



Planet Depos®
We Make It *Happen*™

Transcript of L. Ross Pierce, M.D.

Date: October 4, 2024

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

Planet Depos

Phone: 888.433.3767

Email: transcripts@planetdepos.com

www.planetdepos.com

Moderna 2257
BioNTech-Pfizer v. Moderna
IPR2023-01358

Transcript of L. Ross Pierce, M.D.

1 (1 to 4)

Conducted on October 4, 2024

1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 ----- 4 BIONTECH SE AND PFIZER INC., 5 Petitioners 6 vs 7 MODERNA TX, INC., 8 Patent Owner 9 ----- 10 Case IPR2023-01358 11 U.S. Patent No. 10,702,600 12 and 13 Case IPR2023-01359 14 U.S. Patent No. 10,933,127 15 Oral deposition of 16 L. ROSS PIERCE, M.D. 17 WASHINGTON, DC 18 FRIDAY, OCTOBER 4, 2024 19 9:42 a.m. 20 Job No.: 555080 21 Pages: 1 - 99 22 Reported by: Lisa V. Feissner, RDR, CRR, CLR	3 1 A P P E A R A N C E S: 2 ON BEHALF OF PETITIONER PFIZER: 3 ROBERT F. HARTSMITH, ESQUIRE 4 WILLIAMS & CONNOLLY LLP 5 680 Maine Avenue, SW 6 Washington, DC 20024 7 202-434-5033 8 rhartsmith@wc.com 9 10 ON BEHALF OF PETITIONER BIONTECH: 11 CHETAN R. BANSAL, ESQUIRE 12 RYAN MEUTH, ESQUIRE (NY office) 13 PAUL HASTINGS LLP 14 2050 M Street NW 15 Washington, DC 20036 16 202.551.1948 17 chetanbansal@paulhastings.com 18 ryanmeuth@paulhastings.com 19 20 21 22
2 1 Oral deposition of L. ROSS PIERCE, M.D., held 2 at the offices of: 3 4 PAUL HASTINGS LLP 5 2050 M STREET, NW 6 11TH FLOOR 7 WASHINGTON, DC 20036 8 202.551.1700 9 10 Pursuant to Notice, before Lisa V. Feissner, 11 RDR, CRR, CLR, Notary Public. 12 13 14 15 16 17 18 19 20 21 22	4 1 A P P E A R A N C E S (cont'd): 2 ON BEHALF OF PATENT OWNER: 3 KEVIN S. PRUSSIA, ESQUIRE 4 ANNA WONG, ESQUIRE 5 WILMER CUTLER PICKERING HALE AND DORR LLP 6 60 State Street 7 Boston, MA 02109 8 617.526.6243 9 kevin.prussia@wilmerhale.com 10 anna.wong@wilmerhale.com 11 12 A L S O P R E S E N T: 13 RAYMOND PARKER, ESQ., BioNTech 14 JACOB MOORE, ESQ., Moderna 15 16 17 18 19 20 21 22

PLANET DEPOS

888.433.3767 | WWW.PLANETDEPOS.COM

5	7
1 C O N T E N T S	1 to tell the truth?
2 EXAMINATION OF L. ROSS PIERCE, M.D. PAGE	2 A I do.
3 By Mr. Prussia 6	3 Q And you will tell the truth today?
4	4 A I will.
5	5 Q Is there any reason why you cannot give
6 E X H I B I T S	6 me your best testimony today?
7 (Attached to transcript)	7 A There is not.
8 DEPOSITION EXHIBIT PAGE	8 Q And you will give me your best testimony
9 (None marked.)	9 today?
10	10 A I will give you my best testimony today.
11	11 Q And you've been deposed previously,
12 P R E V I O U S L Y	12 right?
13 M A R K E D E X H I B I T S	13 A I have been deposed once for an -- in the
14 (Referenced)	14 course of a divorce proceeding.
15 EXHIBITS PAGE	15 Q Okay. You have a couple documents in
16 BioNTech-Pfizer Exhibit 1164 8	16 front of you. Do you want to identify what they
17 Moderna 2050 69	17 are, please?
18 Moderna 2051 71	18 A Of course. The first document that I
19 Moderna 2052 72	19 have before me is my declaration in the case of
20 Moderna 2200 9	20 Pfizer and BioNTech versus ModernaTX, Inc.
21	21 Q You just want to give me the exhibit
22	22 number on the bottom right-hand corner?
6	8
1 P R O C E E D I N G S	1 A Sure. It's Exhibit 1164.
2 L. ROSS PIERCE, M.D.,	2 (Previously marked Exhibit 1164
3 having been first duly sworn, was examined and	3 referenced.)
4 testified as follows:	4 BY MR. PRUSSIA:
5 EXAMINATION	5 Q And in which proceeding is that exhibit
6 BY MR. PRUSSIA:	6 in?
7 Q Good morning.	7 A The two case numbers listed on the first
8 A Good morning.	8 page, on the cover page of my declaration are case
9 Q Would you please go ahead and introduce	9 numbers IPR 2023-01358 and case number IPR
10 yourself for the record.	10 2023-1359.
11 A I'm Dr. Leland Ross Pierce.	11 Q And are there any markings in the version
12 Q Dr. Pierce, where do you live?	12 of the Exhibit 1164 that's in front of you?
13 A I live at 1330 West Avenue, Unit 506,	13 A It's a clean copy. I've dog-eared a
14 Miami Beach, Florida, 33139, United States of	14 couple of the pages.
15 America.	15 Q Okay. And why did you dog-ear those
16 Q Should have done this in Miami.	16 pages?
17 A I beg your pardon?	17 A I thought it possible that you might ask
18 Q We should have done this deposition in	18 me questions pertinent to those sections.
19 Miami.	19 Q And there's another document to your
20 Are you currently employed?	20 left.
21 A I'm self-employed. I have an LLC.	21 Is that right?
22 Q You understand that you just took an oath	22 A There is another document to my left.

9 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	11 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
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	12 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	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
14 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.	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.	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?
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	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	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?
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	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	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,
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	28 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.	31 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.
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	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

Conducted on October 4, 2024

33 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,	35 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
34 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	36 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?

Conducted on October 4, 2024

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.	39 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
38 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 Anthraxis, anthrax, an infectious disease, immune 20 globulin intravenous (human); Adynovate, 21 antihemophilic factor (recombinant), PEGylated; and 22 numerous BLA efficacy supplements which are listed	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

Conducted on October 4, 2024

41 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?	43 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
42 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	44 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

Conducted on October 4, 2024

45 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	47 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.
46 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.	48 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

Conducted on October 4, 2024

49 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;	51 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
50 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	52 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."

53 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?	55 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
54 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.	56 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

57 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]	59 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.
58 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	60 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

Conducted on October 4, 2024

61 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?	63 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
62 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.	64 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.

65 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	67 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
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	68 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

69 1 be placed on a clinical hold. 2 Q In identifying that information, is the 3 clinical sponsor making any representation about how 4 those same or similar products function? 5 MR. BANSAL: Objection, form. 6 A Counselor, at various places in my 7 declaration, I state that a sponsor exercises 8 discretion in putting together their submissions to 9 FDA, that their submissions are not meant to be 10 exhaustive review articles, and the information and 11 references that sponsors include in their 12 submissions to FDA are expected to be relevant, 13 accurate, and truthful, and contributory toward the 14 FDA process of evaluating the prospects of safety 15 and efficacy for the proposed investigational 16 product to be used in a human clinical trial. 17 (Previously marked Exhibit 2050 presented 18 to the witness.) 19 BY MR. PRUSSIA: 20 Q So you've been handed what's been marked 21 as Exhibit 2050. 22 A [REDACTED]	71 1 [REDACTED] 2 [REDACTED] 3 protamine (Petsch et al 2012). 4 (Previously marked Exhibit 2051 presented 5 to the witness.) 6 BY MR. PRUSSIA: 7 Q You've been handed Exhibit 2051. 8 Do you have that? 9 A [REDACTED] 10 [REDACTED], Exhibit Moderna 2051, 11 which is a number listed in the table toward the top 12 of page 8, [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 Q Okay. And in Exhibit 2051, at the page 20 ending in Bates stamp 91, [REDACTED] 21 [REDACTED] 22 [REDACTED]
70 1 [REDACTED] 2 [REDACTED] And it's marked as 3 Exhibit 2050, which is listed in my declaration at 4 the top of the table on page 8 as a material 5 considered in the preparation of my declaration 6 responding to Dr. Krause's declaration in this 7 matter. 8 Q Okay. If you look at the page with the 9 Bates stamp ending in 64 at the bottom of the page. 10 A Yes. 11 Q [REDACTED] 12 [REDACTED] 13 Do you see that? 14 A Yes, I do. 15 Q [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 Did I read that correctly? 19 A [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	72 1 [REDACTED]. Right? 2 A [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 (Previously marked Exhibit 2052 presented 14 to the witness.) 15 BY MR. PRUSSIA: 16 Q I'm handing you Exhibit 2052. 17 And the same sentence appears in 18 Exhibit 2052, right? 19 A The exhibit that is marked Moderna 2052 20 that I was just handed appears on my list of 21 materials considered in the preparation of my 22 declaration [REDACTED]

73 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]	75 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?
74 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	76 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]

77

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]

78

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

79

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]

80

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], including 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	83 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.
82 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	84 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 --

85 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.	87 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]
86 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	88 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?

89

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

90

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

91

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 part. 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]

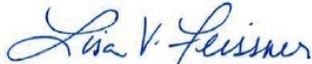
92

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]

93 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?	95 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
94 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]	96 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,

Transcript of L. Ross Pierce, M.D.
Conducted on October 4, 2024

25 (97 to 100)

97 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	99 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  13 NOTARY PUBLIC IN AND FOR 14 THE DISTRICT OF COLUMBIA 15 MY COMMISSION EXPIRES JUNE 15, 2028 16 17 18 19 20 21 22
98 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	

