the FDA received if the well plate was discarded?

A. The well plate is the original data in this case. It would be a means to preserve the original raw data, maintain it through the end of the study. So, in my experience, while working in Dave Krah's lab,



I did see him discard plates which had been sitting there since I had started in January through July after some escalations had happened internally. The very next day after being told that an internal audit would occur, 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 not something I had ever witnessed him doing in my previous months working there.

Q. If an assay was counted accurately and that count was reported to the FDA, would it matter in terms of the accuracy of the data that the FDA is receiving if the plate was subsequently discarded?

MR. KELLER: Objection. Calls for speculation. Asked and answered.

THE WITNESS: So I'll further elaborate that if the plates were discarded, again, that is not maintaining or preserving the raw data for the assay, but further the counting sheets that were used were not

controlled counting sheets. So unlike the laboratory notebook, which was controlled pages where you could see if data was omitted, the counting sheets were a blank piece of paper that an analyst could write on the paper and if they didn't like it because they made too many cross-outs, would be able to toss out that piece of paper and rewrite their results.

BY MR. SANGIAMO:

Q. Suppose an assay was counted and for a given well a determination was made that there were 15 plaques, and suppose that the data were reported to the FDA that way with 15 plaques in that well, would that count of 15 plaques in that well become inaccurate if the well plate were discarded?

MR. KELLER: Objection. Vague and ambiguous. Calls for speculation.

THE WITNESS: That well count would not be able to be confirmed against its original raw data point.

BY MR. SANGIAMO:



Q. Would it be inaccurate?

MR. KELLER: Objection. Vague and ambiguous.

THE WITNESS: I can't answer that question. You know, if it was an original data point transcribed from the plates, there could have been a transcription error from the plate to the counting sheet.

BY MR. SANGIAMO:

Q. Other than there being a transcription error, is there something about the discarding of the plate that makes the prior count inaccurate?

MR. KELLER: Objection. Vague and ambiguous. Lack of foundation. Overbroad.

THE WITNESS: Again, it depends on the -- what was written on the cell counting sheet. I can't say. Some of them may have been. Some of them may have not if there were cross-outs. It may not be an accurate reporting.

Additionally, the plates



themselves could, once the plaques were counted, the plaque counts could be erased from the plate and recounted and then transcribed to a counting sheet.

So, therefore, again, I can't claim that there was accuracy on any given counting sheet at any time. If the method had described what the requirements were for reporting plaque counts, and the criteria for which it was acceptable to perform an additional count, may have given some more information around that. The procedure itself did not have that information until the FDA had audited where there were revisions around the procedures to put some more definitions around what the criteria would be. But by that time the majority of Protocol 007 had already been executed.

BY MR. SANGIAMO:

Q. You just referred to the procedure itself. Are you referring to the SOP?



A. Correct.

Q. Is it your belief that the SOP should specify what the criteria are for when a count should be checked? Is that right?

A. I believe that a count should not have to be rechecked. If the assay is validated and the analysts are trained, the original results should suffice. If during the course of the validation they had some other criteria that they needed to add, then that should have been defined. But it wasn't. It's my understanding that the validation did not occur prior to the initiation of the testing.

Q. What was the -- what is the source of that understanding?

MR. KELLER: Again, I will instruct you not to answer any -- answer the question if in the answer you have to disclose communication you've had with counsel. If you can answer the question without disclosing communications with counsel, you may answer.

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THE WITNESS: I cannot answer the question.
BY MR. SANGIAMO:
Q. Did you know anything about the timing of the validation of the assay at the time that you were working in Dr. Krah's lab?
A. The development information that was provided spoke to concurrent validation with running the human test sera.
Q. What information was this?
A. In the development presentation information or document.
Q. Is it the same document we've been talking about --
A. Yes.
Q. -- that you got from Mr. Krahling?
A. Yes.
Q. That told you what was planned for validation?
A. It stated that there would be concurrent validation to testing of the sera.
Q. Do you know if that is, in fact, what happened?
A. I cannot.

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Q. Strike that. Did you know at the time you were working in Dr. Krah's lab 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. Mischaracterizes her testimony.
THE WITNESS: I don't

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necessarily need to have expertise on plaque reduction neutralization assays in order to make that statement. Again, appropriate method validation should be able to demonstrate robustness, reputability, precision, accuracy that would allow for that.
BY MR. SANGIAMO:
Q. What is it that qualifies you to make that statement as it pertains to plaque reduction neutralizations?
MR. KELLER: Asked and answered.
THE WITNESS: I believe I've already answered that.
BY MR. SANGIAMO:
Q. You've told me what qualifies you for that?
A. My experience in working in the industry and as an analyst performing method validation, that that is what gives me the basis for that response.
Q. Is it your experience that -- strike that.
Have you ever seen an SOP for a

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plaque reduction neutralization assay other 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:
Q. That expectation is not based on having seen any actual SOPs for plaque

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reduction neutralization assays. Right?
A. I cannot recall that I've seen another SOP.
Q. You've made some comments about the plaque counting sheets not being controlled. Right?
A. Correct.
Q. And your point was that the -- that by not being controlled, the data, in your view, is compromised in some way. Right?
MR. KELLER: Objection. Mischaracterizes -- strike that.
You can answer.
THE WITNESS: Can you repeat the question?
BY MR. SANGIAMO:
Q. Is it your view that because you say the plaque counting sheets are not controlled, the data is, therefore, compromised in some way?
MR. KELLER: Objection to form.
THE WITNESS: The data can be compromised. There is no way of ensuring that it hasn't been

