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1 A. From my understanding, yes.
 2 Q. What is the basis of that
 3 understanding?
 4 A. Going back to what I recollect,
 5 what the -- was documented in the development
 6 of the method, that document.
 7 Q. This is the document you
 8 referred to several times that Mr. Krahlung
 9 gave you?
 10 A. Yes.
 11 Q. Do you have the expertise to
 12 state whether the amount that it had been
 13 passaged made it no longer wild type?
 14 MR. KELLER: Objection. Lack
 15 of foundation. Vague and ambiguous.
 16 THE WITNESS: I'm trying to
 17 think through your question. So can
 18 you repeat the question?
 19 BY MR. SANGIAMO:
 20 Q. Let me ask this: Do you know
 21 how many times it was passaged?
 22 A. I do not recall.
 23 Q. Do you have the expertise to
 24 assess whether that number of passages,

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1 whatever it is, was such that it is no longer
 2 wild type?
 3 MR. KELLER: Objection. Lack
 4 of foundation. Vague and ambiguous.
 5 THE WITNESS: I cannot say. I
 6 would say that yes, I lack the
 7 expertise to...
 8 BY MR. SANGIAMO:
 9 Q. Did you participate in the
 10 decision-making about what virus should be
 11 used in the plaque reduction neutralization
 12 assay used in Protocol 007?
 13 A. No.
 14 Q. Do you have firsthand knowledge
 15 of whether the FDA knew what virus Merck was
 16 using in the plaque reduction neutralization
 17 assay for Protocol 007?
 18 MR. KELLER: Objection.
 19 Overbroad.
 20 THE WITNESS: At what time
 21 point are you referring to?
 22 BY MR. SANGIAMO:
 23 Q. Right now.
 24 A. With the exception that the

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1 information related to the testing of the
 2 protocol would have been reported to the FDA
 3 would be the only knowledge I would have
 4 that -- through that reporting and method
 5 validation that the FDA may have that
 6 information.
 7 Q. I'm sorry, ma'am, I don't
 8 follow that. My question is, do you have
 9 firsthand knowledge of whether the FDA knew
 10 what virus was being used in the plaque
 11 reduction neutralization assay? Do you have
 12 firsthand knowledge of that?
 13 MR. KELLER: Objection. Vague
 14 and ambiguous.
 15 THE WITNESS: I have knowledge
 16 that they have received the completed
 17 study, clinical study with the data
 18 reported. Based on my knowledge, they
 19 would also have the validation of the
 20 methodology and through that would be
 21 what I would consider them to have
 22 information around what may or may not
 23 have been used as the virus used in the
 24 methodology.

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1 BY MR. SANGIAMO:
 2 Q. So it's your belief that they
 3 had the validation. Right? Is that your
 4 testimony?
 5 A. Yes.
 6 MR. KELLER: Objection.
 7 BY MR. SANGIAMO:
 8 Q. And it's your belief that the --
 9 MR. KELLER: Hold on. I'm not
 10 done objecting. Give me a second.
 11 Objection.
 12 Could I hear the question back?
 13 - - -
 14 (The court reporter read the
 15 pertinent part of the record.)
 16 - - -
 17 MR. KELLER: Objection.
 18 Mischaracterizes her testimony.
 19 Overbroad, vague and ambiguous.
 20 BY MR. SANGIAMO:
 21 Q. But you said yes. Right?
 22 A. Yes.
 23 Q. And is it your belief that the
 24 validation would have identified the virus

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1 that was used in the assay?
 2 A. I would have expected it to be,
 3 but I can't confirm that.
 4 Q. But if it was, that would be
 5 one means by which the FDA would have known
 6 what virus was being used in the assay. Is
 7 that your testimony?
 8 A. Yes.
 9 Q. Do you have knowledge of
 10 whether the FDA may have learned what virus
 11 was being used in the assay on other
 12 occasions?
 13 MR. KELLER: Objection. Vague
 14 and ambiguous. Overbroad.
 15 THE WITNESS: Not that I can
 16 recall.
 17 BY MR. SANGIAMO:
 18 Q. You also mentioned the use of
 19 antihuman IgG in the assay as a concern of
 20 yours about the design of the assay. Is that
 21 a fair statement?
 22 A. Yes.
 23 Q. Could you turn to Exhibit 6,
 24 please, which is the Amended Complaint in this

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1 case. If you could turn, please, to
 2 paragraph 35. Are you there?
 3 A. Yes.
 4 Q. If you go down five lines
 5 within paragraph 35. Do you see the sentence,
 6 "The use of animal antibodies in laboratory
 7 testing is not uncommon"? Do you see that?
 8 A. Yes.
 9 Q. Is the reference there to
 10 animal antibodies, is that to the antihuman
 11 IgG?
 12 A. Yes.
 13 Q. Do you agree with that
 14 statement that the use of animal antibodies in
 15 laboratory testing is not uncommon?
 16 MR. KELLER: Objection. Seeks
 17 expert testimony from a lay witness.
 18 BY MR. SANGIAMO:
 19 Q. Let me back it up a step to
 20 accommodate Mr. Keller's objection.
 21 Do you have an opinion as to
 22 whether that is an accurate statement?
 23 MR. KELLER: Same objection.
 24 THE WITNESS: Can I read

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1 through further on this?
 2 BY MR. SANGIAMO:
 3 Q. Absolutely.
 4 MR. KELLER: You may want to
 5 start at paragraph 33 to 39.
 6 BY MR. SANGIAMO:
 7 Q. What paragraph are you on?
 8 A. I'm done.
 9 Q. So let's go back to paragraph 35
 10 and the sentence, "The use of animal
 11 antibodies in laboratory testing is not
 12 uncommon." I think the pending question is
 13 whether you have an opinion as to whether that
 14 is an accurate statement?
 15 MR. KELLER: Objection. Seeks
 16 a legal conclusion from a legal document.
 17 Seeks expert opinion from a lay witness.
 18 You can answer.
 19 THE WITNESS: In my opinion,
 20 yes, I have seen animal antibodies
 21 being used in laboratory testing,
 22 not -- which includes testing outside
 23 of PRN methodology.
 24 BY MR. SANGIAMO:

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1 Q. Do you agree that it's not
 2 uncommon? You said you've seen it. I'm
 3 asking do you agree that it's not uncommon?
 4 MR. KELLER: Same objection.
 5 THE WITNESS: I agree.
 6 BY MR. SANGIAMO:
 7 Q. Is your basis for saying it's
 8 not uncommon the fact that you've seen it
 9 yourself in other circumstances?
 10 A. Yes.
 11 Q. Is there any other basis for
 12 your belief that it's not uncommon?
 13 MR. KELLER: Objection. If in
 14 order to answer that question you would
 15 have to disclose communications with
 16 your counsel, I would instruct you not
 17 to answer the question to the extent
 18 that it will disclose communications
 19 with counsel.
 20 THE WITNESS: I cannot answer
 21 the question.
 22 BY MR. SANGIAMO:
 23 Q. So without disclosing
 24 communications with your counsel --

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1 A. Right.
 2 Q. -- you could not answer the
 3 question of whether there are other bases for
 4 your belief it's not uncommon. Do I have it
 5 right?
 6 A. Correct.
 7 Q. How many assays have you seen
 8 animal antibodies used in?
 9 A. What do you mean by "how many
 10 assays"?
 11 Q. Have you seen it referred to in
 12 SOPs in other assays?
 13 A. So you're talking about different
 14 types of assays or how many different ELISAs?
 15 Is it just an ELISA and something else or is
 16 it number of ELISAs, that sort of thing?
 17 Q. I understand your point. Have
 18 you seen it in any assays other than ELISA
 19 assays and the plaque reduction neutralization
 20 assay that you ran at Merck?
 21 MR. KELLER: Objection. Lacks
 22 foundation.
 23 THE WITNESS: So can you break
 24 it down?

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1 BY MR. SANGIAMO:
 2 Q. Same problem?
 3 A. Yes.
 4 Q. Have you seen it used in ELISAs?
 5 A. Yes.
 6 Q. How many different kinds of
 7 ELISAs have you seen animal antibodies used
 8 in?
 9 MR. KELLER: Objection. Lack
 10 of foundation.
 11 THE WITNESS: Many different
 12 kinds.
 13 BY MR. SANGIAMO:
 14 Q. More than five?
 15 A. Yes.
 16 Q. More than ten?
 17 A. Probably.
 18 Q. Are these ELISAs that you ran
 19 at New Haven?
 20 MR. KELLER: Objection. Lack
 21 of foundation.
 22 THE WITNESS: They would be in
 23 ELISAs that I either ran or have seen
 24 the procedure or methodology.

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1 BY MR. SANGIAMO:
 2 Q. In connection with your
 3 employment at various places or just at New
 4 Haven?
 5 A. Various places.
 6 Q. Is there a way for you to
 7 describe what the function is of the animal
 8 antibodies in the ELISAs that you've seen?
 9 MR. KELLER: Objection. Vague
 10 and ambiguous.
 11 THE WITNESS: Can you restate
 12 the question?
 13 BY MR. SANGIAMO:
 14 Q. If at any point you don't have
 15 the expertise to answer one of these
 16 questions, just say so.
 17 A. Uh-huh.
 18 Q. Do you know what role the
 19 animal antibodies played in the operation of
 20 the ELISAs in which you've seen animal
 21 antibodies used?
 22 MR. KELLER: Objection. Vague
 23 and ambiguous. Lack of foundation.
 24 THE WITNESS: Again, it does

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1 help to enhance the reaction by
 2 allowing for more specific -- or not
 3 specific but more binding to what is
 4 being tested.
 5 BY MR. SANGIAMO:
 6 Q. So does it make the assays more
 7 sensitive?
 8 MR. KELLER: Objection. Vague
 9 and ambiguous.
 10 THE WITNESS: It depends on the
 11 assay.
 12 BY MR. SANGIAMO:
 13 Q. Is there any function it
 14 performs as far as you know other than to make
 15 the assay more sensitive?
 16 A. Again, it could be used as much
 17 in here as a highlighter, so there could be
 18 another function. I can't elaborate on it at
 19 this time. Just for my -- not having worked
 20 directly with it at the current time.
 21 Q. Why do you say at the current
 22 time? What do you mean by that?
 23 A. Just, again, I'm not performing
 24 assays myself right now. So just my

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1 familiarity with it.
 2 Q. This is a topic that at one
 3 time you would have felt comfortable
 4 addressing but right now you do not. Do I
 5 have that right?
 6 MR. KELLER: Mischaracterizes
 7 her testimony.
 8 THE WITNESS: That, I mean,
 9 again, if I could refamiliarize myself
 10 at this time I could speak better to
 11 it.
 12 BY MR. SANGIAMO:
 13 Q. Did you have a concern about
 14 the use of antihuman IgG in the plaque
 15 reduction neutralization assay at the time
 16 that you were working in Dr. Krah's lab?
 17 MR. KELLER: Asked and answered.
 18 THE WITNESS: I was aware that
 19 they had used it to enhance the
 20 reaction and -- so, yes.
 21 BY MR. SANGIAMO:
 22 Q. You're aware that they used it
 23 to enhance the reaction?
 24 A. Your question was did I have a

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1 concern while I was in Dave's lab. So the
 2 answer is yes.
 3 Q. Yes, you had a concern, or yes,
 4 you were aware that they were using it to
 5 enhance the reaction?
 6 A. Yes, I was -- yes, I had a
 7 concern, yes.
 8 Q. Did you express that concern to
 9 anyone?
 10 A. Through the -- through my
 11 concern of what was occurring because of the
 12 enhancement. We were also not only enhancing
 13 the post-positive, but we were also enhancing
 14 the pre-positive. So enhancing pre-vaccinated
 15 serum at the same time you are enhancing the
 16 post-vaccinated serum. The fact that we were
 17 getting a high level of pre-positives, that
 18 was the concern. I basically had raised a
 19 concern that, I guess -- sorry, I'm kind of
 20 rambling on.
 21 I raised a concern that we were
 22 being asked to recheck our counts on
 23 pre-positives which was attributed to the
 24 enhancement from the antibodies.

