1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 _____

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 _____

5 MERCK SHARP & DOHME LLC,

6 Petitioner,

7 v.

8 THE JOHNS HOPKINS UNIVERSITY,

9 Patent Owner.

10 _____

11 IPR2024-00240

12 Patent No. 11,591,393

13 _____

14

15 DEPOSITION OF JENNIFER D. NEWBERGER

16 Conducted Virtually

17 Wednesday, December 11, 2024

18 12:01 p.m. EST

19

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22 Reported by: Monique Vouthouris, CCR, RPR, CRR

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6 DEPOSITION OF JENNIFER D. NEWBERGER pursuant to
7 notice, conducted virtually via Zoom Videoconference,
8 before Monique Vouthouris, Certified Court Reporter,
9 Registered Professional Reporter, Certified Realtime
10 Reporter, and Notary Public in and for the States of
11 New Jersey and New York.
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1 A P P E A R A N C E S
2 ON BEHALF OF PETITIONER, MERCK SHARP
3 & DOHME LLC:
4 JESSICA M. STAURING, ESQ.
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10
11 ON BEHALF OF PATENT OWNER, THE JOHNS HOPKINS
12 UNIVERSITY, AND THE WITNESS, JENNIFER D. NEWBERGER:
13 SARAH E. JACK, ESQ.
14 FISH & RICHARDSON, PC
15 60 South 6th Street, Suite 3200
16 Minneapolis, Minnesota 55402
17 612.335.5070
18
19 ALSO PRESENT:
20 KAREN M. MOREIRA, ESQ., Merck In-house Counsel
21 KELLI WELCH, Planet Depos Technician
22

1 C O N T E N T S

2 EXAMINATION OF JENNIFER D. NEWBERGER PAGE
3 By Ms. Stauring 5
4 By Ms. Jack 265

5
6
7 E X H I B I T S

8 (Exhibits 1113 and 1114 attached to transcript.)

9 DEPOSITION EXHIBIT PAGE
10 Exhibit 1113 Hyman, Phelps & McNamara website 9
11 profile of Jennifer D. Newberger,
12 MERCK EX1113.
13 Exhibit 1114 Hyman, Phelps & McNamara FDA 172
14 Law Blog, May 4, 2021, "Where
15 experts go to learn about FDA,"
16 MERCK EX1114.

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1 P R O C E E D I N G S
2
3 JENNIFER D. NEWBERGER,
4 being first duly sworn or affirmed by the Notary,
5 testifies as follows:
6 EXAMINATION
7 BY MS. STAURING:
8 Q Hello, my name is Jessica Stauring with
9 the Paul Hastings law firm, and I am appearing for
10 the petitioner Merck today. I'm joined by Preston
11 Ratliff today, also with Paul Hastings, and
12 appearing for petitioner Merck.
13 In addition, Merck's in-house counsels
14 Karen Moreira and Mark Stewart are or are expected
15 to be on the line today.
16 Good morning. Please state your full name
17 for the record.
18 A Jennifer Diane Newberger.
19 Q How are you feeling today?
20 A I'm doing well, thank you.
21 Q You understand that you're testifying
22 today under oath, correct?

1 A Correct.
2 Q Is there any reason that you cannot
3 testify truthfully today?
4 A No, there is not.
5 Q You're a lawyer working at a private law
6 firm, correct?
7 A That is correct.
8 Q What is your standard hourly rate for your
9 work as a lawyer?
10 A My standard hourly rate is $920 per hour.
11 Q In this matter you're being compensated at
12 a rate of $1,000 per hour, correct?
13 A That is correct.
14 Q Approximately how much time have you spent
15 preparing for this matter?
16 A I would need to go back and look at my
17 hours records to be able to answer that accurately.
18 Q I'm not looking for an exact answer, but,
19 approximately, sitting here today, how much time
20 have you spent on this matter?
21 MS. JACK: Asked and answered.
22 A I -- I am not comfortable making a guess

1 right now without reviewing my records.
2 Q Would you say that it's more than 10
3 hours?
4 A Yes, it is more than 10 hours.
5 Q Would you say that it's more than 30
6 hours?
7 A Yes, it is more than 30 hours.
8 Q So I'm just asking for an approximate
9 amount of time that you've spent on this matter.
10 MS. JACK: Objection; asked and answered.
11 A I -- I truly cannot give you an
12 approximate estimate. I would say that it is likely
13 upwards of 30 hours, but likely less than 50, but I
14 cannot be more certain than that without reviewing
15 my records.
16 Q Okay. Now, you spent nearly 20 years
17 providing counsel to medical device manufacturers of
18 all sizes across all product types throughout the
19 product life cycle, right?
20 MS. JACK: Objection; compound.
21 A I have worked primarily with device
22 manufacturers, yes.

1 Q And that work consists of nearly 20 years
2 providing counsel to medical device manufacturers of
3 all sizes across all product types throughout the
4 product life cycle, right?
5 MS. JACK: Objection; misstates testimony.
6 A I have advised medical device clients on
7 clinical study questions, pre-market questions, and
8 post-market questions.
9 Q You have a website profile with Hyman
10 Phelps, correct?
11 A That is correct.
12 Q Are you familiar with your website
13 profile?
14 A Yes, I am.
15 Q And have you seen your website profile
16 previously?
17 A Yes.
18 Q And your website profile states that you
19 have spent nearly 20 years providing counsel to
20 medical device manufacturers of all product types
21 throughout the product life cycle, right?
22 A It does --

1 MS. JACK: Objection; lack of foundation.
2 A It does state that. It then goes into
3 detail about what product life cycle means.
4 Q And your website profile provides FDA
5 regulatory categories, right?
6 A I would have to go back and look at it to
7 be able to answer with certainty.
8 Q Well, we can take a look at your website
9 profile, and this is a new exhibit that is being
10 premarked as Exhibit 1113. Please let me know when
11 you have that downloaded from the link in the chat.
12 THE TECHNICIAN: The exhibit is uploading
13 to the folder now. I'm sorry, go ahead, please.
14 MS. JACK: Is somebody putting the
15 document into the chat?
16 THE TECHNICIAN: Yes, ma'am. Do you see
17 the link in the chat that starts with "Planet
18 Depos"? If you click on that link, does it open a
19 OneDrive folder?
20 THE WITNESS: Yes, I see it now.
21 BY MS. STAURING:
22 Q And you have the document downloaded

1 before you?
2 A Yes, I do.
3 Q And this is a copy of your website
4 profile. Is that right?
5 A That is correct.
6 Q And your website profile lists under FDA
7 Regulatory Categories Medical Devices, right?
8 A That is correct.
9 Q And your website profile lists only
10 medical devices under the section for FDA Regulatory
11 Categories. Is that right?
12 A That is correct.
13 Q You can put that exhibit away or minimize
14 it on your screen.
15 Have you looked at the patent at issue in
16 this matter?
17 A No, I have not.
18 Q You understand that this is a dispute
19 regarding a United States patent, right?
20 A Yes, I do.
21 Q Did you ask to take a look at the patent
22 at issue in this matter?

1 A I did not.
2 Q Do you know anything about the patent at
3 issue in this matter?
4 MS. JACK: Objection; vague.
5 Q I can ask my question a different way.
6 Are you aware of -- let me start again.
7 Do you understand what the patent at issue
8 in this matter concerns?
9 MS. JACK: Objection; vague.
10 A Can you please clarify?
11 Q Do you have an understanding of what the
12 patent at issue in this matter relates to?
13 MS. JACK: Objection; vague.
14 Q I'm just asking at a high level do you
15 know what the patent at issue in this matter relates
16 to?
17 MS. JACK: Objection; vague.
18 A I have not seen the patent. I did not ask
19 about the patent. I was asked to opine on
20 ClinicalTrials.gov requirements, so all that I am
21 aware of is what is provided in the
22 ClinicalTrials.gov listing.

1 Q Do you understand that the patent owner in
2 this matter is JHU, right?
3 MS. JACK: Objection; vague.
4 A I am not aware of patent ownership.
5 Q This dispute, the party that's designated
6 as the party owner is JHU, right?
7 MS. JACK: Objection; asked and answered.
8 A I was asked to opine solely on
9 ClinicalTrials.gov legal requirements and JHU's
10 compliance with those requirements. I cannot
11 comment on anything outside the scope of my reports.
12 Q So you don't know the -- who owns the
13 patent at issue in this case?
14 MS. JACK: Objection; asked and answered.
15 A As stated, I -- this is outside the scope
16 of my report. I was asked about ClinicalTrials.gov
17 requirements, compliance therewith, that's what's
18 captured in my report and that is what I can speak
19 to.
20 Q Let me try my question again. Do you know
21 who owns the patent at issue in this case?
22 MS. JACK: Objection; asked and answered.

1 This is getting harassing.
2 Q I'm just looking for a yes or no answer as
3 to whether you know who owns the patent at issue in
4 this case.
5 A You stated that JHU owns the patent. I
6 had not previously asked or discussed patent
7 ownership.
8 Q So prior to sitting here today, you did
9 not have an understanding of who owns the patent at
10 issue in this case. Is that correct?
11 A It was not the subject of my report. It
12 was not relevant to what I was asked to opine on.
13 Q Just to be clear, my question is whether
14 prior to sitting here today, did you understand who
15 owned the patent at issue in this case?
16 MS. JACK: Object to form.
17 A I have no recollection of that.
18 Q You submitted a declaration in this case,
19 right?
20 A Correct.
21 Q And did you understand that the case
22 involved a dispute regarding a patent?

1 A Yes, I did.
2 Q And did you ask who owned the patent that
3 was in dispute?
4 A No, I did not ask that question.
5 Q And you were not provided with that
6 information, correct?
7 A I do not recall if I was provided with
8 that information.
9 Q Prior to this matter had you ever worked
10 with JHU?
11 A No, I had not.
12 Q You taught a course at Johns Hopkins
13 University in 2014, right?
14 A I did.
15 Q Other than that work, had you ever done
16 any work with JHU?
17 A No.
18 Q Prior to this matter have you ever worked
19 with the Fish & Richardson law firm?
20 A No, I had not.
21 Q Do you have any documents in the room with
22 you today?

1 A I have a binder that contains my report
2 and the attachments.
3 Q And by "attachments" do you mean Appendix
4 A and Appendix B to your declaration?
5 A All of the appendices, everything that is
6 referenced in my report is in the binder, all of the
7 exhibits.
8 Q Let me ask my question a little
9 differently.
10 Does the binder include only your
11 declaration, Appendix A and Appendix B?
12 A It includes Appendix A, Appendix B, and it
13 includes the exhibits that are referenced in my
14 report.
15 Q What exhibits does it include?
16 A It includes Exhibits 1005, 2138, 2139,
17 2140, 2141, 2142, 2143, 2145, 2146, and 2147.
18 Sorry, there are more. 2148, 2149, 2150, 2151 and
19 2152.
20 Q Are there any markings on the documents
21 that you have in the room with you today?
22 A There are not.

1 Q The exhibits that you just recited, have
2 you read those exhibits?
3 A I have.
4 Q And are you familiar with them?
5 MS. JACK: Objection; vague.
6 A I have read them.
7 Q Do you understand them?
8 A I do understand them.
9 Q Were you confused by any statements in
10 those exhibits?
11 MS. JACK: Objection; vague.
12 A There are a lot of statements over the
13 course of all of those exhibits. I can't say with
14 certainty whether or not there were any particular
15 individual statement that may have been confusing
16 when I read it. I simply do not recall. If you
17 could be more specific in the question, I may be
18 able to better answer you.
19 Q Well, sitting here today, are you confused
20 by anything in your declaration?
21 MS. JACK: Objection; vague.
22 A I'm not confused by anything in my

1 declaration.
2 Q And sitting here today, are you confused
3 about the contents of the exhibits that you just
4 recited?
5 MS. JACK: Objection; vague.
6 A I do not believe that I am.
7 Q Are there any tabs or Post-it notes on the
8 documents in the room with you?
9 A There are tabs separating each of the
10 exhibits.
11 Q Can you please tell us who is in the room
12 with you today?
13 A Sarah Jack is in the room.
14 Q Did you spend any time preparing for
15 today's deposition?
16 A Yes, I did.
17 Q Approximately how much time did you spend
18 preparing?
19 A In addition, obviously, to the time spent
20 preparing the report itself, specifically with
21 respect to preparing for today, I spent
22 approximately 10 to 12 hours.

1 Q And did you review the exhibits cited in
2 your declaration in preparation for today?
3 A Yes, I did.
4 Q And did you review your declaration and
5 Appendix A and Appendix B in preparation for today?
6 A I did.
7 Q Other than the lawyers for -- excuse me.
8 Let me start over.
9 Other than the lawyers representing JHU,
10 did you speak with anyone about this case in
11 preparation for your deposition today?
12 A I mentioned to partners at my firm that I
13 would be unavailable today because I was going to be
14 in this deposition. I did not go into details of
15 what it was for other than to say it was about
16 Clinical Trials' requirements.
17 Q Now, you prepared a declaration in this
18 matter, right?
19 MS. JACK: Asked and answered.
20 A I did prepare a declaration.
21 Q And you signed your declaration on October
22 4, 2024, correct?

1 A That is correct.
2 Q Prior to signing your declaration, did you
3 ever -- did you understand every statement that you
4 provided in your declaration?
5 A I did.
6 Q Prior to signing your declaration, did you
7 understand every conclusion that you provided in
8 your declaration?
9 MS. JACK: Objection; vague.
10 A Yes, I believe I understood the
11 conclusions in my declaration.
12 Q And prior to signing your declaration, did
13 you understand every opinion that you've provided in
14 your declaration?
15 A Yes, I did.
16 Q And prior to signing your declaration,
17 were you familiar with the contents of the exhibits
18 that you cite and reference in your declaration?
19 MS. JACK: Objection; vague.
20 MS. STAURING: Counsel, you're
21 interrupting the deposition with suggestive speaking
22 objections. Please refrain from doing so.

1 MS. JACK: I disagree. This is within the
2 scope of what's allowed in these IPR depositions.
3 But we can continue.
4 A Can you please repeat the question?
5 Q Sure. Prior to signing your declaration,
6 were you familiar with the contents of the exhibits
7 that you cite and reference in your declaration?
8 MS. JACK: Objection; vague.
9 A Yes, I was familiar with the content of
10 the exhibits.
11 Q And prior to signing your declaration,
12 were you familiar with the statutes and the rules
13 that you cite throughout your declaration?
14 MS. JACK: Objection; vague.
15 A Yes, I was familiar with the statute and
16 the regulations cited.
17 Q Are there any errors in your signed
18 declaration?
19 A I am not aware of any errors.
20 Q And you reviewed your declaration prior to
21 signing it, right?
22 A I did.

1 Q As well as in preparation for today,
2 right?
3 A Yes.
4 Q So sitting here today, do you have any
5 reason to believe that your declaration contains any
6 errors?
7 A I do not have any reason to believe that.
8 Q Do you have any corrections to your signed
9 declaration that you wish to make today?
10 A I do not.
11 Q In preparing your declaration, did you
12 speak with any JHU employees?
13 A I did not.
14 Q Did you have any conversations with any
15 JHU scientists?
16 A No, I did not.
17 Q Did you have any conversations with
18 individuals other than the attorneys at Fish &
19 Richardson law firm?
20 A I did not.
21 Q Now, there are two appendices to your
22 declaration, right?

1 A Correct.
2 Q There is Appendix A and Appendix B, right?
3 A Yes.
4 Q And Appendix A is a copy of your CV. Is
5 that correct?
6 A That is correct.
7 Q And your CV states that you provide
8 guidance on clinical study design, protocol
9 development, statistical plan and ClinicalTrials.gov
10 registration requirements. Is that correct?
11 A Yes, that is correct.
12 Q And you discuss ClinicalTrials.gov
13 registration requirements in your declaration,
14 right?
15 A Yes.
16 Q And you agree that the statement contained
17 in your CV doesn't appear in your website profile,
18 right?
19 A That is correct.
20 Q And your website profile does not include
21 anywhere the words, quote, "clinical study design,"
22 is that right?

1 A It does not contain those words, that is
2 correct.
3 Q Your website profile states that you have
4 experience drafting and negotiating, quote,
5 "clinical trial and research agreements between
6 device companies and universities, clinical
7 investigators and contract research organizations,"
8 end quote, right?
9 A I would have to refer back to my bio to
10 confirm.
11 Q Okay. We can pull Exhibit 1113 back up.
12 Please let me know when you have it before you.
13 A I do before it before me, yes.
14 Q And on page 3 of your website bio, the
15 last bullet under Experience, that states that you
16 have experience drafting and negotiating, quote,
17 "clinical trial and research agreements between
18 research companies" -- excuse me -- "between device
19 companies and universities, clinical investigators
20 and contract research organizations," end quote.
21 Is that correct?
22 A That is correct.

1 Q Just to be clear, when your website
2 profile refers to device companies, that means
3 medical device companies, right?
4 A Yes, that is correct.
5 Q You can minimize that exhibit on your
6 screen.
7 A Okay.
8 Q Turning back to your CV at Appendix A,
9 when did you prepare this CV?
10 A I do not recall the date I prepared this
11 CV.
12 Q Did you prepare it for purposes of this
13 matter?
14 A I do not recall.
15 Q Do you know -- did you provide the CV that
16 appears in Appendix A to counsel for JHU?
17 A I did provide this CV to counsel for JHU.
18 Q Prior to providing your CV to counsel for
19 JHU, did you make any changes to your CV?
20 A I do not recall.
21 Q Do you recall if you made any changes to
22 your CV after beginning your role at Hyman Phelps in

1 May of 2024?
2 A Yes. I updated the CV to reflect that I
3 had returned to the firm.
4 Q So is it fair to say that at some point
5 between May of 2024 and signing your declaration on
6 October 4th, 2024, you made changes to your CV?
7 A That is fair to say, yes.
8 Q Did JHU make any changes to your CV?
9 A Not to my knowledge.
10 Q The statement included in your CV provide
11 guidance on clinical study design protocol
12 development, statistical plans and
13 ClinicalTrials.gov registration requirements --
14 A Yes, can you -- sorry, can you point me to
15 where --
16 Q So if you take a look at your CV at
17 Appendix A on page 1, in the right-hand column about
18 halfway down under the title Experience.
19 A Yes, I do see that now.
20 Q And the bullet that states "Provide
21 guidance on clinical study design, protocol
22 development, statistical plans, and

1 ClinicalTrials.gov registration requirements" --
2 A Yes.
3 Q -- did you add that statement to your CV?
4 A I did add it at some point since it is on
5 my CV. I do not know when I added it. This is a
6 regular part of guidance that I give to clients.
7 Q Did you add the statement for the purposes
8 of this matter?
9 A I do not recall whether I added it
10 specifically for purposes of this matter.
11 Q Were you asked to add this statement to
12 your CV for purposes of this matter?
13 A I was not.
14 Q But you don't recall if you added this
15 statement for the purposes of this matter?
16 A I do not recall.
17 Q Did you make any other changes to your CV
18 for the purposes of this matter?
19 A I do not recall.
20 Q Sitting here today, do you have reason to
21 believe that you added this statement for the
22 purposes of this matter?

1 A I do not have reason to believe that I
2 added it for purposes of this matter.
3 Q But you don't remember if you added it for
4 purposes of this matter?
5 A Correct, I do not remember.
6 Q Prior to signing your declaration on
7 October 4, 2024, had you ever submitted your CV in a
8 report or declaration?
9 A No, I have not.
10 Q And prior to signing your declaration on
11 October 4, 2024, do you believe -- let me start that
12 question over.
13 Prior to signing your declaration on
14 October 4, 2024, did you provide an identical CV
15 that appears in Appendix A?
16 MS. JACK: Objection; vague.
17 Q I can ask my question again.
18 Prior to signing your declaration on
19 October 4, 2024, had you ever provided an identical
20 CV to the CV that appears in Appendix A to anyone?
21 MS. JACK: Objection; vague.
22 A And I can't say with certainty. I can't

1 recall that I would have had occasion to provide my
2 updated HPM resum . I can't recall.
3 Q You stated that you updated your CV after
4 you returned to Hyman Phelps in May of 2024.
5 A Correct.
6 Q Did you add this statement at that time?
7 A I did add this statement at that time to
8 reflect my current work at the firm.
9 Q You would agree with me that information
10 that is submitted to the FDA as part of complying
11 with ClinicalTrials.gov registration requirements
12 should be accurate, right?
13 A Yes, it should be accurate.
14 Q And you would agree that when information
15 is submitted to the FDA as part of
16 ClinicalTrials.gov registration requirements, that
17 information should be truthful, right?
18 A Yes, the submitter should certainly
19 believe it to be truthful when it is submitted.
20 Q And you would agree that information that
21 someone submits to the FDA, any information that
22 someone submits to the FDA should be accurate,

1 right?
2 MS. JACK: Objection; compound.
3 A Information submitted to the FDA should be
4 accurate to the knowledge of the submitter at the
5 time of submission, yes.
6 Q And you would agree that any information
7 submitted to the FDA should be truthful, right?
8 A Yes, the submitter should believe the
9 information to be truthful.
10 Q Can you think of any scenario where it
11 would be acceptable to submit something not truthful
12 to the FDA?
13 MS. JACK: Objection; vague, incomplete
14 hypothetical.
15 A I am not aware of a circumstance in which
16 a knowingly false statement should be submitted to
17 FDA.
18 Q So would you agree that you can't think of
19 any scenario where it would be acceptable to submit
20 something not truthful to the FDA?
21 MS. JACK: Objection; misstates testimony.
22 A I would state, again, that at the time of

1 the submission, the submitter should believe that
2 everything in the submission is truthful and
3 accurate.
4 MS. STAURING: Counsel, please be advised
5 that we are going to count up all of your suggestive
6 speaking objections and reserve our right to raise
7 those improper objections with the Board.
8 MS. JACK: My objections have been proper,
9 I've been careful with them, so I'm just trying to
10 keep the record clean for everybody. Thanks,
11 Jessica.
12 BY MS. STAURING:
13 Q Ms. Newberger, can you think of any
14 scenario where it would be acceptable to submit
15 something knowingly inaccurate to the FDA?
16 A A submitter should -- should never provide
17 knowingly inaccurate information to the FDA.
18 Q Now, in your view, JHU registered with
19 ClinicalTrials.gov on June 10, 2013 and included
20 only the information required by law. Is that
21 right?
22 A That is correct.

1 Q And in your work for this matter, did you
2 ever review a copy of the submission that JHU
3 submitted to ClinicalTrials.gov on June 10, 2013?
4 A I submitted what was publicly available --
5 sorry. I reviewed what was publicly available from
6 their June 10, 2013 submission.
7 Q Okay. So that wasn't my question. Let me
8 try again. In your work on this matter, did you
9 ever review a copy of the submission that JHU
10 submitted to ClinicalTrials.gov on June 10, 2013?
11 MS. JACK: Objection; vague.
12 A I did not review anything from JHU. I
13 reviewed what was publicly available on
14 ClinicalTrials.gov.
15 Q So how can you properly conclude that JHU,
16 quote, "properly registered," end quote, if you've
17 not seen that registration that was submitted on
18 June 10th, 2013?
19 A I did see what was registered. What is
20 registered is what is publicly available, that is
21 how the term is used, it is called registration on
22 ClinicalTrials.gov. What is publicly available for

1 viewing is the registration, that is what I
2 reviewed.
3 Q Throughout your declaration you talk about
4 the submission to ClinicalTrials.gov on June 10th,
5 2013, right?
6 A Yes, because the -- sorry. The statute
7 talks about what has to be submitted to
8 ClinicalTrials.gov.
9 Q And did you review the submission that was
10 submitted to ClinicalTrials.gov on June 10, 2013?
11 MS. JACK: Objection; vague.
12 A I reviewed what was publicly available
13 from their June 10th, 2013 submission, their
14 registration.
15 Q So you did not review what was submitted
16 to ClinicalTrials.gov on June 10, 2013. Is that
17 correct?
18 MS. JACK: I object to the form of the
19 question.
20 A The information that is publicly available
21 is their registration on ClinicalTrials.gov, that is
22 what I reviewed.

1 Q So my question is a little different. So
2 let me -- let me back up.
3 You agree that throughout your declaration
4 you discuss the submission to ClinicalTrials.gov on
5 June 10, 2013, right?
6 A Yes, that is correct.
7 Q And I'm asking whether you reviewed the
8 submission that was made on June 10, 2013.
9 A I reviewed what is available online, which
10 I believe would be what was submitted.
11 Q Is the submission to ClinicalTrials.gov
12 publicly available?
13 A The registration on ClinicalTrials.gov
14 reflects the submitted information.
15 Q So just to be clear, the registration
16 that's publicly available is different from the
17 submission to ClinicalTrials.gov, correct?
18 MS. JACK: Objection; misstates testimony.
19 A That is -- I would not agree with that
20 statement.
21 Q Let me ask my question a little
22 differently.

1 Is the submission to ClinicalTrials.gov
2 publicly available? Is what a party submits on
3 ClinicalTrials.gov publicly -- made publicly
4 available?
5 MS. JACK: Objection; compound.
6 A The information that is made publicly
7 available is the information that was submitted by
8 the company to ClinicalTrials.gov.
9 Q Is the June 10, 2013 submission here
10 publicly available?
11 MS. JACK: Objection; vague.
12 A I do not have reason to believe that the
13 submission would be different than what is publicly
14 available on the registration. The submitted
15 documents are reflected on the registration.
16 Q And so my question is not whether they are
17 different or not.
18 So in this case did you review the June
19 10, 2013 submission to ClinicalTrials.gov?
20 MS. JACK: Objection; vague.
21 Q Yes or no?
22 A I reviewed the publicly available

1 registration information which would reflect the
2 submitted information.
3 Q How do you know that that reflects
4 submitted information?
5 A Because in all of the time that I have
6 advised clients on clinical trial submissions, the
7 paperwork mirrors what is reflected and the
8 information is taken from the submission and posted
9 publicly on the website.
10 Q But here did you review what was actually
11 submitted on June 10, 2013?
12 MS. JACK: Objection; vague.
13 A I did not review the paperwork that they
14 sent to ClinicalTrials.gov, but I reviewed the
15 ClinicalTrials.gov registration requirement --
16 registration information, which comes from the
17 submission and nowhere else.
18 Q So you don't know what the paperwork
19 looked like that was submitted on June 10, 2013,
20 right?
21 MS. JACK: I object to the form of the
22 question.