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compromised.
BY MR. SANGIAMO:
Q. Why is that?
MR. KELLER: Asked and answered.
THE WITNESS: The -- as I explained earlier, the laboratory notebook pages are all numbered. You can tell if there is missing information. The counting sheet is not in any way controlled with a numbering. It can be generated and destroyed without anybody knowing.
BY MR. SANGIAMO:
Q. Did you witness any counting sheets being destroyed?
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.
Q. Less than five?
A. No.
Q. Somewhere between five and a

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dozen?
A. Yes.
Q. Who did you see destroy a counting sheet?
A. I'm trying to remember who it was. I don't recall who exactly it was.
Q. Was it a man or a woman?
MR. KELLER: Objection. Compound. Or both.
THE WITNESS: I'm trying to remember. I believe I saw Colleen Barr and Jen Kriss. I believe I was told to discard an assay as well.
BY MR. SANGIAMO:
Q. Did you witness someone else destroying counting sheets other than Colleen Barr and Jenny Kriss?
A. I can't remember.
Q. Did you see them doing it together?
A. No.
Q. How many occasions did you see this happen?
MR. KELLER: Asked and answered.

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THE WITNESS: Yes, I --
BY MR. SANGIAMO:
Q. Before you testified that you think it happened between five and a dozen times. Does that mean somewhere between five and a dozen counting sheets or would that mean something else?
A. Five and a dozen counting sheets, yes.
Q. Did that all occur on one single occasion?
A. No.
Q. How many occasions?
A. The same amount of occasions.
Q. So one counting sheet on 5 to 12 occasions. Do I have it right?
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 were and the transcription to that. And then getting rid of the original document. Again, in my case I was told to just get rid of an

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assay based on the results being faint when I read the -- after I completed reading the entire assay.

Q. Let's continue to focus on the occasions when you saw Colleen Barr and Jenny Kriss discard a counting sheet. I think you said that -- actually, let's focus in on the ones that Colleen Barr discarded. Okay?

A. [Witness nods.]

Q. Were some of the ones that they discarded based on the fact that the original counting sheet was messy?

A. Yes.

Q. All of them?

A. I can't recall because sometimes it wasn't necessarily me seeing them but conversations that were had in the laboratory.

Q. So sometimes you saw it happen?

A. Uh-huh.

Q. When you refer -- you have to say yes.

A. Yes.

Q. When you refer to 5 to 12 occasions previously, which I understand was

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your estimate, those were 5 to 12 times when you saw it happen?

A. Between seeing it happen and hearing about it happen.

Q. How many times did you see it happen?

A. I would have to say, from what I recall, less than five times from what I recall.

Q. Less than three?

A. At most it was three I can think of. Three.

Q. You said you can think of three?

A. Yeah.

Q. Who did it on those three occasions, was it just Colleen, just Jenny or both.

A. The three that I -- the three examples I provided previously. Colleen, Jenny and myself.

Q. So in terms of others discarding counting sheets, you've seen it happen twice that you can recall, once by Colleen and once by Jenny. Right?

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A. Yes.

Q. On the occasion that you saw Colleen do it, where were you in relation to Colleen?

A. We sit in the same area so I was sitting near her in the laboratory.

Q. Did she throw it in the garbage can? Is that how she discarded it?

A. Yes.

Q. Was this an instance of the count sheet that ultimately got discarded being too messy?

A. Yes.

Q. How do you know that?

A. Just because she was transcribing it from one to the other.

Q. Did she say something that led you to believe that it was an issue of messiness?

A. I could see that the counting sheet had many cross-outs on it.

Q. Do you know anything about the accuracy of the transcription done by Colleen from the prior counting sheet to the newer

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counting sheet?

A. I do not.

Q. So as far as you know, the transcription was accurate. Fair statement?

MR. KELLER: Objection. Argumentative.

THE WITNESS: I do not know if it's accurate or not accurate.

BY MR. SANGIAMO:

Q. How about on the one occasion where you saw Jenny Kriss discard a counting sheet, where were you in relation to Ms. Kriss?

A. Again, in the laboratory. She sits across from me.

Q. How did she discard it?

A. She, I believe, also discarded it in the trash.

Q. What information do you have about why she discarded it?

A. I don't know why she discarded it.

Q. I think you said you also heard conversations about people discarding counting sheets. Is that right?

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A. Yeah, conversations about just, again, transcribing or making the data cleaner. And I guess transcribe it to a different data sheet.
Q. I'm asking about conversations about discarding counting sheets?
A. Okay.
MR. KELLER: Objection. Form. Mischaracterizes her testimony.
MR. SANGIAMO: Let's back up.
BY MR. SANGIAMO:
Q. You testified to an occasion when you saw Colleen Barr discard a counting sheet. Correct?
A. Correct.
Q. On another occasion you saw Jenny Kriss discard a counting sheet? Correct?
A. Correct.
Q. Your belief is there were more discarding of counting sheets beyond those two occasions and whatever the occasion was regarding yourself which we'll get to shortly. Right?
A. Right.

