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Transcript of L. Ross Pierce, M.D.

Date: October 4, 2024
Case: BioNTech SE and Pfizer, Inc. -v- Moderna TX, Inc. (PTAB)

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Moderna 2257
BioNTech-Pfizer v. Moderna
IPR2023-01359

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC.,
Petitioners

vs

MODERNA TX, INC.,
Patent Owner

Case IPR2023-01358
U.S. Patent No. 10,702,600
and
Case IPR2023-01359
U.S. Patent No. 10,933,127

Oral deposition of

L. ROSS PIERCE, M.D.

WASHINGTON, DC

FRIDAY, OCTOBER 4, 2024

9:42 a.m.

Job No.: 555080

Pages: 1 - 99

Reported by: Lisa V. Feissner, RDR, CRR, CLR

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Oral deposition of L. ROSS PIERCE, M.D., held at the offices of:

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Pursuant to Notice, before Lisa V. Feissner, RDR, CRR, CLR, Notary Public.

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JACOB MOORE, ESQ., Moderna

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C O N T E N T S

EXAMINATION OF L. ROSS PIERCE, M.D. PAGE
By Mr. Prussia 6

E X H I B I T S

(Attached to transcript)

DEPOSITION EXHIBIT PAGE
(None marked.)

P R E V I O U S L Y
M A R K E D E X H I B I T S
(Referenced)

EXHIBITS PAGE
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Moderna 2200 9

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P R O C E E D I N G S

L. ROSS PIERCE, M.D.,
having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. PRUSSIA:
Q Good morning.
A Good morning.
Q Would you please go ahead and introduce yourself for the record.
A I'm Dr. Leland Ross Pierce.
Q Dr. Pierce, where do you live?
A I live at 1330 West Avenue, Unit 506, Miami Beach, Florida, 33139, United States of America.
Q Should have done this in Miami.
A I beg your pardon?
Q We should have done this deposition in Miami.
Are you currently employed?
A I'm self-employed. I have an LLC.
Q You understand that you just took an oath

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to tell the truth?
A I do.
Q And you will tell the truth today?
A I will.
Q Is there any reason why you cannot give me your best testimony today?
A There is not.
Q And you will give me your best testimony today?
A I will give you my best testimony today.
Q And you've been deposed previously, right?
A I have been deposed once for an -- in the course of a divorce proceeding.
Q Okay. You have a couple documents in front of you. Do you want to identify what they are, please?
A Of course. The first document that I have before me is my declaration in the case of Pfizer and BioNTech versus ModernaTX, Inc.
Q You just want to give me the exhibit number on the bottom right-hand corner?

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A Sure. It's Exhibit 1164.
(Previously marked Exhibit 1164 referenced.)
BY MR. PRUSSIA:
Q And in which proceeding is that exhibit in?
A The two case numbers listed on the first page, on the cover page of my declaration are case numbers IPR 2023-01358 and case number IPR 2023-1359.
Q And are there any markings in the version of the Exhibit 1164 that's in front of you?
A It's a clean copy. I've dog-eared a couple of the pages.
Q Okay. And why did you dog-ear those pages?
A I thought it possible that you might ask me questions pertinent to those sections.
Q And there's another document to your left.
Is that right?
A There is another document to my left.

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1 Q What is that document?
2 **A That document is the declaration of**
3 **Phillip Krause, M.D., and the exhibit number at the**
4 **lower right-hand corner states, Moderna 2200.**
5 (Previously marked Exhibit 2200
6 referenced.)
7 BY MR. PRUSSIA:
8 Q And you reviewed Dr. Krause's declaration
9 in connection with preparing your declaration in
10 these proceedings.
11 Is that right?
12 **A I did review Dr. Krause's declaration in**
13 **the course of preparing my declaration with regard**
14 **to these proceedings.**
15 Q And the purpose of your declaration was
16 to respond to Dr. Krause's opinions.
17 Is that right?
18 **A Not exactly. But partially.**
19 **The purpose -- as stated on page 3 of my**
20 **declaration, I've been asked to respond to the**
21 **declaration of Dr. Phillip Krause as it relates to**
22 **the opinions that Dr. Krause has offered regarding**

10

1 **Moderna's submission of materials to the United**
2 **States Food and Drug Administration, the FDA, and**
3 **particularly certain statements, citations, and**
4 **studies that Moderna included in certain documents**
5 **submitted to FDA in connection with Moderna's**
6 **proposed vaccine products and their interest in**
7 **engaging in clinical trials with those products.**
8 Q And you understand that Dr. Krause was
9 deposed in these proceedings?
10 **A I have an understanding that Dr. Krause**
11 **was deposed in these proceedings.**
12 Q Did you review his deposition transcript?
13 **A I read Dr. Krause's deposition**
14 **transcript.**
15 Q And so your declaration responds to
16 his -- not only his declaration but his deposition
17 testimony on the issues that you just read at page 3
18 of your declaration.
19 Is that right?
20 MR. BANSAL: Objection, form.
21 **A My declaration, as stated on page 3 of my**
22 **declaration, responds to the declaration of**

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1 **Dr. Phillip Krause as it relates to opinions that**
2 **Dr. Krause has offered, and my declaration includes**
3 **footnotes referencing certain statements that**
4 **Dr. Krause made during his deposition regarding his**
5 **declaration.**
6 Q Do you have Appendix A to your -- well,
7 actually, it was marked separately.
8 Do you have Appendix A of your
9 declaration in front of you as well? I think you
10 do, but --
11 **A I have Appendix A of my declaration**
12 **before me, which is my curriculum vitae.**
13 Q Okay. And you obtained a BS in chemistry
14 from MIT, right?
15 **A That is correct.**
16 Q And that was in 1973?
17 **A That is correct.**
18 Q And you began graduate coursework at
19 UC Davis in the same year.
20 Is that right?
21 **A I did graduate work in -- at UC Davis.**
22 Q Just to be clear, did you obtained a

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1 master's degree in connection with that coursework?
2 **A I did not.**
3 Q Did you obtain a Ph.D. in connection with
4 that coursework?
5 **A I did not. However, I passed my oral**
6 **qualifying exam for a Ph.D. and all of the preceding**
7 **written exams.**
8 Q But you didn't actually receive the
9 degree.
10 Is that right?
11 **A I did not.**
12 Q Why is that?
13 **A I did not complete writing my**
14 **dissertation. I would have had to have done it at**
15 **times when I had a choice of working on that or**
16 **going on vacation. And I was in medical school at**
17 **the same time.**
18 **I elected to take some vacations and be**
19 **satisfied with a single doctorate in medicine, and**
20 **did not feel that it was going to further my career**
21 **incrementally to a significant degree by finalizing**
22 **my dissertation and obtaining my Ph.D. in**

13

1 **biochemistry.**
2 Q Okay. Thank you.
3 You noted that you have an M.D., right?
4 **A I have an M.D. degree from the University**
5 **of California at Davis.**
6 Q And you received that in 1978.
7 Is that right?
8 **A I received my M.D. degree from the**
9 **University of California at Davis in 1978.**
10 Q And then afterwards, you were a foreign
11 resident in Paris.
12 Is that correct?
13 **A Yes. I was Medecin Resident Etranger des**
14 **Hopitaux de Paris.**
15 Q And following your time in Paris, you
16 returned to the United States and you completed a
17 residency in internal medicine at Scripps.
18 Is that right?
19 **A Scripps Mercy Hospital, at the time it**
20 **was called Mercy Hospital, in San Diego, affiliated**
21 **with the University of California at San Diego.**
22 Q And then you did your fellowship at the

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1 NIH in endocrinology and metabolism.
2 Is that right?
3 **A Yes, in NIADDK at NIH, I did a three-year**
4 **fellowship in endocrinology and metabolism.**
5 Q And what interested you in endocrinology
6 and metabolism?
7 **A When I was working in Paris, I had an**
8 **opportunity to work for the head of the endocrine**
9 **department at the Pietie-Salpetriere Hospital,**
10 **Prof. Jean-Luc DeGennes. So because of that**
11 **experience with endocrinology, I was quite attracted**
12 **to continue in that subspecialty of internal**
13 **medicine.**
14 Q Today, as you sit here today, do you
15 consider yourself to be an endocrinologist?
16 **A I am an endocrinologist.**
17 Q You began working at FDA in 1985.
18 Is that right?
19 **A I began working at the U.S. Food and Drug**
20 **Administration in 1985.**
21 Q And you started at the Division of
22 Metabolism and Endocrine Drug Products at CDER.