A			
ability	action	42:10, 42:19,	allow
32:16, 35:4,	90:14, 91:1,	45:9, 46:5	68:22, 80:7,
90:2	91:5, 99:2, 99:4	affect	80:8, 95:5
able	activity	59:2	allowing
31:9, 31:11,	21:4	affiliated	68:21
41:19, 46:2,	actually	13:20	alluding
57:3, 58:7,	11:7, 12:8,	after	87:3
77:3, 78:11,	71:17, 88:2,	43:9, 43:16,	alpha-proteinase
79:1, 85:21	88:11	46:13, 46:21,	38:6, 38:7,
about	add	47:10, 54:9,	38:8
37:6, 44:14,	85:6	94:22	already
52:5, 66:22,	addition	afterwards	96:22
67:14, 68:1,	65:1	13:10	also
68:2, 69:3,	additional	again	25:8, 33:7,
75:17, 78:3,	32:19, 35:7	41:20, 44:2,	34:17, 53:8,
80:8, 93:16,	address	80:21	61:19, 65:8,
93:21	33:12, 60:19	against	68:21, 71:15,
above	adequate	29:20, 30:1,	79:22, 80:2,
66:5	67:3, 67:7,	30:14, 70:22,	90:1, 91:1,
acceptable	67:20, 95:7	72:5, 73:14,	93:2, 95:13
35:13	adequately	89:11	ambiguous
access	33:11, 35:16,	agent	88:1
45:22, 75:12,	64:5	66:18	ameliorate
85:8, 92:2, 92:4	adjuvants	agents	27:6, 27:10
accessible	24:20	16:5, 16:6,	ameliorating
81:19	administered	66:18	24:13, 27:15
accomplish	90:3, 94:8	agree	america
67:5	administering	31:9, 31:11,	6:15
accomplishment	54:4, 61:12	61:9, 61:19,	among
66:4	administration	62:3, 62:12,	18:3, 18:11,
according	10:2, 14:20,	62:15, 65:8,	22:8, 28:19,
92:7	19:8, 19:15,	66:16, 77:2	87:18, 93:1
account	38:15, 42:18,	ahead	amount
51:14, 86:14,	43:16, 46:13,	6:9, 61:13	66:2, 66:12
90:19	54:10	aim	animal
accurate	adrenal	24:13	71:1, 72:7,
41:14, 69:13,	15:22	al	73:15, 95:16
96:8	advantage	70:12, 71:3,	anna
achieving	85:9	72:9, 73:17	4:4, 4:10
64:1	adverse	all	another
acid	98:14	12:6, 20:16,	8:19, 8:22,
47:15, 48:10,	advises	27:1, 36:21,	28:14
48:13, 90:3	63:21	59:6, 70:16,	answer
acquisition	adynovate	71:1, 71:22,	28:3, 36:17,
24:15	37:16, 37:17,	72:7, 74:2,	43:6, 45:7,
act	38:2, 38:20,	76:1, 85:8,	46:10, 53:18,
50:1	39:3, 39:5,	89:15, 96:2,	57:3, 59:2,
	40:19, 41:4,	96:5, 97:14	85:6, 87:5,

88:17, 88:18, 89:3, 92:12 answered 33:18, 44:20, 68:5, 76:15, 79:6, 85:5, 86:6 answering 59:22, 60:21, 73:8 anthrasil 38:19 anthrax 38:19 antibodies 44:16, 44:22, 45:12, 46:13, 58:19 anticipate 83:2, 94:2, 96:6 anticipated 64:22 anticipation 52:20, 52:22, 56:9 antihemophilic 38:9, 38:21, 39:13 any 7:5, 8:11, 16:14, 16:20, 17:3, 17:10, 18:14, 18:19, 19:20, 20:3, 22:13, 22:19, 23:7, 23:10, 23:20, 24:1, 25:17, 26:20, 28:10, 30:22, 41:19, 47:20, 48:14, 48:16, 48:20, 48:22, 49:3, 50:10, 54:14, 55:2, 55:10, 60:19, 62:19, 62:20, 69:3, 77:7, 78:15, 79:13,	83:18, 86:10, 94:17, 96:18, 99:2, 99:3 anything 44:9, 96:20 apologies 49:12 apparent 47:20, 80:13, 80:14 apparently 72:4, 73:2, 78:4 appeal 1:2 appear 44:1, 57:19 appears 51:6, 72:17, 72:20 appendix 11:6, 11:8, 11:11 application 20:8, 20:11, 49:20, 63:12, 65:13, 85:9, 89:10 applications 19:11, 20:10, 21:1, 63:10 appropriate 33:6, 34:16, 46:2, 95:2, 96:15 approvability 85:15 approval 34:5, 34:7, 62:7, 62:11, 62:19, 83:18, 85:17, 90:10, 91:5 approve 83:12, 84:1, 84:19, 86:2 approved 23:7, 23:10,	23:13, 23:15, 88:4, 88:12, 89:5, 93:7 approving 90:17, 90:19 approximately 18:7 aralast 38:6 argumentative 87:8 art 51:4, 51:17, 52:9, 52:11 article 80:17 articles 69:10 articulation 21:22 ascertain 77:3, 79:1 ascertained 77:15 aside 55:4 asked 9:20, 30:9, 33:17, 35:16, 44:19, 68:5, 76:14, 79:6, 85:5, 86:6 asking 58:22, 59:7, 82:12, 87:9, 88:16, 88:18 aspects 51:15, 54:20, 59:18, 79:14 assess 27:14, 27:21, 33:5, 34:15 assessed 28:19 assist 25:4, 68:10 associated 15:12, 15:16,	58:18 assume 88:20 assure 66:4 attached 5:7 attachment 58:12, 58:17 attorney 99:3 attr 90:6 attracted 14:11 author 19:5 authority 62:20 available 28:4, 65:5, 68:1, 75:19, 75:20, 93:5, 96:3 avenue 3:5, 6:13 aware 25:19, 26:5, 26:8, 49:7, 84:13 B back 42:8, 45:9 background 44:14, 64:11, 71:10, 71:12, 71:18, 82:19, 89:18 bacterial 19:3 bad 41:6 balance 84:15 bansal 3:11, 10:20, 27:17, 29:3,
--	--	---	--

29:22, 33:17, 42:13, 44:19, 45:14, 46:8, 46:19, 47:1, 56:17, 57:8, 58:3, 58:20, 59:11, 60:8, 62:8, 67:2, 68:4, 69:5, 76:14, 77:19, 79:4, 82:15, 83:15, 85:1, 85:4, 86:5, 87:8, 88:15, 89:8, 90:11, 93:18, 94:14, 96:18 based 52:10, 80:15, 82:3, 83:13, 84:2, 84:19, 86:2, 88:5, 88:13, 88:17, 89:7 basic 36:5, 54:13, 76:6 basically 72:9 basis 31:8, 45:4, 88:18, 90:10, 90:13, 90:22 bates 70:9, 71:20, 73:9 beach 6:14 bear 88:21, 89:1, 93:1 bears 60:14 because 14:10, 26:21, 45:6, 57:22, 75:13, 85:7, 90:9	been 6:3, 7:11, 7:13, 9:20, 22:22, 37:2, 47:5, 47:8, 49:14, 49:17, 49:20, 51:13, 58:7, 66:7, 66:14, 66:19, 66:21, 67:8, 67:11, 69:20, 69:22, 70:22, 71:7, 72:6, 73:14, 73:18, 74:5, 74:7, 74:12, 75:4, 75:18, 75:20, 77:3, 80:13, 80:18, 80:21, 81:8, 81:21, 83:9, 84:3, 90:1, 91:10, 94:6, 96:15 before 1:2, 2:12, 7:19, 11:12, 28:4, 29:16, 62:6, 63:9, 67:8, 67:11, 79:12, 89:12, 98:9, 98:11 beg 6:17 began 11:18, 14:17, 14:19 beginning 70:19 behalf 3:2, 3:10, 4:2 being 19:10, 21:7, 28:21, 68:7, 73:11, 93:8 believe 22:15, 22:21, 23:11, 33:10, 46:11, 65:14,	77:8, 79:22, 84:5 believes 61:11 benefit 57:2, 67:16, 85:13, 95:8, 95:15 berinert 38:16 best 7:6, 7:8, 7:10, 16:22, 90:15 betacoronavirus 59:10 between 32:18, 35:5, 78:16, 78:17, 79:15, 81:5, 82:8, 82:13, 83:4 beyond 43:2 biochemistry 13:1 biologic 85:8, 89:10 biologics 15:4, 17:13, 17:21, 19:17, 20:11, 20:22, 31:17, 40:8, 42:18, 82:22 biontech 1:6, 3:10, 4:13, 7:20, 98:15 biontech-pfizer 5:16 bit 61:4 bla 19:20, 20:3, 38:22, 39:21, 42:9, 88:13, 89:6, 90:17 blas 20:16, 20:17,	20:19, 21:1, 23:20, 24:1, 24:3, 38:5 block 45:12 blood 19:16, 22:7, 37:7, 99:2 board 1:2 body 80:5, 95:3 boost 24:21 boston 4:7 both 16:8, 24:20, 88:20, 95:16, 97:12 bottom 7:22, 37:20, 70:9 branch 17:5, 17:18, 18:17 break 46:20, 46:22, 91:6 bring 88:21 broad 18:14, 26:18, 27:18, 28:3 broader 32:13, 34:22, 66:21, 68:2 brochure 70:1, 71:16, 72:11, 72:22, 91:18, 92:11, 94:1 brochures 76:9, 81:11 brought 45:5, 89:1 bs 11:13
--	--	--	--

C			
cl-esterase	causes	81:1	17:17, 18:17,
38:16	41:5, 89:11	chemically	21:20, 27:13,
calculation	cber	77:18, 79:2	27:19, 28:18,
61:12	15:3, 17:17,	chemistry	28:20, 30:19,
california	18:22, 21:16,	11:13, 40:5,	30:21, 30:22,
13:5, 13:9,	21:17, 22:12,	63:13, 76:6,	31:7, 32:5,
13:21	22:17, 24:5,	79:9, 80:19,	32:11, 33:1,
called	24:9	80:22, 85:10	33:21, 34:6,
13:20, 22:16	cder	chemists	34:11, 34:21,
can't	14:22, 15:2,	81:12	35:13, 37:15,
43:10, 87:5	15:8, 17:6	chetan	40:13, 41:8,
cancer	cell	3:11	46:6, 46:15,
25:10, 25:14,	22:16, 48:6,	chetanbansal@pau-	58:10, 63:13,
25:18, 25:20,	57:18, 58:2,	lhastings	64:20, 65:2,
26:2	58:11, 58:12,	3:17	65:4, 67:15,
candidate	58:17, 60:7	choice	67:17, 68:14,
28:8, 31:10,	cells	12:15	68:22, 69:1,
31:12, 71:13,	57:21, 58:12,	circumstances	69:3, 69:16,
71:16	58:14, 58:17,	33:4, 34:14	74:15, 76:9,
candidates	90:4	citations	78:12, 80:8,
29:20, 30:1,	cellular	10:3	81:12, 82:2,
32:15, 35:2,	22:6	cited	83:6, 84:16,
35:10	center	51:18, 52:9,	85:18, 86:21,
cannot	15:2, 15:3,	78:18	87:14, 88:5,
7:5, 75:11	17:13, 17:15,	claim	88:14, 89:7,
capacity	17:20, 19:16,	50:22	92:15, 92:16,
33:8, 34:18	82:21	claims	92:21, 93:11,
career	certain	51:2	94:3, 94:4, 95:9
12:20, 25:22,	10:3, 10:4,	clarification	clinically
47:8	11:3, 26:10,	88:10, 88:16	36:10
carefully	29:12, 40:7,	clarify	clinicians
86:9	40:11, 43:20,	30:2, 44:9,	81:13
carried	51:15, 54:21	74:19	clotting
35:11	certainly	class	42:19, 43:1,
case	85:14	23:1, 23:9,	44:5
1:13, 1:16,	certificate	62:5, 62:10,	clr
7:19, 8:7, 8:8,	98:1	62:18, 62:21,	1:28, 2:13
8:9, 28:12,	certify	63:1, 93:10	clues
33:7, 34:17,	98:5, 98:14,	classes	95:14
50:16, 50:18,	98:18, 99:1	68:19	cmv
77:11, 96:16	cetera	clean	22:11
case-by-case	64:22, 75:10,	8:13	co-authored
31:8, 45:4	85:12	clear	21:6
cases	changed	11:22, 39:12,	code
27:20, 45:4,	22:2	66:11, 95:19	49:18
58:10, 91:3	characterize	clearly	colleagues
	32:6, 33:22	35:15	74:10, 85:14
	chemical	clinical	columbia
	75:8, 77:11,	10:7, 17:5,	98:4, 99:14