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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.
Q. What you heard was people saying that they had transcribed data from one

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counting sheet to another counting sheet. Right?
A. Yes.
Q. You are inferring that that means that they discounted the earlier counting sheet. Right?
A. Yes.
Q. But you did not actually hear them say that they discarded the earlier counting sheet?
A. Not that I recall.
Q. Who is it that you heard say these things about transcribing data from one counting sheet to another counting sheet?
A. I can't say that I can pinpoint it. It was just conversations within the laboratory.
Q. Now, is this a situation where Mr. Krahling told you he heard this or did you, yourself, hear these conversations?
A. Myself.
Q. Do you recall the gender of the person who was making these statements?
A. There was both men and women in

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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 you to discard?
A. I believe the -- I can't

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remember exactly what he said, but I believe we discarded the plates and the counts.
Q. You discarded the plates and the counts?
A. The -- I did not discard the plates.
Q. Who discarded the plates?
A. I do not know. If they --
Q. How do you know -- sorry.
A. I can't confirm if they were discarded.
Q. Do you think they were?
A. I think they were, but I don't know.
Q. What is the basis of your thinking that?
A. That -- just the basis that he had said to discard it.
Q. Didn't you just tell me you don't remember what he said?
A. He said -- I said he -- you asked me if he said exactly what he told me to discard. And I know he told me to discard it, but I don't know exactly what he was referring

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to as far as discarding.
Q. So you don't know whether he was referring to the plate?
MR. KELLER: Argumentative.
MR. SANGIAMO: This makes no sense, Jeff. I'm just trying to get to the bottom of it.
MR. KELLER: Makes perfect sense.
MR. SANGIAMO: She's accusing a scientist of committing fraud. I'm entitled to find out what the basis is of her accusation.
MR. KELLER: You sure can. But you're not entitled to argue with her. You can ask your questions. The argument is inappropriate. I object. Argumentative.
You can answer the question.
THE WITNESS: He asked me to discard, discard the assay. Based on that, the outcome of whether or not the plates were destroyed, I do not know.
BY MR. SANGIAMO:

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Q. Did you discard the counting sheet?
A. I believe so.
Q. Just threw it in the garbage?
A. I believe so.
Q. What was the procedure in the lab as regards to the -- what was done with the counting sheet once the plaque was -- sorry, once the assay was counted? Do you understand my question? That wasn't phrased very well.
A. Yeah, can you elaborate on that?
Q. I'm asking about the process for documentation of plaque counts when running the plaque reduction neutralization assay in Dr. Krah's lab. My question specifically was supposed to be, after you complete the count and after you finish filling in the counting sheet, what would you do with it then?
A. Based on the mumps procedure or do you want me to explain what we as analysts did?

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MR. KELLER: Objection.
MR. SANGIAMO: You can't object to her answer.
MR. KELLER: I can interpose an objection to your question.
BY MR. SANGIAMO:
Q. I'm asking you what you did, you personally did after you completed filling in the plaque counting sheet, what did you do with the sheet?
MR. KELLER: Objection. Vague and ambiguous.
THE WITNESS: With the sheet itself?
BY MR. SANGIAMO:
Q. Yes.
A. Aside from entering results into the Excel workbook, the sheets, I want to say, were added to the file for the experiment as far as I can recall.
Q. If you continued an assay, are you the one who would then enter the content of the counting sheet into the Excel workbook?
MR. KELLER: Objection.

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Overbroad.
THE WITNESS: From what I recall, I did enter some. I don't know that all of the data was entered by the analyst who conducted the testing. Or sorry, conducted the counting.
BY MR. SANGIAMO:
Q. Again, I'm just referring to your practice.
A. Okay.
Q. Did I hear you to say that sometimes if you did the count of the assay, you would then enter the numbers into the Excel worksheet?
A. Correct.
Q. But sometimes you wouldn't?
A. I want to say that there were occasions that somebody else would enter it as far as I recall.
Q. Was the place where you would enter the data into the Excel worksheet, was that right at your desk?
A. Yes.
Q. Was it the same place where you

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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 experiment.
Q. By you?
A. Yes. If I had entered it into the Excel work file, yes.
Q. Would you do that right away after you were done entering into the Excel work file?
A. I believe so, yes.
Q. You would never give them to Leah Gottlieb?
A. No.
Q. Have you ever given a counting sheet to Leah Gottlieb?
MR. KELLER: Objection. Lack of foundation.
THE WITNESS: Not myself directly that I recall.

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BY MR. SANGIAMO:
Q. Where was this file physically in relation to where you entered the information into the Excel worksheet?
A. It was next to my desk.
Q. Was it a single repository for all the assays or was it just limited to the assays that you were counting?
MR. KELLER: Objection. Compound.
THE WITNESS: Can you repeat that question?
BY MR. SANGIAMO:
Q. I'm trying to figure out the location of the file into which you would put the counting sheet. I think you said it was right next to your desk?
A. Yes.
Q. What I'm trying to figure out is, whether that thing that was right next to your desk simply held the files for the assays that you were counting or did it hold the files for all the assays no matter who counted them or what?

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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 conversation with Dr. Krah?
MR. KELLER: Objection. Vague and ambiguous. Overbroad. Lack of foundation.
MR. SANGIAMO: You know what, I need to go back.
BY MR. SANGIAMO:
Q. On this particular occasion that you're describing where Dr. Krah told you to discard something in connection with the assay, do you recall whether you were the one who entered the information into the Excel worksheet?
MR. KELLER: Objection. Lack of foundation.
THE WITNESS: I can't recall.
BY MR. SANGIAMO:

Q. When you were the one to enter the information into the Excel worksheet, would you do that immediately after completing the count?

MR. KELLER: Objection. Compound.

THE WITNESS: Yeah, I don't know what your definition of "immediately" is. But I don't -- I don't think that it was consistent, the time of entry for different plaque counting.

BY MR. SANGIAMO:

Q. Even within your own practice it was not consistent?

A. As far as I recall.

MR. KELLER: Dino, we've been going about an hour. Can we take a break?

MR. SANGIAMO: Give me one or two more, Jeff.

BY MR. SANGIAMO:

Q. I asked you before whether you would do it immediately, and you appropriately asked for what would one mean by immediately.



I guess I meant would it be the next thing on your to-do list?

MR. KELLER: Objection.