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1 Q. I'm going to try to break that
 2 down, but you tell me if I'm not doing it
 3 correctly. All right?
 4 A. Yes.
 5 Q. I heard you testify that you
 6 believe that the reason why you were being
 7 asked to recheck the pre-positives was because
 8 the antihuman IgG was being used in the assay
 9 which was causing there to be more
 10 pre-positives. Is that part of it right?
 11 A. It was causing an enhancement
 12 across the assay.
 13 Q. Including to the pre-vaccination
 14 samples?
 15 A. Yes.
 16 Q. Which meant -- do I have it
 17 right, which meant in your view it was
 18 creating more pre-positives?
 19 A. It would appear that it would.
 20 Again, when -- based on paragraph 34 here,
 21 there was the original PRN methodology which
 22 had unsatisfactory seroconversion results
 23 based on the objective of greater than a 95
 24 percent seroconversion rate. There was no

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1 explanation for why the methodology that was
 2 originally developed, the original PRN, why
 3 that would have been abandoned and then moved
 4 on to the enhanced. Other than that, from the
 5 data that we've seen is that the enhanced gave
 6 a better seroconversion rate on the -- on
 7 those, at least -- if you exclude the
 8 pre-positives, on their initial testing of the
 9 methodology is what they discovered.
 10 Q. You weren't around when the
 11 decision was made to use antihuman IgG in the
 12 assay. Correct?
 13 A. That is correct.
 14 MR. KELLER: Asked and answered.
 15 BY MR. SANGIAMO:
 16 Q. So I guess what I'm trying to
 17 get at is, whether the concerns that you had
 18 in 2001 when you were working in Dr. Krah's
 19 lab were about the use of antihuman IgG itself
 20 or whether the concerns were just that you
 21 were being asked to check plaque counts?
 22 MR. KELLER: Objection. Asked
 23 and answered. Compound.
 24 THE WITNESS: So the way I

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

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1 mock controls? You said it would normalize
 2 it. What does that mean?
 3 A. If there was non -- again, the
 4 pre and the post sera is calculated against
 5 the mock control. So it would normalize
 6 against that.
 7 Q. Is the concern that the
 8 antihuman IgG might itself neutralize virus?
 9 A. It is a concern that it could
 10 prevent -- let me just get this right. Not
 11 that it would necessarily neutralize virus but
 12 impact the results of the plaques being
 13 formed.
 14 Q. How else could it impact the
 15 result of the plaque being form other than
 16 neutralizing virus?
 17 A. I can't say that without having
 18 that information or that data to test through
 19 a control. I don't know.
 20 Q. Have you ever participated in
 21 the decision about whether to include
 22 antihuman IgG in the control in an assay?
 23 MR. KELLER: Objection.
 24 Overbroad.

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1 THE WITNESS: Could you restate
 2 the question?
 3 BY MR. SANGIAMO:
 4 Q. Have you ever -- strike that.
 5 When an assay is being designed
 6 someone needs to decide whether to include
 7 antihuman IgG in the control. Right?
 8 MR. KELLER: Objection. Lack
 9 of foundation. Overbroad.
 10 THE WITNESS: When an assay is
 11 being designed, yes, somebody has to
 12 define what the parameters are as we
 13 called it before.
 14 BY MR. SANGIAMO:
 15 Q. If an assay is going to be
 16 using an antihuman IgG, one of those
 17 parameters is whether the antihuman IgG is
 18 going to be used in the control. Right?
 19 A. That is correct, yes.
 20 Q. Have you ever participated in
 21 that decision of whether antihuman IgG should
 22 be used in the control?
 23 A. Not that I recall, no.
 24 Q. Have you ever read any

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1 literature about whether an assay that is
 2 using antihuman IgG should use antihuman IgG
 3 in the control?
 4 A. Not that I recall.
 5 Q. Do you have any data to show
 6 that the lack of use of antihuman IgG in the
 7 control in the assay that was used in Protocol
 8 007 had an impact on the assay results?
 9 MR. KELLER: Objection. Vague
 10 and ambiguous. Overbroad. If
 11 requiring to answer that question would
 12 require you to disclose communications
 13 with counsel, I instruct you not to
 14 answer. To the extent that you can
 15 answer independent of communications
 16 with counsel, you can answer.
 17 THE WITNESS: I do not have, I
 18 specifically do not have data to say
 19 whether it does or whether it doesn't.
 20 I also cannot answer specific to
 21 information discussed with my counsel.
 22 - - -
 23 (Exhibit Wlochowski-20,
 24 Sensitive Neutralization Test for Virus

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1 Antibody article, was marked for
 2 identification.)
 3 - - -
 4 BY MR. SANGIAMO:
 5 Q. Ms. Wlochowski, you've just
 6 been handed what has been marked as Exhibit 20
 7 which was among the documents that you
 8 produced from your own files.
 9 A. Okay.
 10 Q. And as is evident here, this is
 11 a journal article entitled Sensitive
 12 Neutralization Test For Virus Antibody. Do
 13 you see that?
 14 A. Where are you referring to?
 15 Q. I'm just looking at the title
 16 of the article.
 17 A. Sorry. Yes.
 18 Q. Do you know when it is that you
 19 obtained a copy of this article?
 20 MR. KELLER: Objection. Lack
 21 of foundation.
 22 MR. SANGIAMO: What is -- what?
 23 BY MR. SANGIAMO:
 24 Q. Did this document come from

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

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1 and ambiguous. Overbroad. The
2 document speaks for itself. Seeking
3 expert testimony from a lay witness.
4 THE WITNESS: The document
5 speaks for itself. There is a number
6 of statements made throughout the
7 document.
8 BY MR. SANGIAMO:
9 Q. Did they describe the use of
10 antihuman IgG in a mumps neutralization assay
11 as a means of making the assay more sensitive?
12 MR. KELLER: Objection. The
13 document speaks for itself. Lack of
14 foundation. Seeking expert testimony
15 from a lay witness.
16 THE WITNESS: Again, I'll
17 repeat by saying that the document
18 speaks for itself. So I'll just leave
19 it at that. There is a lot of
20 conclusions drawn from the document.
21 BY MR. SANGIAMO:
22 Q. Did you disagree with any of
23 the conclusions?
24 A. There are statements that are

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1 made where it states, "The mechanism by which
2 anti-immunoglobulin enhances the neutralizing
3 capacity of immune sera is not fully
4 understood."
5 So there are, again, some
6 conclusions drawn. However, there are some
7 statements made, for instance, "Studies on
8 cross-reactivity of antibody to viruses of the
9 paramyxovirus group with mumps virus in the
10 enhanced neut test are currently in progress."
11 So it makes references to other
12 studies as well as I want to say that based on
13 the different studies throughout the document
14 or different references it's making. I'm not
15 sure, I thought I saw that there was a small
16 sample size used in the study.
17 So there's -- so provides some
18 information, but, again, it's a paper that the
19 experts would have to -- that conducted the
20 study would have to speak to.
21 Q. Just the experts who conducted
22 the study or experts in the field generally?
23 A. I would also reference experts
24 in the field.

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1 Q. I asked the question of whether
2 you disagreed with any of the conclusions in
3 the paper. I'm not sure you answered that.
4 Do you disagree? Is there anything in there
5 that you disagree with?
6 MR. KELLER: Asked and answered.
7 She has testified.
8 BY MR. SANGIAMO:
9 Q. Do you have anything to add to
10 your prior answer in terms of whether there is
11 anything in here that you disagree with?
12 MR. KELLER: Same objection.
13 THE WITNESS: No.
14 BY MR. SANGIAMO:
15 Q. As you read this, did you feel
16 that these FDA researchers were engaged in
17 data manipulation in describing this methodology?
18 MR. KELLER: Objection. Lack
19 of foundation.
20 THE WITNESS: I do not have
21 copies of their data. So I can't say
22 whether they did or they didn't.
23 BY MR. SANGIAMO:
24 Q. Do you have any reason to

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1 believe that they did?
2 MR. KELLER: Objection. Calls
3 for speculation. Lack of foundation.
4 THE WITNESS: I can't speculate
5 on that.
6 BY MR. SANGIAMO:
7 Q. Did you feel that the mere
8 methodology itself constitutes manipulation?
9 MR. KELLER: Objection. Vague
10 and ambiguous. Lack of foundation.
11 Seeking expert witness testimony from a
12 layperson. Calls for speculation.
13 THE WITNESS: Again, to me that
14 would be speculation for me to answer
15 that.
16 BY MR. SANGIAMO:
17 Q. Because you lack the expertise?
18 A. I --
19 MR. KELLER: Mischaracterizes
20 her testimony. You can answer.
21 THE WITNESS: Again, I haven't
22 seen the data would be my response.
23 BY MR. SANGIAMO:
24 Q. So your point is you don't know

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1 whether this article accurately describes the
 2 underlying data from the researcher's work.
 3 Right?
 4 MR. KELLER: Objection.
 5 Mischaracterizes her testimony.
 6 THE WITNESS: Can you ask the
 7 question again?
 8 BY MR. SANGIAMO:
 9 Q. Is the point you're making that
 10 because you haven't seen the underlying data,
 11 you don't know if this article is accurately
 12 describing the underlying data?
 13 MR. KELLER: Objection.
 14 Mischaracterizes her testimony. You're
 15 asking her to speculate about --
 16 MR. SANGIAMO: I'm asking what
 17 her point was.
 18 MR. KELLER: No, you are
 19 recharacterizing --
 20 BY MR. SANGIAMO:
 21 Q. Did I state your point
 22 accurately? If I didn't, just tell me I
 23 didn't, that's fine.
 24 A. I keep losing track of your

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1 actual question, sorry, because of the back
 2 and forth.
 3 Q. Sure. Let me try it again.
 4 A. Sorry.
 5 Q. That's fine.
 6 Does the methodology described
 7 in here itself, the methodology itself,
 8 constitute manipulation in your opinion?
 9 MR. KELLER: Objection. Seeks
 10 a legal conclusion. Seeks expert
 11 opinion from a layperson. Calls for
 12 speculation. Lack of foundation. You
 13 can answer.
 14 THE WITNESS: I don't have a
 15 reason to believe that it was
 16 manipulated, but I cannot confirm if it
 17 has or it hasn't.
 18 BY MR. SANGIAMO:
 19 Q. Nothing in here suggested to
 20 you that the process that they describe is
 21 inherently manipulative. True?
 22 MR. KELLER: Objection. Lack
 23 of foundation. Vague and ambiguous.
 24 Seeks a legal conclusion. Seeks expert

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1 testimony from a lay witness. Calls
 2 for speculation.
 3 THE WITNESS: This question is
 4 different from the previous question in
 5 that --
 6 BY MR. SANGIAMO:
 7 Q. Well, I'm trying to -- what I
 8 can't tell, frankly, in your answers is
 9 whether you are responding to my questions in
 10 terms of whether the underlying data generated
 11 in these tests is accurately described in the
 12 paper, whether you're talking about that, or
 13 whether you are talking about the methodology
 14 itself. That's why I asked my follow-up
 15 question. I was trying to get that.
 16 A. Maybe that's why I'm confused
 17 in answering. To me they go hand in hand.
 18 Q. Let's assume that the data are
 19 accurately described in the paper.
 20 MR. KELLER: Objection. Seeks
 21 a hypothetical.
 22 BY MR. SANGIAMO:
 23 Q. Then would you consider the
 24 methodology described in here to constitute