15

1 Is that right?
2 **A In 1985, CDER, the Center for Drug**
3 **Evaluation and Research, and CBER, the Center for**
4 **Biologics Evaluation and Research, were combined.**
5 **And I worked in the Division of Metabolism and**
6 **Endocrine Drug Products, as you say.**
7 **And later, those two entities within FDA**
8 **separated, and I remained at that point in CDER in**
9 **the Division of Metabolism and Endocrine Drug**
10 **Products.**
11 Q Can you give us examples of some of the
12 diseases that are associated with disorders of the
13 endocrine and metabolic systems?
14 **A Yes, I can.**
15 Q What are some?
16 **A Some of the diseases that are associated**
17 **with the metabolic and endocrine system include**
18 **osteoporosis, lipid disorders such as**
19 **hypercholesterolemia, type 1 and type 2 diabetes,**
20 **hyperparathyroidism, hypoparathyroidism, excess and**
21 **deficiency of various endocrine hormones, including**
22 **cortisol produced by the adrenal glands, disorders**

16

1 **of pituitary function, disorders of gonadal**
2 **function, as examples.**
3 Q And when you were at the Division of
4 Metabolism and Endocrine Drug Products starting in
5 1985, were the agents that you worked on small
6 molecule agents?
7 **A I worked, while in the Division of**
8 **Metabolism and Endocrine Drug Products, on both**
9 **small molecule products as well as polypeptide**
10 **products.**
11 Q Okay. Is it -- do I understand your CV
12 correctly that while at the Division of Metabolism
13 and Endocrine Drug Products, you did not personally
14 participate in the regulatory review of any vaccines
15 for infectious diseases?
16 **A Could you please repeat your question.**
17 Q Sure. Do I understand your CV correctly
18 that while at the Division of Metabolism and
19 Endocrine Drug Products, you did not personally
20 participate in the regulatory review of any vaccines
21 for infectious diseases?
22 **A To the best of my recollection, while I**

17

1 **was in the Division of Metabolism and Endocrine Drug**
2 **Products at FDA, I did not engage in primary review**
3 **of any vaccine products.**
4 Q Okay. At some point, you moved on to the
5 clinical investigations branch of the Division of
6 Scientific Investigations at CDER.
7 Is that right?
8 **A That's correct.**
9 Q And while there, did you personally
10 participate in the regulatory review of any vaccines
11 for infectious diseases?
12 **A I did not. The vaccines are regulated by**
13 **the Center for Biologics Evaluation and Research,**
14 **and the Division of Scientific Investigations was**
15 **within the Center for Drug Evaluation and Research.**
16 Q Okay. At some point, you did move to
17 CBER, and you were working in the clinical review
18 branch for the review of hematologic products,
19 right?
20 **A Correct. I transferred to Center for**
21 **Biologics Evaluation and Research and worked in the**
22 **hematology division there.**

18

1 Q And you were working on products that are
2 used to treat diseases such as hemophilia A, right?
3 **A Hemophilia A was among the many types of**
4 **products for a variety of diseases within many**
5 **subspecialties of medicine, including infectious**
6 **disease, that I worked on while in the division of**
7 **hematology for approximately 20 years.**
8 Q And generally speaking, were these
9 replacement therapies that you worked on while at
10 the division?
11 **A Replacement therapies were among the**
12 **types of therapies that I worked on while in the**
13 **division; however, the types of products that I**
14 **worked on were very broad and were not in any way**
15 **limited to replacement therapy products.**
16 Q Is it correct that while at the -- while
17 in that division for the clinical review branch for
18 hematologic products, you didn't personally
19 participate in the regulatory review of any vaccines
20 for infectious diseases?
21 **A While I was in the division of hematology**
22 **in CBER, I worked on many projects impacting**

19

1 **infectious disease for a variety of viral diseases**
2 **as well as immunoglobulin therapies for -- to**
3 **prevent serious bacterial infections in patients**
4 **with primary humoral immune disorder.**
5 **I was the lead author of a guidance**
6 document on Immune Globulin Intravenous (Human), and
7 I worked on a variety of immunoglobulin products,
8 some of which required the administration of
9 prophylactic vaccines to volunteers in order to
10 prepare the investigational product that was being
11 studied under the applications that I was reviewing.
12 So in the course of doing that, I
13 consulted periodically with the Office of Vaccines
14 during my tenure in the division of hematology at
15 the U.S. Food and Drug Administration in the Office
16 of Blood Research and Review within the Center for
17 Biologics Evaluation and Research.
18 Q Fair enough. But none of the
19 investigational drug products that were the subject
20 of any BLA that you were reviewing while in that
21 division were for a vaccine for an infectious
22 disease, correct?

20

1 **A Could you please repeat your question?**
2 Q Sure. None of the investigational drug
3 products that were the subject of any BLA that you
4 were reviewing while in that division were for a
5 vaccine for an infectious disease, correct?
6 **A Now you are getting into some specifics**
7 **of projects that I worked on at the Investigational**
8 **New Drug Application stage.**
9 **Information related to Investigational**
10 **New Drug Applications that did not necessarily lead**
11 **to a biologics license application or a new drug**
12 **indication are considered commercial confidential**
13 **information under FDA regulation, and I am**
14 **prohibited from going into detail with respect to**
15 **such products.**
16 Q Okay. Let's focus on the BLAs. All
17 right? So for the BLAs that you were personally
18 responsible for reviewing while at the division,
19 none of those BLAs were for a vaccine for an
20 infectious disease, correct?
21 **A While I was in the division of**
22 **hematology, none of the Biologics License**

21

1 **Applications or BLAs that I worked on were for**
2 **prophylactic vaccines to prevent infectious**
3 **diseases.**
4 **I did engage in activity related to viral**
5 **infectious diseases during my tenure there. For**
6 **example, I co-authored a report on fialuridine,**
7 **FIAU, a small molecule which was being studied at**
8 **the National Institutes of Health and during Phase 2**
9 **resulted in numerous deaths to volunteer study**
10 **subjects.**
11 Q Okay. You left FDA in February of 2020.
12 Do I understand that right?
13 **A The last day of leap year in February**
14 **2020 was my last day at FDA.**
15 Q And the last role that you held at FDA
16 was at DCEPT at CBER, right?
17 **A In CBER, right, within the -- within**
18 **DCEPT, yes, that is correct.**
19 Q And DCEPT, just for the record, is the
20 Division of Clinical Evaluation and
21 Pharmacology/Toxicology, right?
22 **A That is a correct articulation of the**

22

1 **name of the division at that time. It has since**
2 **changed names.**
3 Q And during that time, you reviewed some
4 gene therapy products.
5 Is that right?
6 **A Yes. Gene therapy products, cellular**
7 **products, products derived from blood, plasma, and**
8 **recombinant products were among the types of**
9 **products for a wide variety of therapeutic**
10 **indications, including for several viral diseases,**
11 **including CMV, rabies, and hepatitis viruses, while**
12 **working in DCEPT in the -- in CBER.**
13 Q Were any of those first-in-class
14 therapies?
15 **A I believe that during my tenure in the --**
16 **what used to be called the Office of Cell and Gene**
17 **Therapy within CBER, I -- I'm sorry. Could you**
18 **repeat your question?**
19 Q Were any of those gene therapy products
20 that you worked on first-in-class therapies?
21 **A Yes. I believe that some of the gene**
22 **therapy products that I worked on could have been**

23

1 **considered first in class.**
2 Q Which ones?
3 **A Products that were at the time at an**
4 **investigational stage would be considered commercial**
5 **confidential information, which I am not at liberty**
6 **to divulge.**
7 Q Were any of them approved, of the ones
8 that you -- strike that.
9 Of the ones that were first in class,
10 were any of them ultimately approved?
11 **A I do not believe that the particular gene**
12 **therapy products that I worked on while in the -- in**
13 **DCEPT that were approved. However, I had some minor**
14 **degree of involvement in Luxturna, which was a gene**
15 **therapy product that was approved during my tenure**
16 **there.**
17 Q What's Luxturna indicated for?
18 **A Luxturna is indicated for a type of**
19 **congenital vision impairment.**
20 Q Were any of the BLAs that you reviewed
21 while at DCEPT for an infectious disease vaccine?
22 **A Could you please repeat your question?**

24

1 Q Were any of the BLAs that you reviewed
2 while at DCEPT for an infectious disease vaccine?
3 **A I did not review BLAs for infectious**
4 **disease prophylactic vaccines while in DCEPT in**
5 **CBER.**
6 Q You did review -- you were involved in
7 the review of therapeutic vaccines, though, right?
8 **A I had some involvement with therapeutic**
9 **vaccines while working in DCEPT in CBER.**
10 Q What is a therapeutic vaccine?
11 **A A therapeutic vaccine, unlike a**
12 **prophylactic vaccine, is given to individuals with a**
13 **disease generally with the aim of ameliorating the**
14 **status of that disease rather than preventing the**
15 **acquisition of an infectious disease like**
16 **prophylactic vaccines.**
17 **But many of the principles are the same,**
18 **and the review process is similar to that undertaken**
19 **by the Office of Vaccines Research and Review. For**
20 **example, both types of vaccines can use adjuvants in**
21 **order to boost the immunogenicity of the**
22 **investigational product.**

25

1 Q Well, FDA issues guidance regarding the
2 development of therapeutic vaccines, right?
3 **A FDA issues many types of guidance**
4 **documents to assist industry -- regulated industry**
5 **as well as the FDA review staff in the development**
6 **of therapeutic products and other types of products**
7 **relevant to FDA's purview.**
8 Q And FDA also issues -- well, strike that.
9 An example of guidance that FDA issues
10 for therapeutic vaccines is for cancer vaccines,
11 right?
12 **A Please restate your question.**
13 Q Sure. An example of guidance that FDA
14 issues for therapeutic vaccines is for cancer
15 vaccines, right?
16 **A I'm not prepared today to go into the**
17 **specifics of any guidance documents which may or may**
18 **not exist with respect to cancer vaccines.**
19 Q But are you aware that FDA has separate
20 guidance for the development of cancer vaccines?
21 **A I have read many dozens of FDA guidance**
22 **documents over the course of my career, and I do not**