THE WITNESS: I'm trying to think. As far as I can recall, it would be the next thing, yes.

MR. SANGIAMO: Okay. Take a break now.

VIDEOGRAPHER: The time is now 10:43. Off the video record.

- - -

(A recess was taken.)

- - -

VIDEOGRAPHER: The time is now 11:02. This begins disc two. You may proceed.

BY MR. SANGIAMO:

Q. Ms. Wlochowski, before the break we were talking about an occasion on which you discarded a counting sheet. I wonder if I could ask you to take a look at Exhibit 7 which is one of the exhibits we looked at yesterday from that stack right there. Exhibit 7 is your Answers to Merck's



revised first set of Interrogatories. I wonder if I could ask you to turn to page 18. And I'd like to direct your attention to the paragraph at the bottom of page 18 that carries over to page 19. I'm going to start to read that into the record.

"On another occasion, Relator was working in the back laboratory next to Relator Krahling. She showed Relator Krahling her counting sheet that contained 11 pre-positives. Relator Krahling calculated this equaled an 84 percent pre-positive rate. Relator joked sarcastically about the unlikely possibility the data would survive the day. Krah overheard their conversation and came over to look at the plates. He told Relator that the plaques were too faint to count and ordered her to throw away her counting sheet because he intended to retest the entire assay. Relator protested that the plaques were not too faint to count, citing as evidence the fact that she had already counted them. Krah ordered her again to throw out the counting sheet and she complied."



That's the end of the quote from the Interrogatory answer. Is what is described in that paragraph that I just read the incident about which you were testifying just before the break?

A. Yes.

Q. When you prepared the answer to this Interrogatory, how did you know that the number of pre-positives from that assay run was 11?

MR. KELLER: Objection. Strike my objection. In answering this question do not disclose any communications you had with your counsel or any communications that may have occurred in order to answer this question. So if you can answer the question without disclosing communication you had with your counsel, by all means do so. If you can't, then I instruct you not to answer.

THE WITNESS: Can you repeat the question, please?

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BY MR. SANGIAMO:
Q. Let me come at it a different way. If you take a look at the second to the last page of Exhibit 7, we see your Verification there. Right?
A. Correct.
Q. And in that Verification you say that you certify under the penalty of perjury that you've reviewed these responses and the content is true and correct to the best of your knowledge. Right?
A. Correct.
Q. When you did that review, were you also certifying to the accuracy of the fact that there were 11 pre-positives on the particular assay that we've been discussing?
A. Yes.
Q. Are you sure it was 11?
MR. KELLER: Objection. Argumentative. Vague and ambiguous.
THE WITNESS: Based on the information that I had at that time, yes.
BY MR. SANGIAMO:

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Q. At the time you certified?
A. Yes.
Q. What was that information?
MR. KELLER: Do not disclose any communications with counsel. If you can answer without disclosing communications with counsel, you may do so.
THE WITNESS: I cannot provide additional information on that.
BY MR. SANGIAMO:
Q. Did you have any documents that -- associated with this assay at the time that you verified?
A. I cannot remember.
- - -
(Exhibit Wlochowski-15, Mumps AIGENT Processing Workbook, Bates RELATOR_00000716 to 721, was marked for identification.)
- - -
MR. KELLER: What exhibit number is this?
MR. SANGIAMO: 15.

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BY MR. SANGIAMO:
Q. Ms. Wlochowski, you've just been handed what has been marked as Exhibit 15. This is -- what is this document?
A. This is the Excel worksheet that was used to calculate the titers.
Q. This was contained in the production of documents that we received from the Relators. We're checking our records to confirm, but I'll just ask you, do you know if this document was in your possession as distinguished from Mr. Krahling's possession at the time the litigation began?
A. I'm sorry, I didn't hear.
Q. This document was either in your possession or Mr. Krahling's possession at the time the litigation began. We're trying to confirm right now, but if you know, it will save us a minute or two.
A. I can't remember.
Q. I believe based on the information we've been provided by your attorneys, this was in Mr. Krahling's possession, not in your possession, at the

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time we requested documents in this litigation. That's all background, providing that information.
This particular assay run shows nine pre-positives if I'm reading this correctly. Would you be able to confirm that easily? I don't want to take up a whole bunch of time.
MR. KELLER: Take the time. Are you representing there is nine pre-positives?
MR. SANGIAMO: I am. You know what, let's...
MR. KELLER: I don't disagree with you, but I haven't taken the time to...
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 give her the plate layout sheet.
- - -
(Exhibit Wlochowski-16, Plate

Layout Sheet, Bates MRK-KRA00680674, was marked for identification.)

- - -

BY MR. SANGIAMO:

Q. You've just been handed what has been marked as Exhibit 16. Ms. Wlochowski, do you recognize that document?

A. Yes.

Q. What is that?

A. That is the plate layout sheet with the corresponding serum IDs.

Q. If you take a moment, can you see that the assay being referred to in both Exhibit 16 and Exhibit 15 is Assay 211? Do you see that?

A. Yes.

Q. With the aid of the plate layout sheet, Exhibit 16, can you now tell me how many pre-positives you believe are reflected on Exhibit 15, the Excel workbook?

Ms. Wlochowski, we have a ruler here. Will that help at all?

A. Yes. Thank you.

MR. KELLER: Do you have the



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 one that might be pre-positive. Actually is that color ink? Is that blue ink?



MR. KELLER: It's blue ink.

THE WITNESS: Okay.

BY MR. SANGIAMO:

Q. I suggest you put a check mark next to each one that is pre-positive.

- - -

(A discussion off the record occurred.)

- - -

THE WITNESS: I am like having -- I would have to go back and refer to our procedures for counting because I'm having trouble recalling the calculation for figuring out which one is which.