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1 manipulation?
 2 MR. KELLER: Objection. Vague
 3 and ambiguous as to manipulation.
 4 Seeks an expert opinion from a lay
 5 witness. Overbroad. Lack of
 6 foundation. Seeks a legal conclusion.
 7 THE WITNESS: I think I've
 8 already answered.
 9 BY MR. SANGIAMO:
 10 Q. You've answered the best as you
 11 can?
 12 A. Yes.
 13 MR. KELLER: We're at about an
 14 hour. Do you want to take break?
 15 MR. SANGIAMO: Sure.
 16 VIDEOGRAPHER: The time is now
 17 2:32. Going off the video record.
 18 - - -
 19 (A recess was taken.)
 20 - - -
 21 VIDEOGRAPHER: The time is now
 22 2:51. This begins disc four. You may
 23 proceed.
 24 BY MR. SANGIAMO:

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1 Q. Ms. Wlochowski, you gave
2 testimony on several occasions over the course
3 of your deposition about plaque counts being
4 changed to pre-positive samples. Do you
5 recall that?
6 A. Yes.
7 Q. What do you recall Dr. Krah --
8 A. I'm sorry, can you repeat
9 again -- I said yes before I think I heard
10 something different.
11 Q. I just wanted to orient you to
12 your prior testimony on the topic of plaque
13 counts being changed on samples that were
14 pre-positive. There was no actual question
15 other than to orient you.
16 A. I'm sorry. Didn't mean to say
17 question. Yes.
18 Q. What do you recall Dr. Krah
19 saying as regards plaque count changes to
20 pre-positive samples?
21 MR. KELLER: Objection. Asked
22 and answered. You can answer again.
23 THE WITNESS: From my previous
24 responses, again, his indication to us

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1 was that the -- it is not expected to
2 have pre-positives in unvaccinated
3 population, that although it does
4 occur, it doesn't -- you know, it's not
5 occurring often. I'm not quoting him
6 on that, but that is the direction he
7 gave the lab.
8 BY MR. SANGIAMO:
9 Q. Well, so far all you've said is
10 that he said it was not expected to have
11 pre-positives in an unvaccinated population.
12 And that it does occur but not very often. I
13 realize you were not quoting him directly.
14 But then was there some kind of direction he
15 gave to the lab in light of that?
16 A. Based on that, yes, he has on
17 occasion asked to go back and recheck counts
18 where it resulted in a pre-positive.
19 Q. Is that something that you
20 heard him say?
21 A. Yes.
22 Q. How many times?
23 A. I would say it was quite often.
24 Q. More than five?

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1 A. Yes.
2 Q. When you refer to him having
3 given that direction, do you have in mind him
4 giving the direction to the lab as a group or
5 are you referring to instances where he may
6 have said that to individual lab members or
7 something else?
8 MR. KELLER: Objection.
9 Overbroad.
10 THE WITNESS: Since he gave it
11 on different occasions, I recall him
12 saying it to me. I recall him saying
13 it to other staff members. I, myself,
14 at a staff meeting, you know, brought
15 up the fact that, you know, the changes
16 were being made on focusing on
17 pre-positives which is falsifying data.
18 Making the statement that we're not
19 blinded so, therefore, being selective
20 over what we're going back to recount
21 based on what the expectation is.
22 BY MR. SANGIAMO:
23 Q. Can you give me the most
24 specific recollection you have of how he

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1 described what it is that you were supposed to
2 do if you did encounter a pre-positive?
3 A. He would ask us to check our
4 results.
5 Q. Okay. To go back and check to
6 make sure the count was accurate. Is that how
7 he would say it?
8 A. Again, I don't recall his
9 specific words, but I believe that is what he
10 was implying.
11 Q. That is what you understood him
12 to be saying?
13 A. Yes.
14 MR. KELLER: Could I get the
15 last question and answer back? Two
16 last questions and answers.
17 - - -
18 (The court reporter read the
19 pertinent part of the record.)
20 - - -
21 BY MR. SANGIAMO:
22 Q. You described a staff meeting
23 in your testimony a moment ago where, as I
24 understood it, you brought up that changes

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1 were being made to pre-positives and you
 2 considered that to be falsification I think is
 3 the words you used in your testimony just now?
 4 A. Yes.
 5 Q. And do you think that is the
 6 word you used at that staff meeting?
 7 A. I believe I stated that it was
 8 fraud.
 9 Q. You think fraud is the word
 10 that is used?
 11 A. Yes.
 12 Q. Why is that fraud? Why is it
 13 fraud to check the pre-positives?
 14 A. Because you're only selectively
 15 checking your pre-positives. You're not
 16 checking the entire assay. Again, if the
 17 method was validated and analysts were
 18 qualified, then the original results should
 19 serve to provide a result.
 20 Q. So you thought it was fraud in
 21 the sense that if only the pre-positives were
 22 checked, that would bias the results?
 23 A. I'm trying to think. So the --
 24 MR. KELLER: Objection.

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1 Overbroad. You can answer.
 2 THE WITNESS: Can you provide,
 3 I guess provide a different way of
 4 asking the questions. I'm not quite
 5 sure...
 6 BY MR. SANGIAMO:
 7 Q. I asked you why it's fraud to
 8 check only the pre-positives, and part of your
 9 response was because you're only selectively
 10 checking -- I'm paraphrasing, selectively
 11 checking pre-positives, you're not checking
 12 the whole assay. I'm trying to get at why
 13 that amounts to fraud. Can you elaborate at
 14 all on why that is fraud?
 15 MR. KELLER: Objection to form.
 16 BY MR. SANGIAMO:
 17 Q. And I suggested to you that
 18 perhaps it's a matter of biasing the results,
 19 but that's for you to say, not me.
 20 MR. KELLER: Same objection.
 21 THE WITNESS: Yes, in my
 22 opinion, if you are selectively
 23 changing data to reach a desired
 24 outcome, then I would consider that

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1 fraud.
 2 BY MR. SANGIAMO:
 3 Q. You just referred to changing
 4 data, and I gather what you were referring to
 5 there was going back to check a count and then
 6 changing it if you came up with -- if you
 7 counted a different number of plaques on that
 8 count as compared to what was counted on the
 9 first count. Do I have that right?
 10 A. That's correct.
 11 Q. Do you agree that -- strike
 12 that.
 13 Do you have an opinion as to
 14 whether a pre-positive is to be expected or
 15 not?
 16 MR. KELLER: Objection.
 17 BY MR. SANGIAMO:
 18 Q. Do you have an opinion on that?
 19 MR. KELLER: Objection. Vague
 20 and ambiguous. Seeks expert opinion
 21 from a layperson. Lack of foundation
 22 and overbroad.
 23 THE WITNESS: I would defer to
 24 an expert opinion on that.

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1 BY MR. SANGIAMO:
 2 Q. I'm going to ask a slightly
 3 different question using a term you may or may
 4 not have encountered in your assay work. Do
 5 you have an opinion on whether a pre-positive
 6 would be considered an abhorrent result?
 7 MR. KELLER: Objection. Vague
 8 and ambiguous. Overbroad. Lack of
 9 foundation.
 10 THE WITNESS: My opinion on
 11 abhorrent results is that it could be
 12 seen in both a positive or a negative
 13 in either the pre- or the
 14 post-vaccination.
 15 BY MR. SANGIAMO:
 16 Q. What does an abhorrent result
 17 mean to you? What does that term mean to you?
 18 A. I guess I would refer to it as
 19 an unexpected result. Let me think if I can
 20 further define that. Yeah, an unexpected
 21 result.
 22 MR. KELLER: Let me interpose
 23 an objection, lack of foundation.
 24 BY MR. SANGIAMO:

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

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

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1 negatives or pre-negatives, but they just
 2 weren't enough to convert them to a different
 3 status that would impact whether that sample
 4 had seroconverted. Do I have that right?
 5 A. That could be the case. Yeah,
 6 I don't remember if there were or were not any
 7 changes made in the data set.
 8 - - -
 9 (Exhibit Wlochowski-21,
 10 Handwritten document, RELATOR_00001025
 11 & 26, was marked for identification.)
 12 - - -
 13 BY MR. SANGIAMO:
 14 Q. Ms. Wlochowski, you've just
 15 been handed what has been marked as
 16 Exhibit 21. Do you recognize that document?
 17 A. I do.
 18 Q. What is it?
 19 A. It is -- how to describe it.
 20 It is a summary of a data set from different
 21 experiments that were run just to summarize
 22 the results, the results of pre-positives and
 23 whether or not they were changed.
 24 Q. In your testimony a few minutes

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1 ago you referred to a subset of the data that
 2 you had looked at. Is the subset of the data
 3 to which you're referring described here in
 4 this Exhibit 21?
 5 A. Yes, I believe so.
 6 Q. Who performed the analysis that
 7 led to the creation of this document?
 8 A. It was jointly performed by
 9 myself and Steve Krahlung.
 10 Q. To make it easier for us to
 11 talk about this, can we call this an audit?
 12 A. Sure.
 13 Q. Whose idea was it to perform
 14 that audit?
 15 A. I believe it was my idea.
 16 Q. What do you recall about the
 17 initial discussion between you and
 18 Mr. Krahlung about this audit?
 19 A. Just that, you know, again, I
 20 was questioning about being asked to recheck
 21 plates based on pre-negatives as were --
 22 sorry, pre-positives, as were others. And
 23 basically getting no -- I don't know how to
 24 explain it. You know, continuing to be

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1 requested to do that and check that. And
 2 really for me it was a matter of
 3 understanding, well, if it didn't seem to be a
 4 big deal, then let's just look at the data and
 5 see what it's telling us. So that was my
 6 intent of looking at the data and seeing if
 7 there was a bias that occurred.
 8 Q. You were testifying earlier
 9 about Dr. Krahl telling people to check the
 10 plaque counts for pre-positives. When he did
 11 that, would he make the request in general
 12 terms or in your experience was it a matter of
 13 him pointing to a particular sample and asking
 14 the analyst to go recheck that sample?
 15 A. As far as I can recall, it was
 16 a particular sample.
 17 Q. And that's how it occurred in
 18 your case? By your case, I mean the times
 19 when he asked you to check pre-positives?
 20 A. Yes.
 21 Q. Is that what you witnessed with
 22 others?
 23 A. Yes.
 24 Q. Is it your testimony that you

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1 have no recollection of him asking you to
 2 recheck anything other than a pre-positive?
 3 A. I can't say that he didn't ask
 4 that. Yeah, I can't say that that was the
 5 case.
 6 Q. Is that because you don't
 7 recall whether he did or he didn't, or is that
 8 because you remember that he did ask you to
 9 check other plates?
 10 A. I can say more in the lines
 11 that sometimes there were questionable results
 12 or, again, going back to what you were talking
 13 about, what you would consider an abhorrent
 14 result. The replicates didn't align, or if
 15 there were some anomalies with the monolayers,
 16 things like that. So I wouldn't exclude it.
 17 Q. Do you know whether there was
 18 checking of plaque counts by others in the lab
 19 on samples that were not pre-positive? Do you
 20 have knowledge of that?
 21 MR. KELLER: Objection. Vague
 22 and ambiguous. Overbroad.
 23 THE WITNESS: Can you repeat
 24 the question?