26

1 **have a specific recollection of having read a**
2 **guidance document for a cancer therapeutic vaccine;**
3 **however, that in no way would suggest that such a**
4 **guidance may not exist.**
5 Q Okay. Are you aware that FDA has
6 guidance on the development of vaccines for
7 infectious disease?
8 **A I am aware that FDA has issued guidance**
9 **documents related to the development of products for**
10 **prophylactic vaccines for certain infectious**
11 **diseases.**
12 Q And generally, the guidance for
13 development -- strike that.
14 Generally, FDA's guidance for development
15 of infectious disease vaccines is different from the
16 guidance that FDA issues for the development of
17 therapeutic vaccines, right?
18 **A Counselor, that's a very broad question,**
19 **and you used the term "different."**
20 **So, of course, any two guidance documents**
21 **are different, because if you were to do a word**
22 **search on those two guidance documents, the number**

27

1 **of words, first of all, would turn out to be**
2 **different, and qualitatively, the identity of at**
3 **least some of the words in two different guidance**
4 **documents from FDA would be different.**
5 Q Okay. So earlier you mentioned that a
6 goal of a therapeutic vaccine is to ameliorate
7 disease, right?
8 **A I stated earlier that one of the goals of**
9 **the therapeutic vaccine which would be given to an**
10 **individual with a disease would be to ameliorate the**
11 **disease status in that individual receiving the**
12 **therapeutic vaccine.**
13 Q And what are the clinical endpoints that
14 one would utilize to assess whether a therapeutic
15 vaccine was successful in ameliorating a particular
16 condition or disease?
17 MR. BANSAL: Objection, form.
18 **A That's a very broad question. And there**
19 **are a large number of different clinical endpoints**
20 **as well as in some cases surrogate endpoints that**
21 **can be useful to assess during the course of product**
22 **development for therapeutic products in general,**

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1 **including therapeutic vaccines.**
2 **So I construe your question to be so**
3 **broad as to be extremely difficult to answer in the**
4 **time available to us today before midnight.**
5 Q Okay. Would one example of such an
6 endpoint be increased survival?
7 **A Increased survival would be a potential**
8 **candidate endpoint in a trial of a therapeutic**
9 **vaccine; however, the particular endpoints that are**
10 **utilized in any given trial are a function of many**
11 **different variables. So there's a tailoring of the**
12 **endpoints to the specific case.**
13 Q Okay. Fair enough.
14 Would another example of such an endpoint
15 be symptomatic improvement?
16 **A Improvement of symptoms is of interest to**
17 **FDA, and obviously of interest to patients, and**
18 **could be considered to be a clinical trial endpoint**
19 **among generally several endpoints that are assessed**
20 **during the -- during clinical trials in general of**
21 **patients who have diseases being targeted, including**
22 **trials of therapeutic vaccines.**

29

1 Q Okay. What are the efficacy
2 considerations for an infectious disease vaccine?
3 MR. BANSAL: Objection, form.
4 **A Could you please repeat your question?**
5 Q Yes. What are the efficacy
6 considerations for an infectious disease vaccine?
7 **A That question, Counselor, is not a**
8 **question that I had considered during the**
9 **preparation of my declaration today. And as you**
10 **know, my declaration is focused on the opinions of**
11 **Dr. Krause as expressed in his declaration with**
12 **respect to certain submissions by Moderna to FDA**
13 **during the course of their development of mRNA**
14 **vaccines.**
15 **So your question is not something that I**
16 **have given thought to before. It requires**
17 **considerable thought. I'm not prepared to respond**
18 **to your question under oath today.**
19 Q Okay. Generally speaking, for vaccine
20 candidates against an infectious disease, is the
21 typical primary endpoint prevention of infection?
22 MR. BANSAL: Objection, form.

30

1 **A When you say, vaccine candidates against**
2 **a specific disease, could you clarify exactly what**
3 **you mean?**
4 Q I didn't have a particular disease in
5 mind. Would it be helpful for you if I identified a
6 particular disease?
7 **A It may or may not be helpful to me if you**
8 **identify a particular disease in responding to the**
9 **question that I just asked.**
10 Q Okay.
11 **A However, the focus of my question was**
12 **different.**
13 Q Sure. Let me restate the question.
14 For a vaccine against an infectious
15 disease, is it generally correct that the primary
16 endpoint is prevention of infection?
17 **A I would like to point out that I am not**
18 **here today as a technical expert in vaccinology or,**
19 **for that matter, in clinical trials of prophylactic**
20 **vaccines per se. And there are many types, as I**
21 **have outlined to you, of possible clinical endpoints**
22 **for any given clinical trial for developing any**

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1 **particular therapeutic product, including a**
2 **therapeutic vaccine.**
3 **And that the endpoints are tailored to**
4 **the particulars of the situation, and there are**
5 **numerous, numerous factors that go into the proposal**
6 **by sponsors of what the endpoints are in a given**
7 **clinical trial, and these are vetted and negotiated**
8 **with FDA on a case-by-case basis.**
9 Q Okay. Would you be able to agree that
10 when FDA reviews a vaccine candidate -- strike that.
11 Would you be able to agree that when FDA
12 is reviewing the efficacy of a vaccine candidate for
13 infectious disease, that one of the things it's
14 looking for is positive evidence of immunogenicity?
15 **A For therapeutic vaccines, investigation**
16 **of immunogenicity as well as for development of**
17 **biologics in general is an important component of**
18 **development of the product.**
19 Q Yeah. And my question was specific to
20 infectious disease vaccines.
21 Do you have that in mind?
22 **A Please repeat your question.**

32

1 Q Okay. So with reference to infectious
2 disease vaccines, positive evidence of
3 immunogenicity is a good thing, right?
4 **A If we look at my declaration on page 10,**
5 **paragraph 17, it states that, Clinical studies are**
6 **studies conducted in humans designed to characterize**
7 **the tolerability, safety, immunogenicity, and,**
8 **eventually, the efficacy of the investigational**
9 **vaccine product.**
10 **Paragraph 19 on page 11 of my declaration**
11 **reads in part, Phase 2 clinical studies of**
12 **investigational vaccines are typically conducted in**
13 **a larger and broader population. While the emphasis**
14 **in Phase 1 is on safety, Phase 2 studies of vaccine**
15 **candidates typically provide preliminary data**
16 **regarding the ability of the vaccine to generate an**
17 **immune response -- i.e., immunogenicity --**
18 **information on the relationship between vaccine dose**
19 **and immune response, and additional information on**
20 **vaccine safety.**
21 **Paragraph 18 of my declaration on**
22 **page 10, going on to page 11, reads, Phase 1**

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1 clinical studies are typically conducted in a
2 comparatively small population of healthy volunteers
3 or individuals with the disease intended to be
4 treated, depending on the circumstances, and are
5 generally used to assess the tolerability, safety,
6 and appropriate doses for further study in humans.
7 In the case of vaccines, Phase 1 studies may also
8 provide preliminary information on the capacity of
9 the vaccine to elicit an immune response in humans.
10 Counselor, I believe that the sections in
11 my declaration which I have just read adequately
12 address your question.
13 Q And do those sections in your declaration
14 support the statement that positive evidence of
15 immunogenicity is a good thing for vaccines for
16 infectious disease?
17 MR. BANSAL: Objection, asked and
18 answered.
19 A Counselor, I will reiterate that on
20 page 10 of my declaration, paragraph 17 states,
21 Clinical studies are studies conducted in humans
22 designed to characterize the tolerability, safety,

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1 immunogenicity, and, eventually, the efficacy of the
2 investigational vaccine product. Randomized,
3 controlled trials are typically required, with rare
4 exceptions, for a new drug (including a vaccine) to
5 receive marketing approval in the United States.
6 There are generally three phases of clinical studies
7 prior to approval or licensure: Phase 1, Phase 2,
8 and Phase 3.
9 Paragraph 18 of my declaration on
10 page 10, continuing to page 11, reads, Phase 1
11 clinical studies are typically conducted in a
12 comparatively small population of healthy volunteers
13 or individuals with the disease intended to be
14 treated, depending on the circumstances, and are
15 generally used to assess the tolerability, safety,
16 and appropriate doses for further study in humans.
17 In the case of vaccines, Phase 1 studies may also
18 provide preliminary information on the capacity of
19 the vaccine to elicit an immune response in humans.
20 Paragraph 19, the next paragraph, states,
21 Phase 2 clinical studies of investigational vaccines
22 are typically conducted in a larger and broader

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1 population. While the emphasis in Phase 1 is on
2 safety, Phase 2 studies of vaccine candidates
3 typically provide preliminary data regarding the
4 ability of the vaccine to generate an immune
5 response, information on the relationship between
6 the vaccine dose and the immune response, and
7 additional information on vaccine safety.
8 In paragraph 20 of my declaration on
9 page 11, in the middle of that paragraph, it states,
10 Phase 3 studies of vaccine candidates are typically
11 only carried out if the immunogenicity data from the
12 Phase 2 studies support the possibility/likelihood
13 of clinical effectiveness with acceptable safety.
14 Counselor, the sections that I have just
15 read from my declaration, in my view, clearly
16 adequately respond to the question you have asked.
17 Q What are the reasons that FDA is
18 interested in whether a vaccine to an infectious
19 disease generates an immune response?
20 A Could you, Counselor, please repeat your
21 question?
22 Q Yes. What are the reasons that FDA is

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1 interested in whether a vaccine for an infectious
2 disease generates an immune response?
3 A Counselor, I'm not here today as a
4 technical expert in vaccinology.
5 However, on a basic level, the purpose of
6 giving a therapeutic vaccine targeting prevention of
7 an infectious disease involves harnessing the
8 recipient of that vaccine's immune system, which is
9 instrumental in preventing manifestations that could
10 be clinically deleterious of that infectious disease
11 in that individual.
12 Q Is that rationale the same for infectious
13 diseases?
14 A Counselor, I don't quite understand your
15 question.
16 Q Sure. Is the rationale that you just
17 indicated in your answer the same for a vaccine for
18 an infectious disease?
19 A Counselor, could you please state your
20 question in a very complete sentence that
21 encompasses all of the ideas inherent in your
22 question?