com 3:8, 3:17, 3:18, 4:9, 4:10 combined 15:4 come 59:1 comes 61:13 comfort 56:21 comfortable 40:17, 41:16, 43:4, 59:4, 59:21, 60:21 coming 67:13, 90:18 commencement 98:9 commencing 98:21 commercial 20:12, 23:4 commission 99:15 commonly 68:13, 68:20 communicate 63:9 comparatively 33:2, 34:12 comparison 80:15 complete 12:13, 36:20, 41:15, 49:8 completed 13:16, 38:4, 92:15, 92:21, 94:4 complex 38:9, 38:17, 38:18, 45:21 complexed 70:17, 71:2, 72:1, 72:8, 73:16, 73:22, 74:10, 76:19,	76:22, 77:4, 77:16 component 31:17 components 59:16, 75:6 composition 75:13, 77:11 comprise 60:18 comprised 92:21 concatenated 71:14 concentrate 38:17, 38:18 concept 54:5, 70:20, 72:4, 73:12, 73:13, 83:8, 83:14, 84:3, 84:6, 84:20, 86:3, 86:11, 86:12, 86:19, 94:13 concern 40:1, 42:12, 42:17, 43:13, 44:1, 45:3, 46:7, 51:12, 58:19 concise 80:6 conclude 77:17, 81:17 concluded 84:12, 95:1 concludes 81:22 concluding 98:21 conclusion 80:3 condition 27:16 conduct 78:11 conducted 32:6, 32:12,	33:1, 33:21, 34:11, 34:22, 48:9, 48:11, 48:14, 48:16, 48:20, 48:22, 49:3, 63:17 confidential 20:12, 23:5 confirm 97:4 congenital 23:19 connection 9:9, 10:5, 12:1, 12:3, 50:15, 51:9, 53:12, 83:11 connolly 3:4 consider 14:15, 51:7 considerable 29:17 consideration 53:6, 80:12, 84:13 considerations 29:2, 29:6, 40:19, 42:21, 43:3 considered 20:12, 23:1, 23:4, 28:18, 29:8, 53:2, 70:5, 72:21, 78:14 considers 86:10 consisting 81:10 constitute 45:3 constitutes 42:16 construction 50:22 construe 28:2	consult 41:13, 59:19 consultant 47:10 consulted 19:13, 50:15, 50:18 cont'd 4:1 contain 89:15, 90:15 contained 67:4, 74:3, 75:14 containing 85:17 contains 50:6 content 64:7, 79:11 contents 50:4, 50:8, 75:8, 91:21, 92:8 context 45:10, 46:5, 48:19, 54:3, 55:20, 56:12, 56:14, 57:5, 62:5, 67:7, 76:17 continue 14:12, 84:22 continuing 34:10, 70:11 contributory 69:13, 96:11 control 76:7, 79:10 controlled 34:3, 78:4 controls 63:14, 64:17 convince 95:5 copies 56:22 copy 8:13, 56:20
---	--	---	--

corner 7:22, 9:4 correct 11:15, 11:17, 13:12, 17:8, 17:20, 18:16, 19:22, 20:5, 20:20, 21:18, 21:22, 30:15, 37:5, 37:16, 38:2, 48:6, 49:2, 49:13, 50:7, 52:14, 52:17, 52:18, 52:20, 53:7, 53:8, 53:22, 76:13, 76:19, 87:17, 88:6, 88:7, 91:12, 95:20, 95:21 correctly 16:12, 16:17, 37:13, 52:12, 52:13, 61:15, 61:16, 61:22, 70:18 correspondence 91:4 cortisol 15:22 cosmetic 50:1 could 16:16, 20:1, 22:17, 22:22, 23:22, 28:18, 29:4, 30:2, 35:20, 36:9, 36:19, 48:18, 49:21, 53:1, 53:14, 56:19, 66:17, 76:16, 82:11, 83:20, 86:22, 89:21, 89:22, 90:1, 93:2, 93:3 counsel 87:9, 98:16	counselor 26:18, 29:7, 33:10, 33:19, 35:14, 35:20, 36:3, 36:14, 36:19, 37:22, 38:3, 40:2, 41:7, 42:14, 44:21, 46:11, 46:19, 48:18, 48:21, 50:21, 51:11, 53:14, 53:18, 54:1, 54:7, 54:17, 56:6, 56:19, 57:10, 58:5, 58:22, 59:13, 60:3, 60:10, 65:14, 67:3, 68:6, 69:6, 73:6, 74:2, 74:19, 75:4, 76:16, 76:20, 77:21, 79:7, 82:17, 83:17, 84:5, 85:6, 86:7, 86:22, 89:9 couple 7:15, 8:14 course 7:14, 7:18, 9:13, 19:12, 25:22, 26:20, 27:21, 29:13, 49:19, 73:17, 81:17, 85:3, 95:13 coursework 11:18, 12:1, 12:4 court 96:20, 97:2, 97:4, 97:9, 97:14 cover 8:8 covered 57:11	covid 58:10, 89:12 craft 46:2 criteria 83:18 critical 63:22, 64:6, 68:9 crr 1:28, 2:13, 98:3 currently 6:20, 93:8 curriculum 11:12, 39:1 cutler 4:5 cv 16:11, 16:17, 37:18, 38:3, 47:19 D data 32:15, 35:3, 35:11, 64:18, 65:3, 68:13, 68:14, 88:5, 88:14, 89:7, 92:21, 92:22, 93:11, 94:3, 94:4 date 50:20, 51:5, 51:6, 51:7, 51:11 dated 70:1, 71:17, 91:19 datum 94:17 davis 11:19, 11:21, 13:5, 13:9 day 21:13, 21:14, 99:9	dc 1:23, 2:9, 3:6, 3:15 dcept 21:16, 21:18, 21:19, 22:12, 23:13, 23:21, 24:2, 24:4, 24:9 de 13:14 dealing 81:9 deaths 21:9 decades 43:10 decision 80:7 declaration 7:19, 8:8, 9:2, 9:8, 9:9, 9:12, 9:13, 9:15, 9:20, 9:21, 10:15, 10:16, 10:18, 10:21, 10:22, 11:2, 11:5, 11:9, 11:11, 29:9, 29:10, 29:11, 32:4, 32:10, 32:21, 33:11, 33:13, 33:20, 34:9, 35:8, 35:15, 40:15, 43:5, 44:10, 45:15, 46:9, 50:3, 50:6, 50:8, 50:22, 51:10, 51:15, 51:16, 51:21, 52:3, 52:22, 53:2, 53:4, 53:22, 54:2, 54:19, 54:20, 55:5, 56:18, 57:9, 57:12, 58:4, 58:21, 59:12, 59:14,
---	--	---	--

60:9, 60:20, 61:5, 61:6, 61:17, 61:19, 62:5, 63:8, 64:9, 65:15, 66:1, 69:7, 70:3, 70:5, 70:6, 72:22, 77:20, 79:5, 80:17, 83:16, 83:17, 87:13, 87:14, 87:19, 88:17, 88:22, 89:2, 92:6, 94:15, 94:20 deduce 84:9 deficiency 15:21 define 48:18, 76:16 degennes 14:10 degree 12:1, 12:9, 12:21, 13:4, 13:8, 23:14, 49:13, 66:17 deleterious 36:10 delivery 48:5, 48:8, 75:17, 77:12, 78:17, 97:13 delves 54:3 department 14:9 departure 47:10 depending 33:4, 34:14, 93:4 depends 66:5, 66:13 deposed 7:11, 7:13, 10:9, 10:11	deposition 1:21, 2:3, 5:8, 6:18, 10:12, 10:13, 10:16, 11:4, 98:8, 98:10, 98:16, 98:18 derived 22:7 des 13:13 described 66:5 describing 58:8 design 63:13, 63:15, 64:20 designated 96:22 designed 32:6, 33:22, 61:20, 62:13, 62:16, 65:10 detail 20:14, 74:14, 75:12, 83:19 detailed 59:17 details 59:15, 60:20, 79:18 determination 86:15 developed 73:4 developing 30:22 development 25:2, 25:5, 25:20, 26:6, 26:9, 26:13, 26:14, 26:16, 27:22, 29:13, 31:16, 31:18, 41:9, 41:17, 42:22, 44:5, 44:15, 44:22,	45:11, 45:20, 46:5, 75:22, 83:7 diabetes 15:19 diego 13:20, 13:21 difference 81:5 differences 78:15, 79:13, 79:14, 79:18, 79:19, 80:13, 82:6, 82:8, 82:13, 83:3 different 26:15, 26:19, 26:21, 27:2, 27:3, 27:4, 27:19, 28:11, 30:12, 41:2, 73:2, 76:12, 76:16, 81:6, 86:13, 93:7, 95:22 difficult 28:3 digesting 90:21 diminish 43:22 diminution 45:1 disagree 41:22, 42:1 disagreeing 94:19 discipline 91:2 disciplines 81:7, 85:10 discretion 69:8 discuss 53:21, 59:17, 73:7 discussed 73:21, 76:12	discussing 85:13, 88:3 discussion 64:1, 64:4 disease 18:6, 19:1, 19:22, 20:5, 20:20, 23:21, 24:2, 24:4, 24:13, 24:14, 24:15, 26:7, 26:15, 27:7, 27:10, 27:11, 27:16, 29:2, 29:6, 29:20, 30:2, 30:4, 30:6, 30:8, 30:15, 31:13, 31:20, 32:2, 33:3, 33:16, 34:13, 35:19, 36:2, 36:7, 36:10, 36:18, 38:19, 40:22, 41:2, 53:17, 53:21, 54:3, 54:6, 54:8, 54:11, 54:12, 54:15, 55:3, 55:11, 55:19, 55:21 diseases 15:12, 15:16, 16:15, 16:21, 17:11, 18:2, 18:4, 18:20, 19:1, 21:3, 21:5, 22:10, 26:11, 28:21, 36:13 disorder 19:4 disorders 15:12, 15:18, 15:22, 16:1 dissertation 12:14, 12:22 dissimilarity 81:20
--	---	--	--