1 A I did not see that paperwork, but the
2 information that was posted as a result of that
3 submission is what the public relies upon.
4 Q But to be clear, you did not see the
5 paperwork that was submitted on June 10, 2013,
6 right?
7 A I did not see that, the paperwork.
8 Q Did you ever ask for a copy of what was
9 submitted on June 10, 2013?
10 A I did not ask for a copy.
11 Q Do you know whether it is actually
12 paperwork versus an electronic submission, for
13 example?
14 A I do not know what the status was in 2013.
15 Q Do you know if the June 10th, 2013
16 submission was a joint submission by Merck and JHU?
17 A I know only that Merck is indicated as a
18 collaborator. Beyond that, I do not know.
19 Q Do you know who made the submission on
20 June 10, 2013?
21 MS. JACK: Objection; vague.
22 A The responsible party is the person who is

1 responsible for submitting the information, that was
2 specified to be the Sidney Kimmel Comprehensive
3 Cancer Center at Johns Hopkins.
4 Q That's not quite my question.
5 My question is whether you know in this
6 case who made the submission on June 10, 2013.
7 MS. JACK: Objection; vague.
8 A The responsible party is the party that
9 makes the submission. The responsible party was
10 designated as the Sidney Kimmel Comprehensive Cancer
11 Center at Johns Hopkins.
12 Q Why do you call the submission in your
13 declaration a JHU submission if you've never seen
14 the paperwork that is the actual June 10th, 2013
15 submission?
16 A For the reason that I just stated.
17 Q Can you please answer why you call the
18 submission in your declaration a JHU submission if
19 you've never seen the June 10, 2013 submission
20 paperwork?
21 MS. JACK: Objection; asked and answered.
22 A The responsible party named in the

1 registration is the party that is responsible for
2 providing the information to ClinicalTrials.gov.
3 Johns Hopkins is named as the responsible party.
4 Q Is it your testimony that 100 percent of
5 the paperwork was submitted by JHU?
6 A I cannot draw that -- I cannot say with
7 100 percent certainty.
8 Q Do you know whether it was JHU that
9 submitted the paperwork on June 10, 2013?
10 A Based upon the information in the
11 registration database, Johns Hopkins was the
12 responsible party. The responsible party is the
13 party responsible for making the submission.
14 Q My question is not whether Johns Hopkins
15 is reflected as the responsible party.
16 My question is whether you know that it
17 was JHU that submitted the paperwork on June 10,
18 2013 here?
19 MS. JACK: I object to the form of the
20 question.
21 A My answer is what I have previously
22 stated; the responsible party is the party that

1 submits the information. This registration reflects
2 Johns Hopkins as the responsible party.
3 Q Do you know that with 100 percent
4 certainty?
5 MS. JACK: I object to the form of the
6 question.
7 A Can you clarify your question, please?
8 Q Do you know with 100 percent certainty
9 that it was JHU that submitted the paperwork for the
10 June 10, 2013 submission here?
11 MS. JACK: I object to the form of the
12 question.
13 A As I have previously stated, what I can
14 state with 100 percent certainty is that Johns
15 Hopkins is listed as the responsible party for this
16 submission. The responsible party is the party that
17 is responsible for submitting. That is what I can
18 testify to.
19 Q I'm not asking that. I'm asking whether
20 you can say with 100 percent certainty that it was
21 JHU here that made the June 10, 2013 submission?
22 MS. JACK: Objection; asked and answered.

1 A I can't answer it any other way. Johns
2 Hopkins is reflected as the responsible party. In
3 my experience with ClinicalTrials.gov submissions,
4 the entity that is reflected as the responsible
5 party is the party that submits the -- that is
6 responsible for the submission to ClinicalTrials.gov.
7 Q Let me ask one more time.
8 Do you know here with 100 percent
9 certainty that it was JHU and JHU alone that made
10 the submission to ClinicalTrials.gov on June 10,
11 2013?
12 MS. JACK: Objection; asked and answered.
13 A As I previously stated, Merck is indicated
14 as a collaborator. I do not know the extent of
15 their collaboration. Johns Hopkins is the party
16 identified as responsible for the submission. That
17 is what I know.
18 Q So it's possible that Merck was involved
19 in submitting the paperwork to ClinicalTrials.gov on
20 June 10, 2013, right?
21 MS. JACK: Objection; calls for
22 speculation.

1 A I do not know Merck's involvement or why
2 they were indicated as a collaborator.
3 Q My question is a little different. And my
4 question is whether it's possible that Merck was
5 involved in submitting the paperwork to
6 ClinicalTrials.gov on June 10, 2013.
7 MS. JACK: Objection; calls for
8 speculation.
9 A I -- I cannot speculate as to whether
10 Merck could or would have been involved.
11 Q So do you know here who submitted the
12 paperwork to ClinicalTrials.gov on June 10, 2013?
13 MS. JACK: Objection; asked and answered.
14 And it's becoming a little bit harassing here,
15 Jessica.
16 A I don't have an answer different from what
17 I have previously provided.
18 Q So you don't know. Is that correct?
19 A That is not what I said. What I said is
20 that the responsible party is indicated as Johns
21 Hopkins. In my experience, the responsible party is
22 the party that is responsible for the submission.

1 Q So you're making an assumption here,
2 right?
3 MS. JACK: I object to the form of the
4 question.
5 A It's more than an assumption. It's based
6 on experience. It's based on how a responsible
7 party is defined. So I have no reason to believe
8 that Johns Hopkins was not the responsible party
9 when the registration states that Johns Hopkins is
10 the responsible party.
11 Q But to be clear, you're making an
12 assumption here that it was Johns Hopkins that
13 submitted the paperwork to ClinicalTrials.gov on
14 June 10, 2013, right?
15 MS. JACK: Objection; asked and answered.
16 A I do not agree that it is an assumption.
17 It is based upon the information that is publicly
18 available in the registration.
19 Q But I'm not asking about the responsible
20 party. I'm asking about who made the submission to
21 ClinicalTrials.gov on June 10, 2013 in this case.
22 MS. JACK: Is there a question there?

1 Q Yes. My question is whether you know with
2 100 percent certainty that it was JHU that submitted
3 the paperwork to ClinicalTrials.gov on June 10,
4 2013?
5 MS. JACK: Objection; asked and answered.
6 A I cannot state more than I have. They are
7 the responsible party. They are, therefore, the
8 party responsible for the content of the submission.
9 I -- I have nothing more to say on that.
10 Q Now, you've seen a copy of Exhibit 1005
11 that you reference in your declaration, right?
12 A Yes.
13 MS. JACK: Jessica, we have been going
14 about an hour. I don't know if you're
15 transitioning, it would be time for a break.
16 Q Ms. Newberger, would you like to take a
17 break?
18 A I could use a quick bio break, if that's
19 okay.
20 Q Sure.
21 MS. STAURING: We can go off the record.
22 (Recess 12:58 p.m. - 1:10 p.m.)

1 BY MS. STAURING:
2 Q Ms. Newberger, did you speak with anyone
3 during the break regarding your deposition today?
4 A I did not.
5 Q Before we took a break we were discussing
6 Exhibit 1005. Have you seen a copy of that exhibit
7 that you reference in your declaration?
8 A Yes.
9 Q Exhibit 1005 is a study record from
10 ClinicalTrials.gov, right?
11 A That is correct.
12 Q It's the study record for study NCT01876511,
13 right?
14 A Yes. Yes.
15 Q And Exhibit 1005 was published publicly on
16 ClinicalTrials.gov on June 10, 2013, right?
17 A Yes, it indicates that that was the
18 submitted date.
19 Q And I'm asking whether Exhibit 1005 was
20 published on ClinicalTrials.gov on June 10, 2013?
21 A No.
22 Q When was it published?

1 A It looks like it says first posted June
2 12th.
3 Q And that reflects an estimate, correct?
4 A That's -- it says estimate, yes.
5 Q Was it published on June 12, 2013?
6 MS. JACK: Object to the form of the
7 question.
8 A The document does not specify publication
9 beyond the first posted date.
10 Q Do you know when Exhibit 1005 was
11 published on ClinicalTrials.gov?
12 A Based on the first posted date, I believe
13 it was June 12th.
14 Q Throughout your declaration you refer to
15 June 10, 2013, correct?
16 A Yes. That was the submission date.
17 Q Do you know when JHU said that the study
18 record was published on ClinicalTrials.gov?
19 MS. JACK: I object to the form of the
20 question.
21 A As I previously stated, I have not had
22 conversations with JHU, so I do not know what their

1 opinion is.
2 Q Are you aware that JHU has admitted that
3 the study record published on ClinicalTrials.gov on
4 June 10, 2013?
5 MS. JACK: Objection; asked and answered.
6 A I have had no conversations with JHU about
7 the posting date.
8 Q I would like to bring up an exhibit,
9 Exhibit -- actually, I have a question before we do
10 that.
11 I'm not asking whether you had a
12 conversation with JHU. I'm asking whether you're
13 aware that JHU has admitted that the study record
14 was published on June 10, 2013.
15 A I am not aware.
16 MS. STAURING: Let's bring up Exhibit 1029
17 and we can publish this exhibit on the screen at
18 page 8.
19 THE TECHNICIAN: Please stand by.
20 MS. STAURING: Can we turn to page 1
21 first.
22 Q Ms. Newberger, I can represent to you that

1 this is a copy of JHU's first amended answer that
2 JHU filed in District Court in the District of
3 Maryland. And if we turn to page 8, in paragraph 22
4 JHU admits that the study record was published on
5 ClinicalTrials.gov on June 10, 2013.
6 Do you see that?
7 A I do see that.
8 Q And do you have any reason, sitting here
9 today, to disagree with that admission?
10 MS. JACK: Objection. This is outside the
11 scope of the expert report.
12 A I -- all I have is what I reviewed on
13 ClinicalTrials.gov, which says submission of June 10
14 and an estimated post of June 12. I don't know more
15 than that.
16 Q So do you have any reason to disagree with
17 this admission?
18 MS. JACK: Objection. This is outside the
19 scope.
20 MS. STAURING: Counsel, the speaking
21 objections are adding up, and I just want to note
22 that for the record.

1 MS. JACK: All right. Counsel, I'm
2 following the rules. I have a right to object.
3 We can continue.
4 BY MS. STAURING:
5 Q Ms. Newberger, do you have any reason to
6 disagree with JHU's admission?
7 MS. JACK: Objection; it is outside the
8 scope.
9 A I don't have information to agree or
10 disagree.
11 Q Okay. We can take the exhibit down.
12 For your work on this matter, did you ever
13 go to ClinicalTrials.gov to search for or look up
14 any study records concerning pembrolizumab?
15 MS. JACK: I object to the form of the
16 question.
17 A The only study record on ClinicalTrials.gov
18 that I looked at for purposes of my report is this
19 record, this NCT number that you read previously.
20 Q Let me ask a different question.
21 Exhibit 1005 that you cite in your
22 declaration, that reflects a study record for a

1 phase 2 study of MK-3475 in patients with
2 microsatellite unstable MSI tumors, right?
3 MS. JACK: Objection; misstates the
4 document.
5 A The title of the document is "phase 2
6 Study of MK-3475 in Patients with Microsatellite
7 Unstable MSI Tumors."
8 Q Do you understand that MK-3475 is
9 pembrolizumab?
10 MS. JACK: Objection; outside the scope.
11 A I had not heard that name.
12 Q So prior to today, you did not know that
13 MK-3475 was pembrolizumab. Is that correct?
14 MS. JACK: I object to the form of the
15 question.
16 A That is my recollection.
17 Q Just to be clear, do you know whether
18 MK-3475 is pembrolizumab?
19 A I do not independently know that other
20 than what you have just said.
21 Q In your declaration you discuss other
22 versions of this study record. Did you look up

1 those other versions yourself from ClinicalTrials.gov?
2 A Can you be specific about what you mean by
3 other versions?
4 Q Sure. So in Appendix B to your
5 declaration --
6 A Yes, I see that.
7 Q -- you list other study record versions,
8 correct?
9 A They're updates. They're not really other
10 versions. They're updates to the original record.
11 Q Well, the study record refers to these as
12 study record versions, right?
13 A The study record versions and then it says
14 the changes made per version.
15 Q So did you review these other versions of
16 the study record?
17 MS. JACK: Objection; vague.
18 A I reviewed them to indicate what the
19 changes were that were made per each version.
20 Q So you reviewed these other versions. Is
21 that right?
22 A Yes, I reviewed the changes that were made

1 from the prior version to the next version.
2 Q And when you refer to these changes,
3 you're talking about the version that you discuss in
4 Appendix B of your declaration, right?
5 A That is correct.
6 Q And you reviewed each update that you
7 discuss in Appendix B of your declaration, right?
8 A Yes, I would have reviewed the record to
9 be able to compile the changes.
10 Q And did you look these versions of the
11 study record in Appendix B up yourself on
12 ClinicalTrials.gov --
13 MS. JACK: I object to the form of the
14 question.
15 Q -- or were they provided to you?
16 MS. JACK: Objection; compound.
17 A I looked at them on ClinicalTrials.gov.
18 They were not independently provided to me.
19 Q So at the top of Appendix B you write
20 "Updates Made By JHU Before July 10, 2015," right?
21 A That is correct.
22 Q And you list 10 updates in Appendix B,

1 right?
2 A That is correct.
3 Q And you provide these updates before July
4 10, 2015. Is that right?
5 A Yes, that is right.
6 Q What is the significance of the July 10,
7 2015 date included in Appendix B?
8 MS. JACK: Objection; vague.
9 A That is the date that was provided to me
10 to include changes up to. Beyond that, I'm not
11 aware of significance.
12 Q Do you know why you included updates only
13 until that date?
14 A I was asked to provide updates until that
15 date.
16 Q Did you ask why you were asked to provide
17 updates only until that date?
18 A No, I did not.
19 Q Were you curious why you were only
20 providing updates until that date?
21 MS. JACK: Objection; vague.
22 A I have no recollection about whether I was

1 or was not curious at the time that date was
2 provided to me.
3 Q And the study record was updated after
4 that date as well, right?
5 A It was.
6 Q So sitting here today, you don't know why
7 you included only updates until July 10, 2015,
8 right? Let me ask my question differently.
9 Sitting here today, you don't know the
10 significance of the July 10, 2015 date. Is that
11 correct?
12 A Yes, that is correct.
13 Q Before the updates that you list in
14 Appendix B of your declaration, do you know how JHU
15 made those updates to the study record?
16 MS. JACK: Objection; vague.
17 A Can you clarify your question?
18 Q Sure. For example, do you know if JHU
19 made the updates that you recite in Appendix B of
20 your declaration electronically?
21 A I do not know.
22 Q Did you see the paperwork that JHU

1 submitted to ClinicalTrials.gov for the updates that
2 you include in Appendix B of your declaration?
3 MS. JACK: I object to the form of the
4 question.
5 A I saw only what was publicly available on
6 ClinicalTrials.gov.
7 Q Do you know whether it was JHU that made
8 those updates?
9 A As I previously testified, JHU is the
10 responsible party for the submission.
11 Q That wasn't quite my question. Let me try
12 a different way.
13 Sitting here today, do you know who made
14 the updates to the study record that you recite in
15 Appendix B of your declaration?
16 MS. JACK: Objection; vague.
17 A As I have previously testified, as the
18 responsible party, JHU is responsible for ensuring
19 the correctness of the information and providing
20 information when needed. That is what I know.
21 Q And you're discussing the responsible
22 party, but my question is a little different.

1 My question is about whether you know who
2 submitted the updates to ClinicalTrials.gov.
3 MS. JACK: Objection; asked and answered.
4 A As I have previously stated, in my
5 experience, the responsible party submits to
6 ClinicalTrials.gov. The responsible party is
7 responsible for -- for the submission.
8 Q So you don't know whether it was JHU that
9 made these updates to ClinicalTrials.gov. Is that
10 correct?
11 MS. JACK: Objection; misstates testimony.
12 A As the responsible party, JHU would be
13 responsible for updates to the record.
14 Q Let's talk about the specific updates
15 here. So looking at this first update that you
16 include in Appendix B, you state that "JHU submitted
17 an update with respect to the secondary outcome
18 measure."
19 Do you see where you have that written?
20 A Yes.
21 Q Do you know whether JHU submitted the
22 paperwork for that update?

1 MS. JACK: I object to the form of the
2 question.
3 A As the responsible party, JHU is
4 responsible for the information submitted.
5 Q I'm not asking about who is the
6 responsible party. I'm asking if whether you know
7 that it was JHU that submitted the update on June
8 12th, 2013 --
9 MS. JACK: Objection --
10 Q -- as opposed to, for example, Merck. And
11 if you don't know, can you please tell me that.
12 A I have answered this to the best of my
13 ability. The responsible party is responsible for
14 the updates and accuracy of the submission. JHU is
15 the responsible party.
16 Q But I'm not asking who is the responsible
17 party.
18 I'm asking whether you know that it was
19 JHU that made the submission update on June 12th,
20 2013.
21 MS. JACK: Objection; asked and answered.
22 A As the responsible party, JHU is

1 responsible for that information.
2 Q Okay. So for update 2 on September 20th,
3 2013, do you know who submitted the paperwork for
4 that update to the study record?
5 MS. JACK: Objection; vague.
6 A My answer is the same as it has been for
7 these questions.
8 Q So for update 3 on May 21, 2014, do you
9 know who submitted the paperwork for this update?
10 MS. JACK: Objection; vague.
11 A I have the same answer as I have
12 previously stated.
13 Q Well, I need an answer to this question.
14 A As the responsible party, Johns Hopkins is
15 responsible for the submissions.
16 Q But my question is not who is responsible,
17 who is the responsible party.
18 My question is whether you know that JHU
19 made the update on May 21, 2014?
20 MS. JACK: Objection; asked and answered.
21 A I have answered to the best of my ability.
22 Q Update number 4 on June 25, 2014, do you

1 know who submitted the paperwork for that update to
2 ClinicalTrials.gov?
3 MS. JACK: Objection; vague.
4 A My answer remains the same; Johns Hopkins
5 would have been responsible for the submission.
6 Q And for the fifth update on September 15,
7 2014, do you know who submitted the paperwork for
8 that submission?
9 MS. JACK: Objection; vague.
10 A I would respond the same as I have
11 previously; Johns Hopkins would have been
12 responsible for that submission.
13 Q And did JHU make that submission?
14 A As I have previously stated, they would be
15 responsible for the submission.
16 Q So my question is not whether they would
17 be responsible. My question is whether JHU made the
18 submission on September 15, 2014.
19 MS. JACK: Objection; asked and answered.
20 A They are the party indicated as
21 responsible for the records for this study
22 registration. That is all I can attest to.

1 Q So for update number 6 on December 26,
2 2014, did JHU submit the update to ClinicalTrials.gov?
3 A And again, as with the previous, Johns
4 Hopkins is the only party identified as responsible
5 for the content of the submission.
6 Q And for update 7 on January 29, 2014, do
7 you know who submitted the paperwork to
8 ClinicalTrials.gov?
9 MS. JACK: Objection; misstates the
10 document.
11 A Johns Hopkins is the only party listed as
12 responsible for the submission.
13 Q Let me ask my question again just to be
14 clear.
15 On January 29, 2015, do you know who
16 submitted the paperwork to ClinicalTrials.gov?
17 MS. JACK: Objection; vague.
18 A Again, as previously stated, Johns Hopkins
19 is the only party listed as responsible.
20 Q And did JHU alone make that submission on
21 January 29, 2015?
22 A This is outside the scope of my report and

1 would cause me to speculate.
2 Q Just to be clear, you state at the top of
3 Appendix B that Appendix B reflects updates made by
4 JHU before July 10, 2015, right?
5 A Correct.
6 Q And so my question is did JHU alone make
7 the submission on January 29, 2015?
8 MS. JACK: Objection; vague.
9 A My response is that Johns Hopkins is the
10 only party listed as responsible for the content of
11 the submission.
12 Q So did they make that submission on
13 January 29, 2015?
14 MS. JACK: Objection; asked and answered.
15 A They are listed as --
16 Q Yes or no?
17 A -- as the responsible party, that is what
18 I can say.
19 Q For the eighth update on February 26,
20 2015, do you know who submitted the paperwork to
21 ClinicalTrials.gov for that submission?
22 A My answer is the same as the prior

1 updates; Johns Hopkins is named as the party
2 responsible for the submission.
3 Q Did JHU alone make that submission on
4 February 26, 2015?
5 MS. JACK: Objection; vague.
6 A I again repeat my response; Johns Hopkins
7 is named as the responsible party for the
8 submission.
9 Q For the ninth update on April 15, 2015, do
10 you know who submitted the paperwork for that
11 submission to ClinicalTrials.gov?
12 MS. JACK: Objection; vague.
13 A Johns Hopkins is responsible for the
14 submission as the responsible party.
15 Q Did JHU alone make that submission on
16 April 15, 2015?
17 MS. JACK: Objection; vague.
18 A Johns Hopkins is the only responsible
19 party for the submission.
20 Q The last update that you include on June
21 9th, 2015, do you know who submitted the paperwork
22 to ClinicalTrials.gov for that submission?

1 MS. JACK: Objection; vague.
2 A As with the prior updates, Johns Hopkins
3 is named as the responsible party for that
4 submission.
5 Q And did JHU alone make that submission on
6 June 9th, 2015?
7 MS. JACK: Objection; vague.
8 A As with the prior updates, Johns Hopkins
9 is the only named responsible party.
10 Q For each of these submissions identified
11 in your Appendix B, you've never seen the paperwork
12 that was submitted for those updates, right?
13 MS. JACK: I object to the form of the
14 question.
15 A I have seen the public posting of the
16 information. I did not see the paperwork that was
17 provided to ClinicalTrials.gov.
18 Q So in your view, these updates to the
19 study record that you provide in Appendix B were
20 legally required, right?
21 MS. JACK: I object to the form of the
22 question.

1 A Yes, the updates were legally required.
2 Q And in your view, they were legally
3 required to comply with 42 USC 282(j)(4)(C). Is
4 that correct?
5 A I'm looking for the reference. One
6 moment, please.
7 Q And, Ms. Newberger, where are you looking
8 at the moment?
9 A I'm looking in my binder with the -- with
10 the exhibits. And I am in tab 9, which contains the
11 statute, and you said (4)(C), is that correct,
12 updates to clinical trial databank?
13 Q My question isn't asking for you to look
14 at the statute at the moment.
15 My question is whether, sitting here
16 today, your view is that updates to the study record
17 were necessary to comply with 42 USC 282(j)(4)(C)?
18 A Yes, and so I'm referring to the statute
19 to be able to say whether they were responsible for
20 complying with it, and I agree that they were
21 responsible for complying with the updates
22 requirements.

1 Q Well, you state that in your declaration,
2 right?
3 A Yes.
4 Q And are you familiar with this part of
5 your declaration?
6 A Yes.
7 Q Are you familiar with -- let me ask a
8 different question.
9 Is it your view, sitting here today -- let
10 me ask my question a different way.
11 You state in your declaration at paragraph
12 48 that the information, the updates were needed to
13 comply with 42 USC 282(j)(4)(C), correct?
14 A Correct.
15 MS. JACK: Objection; misstates the
16 document.
17 Q And you stand by that conclusion today,
18 right?
19 A I do.
20 Q And, Ms. Newberger, you stated that you
21 were looking at the binder before you, correct?
22 A Correct.

1 MS. STAURING: Counsel, I'll just ask that
2 you please send to our attention as soon as possible
3 for this deposition a copy of the binder that
4 Ms. Newberger has because we don't have that and we
5 need to refer to it.
6 MS. JACK: All right. Counsel, well, she
7 did tell you exactly what's in the binder, which you
8 have all that material, you had a list of all the
9 information, and I don't think it necessary for us
10 to send you copies of information that you already
11 have.
12 MS. STAURING: That's really not
13 acceptable because we need to know what exactly
14 Ms. Newberger is referring to when she's looking at
15 the binder before her.
16 MS. JACK: I think I --
17 MS. STAURING: We don't know how it's
18 compiled or what tab refers to which document.
19 MS. JACK: We'll send you a binder after
20 -- after this is over so you know what she's talking
21 about when she refers to a tab, that's fine.
22 MS. STAURING: We need it for the

1 deposition that's currently taking place and we
2 would like it now.
3 MS. JACK: Well, obviously, that's
4 impractical, and I can just take the binder from her
5 and you can put information into the chat if that's
6 how you prefer to proceed. We've got to be
7 convenient for everybody involved for her to have a
8 copy of her materials since this a remote
9 deposition. But if you disagree with that, she can
10 operate without it.
11 MS. STAURING: We're just asking that you
12 send it to us.
13 MS. JACK: Well, I'm not going to be able
14 to send it to you right now. So either we can
15 proceed and she can tell you what exhibit she's
16 looking at whenever she turns to anything in the
17 binder, which should be fine, you have all the
18 exhibits, or I can take it from her. But we're not
19 going to be able to get it to you today.
20 MS. STAURING: I'll continue with my
21 question.
22 MS. JACK: So should I leave the binder

1 with her?
2 MS. STAURING: I didn't hear your
3 question, counsel.
4 MS. JACK: Should I -- she can keep the
5 binder and I'll have -- Ms. Newberger, if you can
6 just be careful to say what exhibit you're looking
7 at whenever you turn to something.
8 THE WITNESS: I can do that.
9 MS. STAURING: Well, we've asked for you
10 to send the binder, and if you don't send it, then
11 you do that at your peril. But I will continue with
12 my questions.
13 MS. JACK: All right. Thank you.
14 BY MS. STAURING:
15 Q So, Ms. Newberger, you see at paragraph 48
16 where you state that the updates, the study record
17 were needed to comply with 42 USC 282(j)(4)(C),
18 right?
19 A Yes, that is correct.
20 Q And are you familiar with that part of the
21 statute?
22 A Yes.

1 Q You've reviewed that part of the statute,
2 right?
3 A I have.
4 Q And that part of the statute requires
5 submitting clinical trial information that is
6 required to be submitted under paragraph 2 of the
7 same statute, right?
8 MS. JACK: I object to the form of the
9 question.
10 A While I am familiar with that provision, I
11 certainly do not remember every word within it.
12 Would it be okay for me to refer to the statute? Or
13 if you have it and you would like to share it on
14 your screen, that would also be okay.
15 Q I'm just asking generally whether, sitting
16 here today, you understand that that part of the
17 statute requires submitting updates to reflect
18 changes to clinical trial information that is
19 required under a paragraph that comes earlier in the
20 statute.
21 MS. JACK: I object to the form of the
22 question.