37

1 Q I'll withdraw the question.
2 You've been involved in the review of
3 therapeutic protein-based drug products while at
4 FDA, right?
5 A That is correct.
6 Q We talked about some examples of those in
7 the blood replacement therapy space for
8 hemophilia A, right?
9 A I have worked, while at FDA, on
10 replacement therapies, including large molecule
11 replacement therapies, including replacement
12 therapies for hemophilia A.
13 Q And if I recall correctly, but you tell
14 me, one of the products that you reviewed -- that
15 you were involved in the clinical review of was
16 Adynovate, correct?
17 A Adynovate. Please tell me what page on
18 my CV you find that information.
19 Q So I'm looking at what's at page -- it
20 starts at the bottom of page 48 to page 49 of the
21 exhibit, 1164.
22 A Counselor, please restate your question.

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1 Q Yes. One of the products that you
2 reviewed while at FDA was Adynovate, correct?
3 A As stated, Counselor, on my CV on
4 page 49, Dr. Pierce has completed medical reviews of
5 numerous original BLAs including Zemaira,
6 alpha1-proteinase inhibitor (Human); Aralast NP,
7 alpha1-proteinase inhibitor (Human); Glassia,
8 alpha1-proteinase inhibitor (Human); Humate-P,
9 antihemophilic Factor/von Willebrand Factor Complex
10 (Human); Gamunex, immune globulin intravenous
11 (human); Flebogamma, immune globulin intravenous
12 (human); Gammaplex, immune globulin intravenous
13 (human); Vaccinia, immune globulin, which is a
14 product that is given to manage the side effects of
15 a prophylactic vaccine administration;
16 Berinert, C1-esterase inhibitor (Human); Kcentra,
17 prothrombin complex concentrate (human); Octaplex,
18 prothrombin complex concentrate (human);
19 Anthrasil, anthrax, an infectious disease, immune
20 globulin intravenous (human); Adynovate,
21 antihemophilic factor (recombinant), PEGylated; and
22 numerous BLA efficacy supplements which are listed

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1 in the remainder of that paragraph of my curriculum
2 vitae on page 49 of 54.
3 Q Okay. I just want to focus on Adynovate,
4 okay, just for ease of reference, okay.
5 Adynovate is a factor VIII replacement
6 therapy, right?
7 A That is my recollection.
8 Q For the treatment of hemophilia A, right?
9 A A replacement therapy for hemophilia A.
10 Q And it's a recombinant PEGylated product,
11 right?
12 A That is clear from the name of the
13 product here, the proper name, antihemophilic factor
14 (recombinant) (human).
15 Q The peg extends the half-life of the
16 factor VIII -- the recombinant factor VIII protein
17 so it can be dosed less frequently, right?
18 A That is my understanding of the function
19 of the polyethylene-glycol-based polymer, which is
20 linked to the remainder of the recombinant protein.
21 Q And for the review of that BLA,
22 presence -- strike that -- positive evidence of

40

1 immunogenicity was a significant concern, right?
2 A Counselor, you know, I'm not here today
3 speaking as a technical expert on hemophilia. I'm
4 not here today as a technical expert speaking on
5 protein chemistry. I'm not here today even as a
6 technical expert with respect to undesirable
7 immunogenicity that may be a property of certain
8 therapeutic proteins and biologics.
9 Rather, I'm here today to provide insight
10 into FDA's policies and procedures and FDA
11 reviewers' understanding of certain statements and
12 submissions by Moderna in furtherance of their
13 clinical trial of their mRNA vaccines and the
14 opinions that Dr. Krause has expressed in his
15 declaration vis-à-vis some of those statements in
16 the Moderna submissions.
17 I'm not sure that I am comfortable in
18 pursuing a line of questioning relating to
19 Adynovate. The considerations that FDA reviewers
20 may have with respect to undesirable immunogenicity
21 of therapeutic products which are not trying to
22 prevent an infectious disease and immunogenicity of

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1 **therapeutic products that are intended to prevent an**
2 **infectious disease are quite different.**
3 Q Okay. For hemophilia A patients taking
4 Adynovate, if they experience -- if the protein
5 causes immunogenicity -- is immunogenic, that's a
6 bad thing for the patients, right?
7 **A Counselor, I'm not here as a technical**
8 **expert on hemophilia or the clinical sequelae of**
9 **immunogenicity and inhibitor development in**
10 **hemophilic patients who are receiving replacement**
11 **therapies.**
12 **If you pursue this line of questioning, I**
13 **may have to consult a variety of literature**
14 **references in order to provide the most accurate and**
15 **complete testimony under oath, and I'm not**
16 **comfortable doing that.**
17 Q Well, you know that inhibitor development
18 for these patients would mean that they would not be
19 able to take any recombinant factor replacement
20 therapy ever again, right?
21 **A Your statement is inaccurate.**
22 Q You disagree?

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1 **A I disagree --**
2 Q Why?
3 **A -- with the substance of your statement.**
4 Q Why?
5 **A As I have stated, I am not here as a**
6 **technical expert on hemophilia A and those**
7 **replacement therapies.**
8 Q Okay. So let's take a step back, then.
9 So in your review of the BLA for that
10 Adynovate product, was positive evidence of
11 immunogenicity evidence of efficacy or a safety
12 concern?
13 MR. BANSAL: Objection, form.
14 **A As I've stated, Counselor, I'm not here**
15 **today to provide technical expertise with respect to**
16 **hemophilia or immunogenicity as it constitutes a**
17 **potential side effect of concern for the**
18 **administration of nonprophylactic vaccine biologics**
19 **such as Adynovate, a clotting factor replacement in**
20 **hemophilia A.**
21 **There are many considerations with**
22 **respect to the development of inhibitors in**

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1 **hemophilia patients receiving clotting factor**
2 **replacement therapies. It's beyond the range of**
3 **considerations at play in today's proceeding, and**
4 **I'm not comfortable, that since this information was**
5 **not the subject of my declaration, in proceeding to**
6 **give an answer to your question at this time.**
7 Q How many years did you work at FDA?
8 **A 34 years and 7 months I worked at FDA.**
9 Q So after working at FDA for over three
10 decades, you can't provide testimony as to whether
11 the positive evidence of immunogenicity for a
12 therapeutic protein is a signal of efficacy or a
13 signal of a safety concern.
14 Is that your testimony, sir?
15 **A Immunogenicity in therapeutic -- that is**
16 **observed after administration of therapeutic**
17 **proteins is a phenomenon which can have various**
18 **implications or lack of implications.**
19 **There are many examples where**
20 **immunogenicity is observed to occur in a certain**
21 **percentage of patients who receive therapeutic**
22 **proteins that does not diminish their efficacy and**

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1 **does not appear to be a safety concern.**
2 **However, again, I would emphasize that**
3 **I'm not here as a therapeutic -- as an expert, a**
4 **technical expert, with respect to these nuances of**
5 **inhibitor development or immunogenicity of clotting**
6 **factor replacement therapies and other therapeutic**
7 **proteins.**
8 **Rather, the focus of my presence here**
9 **today is to help clarify the -- anything from my**
10 **declaration relating to Dr. Krause's declaration and**
11 **his opinions regarding statements that Moderna has**
12 **made in the submissions that Moderna made to FDA.**
13 Q Okay. But I'm entitled to ask questions
14 about your experience and background. Okay, sir?
15 So my question is this. Development of
16 antibodies can limit product efficacy in patients
17 treated with therapeutic protein products.
18 Is that true?
19 MR. BANSAL: Objection, asked and
20 answered.
21 **A Counselor, I've given an example of where**
22 **the development of antibodies to a protein**

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1 **therapeutic may or may not provide a diminution of**
2 **efficacy of that product, and they may or may not**
3 **constitute a safety concern. We have to look -- FDA**
4 **looks at those cases on a case-by-case basis.**
5 Q Which is why I brought it down to that
6 factor VIII therapy, because I thought it would be
7 helpful for you, but you didn't want to answer that
8 question.
9 Do you want to go back to Adynovate, and
10 I'll ask it in the context of that?
11 The development of neutralizing
12 antibodies in that specific example would block the
13 efficacy of a therapeutic protein. True?
14 MR. BANSAL: Objection, outside the scope
15 of Dr. Pierce's declaration.
16 **A The phrasing of your question is**
17 **problematic, as it does not -- I infer from the**
18 **phrasing of your question that you have a very**
19 **limited understanding of the implications of**
20 **inhibitor development in hemophilia A.**
21 **It is a complex field with a vast**
22 **literature, which I do not have access to at the**

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1 **present time to help educate you so that you would**
2 **be able to craft a more appropriate question in this**
3 **regard.**
4 Q Is the -- is positive evidence of the
5 development of NABs in the context of the Adynovate
6 clinical trials, was that a signal of efficacy or a
7 signal of a safety concern?
8 MR. BANSAL: Objection, outside the scope
9 of Dr. Pierce's declaration.
10 Q Is that a question you can answer, sir?
11 **A Counselor, I believe that I have provided**
12 **insight into your question, stating that when**
13 **antibodies form after administration of a**
14 **therapeutic protein product or replacement therapy,**
15 **they can have variable clinical significance. They**
16 **can have effects on safety or a lack of effect on**
17 **safety. They can potentially have an effect on**
18 **efficacy or a lack of effect on efficacy.**
19 MR. BANSAL: Counselor, is it a good time
20 for a break so that the next one, we can just break
21 for lunch after that?
22 MR. PRUSSIA: Let's take a break.