distinct 77:18, 79:2	75:5, 75:7, 78:18, 80:6, 80:20, 81:2, 81:10, 84:3, 84:7, 86:20, 87:4, 87:11, 87:16, 87:18, 87:21, 90:20, 91:3, 91:10, 91:15, 95:12	58:4, 58:21, 59:12, 60:9, 61:9, 61:19, 65:9, 70:6, 77:20, 79:5, 80:17, 83:16, 94:19, 96:19	earlier 27:5, 27:8, 91:9
district 98:4, 99:14			ease 39:4
division 14:21, 15:5, 15:9, 16:3, 16:7, 16:12, 16:18, 17:1, 17:5, 17:14, 17:22, 18:6, 18:10, 18:13, 18:17, 18:21, 19:14, 19:21, 20:4, 20:18, 20:21, 21:20, 22:1, 82:21	dog-ear 8:15	draft 97:5	educate 46:1, 61:21, 62:13, 62:16, 65:10
divisions 86:14	dog-eared 8:13	drafting 88:22, 89:2	effect 42:17, 46:16, 46:17, 46:18, 92:13
divorce 7:14	doing 19:12, 41:16	drafts 64:19	effectiveness 35:13
divulge 23:6	domain 56:2	drug 10:2, 14:19, 14:22, 15:2, 15:6, 15:9, 16:4, 16:8, 16:13, 16:19, 17:1, 17:15, 19:15, 19:19, 20:2, 20:8, 20:10, 20:11, 34:4, 37:3, 50:1, 61:13, 64:16, 66:3, 66:6, 66:14, 66:20, 66:22, 67:7, 67:10, 68:1, 68:2, 75:22, 83:12, 84:1	effects 38:14, 46:16, 91:22, 92:6, 92:20, 94:13, 95:11
dmid 79:22	done 6:16, 6:18, 12:14, 78:7		efficacy 29:1, 29:5, 31:12, 32:8, 34:1, 38:22, 42:11, 43:12, 43:22, 44:16, 45:2, 45:13, 46:6, 46:18, 65:3, 68:11, 69:15, 77:9, 84:14, 92:18, 93:1, 96:12
dna 81:5, 89:21	dorr 4:5		elected 12:18
doctor 47:5	dosage 65:6	duly 6:3, 98:8	elements 85:8
doctorate 12:19	dose 32:18, 35:6	duration 65:6	elicit 33:9, 34:19
document 7:18, 8:19, 8:22, 9:1, 9:2, 19:6, 26:2, 71:10, 71:12, 71:18, 72:4, 75:1, 87:9, 89:13, 92:3	dosed 39:17	during 11:4, 19:14, 21:5, 21:8, 22:3, 22:15, 23:15, 27:21, 28:20, 29:8, 29:13, 47:8, 47:13, 47:16, 49:19, 81:17	else 96:20
documented 94:6	doses 33:6, 34:16		email 91:4
documents 7:15, 10:4, 25:4, 25:17, 25:22, 26:9, 26:20, 26:22, 27:4, 61:10, 75:2, 75:4,	down 45:5, 85:1	E	emphasis 32:13, 35:1
	dozens 25:21	each 81:14, 84:8	emphasize 44:2
	dr 6:11, 6:12, 9:8, 9:12, 9:16, 9:21, 9:22, 10:8, 10:10, 10:13, 11:1, 11:2, 11:4, 29:11, 38:4, 40:14, 44:10, 45:15, 46:9, 50:21, 51:16, 54:19, 55:5, 56:18, 57:9,		emphasizes 64:6

employed 6:20, 99:3 enable 64:4 encompasses 36:21 end 97:11 ending 70:9, 71:20, 72:2, 73:9 endocrine 14:8, 14:22, 15:6, 15:9, 15:13, 15:17, 15:21, 16:4, 16:8, 16:13, 16:19, 17:1 endocrinologist 14:15, 14:16 endocrinology 14:1, 14:4, 14:5, 14:11 endpoint 28:6, 28:8, 28:14, 28:18, 29:21, 30:16 endpoints 27:13, 27:19, 27:20, 28:9, 28:12, 28:19, 30:21, 31:3, 31:6 engage 17:2, 21:4 engaging 10:7 enhancement 53:17, 53:21, 54:3, 54:6, 54:8, 54:12, 54:13, 54:15, 55:3, 55:11, 55:20, 55:22 enhancing 58:19 enormous 89:13	enough 19:18, 28:13, 50:2, 61:3 enrolled 49:14 ensure 65:3 enter 90:4 entire 64:6, 89:9 entities 15:7, 86:17 entitled 44:13, 70:1, 71:9, 72:22, 73:11 entry 57:18, 58:1, 58:2, 58:12, 58:14, 58:18, 60:6 especially 62:5 esq 4:13, 4:14 esquire 3:3, 3:11, 3:12, 4:3, 4:4 et 64:22, 70:12, 71:3, 72:9, 73:17, 75:10, 85:12 etranger 13:13 evaluated 56:1 evaluating 68:11, 69:14 evaluation 15:3, 15:4, 17:13, 17:15, 17:21, 19:17, 21:20, 77:8, 82:22 even 40:5, 78:17,	80:14, 85:17, 91:3, 93:3, 93:9 eventually 32:8, 34:1 ever 41:20, 47:5, 50:15 evidence 31:14, 32:2, 33:14, 39:22, 42:10, 42:11, 43:11, 46:4, 78:13, 95:4 evident 96:2 exact 87:1 exactly 9:18, 30:2 exam 12:6 examination 5:2, 6:5 examine 96:5 examined 6:3 example 21:6, 24:20, 25:9, 25:13, 28:5, 28:14, 44:21, 45:12, 60:2, 64:15, 76:18, 79:16, 91:13, 91:16, 93:5 examples 15:11, 16:2, 37:6, 43:19 exams 12:7 exceptions 34:4 excerpts 71:13, 75:5, 75:15, 76:21, 79:8, 81:3, 91:10, 91:15	excess 15:20 exchange 64:1 excuse 74:6, 79:20 executed 60:13 exercises 69:7 exhaustive 69:10 exhibit 5:8, 5:16, 7:21, 8:1, 8:2, 8:5, 8:12, 9:3, 9:5, 37:21, 53:5, 53:8, 53:11, 53:15, 53:16, 56:7, 56:20, 57:1, 57:2, 57:14, 58:6, 60:11, 69:17, 69:21, 69:22, 70:3, 71:4, 71:7, 71:9, 71:10, 71:14, 71:19, 72:2, 72:13, 72:16, 72:18, 72:19, 73:7, 73:11, 91:17, 91:18, 92:8, 92:14 exhibits 5:15, 73:19, 76:21, 83:9 exist 25:18, 26:4 existed 78:16 exogenous 48:6, 48:8 expect 93:13 expectation 52:10, 94:10, 96:4
---	--	--	---

expected 66:13, 68:8, 69:12, 89:14	facilitate 65:11	fialuridine 21:6	form 10:20, 27:17,
expects 61:10, 66:22, 67:3	facilitates 58:1	fiau 21:7	29:3, 29:22,
experience 14:11, 41:4, 44:14, 68:6, 75:16, 82:4, 92:9, 92:18, 93:4, 93:6, 93:9, 93:14, 93:15	facilitating 57:18	field 45:21	42:13, 46:13, 58:20, 59:11,
expert 30:18, 36:4, 40:3, 40:4, 40:6, 41:8, 42:6, 44:3, 44:4, 54:8, 60:22, 82:10	facilities 85:12	final 97:5, 97:10	60:8, 62:8, 65:13, 67:2,
expertise 42:15, 82:19	fact 60:4, 62:1, 78:8, 84:9, 93:14	finalizing 12:21	68:4, 69:5, 77:20, 79:4,
expires 99:15	factor 38:9, 38:21, 39:5, 39:13, 39:16, 41:19, 42:19, 43:1, 44:6, 45:6	financially 99:5	81:7, 82:15, 82:19, 83:15,
explained 84:5	fair 19:18, 28:13, 50:2, 51:7, 53:9, 59:6, 61:3, 66:20, 67:21	find 37:18	85:4, 86:5, 88:15, 89:8, 90:11, 93:18, 94:14
expose 95:9	familiar 50:19, 54:5, 56:4, 83:3, 95:1	fine 97:13	formal 49:16
exposing 84:15	favor 61:13	first 6:3, 7:18, 8:7, 23:1, 23:9, 27:1, 61:8, 62:18, 62:21, 63:1, 66:1	forming 51:9, 53:12, 83:11, 94:9
exposure 65:6	fda's 25:7, 26:14, 40:10, 75:12, 96:11	first-in-class 22:13, 22:20	formulation 73:3, 75:10
expressed 29:11, 40:14	february 21:11, 21:13	flebogamma 38:11	formulations 75:9, 78:16, 81:2
extends 39:15	feedback 63:11, 65:12	floor 2:8	forth 59:20, 98:8
extent 66:6, 66:14, 81:19	feel 12:20	florida 6:14	forward 67:17, 95:5
extremely 28:3	feissner 1:28, 2:12, 98:3	focus 20:16, 30:11, 39:3, 44:8, 54:18	frequently 39:17
F	fellowship 13:22, 14:4	focused 29:10	friday 1:24, 98:20
face-to-face 63:16	few 93:12	following 13:15, 70:11, 91:5	front 7:16, 8:12, 11:9, 83:10, 87:5, 87:11
facie 78:13		follows 6:4	function 16:1, 16:2, 28:10, 39:18, 56:15, 57:6, 57:16, 59:15, 59:18, 60:14, 60:17, 69:4
		food 10:2, 14:19, 19:15, 50:1	funded 78:4
		footnotes 11:3	further 12:20, 33:6,
		foreign 13:10	

34:16, 59:17, 66:2, 68:21, 98:14, 98:18, 99:1 furtherance 40:12, 78:9 fusion 58:1, 60:6	28:10, 29:16, 30:22, 31:6, 38:14, 44:21, 79:9, 93:14, 98:12 giving 36:6 glands 15:22 glassia 38:7 global 96:11 globulin 19:6, 38:10, 38:11, 38:12, 38:13, 38:20 go 6:9, 25:16, 31:5, 45:9, 52:2, 59:14, 66:8, 79:18, 87:7, 94:15, 95:5 go-ahead 78:10 goal 27:6, 67:5, 68:21 goals 27:8 goes 62:1, 63:19 going 12:16, 12:20, 20:14, 32:22, 61:13, 67:17, 82:3, 82:4, 82:15, 94:22, 96:5, 96:6 gonadal 16:1 good 6:7, 6:8, 32:3, 33:15, 46:19 graduate 11:18, 11:21 guidance 19:5, 25:1,	25:3, 25:9, 25:13, 25:17, 25:20, 25:21, 26:2, 26:4, 26:6, 26:8, 26:12, 26:14, 26:16, 26:20, 26:22, 27:3, 64:5, 64:13	helps 50:4 hematologic 17:18, 18:18 hematology 17:22, 18:7, 18:21, 19:14, 20:22 hemophilia 18:2, 18:3, 37:8, 37:12, 39:8, 39:9, 40:3, 41:3, 41:8, 42:6, 42:16, 42:20, 43:1, 45:20 hemophilic 41:10 hepatitis 22:11 here 14:14, 30:18, 36:3, 39:13, 40:2, 40:4, 40:5, 40:9, 41:7, 42:5, 42:14, 44:3, 44:8, 54:7, 54:17, 77:6, 78:1, 79:9, 80:2, 82:9, 88:5, 89:12, 95:21 hereby 98:5 hereinbefore 98:8 hereunto 99:8 high 92:9 highly 89:17 himself 87:12 hold 67:15, 69:1, 85:18
G		H	
gammaplex 38:12 gamunex 38:10 gears 61:3 gene 22:4, 22:6, 22:16, 22:19, 22:21, 23:11, 23:14 general 27:22, 28:20, 31:17, 54:13, 83:18, 87:22, 88:19, 88:21, 89:1 generally 18:8, 24:13, 26:12, 26:14, 28:19, 29:19, 30:15, 33:5, 34:6, 34:15, 67:21 generate 32:16, 35:4 generates 35:19, 36:2 germane 57:16 getting 20:6, 78:10 give 7:5, 7:8, 7:10, 7:21, 15:11, 43:6, 56:21, 87:10 given 24:12, 27:9,			