1 A That is my recollection. But, again, I do
2 not have the statute in front of me and I would want
3 to look at it before confirming. But that is my
4 recollection.
5 Q So let's take a look at one of the updates
6 in Appendix B, if you could turn back there, please.
7 And for update 3 you write, "On May 21, 2014, the
8 registration was updated to include 'Keywords' in
9 the 'Conditions' section," right?
10 A Yes, that is what it says.
11 Q And to be clear, we're looking at Appendix
12 B to your declaration, right?
13 A Right, that is correct.
14 Q Was including keywords a required clinical
15 trial element under the statute?
16 A I would have to look at the statute to
17 refresh my memory on each of the elements. There
18 are many.
19 Q So you don't know, sitting here right now,
20 whether keywords is a required clinical trial
21 element under the statute?
22 A I would need to refer back to the statute.

1 Q Okay. We can take a look at the statute
2 that is 42 USC 282(j)(4)(C), and that is Exhibit
3 2148. Please let me know when you have that
4 downloaded.
5 A Yes, I have it.
6 Q Can you please turn to page 8.
7 A Wait, sorry, I think this is -- which is
8 the exhibit number?
9 Q 2148.
10 A This is the regulation. This is not the
11 statute.
12 Q And this is the exhibit that you cite in
13 your declaration, right?
14 A And I'm sorry, you're right, this is the
15 statute. It's in a different format than what I'm
16 looking at. Yes, I see it.
17 Q Do you have page 8 pulled up before you?
18 A Yes.
19 Q So please review the statute and let me
20 know if your opinion -- if, in your opinion, the
21 statute requires updates to include keywords?
22 MS. JACK: Objection; outside the scope of

1 the report.
2 A I'm not -- I'm not seeing on page 8
3 requirements. I see the provision about updates to
4 reflect changes to the clinical trial information
5 submitted under paragraph 2. Is that what --
6 Q You see 42 USC 282(j)(4)(C), right?
7 A Correct.
8 Q And my question is I'm asking you to
9 please review this portion of the statute and then
10 let me know if, in your opinion, the statute legally
11 requires updates to include keywords.
12 MS. JACK: I object to the form of the
13 question.
14 A The statute legally requires updates to
15 reflect changes to the clinical trial information
16 submitted under paragraph 2.
17 Q And are keywords required under paragraph
18 2 of the statute?
19 A I would have to go to paragraph 2.
20 Q So sitting here currently, you don't know
21 whether paragraph 2 requires keywords?
22 MS. JACK: I object to the form of the

1 question.
2 A The change was with respect to the
3 conditions section.
4 Q We can turn to paragraph -- we can turn to
5 paragraph 2, and that's on page 2 of Exhibit 2148.
6 A Yes. And it does require submission of
7 primary disease or condition being studied, and that
8 is the section that was updated on May 21, 2014 was
9 the conditions section.
10 Q To be clear, you're looking under the
11 section (ii) Content, correct?
12 A Correct.
13 Q And the word "keywords" is not included in
14 that portion of the statute, right?
15 A But the word "condition" is and it was the
16 Condition section that was updated.
17 Q My question is a little different. My
18 question is whether this portion of the statute
19 includes the word "keywords"?
20 A My response is that the section that was
21 updated is the conditions section. The condition is
22 specified in (ii)(I)(gg), and if there were updates

1 to the condition section that the responsible party
2 felt were appropriate, they were legally required to
3 provide those updates in whatever form they may have
4 been. The update was to the Condition section.
5 Q Ms. Newberger, do you know what my
6 question was?
7 MS. JACK: Objection; argumentative.
8 Q I'm just trying to clarify whether you
9 heard my question because my question was a little
10 bit different, and it was whether the word
11 "keywords" appears in this portion of the statute.
12 MS. JACK: Object. Is that a question?
13 A I did hear your question. I understand
14 your question is about keywords. But I cannot
15 answer -- I can say that particular word does not
16 appear here.
17 But what I want to make clear is that the
18 updated section was the conditions section for line
19 3, "On May 21, 2014, the registration was updated to
20 include 'Keywords' in the 'Conditions' section." So
21 it was the conditions section that was updated. The
22 conditions section is required and, therefore, was

1 required to be updated if and when the sponsor felt
2 it was appropriate.
3 Q In your view, keywords were legally
4 required to be submitted, right?
5 MS. JACK: Objection; misstates testimony.
6 A In my view, not my view, legally the
7 conditions section was required to be updated.
8 Q Let me ask my question a little
9 differently.
10 So setting aside any updates, were
11 keywords legally required to be updated?
12 MS. JACK: Objection; incomplete
13 hypothetical.
14 A There is not a specific section called
15 Keywords. But keywords may be included in any of
16 the sections at the discretion of the responsible
17 party.
18 Q And I'm specifically asking if it was
19 legally required for this study, this study record,
20 to provide a keyword update.
21 MS. JACK: Objection; outside the scope.
22 A All I can say is that they were legally

1 required to update the conditions if they felt it
2 was appropriate. That is what they did.
3 Q Were they legally required to provide
4 keywords?
5 A They were legally required to update the
6 condition as they felt appropriate. I cannot
7 comment on why they chose to do that specifically,
8 but it was an update to a legally required section.
9 Q So in your view, keywords is a legally
10 required section?
11 MS. JACK: Objection; asked and answered.
12 A That is not what I said.
13 Q Let me ask my question a little
14 differently.
15 Is providing keywords legally required?
16 MS. JACK: Objection; asked and answered.
17 A If keywords are necessary to appropriately
18 provide the information for these sections, then
19 keywords would be required.
20 Q Were keywords necessary for this study
21 record?
22 MS. JACK: Objection; outside the scope.

1 A I can't opine on that.
2 Q In your view, was it legally required to
3 provide an update to this study record to include
4 keywords?
5 MS. JACK: Objection; outside the scope.
6 A They were legally required to update the
7 condition section as they felt appropriate. How or
8 why, in what form is not something that I can opine
9 on.
10 Q I'm asking a slightly different question.
11 So my question is whether it was legally
12 required to provide keywords in this study record.
13 MS. JACK: Objection; outside the scope.
14 A My answer is that keywords were part of
15 the conditions section. Condition is legally
16 required.
17 Q Let me ask one more time.
18 In your view, was it legally required to
19 provide an update for this study record to include
20 keywords?
21 MS. JACK: Objection; asked and answered.
22 A It is outside the scope of my report to

1 say whether the update to the condition section had
2 to be done in that way. But it was legally required
3 to update the condition section. That is what they
4 did.
5 Q Ms. Newberger, it's not outside the scope
6 of your declaration, because you write in paragraph
7 48 that update 3 to the study record as to keywords
8 was legally required. And so I am asking whether in
9 your view, sitting here today, it was legally
10 required to provide an update for this study record
11 to include keywords?
12 MS. JACK: Objection; outside the scope.
13 A It was legally required to update the
14 conditions section, that is what that update
15 reflects, an update to the conditions section.
16 Q I don't think I got an answer to my
17 question.
18 And my question is whether, in your view,
19 it was legally required to provide an update for
20 this study record to include keywords?
21 MS. JACK: Objection; asked and answered.
22 And I think this is probably the fifth time that

1 you've asked this question, so that is harassing,
2 Jessica.
3 A My response remains the same; they were
4 legally required to update the Condition section.
5 How they went about doing that is beyond the scope
6 of my ability to respond to.
7 Q Are you familiar -- sorry, let me ask that
8 a different way.
9 You're aware that ClinicalTrials.gov
10 provides descriptions for the elements that are
11 required to be submitted on ClinicalTrials.gov,
12 right?
13 MS. JACK: Object to the form of the
14 question.
15 A The ClinicalTrials.gov website provides
16 information, yes, to help guide what can be
17 included.
18 Q And you're aware that ClinicalTrials.gov
19 makes providing keywords optional, right?
20 A I would have to refer back to that website
21 on that particular point. What I do recall from
22 that website is at the top it specifically states

1 the responsible parties are responsible for ensuring
2 their compliance with the applicable legal
3 requirements. The page is not intended to be a
4 substitute.
5 Q So are you aware that ClinicalTrials.gov
6 says the keywords are optional?
7 A There is a lot of information on that
8 page. I do not remember how they have categorized
9 each and every element on ClinicalTrials.gov. If
10 you would like to post it, I would be happy to take
11 a look, or I can look at it in the binder and tell
12 you which exhibit it is.
13 Q Are you familiar with ClinicalTrials.gov
14 registration requirements?
15 MS. JACK: Objection; vague.
16 A I am familiar with registration
17 requirements.
18 Q And did you review the information that
19 ClinicalTrials.gov provides regarding registration
20 requirements in your work in this matter?
21 A Yes, I did.
22 Q And you reviewed Exhibit 2149 that you

1 cite that reflects that information from
2 ClinicalTrials.gov, right?
3 A That is correct.
4 Q And you reviewed it carefully, right?
5 A Yes, I did.
6 Q And you weren't confused by anything
7 written in that exhibit, right?
8 MS. JACK: I object to the form of the
9 question.
10 A I do not recall being confused.
11 MS. JACK: Counsel, we have been going for
12 about an hour here. Are you close to a breaking
13 point?
14 BY MS. STAURING:
15 Q Ms. Newberger, would you like to take a
16 break?
17 A We can continue for a little bit more.
18 Q And so I'll ask my question again. You
19 weren't confused by anything written in Exhibit
20 2149, were you?
21 A I do not recall being confused.
22 Q And did you see in Exhibit 2149 where it

1 stated that keyword updates are optional?
2 A May I refer to the exhibit?
3 Q I'm just asking if, sitting here today,
4 you recall seeing that in Exhibit 2149.
5 MS. JACK: I object to the form of the
6 question.
7 A It is a lengthy exhibit, there's a lot of
8 information. I do not recall how that website
9 necessarily categorized each and every element. If
10 I could look at it, that would be great. Otherwise,
11 I do not recall specifically how this was
12 categorized.
13 Q And you don't remember that and you put it
14 in Exhibit B as an update? Sorry, let me restate
15 that.
16 You don't remember that when you put it in
17 Appendix B to your declaration as an update about
18 keywords?
19 A The update that you refer to, update 3, is
20 about an update to the conditions section.
21 Q So are you aware that ClinicalTrials.gov --
22 sorry, let me ask that a different way.

1 The update refers to keywords, right?
2 A I would categorize it differently. The
3 update refers to the conditions section. Keywords
4 refers to how they updated the conditions section.
5 But the conditions section is a legally required
6 section that they were required to update in the
7 manner in which they saw fit.
8 Q But you wrote in Appendix B that the study
9 record was updated to include keywords, right?
10 MS. JACK: I object to the form of the
11 question.
12 A That is not what I wrote. What I wrote is
13 that the registration was updated to include
14 keywords in the conditions section.
15 Q But to be clear, you wrote that the update
16 was to include keywords, right?
17 MS. JACK: Objection; asked and answered.
18 A In the conditions section.
19 Q And I'm not asking about what section the
20 update was made. I'm asking a slightly different
21 question, and that's whether the update was to
22 include keywords.

1 MS. JACK: I object to the form of the
2 question.
3 A My response is that that cannot be
4 answered without citing the section in which those
5 keywords were included, which is the conditions
6 section.
7 Q Well, are you aware that updates to
8 keywords are not legally required under any section?
9 MS. JACK: I object to the form of the
10 question.
11 A As I have previously stated, updates to
12 the conditions section are legally required. The
13 manner in which any particular responsible party
14 chooses to go about updating that conditions section
15 is at their discretion.
16 Q But are you aware that an update to the
17 keywords section as to any section is stated to be
18 optional by the FDA in the exhibit that you cite in
19 your declaration?
20 MS. JACK: I object to the form of the
21 question.
22 A To clarify, it's ClinicalTrials.gov which

1 is NIH, not FDA. But what I am aware is that the
2 conditions section is required and the company may
3 update that however they see fit.
4 Q So the exhibit that you rely upon from
5 ClinicalTrials.gov states that keywords are not
6 required, right?
7 MS. JACK: Objection; asked and answered.
8 A I've asked if I could look at the record,
9 the exhibit.
10 Q Sure. Let's take a look at that exhibit,
11 which is Exhibit 2149 that you cite in your
12 declaration. Please let me know when you have that
13 before you.
14 A Yes, I have it.
15 Q And you see on page 1 that NIH provides a
16 general ledger with symbols, right?
17 A I do see that. I do not know when -- the
18 date of those symbols. It was clearly after 2013.
19 Q Okay. And you see where it states no
20 symbol indicates data element optional by
21 ClinicalTrials.gov, right?
22 A I do.

1 Q On page 1?
2 A Mm-hmm.
3 Q So if we turn to page 11 of that document,
4 and you see at the bottom the element Keywords,
5 correct?
6 A I do.
7 Q And you agree that there is no symbol
8 indicated next to Keywords, right?
9 A There is no symbol next to Keywords, but
10 there is the symbol above it for Primary Disease or
11 Condition Being Studied.
12 Q Okay. But there is no symbol next to
13 Keywords, right?
14 A That is right.
15 Q I'm just asking about the keywords.
16 A There is no symbol.
17 Q So do you understand that ClinicalTrials.gov
18 considers keywords to be an optional element?
19 MS. JACK: Objection; vague.
20 A I do not necessarily reach that conclusion
21 and I cannot speak to what was here in 2013 or 20 --
22 sorry, 2014.

1 Q Why not?
2 A Because this page was posted after 2014.
3 Q Isn't your declaration about what was
4 submitted in 2013?
5 A Correct.
6 Q And you cite to this exhibit in your
7 declaration, right?
8 A I do.
9 Q Do you have any reason, sitting here
10 today, to think -- let me ask that a different way.
11 Do you believe that the keywords updates
12 were legally required before the date of the exhibit
13 that you cite?
14 MS. JACK: Objection; vague.
15 A I believe updates to the conditions
16 section were legally required. How that was done is
17 up to the responsible party.
18 Q But I'm asking about keywords
19 specifically. Let me ask my question again.
20 Do you believe that keywords updates were
21 legally required before the date of the exhibit that
22 you cite in your declaration as Exhibit 2149?

1 MS. JACK: Objection; vague.
2 A I have answered this to the best of my
3 ability. Updates to the conditions section were
4 legally required, that was what this update
5 contained.
6 Q So do you believe that keyword updates
7 were required on May 21, 2014?
8 MS. JACK: Objection; asked and answered.
9 A Updates to conditions sections were
10 required. This was an update to the conditions
11 section.
12 Q My question is whether you believe that
13 keyword updates were legally required on May 21,
14 2014?
15 MS. JACK: Objection; asked and answered.
16 A My response is that as of that date,
17 updates to conditions sections were required. This
18 was an update to the conditions section.
19 Q You understand that ClinicalTrials.gov
20 indicates keywords as an optional element, right, in
21 Exhibit 2149 to your declaration?
22 A I think that that is one reading of it.

1 It could also be read as a subset of the conditions
2 description.
3 Q Looking at page 11 just above where you
4 see the words Conditions and Keywords recited, there
5 is a red asterisk next to that statement?
6 I'm asking you if on page 11 next to
7 Conditions and Keywords there is a red asterisk next
8 to that statement?
9 A There is no red asterisk.
10 Q And ClinicalTrials.gov indicates that a
11 red asterisk means the element is required, right?
12 A Yes.
13 Q So to be clear, there is no indication
14 from ClinicalTrials.gov under the heading titled
15 Conditions and Keywords or under the heading titled
16 Keywords indicating a required element, right?
17 MS. JACK: I object to the form of the
18 question.
19 A Primary disease or condition being studied
20 in the trial or the focus of the study is a required
21 element. How that is accomplished is up to the
22 discretion of the sponsor. This was an update to

1 the conditions section.
2 Q Let me try my question again.
3 There are no -- there is no indication
4 from ClinicalTrials.gov next to the heading titled
5 Conditions and Keywords or the heading titled
6 Keywords on page 11 to indicate a required element,
7 right?
8 MS. JACK: Objection; asked and answered.
9 A It is an incomplete read of that section.
10 Q I am just -- my question is a bit simpler,
11 and it's whether you agree that there is no
12 indication by a red asterisk from ClinicalTrials.gov
13 next to the heading titled Conditions and Keywords
14 or the heading titled Keywords indicating a required
15 element, right?
16 MS. JACK: Objection; asked and answered.
17 A I cannot answer it other than as I have,
18 which is that conditions are required. They are
19 required to be updated. How that is done, whether
20 it's through a keyword or some other mechanism, if
21 the sponsor determined an update was needed, they
22 may do that however they see fit.

1 Q Are you confused by the exhibit you cited
2 in your declaration?
3 MS. JACK: I object to the form of the
4 question.
5 A I am not confused.
6 Q So you understand that ClinicalTrials.gov
7 uses this symbol of a red asterisk to indicate a
8 required element, correct?
9 A I do understand that.
10 Q ClinicalTrials.gov uses no symbol to
11 indicate that an element is considered optional,
12 right?
13 MS. JACK: Objection; asked and answered.
14 A I have nothing additional to add to what I
15 have previously stated.
16 It's also important to note, as I did at
17 the beginning, that at the top of this page it
18 states: The data element entries are annotated with
19 symbols to indicate generally when information is
20 required, the responsible party must ensure that the
21 information provided complies with any applicable
22 laws, regulations or policies.

1 If Johns Hopkins, as the responsible
2 party, believed that in order to appropriately
3 reflect its conditions section, an update was needed
4 and that that update was keywords, they were legally
5 obligated to make that update to the conditions
6 section.
7 Q Let me just ask again.
8 ClinicalTrials.gov uses no symbol to
9 indicate that an element is considered optional,
10 right?
11 MS. JACK: Objection; asked and answered.
12 A I have answered that. That is what it
13 says.
14 Q And this is the exhibit that you cite in
15 your declaration and rely upon, right?
16 MS. JACK: Objection; vague.
17 A I use it to provide additional explanation
18 for each of the required elements from the statute.
19 Q And so you understand that ClinicalTrials.gov
20 uses no symbol to indicate that an element is
21 optional, right?
22 MS. JACK: Objection; asked and answered.

1 A That is -- yeah, I've answered it. That
2 is what it says on the first page.
3 Q And to be clear, you rely upon and cite
4 this exhibit in your declaration, right?
5 MS. JACK: I object to the form of the
6 question.
7 A I have this as an exhibit in my
8 declaration.
9 Q And did you rely upon it?
10 A I did use it in order to form my opinion,
11 yes.
12 Q And so turning back -- let me ask that a
13 slightly different way.
14 Everywhere that we see the word "keywords"
15 and a description of keywords in the exhibit that
16 you cite in your declaration shows that keywords are
17 optional, right?
18 MS. JACK: I object to the form of the
19 question.
20 A Can you provide me with a page number?
21 Q You can look to page 11 of Exhibit 2149
22 that you cite in your declaration.

1 A That's what we're looking at here, right?
2 I thought you said in my report.
3 Q Let me ask my question again.
4 Everywhere that we see the word "keywords"
5 and a description about keywords from
6 ClinicalTrials.gov in the exhibit that you cite and
7 rely upon in your declaration shows that keywords
8 are optional, right?
9 A I would have to look back and see each and
10 every time that keywords is referenced.
11 Putting that aside, the point here is that
12 this was not a keywords section. This was a
13 conditions section, which is obligated and required
14 to be updated. That is what they updated, the
15 conditions section.
16 Q Well, let's look at these two references
17 specifically on page 11. And here where we see the
18 use of the word "keywords" and a description about
19 keywords, ClinicalTrials.gov indicates that keywords
20 are optional, right?
21 MS. JACK: Objection; asked and answered.
22 A I cannot answer it any way other than

1 which I have, which is that it can be included as
2 part of the primary disease or condition being
3 studied if the responsible party feels that it is
4 appropriate. They are responsible for the content
5 of the conditions section in whatever form that may
6 take. They are responsible for ensuring that it is
7 accurate, that it is complete, and that it is up to
8 date.
9 Q I'm asking in the exhibit that you rely
10 upon in your declaration, on page 11 where we see
11 the word "keywords" and a description about
12 keywords, ClinicalTrials.gov shows that keywords are
13 optional, right?
14 MS. JACK: Objection; asked and answered
15 multiple times.
16 A My response to your question, as it has
17 been, is that the absence of the asterisk does not
18 necessarily mean that if a responsible party feels
19 that keywords are needed to accurately describe the
20 condition, that they shouldn't use them. I can't
21 opine as to why Johns Hopkins took the approach that
22 it did. The update was to a legally required

1 section, which was conditions.
2 Q And I'm not asking you to opine on why JHU
3 may have included keywords.
4 I'm asking whether this exhibit that you
5 cite in your declaration indicates on page 11 where
6 we see the word "keywords" that keywords are
7 required?
8 A There is no asterisk next to keywords.
9 But it is ultimately at the determination of the
10 responsible party to determine what is required and
11 in what format the information should be updated.
12 Q So ClinicalTrials.gov does not indicate
13 that keywords are legally required, right?
14 MS. JACK: Objection; asked and answered.
15 A Clinical Trials requires updates to the
16 conditions section. How that is done is at the
17 discretion of the responsible party.
18 Q And my question isn't about updates.
19 My question is whether you agree that
20 ClinicalTrials.gov does not indicate the element
21 keywords as a required element?
22 MS. JACK: Objection; asked and answered.

1 A It indicates that disease or condition
2 being studied is a required element. The content of
3 that section is up to the responsible party.
4 MS. JACK: My computer is going to die
5 here; I just realized it's not plugged in. If we
6 could go ahead and take a break, if that's okay with
7 everybody else.
8 Q Ms. Newberger, would you like to take a
9 break?
10 A Yes, that would be great.
11 MS. STAURING: Okay. We can go off the
12 record.
13 (Recess 2:33 p.m. - 2:46 p.m.)
14 BY MS. STAURING:
15 Q Ms. Newberger, during the break did you
16 speak to anyone about your deposition today?
17 A No, I did not.
18 Q In your declaration you refer to study
19 J1365, right?
20 A Can you point me to the page, please?
21 Q Sure. Can you take a look at your
22 declaration at page 15, paragraph 45, you refer to a

1 study J1365, right?
2 A Yes.
3 Q And you refer to study J1365 in paragraph
4 49 of your declaration, right?
5 A Yes.
6 Q And when you refer to study J1365 in
7 paragraph 49 of your declaration, you're referring
8 to the study MK -- the study of MK-3475 in patients
9 with microsatellite unstable (MSI) tumors, right?
10 MS. JACK: I object to the form of the
11 question.
12 A Yes, the unique protocol ID provided on
13 ClinicalTrials.gov is J1365 for the study titled
14 "phase 2 Study of MK-3475 in Patients with
15 Microsatellite Unstable (MSI) Tumors."
16 Q And that study is the one that we have
17 been discussing that has NCT number 01876511, right?
18 A Yes.
19 Q An NCT number is an identification that
20 the website ClinicalTrials.gov assigns to a trial
21 when it's registered, right?
22 A Yes, that is correct.

1 Q And you call study NCT01876511 JHU study,
2 right?
3 MS. JACK: Objection; vague.
4 A Can you point to me where I use that
5 phrase?
6 Q Don't you know that throughout your --
7 excuse me.
8 Don't you know that throughout your
9 declaration you refer to it as JHU's study?
10 MS. JACK: Objection; vague, lack of
11 foundation.
12 A I certainly know that I used the term
13 "JHU" and I certainly know that I used the term
14 "study." I was asking if you can point me
15 specifically to where it says JHU's study so that I
16 can merely confirm your question.
17 Q Do you recall referring to it throughout
18 your declaration as JHU's study?
19 MS. JACK: Objection; lack of foundation.
20 A I may have referred to it as JHU's study.
21 I may have referred to it as the study. I may have
22 referred to it as probably a number of different

1 ways.
2 Is there a paragraph that you have in mind
3 that you can point to me so that I can say yes, I
4 did refer to it that way?
5 Q You're familiar with your declaration
6 sitting here today, right?
7 A Yes.
8 Q You referred to it as JHU's study in
9 paragraph 45 of your report, right, in paragraph 45
10 of your declaration?
11 A Yes, I see that.
12 Q And you're aware that Merck was a
13 collaborator on that study, right?
14 A I am aware that they were listed as a
15 collaborator on ClinicalTrials.gov registration,
16 yes.
17 Q Are you aware that Merck was a
18 collaborator in that study?
19 MS. JACK: Objection; asked and answered.
20 A I am aware that they are listed as a
21 collaborator. I do not know the extent of the
22 collaboration.

1 Q Do you believe that Merck was not a
2 collaborator on that study?
3 MS. JACK: I object to the form of the
4 question.
5 A I can only report what I see posted on
6 ClinicalTrials.gov, which is yes, Merck is listed as
7 a collaborator on the study.
8 Q And do you believe what you see posted?
9 MS. JACK: Objection; vague.
10 A I don't have a reason to believe that
11 Merck is not a collaborator. I'm simply saying I
12 don't know the extent of that collaboration.
13 Q Do you distrust what was posted on
14 ClinicalTrials.gov?
15 MS. JACK: Objection; vague.
16 A I do not distrust and I don't think that I
17 implied that I distrusted. I stated Merck is listed
18 as a collaborator. Then I also said there is no
19 information, nor does there need to be, about what
20 that collaboration entails.
21 Q So my question is whether you believe that
22 Merck was a collaborator in the study?