BY MR. SANGIAMO:

Q. When you say which one is which, what do you mean?

A. Again, the numbers are just confusing me as far as reporting the outcome.

Q. Why don't we walk through a couple of these, see if that helps any. If we look at Exhibit 16 which is the plate layout sheet --



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 "Plate," there is a column that says "Titer"?

A. Correct.

Q. And the titer there is 512?

A. Yes.
Q. Is what -- so that would be a pre-positive. Correct?
A. Again, I'm trying to go through in my head. I don't want to get it backwards. So, again, I can't --
Q. Ms. Wlochowski, I'm going to suggest something to you and see if it jogs your memory at all. What I'm going to suggest to you is that a titer was considered positive if it was 32 or greater. Does that sound right to you?
MR. KELLER: Objection. Lack of foundation. Do you want to show her the protocol?
THE WITNESS: Again, I would need to go back to the protocol.
- - -
(Exhibit Wlochowski-17, Virus & Cell Biology Research Procedure, Bates MRK-KRA00064382 to 4391, was marked for identification.)
- - -
BY MR. SANGIAMO:



Q. Ms. Wlochowski, I've just handed you what has been marked as Exhibit 17. Do you recognize that document?
A. Yes. That is the SOP.
MR. KELLER: Take your time to review that.
BY MR. SANGIAMO:
Q. Ms. Wlochowski, I'm going to suggest an alternative approach to this. If you could look back again to Exhibit 15 which 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 mean at the time you verified the Answers to Interrogatories?



A. Yes.
Q. Was the data set more than just a printout from the Excel spreadsheet?
A. I can't remember.
Q. The Answers to Interrogatories were verified some 15 years or so after the assay was actually counted.
A. Yes.
Q. With that in mind, I'm just trying to gauge your level of certainty as regards 11 being the number of pre-positives in that particular assay. Could you comment on that?
MR. KELLER: Objection. Argumentative. Vague and ambiguous. You can answer.
THE WITNESS: If I recall, I would have had the data to confirm that.
BY MR. SANGIAMO:
Q. Would you very confidently exclude the possibility that there are actually 9 pre-positives in that assay?
MR. KELLER: Objection.



Argumentative. Vague and ambiguous. Calls for speculation.
THE WITNESS: I can't say.
BY MR. SANGIAMO:
Q. The Answer to Interrogatory says that you were working in the back laboratory next to Relator Krahling. Is that different from your desk?
A. Where are you referring to? Sorry.
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 control and the, what would be a pre-positive.
Q. Just from the counting sheet?

A. You could eyeball it.
Q. You could eyeball it?
A. Meaning that it's a comparison of the reduction against the control, the mock control. So just based on the number of plaques in the control, and the number you were counting as a pre-positive, it was -- at the time you were counting could have a feel for whether it was going to be pre-positive or not.
Q. You could have a feel for it, but you could be off by a little bit. Right?
A. Yes.
Q. Do you recall any occasions other than this one when Dr. Krah told you that an assay needed to be rerun because the plaques were too faint?
A. I can't recall, no.

- - -

(Exhibit Wlochowski-18, Notebook page, Bates MRK-KRA00680669 & 670, was marked for identification.)

- - -

MR. SANGIAMO: That is 18, I



believe.
BY MR. SANGIAMO:
Q. Do you recognize Exhibit 18, Ms. Wlochowski?
A. Yes. It is a page from the laboratory notebook.
Q. And what assays are you referring to?
A. It is referring to the mumps AIGENT assay for Protocol 007.
Q. What assay number?
A. The MMRV-211-01.
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 dated June 29 of '01. Do you see that?
A. Yes.



Q. And that reads, "Large amount of plates in assay showed faint staining. See counting sheet for details. This assay will be repeated per Dave Krah's request." And it's signed by you. Right?
A. Yes.
Q. Do you think this assay 211 is the one that you were describing in your Answers to Interrogatories at page 18?
A. This could be the one, yes.
Q. And you have a vivid recollection of discarding the counting sheet for that assay. Right?
A. I recall being told to discard it. Yes.
Q. Did you discard it?
A. To the best of my recollection.

- - -

(Exhibit Wlochowski-19, Counting sheet, Bates MRK-KRA00680676, was marked for identification.)

- - -

BY MR. SANGIAMO:
Q. Ms. Wlochowski, you've just



been handed what has been marked as Exhibit 19. Do you recognize that document?
A. That is a counting sheet.
Q. Counting sheet for which assay?
A. For 211-01.
Q. Do you see a reference to very faint plaques on the counting sheet?
A. I do.
Q. Is that your handwriting?
A. Yes.
Q. Does that mean that on or around the time that you were counting plaques 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.
You can answer.
THE WITNESS: I do not know.

It could be.
BY MR. SANGIAMO:
Q. How would you describe the fact that we have this counting sheet if you discarded it?
MR. KELLER: Objection. Argumentative.
THE WITNESS: I don't know if it is the one that was being referred to at the time.
BY MR. SANGIAMO:
Q. I'm sorry?
A. I don't know if this is the assay that we were referring to in the Complaint.
Q. In the Answers to Interrogatories, is that what you meant? Just now you said Complaint.
A. Sorry, yes. The Interrogatories, yes.
Q. If you go back to Exhibit 18, do you see down at the bottom of the page there is an entry dated July 23, 2002. Do you see that?



A. Yes.
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?
A. Left, when I transferred out of David Krah's lab?
Q. Yes.
A. No. Sorry, it's 2002. Sorry. Yes.