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1 BY MR. SANGIAMO:
 2 Q. Do you have knowledge of
 3 whether there was checking of plaque counts by
 4 others in the lab to samples other than
 5 pre-positives?
 6 MR. KELLER: Objection. Vague
 7 and ambiguous. Overbroad.
 8 THE WITNESS: My knowledge
 9 would just be drawn from that if he
 10 guided me to do that, he would guide
 11 others based on applying the same
 12 rationale what I just described in my
 13 previous question.
 14 BY MR. SANGIAMO:
 15 Q. So that's an assumption on your
 16 part. Right?
 17 A. Yes.
 18 Q. If we look at Exhibit 21, which
 19 is the documentation of the audit, the audit
 20 you and Mr. Krahling performed, you see the
 21 results. What was the nature of the
 22 underlying data for this?
 23 A. I want to say it was the cell
 24 count sheets.

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1 Q. What did you do with the cell
 2 count sheets?
 3 A. If I remember correctly, we
 4 took that and entered into the Excel workbook
 5 to populate the data.
 6 Q. You would populate the Excel
 7 workbook with the data originally counted? Is
 8 that the idea?
 9 A. So in this instance, original
 10 count would mean what was written on the
 11 counting sheet. Again, whether or not there
 12 were changes between the plates and what was
 13 entered on the counting sheet, we didn't go
 14 back to the plates, we only went back to the
 15 point of the counting sheets. So as there was
 16 a cross out on the counting sheet, we would
 17 factor that into the calculation in the
 18 workbook.
 19 Q. If you encountered a data point
 20 that had been crossed out in the counting
 21 sheet, then what you would enter into the
 22 workbook was the crossed out number, not the
 23 new number. Is that right?
 24 MR. KELLER: Objection.

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1 Mischaracterizes her testimony.
 2 THE WITNESS: What would be
 3 entered is the crossed out number.
 4 BY MR. SANGIAMO:
 5 Q. And this -- you would create a
 6 brand new worksheet for this assay? In other
 7 words, would you enter in every data point for
 8 the assay when you were conducting this audit?
 9 MR. KELLER: Overbroad.
 10 THE WITNESS: Repeat the
 11 question.
 12 BY MR. SANGIAMO:
 13 Q. When you were conducting the
 14 audit for a given assay, would you enter every
 15 data point for that assay?
 16 A. Every data point, yes, on the
 17 counting sheet. So with the -- what we just
 18 described, so the crossed out, not -- yes, so
 19 the crossed out results.
 20 Q. I got you. And then did you
 21 save that?
 22 A. I did not save it myself. I
 23 don't recall if that was saved by Steve.
 24 Q. Did you print it out?

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1 A. I don't recall if he printed it
 2 out.
 3 Q. But you didn't?
 4 A. I'm sorry?
 5 Q. You did not print it out. Right?
 6 A. Correct.
 7 Q. If we take a look at, let's
 8 say, the third row down, and reading across we
 9 see MKY under the column titled "counted by".
 10 Right?
 11 A. Yes.
 12 Q. That indicates that the person
 13 with the initials MKY did the original count
 14 on that?
 15 A. Correct.
 16 Q. Reading across to the right you
 17 say assay number 758-00. Correct?
 18 A. Correct.
 19 Q. Then it says three pre-positives.
 20 Right?
 21 A. Correct.
 22 Q. And then there is a blank next
 23 to that which in the case of this particular
 24 assay means that none of the pre-positives

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1 were changed. Right?
 2 MR. KELLER: Objection.
 3 Overbroad.
 4 THE WITNESS: What it means is
 5 that none of the pre-positives, based
 6 on -- either were not changed or the
 7 result of changing them still resulted
 8 in three pre-positives.
 9 BY MR. SANGIAMO:
 10 Q. And then if we go to the next
 11 line, we see an assay that was counted by JD
 12 and that was assay 759-00. In that instance,
 13 there were six pre-positives. Right?
 14 A. Uh-huh.
 15 Q. And what we see is that for two
 16 of those six, there were changes to the plaque
 17 count that resulted in them becoming
 18 pre-negative. Right?
 19 A. Correct.
 20 Q. And for the other four, either
 21 there were no changes at all or whatever
 22 changes there were did not cause it to convert
 23 from being pre-positive to pre-negative?
 24 A. Correct.

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1 Q. Now, do you have any way of
 2 addressing the question of why it is that
 3 those four pre-positives in 759-00 that did
 4 not convert to pre-negative and the three
 5 pre-positives in 758 that did not convert to
 6 pre-negative, why it is that those were not
 7 changed to pre-negative?
 8 MR. KELLER: Objection. Lack
 9 of foundation. Calls for speculation.
 10 THE WITNESS: It would be a
 11 speculation that no additional plaques
 12 were able to be identified, or if they
 13 were didn't change the results.
 14 BY MR. SANGIAMO:
 15 Q. Did you and Mr. Krahlung in
 16 conducting this audit attempt to determine
 17 what the impact was of these conversions from
 18 pre-positive to pre-negative on the overall
 19 assay -- sorry, on the overall seroconversion
 20 rate?
 21 MR. KELLER: Objection. Vague
 22 and ambiguous. Overbroad. Lacks
 23 foundation.
 24 THE WITNESS: This is only a

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1 subset of the data. So we did not, at
 2 least I did not, I don't recall that
 3 there was anything that Steve had done
 4 to calculate that.
 5 BY MR. SANGIAMO:
 6 Q. So, for example, if you look at
 7 the assay that we were looking at a moment
 8 ago, 759-00 which had six pre-positives and
 9 two pre-positives were changed to
 10 pre-negative, you didn't, and as far as you
 11 know, Steve didn't try and determine whether
 12 those two that were changed were seroconverters.
 13 Right?
 14 A. Not to my recollection.
 15 Q. If they hadn't been seroconverters,
 16 then that would actually be detrimental to the
 17 overall seroconversion rate in the assay.
 18 Right?
 19 MR. KELLER: Objection. Lack
 20 of foundation. Calls for speculation.
 21 THE WITNESS: I can't answer
 22 that in the overall set of data
 23 because, again, it was just a portion
 24 of the data.

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1 BY MR. SANGIAMO:
 2 Q. It would have been detrimental,
 3 you don't know how detrimental, but it would
 4 have been detrimental?
 5 MR. KELLER: Objection. Vague
 6 and ambiguous. Lack of foundation.
 7 Argumentative.
 8 THE WITNESS: I'm trying to
 9 think through the -- so it may or may
 10 not have been, just based on the fact
 11 that, again, that either if
 12 pre-positives were excluded from the
 13 study, and so, therefore, it decreases
 14 your overall sample size, versus having
 15 two more results, maybe one of them
 16 gave you a seroconversion, the other
 17 one didn't, at least it increased your
 18 sample size. So really I can't speak
 19 to whether or not it would have been
 20 detrimental overall.
 21 BY MR. SANGIAMO:
 22 Q. How is seroconversion
 23 calculated in the study?
 24 MR. KELLER: Objection. Lack

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

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1 THE WITNESS: Again, I would
2 defer to an expert witness, but I would
3 also add that the outcome of a study
4 should include the original data, the
5 data integrity should be maintained in
6 the study.
7 BY MR. SANGIAMO:
8 Q. So are you able to answer the
9 question of whether there could be changes to
10 data that would not impact the outcome of the
11 study? Are you able to answer that?
12 MR. KELLER: Asked and answered.
13 She just answered the exact same
14 question.
15 THE WITNESS: I guess I can
16 restate my answer in saying I wouldn't
17 want to know if the changes impacted
18 the study. I would want to know what
19 the real data is and I think that as a
20 scientist we all should want to know
21 what the real data is that would be
22 reported in the study.
23 BY MR. SANGIAMO:
24 Q. Why wouldn't you want to know

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1 whether the changes impacted the outcome of
2 the study?
3 A. Because this is not a research
4 or a developmental study. This is a study
5 that is, again, being performed on clinical
6 Phase III trial human patient serum. You
7 know, I believe there was additional data
8 being generated and supplemental assays that
9 were being tested using the clinical trial
10 serum which is not part of, as far as I
11 understand, the clinical study. The clinical
12 study, the testing should only be conducted on
13 what was stated in the clinical study until
14 the clinical study was closed and completed.
15 Q. Did you say you had an
16 understanding that there were additional
17 assays being conducted on the clinical trial
18 serum that were not part of the clinical
19 trial?
20 A. There were the supplemental
21 testing, I believe, utilized the serum that
22 was generated or obtained as part of the
23 trial.
24 Q. What supplemental testing are

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1 you referring to?
2 A. The -- what I spoke about
3 earlier where we were doing testing of high
4 and low passage cell lines.
5 Q. You think that was improper?
6 A. I do because you're generating
7 additional data on those test articles that
8 could also influence your results.
9 Q. How would that happen?
10 A. If somebody would make a
11 comparison to the results or try to draw
12 conclusions from that.
13 Q. I'm sorry, could you spell that
14 out? I don't understand.
15 A. If during the course of the
16 testing of the mumps neutralization assay for
17 the Protocol 007 you, say, saw a seroconversion
18 and then if you ran two other assays and a
19 supplemental assay and then saw something
20 different, it may make you question your
21 results in the assay that was being tested for
22 Protocol 007.
23 Q. Do you know if that happened?
24 A. I do not know if that happened.

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1 Q. Do you have any reason to
2 believe that it did happen?
3 MR. KELLER: Lack of foundation.
4 MR. SANGIAMO: That's kind of
5 my point.
6 BY MR. SANGIAMO:
7 Q. Do you have any reason to
8 believe that it did happen here?
9 A. I do not have any reason to
10 believe that it did or didn't happen. Again,
11 the test articles, I would just expect it to,
12 you know, be used in what it was intended to
13 be used in at the time for Protocol 007.
14 Q. Do you even know that the
15 supplemental testing involved serum from
16 Protocol 007?
17 A. I recall Dave Krah asking us to
18 hold performing any additional supplemental
19 testing as their, I think, again, not wanting
20 to generate additional results on the test
21 sera. So I, again, may be speculation, but to
22 me at the time of -- the timing of his e-mail
23 after the FDA inspection would lead me to
24 believe that those were the test articles for

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

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1 count? Did Dr. Krah say it was a low plaque
 2 count and that that was part of the reason
 3 that the assay would have to be discarded?
 4 A. Well, if the monolayer is torn,
 5 as he said, then the plaque count would be --
 6 you know, you wouldn't be able to provide a --
 7 you wouldn't have the full count for a
 8 confluent monolayer.
 9 Q. How many wells were there for
 10 the mock?
 11 A. I don't recall.
 12 Q. Could you take a look at
 13 Exhibit 16, please, which is the plate layout
 14 sheet for assay 211. Right?
 15 A. Yes.
 16 Q. Does that show how many plates
 17 were used for the mock?
 18 A. It shows that there was one
 19 plate.
 20 Q. How many wells on a plate?
 21 A. Going to get this right.
 22 Q. If it helps you any, you might
 23 want to look at Exhibit 19. I don't know if
 24 it will help you any.