1 MS. JACK: Objection; asked and answered.
2 A They are posted as a collaborator on
3 ClinicalTrials.gov, so, yes, they collaborated in
4 some form. I do not know what that form is.
5 Q And Merck was listed as the sole
6 collaborator for the study, right?
7 A That is my recollection, yes.
8 Q And you know that ClinicalTrials.gov
9 provided a description of a collaborator, right?
10 A I do know that.
11 Q And are you familiar with the definition
12 of collaborator?
13 A I believe -- my recollection, and I'm not
14 looking at the definition, my recollection is that
15 it referred to potentially things such as funding,
16 it could be study design, those were two that I --
17 that I recall. There were a few other examples.
18 Q And ClinicalTrials.gov identifies the
19 collaborator as other organizations that provide
20 support, correct?
21 MS. JACK: Objection; lack of foundation.
22 A May I refer back to Exhibit 2149? I

1 believe that's where it's located.
2 Q I'm just asking if, sitting here today,
3 you understand that ClinicalTrials.gov states that a
4 collaborator is an organization that provides
5 support?
6 MS. JACK: I object to the form of the
7 question.
8 A My recollection is that there was more
9 information provided than merely what you have just
10 stated.
11 Q If you need to refer to Exhibit 2149 to
12 answer my question, that's fine.
13 MS. JACK: Is there a question pending,
14 Jessica?
15 Q Ms. Newberger, do you need me to repeat my
16 question?
17 A I am looking for where it defines
18 collaborator. Yes. So, as I stated, it does
19 provide more information than what you read. It
20 specifically states other organizations, if any,
21 providing support. Support may include funding,
22 design, implementation, data analysis or reporting,

1 and then it states the responsible party is
2 responsible for confirming all collaborators before
3 listing them.
4 Q Okay. So you understand that
5 ClinicalTrials.gov defines a collaborator as an
6 other organization providing support, right?
7 MS. JACK: Objection; misstates testimony.
8 A That is part of the definition. It is not
9 the complete definition. I previously read the
10 complete definition.
11 Q Well, I'm just asking about what
12 ClinicalTrials.gov defines as a collaborator and not
13 the support that it recites. I'm just asking
14 whether ClinicalTrials.gov describes collaborators
15 as other organizations providing support?
16 MS. JACK: Objection; asked and answered.
17 A It states that, but it can't be read
18 without then reading what support may include. So I
19 just want to be complete in the definition of what
20 does a collaborator actually mean. It does state
21 what you said, that is the definition of a
22 collaborator, other organizations, if any, providing

1 support, but it then goes on to state what that
2 support may include, funding, design,
3 implementation, data analysis, or reporting.
4 Q Okay. So you understand that support may
5 include funding, design, implementation, data
6 analysis, or reporting, correct?
7 A That is what it states, yes.
8 Q As part of your work on this matter, did
9 you speak with anyone from Merck?
10 A I did not.
11 Q So you did not discuss with anyone from
12 Merck the support for the study that Merck may have
13 provided, right?
14 A That is correct. It was outside the scope
15 of the report that I was asked to write.
16 Q Well, I'm asking the question of whether
17 you spoke to anyone at Merck about the support that
18 Merck provided for the study.
19 MS. JACK: Objection; asked and answered.
20 A I answered the question. I said that I
21 did not speak to anyone at Merck.
22 Q Did you ask if you could speak to anyone

1 at Merck about its support for the study?
2 A I did not.
3 Q Did you ask -- let me ask my question
4 differently.
5 So it's fair to say, sitting here today,
6 that you do not know what support Merck provided for
7 the study, correct?
8 A That is correct.
9 Q And you don't know whether Merck provided
10 funding for the study, right?
11 A As previously stated, I do not know. It
12 was outside the scope of ClinicalTrials.gov
13 requirements, which does not require knowledge of
14 what the collaborator did or did not do.
15 Q So sitting here today, you don't know what
16 implementation Merck might have provided, right?
17 MS. JACK: Objection; vague.
18 A I don't know whether Merck provided
19 implementation work at all. I don't know what you
20 mean by that word. I do not know what support Merck
21 provided.
22 Q Sitting here today, you do not know what

1 data analysis or reporting work Merck provided for
2 the study, right?
3 MS. JACK: Object to the form of the
4 question.
5 A I don't know if they did any data analysis
6 or reporting. It was not part -- it's outside the
7 scope of my report.
8 Q And just to be clear, you do not know what
9 implementation work Merck provided for the study
10 here, correct?
11 MS. JACK: Objection; asked and answered.
12 A I previously stated outside the scope of
13 what I was asked to provide a report on, I have no
14 information about what Merck did or did not do as
15 part of the study.
16 Q But you refer throughout your report to
17 the study as JHU's study, correct?
18 A Yes. And I do that because JHU is listed
19 as the sponsor, and it is common when discussing a
20 clinical study to refer to a study as that of the
21 sponsor.
22 Q The only reason that you call it JHU's

1 study is because JHU is listed as the sponsor. Is
2 that right?
3 MS. JACK: Objection; misstates testimony.
4 Q Let me ask in a different way.
5 The only reason you call it JHU's study in
6 your declaration is because JHU is listed as the
7 sponsor. Is that right?
8 MS. JACK: Objection; misstates testimony.
9 A JHU is listed as the sponsor and,
10 therefore, I referred to it as JHU's study, which is
11 common for referring to clinical studies with the
12 name of the sponsor.
13 Q So is the only reason that you list it as
14 JHU's study throughout your declaration because JHU
15 is the sponsor?
16 MS. JACK: Objection; asked and answered.
17 A As I previously stated, JHU is the sponsor
18 of the study. It, therefore, was reasonable to
19 state that it's JHU's study. They are responsible
20 for the study as the study sponsor.
21 Q And I'm not suggesting listing it as JHU's
22 study is reasonable or not.

1 I'm asking if the only reason that you
2 listed it as JHU's study throughout your declaration
3 is because JHU is listed as the study sponsor?
4 A The only information I have about the
5 study is what is publicly available on
6 ClinicalTrials.gov, which states that it's the
7 sponsor. So that was the basis for concluding that
8 it is JHU's study.
9 Q And you also have the information that
10 Merck was the sole collaborator, right?
11 MS. JACK: I object to the form of the
12 question.
13 A Yes, the information on ClinicalTrials.gov
14 only lists one collaborator.
15 Q And it lists Merck as the collaborator,
16 right?
17 A That is correct.
18 Q And you agree that support -- let me ask
19 it a different way.
20 A collaborator may provide support that
21 includes implementation, right?
22 MS. JACK: Object to the form of the

1 question.
2 A The document states support may include
3 funding, design, implementation, data analysis or
4 reporting -- so, yes, implementation could be a form
5 of support.
6 Q And do you know what implementation means
7 in Exhibit 2149?
8 MS. JACK: Objection; vague.
9 A Are you asking me to opine on how the
10 person who wrote that paragraph thought about the
11 word "implementation"? I can't do that.
12 Q No. I'm asking if you have an
13 understanding of what implementation means in the
14 exhibit that you cited in your declaration.
15 A I cannot opine on what the author of this
16 web page was thinking when they wrote the word
17 "implementation." My interpretation of
18 implementation may be different from somebody else's
19 interpretation of implementation.
20 Q And what is your interpretation of
21 implementation?
22 A Implementation would be assisting with

1 execution of a clinical study.
2 Q Anything else?
3 A That is how I would interpret that word.
4 Q In your declaration you don't mention that
5 Merck was a collaborator for study NCT01876511,
6 right?
7 MS. JACK: Objection --
8 A I would have to check.
9 MS. JACK: -- to form.
10 Q You don't know whether you mentioned that
11 Merck was the sole collaborator for the study?
12 A I do not indicate that, no.
13 Q Aside from this study, do you know whether
14 Merck has conducted any studies of its own involving
15 treating patients with MSI tumors?
16 MS. JACK: Objection; outside the scope.
17 A I have no knowledge of any studies that
18 Merck is involved in.
19 Q Did you ask about any studies that Merck
20 may have conducted on its own involving patients
21 having MSI-high tumors?
22 MS. JACK: Objection; outside the scope.

1 A I did not ask outside the scope of what I
2 was asked to opine on.
3 Q You know that Merck was involved in the
4 study reflected in the posted study record in your
5 declaration, right?
6 MS. JACK: Objection to the form of the
7 question.
8 A As I previously stated, all I know is that
9 they are listed as a collaborator. I don't know any
10 more about their involvement or in what form they
11 collaborated.
12 Q Sitting here today, is it your belief that
13 this study is the only clinical study involving
14 treating patients having MSI-high tumors?
15 MS. JACK: Objection; outside the scope.
16 A I cannot -- I cannot answer that question.
17 Q This study concerns -- let me ask that a
18 different way. The study that you reference
19 throughout your declaration is a phase 2 study of
20 MK-3475 in patients with microsatellite unstable
21 (MSI) tumors, right?
22 MS. JACK: Objection; mischaracterizes the

1 document.
2 A The title of the study is "phase 2 Study
3 of MK-3475 in Patients with Microsatellite Unstable
4 (MSI) Tumors."
5 Q And is it your belief, sitting here today,
6 that Merck did not conduct any of its own studies on
7 patients having MSI-high tumors?
8 MS. JACK: Objection; outside the scope.
9 A It's outside the scope of my opinion. I
10 do not know. I have no opinion on that.
11 MS. STAURING: Counsel, your speaking
12 objections are adding up I would like it noted for
13 the record.
14 Q Do you know how many patients were
15 anticipated to be enrolled in this study?
16 A My recollection is that it was 71.
17 Q In your declaration you refer to study
18 NCT01876511, the unique protocol ID J1365, right?
19 A Yes, I did that in certain -- certain
20 paragraphs, I believe.
21 Q And the unique protocol identification
22 number is any unique identifier assigned to the

1 protocol by the study sponsor, right?
2 A I would have to confirm that definition,
3 but that sounds correct.
4 Q Are you aware that that's the definition
5 that ClinicalTrials.gov provides?
6 A If I can look, I can -- I can confirm.
7 Q So you don't remember whether the exhibit
8 that you cite in your declaration includes that
9 definition?
10 MS. JACK: I object to the form of the
11 question.
12 A Can you -- can you rephrase the question,
13 please?
14 Q You don't remember what is a unique
15 identification number -- excuse me -- a unique
16 protocol identification number?
17 MS. JACK: I object to the form of the
18 question.
19 A I cannot say that word for word I recall
20 the definition. I know what it is. The way you
21 described it sounds accurate. But you are asking me
22 if that is specifically how ClinicalTrials.gov

1 defines it. I cannot state with certainty that
2 there is not a word that is different between what
3 you stated and what is on their website. I would be
4 happy to confirm.
5 Q Okay. If you don't know, that's fine.
6 The study here has two secondary IDs,
7 right?
8 A Yes, I see those.
9 Q And a secondary ID is an identifier other
10 than the unique protocol identification number or
11 NCT number that is assigned to the clinical study,
12 right?
13 MS. JACK: Objection; lacks foundation.
14 A Again, if you're asking me for the precise
15 definition, I would need to refer to that. But
16 there are other identifiers for the study, yes.
17 Q I'm asking for your recollection based on
18 your knowledge.
19 A My recollection of what?
20 Q That a secondary ID is an identifier other
21 than the unique protocol identification number, or
22 the NCT number, that is assigned to the clinical

1 study.
2 MS. JACK: Object to the form of the
3 question.
4 A I have answered it by saying that sounds,
5 to the best of my recollection, correct, but I
6 cannot say with certainty that that is the precise
7 definition unless I looked at the precise wording.
8 My recollection is that that sounds correct.
9 Q One secondary ID for the clinical study
10 here that you mention in your declaration is
11 MK-3475-016, right?
12 A Yes, that is correct.
13 Q And that's an identifier associated with
14 the study collaborator, Merck, right?
15 MS. JACK: I object to the form of the
16 question.
17 A I can only say that it -- after the
18 secondary ID MK-3475-016 it states in brackets
19 Merck. I don't know anything more about that ID.
20 Q Do you understand that the -- do you
21 understand that secondary ID to be associated with
22 Merck then?

1 MS. JACK: I object --
2 A It states Merck.
3 MS. JACK: -- to the form of the question.
4 Q Do you not believe that that secondary ID
5 is associated with Merck?
6 MS. JACK: I object to the form of the
7 question.
8 A All I know is what it says. It identifies
9 it as Merck.
10 MS. STAURING: Counsel, I'm going to ask
11 that you please refrain from rolling your eyes, it's
12 unprofessional.
13 MS. JACK: I didn't. I'm sorry, I've got,
14 like, multiple screens. I apologize if you saw
15 something that was misinterpreted. I wasn't. I
16 hope that I didn't throw you off.
17 BY MS. STAURING:
18 Q Ms. Newberger, you use in your declaration
19 the term "responsible parties," right?
20 A I believe "responsible party" singular,
21 yes.
22 Q You don't use the phrase "responsible

1 parties"?
2 A Did you say party singular or parties
3 plural?
4 Q I'm referring to your reference in your
5 declaration to responsible -- the phrase
6 "responsible parties."
7 A Yes.
8 Q And this appears at paragraph 46.
9 A Yes.
10 Q And it's your understanding that JHU was
11 the responsible party for the study MK-3475-016,
12 right?
13 A Yes, they are identified as the
14 responsible party on ClinicalTrials.gov.
15 Q And as the responsible party, you would
16 agree that JHU was responsible for confirming all
17 study collaborators before listing them, right?
18 A That is what the ClinicalTrials.gov
19 website states, the responsible party is responsible
20 for confirming all collaborators before listing
21 them.
22 Q And to be clear, here there was just one

1 study collaborator, Merck, right?
2 MS. JACK: I object to the form of the
3 question.
4 A There is only one identified in
5 ClinicalTrials.gov, correct.
6 Q If there were other study collaborators,
7 JHU as the responsible party would be required to
8 list them, right? Excuse me. Let me ask my
9 question again.
10 As the responsible party, JHU would be
11 responsible for confirming all collaborators before
12 listing them, correct?
13 MS. JACK: I object to the form of the
14 question.
15 A If JHU felt that it was appropriate to
16 list a collaborator, they would be responsible for
17 confirming the collaborator before listing them.
18 Q Now, ClinicalTrials.gov is a government
19 registry of clinical trials, right?
20 A Yes, that is correct.
21 Q And that registry is made publicly
22 available through the internet, right?

1 A Yes, that is correct.
2 Q It was created to provide a data bank of
3 information to the public about clinical trials,
4 correct?
5 MS. JACK: I object to the form of the
6 question.
7 A Yes, it was -- it was created to provide
8 information to the public about clinical trials.
9 Q And the purpose of ClinicalTrials.gov is
10 to provide information about clinical research
11 studies to the public researchers, and healthcare
12 professionals, right?
13 A Yes, I think that that is an accurate
14 summary.
15 Q And in your view, clinical trial
16 registration is important to ensure that healthcare
17 providers have all available evidence when making
18 decisions about treating -- treatment for patients,
19 right?
20 MS. JACK: I object to the form of the
21 question.
22 A I believe that I -- one of my exhibits

1 references an article that supports that position.
2 Q Is it your view that clinical trial
3 registration is important to ensure that healthcare
4 providers have all available evidence when making
5 decisions about treatment for patients?
6 MS. JACK: I object to the form of the
7 question.
8 A There are publications, some of which are
9 in my exhibits, that state that that was the reason
10 for the creation of ClinicalTrials.gov.
11 Q And you state that in your declaration,
12 right?
13 A I do state that and I believe I reference
14 those exhibits.
15 Q In paragraph 14 of your declaration, you
16 state, quote, "Trial registration is important to
17 ensure that healthcare providers have all available
18 evidence when making decisions about treatment for
19 patients," right?
20 A Correct.
21 Q And you believe that, right?
22 A I do believe that.

1 Q Another aspect of registration is
2 transparency of clinical trial information, right?
3 A Yes, correct.
4 Q And in your view, registration facilitates
5 recruitment by making potential participants aware
6 of studies for which they may be eligible, right?
7 A It's less opinion and more experience.
8 But yes, when studies are published on
9 ClinicalTrials.gov, companies are able to recruit
10 more easily oftentimes.
11 Q Let me try that again.
12 In your view, registration facilitates
13 recruitment by making potential participants aware
14 of studies for which they may be eligible, right?
15 MS. JACK: Objection; asked and answered.
16 A Yes, that is one purpose of ClinicalTrials.gov.
17 Q And you state in your declaration at
18 paragraph 16 that clinical trial information is,
19 quote, "necessary to facilitate recruitment by
20 making potential participants aware of studies for
21 which they may be eligible," right?
22 MS. JACK: Objection; misstates the

1 document.
2 A That statement starts with "Transparency
3 of clinical trial information is also necessary to
4 facilitate recruitment by making potential
5 participants aware of studies for which they may be
6 eligible."
7 Q And you believe, sitting here today, that
8 registration on ClinicalTrials.gov facilitates
9 recruitment by making potential participants aware
10 of studies for which they may be eligible, right?
11 MS. JACK: Objection; misstates the
12 document.
13 A ClinicalTrials.gov serves as a repository
14 of information for patients who are interested in
15 clinical studies, and by doing so, it can facilitate
16 recruitment.
17 Q So registration facilitates recruitment by
18 making potential participants aware of studies for
19 which they may be eligible. Is that correct?
20 A So long as that information is
21 transparent, and as required, easily understandable
22 by a lay user.

1 Q Let's look at paragraph 16 to your
2 declaration.
3 A Okay.
4 Q Do you have that before you?
5 A I do.
6 Q Do you disagree with what you wrote in
7 paragraph 16?
8 A I do not disagree with what I wrote, and
9 what I said does not disagree with what I wrote. I
10 said what's important is that the clinical trial
11 information be transparent in order to facilitate
12 recruitment in order to make participants aware of
13 the studies.
14 Q So in your view, would you agree that
15 another aspect of registration is that it
16 facilitates recruitment by making potential
17 participants aware of studies for which they may be
18 eligible?
19 MS. JACK: Objection; asked and answered.
20 A I have answered this. As I stated in my
21 declaration, and I still agree, "Transparency of
22 clinical trial information is also necessary to

1 facilitate recruitment by making potential
2 participants aware of studies for which they may be
3 eligible."
4 Q So does clinical trial registration
5 facilitate recruitment by making potential
6 participants aware of studies for which they may be
7 eligible?
8 A It can serve that purpose, yes.
9 Q Here the study record is intended to
10 accomplish that task, right?
11 A Not exclusively.
12 Q I didn't ask exclusively, so let me try my
13 question again.
14 The study record here is intended to
15 accomplish that task, right?
16 MS. JACK: Objection; asked and answered.
17 A My response is the same, that is one
18 aspect of what it would be intended to accomplish.
19 Q Now, you provide a table in your
20 declaration titled Table 1, correct?
21 A Yes.
22 Q And Table 1 provides your analysis of the

1 June 10, 2013 posting to ClinicalTrials.gov, right?
2 A Yes.
3 Q And Table 1 spans 8 and a half pages of
4 your declaration from pages 16 to 24, right?
5 A Yes, that's correct.
6 Q And Table 1 contains 27 rows of
7 information posted on ClinicalTrials.gov on June 10,
8 2013, right?
9 A I'm happy to count the rows if you would
10 like me to confirm 27. They are not numbered.
11 Q You can take a minute to count them.
12 A Okay. Yes, 27 substantive rows.
13 Q And there are four columns included in
14 Table 1, right?
15 A Yes.
16 Q And those columns are titled Posted
17 Element, Information Posted, Legal Requirement and
18 NIH Description, right?
19 A Yes, that is correct.
20 Q Okay. So let's talk about some of the
21 information posted on ClinicalTrials.gov.
22 So the study record -- sorry. The posted

1 study record contains information on the study
2 sponsor. Is that correct?
3 A Yes.
4 Q And the posted study record provides a
5 brief summary of the clinical study written in
6 language for the lay public, right?
7 A Yes.
8 Q And the posted study -- let me ask that a
9 different way.
10 A member of the lay public could be a
11 potential patient, right?
12 MS. JACK: Objection; outside the scope.
13 A As stated, I do believe the purpose of
14 registration was intended to facilitate recruitment,
15 so, yes, it could be a potential patient.
16 Q And a member of the lay public could be an
17 oncologist with at least five years of experience,
18 right?
19 MS. JACK: I object to the form of the
20 question.
21 A I certainly can't comment on how many
22 years of experience an oncologist would need to have

1 to be considered a member of the lay public.
2 Q A member of the public could be an
3 oncologist with at least five years of experience,
4 right?
5 MS. JACK: I object to the form of the
6 question.
7 A A member of the lay public could be
8 anyone.
9 Q Do you agree that a member of the lay
10 public could be an oncologist?
11 MS. JACK: Objection; outside the scope.
12 Q Right?
13 A Anyone could be considered. It could be
14 an oncologist, it could be a lawyer, it could be a
15 cardiologist, it could be an electrician.
16 Q And the posted study record contains
17 information on the study collaborator, right?
18 A It does.
19 Q The posted study record contains
20 information on the collaborator, but you don't
21 include the collaborator in Table 1 in your
22 declaration, right?

1 A You're right, it's not present.
2 Q Did you purposely choose not to include
3 the collaborator in Table 1 in your declaration?
4 A I do not recall purposely making that
5 choice, no.
6 Q Your heading included on page 18 of the
7 table refers to collaborators, right?
8 A It does.
9 Q But you did not include the collaborator
10 here in Table 1, right?
11 A It is not here, that's correct.
12 Q Based on your analysis, the study record
13 here has the title of the study written in language
14 for the lay public, right?
15 A Yes.
16 Q And the title should include information
17 on the condition being evaluated, right?
18 MS. JACK: I object to the form of the
19 question.
20 A I believe that that is included in the
21 definition of title. I mean, I see the description,
22 "A short title is a clinical study written in

1 language intended for the lay public. It should
2 include, where possible, information on the
3 participant's condition being evaluated and
4 interventions studied."
5 Q And here the posted study record included
6 the condition being evaluated in the title, correct?
7 MS. JACK: Objection; outside the scope.
8 A I cannot comment. It says "where
9 possible," the description says "where possible."
10 Q Let's take a look at that particular
11 element. So we're looking at page 16 of Table 1 and
12 we're looking at your declaration and your analysis
13 in Table 1, right?
14 A Table 1 is not analysis, right. Table 1
15 is what was posted, the header under which it was
16 posted, the corresponding statutory requirement, and
17 then NIH description of that section.
18 Q But Table 1 is your analysis of the study
19 record?
20 A Yes, it was my read of the study record.
21 Q And you include the column Information
22 Posted, right?

1 A Yes.
2 Q And the information posted came from your
3 analysis, correct?
4 MS. JACK: I object to the form of the
5 question.
6 A The information posted does not reflect
7 analysis the way that I would think of analysis.
8 The information posted comes directly from what was
9 on the ClinicalTrials.gov website for that category.
10 Q The information posted -- let me ask that
11 a different way.
12 What you include in the column under
13 Information Posted came from you, correct?
14 MS. JACK: I object to the form of the
15 question.
16 A I put it in this table, I took it from the
17 ClinicalTrials.gov registration public posting.
18 Q And so Table 1 reflects your analysis of
19 the posted element and the information posted,
20 correct?
21 MS. JACK: Objection; vague.
22 A I don't think that I would agree with that

1 assessment. It is the header and what was posted,
2 the statutory requirement for posting that
3 information, and NIH's description as presented in
4 the exhibit that we talked about earlier today. I
5 did not create -- I did not independently create
6 this language. I took it from the posting and I put
7 it here.
8 Q Let me ask a different question.
9 Table 1 reflects your read of the posted
10 study record and how that matches up with your view
11 of the legal requirements, right?
12 MS. JACK: Objection; asked and answered.
13 A It matches up with the legal requirements,
14 yes.
15 Q And it reflects your view on how the
16 posted information matches up with the legal
17 requirements, right?
18 MS. JACK: Object to the form of the
19 question.
20 A Yes, I looked at the list of required
21 elements in the statute and those are aligned with
22 the information in the chart.

1 Q Based upon your review, the posted study
2 record provides a statement about the conditions to
3 be treated and specifically mentions MSI positive
4 colorectal cancer, right?
5 MS. JACK: I object to the form of the
6 question.
7 A Conditions to be treated, it includes MSI
8 positive colorectal cancer, MSI negative colorectal
9 cancer, and MSI positive non-colorectal cancers.
10 Q Let me try my question again.
11 Based upon your review, the posted study
12 record provides a statement about the conditions to
13 be treated and specifically mentions MSI positive
14 colorectal cancer, right?
15 MS. JACK: Objection; asked and answered.
16 A It states under conditions MSI positive
17 colorectal cancer, MSI negative colorectal cancer,
18 and MSI positive non-colorectal cancers, those are
19 what are provided under conditions in the
20 registration for the study.
21 Q I'm not asking for everything listed under
22 conditions for the study.

1 I'm asking, based upon your review,
2 whether the study records provides a statement about
3 the conditions to be treated and specifically
4 mentions MSI positive colorectal cancer?
5 A I disagree that it provides a statement
6 about the conditions to be treated. It does not
7 provide a statement. It lists three conditions in
8 the conditions box, one of which is MSI positive
9 colorectal cancer.
10 Q Does it provide information posted about
11 the conditions to be treated?
12 MS. JACK: Objection; vague.
13 A All I can attest to is what the
14 registration itself states. It's looking at three
15 different patient populations, including patients
16 with MSI positive colon cancer, patients with MSI
17 negative colon cancer, and patients with other MSI
18 positive cancers, that is what it states.
19 Q So you agree that part of the information
20 posted about the conditions to be treated is MSI
21 positive colorectal cancer, correct?
22 MS. JACK: Objection; asked and answered.

1 A I have answered with respect to what it
2 states in the brief summary and the conditions. It
3 says that it is looking at three patient
4 populations; patients with MSI positive colon
5 cancer, patients with negative MSI colon cancer, and
6 patients with other MSI positive cancers. I can
7 only comment on the information that is in the
8 registration itself.
9 Q Right, and I am not asking for you to
10 provide the information that it states.
11 I'm asking does it provide -- does the
12 information posted about the conditions to be
13 treated provide MSI positive colorectal cancer?
14 MS. JACK: Objection; asked and answered.
15 A The registration --
16 Q I'm asking --
17 A -- that one condition is MSI positive
18 colorectal cancer.
19 Q And just to be clear, one of the
20 conditions to be treated is MSI positive colorectal
21 cancer, right?
22 MS. JACK: Objection; asked and answered.

1 A I am looking for the language about to be
2 treated. The registration does not state that. The
3 registration states that it is looking at use of
4 this product in three different patient populations,
5 one of which is patients with MSI positive colon
6 cancer.
7 Q You used the phrase "conditions to be
8 treated" in Table 1, right?
9 A I believe that is the statutory language,
10 but that is not what it says on the registration
11 page. It says conditions, MSI positive colorectal
12 cancer, and two others.
13 Q I'm not asking about what it states on the
14 study record. I am asking about your table, and you
15 state that one of the conditions to be treated is
16 MSI positive colorectal cancer. Is that right?
17 A That is what the table states, yes.
18 Q And that was provided by you, correct?
19 Let me rephrase my question.
20 It states that in the table that you
21 created, right?
22 A Yes.