Q. The next sentence reads, "The faint plaque appearance was not described specifically in the SOP for the assay as a reason to invalidate a sample or the assay. There were no documented technical errors during the...," next word is hard to read, "...to account for the faint plaques...Therefore, the assay and the individual sample results are considered valid." Right?
MR. KELLER: That's not exactly what it reads, but you can answer. The document speaks for itself.
THE WITNESS: Yes. So the assay was repeated in June of 2001 and the entry that was entered by Dave Krah about the assay being valid and reporting to -- the results to the clinical database was made in 2002, a year later.
BY MR. SANGIAMO:
Q. And sitting here right now, you don't know whether the results that were submitted to the clinical database were the results from the running of the assay as



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 over. Do you have any other belief that original data was not retained in the running of the assay generally?
MR. KELLER: Objection. Overbroad.

THE WITNESS: When I had mentioned earlier about the discarding of the plates is an example of not retaining the original data as well as when analysts would read or count the plaques, there were instances of wiping out the original plaque counts on the plate and repeating the plaque counts. So, therefore, again, I consider that the original data was not maintained.

BY MR. SANGIAMO:

Q. Did you witness that occurring?

A. Yes.

Q. Did you, yourself, do that?

A. I believe in the beginning I may have done that, yes.

Q. How many times did you do it? Just to be clear -- my question is unclear. What I had in mind was how many times did you wipe the plate clean and then do the count over again?

A. I can't recall how many times.

Q. More than five?

A. I can't recall.



Q. How many times did you see it done by others?

A. I don't know. Again, conversations 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 was told there should be more plaques in the pre-positive result where she would -- basically as a college intern was being -- with her supervisor standing over her shoulder telling her she needs to find more was kind of, as she described it, tap the plate four more times in order to, you know, add more plaques because he was stating that there should be more.

Q. Did you witness any instance in which -- I'm sorry, strike that.

So how many times, is it your testimony that you don't recall how many times you saw someone wipe the plate clean?

A. Yes.



Q. Can you give me your best approximation?

MR. KELLER: Objection to form.

THE WITNESS: I cannot because there's instances of discussions as well as, you know, somebody actually doing it. There was, you know, alcohol wipe in the lab and you could easily just wipe off the counts.

BY MR. SANGIAMO:

Q. And, of course, that's standard practice for when you want to check a count in a plaque reduction neutralization assay. Right?

MR. KELLER: Objection. Lack of foundation.

BY MR. SANGIAMO:

Q. Do you know whether that is standard practice when you want to check a count in a plaque reduction neutralization assay?

MR. KELLER: Same objection.

THE WITNESS: I would go back to my original statement that, again,



the assay should be validated to be able to read a plate and generate the 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.

Q. So let's focus in on what you saw and that's where I'm asking for your best approximation of the number of times you saw that happen, not heard discussion about it, saw it happen.

MR. KELLER: Calls for speculation. You're not entitled -- he's not entitled to have you guess at numbers. If you have an understanding or a reasonable basis that you saw somebody wiping plates, you can testify to that.

THE WITNESS: I can't give you an exact number, if I saw it once or saw it not at all. The whole, you

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know, basis of the plaque counting, what I was, you know, conducting in the lab at that time I was not comfortable with. I, you know -- again, this may be some of the reason why there were different people who conformed who agreed, yes, we'll count again, we'll change our results, we are not blinded to what is pre-vaccination versus post-vaccination sera so we could, you know, go back and make that determination and able to change those results. If we didn't know -- if we were just given prepared serum and didn't know what was pre and post, I think our -- you know, what we conducted in the lab would be handled a lot differently. We would not be targeting specific, specific plaque counts to go back and recheck based on it was not expected.

MR. SANGIAMO: Move to strike that answer.

BY MR. SANGIAMO:

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Q. Ma'am, how many times did you witness someone wiping a plate clean?

A. I cannot give you a number.

Q. It could be zero. Right?

A. I wouldn't say it would be zero.

Q. Did you definitely see it, ma'am?

MR. KELLER: Argumentative. She's already testified.

THE WITNESS: Yes.

BY MR. SANGIAMO:

Q. But it could have been just once. Is that your testimony?

MR. KELLER: Objection. Mischaracterizes her testimony.

THE WITNESS: It could have been once or more.

BY MR. SANGIAMO:

Q. On that occasion, although you're not sure of it, but on that occasion --

MR. KELLER: Objection.

BY MR. SANGIAMO:

Q. -- did you -- strike that.

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On that occasion, do you know whether the person had already recorded the plaque counts on a counting sheet?

A. I do not know.

Q. Who was it on that one occasion that you may remember?

A. I would have to say it was Jenny Kriss.

Q. So you remember that?

A. Yes.

Q. Now, you said you also heard discussions about people wiping the plate clean. Right?

A. Yes.

Q. How many times did you hear that discussed?

A. Again, I can't give you a number. We all sat in the same laboratory, we -- counting plates together. A group of people, a group of staff in the laboratory, there's different conversations going on. I remember instances of, you know, someone saying I can't find more plaques, you know, asking somebody else to look at it. And being

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frustrated because they can't find more plaques but they know they need to.

Q. Do you have a recollection of people discussing wiping the plate clean?

A. Yes.

Q. Can you give me any approximation right now how many times you heard that or would you just be guessing?

MR. KELLER: Objection.

THE WITNESS: I cannot give you an approximation.

BY MR. SANGIAMO:

Q. Is that because you would have to speculate?

MR. KELLER: Objection. Argumentative. Asked and answered.

THE WITNESS: Yes.

BY MR. SANGIAMO:

Q. On those occasions when you heard people talking about wiping the plate clean, did those people comment one way or the other as to whether they had already recorded the plaque counts on the counting sheet at the time that they wiped the plate clean?