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1 A. So it was 12 wells per plate.
 2 Q. 12 wells per plate, is that
 3 what you said, Ms. Wlochowski?
 4 A. Yes.
 5 Q. Is it your recollection there
 6 was a tear in one of those 12 wells, the assay
 7 would have to be discarded?
 8 A. Sometimes if there is a tear,
 9 it could occur across a plate, across wells.
 10 So if you're -- as you're, you know, dumping
 11 out the stain or the media, the aspirate, the
 12 media, but it could be a trigger that occurs
 13 across the plate.
 14 Q. Across all 12 wells?
 15 A. Not across 12 wells, but it
 16 could. Sometimes as you're fixing the edges
 17 of the monolayers across the plate, it could
 18 start to come off. It depends on, you know --
 19 again, going back to the variability within
 20 cell-based assays, that could occur, or it
 21 could be something during the course of
 22 running the assay that could cause that to
 23 occur.
 24 Q. But you don't have a recollection

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1 right now of how many wells Dr. Krah said were
 2 torn in this particular assay. Right?
 3 A. No. Maybe the wording is
 4 misleading just to say it's a torn monolayer
 5 and that would indicate one well, but it could
 6 mean across the plate.
 7 Q. Are you asserting that that is
 8 what he said?
 9 MR. KELLER: Mischaracterizes
 10 her testimony.
 11 MR. SANGIAMO: I'm trying to
 12 get to the bottom of this, Jeff.
 13 MR. KELLER: She just testified
 14 she doesn't recall.
 15 MR. SANGIAMO: She put something
 16 in verified Answers to Interrogatories
 17 accusing Dr. Krah of wrongdoing. I
 18 need to find out what Dr. Krah said.
 19 MR. KELLER: To be fair to the
 20 witness, she signed the Verification
 21 May 20, 2015. So two years ago.
 22 BY MR. SANGIAMO:
 23 Q. Ms. Wlochowski, yesterday I
 24 asked you which of these Interrogatories

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1 Mr. Krahling had input into. Did Mr. Krahling
 2 have any input into this paragraph?
 3 A. No.
 4 Q. This was all your writing with
 5 your counsel?
 6 A. Yes.
 7 Q. And so what is your best
 8 recollection of what Dr. Krah said that you're
 9 trying to capture there in the second sentence
 10 of this paragraph?
 11 A. It's just exactly that. That
 12 the cell monolayer was torn. Whether he's
 13 indicating one or multiple wells, I don't
 14 know.
 15 Q. You also don't know what it is
 16 that he said in terms of what needed to be
 17 done with the assay other than you've captured
 18 here him saying it needed to be thrown out.
 19 Is that right?
 20 A. Yes.
 21 Q. Ms. Wlochowski, when I looked
 22 at that paragraph and when I looked at what
 23 was marked as Exhibit 22 that raised a
 24 question in my mind which I'm going to ask you

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1 now to address if you could, whether there is
 2 any relationship between the events described
 3 in the paragraphs and what is captured in
 4 Exhibit 22?
 5 MR. KELLER: For the record,
 6 give her chance to look at Exhibit 22.
 7 MR. SANGIAMO: She spent a few
 8 minutes looking at it previously.
 9 THE WITNESS: So you want to --
 10 you're asking me if what is in the
 11 paragraph relates to what is in
 12 Exhibit 22?
 13 BY MR. SANGIAMO:
 14 Q. Yes, I am. If I could direct
 15 your attention to 1017 of Exhibit 22 using the
 16 Bates numbers in the bottom right-hand corner?
 17 A. Okay.
 18 Q. You may note that this purports
 19 to describe counts done by you, Mr. Gombola,
 20 Dr. Krah and Mr. Krahling. Right?
 21 A. Not necessarily.
 22 Q. Page 1017 does not --
 23 A. Oh, sorry. So page 1017 refers
 24 to -- can you repeat your question?

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1 Q. I was trying to direct your
 2 attention to the fact that page 1017 purports
 3 to show counts being done by you, Mr. Gombola,
 4 Dr. Krah and Mr. Krahling. Do you agree with
 5 that?
 6 A. Yes.
 7 Q. And the paragraph in your
 8 Answers to Interrogatories on page 18, as I
 9 read it, is describing an instance in which a
 10 certain mock was looked at by you, Mr. Gombola,
 11 Dr. Krah and Mr. Krahling. Right?
 12 A. Correct.
 13 Q. And if we go back to page 1017
 14 it appears that in one of the 12 wells in the
 15 data as reported by Dr. Krah the word "torn"
 16 appears. Right?
 17 A. Correct.
 18 Q. And in the corresponding wells
 19 in the counts as done by you, Mr. Gombola and
 20 Mr. Krahling, there is no indication of a
 21 tear. Right?
 22 A. Correct.
 23 Q. So it was on that basis that I
 24 wondered, and I'm asking you to address it, of

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1 whether what is contained here in Exhibit 22
 2 relates to what is described on page 18 of
 3 your Answers to Interrogatories?
 4 A. I cannot confirm that. I do
 5 not know.
 6 Q. Now, I think I -- when I first
 7 asked you if you recognized this document, you
 8 said something like I'm not certain if I
 9 recognize it.
 10 A. Yes.
 11 Q. You now looked at it a little
 12 more. Do you recognize it at all?
 13 A. I do not remember what this
 14 document is for. It looks like there was a
 15 comparison done, but I do not remember the
 16 intent of the data that is being presented
 17 here.
 18 Q. Have you seen the document
 19 before?
 20 MR. KELLER: Asked and answered.
 21 BY MR. SANGIAMO:
 22 Q. Don't tell me if you saw it in
 23 your meetings with counsel, but other than
 24 that, have you seen it before?

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1 A. Yes, because I signed it.
 2 Q. Are you sure you signed it?
 3 Your signature appears there.
 4 A. Yes, my signature.
 5 Q. Do you recall signing it?
 6 MR. KELLER: Are you -- you can
 7 answer.
 8 THE WITNESS: I don't remember
 9 if I signed it, but I believe that to
 10 be my signature.
 11 BY MR. SANGIAMO:
 12 Q. Well, do you have any way of
 13 assessing whether it's a photocopy of your
 14 signature as opposed to your original
 15 signature?
 16 A. I mean, it is a photocopy here
 17 today.
 18 Q. Right.
 19 A. That -- I don't have any reason
 20 to believe that it's not my signature.
 21 Q. Do you remember doing a count
 22 of mocks under these special circumstances
 23 that appear to be reflected here in this
 24 document?

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

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

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1 Q. What do you mean covered with
 2 dust?
 3 A. They had been there for some
 4 time. There was a number of plates.
 5 Q. Do you mean literally covered
 6 with dust or are you using that figuratively?
 7 A. That's what I recall, yes.
 8 Q. What was -- -- strike that.
 9 Did Dr. Krah alter his conduct
 10 when he saw you?
 11 A. I don't think so.
 12 Q. You said you left the room to
 13 then go talk to Mr. Krahling?
 14 A. I did.
 15 Q. Was it unusual for Mr. Krahling
 16 to be in at that hour?
 17 A. He was typically in before Dave
 18 was.
 19 Q. Okay. And 8:00, that was your
 20 arrival time at that time. Right?
 21 A. Yes.
 22 Q. What was Mr. Krahling's
 23 reaction when you told him what you saw?
 24 A. I think he was somewhat shocked.

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1 Q. What did he say? I'm sorry,
 2 continue.
 3 A. I was going to say he was in
 4 shock he was doing it. Your question?
 5 Q. Do you recall what words
 6 Mr. Krahling spoke?
 7 A. I do not recall.
 8 Q. Do you know what the process
 9 was generally for discarding the plates that
 10 were used in Protocol 007?
 11 A. I do not know what the process
 12 was that I can recall.
 13 Q. Have you had any involvement in
 14 the discarding of plates -- strike that.
 15 Have you had any involvement in
 16 the discarding of test samples that contain a
 17 live virus in your career?
 18 A. Yes.
 19 Q. Is that at Pfizer?
 20 A. At Yale. I can't remember if
 21 at Pfizer. And there may have been other
 22 instances, but I can say at Yale that I did it.
 23 Q. Do you have any recollection of
 24 what the procedure was for discarding the test

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1 samples containing live virus at New Haven?
 2 A. We discarded into a biohazard
 3 waste container.
 4 Q. Would you do that right after
 5 the testing?
 6 A. When the test was complete, yes.
 7 Q. As I understand your testimony
 8 sitting here right now, you don't have a
 9 recollection of being involved in the
 10 discarding of test samples containing a live
 11 virus in your time at Pfizer or Amgen. Right?
 12 A. I'm not excluding it, but I
 13 don't recall.
 14 Q. Could you flip back to page 14,
 15 please, of Exhibit 7? I want to direct your
 16 attention to the first paragraph on that page.
 17 In particular, I was going to ask you about
 18 the sentence in the fifth line that reads,
 19 "Kennedy agreed that there was fraud in the
 20 lab regarding Protocol 007, but he did not
 21 want to be a part of taking a stand against it
 22 as he did not want to lose his job."
 23 My question is going to be your
 24 best recollection of exactly what it is that

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

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1 again, Suzanne and Jon were willing to -- they
 2 were more willing to speak up in the audit if
 3 there was opportunity as, again, Jill and
 4 Frank were, although they agreed, they weren't
 5 going to -- they weren't going to volunteer
 6 that information.
 7 Q. Weren't going to volunteer what
 8 information?
 9 A. Of, again, the data changes
 10 that were occurring on the pre-positives.
 11 Q. Did they express any reluctance
 12 to reveal it?
 13 A. They were reluctant based on
 14 the -- what we went over previously with my
 15 response to Frank. Again, his reluctance was
 16 around potentially losing his job for
 17 providing information.
 18 Q. Is that what he said?
 19 MR. KELLER: Objection. Asked
 20 and answered.
 21 BY MR. SANGIAMO:
 22 Q. Did he say if I tell the truth
 23 I might lose my job?
 24 A. Again, in the general sense, yes.

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1 Q. Did he indicate that anyone
 2 ever told him that that was so?
 3 MR. KELLER: I'm sorry, can you
 4 read that question back?
 5 BY MR. SANGIAMO:
 6 Q. Did he indicate that anyone
 7 ever told him that was so?
 8 A. When he had -- he had indicated
 9 he, himself, also felt isolated from the lab
 10 group and, you know, he didn't want to put
 11 anything, any additional stresses on his
 12 acceptance and maintaining his job.
 13 Q. Did anyone ever indicate to
 14 Mr. Kennedy that he might lose his job if he
 15 answered the questions of the auditor at the
 16 audit?
 17 MR. KELLER: Objection. Asked
 18 and answered.
 19 THE WITNESS: Again, if you are
 20 being targeted and don't feel
 21 comfortable with something that could
 22 put your job at risk, then that was his
 23 feeling.
 24 BY MR. SANGIAMO:

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1 Q. Is that the entirety of what
 2 you have to say to me in terms of whether he
 3 was ever told that he might lose his job if he
 4 answered the questions at the audit?
 5 A. Yes.
 6 MR. KELLER: Objection. Lack
 7 of foundation. Interpose an objection.
 8 Lack of foundation.
 9 BY MR. SANGIAMO:
 10 Q. If you turn to page 20 of your
 11 Answers to Interrogatories. The last full
 12 paragraph on that page reads, "Relator had
 13 multiple communications with Alan Shaw about
 14 topics relating to allegations in the
 15 complaint regarding the mumps vaccine. These
 16 communications took place in person at Merck's
 17 facility where they worked in West Point,
 18 Pennsylvania between January and September 2001.
 19 Relator specifically recalls the day that Shaw
 20 came into the lab to tell the team that the
 21 FDA was on site. Shaw was white as a ghost
 22 and left quickly after making the
 23 announcement. Relator does not know Shaw's
 24 current or last known address or place of

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1 employment."
 2 When you say Shaw was white as
 3 a ghost, that is colorful phrasing. Do you
 4 mean his natural complexion was different than
 5 what it usually is?
 6 A. Yes.
 7 Q. Was his complexion pretty pale
 8 to begin with?
 9 A. It is, but his -- my impression
 10 of Alan Shaw is he always carried himself with
 11 confidence. This particular day, was -- it
 12 was as they came in, he had a look of --
 13 trying to find the right word. I guess a look
 14 of concern.
 15 Q. As one would expect a
 16 pharmaceutical executive to have if there was
 17 an FDA inspection. Right?
 18 MR. KELLER: Objection.
 19 Objection. Lack of foundation. Calls
 20 for speculation.
 21 THE WITNESS: Pharmaceutical
 22 companies are, you know, inspected
 23 regularly. So those who are seasoned
 24 are used to handling this -- handling

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1 an inspection and typically there is a
 2 different -- I guess it does put you on
 3 guard, but, again, it's not -- he
 4 seemed to be a bit more concerned than
 5 I would expect him.
 6 BY MR. SANGIAMO:
 7 Q. Inspections are usually of
 8 manufacturing facilities by the FDA?
 9 MR. KELLER: Objection.
 10 Foundation. Overbroad.
 11 BY MR. SANGIAMO:
 12 Q. Do you know?
 13 A. I do know that it goes beyond
 14 manufacturing facilities.
 15 Q. How many inspections do you
 16 have knowledge of in your career, FDA
 17 inspections?
 18 A. What do you mean do I have
 19 knowledge of?
 20 Q. That you're aware of. That is
 21 a fair question. How many inspections are you
 22 aware of that have occurred at pharmaceutical
 23 companies while you were working there?
 24 A. That's pretty broad, too.