hopitaux 13:14	I	implications 43:18, 45:19	78:16, 81:11, 88:2
hormones 15:21	ideas 36:21	importance 84:8, 94:17, 94:21, 95:14, 95:22	inclusion 84:11
hospital 13:19, 13:20, 14:9	identical 68:17	important 31:17, 84:12, 86:13, 90:21, 95:13	increased 28:6, 28:7
host 57:20	identified 30:5, 88:1	impossible 85:20	incrementally 12:21
however 12:5, 18:13, 23:13, 26:3, 28:9, 30:11, 36:5, 44:2, 60:16, 86:12, 87:21	identify 7:16, 30:8	improvement 28:15, 28:16	incumbent 67:11
human 19:6, 39:14, 65:5, 69:16	identifying 69:2	inaccurate 41:21	ind 63:10, 63:12, 65:13, 66:2, 66:4, 66:13, 78:11, 85:17
human) 38:6, 38:7, 38:8, 38:10, 38:11, 38:12, 38:13, 38:16, 38:17, 38:18, 38:20	identity 27:2, 76:6	inappropriate 95:9	indicated 23:17, 23:18, 36:17
humans 32:6, 33:6, 33:9, 33:21, 34:16, 34:19, 91:22, 92:7, 92:14, 92:20, 94:13, 95:11	iii 51:1	inc 1:6, 1:9, 7:20, 98:15	indicates 74:5, 74:8
humate-p 38:8	imagination 86:11	include 15:17, 64:11, 64:15, 66:13, 69:11, 75:6, 79:9, 88:20, 90:22, 91:1, 92:15, 93:2, 93:3, 93:16, 93:20, 94:5, 95:2	indication 20:12, 93:8
humoral 19:4	immune 19:4, 19:6, 32:17, 32:19, 33:9, 34:19, 35:4, 35:6, 35:19, 36:2, 36:8, 38:10, 38:11, 38:12, 38:13, 38:19, 93:17, 93:22, 94:6, 94:11	included 10:4, 64:13, 78:8, 79:20, 79:22, 80:18, 89:19, 89:21, 89:22, 95:16	indications 22:10
hypercholesterol- emia 15:19	immunogenic 41:5	includes 11:2	indicative 80:3
hyperparathyroid- ism 15:20	immunogenicity 24:21, 31:14, 31:16, 32:3, 32:7, 32:17, 33:15, 34:1, 35:11, 40:1, 40:7, 40:20, 40:22, 41:5, 41:9, 42:11, 42:16, 43:11, 43:15, 43:20, 44:5	including 15:21, 18:5, 22:10, 22:11, 28:1, 28:21, 31:1, 34:4, 37:10, 37:11, 38:5, 63:12, 75:8, 76:8, 77:10, 78:6,	individual 27:10, 27:11, 36:11, 91:1
hypoparathyroidi- sm 15:20	immunoglobulin 19:2, 19:7		individuals 24:12, 33:3, 34:13, 83:2
hypothetical 85:16	impacting 18:22		inds 68:21, 83:7
	impairment 23:19		induce 93:17, 93:22, 94:11
			industry 25:4, 63:22, 76:5
			infection 29:21, 30:16, 57:20, 58:9, 70:22, 72:6, 73:14
			infections 19:3
			infectious 16:15, 16:21,

17:11, 18:5, 18:20, 19:1, 19:21, 20:5, 20:20, 21:2, 21:5, 23:21, 24:2, 24:3, 24:15, 26:7, 26:10, 26:15, 29:2, 29:6, 29:20, 30:14, 31:13, 31:20, 32:1, 33:16, 35:18, 36:1, 36:7, 36:10, 36:12, 36:18, 38:19, 40:22, 41:2 infer 45:17 influence 70:22 influenced 66:17 influenza 72:6, 73:14 information 20:9, 20:13, 23:5, 32:18, 32:19, 33:8, 34:18, 35:5, 35:7, 37:18, 43:4, 56:2, 59:3, 60:17, 63:2, 64:2, 64:3, 64:11, 64:13, 64:16, 66:3, 66:12, 66:21, 67:4, 67:12, 67:22, 68:2, 68:10, 68:19, 69:2, 69:10, 74:3, 74:4, 74:18, 74:20, 75:11, 75:14, 75:17, 76:4, 76:7, 78:3, 79:22, 80:10, 80:16,	80:18, 80:19, 81:18, 81:21, 83:13, 84:2, 84:7, 84:20, 85:18, 86:2, 86:8, 86:9, 87:19, 88:17, 89:15, 89:18, 90:2, 90:16, 90:19, 92:10, 93:3, 93:16, 93:21, 94:5, 94:18, 95:11, 96:1, 96:3, 96:6, 96:7, 96:10 informative 67:13 informed 60:10, 80:7 informs 67:19 inherent 36:21 inhibitor 38:6, 38:7, 38:8, 38:16, 41:9, 41:17, 44:5, 45:20 inhibitors 42:22 input 85:9 insight 40:9, 46:12, 54:18, 65:15 insights 92:12 inspection 85:12 instance 67:20 instances 49:22 instead 52:1 institutes 21:8	instructs 64:2 instrumental 36:9 intact 59:16 intended 33:3, 34:13, 41:1, 64:7, 64:21 interest 10:6, 28:16, 28:17 interested 14:5, 35:18, 36:1, 56:1, 99:5 interfering 90:4 interim 92:22, 94:3 internal 13:17, 14:12 interpret 49:17, 49:22 interpreted 51:2 intravenous 19:6, 38:10, 38:11, 38:12, 38:20 introduce 6:9 investigate 83:6 investigating 49:4 investigation 31:15, 72:12, 74:1, 82:1 investigational 19:10, 19:19, 20:2, 20:7, 20:9, 23:4, 24:22, 32:8, 32:12, 34:2, 34:21, 62:17, 68:12, 68:16, 68:17, 69:15,	77:9, 78:12, 84:17, 84:19, 96:9 investigations 17:5, 17:6, 17:14, 81:22 investigator 71:15, 76:9, 79:1, 92:11, 94:1, 94:12 investigator's 70:1, 72:11, 72:22, 81:11, 91:18 involve 54:20 involved 24:6, 37:2, 37:15, 47:5, 47:9, 47:14, 47:17, 47:21, 48:2, 48:5, 48:7, 49:20, 58:11, 58:16, 60:6, 68:7 involvement 23:14, 24:8, 47:11, 55:7, 55:9, 55:13, 55:18 involves 36:7, 68:13 involving 48:9, 48:12, 48:15, 48:17, 49:1 ipr 1:13, 1:16, 8:9 irrespective 62:17, 62:18, 67:10 issue 51:8, 54:15, 55:3, 55:11, 78:1, 80:2 issued 26:8, 50:10, 50:13
--	--	---	--

issues 10:17, 25:1, 25:3, 25:8, 25:9, 25:14, 26:16	krause 9:3, 9:21, 9:22, 10:8, 10:10, 11:1, 11:2, 11:4, 29:11, 40:14, 61:9, 61:19, 65:9, 94:20	least 27:3 left 8:20, 8:22, 21:11 legal 49:15, 49:16, 50:7, 50:9, 51:1 leland 6:11 less 39:17, 66:20, 67:22 let's 20:16, 42:8, 46:22, 91:6 level 36:5, 54:13, 92:9 liberty 23:5 license 20:11, 20:22, 85:8, 89:10 licensed 60:13, 90:5 licensing 89:16 licensure 34:7 likelihood 35:12 likely 65:13 likewise 52:19 limit 44:16 limited 18:15, 45:19, 63:4, 86:10, 87:12 line 40:18, 41:12, 87:6 linked 39:20 lipid 15:18	lisa 1:28, 2:12, 98:3 list 72:20, 92:18 listed 8:7, 38:22, 53:5, 70:3, 71:11, 75:7 literature 41:13, 45:22, 59:19, 80:5, 94:22 little 61:3 live 6:12, 6:13 llc 6:21 llp 2:6, 3:4, 3:13, 4:5, 98:20 location 87:1 look 32:4, 45:3, 50:4, 51:20, 61:4, 61:18, 65:22, 70:8, 82:3, 86:14, 91:16 looked 62:4, 71:21, 86:3 looking 31:14, 37:19, 47:19, 63:2, 75:2, 80:4, 83:9, 84:4, 84:14, 91:10, 92:13 looks 45:4, 86:7 lot 74:13 lower 9:4 lunch 46:21
J			
jacob 4:14 jean-luc 14:10 job 1:26 journals 47:21, 48:5 judgments 94:16 june 99:15 justification 95:7 justify 67:17	krause's 9:8, 9:12, 9:16, 10:13, 44:10, 50:21, 51:16, 54:19, 55:5, 70:6, 80:17		
K	L		
kcentra 38:16 kevin 4:3, 4:9 key 57:19 kind 61:10 know 29:10, 40:2, 41:17, 53:18, 56:15, 57:6, 59:7, 59:8, 59:9, 60:1, 60:4, 78:5, 80:5, 80:22, 84:18, 90:9 knowledge 54:14, 55:2, 55:10, 88:19, 88:21, 89:1 known 76:11	laboratories 78:4 lack 43:18, 46:16, 46:18 language 56:6, 56:10, 57:15, 58:8, 60:11 large 27:19, 37:10 larger 32:13, 34:22 last 21:13, 21:14, 21:15 later 15:7, 60:13, 71:17 law 49:13, 49:14, 50:18 lawyer 49:5, 49:6, 49:9, 49:10 lead 19:5, 20:10 leading 58:9 leap 21:13		

luxturna 23:14, 23:17, 23:18	marriage 99:3	members 68:18	5:17, 5:18, 5:19, 5:20, 9:4, 10:4, 29:12, 40:12, 40:16, 44:11, 44:12, 56:8, 60:12, 71:10, 72:11, 72:12, 72:19, 73:4, 73:22, 74:5, 74:8, 74:14, 75:13, 75:18, 76:4, 76:13, 76:22, 77:4, 77:13, 77:16, 77:21, 78:5, 78:8, 78:14, 78:19, 79:8, 79:15, 79:20, 80:4, 80:11, 81:9, 83:1, 83:5, 84:10, 84:12, 86:20, 87:16, 87:20, 88:2, 91:14, 92:8, 94:21, 95:17, 96:1, 96:3, 96:7, 96:9, 96:13
M	mass 68:9	memos 91:2	moderna's 10:1, 10:5, 54:21, 82:2, 84:16, 87:2, 87:14, 88:5, 88:14, 89:7, 89:10
ma 4:7	master's 12:1	mentioned 27:5, 91:9	modernatx 7:20
made 11:4, 44:12, 86:20, 87:16	material 1:19, 70:4	mercy 13:19, 13:20	molecule 16:6, 16:9, 21:7, 37:10
maine 3:5	materials 10:1, 53:1, 53:6, 63:5, 68:20, 72:21	metabolic 15:13, 15:17	molecules 68:15
majority 75:6	matter 30:19, 57:11, 60:22, 70:7, 82:10, 99:6	metabolism 14:1, 14:4, 14:6, 14:22, 15:5, 15:9, 16:4, 16:8, 16:12, 16:18, 17:1, 92:17, 93:3	moment 76:1
make 80:7, 94:16	maybe 53:20	methodology 77:12, 78:17	monitoring 64:21
making 69:3, 86:15	mean 30:3, 41:18, 75:22	meuth 3:12, 97:12	months 43:8
manage 38:14	meaning 67:19	miami 6:14, 6:16, 6:19	
management 85:14	meant 69:9, 85:6	microbiologists 81:14	
manifestations 36:9	mechanism 57:20	middle 35:9, 52:5	
manufacturing 63:14, 64:17, 76:6, 79:10, 80:19	medecin 13:13	midnight 28:4	
many 18:3, 18:4, 18:22, 24:17, 25:3, 25:21, 28:10, 30:20, 42:21, 43:7, 43:19, 59:1, 81:6	mediates 57:22, 58:1	might 8:17, 80:13	
marked 5:9, 8:2, 9:5, 11:7, 69:17, 69:20, 70:2, 71:4, 72:13, 72:19	mediating 60:6	mind 30:5, 31:21, 67:9	
marketing 34:5, 85:16, 92:18, 93:4, 93:6, 93:9	medical 12:16, 38:4	minor 23:13	
markings 8:11	medicine 12:19, 13:17, 14:13, 18:5	minutes 47:1	
	meeting 56:7, 57:15, 63:5, 63:8, 63:10, 63:16, 63:20, 63:21, 64:2, 64:5, 64:7, 64:10, 64:14, 68:20, 71:12, 71:18, 81:10	misheard 49:10	
		mit 11:14	
		models 71:1, 72:7, 73:15	
		moderna 1:9, 4:14,	