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A. I'm sorry, can you repeat that question?
Q. On the occasions when you heard people commenting on wiping the plate clean, did they say anything one way or the other whether they had already recorded the plaque counts on the counting sheet at the time they wiped the plate clean?
A. I cannot recall, no.
Q. Do you have an understanding as to whether the data that Merck used in support of its submission for Protocol 007 was the data as originally counted versus the data as it stood after recounts had been done?
MR. KELLER: Objection. Vague and ambiguous. Overbroad.
THE WITNESS: I cannot say whether original data was submitted. If it was, it would be very difficult to determine what original data was. In some cases there could be transcription errors on a counting sheet that if you went back to the original data, then you would be

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accounting for a transcription error. So, you know, if that was the case, then the reliability of the results, again, would be questioned.
BY MR. SANGIAMO:
Q. So is it the case that you have no understanding as to whether the data as submitted by Merck to the FDA in support of 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 original. So she's already answered the question.

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BY MR. SANGIAMO:
Q. Do you have anything to add to your last answer?
A. No.
Q. Is it your testimony that because there could possibly be transcription errors, we can't know what the original data was?
MR. KELLER: Objection. Overbroad. Argumentative.
THE WITNESS: That is part of -- yes, not knowing the original data.
BY MR. SANGIAMO:
Q. Are there any other reasons why we wouldn't know what the original data is?
MR. KELLER: Objection. Asked and answered. You can answer.
THE WITNESS: Again, if there -- if plates are being tossed out, if data is being changed before it's entered onto the sheet, if data -- if the sheet itself is not the original sheet, it would be very difficult to

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say if you would be able to provide original data.
BY MR. SANGIAMO:
Q. Would there always be a risk of a transcription error?
MR. KELLER: Objection. Overbroad. Lack of foundation. 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.
THE WITNESS: Transcription error can occur, but if it is

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documented as a transcription error, then it would be detectable. If it's not documented that that is what the cross out is, then it's not necessarily detectable.

BY MR. SANGIAMO:

Q. If Merck submitted the data as originally counted in support of the label change application associated with Protocol 007, then who has been harmed as a result of a plaque recounts having been done?

MR. KELLER: Objection. Calls for expert opinion. Calls for speculation. Lack of foundation. Incomplete hypothetical. Vague and ambiguous. Legal conclusion.

THE WITNESS: Can you repeat the question?

BY MR. SANGIAMO:

Q. If Merck submitted the data in support of the label change associated with Protocol 007 based on the plaques as originally counted rather than the counts as recounted, who has been harmed as a result of

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the recounts?

MR. KELLER: Objection. Same objection as the last question.

THE WITNESS: Again, I guess I would question the methodology that is being employed, that there would be a recount being done and all that time 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 resort back afterwards. To me, it was just lack of control during the course

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of executing the testing. Originally while I was there, originally the assay was to be transferred and outsourced, so transferred to an outside laboratory which I believe may have been set up to conduct this type of study in a controlled manner. That didn't occur as far as I knew because the transfer, we could not transfer it. It didn't qualify in that laboratory. So, to me, that's -- I would just, as a matter of compliance, question it.

BY MR. SANGIAMO:

Q. Can you identify a party that has been misled as a result of the counting rechecks and the recounts?

MR. KELLER: Objection. Seeks a legal conclusion. Vague and ambiguous. Lack of foundation. Seeking expert testimony from a lay witness. Vague and ambiguous. Overbroad. Objection to form.

THE WITNESS: I would say from being there, I was misled.

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BY MR. SANGIAMO:

Q. Anybody else?

A. Everybody that was in that lab was misled.

Q. Anyone else?

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 here today.

MR. KELLER: Let me interpose

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an objection. Lack of foundation. Argumentative.
BY MR. SANGIAMO:
Q. So do you believe the public was misled by the recounts?
A. Yes.
Q. And do you have any knowledge of the public knowing about the recounts other than you having filed this lawsuit?
A. What I have --
MR. KELLER: Objection. Lack of foundation. Overbroad. Calls for speculation.
THE WITNESS: What I have knowledge of is it would be the public's expectation that the manufacturing site would be complying with the regulations set forth by the health authorities.
BY MR. SANGIAMO:
Q. You gave some testimony about another lab that was supposed to run the assay at one point. What lab was that?
A. It was a lab out in Ohio. I

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believe it was Dr. Ward's lab.
Q. When did you first learn about the idea of Dr. Ward's lab running the assay?
A. I can't remember. I believe it was springtime or early on while I was there.
Q. You're referring to 2001?
A. Yes.
Q. Who did you hear that from?
A. I want to -- I do know that it was part of a document that -- again, about the development of the assay. I want to say that Dave was -- had also discussed and provided information that it was going to be transferred. I do know from discussions within the laboratory that Colleen Barr was -- I can't remember if she had already gone out there or was going out there, but I do remember her being part of that.
Q. So the basis for your knowledge that it was going to be transferred is the document to which you previously referred that you got from Mr. Krahling, statements that Dr. Krah made and your knowledge about Colleen Barr going out to that lab?