1 Q Based upon your review, the posted study
2 record provides that the primary purpose of the
3 study is treatment, right?
4 MS. JACK: Objection; mischaracterizes the
5 document.
6 A Yes, that is what the table says, the
7 ClinicalTrials.gov registration says primary purpose
8 treatment.
9 Q And the posted study record identifies the
10 drug that will be given to patients, right?
11 A It does in the assigned interventions.
12 Q And so the posted study record indicates
13 the main objective of this intervention is
14 treatment, right?
15 MS. JACK: Objection; mischaracterizes the
16 document.
17 A It doesn't say objective. It says primary
18 purpose. The NIH description says main objective.
19 The posted element is primary purpose. I would have
20 to refer back to 42 USC 282 to see if they use the
21 word "purpose" or "objective."
22 Q Are you saying that the posted study

1 record does not include the main objective of the
2 intervention being evaluated by the clinical trial?
3 MS. JACK: Objection; misstates testimony.
4 A I am stating that the word in the posting
5 is "purpose," that's ClinicalTrials.gov's word.
6 Q But you indicate in Table 1 that primary
7 purpose is the main objective of the intervention
8 (s) being evaluated by the clinical trial, right?
9 A That is the language in the NIH
10 description on the web page, yes.
11 Q That is language that you've included here
12 to describe the posted element primary purpose,
13 right?
14 MS. JACK: I object to the form of the
15 question.
16 A It is NIH's language that I took and
17 included here, yes.
18 Q And does the posted study record, in your
19 opinion, identify the main objective of the
20 intervention being evaluated by the clinical trial?
21 MS. JACK: Objection; outside the scope.
22 A I can only comment on the study element,

1 which are pre-specified by the ClinicalTrials.gov
2 registry, it says primary purpose treatment. The
3 fact that NIH uses the word "objective" I cannot
4 comment on. The study registration identifies the
5 primary purpose as treatment.
6 Q But you provided the NIH description to
7 describe the posted element primary purpose in your
8 table, correct?
9 MS. JACK: I object to the form of the
10 question.
11 A I used the descriptions to provide
12 additional information about what was required in
13 the statute.
14 Q Okay. Let's -- let's take it from the top
15 of Table 1 in your declaration, and that's on page
16 16. Does the posted study record contain any unique
17 identifier assigned to the protocol by the sponsor?
18 A Yes. It includes J1365.
19 Q Does the posted study record include a
20 short title of the clinical study written in
21 language intended for the lay public?
22 A It includes a title that the responsible

1 party believed was intended for the lay public, yes.
2 Q And does the posted study record include
3 identifiers, if any, other than the organization's
4 unique protocol identification number or the NCT
5 number that is assigned to the clinical study?
6 A Yes.
7 Q And does the posted study record include
8 the nature of the investigation or investigational
9 use for which clinical study information is being
10 submitted?
11 A The information posted was interventional.
12 I believe that the ClinicalTrials.gov has certain
13 options you have to choose from. I do not believe
14 this is a free-form box.
15 Q So does the posted study record include
16 the nature of the investigation or investigational
17 use for which clinical study information is being
18 submitted?
19 A That is -- that is helpful to describe the
20 study type, which is listed as interventional.
21 Q And I'm not asking what is helpful. My
22 question is about this posted study record and

1 whether it includes the nature of the investigation
2 or investigational use for which clinical study
3 information is being submitted?
4 MS. JACK: Objection; asked and answered.
5 A And my response to all of these in the NIH
6 description is that these are intended to be helpful
7 aids to the responsible party. The study elements
8 align with the legal requirements. The study type
9 selected was interventional.
10 Q And I'm not asking what aligns. I am
11 asking if the posted study record includes the
12 nature of the investigation or investigational use
13 for which clinical study information is being
14 submitted?
15 MS. JACK: Objection; asked and answered.
16 A The legal requirement is study type, that
17 is what is provided.
18 Q Let me try my question one more time.
19 Did the posted study record include the
20 nature of the investigation or investigational use
21 for which clinical study information is being
22 submitted? If you don't know, can you please say

1 that?
2 MS. JACK: Objection; asked and answered.
3 A I am not saying that I don't know. What I
4 am saying is that the NIH description is
5 supplemental helpful information. The question is
6 does the information posted describe a study type;
7 it does.
8 Q No, my question was a little different.
9 My question was does the posted study
10 record include the nature of the investigation or
11 investigational use for which clinical study
12 information is being submitted?
13 MS. JACK: Objection; asked and answered
14 four times, I think.
15 A I have given my answer. It states
16 interventional as the study type.
17 Q But that's not my question. My question
18 is whether the posted study record includes the
19 nature of the investigation or investigational use
20 for which clinical study information is being
21 submitted, yes or no?
22 MS. JACK: Objection; asked and answered.

1 A My answer is that more context is needed.
2 That is NIH's descriptor to help a responsible party
3 choose the appropriate study type. The legal
4 requirement is study type.
5 Q Does the posted study record include the
6 recruitment status for the clinical study as a whole
7 based upon the status of the individual sites?
8 MS. JACK: Objection; outside the scope.
9 A For recruitment status it said not yet
10 recruiting, which is very common for an initial
11 posting.
12 Q Does the posted study record include the
13 recruitment status for the clinical study as a whole
14 based upon the status of the individual sites?
15 MS. JACK: Objection; asked and answered.
16 A Based upon the posting, the recruitment
17 status was not yet recruiting.
18 Q So does the posted study record include
19 the recruitment status for the clinical study as a
20 whole based upon the status of the individual sites?
21 MS. JACK: Objection; asked and answered.
22 A The recruitment status says not yet

1 recruiting. That would mean no sites were yet
2 recruiting the study was not recruiting
3 participants.
4 Q Does the posted study record include the
5 estimated date on which the clinical study will be
6 open for recruitment of participants or the actual
7 date on which the first participant was enrolled?
8 A It provided a date of July 2013 as the
9 study start date.
10 Q Does the posted study record include the
11 date that the final participant was examined or
12 received an intervention for the purposes of final
13 collection of data for the primary outcome, whether
14 the clinical study concluded according to the
15 pre-specified protocol or was terminated?
16 A There is an estimated date for when they
17 anticipated completion.
18 Q Does the posted study record include a
19 short description of the clinical study including a
20 brief statement of the clinical study's hypothesis
21 written in language intended for the lay public?
22 A It includes a brief -- a short description

1 of the study, yes. I cannot opine on how the
2 responsible party assessed whether it was written in
3 language intended for the lay public.
4 Q And does the posted study record include
5 the names of the diseases or conditions studied in
6 the clinical study or the focus of the clinical
7 study?
8 A For the conditions it states three, yes;
9 MSI positive colorectal cancer, MSI negative colorectal
10 cancer, and MSI positive non-colorectal cancers.
11 Q Let me try my question again.
12 Does the posted study record include the
13 names of the diseases or conditions studied in the
14 clinical study or the focus of the clinical study?
15 MS. JACK: Objection; asked and answered.
16 A In the conditions section of the
17 registration it does include the name of the
18 conditions that will be studied in this clinical
19 trial.
20 Q Does the posted study record include the
21 main objective of the intervention being evaluated
22 by the clinical trial?

1 A As previously stated, the record states
2 interventional study design for which NIH has
3 interpreted to mean main objective.
4 Q Does the posted study record include --
5 let me rephrase my question.
6 You also include the description the main
7 objective of the intervention being evaluated by the
8 clinical trial for the primary purpose, correct?
9 MS. JACK: I object to the form of the
10 question.
11 A So, again, to be clear, I did not create
12 that language. That is how NIH defines those two
13 buckets.
14 Q In your view, is the posted element study
15 design primary purpose -- let me rephrase that.
16 In your view, are the posted elements
17 study design and primary purpose the same?
18 MS. JACK: I object to the form of the
19 question.
20 A It is outside the scope of what I was
21 asked to opine on.
22 Q You provided these elements in your table,

1 correct?
2 A Correct.
3 Q And you put in Table 1 the posted element
4 study design, right?
5 A That is from the registration page, yes.
6 I did not make that term up.
7 Q But you put that as a posted element in
8 your table, right?
9 A Yes.
10 Q Do you know what study design means?
11 MS. JACK: Objection; outside the scope.
12 A I do know what study design means. It can
13 mean a lot of different things. That is outside the
14 scope of what I was asked to write this report on I
15 was not asked to opine on what study design means.
16 Q But do you know what the posted element
17 study design means?
18 A Yes.
19 Q And so what does it mean as it applies to
20 the posted study record here?
21 A That the study design here was an
22 interventional study.

1 Q And you included -- let me rephrase that.
2 What does study design mean?
3 MS. JACK: Objection; outside the scope.
4 A NIH has provided its interpretation.
5 Q And you provided the posted element study
6 design in your table, correct?
7 A Yes.
8 Q And you're the one that put study -- the
9 posted element of study design in this table,
10 correct?
11 MS. JACK: Objection; asked and answered.
12 A I took the information from the posting
13 and I put it here. One of the elements was study
14 design that is also legally required by the statute
15 so I put that here. Study design for
16 ClinicalTrials.gov can be interventional or
17 observational. I'm not aware if there are other
18 options.
19 MS. JACK: Counsel, we have been going a
20 little over an hour here, I think, and our lunch is
21 here. Is it okay if we take a break to eat?
22 Q Ms. Newberger, would you like to break?

1 A I would like to break, but I would rather
2 -- I mean, if there's more questions on that one
3 particular row, let's finish that and then break.
4 Q All right. Do you know what the posted
5 element study design means?
6 A I have the information from NIH as noted,
7 which is here the way that it is interpreted as
8 interventional or observational study design seems
9 to be getting at is an experimental intervention
10 being used in the study. In this case there is an
11 investigational drug that was being used, so it's an
12 interventional study.
13 Q And what was the investigational drug?
14 MS. JACK: Objection; outside the scope.
15 A It's what's named in the title of the
16 study MK -- let's see. MK-3475.
17 Q And you understand that was the drug being
18 used in the study, correct?
19 A Correct. It is provided as an
20 intervention on the next page.
21 MS. STAURING: Okay. We can go off the
22 record and break for lunch.

1 (Recess 4:11 p.m. - 5:00 p.m.)
2 BY MS. STAURING:
3 Q Ms. Newberger, did you speak with anyone
4 during the break about your deposition today?
5 A No, I did not.
6 Q The posted study records here -- let me
7 rephrase that.
8 Did the posted study record include the
9 numerical phase of the clinical trial consistent
10 with terminology in 21 CFR 312.21 and in 21 CFR
11 312.85 for phase 4 studies?
12 MS. JACK: Objection; lack of foundation.
13 A Can you clarify the question, please?
14 Q Sure. And we're looking at page 19 of
15 your declaration where we left off.
16 A Okay.
17 Q And my question is did the posted study
18 record here include the numerical phase -- let me
19 ask a different question.
20 Did the posted study record here include
21 the numerical phase of the clinical trial?
22 A Yes, it did.

1 Q And did the posted study record include
2 the strategy for assigning interventions to
3 participants?
4 A Yes, it did.
5 Q And did the posted study record include
6 the number of arms in the clinical trial?
7 A Yes, it did.
8 Q Did the posted study record include
9 whether the party or parties involved in the
10 clinical trial who are prevented from having
11 knowledge of the intervention assigned to individual
12 participants?
13 A Yes, it did.
14 Q And did the posted study record the method
15 by which participants are assigned to arms in a
16 clinical trial?
17 A Yes, it did.
18 Q Did the posted study record include the
19 estimated total number of participants to be
20 enrolled or the actual total number of participants
21 that are enrolled in the clinical study?
22 MS. JACK: Objection; vague.

1 A Yes, it provided an estimated number.
2 Q Did the posted study record include a
3 description of each arm of the clinical trial that
4 indicates its role in the clinical trial provides --
5 you can answer.
6 (Simultaneous speaking.)
7 Q Let me repeat my question. The posted
8 study record includes a description of each arm of
9 the clinical trial that indicates its role in the
10 clinical trial, right?
11 A Yes, it does include each arm of the
12 clinical trial, and it indicates that each arm is an
13 experimental arm.
14 Q And does the posted study record specify
15 the interventions associated with each arm?
16 A Yes, it does.
17 Q Does the posted study record include a
18 description of each primary outcome measure?
19 A Yes, it does.
20 Q Does the posted study record include a
21 description of each secondary outcome measure?
22 A Yes, it does.

1 Q Does the posted study record include a
2 limited list of criteria for selection of
3 participants in the clinical study provided in terms
4 of inclusion and exclusion criteria?
5 A It does provide a list of inclusion and
6 exclusion criteria.
7 Q And does the posted study record -- let me
8 change my question.
9 Going back to page 16 at the top -- at the
10 start of your Table 1, can you please let me know
11 when you're there.
12 A Yes.
13 Q The posted study record -- let me rephrase
14 that.
15 A brief title of the study was included in
16 the posted study record, correct?
17 A Yes, that is correct.
18 Q Let's turn back to page 24 momentarily.
19 The posted study record includes for each facility
20 participating in a clinical study the name or title,
21 telephone number and email address of a person to
22 whom questions concerning the study and enrollment

1 at that site can be addressed, correct?
2 A Yes, that is correct.
3 Q Now turning back to page 16 of your
4 declaration, posted element -- the posted study
5 record included a brief title of the study, correct?
6 A Yes, it did.
7 Q And the posted study record included a
8 brief summary of the study, correct?
9 MS. JACK: Objection; asked and answered.
10 A Yes, there's a brief summary.
11 Q Did the posted study record identify the
12 conditions to be treated?
13 MS. JACK: Objection; asked and answered.
14 A As I previously stated, the registration
15 stated that the conditions are MSI positive
16 colorectal cancer, MSI negative colorectal cancer,
17 and MSI positive non-colorectal cancer.
18 Q Let me try again.
19 Does the posted study record identify the
20 conditions to be treated?
21 MS. JACK: Objection; asked and answered.
22 A The posted study record contains the

1 conditions, yes.
2 Q And the posted study record -- does the
3 posted study record include the study design?
4 MS. JACK: Objection; asked and answered.
5 A Yes, it does.
6 Q Does the posted study record include the
7 primary purpose?
8 A As I -- as I previously stated, the
9 primary purpose is included in the posted study
10 record.
11 Q And does the posted study record include
12 the interventional study model?
13 A As I previously stated, yes, it does.
14 Q And does the posted study record include
15 arm information?
16 MS. JACK: Objection; vague.
17 A As I previously stated, yes.
18 Q And does the posted study record include
19 interventions?
20 MS. JACK: Objection; asked and answered.
21 A As I previously stated, yes.
22 Q Does the posted study record include

1 primary outcome measure information?
2 MS. JACK: Objection; asked and answered.
3 A As I previously stated, the information
4 was provided for primary outcome measure
5 information.
6 Q Does the posted study record include the
7 secondary outcome measures?
8 MS. JACK: Objection; asked and answered.
9 A Yes, it does.
10 Q Does the posted study record include
11 eligibility criteria?
12 MS. JACK: Objection; asked and answered.
13 A Yes. Yes, it does.
14 Q And does the posted study record provide
15 eligibility criteria in terms of inclusion and
16 exclusion criteria?
17 MS. JACK: Objection; asked and answered.
18 A Yes, as required, it does provide
19 inclusion and exclusion criteria.
20 Q And does the posted study record include
21 10 inclusion criteria?
22 A Yes, it does.

1 Q And does the posted study record include
2 seven exclusion criteria?
3 MS. JACK: Objection; vague.
4 A Yes, it does.
5 Q Does the posted study record include the
6 drug to be given to patients in the study?
7 A Yes, in response to interventions, it
8 provides the drug.
9 Q And does the posted study record indicate
10 giving the drug at a dose of 10 milligrams per
11 kilogram every 14 days?
12 A Yes, it does.
13 Q Ms. Newberger, in your view, the
14 information that is required to be submitted to
15 ClinicalTrials.gov is set forth by statute, right?
16 MS. JACK: Objection; vague.
17 A I would say it is not my view. The
18 statute does set forth the information to be
19 provided.
20 Q In your view, the failure to submit
21 required information to ClinicalTrials.gov results
22 in civil money penalties. Is that right?

1 MS. JACK: Objection; vague.
2 A I would again answer it's not my view.
3 It's what the statutory language says.
4 Q And the statute that you're referring to,
5 is that 21 USC 333(f)(3)(A)?
6 A Yes.
7 Q And did you review that statute?
8 A Yes, I did.
9 Q Are you familiar with that statute?
10 MS. JACK: Objection; vague.
11 A I am familiar with it with the caveat I've
12 given always that I don't necessarily recall every
13 single word within it.
14 Q Section of the statute 21 USC 333(f)(3)(A)
15 is what you cite in your declaration, correct?
16 A That is correct.
17 Q That section of the statute provides for
18 violations related to devices, right?
19 A That is the header. That is not actually
20 what each of the provisions that follow pertain to.
21 Q But that portion of the statute states
22 that it provides for violations related to devices,

1 correct?
2 MS. JACK: Objection; asked and answered.
3 A The header states that. When the statute
4 was updated, however, provisions that fall under
5 that very clearly relate to products that go well
6 beyond devices. So it's inappropriate to rely
7 solely on the header when the provisions apply more
8 broadly.
9 Q When you say devices, that's medical
10 devices, correct?
11 A Correct.
12 Q When was the statute updated?
13 A I would have to confirm. My recollection
14 is that it was updated when FDAAA went into effect.
15 So if I recall correctly, that would have been
16 September 2007, but I would have to confirm.
17 Q The exhibit that you cite in your
18 declaration states that that section of the statute
19 relates to violations related to devices, right?
20 MS. JACK: Objection; asked and answered.
21 A As I previously stated, there is an
22 inconsistency between the header of the section and

1 the actual provisions of that section. If I recall,
2 there are some provisions in that section that
3 specifically apply to foods which are clearly not
4 medical devices. This provision applies to any
5 person who fails to submit the required information.
6 The header does not accurately reflect the content
7 of the subparts.
8 Q Have you ever pointed out the supposed
9 inconsistency to anyone at the FDA?
10 MS. JACK: Objection; vague.
11 A It is outside the scope to report an
12 inconsistent statutory issue, which actually would
13 not be an FDA issue; it would be a congressional
14 issue.
15 Q Let me ask my question again.
16 Have you ever pointed out the supposed
17 inconsistency to anyone at the FDA?
18 MS. JACK: Objection; asked and answered.
19 A First, it's not a supposed inconsistency.
20 It is an actual inconsistency. Second, as I stated,
21 this is a congressional issue, not an FDA issue.
22 Q Let me ask the question again.

1 Have you ever pointed out the supposed
2 inconsistency to anyone at the FDA?
3 A As I have previously stated, it is an
4 actual, not supposed. And it is not an FDA
5 inconsistency; it is a congressional statutory
6 inconsistency.
7 Q Let me try my question a different way.
8 Have you ever pointed out what you say is
9 an actual inconsistency to anyone at the FDA?
10 MS. JACK: Objection; asked and answered.
11 A I have nothing further to add to my prior
12 response. It is a congressional inconsistency.
13 Congress wrote the statute.
14 Q Have you ever pointed out what you say is
15 an actual inconsistency to anyone in Congress?
16 MS. JACK: Objection; argumentative.
17 A I have never. Those of us who work in
18 this space understand that there are some times
19 these things that come up FDA enforces against this
20 provision with respect to drugs and devices. It is
21 not -- so there has never been a need to raise the
22 issue.

1 Q And I'm not asking your understanding.
2 I'm asking what you've done, and I'm not asking if
3 there is a need. I'm just asking what you have
4 done.
5 And so my question is whether you have
6 ever pointed out to anyone in Congress this actual
7 inconsistency, as you've stated it?
8 MS. JACK: Objection; asked and answered.
9 A And my response is as it was. Given that
10 it does not affect how FDA enforces this provision,
11 there is no need to raise the issue, and, therefore,
12 I did not raise the issue, and nobody I know who has
13 been working in this space for decades now has ever
14 raised the issue.
15 Q Have you ever pointed out what you say is
16 an actual inconsistency to anyone at ClinicalTrials.gov?
17 MS. JACK: Objection; vague.
18 A I have already answered the question. The
19 inconsistency causes no practical impact on
20 enforcement of the requirements or the penalties
21 imposed, so I would have no reason to raise it.
22 Q I don't think I have an answer to my

1 question. Have you ever pointed out what you say is
2 an actual inconsistency to anyone at ClinicalTrials.gov?
3 MS. JACK: Objection; asked and answered.
4 A I have provided an answer multiple times.
5 That answer is that there is no need to do so
6 because FDA understands what its enforcement
7 abilities are under the statute as written.
8 Therefore, because there was no need to raise it, it
9 would have no impact on the day-to-day, I have not
10 raised it.
11 Q Have you ever presented publicly on what
12 you say is an actual inconsistency with the statute?
13 MS. JACK: Objection; vague.
14 A I have never presented publicly on this.
15 Q Have you ever written any articles
16 about -- on what you say is an actual inconsistency
17 with the statute?
18 MS. JACK: Objection. We're pretty far
19 outside the scope here.
20 A To those of us who work in this space, we
21 understand what this provision means. There is no
22 need to write about it, to make a big deal about it

1 or otherwise talk about it. FDA enforces against it
2 for drugs and devices. We can read the language of
3 the statute. You can see clearly that that entire
4 section is misnamed, and there would never be any
5 reason for anyone to raise this to anything more
6 than that.
7 Q So does that mean you did not write about
8 this?
9 A I did not write about this. There would
10 have been no occasion or reason for me to write
11 about this.
12 Q And to be clear, write about this, what
13 you mean is what you say is an actual inconsistency,
14 right?
15 MS. JACK: Objection; misstates testimony.
16 A To write about the fact that the header
17 says devices when many of the subparts very clearly
18 and explicitly refer to other product types.
19 Q And so to be clear, you did not write
20 about what you say is an actual inconsistency,
21 right?
22 MS. JACK: Objection; asked and answered.

1 A I've answered this multiple times. It
2 does not rise to the significance. I would never
3 have written about this. It has no practical
4 impact.
5 Q Did you mention what you say is an actual
6 inconsistency in your declaration?
7 A I did not because the language of the
8 provision that I cited clearly states that it
9 applies to any person.
10 Q But do you agree that the exhibit that you
11 reference and cite in your declaration reflects that
12 provision falling under the header violations
13 related to devices?
14 MS. JACK: Objection; misstates the
15 document.
16 A The exhibit includes the statutory
17 provision. I certainly can't control the header.
18 It is what it is. But the provision itself is very
19 clear and the statement that I have in paragraph 41
20 is accurate.
21 Q In any event, the FDA did not have a
22 process for addressing noncompliance for failure to

1 submit required information to ClinicalTrials.gov
2 until implementing regulations issued in 2016,
3 right?
4 MS. JACK: Objection; lack of foundation.
5 A The statute certainly provided FDA the
6 ability to deem a product misbranded, to deem the
7 failure to register a violative act. That was in
8 the statute.
9 Q Let me try asking my question a little
10 differently. Did the FDA have a process prior to
11 2016 for assessing noncompliance for failure to
12 submit required information to ClinicalTrials.gov?
13 A I do not know what process FDA had in
14 place prior to 2016. They had the legal and
15 statutory authority to take action against companies
16 that failed to properly register with ClinicalTrials.gov.
17 Q So you do not know what process FDA had in
18 place prior to 2016?
19 A FDA does not always necessarily specify
20 this is how or against whom we intend to take
21 enforcement action. They had the legal authority to
22 do it. Whether they had an internal process I

1 cannot speak to.
2 Q To be clear, at the time the posted study
3 record -- at the time of the posted study record,
4 you don't know if there was or was not a process for
5 the FDA to assess noncompliance for failure to
6 submit required information to ClinicalTrials.gov.
7 Is that correct?
8 MS. JACK: Objection; asked and answered.
9 A That is not correct. They had the legal
10 authority to hold the manufacturer in violation of
11 the statute. That is all they need to take action.
12 They do not need any more.
13 Q And my question isn't about the legal
14 authority.
15 My question is whether at the time of the
16 posted clinical -- excuse me. Let me start over.
17 My question is whether at the time that
18 the study record was posted, did the -- you do not
19 know whether the FDA had a process for assessing
20 noncompliance for failure to submit required
21 information to ClinicalTrials.gov, correct?
22 MS. JACK: Objection; asked and answered.

1 A At the time of the 2013 submission, the
2 law was in place that required submission of these
3 elements to ClinicalTrials.gov, and the law was in
4 place that stated the failure to do so was
5 considered a violation of the FDCA. So a company
6 failing to comply with required posting would have
7 been doing so at risk given that the legal
8 enforcement ability was clearly set forth in the
9 statute.
10 Q And I'm not asking whether the law was in
11 place. Please understand that I'm asking something
12 different. And what I'm asking is whether at the
13 time the study record was posted, do you know
14 whether the FDA had a process for assessing
15 noncompliance for failure to submit required
16 information to ClinicalTrials.gov?
17 MS. JACK: Objection; asked and answered.
18 A I have answered this to the best of my
19 ability. FDA certainly had the ability, the
20 enforcement authority, the legal authority to do so.
21 Q Did the FDA have a process for issuing
22 notices of noncompliance to responsible parties

1 prior to 2016?
2 A I am not aware of a process prior to 2016
3 for that specific act.
4 Q So at the time the study record was
5 posted, the FDA did not have a process for issuing
6 notices of non-compliance to responsible parties,
7 correct?
8 A I am not aware of a public process. But
9 they don't need a public process when they have the
10 statutory authority to declare a product violative
11 by virtue of what the statute says. That's enough
12 for me to comfortably say that whether there was a
13 public process or not, FDA had authority to enforce
14 against this statute for failure to comply.
15 Q Okay. You would agree with me that prior
16 to 2016 the FDA historically had not enforced
17 ClinicalTrials.gov reporting requirements, right?
18 MS. JACK: Objection; lack of foundation,
19 outside the scope.
20 A This is outside the scope of what my
21 report addresses.
22 Q I disagree, and I would ask that you

1 please answer my question, which is whether you
2 would agree that prior to 2016, the FDA historically
3 had not enforced ClinicalTrials.gov reporting
4 requirements?
5 MS. JACK: Same objection.
6 A I have answered the question. They had
7 the legal authority to do so. Companies were
8 legally prohibited from failing to comply with the
9 registration.gov requirements.
10 I also am in no position to speak to what
11 FDA may have done privately. Not all of its
12 enforcement actions are public.
13 Q I don't think I got the answer to my
14 question, so let me try again.
15 My question is whether you would agree
16 that prior to 2016, the FDA had not -- historically
17 not enforced ClinicalTrials.gov reporting
18 requirements?
19 MS. JACK: Objection; outside the scope,
20 lack of foundation.
21 Q You can answer, Ms. Newberger.
22 A I have answered. I cannot speak to what

1 private enforcement may have been undertaken in the
2 years prior to issuance of the regulation.
3 Q Do you know whether at the time the study
4 record was posted, if the FDA had ever enforced
5 ClinicalTrials.gov reporting requirements?
6 MS. JACK: Objection; asked and answered.
7 A I do not know if FDA ever had. I
8 certainly can't answer that off the top of my head.
9 But that doesn't excuse the legal obligation of the
10 company to provide the information. FDA had the
11 legal authority to take enforcement action at the
12 time. I would certainly never advise a client to do
13 something illegal just because FDA may not enforce.
14 Q Do you understand that my question is not
15 about legal authority?
16 A You are asking about FDA enforcement,
17 which they can only do if they have the legal
18 authority to do so.
19 Q But my question is specifically whether
20 you know prior to 2016 whether the FDA historically
21 had not enforced the ClinicalTrials.gov reporting
22 requirements?