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1 MR. BANSAL: Ten minutes?
2 MR. PRUSSIA: Sure.
3 (Recess from 10:38 a.m. until 10:49 a.m.)
4 BY MR. PRUSSIA:
5 Q So Doctor, have you ever been involved
6 personally in the regulatory review of an mRNA
7 vaccine?
8 **A During my career at FDA, I have not been**
9 **personally involved in the regulatory review of an**
10 **mRNA vaccine. As a consultant, after my departure**
11 **from FDA in 2020, I have had some involvement in**
12 **mRNA vaccine.**
13 Q During your time at FDA, were you
14 personally involved in the regulatory review of a
15 prophylactic nucleic acid vaccine?
16 **A During my time at FDA, I was not**
17 **personally involved in the regulatory review of an**
18 **mRNA prophylactic vaccine.**
19 Q And I was looking through your CV, and I
20 didn't -- it wasn't apparent to me that any of your
21 publications in peer-reviewed journals involved mRNA
22 vaccines.

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1 Is that true?
2 **A None of my publications have involved**
3 **mRNA vaccines.**
4 Q And so none of your publications in
5 peer-reviewed journals involved the delivery of
6 exogenous mRNA, correct, to a cell?
7 **A None of my publications have involved**
8 **delivery of exogenous mRNA.**
9 Q Have you conducted research involving
10 nucleic acid vaccines?
11 **A I have not conducted research**
12 **involving -- original research involving nucleic**
13 **acid vaccines.**
14 Q Have you conducted any original research
15 involving -- well, strike that.
16 So then you've not conducted any original
17 research involving mRNA vaccines, right?
18 **A Counselor, could you please define for me**
19 **in the context of your question the word "research"?**
20 Q Well, any study that you have conducted.
21 **A Counselor, please repeat your question.**
22 Q So you have not conducted any original

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1 research involving mRNA vaccines.
2 Is that correct?
3 **A I have not conducted any original**
4 **research investigating mRNA vaccines.**
5 Q Okay. You're not a lawyer, right?
6 You're not a lawyer, right?
7 **A I'm not aware of -- please state a**
8 **complete question.**
9 Q You're not a lawyer, right?
10 **A Oh, a lawyer. I misheard you.**
11 Q That's okay.
12 **A My apologies.**
13 **Correct. I have no law degree. I have**
14 **not been enrolled in law school.**
15 Q And you have no legal training, right?
16 **A I have no formal legal training.**
17 Q And you haven't been trained to interpret
18 statutes of the United States Code, right?
19 **A I have, during the course of my FDA work,**
20 **been involved with the application of FDA**
21 **regulations, and it could be said that in some**
22 **instances, FDA regulations interpret statutes;**

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1 **namely, the Food, Drug, and Cosmetic Act.**
2 Q Okay. Fair enough.
3 You have your declaration open, and if it
4 helps, you can look at your table of contents. But
5 my question is this.
6 Your declaration contains no section on
7 legal standards, correct?
8 **A My table of contents in my declaration**
9 **does not show a section relating to legal standards.**
10 Q Do you have any issued patents in your
11 name?
12 **A I have no patents that I have -- that I**
13 **have had issued in my name.**
14 Q And prior to your work in these
15 proceedings, had you ever consulted in connection
16 with a patent case?
17 **A Prior to this project, I have not**
18 **previously consulted in a patent law case.**
19 Q Are you familiar with the term "priority
20 date"?
21 **A Counselor, on page 7 of Dr. Krause's**
22 **declaration, under Claim Construction, Roman numeral**

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1 **III, Legal Standards, A, paragraph 13, it reads, I**
2 **understand that patent claims are interpreted from**
3 **the perspective of a person of ordinary skill in the**
4 **art at the time of the patent's relevant priority**
5 **date.**
6 **There appears the term "priority date."**
7 Q Fair. Did you consider the priority date
8 of the patents at issue in these proceedings in
9 connection with forming your opinions as stated in
10 your declaration?
11 **A Counselor, the priority date of these**
12 **patents was not a primary or substantive concern**
13 **that would have been taken -- that was taken into**
14 **account in my preparation of the -- of my**
15 **declaration which responds to certain aspects of**
16 **Dr. Phillip Krause's declaration.**
17 Q And you did not review the prior art
18 cited by petitioners in these proceedings, right?
19 Well, I can help you. Paragraph 47, if
20 you want to look at paragraph 47 of your
21 declaration.
22 I'll withdraw the prior question. I'll

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1 ask this question instead.
2 If you go to paragraph 47 of your
3 declaration --
4 **A Yes.**
5 Q -- about halfway in the middle of the
6 paragraph --
7 **A Yes.**
8 Q -- you state, I have not reviewed the
9 prior art cited by petitioners and offer no opinions
10 on reasonable expectation of success based on that
11 prior art.
12 Did I read that correctly?
13 **A You read it correctly, and those**
14 **statements are true and correct.**
15 Q Thank you.
16 And so you are not offering an opinion on
17 obviousness, correct?
18 **A That is correct.**
19 Q And you are likewise not offering an
20 opinion on anticipation, correct?
21 **A I have not offered an opinion in my**
22 **declaration on the term "anticipation."**

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1 Q If you could please turn to the materials
2 considered section of your declaration. It's on
3 page 7 and 8.
4 **A Pages 7 and 8 of my declaration.**
5 Q I do not see Exhibit 2057 listed in your
6 materials consideration.
7 Is that correct?
8 **A Correct. I also do not see Exhibit 2057.**
9 Q And so is that fair to say that you did
10 not review or -- strike that.
11 You did not review Exhibit 2057 in
12 connection with forming your opinions in these
13 proceedings?
14 **A Counselor, could you read the title of**
15 **Exhibit 2057?**
16 Q The title of Exhibit 2057 is, SARS-CoV-2
17 Disease Enhancement and Vaccination.
18 **A Counselor, I do not know the answer to**
19 **your question.**
20 Q Okay. Maybe this will help.
21 You do not discuss disease enhancement in
22 your declaration, correct?

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1 **A Counselor, to my recollection, I do not**
2 **have a specific section of my declaration which**
3 **delves into disease enhancement in the context of**
4 **administering prophylactic vaccines.**
5 Q Are you familiar with the concept of
6 disease enhancement?
7 **A Counselor, I'm not here today as an**
8 **expert in vaccinology or in disease enhancement,**
9 **which is a phenomenon that can sometimes occur after**
10 **the administration of prophylactic vaccines.**
11 **I have heard the term "disease**
12 **enhancement," and my understanding of disease**
13 **enhancement is at a basic general level.**
14 Q Do you have any personal knowledge of the
15 issue of disease enhancement as it specifically
16 relates to SARS-CoV-2?
17 **A Counselor, I'm here today with the**
18 **primary focus of providing insight into my**
19 **declaration, which is responding to Dr. Krause's**
20 **declaration, the aspects of which involve his**
21 **opinions relating to certain statements in Moderna's**
22 **submissions to FDA.**

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1 **Would you please repeat your question?**
2 Q Yeah. Do you have any personal knowledge
3 of the issue of disease enhancement as it
4 specifically relates to SARS-CoV-2, aside from what
5 is stated in Dr. Krause's declaration?
6 Let me ask it this way. Prior to your
7 involvement -- I'll withdraw the question, ask it
8 this way.
9 Prior to your involvement in these
10 proceedings, did you have any personal knowledge of
11 the issue of disease enhancement as it specifically
12 related to SARS-CoV-2?
13 **A Prior to my involvement in these**
14 **proceedings, yes.**
15 Q Okay. And what was your understanding of
16 that?
17 **A Prior to my understanding of -- prior to**
18 **my involvement in these proceedings, my**
19 **understanding of disease -- possible disease**
20 **enhancement in the context of vaccines for**
21 **SARS-CoV-2 was that the possibility of disease**
22 **enhancement would be something that FDA was**

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1 **interested in having evaluated. There was**
2 **information in the public domain relating to this,**
3 **as I recall.**
4 Q And you're familiar with the spike
5 protein of SARS-CoV-2, right?
6 **A** [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 Q In the context of the viral SARS-CoV --
13 strike that.
14 In the context of the viral protein,
15 SARS-CoV-2, do you know what the function is of the
16 spike protein?
17 MR. BANSAL: Objection, outside the scope
18 of Dr. Pierce's declaration.
19 **A Counselor, could you provide me with**
20 **Exhibit 2056, a copy thereof, in order that I may**
21 **give -- have more comfort in providing my response?**
22 Q So we don't have copies of it as an

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1 exhibit for this proceeding.
2 So without the benefit of Exhibit 2056,
3 are you able to answer the question?
4 **A Please restate the question.**
5 Q Sure. In the context of the viral
6 protein SARS-CoV-2, do you know what the function is
7 of the spike protein?
8 MR. BANSAL: Objection, outside the scope
9 of Dr. Pierce's declaration.
10 **A Counselor, this is not something, as a**
11 **technical matter, that was covered in my**
12 **declaration.**
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted] .
19 [redacted]
20 [redacted]
21 [redacted]
22 Q [redacted]