moore 4:14	must 63:20, 64:10, 66:3	non-moderna-affi- liated 78:6	numerals 72:3
more 46:2, 56:21, 93:12, 94:12	N	nonclinical 65:4	numerous 21:9, 31:5, 38:5, 38:22
morning 6:7, 6:8	nabs 46:5	noncontributory 61:1	nw 2:7, 3:14
most 41:14, 76:8, 91:14	name 22:1, 39:12, 39:13, 50:11, 50:13	none 5:9, 19:18, 20:2, 20:19, 20:22, 48:2, 48:4, 48:7	ny 3:12
move 17:16, 78:20	namely 50:1	nonidentical 79:15	O
moved 17:4	names 22:2	nonprophylactic 42:18	oath 6:22, 29:18, 41:15, 85:22
mrna 29:13, 40:13, 47:6, 47:10, 47:12, 47:18, 47:21, 48:3, 48:6, 48:8, 48:17, 49:1, 49:4, 70:2, 70:15, 70:16, 70:20, 70:21, 71:1, 71:2, 71:9, 71:13, 71:16, 71:21, 71:22, 72:5, 72:7, 72:8, 72:12, 73:1, 73:2, 73:3, 73:13, 73:15, 73:16, 74:5, 74:9, 74:14, 75:18, 78:12, 78:19, 79:15, 80:9, 80:12, 81:5, 82:2, 82:8, 83:4, 83:5, 84:17, 86:21, 87:17, 89:11, 90:1, 91:19, 94:10, 95:6, 95:17	national 21:8	nonresponsive 78:21, 90:8	object 82:15
mrna-based 73:12	natural 58:9	normal 81:17	objection 10:20, 27:17, 29:3, 29:22, 33:17, 42:13, 44:19, 45:14, 46:8, 56:17, 57:8, 58:3, 58:20, 59:11, 60:8, 62:8, 67:2, 68:4, 69:5, 76:14, 77:19, 77:20, 79:4, 79:6, 83:15, 85:2, 85:4, 86:5, 87:8, 88:15, 89:8, 90:11, 93:18, 94:14
multiple 59:4	nature 65:16	normally 80:18	objectives 64:8, 64:21, 66:5
	necessarily 20:10	notary 2:13, 98:1, 98:3, 99:13	observation 94:21
	need 97:8, 97:9, 97:10, 97:15	noted 13:3	observed 43:16, 43:20
	needs 68:2	notice 2:12	obtain 12:3
	negotiated 31:7	notwithstanding 78:15, 79:19, 80:12	obtained 11:13, 11:22
	neutralizing 45:11	novelty 66:6	obtaining 12:22
	never 62:6, 62:11, 89:14	np 38:6	obviously 28:17
	nevertheless 81:16	nuances 44:4	
	new 20:8, 20:10, 20:11, 34:4	nucleic 47:15, 48:10, 48:12, 90:2	
	next 34:20, 46:20, 97:11	number 7:22, 8:9, 9:3, 26:22, 27:19, 71:11, 71:15	
	niaddk 14:3	numbers 8:7, 8:9	
	nih 14:1, 14:3	numeral 50:22	
	non-moderna 78:17		

obviousness 52:17 occur 43:20, 54:9, 63:16 occurred 98:19 octaplex 38:17 october 1:24, 98:20, 99:9 offer 52:9, 85:1, 95:21 offered 9:22, 11:2, 52:21, 95:20 offering 52:16, 52:19 office 1:1, 3:12, 19:13, 19:15, 22:16, 24:19, 82:21 offices 2:4, 98:19 oh 49:10 okay 7:15, 8:15, 11:13, 13:2, 16:11, 17:4, 17:16, 20:16, 21:11, 26:5, 27:5, 28:5, 28:13, 29:1, 29:19, 30:10, 31:9, 32:1, 39:3, 39:4, 41:3, 42:8, 44:13, 44:14, 49:5, 49:11, 50:2, 53:20, 55:15, 59:6, 60:1, 65:18, 67:8, 70:8, 71:19, 73:20,	74:11, 76:11, 77:2, 78:20, 84:18, 88:9, 89:3, 89:5, 93:12, 94:9 once 7:13 one 27:8, 27:14, 28:5, 31:13, 37:14, 38:1, 46:20, 57:16, 84:7, 94:2 ones 23:2, 23:7, 23:9 ongoing 92:15, 92:22 only 10:16, 35:11, 78:22, 91:10 open 50:3 opine 85:15 opinion 52:16, 52:20, 52:21, 67:14, 95:20, 95:22 opinions 9:16, 9:22, 11:1, 29:10, 40:14, 44:11, 51:9, 52:9, 53:12, 54:21, 83:11 opportunity 14:8 oral 1:21, 2:3, 12:5 order 1:19, 19:9, 24:21, 41:14, 56:20, 59:17 orders 97:5 ordinary 51:3	original 38:5, 48:12, 48:14, 48:16, 48:22, 49:3, 72:3, 75:7, 85:7 osteoporosis 15:18 other 25:6, 44:6, 59:9, 60:17, 60:19, 62:20, 78:5, 85:10, 85:14, 91:3, 93:1, 95:14 others 81:14 otherwise 99:5 out 27:1, 30:17, 35:11, 61:13, 94:20 outcome 99:6 outlined 30:21, 82:17 outlines 64:19 outside 45:14, 46:8, 56:17, 57:8, 58:3, 58:21, 59:12, 60:9, 77:19, 79:5, 83:16 over 25:22, 43:9, 68:8 overseas 93:5 own 81:14, 84:8, 86:20, 87:2, 87:14, 87:17, 88:2, 88:5, 88:14, 88:21, 89:7 owner 1:10, 4:2	P package 63:21, 64:2, 64:7, 64:10, 64:12, 64:14, 64:15 page 5:2, 5:8, 5:15, 8:8, 9:19, 10:17, 10:21, 32:4, 32:10, 32:22, 33:20, 34:10, 35:9, 37:17, 37:19, 37:20, 38:4, 39:2, 50:21, 53:3, 61:7, 61:17, 63:7, 64:9, 70:4, 70:8, 70:9, 70:11, 71:12, 71:19, 72:2, 72:3, 73:9, 87:6, 91:22, 92:1, 92:7 pages 1:27, 8:14, 8:16, 53:4 paragraph 32:5, 32:10, 32:21, 33:20, 34:9, 34:20, 35:8, 35:9, 39:1, 51:1, 51:19, 51:20, 52:2, 52:6, 61:4, 61:6, 61:17, 61:18, 63:19, 64:9, 65:1, 65:8, 65:22 pardon 6:17 parent 91:14 parentheses 62:2
---	---	---	---

paris 13:11, 13:14, 13:15, 14:7	patient 64:21	71:21, 72:9, 73:17, 73:21, 74:9, 76:12, 76:18, 78:7, 79:17, 79:21, 80:11, 80:17	pierce 1:22, 2:3, 5:2, 6:2, 6:11, 6:12, 38:4, 96:19, 98:7, 98:19
parker 4:13	patients 19:3, 28:17, 28:21, 41:3, 41:6, 41:10, 41:18, 43:1, 43:21, 44:16	pfizer 1:6, 3:2, 7:20, 98:15	pierce's 45:15, 46:9, 56:18, 57:9, 58:4, 58:21, 59:12, 60:9, 77:20, 79:5, 83:16
part 32:11, 60:18, 80:4, 81:7, 82:19, 82:21, 84:7, 84:8	paul 2:6, 3:13, 98:20	ph 12:3, 12:6, 12:22	pietie-salpetrie- re 14:9
partially 9:18	peer-reviewed 47:21, 48:5	pharmaceutical 75:9, 75:10, 81:1	pituitary 16:1
participate 16:14, 16:20, 17:10, 18:19	peg 39:15	pharmacokinetic 93:2	placed 69:1, 85:18
particular 23:11, 27:15, 28:9, 30:4, 30:6, 30:8, 31:1, 66:3, 66:18, 68:1, 79:14, 94:17, 96:10	pegylated 38:21, 39:10	pharmacokinetics 92:17	places 69:6
particularly 10:3, 76:8	people 82:18	pharmacologists 81:12	planned 63:12, 82:1, 92:16
particulars 31:4	percent 60:3	pharmacology 21:21, 64:17, 85:11	planning 65:2
parties 98:15, 99:2, 99:4	percentage 43:21	phase 21:8, 32:11, 32:14, 32:22, 33:7, 34:7, 34:8, 34:10, 34:17, 34:21, 35:1, 35:2, 35:10, 35:12, 56:9, 60:12	plasma 22:7
parts 65:12, 65:13	performed 78:3, 87:20	phenomenon 43:17, 54:9	platform 86:21, 87:17
pass 96:17	periodically 19:13	phillip 9:3, 9:21, 11:1, 51:16, 94:19	plausible 89:17
passed 12:5	person 51:3, 61:13	phases 34:6	play 43:3, 59:2
past 90:13	personal 54:14, 55:2, 55:10, 68:6	phrasing 45:16, 45:18	please 6:9, 7:17, 16:16, 20:1, 23:22, 25:12, 29:4, 31:22, 35:20, 36:19, 37:17, 37:22, 48:18, 48:21, 49:7, 53:1, 55:1, 57:4, 62:9, 73:6, 74:19, 82:11, 83:20, 86:22, 89:3, 89:4,
patent 1:1, 1:2, 1:10, 1:14, 1:17, 4:2, 50:16, 50:18, 51:2	personally 16:13, 16:19, 17:9, 18:18, 20:17, 47:6, 47:9, 47:14, 47:17, 61:1	physical 75:8, 80:22	
patent's 51:4	perspective 51:3, 81:15	pickering 4:5	
patents 50:10, 50:12, 51:8, 51:12	pertinent 8:18, 77:8	piece 94:17	
	petitioner 3:2, 3:10		
	petitioners 1:7, 51:18, 52:9		
	petsch 70:12, 71:3,		