1 MS. JACK: Objection; asked and answered.
2 A I have answered multiple times. I do not
3 know what FDA may have done through private
4 enforcement actions prior to 2016.
5 Q And my question is not limited to private
6 enforcement actions.
7 A Your question was whether FDA had
8 historically enforced prior to 2016, and I am saying
9 I cannot answer that because I certainly do not have
10 visibility into every company that may have violated
11 the ClinicalTrials.gov provisions prior to that
12 date, and what, if any, action FDA took against
13 them.
14 Q Are you aware that one of the lawyers at
15 your law firm wrote an article about the
16 ClinicalTrials.gov reporting requirements and FDA's
17 enforcement of noncompliance with those reporting
18 requirements?
19 MS. JACK: Objection; outside the scope.
20 A I'm not surprised to hear that. I don't
21 recall every article that's been written by everyone
22 at my firm.

1 Q And my question was not if you recalled
2 every article written by everyone at your firm. I
3 asked whether you were aware that one of the lawyers
4 at your law firm wrote an article about the
5 ClinicalTrials.gov reporting requirements and FDA's
6 enforcement of noncompliance with those
7 requirements?
8 MS. JACK: Objection; vague and outside
9 the scope.
10 A I do not recall.
11 Q That article, the lawyer at your law firm
12 wrote that FDA historically had not enforced the
13 ClinicalTrials.gov reporting requirements due in
14 part to HHS's long delay in issuing implementing
15 regulations.
16 Maybe it would be helpful for these
17 questions if we took a look at that article. So
18 let's bring up Exhibit 1114 that I've premarked, and
19 this is a new exhibit. Please let me know when you
20 have Exhibit 1114 downloaded.
21 A I have it.
22 Q And this is an article from your law firm,

1 Hyman, Phelps & McNamara?
2 A Yes, that is correct.
3 Q And it published on May 4, 2021, right?
4 A Yes, that is correct.
5 Q And its authors are listed as McKenzie E.
6 Cato and Michelle L. Butler, right?
7 A Yes, that's correct.
8 Q And the date that this article published
9 is many years after the study record was posted to
10 ClinicalTrials.gov on June 10, 2013, right?
11 MS. JACK: Objection; vague.
12 A Yes.
13 Q And if you look at page 2 of this exhibit,
14 do you see where it states, quote, "FDA historically
15 had not enforced the ClinicalTrials.gov reporting
16 requirements"?
17 A I do see that. It does not state that FDA
18 had never enforced.
19 Q I didn't say that. My question was
20 whether you saw that the lawyers at your firm wrote,
21 quote, "FDA historically had not enforced the
22 ClinicalTrials.gov reporting requirements" in this

1 article that's dated May 4, 2021?
2 MS. JACK: Objection; asked and answered.
3 A I have answered I do see it, I am looking
4 at it, yes.
5 Q And do you disagree with this statement
6 from the lawyers at your law firm?
7 MS. JACK: Objection; outside the scope.
8 A This is a statement in a blog post. This
9 is not legal advice. This is the opinion of two
10 authors. And as I previously stated, even if this
11 is true that they had historically not enforced and
12 had not enforced publicly, I cannot say, nor could
13 McKenzie or Michelle say whether companies had been
14 enforced against privately.
15 Q That wasn't quite my question. My
16 question was whether you disagreed with the
17 statement from the lawyers at your law firm.
18 MS. JACK: Objection.
19 A I answered your question.
20 MS. JACK: Asked and answered.
21 A I said that while I do not disagree with
22 the statement, there is more context needed. This

1 is a line in a page and a half long blog post. It's
2 not legal advice. So I don't disagree with the
3 statement. But it also does not say that there was
4 no risk of enforcement before. It does not say that
5 no one had ever been enforced against, and it
6 certainly doesn't say that a company should not have
7 followed the law because maybe FDA wouldn't enforce.
8 Q And that wasn't quite my question. But I
9 have a different question.
10 When members of your firm write in blog
11 posts, is that not information to be believed?
12 MS. JACK: I object to the form of the
13 question.
14 A I didn't say that it is not to be
15 believed, but it has to be taken in context. I
16 clearly stated that I do not disagree with this, but
17 that is not the end of the inquiry.
18 Q When members of your law firm write in
19 blog posts, is that not -- is that information not
20 truthful?
21 MS. JACK: I object to the form of the
22 question.

1 A You are taking words that I did not say.
2 It is truthful, in the experience of the authors of
3 the post, it's truthful, it is accurate. But it
4 also has to be taken in context for what it is.
5 Q I would like to look at another statement
6 in this article that's on page 1. We're looking at
7 Exhibit 1114, which is the article from lawyers at
8 your law firm, and the statement reads, "On April 28
9 FDA issued its first notice of noncompliance for
10 failure to submit required clinical trial results
11 information to ClinicalTrials.gov," end quote.
12 Do you see that?
13 A This is on page 1?
14 Q Yes. We're looking at the first sentence --
15 A Oh, yes, first sentence. Yes, I do see
16 it.
17 Q And on page 2 of the document, in the
18 fourth paragraph down, do you see where the lawyers
19 at your firm state: The April 28th notice of
20 noncompliance is noteworthy because it is the first
21 ever issued by the agency?
22 A Yes.

1 Q Do you disagree?
2 A I do not disagree that it was the first
3 notice of noncompliance. That is different from
4 asking whether that is the first time FDA ever took
5 enforcement action against a company. That's the
6 distinction that I am making. Those are two
7 different things.
8 Q And do you believe -- let me try a
9 different question.
10 I'm not making distinctions and I'm not
11 sure why you are. My question was focused on
12 whether FDA historically had not enforced the
13 ClinicalTrials.gov reporting requirements. And the
14 lawyers at your firm write that the April 28th, 2021
15 notice of noncompliance is noteworthy because it is
16 the first ever issued by the agency.
17 My question is whether what the lawyers
18 wrote is to be believed.
19 MS. JACK: Objection; asked and answered.
20 A I have answered this many times. It is to
21 be believed. It is accurate. Just because there
22 was no notice of noncompliance available before this

1 does not mean that FDA never enforced, and it
2 certainly doesn't say anywhere here that FDA
3 couldn't have enforced. There was a legal
4 requirement in 2013 to comply with the requirements
5 of ClinicalTrials.gov. The statute also provided
6 the ability to FDA to take enforcement action
7 against companies who failed to comply. That is all
8 I was asked to opine on. That is what my report
9 reflects.
10 Q What the members of your law firm wrote
11 was truthful, right?
12 MS. JACK: Objection; asked and answered.
13 A I cannot answer it any other way than I
14 already have. It is truthful. But the distinction
15 that you stated you are not making is critically
16 important and so I will continue to make it. What
17 they wrote is truthful. At the time of the posting
18 FDA had the legal authority to enforce.
19 Q But my question is not whether the FDA had
20 the legal authority to enforce. My question is
21 whether what the lawyers at your law firm wrote that
22 FDA historically had not enforced the

1 ClinicalTrials.gov reporting requirements is to be
2 believed?
3 MS. JACK: Objection; asked and answered.
4 A I have answered this. I cannot say it
5 again. It is to be believed. It is not the
6 complete story. And it says historically, which is
7 an important word. That doesn't mean ever. What
8 they wrote is accurate. It is to be believed. That
9 has nothing to do, however, with what the legal
10 requirements were in 2013, which was what I was
11 asked to write a report on, and whether there were
12 penalties that could have been issued had they
13 failed to do so. The answer is yes, there were
14 legal obligations, and yes, there were potential
15 penalties that FDA could have imposed had they
16 failed to do so at the time of the submission.
17 Q And what the members of your law firm
18 wrote is truthful, correct?
19 MS. JACK: Objection; asked and answered
20 at least three times.
21 A I refer back to what I just finished
22 saying about that.

1 Q Can you please answer my question? My
2 question is whether what the members of your law
3 firm wrote in Exhibit 1114 is truthful?
4 MS. JACK: Objection; asked and answered.
5 This is becoming harassing.
6 A I clearly stated that it is truthful, so I
7 did answer your question. But that answer needs
8 additional context. I was asked to write about were
9 these obligations applicable at the time and were
10 there penalties should they fail to comply, the
11 answer is yes, that can be true. It can also be
12 true that this statement by my colleagues is also
13 true.
14 Q And these statements are to be believed,
15 right?
16 MS. JACK: Objection. This has been asked
17 and answered several times now.
18 A I have said that it is to be believed. I
19 have said that it is to be truthful. I have said
20 that that is not the entirety of the story.
21 Q Ms. Newberger, I think your audio might be
22 getting a little loud, it might be a setting.

1 A Nobody wants to hear me louder than I
2 actually am. Let me see if I can fix that. Oh,
3 yeah, that did get very loud. Is that better? Is
4 that better? No, that's my speakers. Yes, it's
5 better?
6 Q That sounds better, I think so. Let's --
7 A Sorry, I didn't change anything. But,
8 yeah, let me know if that gets -- if that gets too
9 loud.
10 Q Do you know if the FDA has ever subjected
11 a responsible party to civil money penalties?
12 MS. JACK: Objection; asked and answered.
13 A I do not know off the top of my head.
14 Q Do you agree that at the time of the study
15 record submission, JHU would have been aware that
16 the FDA had never enforced reporting requirements --
17 enforced noncompliance with reporting requirements
18 to ClinicalTrials.gov?
19 MS. JACK: Objection; assumes facts not in
20 evidence.
21 A I have no idea what JHU knew or did not
22 know at the time of the submission.

1 Q But you would agree that at the time of
2 the study record submission, FDA had not enforced
3 reporting requirements with respect to ClinicalTrials.gov,
4 right?
5 MS. JACK: Objection; asked and answered
6 many times.
7 A I do not agree with that statement. I do
8 not know for a fact that FDA never took action.
9 That was not made public. I can't answer that.
10 Q Would you agree that at the time of the
11 study record submission, the public would have been
12 aware that FDA had not enforced the ClinicalTrials.gov
13 reporting requirements?
14 MS. JACK: Objection; calls for
15 speculation.
16 A I can't speculate as to what the public
17 generally would or would not have known.
18 Q Were you aware at the time of the study
19 records submission in June of 2013 that the FDA had
20 not -- let me ask my question again.
21 Would you have been aware at the time of
22 the study record submission in June of 2013 if the

1 FDA had enforced ClinicalTrials.gov reporting
2 requirements?
3 MS. JACK: I object to the form of the
4 question.
5 A I would not necessarily have known if FDA
6 had enforced these provisions.
7 Q Would you agree that as of 2020, you were
8 not aware of a single instance where the FDA
9 enforced ClinicalTrials.gov reporting requirements?
10 MS. JACK: Objection; lack of foundation.
11 A I cannot agree. I do not -- I do not
12 know. And, again, this is outside the scope of my
13 report.
14 Q Would you agree that as of 2020, there was
15 not a single instance where the FDA had issued a
16 noncompliance letter with respect to the reporting
17 requirements of ClinicalTrials.gov?
18 MS. JACK: Objection; lack of foundation.
19 A I would agree that that specific action
20 had not been taken prior to that date in 2020.
21 There are certainly other enforcement actions
22 readily available to the agency.

1 Q Would you agree that the public would have
2 also not been aware of a single instance before 2020
3 where the FDA had issued noncompliance with respect
4 to ClinicalTrials.gov reporting requirements?
5 MS. JACK: Objection; calls for
6 speculation.
7 A As I previously stated, I cannot comment
8 on what the public writ large may or may not have
9 known.
10 Q Are you aware that the FDA -- let me ask
11 that a different way.
12 Are you aware that the FDA maintains a
13 list of any notices of noncompliance?
14 A Yes, I am aware of that.
15 Q And are you aware that there is not a
16 single instance of a notice of noncompliance being
17 issued before 2021?
18 MS. JACK: Objection; vague.
19 A As I have stated multiple times, I agree
20 with you that there were no notices of noncompliance
21 prior to the issuance of the letter referred to in
22 this blog post.

1 It did not -- that does not mean that
2 there was no enforcement action, and that does not
3 mean that there was not a legal requirement to
4 comply with ClinicalTrials.gov registration. That
5 is what I was asked to opine on, were these legal
6 obligations in place at the time; yes. Did FDA have
7 the legal authority to enforce against violators at
8 the time; yes.
9 Q To be clear, when you refer to the blog
10 post, that's the article by the members of your law
11 firm, correct?
12 A Yes.
13 Q And the list that FDA maintains for any
14 notices of noncompliance, where is that posted?
15 MS. JACK: Objection; vague.
16 A It is on FDA's website. I don't recall
17 more specifically than that.
18 Q And do you know when that list was
19 created?
20 A I do not know off the top of my head, no.
21 Again, this is beyond what I -- what my report is
22 about. This is beyond what I was asked to do, so I

1 would need to do independent research to be able to
2 get you that information.
3 Q Do you know if the list was created prior
4 to 2016?
5 MS. JACK: Objection; asked and answered.
6 A My recollection is that it did not exist
7 prior to 2016. But as I have stated multiple times,
8 the existence of the list with the notices of
9 noncompliance is distinct from any independent
10 enforcement that the agency had prior to creation of
11 that list.
12 Q Don't you state in your CV, that is in
13 Appendix A of your declaration, that you provide
14 guidance on clinical study design, protocol
15 development, statistical plans and
16 ClinicalTrials.gov registration requirements?
17 A Yes, I do.
18 Q And it's your view that it's beyond the
19 scope for me to ask you questions about that
20 experience?
21 MS. JACK: Objection; argumentative.
22 A You are not asking me about my experience

1 advising on ClinicalTrials.gov requirements. You
2 are asking me if I remember something that may or
3 may not have happened prior to a certain date with
4 respect to enforcement. Those are not the same
5 thing.
6 Q In your declaration don't you talk about
7 criminal penalties for failing to submit required
8 information to ClinicalTrials.gov?
9 A I provide the statutory language where
10 that authority is given to the agency.
11 Q And don't you state that had JHU failed to
12 include information, it would have been subjecting
13 itself to civil money penalties?
14 A That is correct.
15 Q And so in your declaration you talk about
16 penalties for failing to submit required information
17 to ClinicalTrials.gov, right?
18 A Yes. I specify the penalties that are
19 available, yes.
20 Q And are you aware of any such penalties
21 ever being -- are you aware of any such penalties
22 ever happening at the time the study record was

1 posted?
2 MS. JACK: Objection; asked and answered.
3 A I do not know whether there were any
4 penalties that had been enforced. But, again, when
5 I give legal advice, I don't give it based upon
6 likelihood of getting caught. FDA had the authority
7 to impose civil penalties on a noncompliant entity.
8 Therefore, any advice I would have given about
9 registration on ClinicalTrials.gov, even prior to
10 2016 and 2020, would have said you are legally
11 obligated to comply; FDA can take enforcement action
12 against you.
13 Q But I'm not asking about your legal
14 advice. I'm asking if you are aware of any such
15 penalties ever happening at the time the study
16 record was posted.
17 MS. JACK: Objection; asked and answered.
18 A I did not -- was not asked to include that
19 in my report, so it is not here. I certainly do not
20 remember everything that I did or did not know in
21 2013. I do not know.
22 Q Sitting here today, are you aware of any

1 such penalties happening at any point in time?
2 MS. JACK: Objection; vague.
3 A As I have stated many times, I do not have
4 knowledge about every company's interactions with
5 the agency. So I cannot state whether FDA has ever
6 imposed these penalties. This is outside the scope
7 of what I wrote about in the report. I can do
8 additional research to answer the question if you
9 would like.
10 Q Let me try a different question because I
11 don't think you've answered the question.
12 Are you aware of any such penalties being
13 issued at any point in time?
14 MS. JACK: Objection; asked and answered.
15 A This is not in the scope of my report. I
16 would have to do additional research.
17 Q So that sitting here today, are you aware
18 of any criminal penalties ever happening at any
19 point in time?
20 MS. JACK: Objection; very vague.
21 A I am aware of at least one lawsuit that
22 was brought, but I do not recall the details because

1 I was not asked to opine on it for purposes of my
2 report. So I am answering truthfully that I believe
3 there was at least one court case, but I cannot
4 provide the details. It was not relevant for
5 purposes of my report.
6 Q Let me try my question a little
7 differently.
8 Sitting here today, are you aware of any
9 penalties being assessed for failure to comply with
10 ClinicalTrials.gov reporting requirements at any
11 point in time?
12 MS. JACK: Objection; asked and answered.
13 A I have answered the question to the best
14 of my ability.
15 Q And what is your answer to the question,
16 Ms. Newberger?
17 A As previously stated, this is not within
18 the scope of my report. So any answer I give I
19 would need additional time to conduct research to
20 confirm my response.
21 Q We disagree about the scope of your
22 report, and so I'll ask my question again.

1 Sitting here today, are you aware of any
2 penalties being assessed for failure to comply with
3 ClinicalTrials.gov reporting requirements at any
4 point in time? And if you don't know, you can just
5 say that and we'll move to the next question.
6 MS. JACK: Objection; asked and answered.
7 A I have answered saying that I cannot
8 answer. This is not within the scope of my report.
9 I did not look into this in order to write this
10 report, so I cannot answer that question right now.
11 Q Okay. You cannot answer. So we can move
12 to the next question.
13 MS. JACK: Is this a good time for a
14 break? We have been going for about an hour or
15 longer.
16 Q Ms. Newberger, did you want to take a
17 break?
18 A If we could take a quick break, 10 minutes
19 would be fine, yeah.
20 MS. STAURING: Sure. We can go off the
21 record.
22 (Recess 6:13 p.m. - 6:24 p.m.)

1 BY MS. STAURING:
2 Q Ms. Newberger, did you speak with anyone
3 about your deposition during the break?
4 A No, I did not.
5 Q I would like to turn back to the exhibit
6 that we were discussing earlier, Exhibit 1114, the
7 article from the lawyers at your law firm. Do you
8 have it before you?
9 A I do, yes.
10 Q And the lawyers at your firm state on page
11 2 that, quote, "Companies are now on notice that FDA
12 is starting to enforce ClinicalTrials.gov reporting
13 requirements," end quote; correct?
14 A That is what it says, correct.
15 Q And the lawyers at your firm are saying
16 this as of May 4, 2021. Is that correct?
17 A That is correct.
18 MS. JACK: Objection; vague.
19 A The article is dated May 4th, yes,
20 correct, 2021.
21 Q And that's many years after the study
22 record posted to ClinicalTrials.gov, right?

1 MS. JACK: Objection; vague.
2 A 2021 is, yes, several years after 2013.
3 Q Do you disagree with the statement that
4 the lawyer at your firm wrote that "Companies are
5 now on notice that FDA is starting to enforce
6 ClinicalTrials.gov reporting requirements"?
7 A I do not disagree with that statement. I
8 would also, however, note that at the top of that
9 page they state, "The failure to submit clinical
10 trial information to ClinicalTrials.gov as required
11 is," not now is, "is also a prohibited act. This
12 violation is subject to potential civil monetary
13 penalties of up to $10,000 for each day the
14 violation continues."
15 So they also have acknowledged that
16 those -- that failure and that violation and those
17 penalties were already in place. This goes back to
18 the public versus the private.
19 Q And, Ms. Newberger, I know that you have
20 positions and those positions are in your
21 declaration.
22 But my question is whether you disagree

1 with the statement that companies are now on notice
2 that FDA is starting to enforce ClinicalTrials.gov
3 reporting requirements?
4 MS. JACK: Objection; asked and answered.
5 A As I just said, I do not disagree with the
6 statement. I believe it is not comprehensive.
7 The article also clearly states what the
8 penalties are and do not -- does not state that
9 those penalties are now enforceable. So I agree
10 with the statement. It is not enough context.
11 Q And that statement that the lawyers at
12 your firm wrote is truthful, correct?
13 A Yes, it is truthful.
14 Q And that statement is to be believed,
15 correct?
16 A Yes, it is to be believed.
17 Q And that statement is accurate, correct?
18 MS. JACK: Objection; asked and answered.
19 A It is accurate with respect to the fact
20 that there are now these public notices of
21 noncompliance, yes.
22 Q Okay. You can minimize that exhibit on

1 your screen.
2 Now, in your view, the June 10th, 2013
3 ClinicalTrials.gov submission included the elements
4 required by statute, right?
5 A Yes.
6 Q And in your view, JHU did not submit any
7 more information than was required to fulfill its
8 legal obligations, right?
9 MS. JACK: I object to the form of the
10 question.
11 A Yes, it is my opinion that they complied
12 with the legal requirements.
13 Q My question is a little different. In
14 your view, JHU did not submit any more information
15 than was required to fulfill its legal obligations.
16 Is that right?
17 MS. JACK: I object to the form of the
18 question.
19 A Based on my review of their posting, I
20 agree that they submitted what was required and did
21 not submit more than what was required.
22 Q And you state that on page 25 at paragraph

1 51 of your declaration, right?
2 A Yes, that is correct.
3 Q To be clear, in that paragraph you state,
4 quote, "JHU did not submit any more information than
5 was required and necessary to fulfill its legal
6 obligations," end quote; right?
7 A Yes, that is what paragraph 51 states.
8 Q And that is included in the conclusion
9 section of your declaration, right?
10 A Yes, that is correct.
11 Q And you also state that on page 25 at
12 paragraph 49, right?
13 A Yes, that is correct.
14 Q And that is also included in the
15 conclusion section of your declaration, correct?
16 A Yes.
17 Q And you also state that on page 14 in
18 heading E, right?
19 A Yes.
20 Q Now, do you stand by that conclusion?
21 A Yes, I do.
22 Q Looking back at Table 1 of your

1 declaration that begins on page 16 of your
2 declaration, you provide in the column titled Legal
3 Requirement your view of the elements required by 42
4 USC (j)(2)(A). Is that right?
5 MS. JACK: Objection; misstates the
6 document.
7 A It's not my view. It is what the statute
8 calls for.
9 Q And the column next to the column titled
10 Legal Requirement titled NIH Description provides
11 the descriptions of the elements that you believe
12 are required by that statute as provided by NIH on
13 its website. Is that correct?
14 MS. JACK: Objection; mischaracterizes the
15 document.
16 A I would not agree with that statement.
17 Q You state in paragraph 47 of your
18 declaration that you provide in Table 1 the elements
19 required by 42 USC 282(j)(2)(A), correct?
20 A Yes, that is correct.
21 Q And you state that Table 1 reflects your
22 analysis -- or reflects information in the first

1 submission of the June 10, 2013 submission to
2 ClinicalTrials.gov, right?
3 MS. JACK: Objection; mischaracterizes the
4 document.
5 A It states that the first submission
6 included the elements required by law and complied
7 with the descriptions of the required information
8 provided by NIH on its website. NIH's website
9 provides supplementary descriptive information to
10 help interpret the statutory requirement.
11 Q So my question is the descriptions that
12 you provide in the column under this title NIH
13 Description that corresponds to the statutory
14 provisions that you provide in the column titled
15 Legal Requirement, correct?
16 MS. JACK: Objection; asked and answered.
17 A The NIH description is on NIH's website.
18 NIH has determined that that description describes
19 the statutory requirement.
20 Q So are you saying that the NIH
21 descriptions in the table are meant to correspond to
22 the legal requirements that you put in the table

1 under the column titled Legal Requirement?
2 MS. JACK: Objection; asked and answered.
3 A Yes, if I recall, NIH says at the
4 beginning of that page that is intended to describe
5 the information generally that would be expected,
6 but that responsible parties are still obligated to
7 ensure appropriate compliance with all applicable
8 legal and regulatory requirements.
9 Q In your view, the elements required by 42
10 USC 282(j)(2)(A) were in effect when the study
11 record was posted on June 10, 2013, right?
12 MS. JACK: I object to the form of the
13 question.
14 A It's not in my view. They were -- they
15 were in effect in 2013.
16 Q So just to be clear, in your view, the
17 posted elements that you provide in Table 1 were
18 required by 42 USC 282(j)(2)(A) when the study
19 record was posted, correct?
20 A The study elements in the Posted Element
21 column were required in 2013, yes, before 2013, yes.
22 Q So just for example, if we take a look at

1 the brief title of the study in row 2 of your table,
2 you provide that the posted element is brief title
3 of the study, right?
4 A Correct.
5 Q And the NIH description for brief title of
6 the study is a short title of the clinical study
7 written in language intended for the lay public,
8 right?
9 MS. JACK: Misstates the document.
10 Objection.
11 A Yes, NIH, the NIH description is a short
12 title of the clinical study written in language
13 intended for the lay public.
14 Q And the posted study record included a
15 brief title of the study, and that title you
16 indicate is "Phase 2 Study of MK-3475 in Patients
17 with Microsatellite Unstable (MSI) Tumors," right?
18 MS. JACK: Objection; compound.
19 A That is the brief title that was provided
20 in the registration.
21 Q Just to be clear, that is the brief title
22 included in the posted study record, right?

1 A Yes, that is correct.
2 Q And in your view, the posted element brief
3 title of the study is legally required by 42 USC
4 282(j)(2)(A)(ii)(I)(aa). Is that right?
5 MS. JACK: Object to the form of the
6 question.
7 A Yes, that is what this column states.
8 Q Is that your view of what that -- is it
9 your view that that provision of the statute legally
10 requires inclusion of the brief title of the study?
11 MS. JACK: I object to the form of the
12 question.
13 A Yes, that is my view.
14 Q If you turn to page 19 of your
15 declaration, you provide a posted element
16 interventional study model. Is that correct? And
17 we're looking at Table 1 of your declaration on page
18 19.
19 A Under the Study Design header, correct.
20 Q And this -- and you included the posted
21 element in this table in your declaration, correct?
22 A Yes.