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1 MR. KELLER: That's very broad.
 2 BY MR. SANGIAMO:
 3 Q. FDA inspections.
 4 MR. KELLER: Same.
 5 THE WITNESS: I worked for
 6 multiple pharmaceutical companies. I
 7 guess I'm not --
 8 BY MR. SANGIAMO:
 9 Q. So you think it could be more
 10 than 50 or something?
 11 A. Are you saying at the company
 12 that I worked at?
 13 Q. Uh-huh.
 14 A. And over the course of what --
 15 I guess I'm -- again, it's still very broad to
 16 me.
 17 Q. When you were working there.
 18 A. When I was working where?
 19 Q. At the various pharmaceutical
 20 companies that you've worked at?
 21 A. And you're asking the question,
 22 again, about the --
 23 Q. Number of FDA inspections.
 24 A. The number of FDA inspections

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1 at the company?
 2 Q. Yes. For example. How many
 3 FDA inspections were there at Amgen while you
 4 were working at Amgen, added to the number of
 5 FDA inspections at Pfizer while you were
 6 working at Pfizer, added to the number of FDA
 7 inspections at Alexion while you were working
 8 at Alexion.
 9 A. Again, those are global companies
 10 so --
 11 MR. KELLER: Objection.
 12 Overbroad. Lack of foundation.
 13 BY MR. SANGIAMO:
 14 Q. The ones you know of.
 15 MR. KELLER: Still overbroad.
 16 Lack of foundation.
 17 THE WITNESS: If you are asking
 18 me -- maybe I can make it easier.
 19 BY MR. SANGIAMO:
 20 Q. Sure.
 21 A. So typically there would be an
 22 annual or biannual inspection. There could be
 23 a follow-up inspection. But FDA inspections
 24 are usually unannounced, but pharmaceutical

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1 companies typically have an indication of when
 2 they expect the next visit to occur. The
 3 exception would be if there was a for-cause
 4 audit that the FDA could come in on that
 5 non-routine schedule to inspect.
 6 Q. You say in your -- the
 7 paragraph in your Answers to Interrogatories
 8 that we were just reading that you had
 9 multiple communications with Alan Shaw about
 10 topics relating to allegations in the
 11 Complaint regarding the mumps vaccine. Were
 12 any of those one-on-one conversations between
 13 you and Dr. Shaw?
 14 A. I don't recall one-on-one
 15 conversations.
 16 Q. What do you recall about the
 17 context of the communications that are
 18 referred to in that response?
 19 A. I believe when we had -- when
 20 we had the meeting with Emilio, I believe that
 21 Alan was present. So this was the meeting
 22 where Emilio was enforcing the importance of
 23 the lab being able to complete the testing in,
 24 I guess, an expedited manner and that bonuses

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1 would be given for completion of the testing.
 2 I'm trying to remember other examples. That's
 3 all I can remember at this time specifically.
 4 Q. That's all you can remember by
 5 way of occasions in which Dr. Shaw
 6 communicated with you about the topics related
 7 to allegations in the Complaint regarding
 8 mumps vaccine?
 9 A. Yes.
 10 Q. What do you recall Dr. Shaw
 11 saying at that meeting?
 12 A. I don't recall if he said
 13 anything at that meeting.
 14 Q. Do you recall having any
 15 communications with Dr. Emini other than at
 16 the meeting you just described?
 17 A. Not directly, no.
 18 Q. Okay. Make sure I understand
 19 what that means. Does that mean that --
 20 actually, what does that mean?
 21 A. I mean, it doesn't make sense,
 22 I guess. So I did not have a conversation
 23 with Emilio. I know that through Bob Suter
 24 that one of the exhibits that we looked at the

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1 other day was after my talking to Bob, Bob
 2 talked to Emilio. So that's the extent.
 3 Q. I see. You just now said --
 4 you just now spoke in terms of conversations
 5 with Emilio. Make sure I have a full
 6 understanding. Do you recall any other kind
 7 of direct communication with Emilio other than
 8 the one meeting that you described?
 9 A. So I believe there was a
 10 departmental meeting that Emilio had provided
 11 following the FDA inspection. That's what I
 12 recall.
 13 Q. Anything else?
 14 A. I can't recall at this time.
 15 Q. What do you recall about the
 16 departmental meeting following the FDA
 17 inspection in terms of what Dr. Emini said?
 18 A. I want to say he gave a summary
 19 of the 483 responses.
 20 Q. Okay. Did he talk about next
 21 steps?
 22 A. Yes, I believe so.
 23 Q. Who was at this departmental
 24 meeting, I'm not asking for a roster of all

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1 attendees, but was it multiple labs?
 2 A. From what I recall, yes, I
 3 think it was the whole department of virus and
 4 cell biology.
 5 Q. Did anyone else speak at this
 6 meeting?
 7 A. I can't recall.
 8 Q. What did Dr. Emini say about
 9 next steps?
 10 A. So that, again, I would have
 11 to -- to the best of my recollection, I
 12 believe there was a statement around the
 13 application of -- I can't remember. I know I
 14 have a summary of it.
 15 Q. You said you know you have a
 16 summary of it?
 17 A. Yes.
 18 Q. You mean in writing?
 19 A. Yes.
 20 Q. But other than that summary,
 21 you don't have a recollection?
 22 A. Because, again, it's getting
 23 blurred with other information. I know we had
 24 some after the FDA inspection, we had

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1 training, other presentation information that
 2 was given to us on -- I'm just blurring on
 3 what his direction was.
 4 Q. You gave some testimony earlier
 5 about the meeting attended by Dr. Emini and
 6 Dr. Shaw during which Dr. Emini mentioned the
 7 importance of completing the study and the
 8 bonuses to the lab if this study was completed
 9 on a certain schedule?
 10 A. Yes.
 11 Q. Do you recall anything else
 12 about what Dr. Emini said at that meeting?
 13 A. I do not.
 14 Q. Was it a short meeting?
 15 A. To the best I can recall, yes.
 16 Q. If you had to estimate the
 17 length of the meeting, what would be your best
 18 estimate?
 19 A. Not more than a half an hour.
 20 Q. Could you turn to page 8 of the
 21 Answers to Interrogatories, please. If you
 22 look at the paragraph under the heading 1, do
 23 you see that?
 24 A. Yes.

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1 Q. It says, "Relator Krahling told
2 Relator what he learned from Krah of numerous
3 communications -- both written and verbal --
4 that Merck had with the FDA in the 1999-2001
5 time frame in connection with its Protocol 007
6 testing. Relator knows these communications
7 occurred and that these communications did not
8 disclose what Merck knew about the
9 significantly diminished efficacy of the
10 vaccine and the steps it was taking to conceal
11 this from the FDA." That's the end of the
12 quote.
13 How is it that you know that
14 these communications occurred and that these
15 communications did not disclose what Merck
16 knew about the significant diminished efficacy
17 of the vaccine and the steps it was taking to
18 conceal this from the FDA?
19 MR. KELLER: I object. The
20 responses to Interrogatories were
21 written by both lawyers and the
22 verifier. And I object as a legal
23 conclusion to that question. To the
24 extent you can answer it. And to the

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1 extent the question is compound, I
2 object to that as well.
3 THE WITNESS: Can I read the
4 context of the question?
5 BY MR. SANGIAMO:
6 Q. Sure. I may be able to
7 simplify this for you. Do you have any
8 personal knowledge of what is stated there in
9 the second sentence of the response under
10 paragraph number 1 on page 8 of your Answers
11 to Interrogatories, the sentence that begins,
12 "Relator knows these communications
13 occurred..." and so forth?
14 MR. KELLER: Objection.
15 Overbroad.
16 THE WITNESS: Can you define
17 what you mean by personal knowledge
18 here?
19 BY MR. SANGIAMO:
20 Q. What is the basis of your
21 knowledge supporting that statement? Let's
22 try that question.
23 MR. KELLER: Again, seeks a
24 legal conclusion.

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1 THE WITNESS: So I can't -- I
2 don't think I can answer that question
3 based on what I've discussed with legal
4 counsel.
5 BY MR. SANGIAMO:
6 Q. Right. So you don't know
7 anything about that other than what you have
8 discussed with counsel. Is that a fair
9 statement?
10 A. To the extent of my knowledge,
11 beyond what counsel has told me, I know that,
12 again, the -- what is currently reported in
13 the label is referencing to the original data
14 that was generated from the approval of the
15 vaccine when it was first approved. This is
16 because -- I guess I'll let you hook that into
17 my response.
18 MR. KELLER: Let me interpose
19 an objection. Asked and answered this
20 question previously.
21 - - -
22 (Exhibit Wlochowski-23,
23 Handwritten document, Bates RELATOR
24 00000707, was marked for identification.)