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A. Yes.
Q. Did Dr. Krah tell you exactly what testing that lab was going to do?
A. I believe, to the best of my knowledge, that he was referring to the PRN assay.
Q. In which samples, did he say?
A. For Protocol 007.
Q. Was he any more specific than that?
A. No.
MR. KELLER: We've been going about an hour. Do you want to take a break?
MR. SANGIAMO: Why don't we finish up this. I don't think it will take long.
BY MR. SANGIAMO:
Q. Did you have an understanding at the time that you worked in Dr. Krah's lab regarding why Dr. Ward's lab was not going to run any assay samples?
A. While I was in Dr. Krah's lab, I don't -- I didn't have an understanding why

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it wasn't going -- it wasn't carried out.
Q. Have you developed an understanding since then?
A. I can't recall.
Q. Do you have a current understanding of why there was --
A. I can't recall if it's speculation or based on information that I know today. So I don't want to say. My belief is, again, that it didn't -- they weren't able to transfer it, they weren't able to qualify it in that laboratory. There were -- we were held to, you know, a very strict timeline to complete Protocol 007 by August. We were being, you know, told that if we were able to complete it by August, that we would get bonuses for completion of that work on time. So I think it was a matter of being able to meet the timeline and having the assay qualified in the laboratory, the outsourced laboratory.
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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being qualified?
A. That's the piece I can't recall, can't confirm.
Q. Would it be fair to say that you simply don't know why it is that the assay was not performed in Dr. Ward's lab?
MR. KELLER: Objection. Asked and answered. Argumentative.
You can try to answer again.
THE WITNESS: If it was a matter of timing in order to complete the assay transfer and complete the testing in that timeline, that would be -- that would suggest that that was part of the reason.
BY MR. SANGIAMO:
Q. Is it your testimony that that was part of the reason? I'm just trying to understand your testimony, ma'am.
MR. KELLER: Objection. Asked and answered. She just testified to it.
THE WITNESS: I truly don't know as I sit here today. I can't

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confirm one way or the other.
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 12:11. Going off the video record.
- - -
(A recess was taken.)
- - -
VIDEOGRAPHER: The time is now 1:22. This begins disc three. You may proceed.
BY MR. SANGIAMO:
Q. Ms. Wlochowski, when you were working in Dr. Krah's lab, did you have any belief at that time that there were improprieties associated with the design of the plaque reduction neutralization assay?
MR. KELLER: Objection. Vague and ambiguous.

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THE WITNESS: Can you elaborate on that?
BY MR. SANGIAMO:
Q. Do you have an understanding what the word design might mean in the context of an assay?
A. Can you define what you mean by that?
Q. Suppose I were to use the term parameters, the parameters for the assay, would that have any better meaning for you?
MR. KELLER: Same objection.
THE WITNESS: Again, do you want to describe which parameters you're referring to?
BY MR. SANGIAMO:
Q. What term would you use to describe the methodology of an assay as well as the reagents to be used in the assay?
MR. KELLER: Objection.
THE WITNESS: So I think I know what you're referring to as far as design. I guess to me that would be the procedure itself that has already

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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 protocols, there's validations.
MR. SANGIAMO: You're getting closer, Jeff. Why don't you back off.
BY MR. SANGIAMO:
Q. Did you have any concerns about the methodology of the assay?
MR. KELLER: Objection. Vague and ambiguous. Lack of foundation.
THE WITNESS: So we had talked before about the use of the enhanced -- using the rabbit antibodies, the enhancement that was incorporated into the assay that was used.
BY MR. SANGIAMO:
Q. Anything else?

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A. I think we also talked about the use of what was called a wild type actually being the vaccine strain as a concern as well.
Q. Any others?
A. Let me think. So I think that those are the key points with the addition of concerns over the assay not being fully validated before it was being used in testing.
Q. Anything else?
A. Can I look at one of my SOPs that's here?
Q. Yes.
A. I guess in general, as I sit here today, when I look through the way the procedure is written, in some areas it's not very clear what exactly is being conducted. And in some cases, you know, it calls out not used for routine testing. So it kind of lays it open to what you mean by routine testing, but yes, it was in a procedure that was used for testing in the clinical protocol.
In this procedure, at least I'm not seeing it right now, as I look at it

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doesn't describe the methodology for performing the counting. That's my overview of the methodology.
Q. Do you have any other concerns about the methodology other than what you've just told us?
MR. KELLER: Objection. Overbroad. Vague and ambiguous.
THE WITNESS: Based on --
MR. KELLER: Sorry. Lack of foundation. Seeking testimony from a lay witness.
THE WITNESS: Based on what I looked at, at this time, that those are the key points.
BY MR. SANGIAMO:
Q. So you can't think of any others right now. Is that a fair statement?
A. Yes.
Q. Let's talk about the virus that was used in the assay. What is a wild type virus? What does that mean?
A. It's the strain that would be in the population. Different types of strains.

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Q. Have you ever run an assay that used a wild type virus?
A. I cannot recall.
Q. Does the wild type virus have to be passaged before it can be used in a plaque reduction neutralization assay?
MR. KELLER: Objection. Lack of foundation.
THE WITNESS: Does a wild type virus have to be passaged before it can be used in an assay. Is that your question?
BY MR. SANGIAMO:
Q. Yes.
MR. KELLER: Same objection.
THE WITNESS: I don't know that it has to be. Typically -- it's my understanding that typically it would be.
BY MR. SANGIAMO:
Q. That it would be passaged?
A. Yes.
Q. Before it could be used in an assay?

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A. That it would be.
Q. How many times can a virus be passaged before it is no longer a wild type virus?
MR. KELLER: Objection. Lack of foundation. Seeks testimony from a lay witness.
BY MR. SANGIAMO:
Q. Do you have the expertise to answer that question?
A. I do not.
Q. Was the virus that was used in the plaque reduction neutralization assay in Protocol 007 a wild type virus?
MR. KELLER: Objection. Lack of foundation. Seeks expert --
BY MR. SANGIAMO:
Q. If you don't have the expertise to answer that, just say so.
A. It was a strain of virus that at one point was a wild type virus in my understanding.
Q. Had it been passaged since that time?