1 Q And the description that the NIH provides
2 for interventional study model that you provide in
3 Table 1 of your declaration is "The strategy for
4 assigning interventions to participants," right?
5 MS. JACK: I object to the form of the
6 question.
7 A Yes, the NIH description states, "The
8 strategy for assigning interventions to
9 participants."
10 Q And you included this description in your
11 Table 1 of your declaration, correct?
12 A Yes, I did.
13 Q And you believe that the NIH description
14 corresponds to -- let me ask that a different way.
15 You believe that the NIH description here
16 corresponds to posted element interventional study
17 model, right?
18 A Yes. There are likely other ways that
19 somebody could have written a description for
20 interventional study model, but strategy for
21 assigning interventions is the interventional study
22 model.

1 Q And in your view, the posted element
2 interventional study model was legally required by
3 42 USC 282(j)(2)(A)(ii)(I)(hh) at the time that the
4 submission was made to ClinicalTrials.gov, right?
5 MS. JACK: Objection; vague.
6 A Yes.
7 Q And you're familiar with this statute,
8 right?
9 A As I have stated, I am familiar with the
10 statute. I cannot recite the entirety of it word
11 for word off the top of my head, but I am familiar
12 with it.
13 Q And you read the statute, right?
14 A Yes, I did.
15 Q And just to be clear, I'm not asking you
16 to recite the statute word for word, right?
17 A That's correct.
18 Q And you read the statute carefully before
19 you listed it in Table 1 of your declaration, right?
20 MS. JACK: Objection; vague.
21 A Yes, I did.
22 Q And did you understand this statute before

1 you listed it in Table 1 in your declaration?
2 MS. JACK: Objection; vague.
3 A Can you clarify what you mean by did I
4 understand it?
5 Q Sitting here today, do you understand the
6 statute that you cite in Table 1 of your
7 declaration?
8 MS. JACK: Objection; asked and answered.
9 A Yes, I understand the statute.
10 Q And did you understand the statute before
11 you included it in Table 1 of your declaration?
12 MS. JACK: Objection; vague.
13 A Yes, I did.
14 Q Were you confused by anything in 42 USC
15 282(j)(2)(A)(ii)(I)(hh) before you listed it in
16 Table 1 as corresponding with the interventional
17 study model?
18 MS. JACK: Objection; asked and answered.
19 A I don't recall any confusion.
20 Q Do you have any reason to believe, sitting
21 here today, that you had any confusion?
22 A I do not.

1 Q That portion of the statute requires
2 inclusion of the intervention name and the
3 intervention type, right?
4 A I would have to look at the statute to
5 confirm.
6 Q We can take a look at it. And this is
7 Exhibit 2148 that you cite in your declaration.
8 Please let me know when you have downloaded it on
9 your screen.
10 THE TECHNICIAN: I'm sorry, counsel, can
11 you repeat the number?
12 MS. STAURING: The exhibit is Exhibit
13 2148.
14 A I have it. Do you have the page number?
15 Q If you turn to page 2 of the exhibit --
16 A Yes.
17 Q -- do you see the provision --
18 A Yes.
19 Q -- that you recite in your declaration at
20 Table 1?
21 A Yes, I do.
22 Q And that portion of the statute requires

1 the intervention name and intervention type, right?
2 A Yes, that is what the statute states.
3 Q Intervention name is different from
4 interventional study model, right?
5 MS. JACK: I'm going to object to the form
6 of the question.
7 A I don't know that it necessarily has to
8 be.
9 Q I'm asking whether you believe intervention
10 name to be different from interventional study
11 model?
12 MS. JACK: Objection; vague.
13 A (Hh) not only says intervention name, it
14 also says intervention type. An intervention study
15 model with a parallel assignment is the type of
16 intervention.
17 Q My question is a little different. My
18 question is whether intervention name is different
19 from interventional study model.
20 MS. JACK: Objection; asked and answered.
21 A My answer to that, as I previously stated,
22 is that you are not reading all of (hh). It is

1 intervention name and intervention type.
2 Q Let me ask a different question.
3 Does the statute state interventional
4 study model?
5 MS. JACK: Objection; vague.
6 A I do not believe it states interventional
7 study model.
8 Q Does it use the words "interventional
9 study model" anywhere?
10 MS. JACK: Objection; asked and answered.
11 A It does not use that term in this little
12 (ii) section. I cannot speak to the entirety of the
13 statute. Interventional study model is the language
14 on ClinicalTrials.gov registration.
15 Q Well, we're talking about the statute that
16 you cited in your declaration and that you reviewed
17 and were not confused by, correct?
18 A Yes, that's correct.
19 Q And we're only talking about section (hh).
20 And my question is whether section (hh) uses the
21 words "interventional study model"?
22 MS. JACK: Objection; asked and answered.

1 A As I have stated, it does not use those
2 words, but it does use the word "intervention type."
3 I cannot comment on why ClinicalTrials.gov used
4 "interventional study model" terminology.
5 Q Just to be clear, you included the posted
6 element interventional study model in your Table 1
7 in your declaration, right?
8 MS. JACK: Objection; asked and answered.
9 A It was in the list of posted information
10 and I included it in this table.
11 Q Do you believe intervention type and
12 interventional study model to be the same?
13 MS. JACK: Objection; asked and answered.
14 A I previously stated that interventional
15 study model and intervention type can be the same.
16 Q My question is slightly different. My
17 question is whether you believe that intervention
18 type and interventional study model are the same?
19 MS. JACK: Objection; asked and answered.
20 A Interventional study model and
21 intervention type can be the same. That is my
22 answer.

1 Q Are you a hundred percent sure that you're
2 citing the correct section of the statute for what
3 you believe is required posted element
4 interventional study model?
5 MS. JACK: Objection; vague.
6 A Yes, I am certain, intervention type, a
7 parallel assignment is an intervention type.
8 Q That wasn't my question. Let me ask
9 again.
10 Are you a hundred percent sure that you
11 are citing the correct section of the statute for
12 what you believe is required posted element
13 interventional study model?
14 MS. JACK: Objection; asked and answered.
15 A Yes.
16 Q To be clear, are you certain that section
17 42 USC 282(j)(2)(A)(ii)(I)(hh) is the correct
18 section of the statute for posted element
19 interventional study model?
20 MS. JACK: Objection; asked and answered.
21 A Yes, it is my position that that is
22 correct.

1 Q And you are certain of that despite the
2 fact that the section of the statute does not say
3 interventional study model, right?
4 MS. JACK: Objection; asked and answered.
5 This is badgering.
6 A Yes.
7 Q You're aware that ClinicalTrials.gov
8 provides descriptions for these posted elements,
9 which you cited in your declaration as Exhibit 2149,
10 right?
11 MS. JACK: Objection; asked and answered.
12 A Yes.
13 Q Do you know the definition that the
14 government provides for intervention type?
15 MS. JACK: Objection; asked and answered,
16 vague.
17 A Are you referring to the NIH guidance, NIH
18 website when you say the government?
19 Q What you cite as Exhibit 2149 in your
20 declaration from the NIH.
21 A Yes.
22 Q You know the definition that the

1 government provides for intervention type?
2 A I would have to refer to it. I don't
3 recall it off the top of my head.
4 Q I'm not sure if that's true. But if it
5 is, do you know there are definitions for
6 intervention type and for interventional study
7 model?
8 MS. JACK: Objection; vague.
9 A What I said is true, that I do not recall
10 the definition off the top of my head.
11 Q And do you know that there are definitions
12 for both intervention type and interventional study
13 model included in Exhibit 2149 that you cite in your
14 declaration?
15 A I would need to refer to it to confirm.
16 Q We can turn to that exhibit. And there is
17 Exhibit 2149 cited in your declaration.
18 A Okay. I have it open.
19 Q And do you know as defined that
20 intervention type and interventional study model are
21 not the same?
22 MS. JACK: Objection; misstates the

1 testimony.
2 Q I'm just asking whether, sitting here
3 today, whether you know that the definitions
4 provided are not the same?
5 MS. JACK: Objection; lack of foundation.
6 A I see interventional study model --
7 (Simultaneous speaking.)
8 Q So can you take a look at the document
9 that you rely on as Exhibit 2149 and you can look at
10 page 13 and page 18.
11 A Yes, I see.
12 (Simultaneous speaking.)
13 Q Please go ahead.
14 A I see study model, interventional study
15 model on 13, yes, correct.
16 Q And intervention type is described on page
17 18, correct?
18 A That is correct.
19 Q And are the definitions provided for
20 interventional study model and intervention type the
21 same or are they different?
22 A The definitions provided are different.

1 Q And is it your belief that interventional
2 study model and intervention type are the same
3 thing?
4 MS. JACK: I object to the form of the
5 question.
6 A I believe that the type can include more
7 than only the drug, and there's a different entry
8 for that in the posted data that is specifically
9 under intervention.
10 (Simultaneous speaking.)
11 Q I'm asking whether -- I'm asking whether
12 you believe interventional study model and
13 intervention type to be the same thing or different.
14 A I believe that intervention type can be
15 made up of more than one thing; I think it can be
16 made up of the product administered, as well as the
17 study model.
18 Q The definition that ClinicalTrials.gov and
19 the NIH provide for intervention type is the general
20 type of intervention selected from a list of choices
21 that include drug, device, biological, vaccine,
22 procedure, surgery, radiation, behavioral, genetic,

1 dietary supplement, combination product, diagnostic
2 test, or other, correct?
3 MS. JACK: Objection; misstates the
4 document.
5 A The NIH guidance provides, yes, the
6 definition that includes a variety of options for
7 the responsible party to select from.
8 Q And the intervention type does not include
9 the strategy for assigning intervention to
10 participants, right?
11 MS. JACK: Objection; misstates the
12 document.
13 A This NIH guidance also does not track the
14 statute item by item. So just because there's a
15 different definition does not mean that it's not a
16 reasonable conclusion that type would also be
17 inclusive of the model.
18 Q And, Ms. Newberger, I recognize that you
19 have positions, but I would like an answer to my
20 question. And my question was whether you agree
21 that intervention type does not include the strategy
22 for assigning intervention to participants on

1 ClinicalTrials.gov?
2 MS. JACK: Objection; asked and answered.
3 A The definition is not the same, but it is
4 under study design with the elements that were
5 selected on the ClinicalTrials.gov registration.
6 Q So it's your view -- sorry, go ahead.
7 A I was going to say it's considered an
8 element of study design.
9 Q Study design is in a different portion of
10 the statute than what you cite for interventional
11 study model, right?
12 A May I open that exhibit?
13 Q Yes, you can open that exhibit. It's
14 Exhibit 2148 that you cited in your declaration.
15 And just to be clear, study design is not the same
16 thing as interventional study model, correct?
17 MS. JACK: I object to the form of the
18 question.
19 A It appears to be a subset of study design.
20 Q Do you believe study design and
21 interventional study model are the same?
22 MS. JACK: I object to the form of the

1 question.
2 A Interventional study model, per the
3 ClinicalTrials.gov posting, is a subset of study
4 design.
5 Q That's not what I asked, Ms. Newberger.
6 My question was do you believe study
7 design and interventional study model are the same?
8 MS. JACK: Objection; asked and answered.
9 A I have answered the question.
10 Interventional study model is not the entirety of
11 the study design. It is one aspect along with
12 others that are provided here, some of which have
13 separate statutory provisions and some do not.
14 Q So they are not the same thing, right?
15 MS. JACK: Objection; asked and answered.
16 A That is not -- that is not what I said.
17 Study design involves many different aspects.
18 Interventional study model is one of those.
19 Q Do you believe that the posted elements
20 study design and interventional study model that you
21 include in table of your declaration are the same
22 thing?

1 MS. JACK: I object to the form of the
2 question.
3 A As I just stated, one is a subset of the
4 other. It is a part of it.
5 Q If you believe they are the same, then why
6 do you include them as two separate rows in Table 1
7 in your declaration?
8 MS. JACK: I object to the form of the
9 question.
10 A You have mischaracterized what I said. I
11 did not say that I believe they are the same thing,
12 I want to be clear on that. Study design
13 encompasses many things. And as you can see on the
14 ClinicalTrials.gov registration posting, under the
15 header of study design there are a variety of
16 things; study type, primary purpose, study phase,
17 interventional study model, number of arms, masking,
18 allocation and enrollment. Those are the lines that
19 are included here under the header of Study Design.
20 Q Ms. Newberger, your audio is getting loud
21 again.
22 A I'm sorry, I really don't know why that is

1 happening.
2 MS. JACK: Counsel, you should turn down
3 your volume. Or what's the issue --
4 A Is it just happening randomly? Is it okay
5 now? Can you hear me?
6 Q Yes, I can hear you now.
7 A Is it better?
8 Q Yes, it's better now.
9 A Sorry, I don't know why that's -- why
10 that's happening. It's pretty low now, so hopefully
11 it will stay that way. Sorry about that.
12 Q So let me re-ask my question, very simply,
13 if you believe -- do you believe that the posted
14 element study design and interventional study model
15 that you include in two separate rows of your
16 declaration -- of Table 1 in your declaration are
17 the same, yes or no?
18 MS. JACK: Objection; asked and answered.
19 A It is not a yes/no question. One is a
20 subset of the other. The interventional study model
21 is one element that makes up the overall study
22 design.

1 Q But to be clear, in Table 1 in your
2 declaration, you include the posted elements of
3 study design and interventional study model as
4 separate rows, correct?
5 MS. JACK: Objection; asked and answered.
6 A They are separate rows under the header of
7 Study Design, just like primary purpose, study phase
8 and number of arms.
9 Q And you point to different portions of the
10 statute for each, correct?
11 A Yes, that is correct.
12 Q So one last time, do you believe that the
13 posted elements study design and interventional
14 study model are the same thing?
15 MS. JACK: Objection; asked and answered.
16 A I will repeat what I have said also one
17 last time. Interventional study model is one aspect
18 of an overall study design.
19 Q I don't think I got an answer to my
20 question. Are posted element study design and
21 interventional study model the same thing, yes or
22 no?

1 MS. JACK: Objection; asked and answered
2 again.
3 A I have answered the question. You want it
4 to be a yes/no. It's not a yes/no. One is part of
5 the other. Interventional study model in and of
6 itself does not capture the entirety of the study
7 design. That's why there's a header for study
8 design with subparts, including this one.
9 Q It sounds like you're getting -- your
10 volume is getting loud again, Ms. Newberger.
11 MS. JACK: Monique, are you having any
12 issues with the sound, or Kelli?
13 THE TECHNICIAN: I'm not hearing anything
14 different, but we can go off the record if you would
15 like to troubleshoot.
16 MS. JACK: I would like to stay on the
17 record. I mean, you keep on bringing this up on the
18 record kind of burning the clock. I mean, I don't
19 know if you're trying to create a record that
20 there's a technical problem, Jessica, or if you're
21 just actually having a problem on your end.
22 Christine also says that she's not having an issue,

1 so I think it might be just you.
2 MS. STAURING: She's really loud on our
3 end. But I'll move on to my next question.
4 BY MS. STAURING:
5 Q ClinicalTrials.gov provides the
6 description for interventional study model on page
7 13 in Exhibit 2149 that you cite in your
8 declaration, right?
9 A Yes, that is correct.
10 Q And you're aware that ClinicalTrials.gov
11 states that the element interventional study model
12 was only required if the study start date is on or
13 after January 18th, 2017, right?
14 MS. JACK: Objection; misstates the
15 document.
16 A While it does specify that with that
17 annotation, this was available to be filled in at
18 the time and it helps answer the entirety of the
19 question related to study design. So, again, as I
20 stated earlier when we talked about these
21 annotations, I cannot speak to how or why NIH made
22 the decisions that it did.

1 Q My question was not what was available to
2 be filled in.
3 My question was whether you're aware that
4 ClinicalTrials.gov states that the posted element
5 interventional study model was not required if the
6 study start date is on -- was only required if the
7 study start date is on or after January 18th, 2017?
8 MS. JACK: Objection; asked and answered.
9 A As I stated, while I agree that that is
10 what that indicates, in 2013 that language about
11 only required if wouldn't have been available. It
12 was here as part of study design and study design
13 and intervention type were required elements. It,
14 therefore, is reasonable to conclude that they were
15 required elements in 2013.
16 Q When was the start date for the study
17 record that you talk about in your declaration?
18 MS. JACK: Objection; vague.
19 A The start date that was posted was July
20 2013.
21 Q And you say that interventional study
22 model was required. But can you point to an actual

1 portion of the statute that includes the words
2 "interventional study model"?
3 MS. JACK: Objection; asked and answered.
4 A I had previously stated that the statute
5 does not use those words. However, it was an
6 element that was available on ClinicalTrials.gov for
7 a responsible party to submit in order to complete
8 study design. And it is a reasonable conclusion, as
9 I concluded, that interventional study model is a
10 part of study design, which is a required element.
11 Q My question was a little different. My
12 question was can you point to an actual portion of
13 the statute that includes the words "interventional
14 study model"?
15 MS. JACK: Objection; asked and answered.
16 A I did answer that question. I clearly
17 stated that the statute does not use those words,
18 but that does not mean that the element was not
19 otherwise required in order to meet, for example,
20 completing an accurate assessment of study design.
21 Q So why do you cite a portion of the
22 statute in your table if you are saying it was a

1 requirement -- let me start that again.
2 Why do you cite 42 USC 282(j)(2)(A)
3 (ii)(I)(hh) when that does not even refer to
4 interventional study model?
5 MS. JACK: Objection; vague.
6 A It refers to intervention type, and in my
7 experience, an intervention type can be inclusive of
8 an interventional study model.
9 Q But you know that Exhibit 2149, that you
10 cite in your declaration, ClinicalTrials.gov defines
11 those two things as different, right?
12 MS. JACK: Objection; asked and answered.
13 A The definitions are different. Given the
14 language about the timing, it is reasonable to
15 believe that these definitions were not available to
16 the responsible party in 2013.
17 Q Table 1 in your declaration is to be
18 understood as your review of the study record posted
19 June 10, 2013, right?
20 A Yes, that is correct.
21 Q Why are you citing something if you are
22 now saying that it was not available in 2013?

1 MS. JACK: Objection; vague.
2 A That is not what I said. The legal
3 requirement is the basis for what was required. The
4 NIH description has been added and is helpful. But
5 at the time I don't know what description was or was
6 not there.
7 But there was, nevertheless, a legal
8 requirement to include information about
9 intervention type, and a reasonable conclusion is
10 that intervention type includes interventional study
11 model.
12 Q Why are you citing and relying on the
13 exhibit from ClinicalTrials.gov in your declaration
14 if you are now saying that it was not available in
15 2013?
16 MS. JACK: Objection; asked and answered.
17 A What I said is that I do not know what it
18 looked like in 2013, but that it, nevertheless,
19 today, provides insight into how ClinicalTrials.gov
20 is thinking about these requirements.
21 Q Okay. But we can agree that the statutory
22 provision you cite in Table 1 ending in (hh) as

1 corresponding to interventional study model,
2 interventional study model is not mentioned anywhere
3 in that section of the statute, right?
4 MS. JACK: Objection; asked and answered
5 multiple times.
6 A Those words are not there, but that's not
7 the end of the inquiry.
8 Q And ClinicalTrials.gov, and the view of
9 ClinicalTrials.gov is that interventional study
10 model was not required if the study start date --
11 excuse me, was required only if the study start date
12 is on or after January 18th, 2017, correct?
13 MS. JACK: Objection; vague, and calls for
14 speculation.
15 A That is what the website states. I do not
16 know what ClinicalTrials.gov stated on 2013. So I
17 go back to the statute, which, of course, is the
18 guiding document. Intervention type is reasonably
19 inclusive of interventional study model, which is
20 then part of study design, which is how
21 ClinicalTrials.gov has it categorized.
22 Q And just to be clear, my question was a

1 little different. I'll move on to my next question.
2 Study start date here was before January
3 18th, 2017, right?
4 A Yes, that is correct.
5 Q Okay. I would like to turn to some other
6 elements in your Table 1. So based on your
7 analysis, the posted study record included the
8 number of arms, right?
9 A That is correct.
10 Q And the posted study record included the
11 element masking, correct?
12 MS. JACK: Objection; asked and answered.
13 A Yes.
14 Q And the posted study record included the
15 element allocation, right?
16 MS. JACK: Objection; asked and answered.
17 A Yes.
18 Q And in your view, those elements were
19 required by 42 USC 282(j)(2)(A)(ii)(I)(ff), right?
20 MS. JACK: Objection; vague.
21 A Yes, that is the provision that is in the
22 table for masking and allocation.

1 Q Let me ask my question again because I
2 think there might be some misunderstanding.
3 In your view, the elements of number of
4 arms, masking and allocation were required by 42 USC
5 282(j)(2)(A)(ii)(I)(ff), right?
6 MS. JACK: Objection; asked and answered.
7 A Yes.
8 Q The word "number of arms," "masking" --
9 let me ask that a different way.
10 Do you stand by that conclusion sitting
11 here today?
12 A Yes, I do.
13 Q And did you review that portion of the
14 statute that you cite?
15 MS. JACK: Objection; asked and answered.
16 A Yes, I did.
17 Q And did you review that portion of the
18 statute that you cite carefully?
19 MS. JACK: Objection; asked and answered.
20 A Yes, I did.
21 Q You weren't confused by that portion of
22 the statute, right?

1 MS. JACK: Objection; asked and answered.
2 A I have no recollection of confusion.
3 Q Sitting here today, do you have any reason
4 to believe you were confused by that portion of the
5 statute when you included it in Table 1 in your
6 declaration?
7 MS. JACK: Objection; asked and answered.
8 A I have no reason to believe that I was
9 confused.
10 Q The words "allocation," "masking" and
11 "number of arms" do not appear in that section of
12 the statute, correct?
13 MS. JACK: Objection; compound.
14 A They do not appear, as I previously
15 stated. The statute has higher level language, in
16 this case study type is what I referenced, and in
17 order to accurately describe the study type, this
18 information was provided.
19 Q Let me ask my question a little
20 differently. Do the words "number of arms" appear
21 in that portion of the statute?
22 MS. JACK: Objection; asked and answered.

1 A As I previously stated, the words do not
2 appear, but that is not the end of the inquiry about
3 whether it is required per statute.
4 Q And does the word "masking" appear in that
5 portion of the statute?
6 MS. JACK: Objection; asked and answered.
7 A I would repeat my answer. "Masking" does
8 not appear, but that does not mean that it is not
9 still required in order to accurately and truthfully
10 describe the study.
11 Q Can you please identify the higher level
12 language of the portion of the statute that you cite
13 42 USC 282(j)(2)(A)(ii)(I)(ff) for which you believe
14 number of arms is legally required?
15 MS. JACK: Objection; vague.
16 A Study type.
17 Q And that portion of the statute does not
18 include the word "allocation," right?
19 MS. JACK: Objection; asked and answered.
20 A As I previously stated, it does not, but
21 allocation is reasonably considered part of the
22 study type.

1 Q Was allocation legally required at the
2 time of the study record submission?
3 MS. JACK: Objection; asked and answered.
4 A In my opinion, based on my experience with
5 ClinicalTrials.gov, it is a necessary aspect in
6 order to truthfully describe a study type.
7 Q Can you please identify the higher level
8 language of the portion of the statute that you cite
9 42 USC 282(j)(2)(A)(ii)(I)(ff) for which you believe
10 masking was required at the time the study record
11 was submitted?
12 MS. JACK: Objection; vague.
13 A This is the same provision we just
14 discussed, study type.
15 Q Can you please identify the higher level
16 language of the portion of the statute that you cite
17 42 USC 282(j)(2)(A)(ii)(I)(ff) for which you believe
18 allocation was required at the time the study record
19 was submitted?
20 MS. JACK: Objection; vague.
21 A It is the same provision, study type.
22 Q You do recognize that study type is a

1 different posted element from masking, right?
2 MS. JACK: Objection; asked and answered.
3 A Can you point me to what you're referring
4 to?
5 Q In your table that you include in your
6 declaration, you include study type on page 17 as a
7 different posted element from masking that you
8 include on page 20 of your declaration in the table
9 that you created, correct?
10 A I don't have -- I don't have page numbers.
11 Where does it say study type? What's the header?
12 Q Are you looking at the declaration that
13 you prepared?
14 A I am.
15 Q And your declaration does not have page
16 numbers?
17 A No.
18 MS. STAURING: And I just want to state
19 that we are leaving this deposition open. We have
20 zero confidence that we are looking at the same
21 thing --
22 MS. JACK: Well, I'm not going to agree

1 with that, but we can go ahead with the questions.
2 Ms. Newberger's declaration as drafted and signed by
3 her did not have page numbers. Perhaps your exhibit
4 does --
5 THE COURT REPORTER: Counsel, can you
6 speak up? I can't hear you well.
7 MS. JACK: Did you turn down, like, the
8 volume? It's like -- anyways, we're not leaving the
9 deposition open. But you can go ahead with your
10 questions.
11 MS. STAURING: Counsel, we immediately
12 request that you send us a copy of what Ms. Newberger
13 has before her.
14 MS. JACK: You have a copy of what she has
15 before her.
16 MS. STAURING: Well, the declaration that
17 was provided to us has page numbers and what she has
18 before her does not have page numbers.
19 MS. JACK: The IPR exhibit has page
20 numbers, the declaration itself does not have page
21 numbers. We can send you an email of the unnumbered
22 declaration, if you would like.