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1 [redacted]
2 [redacted]
3 MR. BANSAL: Objection, outside the scope
4 of Dr. Pierce's declaration.
5 **A** [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 Q And so --
14 **A** [redacted]
15 Q And so if the -- strike that.
16 And so if the spike protein is involved
17 in attachment of the virus to the cells and cell
18 entry, if that protein is associated with potential
19 enhancing antibodies, would that be a concern?
20 MR. BANSAL: Objection, form. Objection,
21 outside the scope of Dr. Pierce's declaration.
22 **A Counselor, you're asking me a question in**

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1 **which there are many factors that would come into**
2 **play which would affect my answer, and I don't have**
3 **the information regarding what the status of those**
4 **multiple factors are. So I'm not comfortable in**
5 **responding to your question today.**
6 Q Okay. All right. Fair.
7 Do you know -- I'm just asking if you
8 know.
9 Do you know what the other surface
10 proteins are on a betacoronavirus?
11 MR. BANSAL: Objection, form. Objection,
12 outside the scope of Dr. Pierce's declaration.
13 **A Counselor, I've stated that I'm not a**
14 **virologist. My declaration does not go into those**
15 **details of SARS-CoV-2 structure and function of**
16 **various components of the intact SARS-CoV-2 virus in**
17 **order for me to discuss further as- -- detailed**
18 **aspects of virus structure and function. I would**
19 **have to consult the literature.**
20 **We don't, I would put forth, have time**
21 **for me to do that today. So I'm not comfortable in**
22 **answering your question.**

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1 Q Okay. Just do you know what, for
2 example, what the N protein is?
3 **A Counselor, I am not 100 percent sure that**
4 **I know, in fact, what the N protein is.**
5 Q Do you have an understanding as to
6 whether it's involved in mediating fusion and entry
7 into the cell?
8 MR. BANSAL: Objection, form. Objection,
9 outside the scope of Dr. Pierce's declaration.
10 **A Counselor, I have informed you that** [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 **I didn't address any other proteins or**
20 **viral structure details in my declaration, and I'm**
21 **not comfortable in answering questions in that**
22 **regard as I'm not an expert in the matter. And**

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1 **personally, it seems to me to be noncontributory to**
2 **these proceedings.**
3 Q Fair enough. So switching gears a little
4 bit, if you look at paragraph 30 of your
5 declaration.
6 **A Paragraph 30 of my declaration, I am**
7 **turning to it. On page 15. Yes.**
8 Q And in that first sentence, you state, I
9 agree with Dr. Krause that, within these pre-IND
10 documents, FDA expects to see some kind of rationale
11 from the sponsor for why the sponsor believes that
12 the risk-benefit calculation for administering the
13 drug to a person comes out in favor of going ahead
14 with a trial.
15 Did I read that correctly?
16 **A You did read that sentence correctly in**
17 **paragraph 30 of my declaration on page 15.**
18 Q And if you look at paragraph 35 of your
19 declaration, you also agree with Dr. Krause that the
20 sponsor's pre-IND submissions are designed to
21 educate the FDA regarding the proposed product.
22 Did I read that correctly?

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1 **A Yes. In fact, the sentence goes on to**
2 say in parentheses, product (such as a vaccine).
3 Q Now, would you agree that the pre-IND
4 takes on that purpose that we just looked at in your
5 declaration, especially in the context of a class of
6 products that had never before received regulatory
7 approval?
8 MR. BANSAL: Objection, form.
9 **A Please restate your question.**
10 Q Sure. For a class of products that had
11 never previously received regulatory approval, do
12 you agree that it's true that the pre-IND
13 submissions are designed to educate the FDA
14 regarding the proposed product?
15 **A I agree that pre-IND submissions are**
16 **designed to educate the FDA regarding the proposed**
17 **investigational product, irrespective of whether**
18 **that product is first in class and irrespective of**
19 **whether any similar products have received approval**
20 **by FDA or any other regulatory authority.**
21 Q For a product that is first in class,
22 would -- strike that.

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1 For a product that is first in class,
2 what sort of information is the FDA looking for in
3 the pre-IND?
4 **A So your question is limited to pre-IND**
5 **meeting materials?**
6 Q Yes, sir.
7 **A Yes. As stated on page 16 and 17 of my**
8 **declaration, A pre-IND meeting is a tool for**
9 **sponsors to communicate with FDA before submitting**
10 **IND applications. The meeting may serve as a way**
11 **for the sponsor to receive specific feedback on its**
12 **planned IND application, including as to the**
13 **sponsor's proposed clinical study design, chemistry,**
14 **manufacturing and quality controls, as well as the**
15 **design and results of the sponsor's preclinical**
16 **studies. A pre-IND meeting may occur face-to-face,**
17 **but typically is conducted via teleconference or via**
18 **written response.**
19 **Paragraph 32 goes on to state that, Prior**
20 **to a pre-IND meeting, the sponsor must submit a**
21 **meeting request and a meeting package. FDA advises**
22 **industry that "premeeting preparation is critical**

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1 **for achieving a productive discussion or exchange of**
2 **information" and instructs that the meeting package**
3 **"should provide information relevant to the**
4 **discussion topics and enable the FDA to prepare**
5 **adequately for the meeting." FDA guidance**
6 **emphasizes that "it is critical that the entire**
7 **meeting package content support the intended meeting**
8 **objectives."**
9 **Paragraph 33 of my declaration on page 17**
10 **at the top states, The pre-IND meeting package must**
11 **include sufficient background information to support**
12 **the questions in the package. FDA provides some**
13 **guidance as to what information should be included**
14 **within the meeting package.**
15 **For example, the package may include**
16 information on (1) the drug product such as the
17 manufacturing process and controls; (2) pharmacology
18 and toxicology, such as data from preclinical
19 studies; and/or (3) outlines or drafts of the
20 proposes clinical trials, such as trial design,
21 objectives, intended patient population, monitoring
22 procedures, anticipated risks, et cetera.

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1 Paragraph 34 states that, In addition,
2 when planning clinical trials, the sponsor should
3 ensure that sufficient safety and efficacy data from
4 nonclinical studies and/or clinical trials, if
5 they're available, are available to support human
6 exposure by the route at the dosage for the duration
7 and in the trial population to be studied.
8 Paragraph 35 says, I also agree with
9 Dr. Krause that the sponsor's pre-IND submissions
10 are designed to educate FDA regarding the proposed
11 product, such as a vaccine, and to facilitate
12 receiving feedback on parts of the submission that
13 will likely form parts of the IND application.
14 So Counselor, I believe that the sections
15 of my declaration that I have read provide insight
16 into the nature and purpose of pre-IND submissions
17 and the way that they are used by FDA --
18 Q Okay. Thank you.
19 **A -- and sponsors, and is responsive to**
20 **your question.**
21 Q Thank you for that.
22 If you look at paragraph 37 of your

66

1 declaration. You state in that first sentence that,
2 The IND regulations further provide that the amount
3 of information on a particular drug that must be
4 submitted in an IND to assure the accomplishment of
5 the objectives described above depends upon such
6 factors as the novelty of the drug, the extent to
7 which it has been previously studied, and then you
8 go on.
9 Do you see that?
10 **A I do.**
11 Q And so for -- so just to be clear, the
12 amount of information in a pre-IND submission for an
13 IND, that a sponsor is expected to include depends
14 upon the extent to which the drug has been
15 previously studied.
16 Do you agree with that?
17 **A It could well be influenced by the degree**
18 **to which the particular agent and similar agents**
19 **have been previously studied, yes.**
20 Q Is it fair to say that the less a drug
21 has been previously studied, the broader information
22 that -- about that drug FDA expects a sponsor to

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1 submit?
2 MR. BANSAL: Objection, form.
3 **A Counselor, FDA expects that adequate**
4 **information will be contained within FDA submissions**
5 **to accomplish the goal of that submission to FDA.**
6 Q I'm just trying to understand what
7 "adequate" is in the context of a drug that had not
8 been previously studied before. Okay? Do you have
9 that in mind?
10 **A So irrespective of whether a drug has**
11 **been studied before, there is -- it is incumbent**
12 **upon the sponsor to submit information that is**
13 **relevant and informative to FDA in coming to an**
14 **opinion about whether there are unreasonable risks**
15 **that would result in a clinical hold of a proposed**
16 **protocol and whether there is a prospect of benefit**
17 **that would justify going forward with a clinical**
18 **trial.**
19 **So that informs the meaning of the word**
20 **"adequate" in this instance.**
21 Q So is it fair to say that, generally
22 speaking, the less that -- the less information

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1 that's available about the particular study drug,
2 the broader the information about that drug needs to
3 be submitted to FDA?
4 MR. BANSAL: Objection, form. Objection,
5 asked and answered.
6 **A Counselor, in my personal experience as**
7 **an FDA reviewer and being involved with FDA review**
8 **process for over 34 years, it is expected by FDA**
9 **reviewers that a sponsor will submit a critical mass**
10 **of relevant information that will assist FDA in**
11 **evaluating the potential safety and efficacy of the**
12 **investigational product.**
13 **And this very commonly involves data,**
14 **preclinical data and sometimes clinical data, on**
15 **molecules that have some relationship to the**
16 **proposed investigational product but are not**
17 **identical to the proposed investigational product.**
18 **So related products, members of a same or**
19 **similar classes, information on such products are**
20 **commonly submitted in pre-IND meeting materials and**
21 **also in INDs to further a sponsor's goal of allowing**
22 **FDA to allow a clinical study to proceed rather than**