93:19	potentially	presenting	86:15
plural	46:17	96:7	proceeding
88:8	practice	presumably	7:14, 8:5,
point	76:5	89:13	43:3, 43:5,
15:8, 17:4,	pre-ind	prevent	57:1, 92:5
17:16, 30:17,	56:7, 57:15,	19:3, 21:2,	proceedings
73:6, 74:20,	61:9, 61:20,	40:22, 41:1	9:10, 9:14,
75:21, 88:16	62:3, 62:12,	preventing	10:9, 10:11,
pointed	62:15, 63:3,	24:14, 36:9	50:15, 51:8,
94:20	63:4, 63:8,	prevention	51:18, 53:13,
policies	63:16, 63:20,	29:21, 30:16,	55:10, 55:14,
40:10	64:10, 65:9,	36:6	55:18, 61:2,
polyethylene-gly-	65:16, 66:12,	previously	83:12
col-based	68:20, 71:10,	7:11, 8:2, 9:5,	process
39:19	71:12, 71:17,	50:18, 62:11,	24:18, 64:17,
polymer	76:2, 76:8,	66:7, 66:15,	68:8, 69:14,
39:19	81:10	66:19, 66:21,	75:22
polyneuropathy	preceding	67:8, 69:17,	produce
90:6	12:6	71:4, 72:13	58:7
polypeptide	preclinical	prima	produced
16:9	63:15, 64:18,	78:13	15:22
population	68:14	primarily	product
32:13, 33:2,	preliminary	92:21	19:10, 23:15,
34:12, 35:1,	32:15, 33:8,	primary	24:22, 27:21,
64:21, 65:7	34:18, 35:3	17:2, 19:4,	31:1, 31:18,
portion	premeeting	29:21, 30:15,	32:9, 34:2,
92:2	63:22	51:12, 54:18	38:14, 39:10,
position	preparation	principles	39:13, 42:10,
85:15	29:9, 51:14,	24:17	44:16, 45:2,
positive	63:22, 70:5,	prior	46:14, 61:21,
31:14, 32:2,	72:21, 92:6	34:7, 50:14,	62:2, 62:14,
33:14, 39:22,	preparations	50:17, 51:17,	62:17, 62:18,
42:10, 43:11,	92:5	51:22, 52:9,	62:21, 63:1,
46:4	prepare	52:11, 55:6,	64:16, 65:11,
possibility	19:10, 64:4	55:9, 55:13,	68:12, 68:16,
35:12, 55:21	prepared	55:17, 63:19,	68:17, 69:16,
possible	25:16, 29:17	87:22, 89:16	72:12, 77:10,
8:17, 30:21,	preparing	priority	83:12, 83:19,
55:19	9:9, 9:13,	50:19, 51:4,	84:1, 84:19,
possibly	87:19	51:6, 51:7,	85:11, 86:2,
93:10	presence	51:11	89:17, 90:5,
posted	39:22, 44:8	probably	93:4, 93:9,
91:5	present	80:14	94:10
potential	46:1	problematic	productive
28:7, 42:17,	presented	45:17	64:1
58:18, 68:11,	69:17, 71:4,	procedures	products
77:9, 84:14,	72:13, 86:8,	40:10, 64:22	10:6, 10:7,
95:14, 96:12	95:4	proceed	14:22, 15:6,
		68:22, 80:9,	

15:10, 16:4, 16:8, 16:9, 16:10, 16:13, 16:19, 17:2, 17:3, 17:18, 18:1, 18:4, 18:13, 18:15, 18:18, 19:7, 19:19, 20:3, 20:15, 22:4, 22:6, 22:7, 22:8, 22:9, 22:19, 22:22, 23:3, 23:12, 25:6, 26:9, 27:22, 37:3, 37:14, 38:1, 40:21, 41:1, 44:17, 62:6, 62:10, 62:19, 68:18, 68:19, 69:4, 74:6, 81:20, 84:10, 89:20, 90:3, 93:10, 93:11, 95:17, 95:18, 96:13 prof 14:10 program 83:7 prohibited 20:14 project 50:17 projects 18:22, 20:7 proof 70:19, 70:20, 72:4, 73:11, 73:12, 83:8, 83:14, 84:3, 84:6, 84:20, 86:3, 86:11, 86:12, 86:19, 94:13 proper 39:13	properties 75:9, 81:1 property 40:7 prophylactic 19:9, 21:2, 24:4, 24:12, 24:16, 26:10, 30:19, 38:15, 47:15, 47:18, 54:4, 54:10, 73:13, 94:2 prophylaxis 70:21, 72:5 proposal 31:5 proposals 86:17 proposed 10:6, 61:21, 62:14, 62:16, 63:13, 65:10, 67:15, 68:16, 68:17, 69:15, 74:15, 76:13, 84:16 proposes 64:20 proposing 83:6 prospect 67:16, 95:7, 95:15 prospects 69:14 protamine 70:17, 71:3, 72:1, 72:9, 73:17, 73:22, 74:10, 76:19, 77:1, 77:5, 77:16 protective 1:19 protein 39:16, 39:20, 40:5, 41:4, 43:12, 44:17,	44:22, 45:13, 46:14, 56:5, 56:11, 56:14, 56:16, 57:6, 57:7, 57:17, 58:8, 58:11, 58:16, 58:18, 60:2, 60:4, 60:15 protein-based 37:3 proteins 40:8, 43:17, 43:22, 44:7, 59:10, 60:18, 60:19 prothrombin 38:17, 38:18 protocol 56:10, 57:14, 60:11, 67:16, 80:1 protocols 76:10, 81:11 provide 32:15, 33:8, 34:18, 35:3, 40:9, 41:14, 42:15, 43:10, 45:1, 56:19, 64:3, 65:15, 66:2, 74:13 provided 46:11, 75:5, 75:19, 75:20, 76:7, 80:22, 83:13, 84:2, 84:20, 92:10 provides 64:12 providing 54:18, 56:21 prussia 4:3, 5:3, 6:6, 8:4, 9:7, 46:22, 47:2, 47:4, 69:19, 71:6, 72:15, 78:20,	87:11, 90:7, 91:6, 91:8, 96:17, 96:22, 97:3, 97:7, 97:10 prussia@wilmerha- le 4:9 public 2:13, 56:2, 98:1, 98:4, 99:13 publications 47:21, 48:2, 48:4, 48:7 purpose 9:15, 9:19, 36:5, 62:4, 65:16 pursuant 2:12 pursue 41:12 pursuing 40:18, 96:9 purview 25:7 put 59:20 putting 69:8, 80:6 Q qualifying 12:6 qualitatively 27:2 quality 63:14 question 16:16, 20:1, 22:18, 23:22, 25:12, 26:18, 27:18, 28:2, 29:4, 29:7, 29:8, 29:15, 29:18, 30:9, 30:11, 30:13,
---	--	---	--

31:19, 31:22, 33:12, 35:16, 35:21, 36:15, 36:20, 36:22, 37:1, 37:22, 43:6, 44:15, 45:8, 45:16, 45:18, 46:2, 46:10, 46:12, 48:19, 48:21, 49:8, 50:5, 51:22, 52:1, 53:19, 55:1, 55:7, 57:3, 57:4, 58:22, 59:5, 59:22, 62:9, 63:4, 65:20, 73:8, 74:6, 77:7, 78:22, 82:11, 82:16, 83:21, 85:7, 86:18, 87:5, 87:15, 89:3, 89:4, 92:12, 93:19 questioning 40:18, 41:12 questions 8:18, 44:13, 60:21, 64:12, 77:10, 93:12, 96:18 quite 14:11, 36:14, 41:2	94:19, 96:2 rationale 36:12, 36:16, 61:10 raymond 4:13 rd 70:1 rdr 1:28, 2:13, 98:3 read 10:13, 10:17, 25:21, 26:1, 33:11, 35:15, 52:12, 52:13, 53:14, 61:15, 61:16, 61:22, 65:15, 70:18, 90:13 reading 72:10, 73:19, 74:5, 74:8, 74:12, 76:20 reads 32:11, 32:22, 34:10, 51:1, 70:15, 70:20, 72:4, 73:12 really 94:15 reason 7:5 reasonable 52:10, 81:16 reasons 35:17, 35:22 recall 37:13, 56:3, 57:18, 90:12 receive 12:8, 34:5, 43:21, 63:11 received 13:6, 13:8, 62:6, 62:11, 62:19 receiving 27:11, 41:10,	43:1, 65:12 recently 81:3 recess 47:3, 91:7 recipient 36:8 recollection 16:22, 26:1, 39:7, 54:1, 58:6, 74:13, 76:20 recombinant 22:8, 38:21, 39:10, 39:14, 39:16, 39:20, 41:19 record 6:10, 21:19, 96:21, 97:16, 98:11 reference 32:1, 39:4, 79:17, 79:20, 86:20, 87:17 referenced 5:14, 8:3, 9:6, 80:16 references 41:14, 69:11, 87:2, 92:19, 96:10, 96:14 referencing 11:3 referring 87:14 refers 70:12 regard 9:13, 46:3, 60:22, 80:16 regarding 9:22, 11:4, 25:1, 32:16, 35:3, 44:11, 59:3, 61:21, 62:14, 62:16, 65:10, 74:14,	75:12, 90:2 regular 97:13 regulated 17:12, 25:4, 86:16 regulation 20:13, 86:16 regulations 49:21, 49:22, 66:2 regulatory 16:14, 16:20, 17:10, 18:19, 47:6, 47:9, 47:14, 47:17, 62:6, 62:11, 62:20, 90:13, 90:22 reiterate 33:19, 80:21 related 20:9, 21:4, 26:9, 55:12, 68:18, 84:10, 89:19, 91:3, 93:10, 93:11, 95:17, 99:1 relates 9:21, 11:1, 54:16, 55:4 relating 40:18, 44:10, 50:9, 54:21, 56:2, 56:10, 60:17, 77:10, 87:20 relationship 32:18, 35:5, 68:15 relative 94:16, 94:17, 95:22 relevant 25:7, 51:4, 64:3, 67:13, 68:10, 69:12, 78:14, 80:11,
R			
rabies 22:11 randomized 34:2 range 43:2 rare 34:3 rather 24:14, 40:9, 44:8, 68:22,			