1 MS. STAURING: No. We'll leave the
2 deposition open.
3 MS. JACK: We are not leaving the
4 deposition open. We will send you right now a PDF
5 of the exact same document we have been looking at
6 the entire time.
7 MS. STAURING: We'll leave the deposition
8 open because you have not sent us the material that
9 Ms. Newberger has before her.
10 MS. JACK: Well, we offered to remove them
11 from Ms. Newberger and you declined that offer, and
12 you have declined to enter as an exhibit in this
13 deposition her declaration for her to refer to. You
14 instead relied on this binder of materials that was
15 prepared for her. That is on you. That is not on
16 us. We are not leaving the deposition open.
17 But you can continue your questions.
18 We're burning your clock.
19 MS. STAURING: You have our position,
20 counsel, and this is wasting our time.
21 BY MS. STAURING:
22 Q Ms. Newberger, taking a look at the table

1 in your declaration, and you include study type on
2 the second page where your table appears in your
3 declaration, correct?
4 A Yes, I see it.
5 Q And that's page 17, understanding that you
6 do not have page numbers on the document before you.
7 And so you include study type in this portion of
8 your table as a different posted element from
9 masking that you include in your -- on page 20 of
10 your declaration in the table that you created,
11 right?
12 MS. JACK: Objection; vague.
13 A Because they are different posted
14 elements. The study type is interventional or
15 observational, I believe. But there are a number of
16 other aspects that go into accurately and truthfully
17 describing the study type.
18 Q So you agree that study type is different
19 from masking, correct?
20 MS. JACK: Objection; asked and answered.
21 A That is not what I said. I do not agree.
22 What I said is that masking is one aspect of the

1 study type.
2 Q But in the table that you created and
3 included in your declaration, you identify study
4 type as a different posted element than masking,
5 right?
6 A Because I followed the way that it is
7 presented on ClinicalTrials.gov, study type has an
8 entry as interventional, masking has an entry,
9 allocation has an entry, and they are all subparts
10 of the overall study design.
11 Q Do you believe that study type is the same
12 posted element as masking?
13 A I have not said that and I do not agree.
14 Q Do you believe that study type is the same
15 posted element as allocation?
16 MS. JACK: Objection; asked and answered.
17 A I did not say that and I do not agree.
18 Q Do you believe that study type is the same
19 posted element as number of arms?
20 MS. JACK: Objection; asked and answered.
21 A I did not say that and I do not agree.
22 Q And do you understand -- have you seen

1 anywhere in 42 USC 282(j)(2)(A) the word
2 "allocation"?
3 MS. JACK: Objection; vague.
4 A I do not recall, but would need to, you
5 know, read every single word again, looking
6 specifically for it. It is not in (ii).
7 Q And have you seen anywhere in 42 USC
8 282(j)(2)(A) reference to the posted element
9 allocation?
10 MS. JACK: Objection; vague.
11 A I believe I just answered that.
12 MS. JACK: Counsel, we have been going a
13 little bit over an hour now, so maybe it's a good
14 time for a break.
15 Q Would you like to take a break,
16 Ms. Newberger?
17 A You can go a few more minutes.
18 Q And have you seen anywhere in 42 USC
19 282(j)(2)(A) reference to the posted element
20 masking?
21 A You mean (j)(2)(I), correct?
22 Q (j)(2)(A).

1 A I see what you mean. Yes. Yes, I was
2 thinking the little 2, the little 2. Yes,
3 (j)(2)(A)(ii). I do not -- I am not aware that that
4 particular term was used.
5 Q And have you seen anywhere in 42 USC
6 282(j)(2)(A) reference to the posted element number
7 of arms?
8 MS. JACK: Objection; vague.
9 A That terminology is not in the statute,
10 but I maintain that it is part of study type, it is
11 required in order to truthfully, accurately and
12 completely provide the required information.
13 Q And I understand that you have a position,
14 but I am just looking for the answers to my
15 questions.
16 And you understand that ClinicalTrials.gov
17 provides different descriptions for the posted
18 elements study type, number of arms, masking and
19 allocation, right?
20 MS. JACK: Objection; vague.
21 A I, again, need to refer -- I do not recall
22 every word, but that would seem appropriate.

1 Q You include in the table in your
2 declaration descriptions of the posted elements
3 study type, masking, number of arms and allocation,
4 right?
5 A Yes.
6 Q And the descriptions that you provide in
7 your table for those posted elements are different
8 from one another, right?
9 A Yes, they are.
10 MS. JACK: Objection; misstates the
11 document.
12 Q And are you aware that ClinicalTrials.gov
13 indicates that the inclusion of elements, number of
14 arms, masking and allocation were only required if
15 the study start date is on or after January 18th,
16 2017?
17 MS. JACK: I object to the form of the
18 question.
19 A I disagree with that statement.
20 Q To be clear, ClinicalTrials.gov indicates
21 certain posted elements as required only if the
22 study start date is on or after January 18, 2017,

1 right?
2 MS. JACK: Objection; vague.
3 A That is correct. But I disagree that
4 information about arms falls into that category.
5 Q And you know that from the exhibit in your
6 declaration that you rely upon, right?
7 A Can you reframe the question, please?
8 Q Sure. Let me ask my question again.
9 ClinicalTrials.gov indicates certain
10 posted elements as required only if the study start
11 date is on or after January 18, 2017, right?
12 MS. JACK: Objection; vague.
13 A It does -- it does state that. As I
14 stated previously, I do not know what information
15 was included in 2013.
16 Q And you know that from the exhibit that
17 you cite and rely upon in your declaration, right?
18 MS. JACK: Objection; asked and answered.
19 A Yes, correct.
20 Q And you understand that there is a symbol
21 that indicates if an element is required if the
22 study start date is on or after January 18, 2017?

1 MS. JACK: Objection; asked and answered.
2 A Right, as I just stated, there is that
3 symbol, but it is not clear what was there for a
4 descriptor at the time of the 2013 submission.
5 Q And did you do any work to determine what
6 ClinicalTrials.gov said in 2013?
7 A I was unable to find the website from
8 2013.
9 Q And do you know the year of the document
10 that you cite in your declaration as Exhibit 2149?
11 A I would have to look at it to see if there
12 is a specific publication date. I know only that it
13 would have been after the January 18th, 2017 date.
14 Q So you said that you were unable to find
15 the 2013 ClinicalTrials.gov information. What did
16 you do to try to find that information?
17 A Just looking for archived versions.
18 Q And when you say looking, what do you
19 mean?
20 A Looking on the ClinicalTrials.gov for any
21 archived versions of the page.
22 Q Did you look anywhere other than

1 ClinicalTrials.gov?
2 A I don't recall.
3 Q Did you go to the library, for example?
4 A I did not go into the library.
5 Q And to be clear, did you personally look
6 to find the 2013 ClinicalTrials.gov material?
7 A I did.
8 Q And did you ask for anyone to help you
9 search for the 2013 ClinicalTrials.gov material?
10 A I did not.
11 Q Why did you want the 2013 ClinicalTrials.gov
12 material?
13 MS. JACK: Objection; vague.
14 A To see if there was a difference between
15 required elements.
16 Q So sitting here today, you don't know
17 whether there was a difference between required
18 elements in 2013 to now?
19 MS. JACK: Objection; misstates the
20 testimony.
21 A What I do not know is whether
22 ClinicalTrials.gov itself had made that indication.

1 I know it was required by the statute, I know it was
2 required then, I know what is required now, and
3 those requirements have not changed.
4 Q Was looking for the 2013 ClinicalTrials.gov
5 material part of the assignment that you were given?
6 A There was not a specific request to do so.
7 Q So why did you feel it important enough to
8 look for the 2013 ClinicalTrials.gov material?
9 A It was not something I spent a long time
10 on. I looked quickly just to see if I could find
11 anything from then. I didn't have any luck, so I
12 didn't feel that it was critical enough to spend
13 more time on.
14 Q And what would you consider a long time?
15 A I do not recall how much time I spent.
16 Q Do you have an approximation of how much
17 time you spent looking for the 2013 ClinicalTrials.gov
18 material?
19 A I do not.
20 Q Did you look for ClinicalTrials.gov
21 material from any other years?
22 A I did not.

1 MS. JACK: Would now be a good time for a
2 break, counsel?
3 Q Ms. Newberger, would you like to take a
4 break?
5 A Yes, I think this would be a good time.
6 MS. STAURING: Okay. We can go off the
7 record.
8 (Recess 7:56 p.m. - 8:10 p.m.)
9 BY MS. STAURING:
10 Q Ms. Newberger, did you speak to anyone
11 about your deposition today during the break?
12 A I did not.
13 Q Ms. Newberger, you include in Table 1 the
14 elements legally required to be included in
15 submissions to ClinicalTrials.gov, right?
16 A Yes.
17 Q And based on your review of the posted
18 study record here, you included all elements in
19 Table 1 in your declaration that you believe to be
20 legally required, right?
21 MS. JACK: Objection; vague.
22 A Yes, I included statutory requirement for

1 each.
2 Q And based on your review of the posted
3 study record, you included all elements in Table 1
4 of your declaration that you believe to be legally
5 required, right?
6 MS. JACK: Objection; vague.
7 A Yes.
8 Q And you included all of the elements in
9 Table 1 in your declaration that you believe to be
10 legally required at the time the study record was
11 submitted, right?
12 A Yes.
13 Q Did you review the elements that you
14 included in Table 1 carefully?
15 MS. JACK: Objection; asked and answered.
16 A Yes, I did.
17 Q And so sitting here today, you believe
18 that you included all elements in Table 1 that were
19 legally required at the time the study record was
20 submitted, right?
21 MS. JACK: Objection; asked and answered.
22 A Yes.

1 Q And there are no legally required elements
2 missing from Table 1 in your declaration. Is that
3 correct?
4 MS. JACK: Objection; asked and answered.
5 A To my knowledge, there are no legally
6 required elements missing.
7 Q And you did not omit any legally required
8 elements contained in the posted study record from
9 Table 1 that's included in your declaration, right?
10 MS. JACK: Objection; vague.
11 A As I stated, this represents my assessment
12 of legally required elements.
13 Q And this reflects all of the posted
14 elements in the study record that you believe to be
15 legally required at the time the study record was
16 submitted, right?
17 MS. JACK: Objection; asked and answered.
18 A That's correct.
19 Q You did not include the collaborator in
20 Table 1 in your declaration, correct?
21 A That's correct.
22 Q And you don't discuss the collaborator

1 information in your declaration. Is that correct?
2 A That's correct.
3 Q So is it your understanding that at the
4 time of the submission information about the
5 collaborator was not required to be included in
6 submissions to ClinicalTrials.gov?
7 MS. JACK: Objection --
8 Q Let me ask my question differently.
9 JHU did include information about the
10 collaborator in its submission to ClinicalTrials.gov,
11 right?
12 A That is correct.
13 Q And the posted study record reflects Merck
14 Sharp & Dohme LLC as the collaborator, right?
15 A Yes, that is correct.
16 Q And so the submission of that information
17 was more information than was required and necessary
18 for JHU to fulfill its legal obligations at the time
19 of the submission, right?
20 MS. JACK: I object to the form of the
21 question.
22 A That is -- I did not state that.

1 Q I'm asking you the submission of that
2 information was more information than was required
3 and necessary to fulfill JHU's legal obligations at
4 the time of the study record submission, right?
5 MS. JACK: Objection; asked and answered.
6 A I am not agreeing with that.
7 Q The submission of collaborator information
8 was not legally required at the time of the
9 submission, right?
10 MS. JACK: Objection; asked and answered.
11 A I would have to go back and review.
12 Q But you didn't include collaborator
13 information in Table 1 in your declaration and you
14 said that you did not omit any legal requirement
15 from Table 1. Is that right?
16 MS. JACK: Objection; misstates the
17 testimony.
18 A I did state that, I previously stated
19 earlier that I don't recall why a collaborator was
20 not included.
21 Q But to be clear, you don't include
22 collaborator information in Table 1, correct?

1 A That's correct.
2 Q And so the submission of that information
3 to ClinicalTrials.gov at the time of the study
4 record submission was more information than was
5 legally required, correct?
6 MS. JACK: Objection; asked and answered.
7 A That is not what I am stating.
8 Q I am asking you was the submission of that
9 information to ClinicalTrials.gov at the time of the
10 study record submission more information than was
11 legally required?
12 MS. JACK: Objection; asked and answered.
13 A I have stated that I would have to review
14 the exhibits to be able to comment on that.
15 Q Well, sitting here today, can you think of
16 any statute that requires submission of collaborator
17 information to ClinicalTrials.gov at the time the
18 study record was submitted?
19 MS. JACK: Objection; vague.
20 A I do not recall collaborator being in the
21 statute. But as we previously discussed, the
22 absence of the word from the statute does not mean

1 that it would have been -- that it could not have
2 been interpreted by the posting party as necessary
3 to meet its obligation.
4 Q And we don't have any guidance from
5 ClinicalTrials.gov from 2013 because you could not
6 find any, correct?
7 MS. JACK: Objection; misstates testimony.
8 A I did not find any.
9 Q And you said that you -- you put together
10 Table 1 carefully, right, and did not omit anything
11 that was legally required at the time of the study
12 record submission, right?
13 MS. JACK: Objection; asked and answered,
14 also misstates testimony.
15 A Yes, by creation of Table 1 was intended
16 to capture the study elements that were legally
17 required.
18 Q And you did not include in your Table 1
19 information on data monitoring, did you?
20 MS. JACK: Objection; vague.
21 A Data monitoring. I don't recall including
22 data monitoring. I can go back and look. I also

1 don't see data monitoring in the posting.
2 Q You don't recall seeing data monitoring in
3 the study record posted on ClinicalTrials.gov on
4 June 10th, 2013?
5 MS. JACK: Objection; asked and answered.
6 Q If you would like to pull up Exhibit 1005,
7 I can direct you to where that's recited in the
8 study record.
9 A Yeah, I don't see it -- I don't see it in
10 the study record.
11 Q You said that you reviewed the study
12 record carefully, right?
13 A Yes.
14 Q And Table 1 reflects your review of the
15 study record, correct?
16 MS. JACK: Objection; asked and answered.
17 A Table 1 reflects my review of the study
18 record in Exhibit 1005.
19 Q Okay. Let's take a look at that Exhibit
20 1005, which is the posted study record. Please let
21 me know when you have that downloaded to your
22 computer.

1 A Okay. I have it.
2 Q Do you see on page 3 of Exhibit 1005 data
3 monitoring information?
4 MS. JACK: Objection; misstates the
5 document.
6 Q It's under the heading Oversight.
7 A On page 2? Sorry --
8 Q On page 3 of the posted study record under
9 the heading Oversight.
10 A Oh, yes, I do see that now.
11 Q And it states "yes" next to data
12 monitoring, correct?
13 A That's correct.
14 Q And you do not discuss data monitoring in
15 Table 1 included in your declaration, correct?
16 A That is correct.
17 Q And this is information that JHU submitted
18 to ClinicalTrials.gov on June 10, 2013, right?
19 A Yes.
20 Q And do you know what data monitoring means
21 in the context of the study record?
22 MS. JACK: Objection; outside the scope.

1 A I do not know what that entry is intended
2 to capture.
3 Q And data monitoring information was
4 information that was more than what was required and
5 necessary for JHU to fulfill its legal obligations,
6 right?
7 MS. JACK: I object to the form of the
8 question.
9 A I would need to go back and review. I
10 cannot confirm that at this time.
11 Q You don't include data monitoring in Table
12 1 in your declaration that you prepared, correct?
13 MS. JACK: Objection; asked and answered.
14 A Correct, it is not there.
15 Q So sitting here today now, do you believe
16 you actually missed legal requirements in Table 1?
17 MS. JACK: I object to the form of the
18 question.
19 A I cannot comment without doing additional
20 research.
21 Q But you reviewed the legal requirements
22 for submission to ClinicalTrials.gov, correct?

1 MS. JACK: Objection; asked and answered.
2 A I reviewed the statute, yes.
3 Q Can you think of any statute that requires
4 data monitoring information to be submitted at the
5 time of the study records posting?
6 MS. JACK: Objection; vague.
7 A I cannot speak to whether Johns Hopkins
8 interpreted any of the legal requirements as
9 requiring inclusion of data monitoring.
10 As we discussed in length in great detail
11 earlier, just because there is a word that is not
12 present in the statute does not mean that the
13 conclusion is that it is not required.
14 Q And so I'm not asking about JHU's
15 interpretations. I'm asking about, in your view,
16 can you think of any statute that requires data
17 monitoring submission, data monitoring information
18 to be submitted at the time the study record was
19 posted?
20 MS. JACK: Objection; asked and answered.
21 A I think the data monitoring could be
22 included as part of the study design. Again, I do

1 not -- I cannot comment on whether Johns Hopkins
2 viewed it under which statutory provision.
3 Q You think or do you know?
4 A Sorry, I don't understand the question.
5 Q You stated, "I think the data monitoring
6 could be included as part of the study design," and
7 I'm asking whether that's something you think or do
8 you know that?
9 A In my experience, data monitoring is part
10 of study design, can be part of study design.
11 Q In your view -- let me ask a different
12 question.
13 Was submission of data monitoring
14 information legally required at the time of the
15 study record's posting?
16 MS. JACK: Objection; asked and answered.
17 A I believe data monitoring is part of study
18 design.
19 Q Let me ask my question again. Was
20 submission of data monitoring information legally
21 required at the time of the study record's posting?
22 MS. JACK: Objection; asked and answered.

1 A The words "data monitoring" are not
2 included in the statute. But data monitoring could
3 reasonably be seen as part of study design, which
4 would make it legally required.
5 Q But I'm not asking you whether it was part
6 of study design. I'm asking whether data monitoring
7 information was required to be submitted at the time
8 of the study record's posting.
9 MS. JACK: Objection; asked and answered.
10 A And my response is that if considered part
11 of study design, then it would have been legally
12 required to be submitted at the time of posting.
13 Q And data monitoring was not something that
14 you included in your Table 1 that you said you
15 carefully prepared and contained no omissions,
16 correct?
17 MS. JACK: Objection; asked and answered.
18 A I stated that I believe that it accurately
19 contained the legally required elements.
20 Q You stated that you did not believe that
21 it -- that it omitted any legally required elements,
22 did you not?

1 MS. JACK: Objection; misstates testimony.
2 A I don't recall my exact words. Can you
3 read them?
4 Q I asked: "You did not omit any legally
5 required elements contained in the posted study
6 record from Table 1 that's included in your
7 declaration, right?"
8 And you stated: "As I stated, this
9 represents my assessment of legally required
10 elements."
11 And I asked: "And this reflects all of
12 the posted elements in the study record that you
13 believe to be legally required at the time the study
14 record was submitted, right?"
15 And you stated: "That's correct."
16 So I'll repeat my question. Data
17 monitoring was not something that you included in
18 your Table 1 that you said was carefully prepared
19 and contained no omissions, correct?
20 MS. JACK: Objection; asked and answered.
21 A At the time that I prepared it I did not
22 believe that it had any omissions.

1 Q And just a few minutes ago you did not
2 believe that it had any omissions, correct?
3 MS. JACK: Objection; asked and answered.
4 A That is correct.
5 Q So, Ms. Newberger, sitting here right now,
6 you don't know whether or not data monitoring was a
7 legal requirement at the time of the study records
8 posting. Is that correct?
9 MS. JACK: Objection; misstates testimony.
10 A That is not what I said. I believe data
11 monitoring could appropriately be listed as an
12 aspect of study design.
13 Q But my question is not whether data
14 monitoring could be listed as an aspect of study
15 design.
16 My question is whether, sitting here right
17 now, do you know whether or not data monitoring was
18 a legal requirement at the time of the study records
19 posting?
20 MS. JACK: Objection; asked and answered.
21 A As I have stated, a lot of this is up to
22 the interpretation of the responsible party. If the

1 responsible party viewed data monitoring as part of
2 study design, then it would have been legally
3 required at the time.
4 Q And you've not spoken with the responsible
5 party here, right?
6 MS. JACK: Objection; asked and answered.
7 A Correct, as I previously stated, I have
8 not spoken with the responsible party.
9 Q And you didn't ask to speak with the
10 responsible party here, right?
11 MS. JACK: Objection; asked and answered.
12 A That is correct.
13 Q Ms. Newberger, are you aware that
14 ClinicalTrials.gov indicates that data monitoring is
15 an element that's optional?
16 MS. JACK: Objection; vague.
17 A I would need to refer to the exhibit to
18 confirm that statement.
19 Q And by the exhibit, you mean the exhibit
20 that you rely on in your declaration, correct?
21 A That is correct.
22 Q We can take a look at that exhibit, and

1 that's Exhibit 2149 that you cite in your
2 declaration.
3 A Okay.
4 Q Please let me know when you have that
5 available on your computer.
6 A I have it available.
7 Q If you turn to page 10 of the exhibit, do
8 you see the heading Data Monitoring Committee?
9 A Yes.
10 Q And there is no symbol next to the heading
11 Data Monitoring Committee, correct?
12 A That is correct. Again, I would reiterate
13 these symbols were provided at a later date.
14 Q And no symbol denotes that is an element
15 that is not legally required, correct?
16 MS. JACK: Objection; asked and answered.
17 A As I just stated, I agree that there is no
18 asterisk. But I also think it's important to
19 continue noting that these symbols were added to
20 this document after 2013.
21 Q Is it your belief that data monitoring
22 information was legally required before -- sorry.

1 Let me ask that a different way.
2 Was it your belief that data monitoring
3 information was legally required at the time the
4 study record was posted in 2013?
5 MS. JACK: Objection; asked and answered.
6 Counsel, you're out of time.
7 A Data monitoring, if considered by JHU to
8 be part of study design, would have been required.
9 Q I don't think that answers my question, so
10 let me ask again --
11 MS. JACK: You're out of time, Jessica.
12 Your seven hours are up. Or am I wrong? I guess
13 the court reporter can say for sure.
14 MS. STAURING: Counsel, are you going to
15 cut me off? I just have a few more questions.
16 MS. JACK: I would like to confirm the
17 clock and confirm that you are over time and I want
18 to make sure that I've got the time right.
19 THE TECHNICIAN: This is the remote
20 technician. Would Madam Court Reporter like me to
21 read the time?
22 THE COURT REPORTER: Please.

1 THE TECHNICIAN: I have 6 hours 59 minutes
2 and about 30 seconds.
3 MS. JACK: All right. So you have 30
4 seconds.
5 MS. STAURING: And, counsel, you just
6 interrupted and lost a lot of my time with this
7 discussion.
8 BY MS. STAURING:
9 Q So, Ms. Newberger, apparently you didn't
10 think data monitoring was required at the time the
11 study record was posted because it's not included in
12 Table 1 that you created, correct?
13 MS. JACK: Objection; asked and answered.
14 A I cannot agree with that conclusion.
15 Q You did not include data monitoring in the
16 table that you prepared and included in your
17 declaration, correct?
18 MS. JACK: Objection; asked and answered.
19 A That's correct, it is not in the table.
20 Q So you did not prepare Table 1 with care
21 then, correct?
22 MS. JACK: Objection; mischaracterizes

1 testimony.
2 A That is not correct.
3 Q Apparently you didn't think collaborator
4 information was required at the time the study
5 record was posted, because that is also not included
6 in the table that you created in your declaration,
7 correct?
8 MS. JACK: Objection; asked and answered.
9 A Not correct.
10 Q Sitting here today now, are you saying
11 that Table 1 could have omissions in it?
12 A I would need to go back and review to see
13 if data monitoring committee and collaborator should
14 be included.
15 MS. JACK: Counsel, I've let you go well
16 over 30 more seconds here, so you're out of time.
17 MS. STAURING: Counsel, please stop
18 interrupting.
19 Q Ms. Newberger, sitting here today now, are
20 you saying that Table 1 could have omissions in it?
21 MS. JACK: You're out of time.
22 Ms. Newberger has no obligation to answer your

1 questions. I'm sorry, but we're done here.
2 Q Ms. Newberger, you can answer the
3 question.
4 MS. JACK: Ms. Newberger has no obligation
5 to answer any more questions. Your seven hours is
6 up.
7 MS. STAURING: Counsel, please stop
8 interrupting.
9 Q Ms. Newberger, I have this issue with
10 counsel, but I have a question pending for you, so
11 can you please respond to it.
12 A Can you please repeat the question?
13 Q Sure. Sitting here today now, are you
14 saying that Table 1 could have omissions in it? Is
15 that your testimony?
16 MS. JACK: And I will object that this
17 question is out of time, well after the seven-hour
18 mark. Ms. Newberger has no more obligation to
19 continue answering your questions.
20 A I would need to go back and review whether
21 those lines should have been included in the table.
22 MS. STAURING: Okay. Ms. Newberger, I

1 don't have any additional questions for you at this
2 time, but we are leaving the deposition open for the
3 reasons that are stated on the record. And your
4 counsel may have questions for you and I may have
5 further questions, but --
6 MS. JACK: I will say for the record that
7 you are not leaving this deposition open. You can
8 move the Board to reopen or recall Ms. Newberger for
9 a deposition, but we're not leaving this deposition
10 open.
11 (Court Reporter clarification.)
12 EXAMINATION
13 BY MS. JACK:
14 Q Ms. Newberger, I do have a couple
15 questions for you.
16 Counsel today asked you several questions
17 about the posted study record in conjunction with
18 Table 1 in your report, right, Ms. Newberger?
19 A Yes, that is correct.
20 Q Which posted study record specifically
21 were you analyzing in Table 1?
22 A The June 10, 2013 posted study record.

1 MS. JACK: I have no further questions.
2 MS. STAURING: I'll just restate our
3 position that we are keeping the deposition open for
4 the reasons stated on the record.
5 MS. JACK: And we disagree that the
6 deposition remains open, as I explained. We
7 disagree that there are any reasons for such a
8 position, and if -- if you want to, you can raise
9 that issue with the Board, but we disagree there's
10 any basis.
11 MS. STAURING: Thank you, Ms. Newberger,
12 for your time today, and we may be seeing you again
13 because of your counsel.
14 MS. JACK: Jessica, that is entirely
15 inappropriate. But I hope you have a good evening.
16 (Time noted: 8:46 p.m.)
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1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER
2 NOTARY PUBLIC
3 I, MONIQUE VOUTHOURIS, Certified Court Reporter
4 and Notary Public within and for the State of New
5 Jersey, do hereby certify:
6 That JENNIFER D. NEWBERGER, the witness whose
7 remote deposition is hereinbefore set forth, was
8 duly sworn by me before the commencement of such
9 deposition, and that such deposition was taken
10 before me and is a true record of the testimony
11 given by such witness.
12 I further certify that the adverse party, THE
13 JOHNS HOPKINS UNIVERSITY, was represented by counsel
14 at the deposition.
15 I further certify that the deposition of
16 JENNIFER D. NEWBERGER, occurred remotely via Zoom
17 Videoconference, on Wednesday, December 11, 2024,
18 commencing at 12:01 p.m. EST to 8:46 p.m. EST.
19 I further certify that I am not related to any
20 of the parties to this action by blood or marriage,
21 I am not employed by or an attorney to any of the
22 parties to this action, and that I am in no way

1 interested, financially or otherwise, in the outcome
2 of this matter.
3
4 IN WITNESS WHEREOF, I have hereunto set my hand
5 this 16th day of December 2024.
6
7
8
9 Monique Vouthouris
10 Monique Vouthouris, CCR, RPR, CRR
11 Notary Public of the State of New Jersey
12 My commission expires: April 8, 2029
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