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be placed on a clinical hold.
Q In identifying that information, is the clinical sponsor making any representation about how those same or similar products function?
MR. BANSAL: Objection, form.
A Counselor, at various places in my declaration, I state that a sponsor exercises discretion in putting together their submissions to FDA, that their submissions are not meant to be exhaustive review articles, and the information and references that sponsors include in their submissions to FDA are expected to be relevant, accurate, and truthful, and contributory toward the FDA process of evaluating the prospects of safety and efficacy for the proposed investigational product to be used in a human clinical trial.
(Previously marked Exhibit 2050 presented to the witness.)
BY MR. PRUSSIA:
Q So you've been handed what's been marked as Exhibit 2050.
A [redacted]

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[redacted] **And it's marked as Exhibit 2050, which is listed in my declaration at the top of the table on page 8 as a material considered in the preparation of my declaration responding to Dr. Krause's declaration in this matter.**
Q Okay. If you look at the page with the Bates stamp ending in 64 at the bottom of the page.
A Yes.
Q [redacted]
Do you see that?
A Yes, I do.
Q [redacted]
Did I read that correctly?
A [redacted]

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[redacted]
protamine (Petsch et al 2012).
(Previously marked Exhibit 2051 presented to the witness.)
BY MR. PRUSSIA:
Q You've been handed Exhibit 2051.
Do you have that?
A [redacted] **, Exhibit Moderna 2051, which is a number listed in the table toward the top of page 8,** [redacted]
Q Okay. And in Exhibit 2051, at the page ending in Bates stamp 91, [redacted]

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[redacted]. Right?
A [redacted]
(Previously marked Exhibit 2052 presented to the witness.)
BY MR. PRUSSIA:
Q I'm handing you Exhibit 2052.
And the same sentence appears in Exhibit 2052, right?
A The exhibit that is marked Moderna 2052 that I was just handed appears on my list of materials considered in the preparation of my declaration [redacted]

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1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted].
5 **And turning to the section -- I'm sorry,**
6 **Counselor. Please point me to the section in**
7 **Exhibit 2052 that you wish me to discuss in**
8 **answering your question.**
9 Q It's on the page ending in Bates 82.
10 **A 182.** [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 Q Okay. [redacted]
21 [redacted]
22 [redacted]

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1 [redacted]
2 **A Counselor, FDA reviewers review all of**
3 **the information that is contained within FDA**
4 **submissions,** [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 Q Okay. So the vaccine --
12 **A** [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 Q But the FDA reviewer would have had that
18 information, right?
19 **A Counselor, please clarify. Would have**
20 **had that information at what point in time?**
21 Q At the time --
22 **A Through the submission of what type of**

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1 **document?**
2 Q Through the documents that we're looking
3 at.
4 **A Counselor,** [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 **So I cannot speak to the information in**
12 **detail that FDA's had access to** [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 Q And in your experience as an FDA
17 reviewer, information about the delivery vehicle for
18 the mRNA used in the Moderna vaccine would have been
19 provided and available to the FDA reviewer, right?
20 **A Would have been provided and available to**
21 **the FDA reviewer in which submission? At what point**
22 **in time in the drug development process do you mean?**

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1 Q At all stages, from the moment the
2 pre-IND is submitted.
3 Is it your testimony that FDA would not
4 have required that information from Moderna?
5 **A It is standard industry practice that**
6 **identity and basic chemistry and manufacturing**
7 **control information is routinely provided to FDA in**
8 **submissions, including most particularly pre-IND**
9 **submissions, investigator brochures, and clinical**
10 **trial protocols.**
11 Q Okay. So the FDA would have known that
12 [redacted]
13 [redacted]
14 MR. BANSAL: Objection, asked and
15 answered.
16 **A Counselor, could you define "different"**
17 **in this context?**
18 Q For example, the Petsch vaccine was
19 complexed with protamine, correct?
20 **A Counselor,** [redacted]
21 [redacted]
22 [redacted]

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1 [redacted].
2 Q Okay. But you agree that [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 **A FDA reviewers, like you today here, sir,**
7 **have the right to ask the sponsor any question that**
8 **they believe is pertinent to their evaluation of the**
9 **potential efficacy and safety of an investigational**
10 **product, including questions relating to the**
11 **chemical composition, and in the case of a**
12 **therapeutic vaccine, the delivery methodology.**
13 Q And if the Moderna vaccine -- if the
14 FDA -- strike that.
15 If the FDA reviewer ascertained that the
16 Moderna vaccine was not complexed with protamine,
17 then the FDA reviewer would conclude that the two
18 vaccines were chemically distinct. True?
19 MR. BANSAL: Objection, outside the scope
20 of Dr. Pierce's declaration. Objection, form.
21 **A Counselor, we have reviewed that** [redacted]
22 [redacted]

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1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 MR. PRUSSIA: Okay. Move to strike,
21 nonresponsive.
22 Q Sir, my only question is, the FDA

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1 investigator would be able to ascertain whether the
2 two vaccines are chemically distinct.
3 True or not?
4 MR. BANSAL: Objection, form. Objection,
5 outside the scope of Dr. Pierce's declaration.
6 Objection, asked and answered.
7 **A Counselor, I have stated that** [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 [redacted]
21 [redacted]
22 [redacted]

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1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 [redacted]
21 [redacted]
22 [redacted]

81

1 [redacted]
2 [redacted]
3 [redacted]
4 Q Would the FDA reviewer understand the
5 difference between mRNA and DNA?
6 **A There are many different reviewing**
7 **disciplines at FDA that form part of a team**
8 **reviewing submissions such as what we've been**
9 **dealing with today in** [redacted]
10 [redacted]
11 [redacted]**, including**
12 **chemists, clinical pharmacologists, pharmacologists,**
13 **toxicologists, statisticians, clinicians,**
14 **microbiologists, and others. And each has their own**
15 **unique perspective.**
16 **And it's -- nevertheless, it's reasonable**
17 **to conclude that during the course of a normal FDA**
18 **review, the information -- if the information is**
19 **accessible to FDA to show, to the extent of**
20 **similarity and dissimilarity of products that are --**
21 **for which information has been submitted as to**
22 **results of investigations that the sponsor concludes**

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1 **are relevant to the investigation that's planned for**
2 **their clinical trial of Moderna's mRNA vaccine, then**
3 **the reviewers are going to look at that, and based**
4 **on their training and experience, they're going to**
5 **have an understanding of those similarities and**
6 **differences.**
7 Q Would the FDA review team understand the
8 differences between replicon-based RNA and mRNA?
9 **A Sir, I'm not here today as a subject**
10 **matter expert in replicon-based vaccinology.**
11 **Could you please repeat your question?**
12 Q I'm just asking whether the FDA review
13 team would understand the differences between the
14 two.
15 MR. BANSAL: I'm going to object to form
16 of that question.
17 **A Counselor, as I've just outlined, there**
18 **are people at FDA with a variety of types of**
19 **background and expertise that form part of a team in**
20 **reviewing FDA submissions, and the -- in the**
21 **division and office, as part of the Center for**
22 **Biologics Evaluation and Research, that would be**

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1 **reviewing** [redacted]**, I**
2 **anticipate that there would be individuals that**
3 **would be familiar with the differences and**
4 **similarities between replicon-based mRNA vaccines**
5 **and the type of mRNA vaccines that Moderna was**
6 **proposing to investigate in its clinical trial**
7 **development program under INDs.**
8 Q With respect to [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted] would the FDA approve a drug product
13 solely based on the information provided in the
14 proof of concept?
15 MR. BANSAL: Objection, form. Objection,
16 outside the scope of Dr. Pierce's declaration.
17 **A Counselor, my declaration does not in**
18 **general touch on criteria for approval of any**
19 **specific product in detail.**
20 **But could you please restate your**
21 **question?**
22 Q Well, I'll shorten it.

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1 Would the FDA approve a drug product
2 solely based on the information provided in the
3 proof of concept section [redacted]
4 [redacted]
5 **A Counselor, as I've explained, I believe**
6 **the proof of concept section in these types of**
7 **documents are one part of a totality of information**
8 **that FDA reviews. Each part has its own importance.**
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 Q Okay. You know, sir, the FDA would not
19 approve the investigational product based on the
20 information provided in the proof of concept
21 section, don't you?
22 **A To continue with the --**

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1 MR. BANSAL: Slow down. Let me offer my
2 objection.
3 THE WITNESS: Of course, I'm sorry.
4 MR. BANSAL: Objection, form. Objection,
5 asked and answered.
6 **A So Counselor, I meant to add to my answer**
7 **to your original question that because I don't have**
8 **access to all of the elements of a biologic license**
9 **application and don't have the advantage of input**
10 **from other reviewing disciplines -- chemistry,**
11 **product reviewers, pharmacology, toxicology,**
12 **statistics, facilities inspection, et cetera -- and**
13 **the benefit of discussing with supervisors and**
14 **management and other colleagues, I'm certainly not**
15 **in a position to opine on the approvability of a**
16 **hypothetical submission to FDA in terms of marketing**
17 **approval or even whether an IND would -- containing**
18 **this information would be placed on clinical hold or**
19 **not.**
20 **That's an impossible task for me today.**
21 **And I wouldn't be able to respond to that under**
22 **oath.**

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1 Q So it's your testimony that FDA would
2 approve the product based on the information in the
3 proof of concept section [redacted] Is
4 that your testimony, sir?
5 MR. BANSAL: Objection, form. Objection,
6 asked and answered.
7 **A Counselor, I have stated that FDA looks**
8 **at the totality of information that is presented in**
9 **submissions. The information that FDA carefully**
10 **considers is not limited in any stretch of the**
11 **imagination to the proof of concept section.**
12 **However, the proof of concept section is**
13 **an important section that several different**
14 **reviewing divisions look at and take into account in**
15 **making their determination of how to proceed in a --**
16 **with respect to regulation of the regulated**
17 **entities' proposals under the FDA submission in**
18 **question.**
19 Q [redacted]
20 [redacted]
21 [redacted]
22 **A Counselor, could you please hand me**