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1 - - -
2 BY MR. SANGIAMO:
3 Q. Ms. Wlochowski, you've been
4 handed what has been marked as Exhibit 23. A
5 few minutes ago you were giving testimony
6 about a meeting that you attended in which Dr.
7 Emini discussed the inspection and the next
8 steps after the inspection. I believe while
9 you were giving that testimony you indicated
10 you had documentation of what was discussed at
11 that meeting. Is that right?
12 A. Yes.
13 Q. Exhibit 23, is that the
14 documentation you were referring to?
15 A. Yes.
16 Q. Down at the very bottom of the
17 page it says, "human subject must be GMP."
18 Right?
19 A. Yes.
20 Q. And there is a little mark of
21 some sort just to the left of human. Do you
22 know what that is?
23 A. That's a star, an asterisk.
24 Q. Do you recall exactly what it

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

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1 by an August deadline."
 2 What was the procedure to avoid
 3 invalidating assays?
 4 MR. KELLER: If you need to
 5 read the entire paragraph...
 6 MR. SANGIAMO: I thought she
 7 did.
 8 MR. KELLER: I wasn't sure if
 9 she did.
 10 BY MR. SANGIAMO:
 11 Q. Have you read that paragraph
 12 already?
 13 A. I didn't finish. Repeat your
 14 question.
 15 Q. My question is, what is the
 16 procedure to which you are referring in the
 17 last sentence of that paragraph?
 18 A. In the sense that I don't think
 19 procedure means an SOP document as, again,
 20 similar to -- let's see if I can get an
 21 example. So similar to above where Krah had
 22 explained that a sample would be recounted, if
 23 it was determined to show a pre-positive
 24 result. He also had advised on a procedure

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1 that -- I shouldn't say a procedure, but he
 2 had also advised the same for assays which may
 3 have resulted in invalid assays, to recheck
 4 those as well.
 5 Q. To recheck those to make sure
 6 that the plaques are counted accurately
 7 because if they weren't, and they were changed
 8 to an accurate count, an invalid assay would
 9 become valid?
 10 A. To recheck the count to see if
 11 you could either find more plaques because
 12 that would make it positive or less plaques
 13 because -- I'm sorry, find more plaques
 14 because that would make the assay valid or to
 15 find less plaques because that would make the
 16 assay valid depending on what it was that you
 17 were rechecking.
 18 - - -
 19 (Exhibit Wlochowski-24,
 20 Responses and Objections to Merck's
 21 First Set of Interrogatories, was
 22 marked for identification.)
 23 - - -
 24 BY MR. SANGIAMO:

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1 Q. You've just been handed what
 2 has been marked as Exhibit 24. These are your
 3 Answers to Merck's First Set of Interrogatories.
 4 Right? If you're wondering what the relationship
 5 is between --
 6 A. They look very similar.
 7 Q. They are. It looks like Jeff
 8 is about to tell you.
 9 MR. KELLER: One is revised,
 10 one is original.
 11 THE WITNESS: So the one we
 12 were looking at first is the revised
 13 but this is the first set.
 14 BY MR. SANGIAMO:
 15 Q. Yes.
 16 A. So they're in reverse.
 17 Q. Yes. Exactly.
 18 I was going to ask you to turn
 19 to page 14, please, where there is a paragraph
 20 at the top that reads as follows: "Relator
 21 was working in David Krah's lab on August 6,
 22 2001, along with Stephen Krahling and others.
 23 Alan Shaw came in to Krah's lab and told
 24 Relator that the FDA was 'here.' Relator

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1 continued to go about her work while the FDA
 2 representative was in Krah's lab. Relator saw
 3 Mr. Krahling sitting at his desk near where
 4 Krah, Shaw and the FDA representative
 5 were talking in Mr. Krah's office.
 6 Thereafter, Mr. Krahling informed Relator that
 7 he overheard the conversations between the FDA
 8 representative, Krah and Shaw on August 6,
 9 2001 described in Relators' complaint."
 10 Did you, yourself, hear what
 11 was said between Dr. Krah and the FDA on
 12 August 6, 2001?
 13 MR. KELLER: Objection. Asked
 14 and answered. Answer again.
 15 THE WITNESS: I did not hear
 16 what was being discussed between the
 17 FDA and Krah and Shaw.
 18 BY MR. SANGIAMO:
 19 Q. Is your understanding of what
 20 was discussed between the FDA and Krah and
 21 Shaw based on what Mr. Krahling told you?
 22 A. Yes.
 23 Q. And what you witnessed is that
 24 Dr. Krah and Dr. Shaw and the FDA representative

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

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1 participate in the fraud.
 2 BY MR. SANGIAMO:
 3 Q. You said Dr. Krah was asking
 4 you to change data. You're referring to the
 5 fact that Dr. Krah was asking you to go back
 6 and check the plaque counts for the
 7 pre-positives that you testified about
 8 earlier. Right?
 9 A. Yes.
 10 Q. And you say that Dr. Emini
 11 offered bonuses. He offered bonuses for
 12 completing the work under a certain schedule.
 13 Right?
 14 A. Yes.
 15 Q. Did he describe any other
 16 condition for the bonus?
 17 A. I don't recall him describing
 18 any other conditions.
 19 Q. And then that sentence also
 20 refers to a subsequent cover up. What are you
 21 referring to there?
 22 MR. KELLER: Same objection.
 23 Seeks a legal conclusion.
 24 THE WITNESS: I'm just trying

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1 to think. I can't think of an example
 2 at the moment.
 3 BY MR. SANGIAMO:
 4 Q. If you turn to the next page,
 5 paragraph 5.
 6 MR. KELLER: Are you going to
 7 ask this again?
 8 BY MR. SANGIAMO:
 9 Q. The first sentence reads,
 10 "Merck's failure to disclose what it knew
 11 about the diminished efficacy of its mumps
 12 vaccine has caused the government to purchase
 13 mislabeled, misbranded, adulterated and
 14 falsely certified vaccines in violation of
 15 Merck's contract with the Centers for Disease
 16 Control...and in violation of the law."
 17 My question to you is, what is
 18 your basis for any assertion you might be
 19 making there that Merck knew about diminished
 20 efficacy of the mumps vaccine? Is there
 21 anything there beyond what you already
 22 testified to in this deposition?
 23 MR. KELLER: Objection.
 24 Overbroad. Seeks a legal conclusion.

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1 Vague and ambiguous.
 2 THE WITNESS: It is a pretty
 3 broad statement. I think that the --
 4 based on what I've already spoke to,
 5 supports that paragraph.
 6 BY MR. SANGIAMO:
 7 Q. Do you have anything else to
 8 support it?
 9 MR. KELLER: Same objection.
 10 THE WITNESS: Again, there is a
 11 lot of documentation that we have, so I
 12 think I have highlighted the key points
 13 that would support that.
 14 BY MR. SANGIAMO:
 15 Q. That would support that Merck
 16 knew there was diminished efficacy?
 17 MR. KELLER: Asked and answered.
 18 THE WITNESS: Yes.
 19 BY MR. SANGIAMO:
 20 Q. Yes?
 21 A. Yes.
 22 Q. You said you highlighted the
 23 key points. You mean there are other points,
 24 you just haven't made them yet in the

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1 deposition?
 2 A. Again, we spoke about a lot of
 3 things. We have a lot of documents. So I
 4 think I have summarized what -- already what
 5 supports that statement.
 6 Q. Turn to paragraph 21, please.
 7 MR. KELLER: We've been going
 8 for an hour, take a break.
 9 MR. SANGIAMO: Fine by me.
 10 VIDEOGRAPHER: The time is now
 11 5:37.
 12 - - -
 13 (A recess was taken.)
 14 - - -
 15 VIDEOGRAPHER: The time is now
 16 5:46. This begins disc six. You may
 17 proceed.
 18 BY MR. SANGIAMO:
 19 Q. Ms. Wlochowski, could you take
 20 a look at paragraph 21 of Exhibit 6? It's on
 21 page 7. The first sentence begins, "Merck
 22 predicted the resurgence of outbreaks given
 23 the diminished effectiveness of its mumps
 24 vaccine."

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1 Do you see that?
 2 A. Yes.
 3 Q. Is that something you have
 4 knowledge of?
 5 MR. KELLER: Objection. Seeks
 6 a legal conclusion. Overbroad.
 7 THE WITNESS: Yes.
 8 BY MR. SANGIAMO:
 9 Q. Had Merck made that prediction?
 10 You have knowledge of that?
 11 A. Yes.
 12 Q. What is your knowledge of that?
 13 MR. KELLER: Same objection.
 14 You can answer. Overbroad. In
 15 answering the question, please do not
 16 disclose any communications you may
 17 have had with your counsel. To the
 18 extent you can answer without disclosing
 19 those communications, you may.
 20 THE WITNESS: I cannot disclose
 21 based on my conversations with counsel.
 22 BY MR. SANGIAMO:
 23 Q. You don't have any knowledge of
 24 that other than what you may have discussed

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1 with your counsel?
 2 A. I believe so.
 3 Q. The third sentence reads, of
 4 paragraph 21 reads, "Merck knows that the
 5 continued passaging of the attenuated virus to
 6 make more vaccines for distribution has
 7 altered the virus and has degraded the
 8 efficacy of the product."
 9 Do you have personal knowledge
 10 of the basis of that allegation?
 11 MR. KELLER: I object. Seeks a
 12 legal question. Answer to the extent
 13 you don't disclose communications with
 14 counsel. If you can answer the question
 15 without disclosing communications with
 16 counsel, you may do so.
 17 THE WITNESS: Again, I cannot
 18 answer based on my discussion with
 19 counsel.
 20 BY MR. SANGIAMO:
 21 Q. If you look at paragraph 22.
 22 Seven lines down, paragraph reads, "However,
 23 beginning in the late 1990s, Merck...,"
 24 Strike that.

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1 MR. KELLER: Thank you.
 2 BY MR. SANGIAMO:
 3 Q. Paragraph 23, first sentence,
 4 "Without demonstrating that its mumps vaccine
 5 continued to be 95 percent effective, Merck
 6 risked losing the monopoly it had over the
 7 sale of the mumps vaccine in the U.S."
 8 Is that something that you have
 9 knowledge of?
 10 MR. KELLER: Objection. Seeks
 11 a legal conclusion. And if you can
 12 answer the question without disclosing
 13 communications with counsel, feel free
 14 to answer. If you can't answer without
 15 disclosing communications with counsel,
 16 then please do not.
 17 THE WITNESS: Again, I mean,
 18 that's just general knowledge that if a
 19 product is less effective, it would be
 20 -- it would open up the doors for a
 21 competitor to be able to provide a
 22 better product that's more effective.
 23 BY MR. SANGIAMO:
 24 Q. So you're just referring to

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1 general principles of competition in support
 2 of that sentence?
 3 A. In support of that sentence as
 4 well as conversations I've had with counsel.
 5 Q. Paragraph 30. The first
 6 sentence reads, "Even with a deviation that
 7 could only overstate how well the vaccine
 8 worked, the results from Merck's preliminary
 9 testing (which involved testing blood samples
 10 of approximately 60-100 children) yielded
 11 seroconversion rates significantly below the
 12 desired 95 percent threshold."
 13 Do you have personal knowledge
 14 of that?
 15 MR. KELLER: If you need to
 16 read the paragraph before that, feel
 17 free to do so. If you need to read the
 18 rest of paragraph 30, do so as well.
 19 THE WITNESS: So I do have
 20 personal knowledge of the preliminary
 21 testing yielding seroconversion rates
 22 significantly lower than the 95 percent
 23 threshold.
 24 BY MR. SANGIAMO:

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

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1 When I started working in the other lab, I
 2 felt more at ease in that surprisingly the --
 3 even though I believe it was in a separate
 4 building, the people from that lab knew about
 5 Dave Krah and were actually supportive of me
 6 in the move. They're -- as one person stated,
 7 you're not part of Dave Krah's harem is the
 8 terminology that they used. So it made me
 9 think it wasn't, again, just me thinking that.
 10 There was something that was recognized
 11 outside of his laboratory.
 12 Q. Ma'am, were you told you had no
 13 choice but to leave Dr. Krah's lab?
 14 MR. KELLER: Asked and answered.
 15 Come on. Argumentative.
 16 MR. SANGIAMO: She doesn't get
 17 to do this, Jeff. She has to answer
 18 the question. She doesn't get to make
 19 a speech after that.
 20 MR. KELLER: You're not
 21 entitled to badger the witness and
 22 harass her. Ask your question again,
 23 she'll answer again. It's getting
 24 harassing at this point, Dino.