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1 **and/or tell me the exact location of those**
2 **references** [redacted]
3 [redacted]
4 Q In the sections of the documents that are
5 in front of you. You can't answer that question,
6 sir, without me showing you line and page where to
7 go?
8 MR. BANSAL: Objection, argumentative.
9 Counsel, if he's asking for a document,
10 can you just give it to him?
11 MR. PRUSSIA: The documents are in front
12 of him. As he said himself, he has a limited
13 declaration. And he has statements in his
14 declaration referring to M[redacted]
15 [redacted] It's a very simple question.
16 Q In these documents, [redacted]
17 [redacted]
18 **A Among the documents that I have reviewed**
19 **in preparing my declaration,** [redacted]
20 [redacted]
21 [redacted]
22 [redacted]

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1 [redacted]
2 [redacted]
3 [redacted]
4 Q And FDA ultimately approved the vaccines
5 in here based on Moderna's own clinical data,
6 correct?
7 **A That is not correct. You've used**
8 **vaccines in the plural.**
9 Q Okay, okay. Thank you for that
10 clarification.
11 FDA ultimately -- well, actually --
12 FDA ultimately approved the vaccine that
13 was subject of the BLA for SARS-CoV-2 based on
14 Moderna's own clinical data. True?
15 MR. BANSAL: Objection, form.
16 **A Point of clarification. Are you asking**
17 **me to answer based on information in my declaration,**
18 **or are you asking me to answer on the basis of my**
19 **general knowledge?**
20 Q I would assume it would include both.
21 Didn't you bring your own general knowledge to bear
22 in drafting your declaration?

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1 A I brought my general knowledge to bear in
2 drafting my declaration.
3 Q Okay. So please answer the question.
4 A Please restate the question.
5 Q Okay. FDA ultimately approved the
6 vaccine that was subject of the BLA for SARS-CoV-2
7 based on Moderna's own clinical data, right?
8 MR. BANSAL: Objection, form.
9 A Counselor, I do not have the entire
10 biologic license application for Spikevax, Moderna's
11 mRNA vaccine against SARS-CoV-2 virus, which causes
12 COVID-19, before me here today.
13 This is presumably an enormous document.
14 I have never seen it. It would be expected to
15 contain a wide variety of information, all of which
16 was subject to FDA review prior to licensing the
17 product, and it is highly plausible that there was
18 significant information in various background
19 sections that would have included studies of related
20 products.
21 These could have included DNA vaccines.
22 These could have included replicon-based

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1 self-amplifying mRNA. There could also have been
2 information regarding the ability of some nucleic
3 acid products to be administered and to successfully
4 enter cells, such as small interfering RNA, which
5 was ultimately a product licensed for the treatment
6 of ATTR, polyneuropathy.
7 MR. PRUSSIA: Strike that.
8 Nonresponsive.
9 Q You don't know, right, because you didn't
10 review the Summary Basis of Approval, right?
11 MR. BANSAL: Objection, form.
12 A I do not recall whether or not I have
13 read in the past the Summary Basis of Regulatory
14 Action for Spikevax.
15 Q And that would contain the best
16 information with respect to what FDA relied upon in
17 approving the BLA, right?
18 A In coming to an understanding of the
19 information that FDA took into account in approving
20 Spikevax, there are a variety of documents which
21 would be important in digesting, and these -- while
22 these would include the Summary Basis of Regulatory

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1 Action, they would also include the individual
2 discipline reviews, supervisory reviews and memos,
3 and other related documents, even in some cases
4 email correspondence that from time to time is
5 posted on the web following an approval action.
6 MR. PRUSSIA: Let's take a break.
7 (Recess from 11:57 a.m. until 12:13 p.m.)
8 BY MR. PRUSSIA:
9 Q You mentioned earlier that these
10 documents we've been looking at are only excerpts,
11 right?
12 A That is correct.
13 Q So for example --
14 A For the most parent. The Moderna
15 documents are excerpts.
16 Q So, for example, if you look at
17 Exhibit 2050.
18 A Exhibit 2050, [redacted]
19 [redacted]
20 Q Do you see section 5 in the table of
21 contents?
22 A Section 5 on page 4, [redacted]

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1 starting on page 28.
2 Q You didn't have access to that portion of
3 the document, right?
4 A I did not have access through this --
5 through the preparations for this proceeding and the
6 preparation of my declaration to section 5, [redacted]
7 [redacted] starting on page 28, according to the
8 table of contents for Moderna Exhibit 2050.
9 Q And in your experience, at a high level,
10 what sort of information is provided in section 5?
11 A [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]
19 [redacted]
20 [redacted]
21 [redacted]
22 [redacted]

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1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 Q Okay. Just a few more questions.
13 Would you expect that -- strike that.
14 In your experience -- given the fact this
15 is a vaccine, in your experience, would section 5
16 [redacted]
17 [redacted]
18 MR. BANSAL: Objection, form.
19 **A Please repeat your question.**
20 Q Sure. Would section 5 include
21 information about whether the vaccine would work to
22 induce an immune response?

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1 **A** [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 Q Okay. So in terms of forming an
10 expectation as to whether the mRNA vaccine product
11 would work to induce an immune response, what would
12 be more relevant for the investigator, section 5
13 [redacted]
14 MR. BANSAL: Objection, form.
15 **A Sir, my declaration does not really go**
16 **into trying to make relative value judgments of the**
17 **relative importance of any particular datum or piece**
18 **of information or study.**
19 **Rather, in disagreeing with Dr. Phillip**
20 **Krause and his declaration, I've pointed out that**
21 **the importance of the observation that** [redacted]
22 [redacted]

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1 [redacted]
2 [redacted]
3 [redacted]
4 [redacted]
5 [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 [redacted]
12 [redacted]
13 [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 [redacted]
18 [redacted]**.**
19 Q So I just want to be clear. That's not
20 something you've offered an opinion on, correct?
21 **A Correct. I'm not here today to offer an**
22 **opinion on the relative importance of different**

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1 **types of information in Moderna submissions.**
2 **Rather, it's evident that all of the**
3 **information in the Moderna submissions was available**
4 **to FDA reviewers. The expectation is that the FDA**
5 **reviewers are going to examine all of this**
6 **information; that they're going to anticipate that**
7 **the information that Moderna is presenting to them**
8 **is accurate, truthful, and relevant to the**
9 **investigational vaccine that Moderna is pursuing;**
10 **and that if information or particular references**
11 **were not relevant or contributory to FDA's global**
12 **understanding of the potential safety and efficacy**
13 **of those products, that** [redacted]
14 [redacted]
15 [redacted]
16 [redacted]
17 MR. PRUSSIA: We pass.
18 MR. BANSAL: We don't have any questions
19 for Dr. Pierce. Thank you for your time.
20 COURT REPORTER: Anything else for the
21 record?
22 MR. PRUSSIA: We already designated it,

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1 right?
2 COURT REPORTER: Yes.
3 MR. PRUSSIA: Then we're set. Thank you.
4 COURT REPORTER: Confirm your transcript
5 orders. Two rough draft and final transcript sooner
6 than two weeks.
7 MR. PRUSSIA: I would like a rough, and
8 we do need it sooner than two week. So a rush, yes.
9 COURT REPORTER: How soon do you need it?
10 MR. PRUSSIA: I just need the final by
11 the end of next week.
12 MR. MEUTH: We'll both take roughs, and
13 regular delivery is fine with us.
14 COURT REPORTER: Thank you. That's all I
15 need.
16 (Off the record at 12:23 p.m.)
17
18
19
20
21
22

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2
3 I, Lisa V. Feissner, RDR, CRR and Notary
4 Public in and for the District of Columbia, do
5 hereby certify:
6
7 That L. ROSS PIERCE, M.D., the witness
8 whose deposition is hereinbefore set forth, was duly
9 sworn by me before the commencement of such
10 deposition, and that such deposition was taken
11 before me and is a true record of the testimony
12 given by such witness.
13
14 I further certify that the adverse
15 parties, BIONTECH SE and PFIZER INC., were
16 represented by counsel at the deposition.
17
18 I further certify that the deposition of
19 L. ROSS PIERCE, M.D., occurred at the offices of
20 PAUL HASTINGS LLP on FRIDAY, OCTOBER 4, 2024,
21 commencing at 9:42 and concluding at 12:23.
22

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1 I further certify that I am not related
2 to any of the parties to this action by blood or
3 marriage, I am not employed by or an attorney to any
4 of the parties to this action, and that I am in no
5 way interested, financially or otherwise, in the
6 outcome of this matter.
7
8 IN WITNESS WHEREOF, I have hereunto set
9 my hand this 9TH day of OCTOBER, 2024.
10
11
12 Lisa V. Feissner
13 NOTARY PUBLIC IN AND FOR
14 THE DISTRICT OF COLUMBIA
15 MY COMMISSION EXPIRES JUNE 15, 2028
16
17
18
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20
21
22

A
ability 32:16, 35:4, 90:2
able 31:9, 31:11, 41:19, 46:2, 57:3, 58:7, 77:3, 78:11, 79:1, 85:21
about 37:6, 44:14, 52:5, 66:22, 67:14, 68:1, 68:2, 69:3, 75:17, 78:3, 80:8, 93:16, 93:21
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