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1 THE WITNESS: As I had already
 2 responded in the previous question, no,
 3 I was not told I had no choice.
 4 BY MR. SANGIAMO:
 5 Q. You said something in your last
 6 answer about -- you said you felt embarrassed
 7 by it because I felt like it was arranged just
 8 to get me out of there.
 9 A. Yes.
 10 Q. What were you referring to
 11 there?
 12 A. Again, if I wasn't willing to
 13 comply with the fraud in the lab, I felt like
 14 for them it was easier to remove me than to
 15 address it.
 16 Q. Did they say that to you?
 17 A. No. Again, I stated it as a
 18 feeling that I had.
 19 Q. But it's not a feeling that was
 20 based on anything that anybody said to you.
 21 Right?
 22 MR. KELLER: Objection.
 23 THE WITNESS: Correct.
 24 BY MR. SANGIAMO:

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1 Q. Who was it that said you're no
 2 longer part of Dave's harem?
 3 A. I would -- I believe it was Kim
 4 Johnstone.
 5 Q. Did she elaborate on what she
 6 meant by that?
 7 A. I don't think so.
 8 Q. Do you have any knowledge of
 9 whether Mr. Krahling signed a separation
 10 agreement with Merck?
 11 MR. KELLER: I'm going to ask
 12 you -- you can answer that question yes
 13 or no.
 14 THE WITNESS: Yes.
 15 BY MR. SANGIAMO:
 16 Q. Did he discuss the separation
 17 agreement with you in 2001?
 18 A. What do you mean by discuss the
 19 agreement?
 20 Q. Did he mention to you anything
 21 about a possibility of a separation agreement
 22 between him and Merck?
 23 MR. KELLER: Objection. Lack
 24 of foundation.

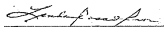
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1 THE WITNESS: I want to say
 2 that he actually mentioned it but it
 3 was never confirmed. I didn't know at
 4 that time if he actually did from my
 5 recollection.
 6 BY MR. SANGIAMO:
 7 Q. When he mentioned it to you,
 8 was that at a time period before he had
 9 actually signed anything, to your knowledge?
 10 A. I don't recall.
 11 Q. Did he mention it to you in the
 12 context of discussing with you whether he
 13 should sign a separation agreement?
 14 A. No, I don't believe so.
 15 Q. Did he tell you anything about
 16 what the terms of the separation agreement
 17 might be?
 18 A. No.
 19 Q. Has he ever told you that?
 20 MR. KELLER: You can answer as
 21 long as you don't answer if counsel was
 22 present.
 23 THE WITNESS: I cannot answer
 24 based on conversations with counsel.

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<p style="text-align: right;">Page 553</p> <p>1 BY MR. SANGIAMO: 2 Q. How frequently did you see 3 Mr. Kraehling in September of 2001, if you 4 recall? 5 A. I don't recall when he left 6 Merck. 7 Q. When you say when he left 8 Merck, that's a reference to his last day of 9 work at Merck? Do you understand what I'm 10 saying? 11 A. I do. I don't know when his 12 last day of work was at Merck. 13 Q. Did you have discussions with 14 him about the separation agreement after he 15 had stopped working there? 16 A. I can't remember if it was 17 prior or -- I want to say after he left Merck, 18 no. 19 Q. Did Mr. Kraehling ever tell you 20 that he thought his life was in danger? 21 A. He may have stated something 22 around that, you know, and based on what we 23 were going through at the time, it's -- again, 24 it's a stretch but it's also part of what we</p>	<p style="text-align: right;">Page 555</p> <p>1 MR. SANGIAMO: She's not 2 answering, Jeff. Let's get an answer. 3 MR. KELLER: Objection to form. 4 THE WITNESS: So if you're 5 asking physically safe, I can't say 6 that I felt that, felt that I was 7 physically threatened. I can't say 8 that it wouldn't happen, but it was, 9 yeah, it was not, you know -- like I 10 said, it's a stretch. 11 BY MR. SANGIAMO: 12 Q. So you did not feel physically 13 threatened. Right? 14 MR. KELLER: Asked and answered. 15 This is the third time now. I know you 16 don't like her answer, but you can 17 answer again. 18 THE WITNESS: What I said 19 previously was that I did not feel 20 physically threatened because it was a 21 stretch, and -- but I can't say that's 22 something that wouldn't have happened. 23 You never know. 24 BY MR. SANGIAMO:</p>
<p style="text-align: right;">Page 554</p> <p>1 were feeling. We were up -- it's almost as 2 though we were up against the world. At least 3 for me, that's how I felt as well. 4 It was very clear to me that 5 there was data being changed to reach a 6 desired outcome. We had discussed it, 7 addressed it. We had raised it internally. 8 We had contacted the FDA. It was a difficult 9 thing to do to raise something at a big 10 company like Merck. It's scary. 11 Q. Did you think your life was in 12 danger? 13 A. I don't -- I can tell you I had 14 nightmares. It's not a good feeling. 15 Q. Did you fear for your safety? 16 MR. KELLER: Asked and answered. 17 THE WITNESS: That was my 18 feeling. I was scared. So if scared 19 is part of being -- having feelings 20 against feeling safe and comfortable. 21 BY MR. SANGIAMO: 22 Q. Feeling physically safe you 23 mean? 24 MR. KELLER: Asked and answered.</p>	<p style="text-align: right;">Page 556</p> <p>1 Q. You never told anybody that you 2 felt physically threatened. Right? 3 A. I can't recall. 4 MR. SANGIAMO: Give me a second 5 here. No further questions. 6 MR. KELLER: I've just got a 7 couple of questions. 8 - - - 9 EXAMINATION 10 - - - 11 BY MR. KELLER: 12 Q. Could you take a look at 13 Exhibit 7, your revised Interrogatories, 14 particularly page 18? 15 COURT REPORTER: I can't hear 16 you. 17 BY MR. KELLER: 18 Q. Could you take a look at 19 Exhibit 7, your revised Interrogatories, 20 particularly page 18? 21 In the fourth paragraph where 22 you testified about the plaques that were too 23 faint to count, in response to this 24 Interrogatory, do you recall whether or not</p>

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<p style="text-align: right;">Page 557</p> <p>1 the plaques that were too faint to count were 2 just a -- was it more than one cell plate or 3 was it the entire assay that was too faint to 4 count, if you recall? 5 MR. SANGIAMO: Object to form. 6 THE WITNESS: And just to 7 clarify, I think that you're referring 8 to the third paragraph? 9 BY MR. KELLER: 10 Q. The bottom paragraph. 11 A. The bottom paragraph. From 12 what I recall of that reference was that the 13 entire assay had the same staining. And that 14 they were faint. 15 Q. If you go back to Exhibit 19 16 which is the counting sheet that was put in 17 front of you and asked whether or not this 18 counting sheet referenced those particular -- 19 the assay identified at page 18 of Exhibit 7, 20 here in Exhibit 19 only a couple of the plates 21 were, in fact, faint. Correct? 22 MR. SANGIAMO: Object to the 23 form. 24 THE WITNESS: Yes, some of the</p>	<p style="text-align: right;">Page 559</p> <p>1 times, but he is a very knowledgeable 2 and trustworthy person. I, again, 3 don't believe everything I hear, so, 4 you know, my opinions about the data 5 falsification are my own opinions. 6 Again, I wouldn't put myself in this 7 position to be here today if I didn't 8 feel myself that this occurrence was 9 true. 10 MR. KELLER: I have no further 11 questions. 12 MR. SANGIAMO: Nothing further. 13 VIDEOGRAPHER: The time is now 14 6:18. This concludes the video 15 deposition. 16 - - - 17 (Witness excused.) 18 - - - 19 (Deposition concluded at 6:18 20 p.m.) 21 22 23 24</p>
<p style="text-align: right;">Page 558</p> <p>1 plates but not all. 2 BY MR. KELLER: 3 Q. Would that lead you to believe 4 that this assay 211-1 was not the assay that 5 you referred to on page 18 in the last 6 paragraph of Exhibit 7? 7 MR. SANGIAMO: Object to the 8 form. 9 THE WITNESS: It could, yes, it 10 could be that this is not the assay 11 that I was referencing. 12 BY MR. KELLER: 13 Q. Let me ask you one more 14 question. 15 You've known Steve Krahlung now 16 for over 17 years. Correct? 17 A. Correct. 18 Q. During those 17 years, have you 19 ever known Mr. Krahlung to be dishonest? 20 MR. SANGIAMO: Object to the 21 form. 22 THE WITNESS: No. My impression 23 of Steve is he's very knowledgeable. 24 And he may throw in some sarcasm at</p>	<p style="text-align: right;">Page 560</p> <p>1 CERTIFICATE 2 3 4 I do hereby certify that I am a Notary 5 Public in good standing, that the aforesaid 6 testimony was taken before me, pursuant to 7 notice, at the time and place indicated; that 8 said deponent was by me duly sworn to tell the 9 truth, the whole truth, and nothing but the 10 truth; that the testimony of said deponent was 11 correctly recorded in machine shorthand by me 12 and thereafter transcribed under my 13 supervision with computer-aided transcription; 14 that the deposition is a true and correct 15 record of the testimony given by the witness; 16 and that I am neither of counsel nor kin to 17 any party in said action, nor interested in 18 the outcome thereof. 19 20 WITNESS my hand and official seal this 21 20th day of June, 2017. 22 23 24  _____ Linda Rossi-Rios, RPR, CSR Notary Public</p>

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<p style="text-align: right;">Page 561</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2 Please read your deposition over</p> <p>3 carefully and make any necessary corrections.</p> <p>4 You should state the reason in the appropriate</p> <p>5 space on the errata sheet for any corrections</p> <p>6 that are made.</p> <p>7 After doing so, please sign the errata</p> <p>8 sheet and date it.</p> <p>9 You are signing same subject to the</p> <p>10 changes you have noted on the errata sheet,</p> <p>11 which will be attached to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney</p> <p>14 within thirty (30) days of receipt of the</p> <p>15 deposition transcript by you. If you fail to</p> <p>16 do so, the deposition transcript may be deemed</p> <p>17 to be accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 563</p> <p>1</p> <p>2</p> <p>3 ACKNOWLEDGMENT OF DEPONENT</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the foregoing</p> <p>6 pages and that the same is a correct</p> <p>7 transcription of the answers given by me to</p> <p>8 the questions therein propounded, except for</p> <p>9 the corrections or changes in form or</p> <p>10 substance, if any, noted in the attached</p> <p>11 Errata Sheet.</p> <p>12</p> <p>13 _____</p> <p>14 DATE SIGNATURE</p> <p>15</p> <p>16 Subscribed and sworn to before me this</p> <p>17 _____ day of _____, 2017.</p> <p>18</p> <p>19 My commission expires: _____</p> <p>20</p> <p>21 _____</p> <p>22 Notary Public</p> <p>23</p> <p>24 Assignment: 2632763</p>
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<p style="text-align: right;">Page 562</p> <p>1 -----</p> <p> E R R A T A</p> <p>2 -----</p> <p>3 PAGE LINE CHANGE</p> <p>4 -----</p> <p>5 Reason for Change:</p> <p>6 _____</p> <p>7 -----</p> <p>8 Reason for Change:</p> <p>9 _____</p> <p>10 -----</p> <p>11 Reason for Change:</p> <p>12 _____</p> <p>13 -----</p> <p>14 Reason for Change:</p> <p>15 _____</p> <p>16 -----</p> <p>17 Reason for Change:</p> <p>18 _____</p> <p>19 -----</p> <p>20 Reason for Change:</p> <p>21 _____</p> <p>22 -----</p> <p>23 Reason for Change:</p> <p>24 Job No. PA2632763 _____</p>	
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