82:1, 94:12, 95:2, 96:8, 96:11 relied 90:16 remainder 39:1, 39:20 remained 15:8 repeat 16:16, 20:1, 22:18, 23:22, 29:4, 31:22, 35:20, 48:21, 55:1, 82:11, 93:19 repeatedly 79:21 replacement 18:9, 18:11, 18:15, 37:7, 37:10, 37:11, 39:5, 39:9, 41:10, 41:19, 42:7, 42:19, 43:2, 44:6, 46:14 replicon-based 82:8, 82:10, 83:4, 89:22 report 21:6 reported 1:28, 74:9 reporter 96:20, 97:2, 97:4, 97:9, 97:14, 98:1 representation 69:3 represented 98:16 request 56:8, 57:15, 63:21 required 19:8, 34:3, 76:4	requires 29:16 research 15:3, 15:4, 17:13, 17:15, 17:21, 19:16, 19:17, 24:19, 48:9, 48:11, 48:12, 48:14, 48:17, 48:19, 49:1, 49:4, 82:22 researchers 78:5, 78:6 residency 13:17 resident 13:11, 13:13 respect 20:14, 25:18, 29:12, 40:6, 40:20, 42:15, 42:22, 44:4, 57:17, 71:21, 83:8, 86:16, 87:22, 90:16, 95:14 respond 9:16, 9:20, 29:17, 35:16, 85:21 responding 30:8, 54:19, 59:5, 70:6 responds 10:15, 10:22, 51:15 response 32:17, 32:19, 33:9, 34:19, 35:5, 35:6, 35:19, 36:2, 56:21, 63:18, 93:17, 93:22, 94:6, 94:7, 94:11 responsible 20:18	responsive 65:19 restate 25:12, 30:13, 37:22, 57:4, 62:9, 74:6, 83:20, 89:4 result 67:15 resulted 21:9 results 63:15, 81:22 returned 13:16 review 9:12, 10:12, 16:14, 16:20, 17:2, 17:10, 17:17, 17:18, 18:17, 18:19, 19:16, 24:3, 24:6, 24:7, 24:18, 24:19, 25:5, 37:2, 37:15, 39:21, 42:9, 47:6, 47:9, 47:14, 47:17, 51:17, 53:10, 53:11, 68:7, 69:10, 74:2, 80:7, 81:18, 82:7, 82:12, 89:16, 90:10, 94:5 reviewed 9:8, 22:3, 23:20, 24:1, 37:14, 38:2, 52:8, 77:21, 83:10, 87:18 reviewer 68:7, 73:20, 74:17, 75:17, 75:19, 75:21, 77:15, 77:17, 80:14, 80:15, 81:4	reviewers 40:11, 40:19, 68:9, 74:2, 77:3, 77:6, 82:3, 85:11, 96:4, 96:5 reviewing 19:11, 19:20, 20:4, 20:18, 31:12, 81:6, 81:8, 82:20, 83:1, 84:4, 85:10, 86:14 reviews 31:10, 38:4, 84:8, 91:2 rhartsmith@wc 3:8 right 7:12, 8:21, 9:11, 9:17, 10:19, 11:14, 11:20, 12:10, 13:3, 13:7, 13:18, 14:2, 14:18, 15:1, 17:7, 17:19, 18:2, 20:17, 21:12, 21:16, 21:17, 21:21, 22:5, 24:7, 25:2, 25:11, 25:15, 26:17, 27:7, 32:3, 37:4, 37:8, 39:6, 39:8, 39:11, 39:17, 40:1, 41:6, 41:20, 48:17, 49:5, 49:6, 49:9, 49:15, 49:18, 51:18, 56:5, 59:6, 72:1, 72:18, 74:18, 75:19, 77:5, 77:7, 86:21, 89:7, 90:9, 90:10,
---	---	--	--

90:17, 91:11, 92:3, 97:1 right-hand 7:22, 9:4 risk 84:15 risk-benefit 61:12 risks 64:22, 67:14, 95:8 rna 82:8, 90:4 robert 3:3 role 21:15, 58:8 roman 50:22 ross 1:22, 2:3, 5:2, 6:2, 6:11, 98:7, 98:19 rough 97:5, 97:7 roughs 97:12 route 65:6 routinely 76:7 rush 97:8 ryan 3:12 ryanmeuth@paulha- stings 3:18	43:13, 44:1, 45:3, 46:7, 46:16, 46:17, 65:3, 68:11, 69:14, 77:9, 84:14, 92:17, 93:1, 95:15, 96:12 said 49:21, 58:5, 87:12 same 11:19, 12:17, 24:17, 36:12, 36:17, 68:18, 69:4, 71:14, 71:20, 72:10, 72:17 san 13:20, 13:21 sars-cov 56:12 sars-cov-2 53:16, 54:16, 55:4, 55:12, 55:21, 56:5, 56:8, 56:11, 56:15, 57:6, 57:17, 57:20, 58:9, 59:15, 59:16, 60:13, 60:18, 88:13, 89:6, 89:11 satisfied 12:19 say 15:6, 30:1, 53:9, 62:2, 66:20, 67:21 says 65:8 school 12:16, 49:14 scientific 17:6, 17:14 scope 45:14, 46:8, 56:17, 57:8,	58:3, 58:21, 59:12, 60:9, 77:19, 79:5, 83:16 scripps 13:17, 13:19 se 1:6, 30:20, 98:15 search 26:22 section 50:6, 50:9, 53:2, 54:2, 56:10, 57:14, 60:16, 70:19, 73:5, 73:6, 73:10, 73:11, 74:12, 81:2, 84:3, 84:6, 84:21, 86:3, 86:11, 86:12, 86:13, 91:20, 91:22, 92:6, 92:10, 92:13, 93:15, 93:20, 94:12, 94:13, 95:12 sections 8:18, 33:10, 33:13, 35:14, 65:14, 74:7, 79:10, 79:11, 80:20, 83:9, 86:19, 87:4, 89:19 see 53:5, 53:8, 61:10, 66:9, 70:13, 91:20 seems 61:1 seen 89:14 selected 84:10 self-amplifying 90:1	self-employed 6:21 sentence 36:20, 61:8, 61:16, 62:1, 66:1, 70:15, 71:20, 72:17 separate 25:19 separated 15:8 separately 11:7 september 70:2, 91:19 sequelae 41:8 serious 19:3 serve 63:10 set 97:3, 98:8, 99:8 several 22:10, 28:19, 86:13, 87:21 shorten 83:22 shorthand 98:1 should 6:16, 6:18, 64:3, 64:13, 65:2 show 50:9, 81:19 showing 87:6 shown 70:22, 72:6, 73:14 side 38:14, 42:17 signal 43:12, 43:13, 46:6, 46:7 signature-plkal 99:11
S			
s 3:1 safety 32:7, 32:14, 32:20, 33:5, 33:22, 34:15, 35:2, 35:7, 35:13, 42:11,			

significance 46:15	23:13, 24:8, 27:3, 27:20,	58:10, 58:16, 60:15	27:8, 38:3, 42:5, 42:14,
significant 12:21, 40:1, 80:5, 89:18	37:6, 40:15, 47:11, 49:21,	spikevax 60:14, 89:10, 90:14, 90:20	51:9, 55:5, 59:13, 63:7, 79:7, 86:7
similar 24:18, 62:19, 66:18, 68:19, 69:4, 73:18	58:10, 61:10, 64:12, 68:15, 80:1, 90:2, 91:3	sponsor 61:11, 63:11, 63:20, 65:2, 66:13, 66:22, 67:12, 68:9, 69:3, 69:7, 77:7, 81:22, 93:9	statement 33:14, 41:21, 42:3, 72:10
similarities 82:5, 83:4	something 29:15, 55:22, 57:10, 95:20	sponsor's 61:20, 63:13, 63:15, 65:9, 68:21	statements 10:3, 11:3, 40:11, 40:15, 44:11, 52:14, 54:21, 73:18, 87:13, 87:22
similarity 81:20	sometimes 54:9, 68:14	sponsors 31:6, 63:9, 65:19, 69:11	states 1:1, 6:14, 9:4, 10:2, 13:16, 32:5, 33:20, 34:5, 34:20, 35:9, 49:18, 64:10, 65:1, 93:6, 93:7
simple 87:15	soon 97:9	staff 25:5	stating 46:12
simply 57:13	sooner 97:5, 97:8	stage 20:8, 23:4	statisticians 81:13
since 22:1, 43:4	sorry 22:17, 73:5, 85:3	stages 76:1	statistics 85:12
single 12:19	sort 63:2, 92:10	stamp 70:9, 71:20	status 24:14, 27:11, 59:3
sir 43:14, 44:14, 46:10, 63:6, 77:6, 78:22, 82:9, 84:18, 86:4, 87:6, 94:15	sought 93:8	standards 50:7, 50:9, 51:1	statutes 49:18, 49:22
sit 14:14	space 37:7	started 14:21	step 42:8, 57:19
situation 31:4	speak 75:11	starting 16:4, 92:1, 92:7	street 2:7, 3:14, 4:6
skill 51:3	speaking 18:8, 29:19, 40:3, 40:4, 67:22	starts 37:20	stretch 86:10
slow 85:1	specific 26:1, 28:12, 30:2, 31:19, 45:12, 54:2, 63:11, 78:16, 83:19	state 4:6, 36:19, 49:7, 52:8, 57:13, 61:8, 63:19, 66:1, 69:7, 76:22	strike 23:8, 25:8, 26:13, 31:10, 39:22, 48:15, 53:10, 56:13, 58:15, 62:22, 77:14, 78:20, 90:7, 93:13
small 16:5, 16:9, 21:7, 33:2, 34:12, 90:4	specifically 54:15, 55:4, 55:11, 76:21	stated 9:19, 10:21,	structure 59:15, 59:18,
solely 83:13, 84:2	specifics 20:6, 25:17		
some 12:18, 15:11, 15:15, 15:16, 17:4, 17:16, 19:8, 20:6, 22:3, 22:21,	speculating 79:11		
	spike 56:4, 56:11, 56:16, 57:7, 57:17, 58:8,		

60:20, 74:14, 75:10, 75:13 studied 19:11, 21:7, 65:7, 66:7, 66:15, 66:19, 66:21, 67:8, 67:11, 79:16 studies 10:4, 32:5, 32:6, 32:11, 32:14, 33:1, 33:7, 33:21, 34:6, 34:11, 34:17, 34:21, 35:2, 35:10, 35:12, 63:16, 64:19, 65:4, 70:16, 71:2, 71:22, 72:8, 73:16, 78:3, 78:9, 78:14, 78:18, 79:21, 80:11, 84:10, 87:2, 87:15, 87:20, 88:3, 89:19, 92:15, 92:16, 92:22, 94:4, 94:7, 94:8, 94:22, 95:2, 95:16, 96:14 study 21:9, 33:6, 34:16, 48:20, 63:13, 68:1, 68:22, 70:12, 94:18 subject 19:19, 20:3, 43:5, 82:9, 88:13, 89:6, 89:16 subjects 21:10, 84:15, 95:10 submission 10:1, 65:12,	66:12, 67:5, 74:22, 75:21, 85:16, 86:17 submissions 29:12, 40:12, 40:16, 44:12, 54:22, 61:20, 62:13, 62:15, 65:9, 65:16, 67:4, 69:8, 69:9, 69:12, 74:4, 74:8, 76:8, 76:9, 77:22, 78:2, 78:9, 79:8, 79:21, 80:1, 81:8, 81:9, 82:20, 83:1, 84:11, 86:9, 95:3, 96:1, 96:3 submit 63:20, 67:1, 67:12, 68:9 submitted 10:5, 66:4, 68:3, 68:20, 76:2, 77:22, 78:11, 81:21, 96:14 submitting 63:9 subsections 92:13, 92:14 subspecialties 18:5 subspecialty 14:12 substance 42:3 substantive 51:12 success 52:10 successful 27:15 successfully 90:3 sufficient 64:11, 65:3	suggest 26:3 summarized 96:15 summary 90:10, 90:13, 90:22 supervisors 85:13 supervisory 91:2 supplements 38:22 support 33:14, 35:12, 64:7, 64:11, 65:5 sure 8:1, 16:17, 20:2, 25:13, 30:13, 36:16, 40:17, 47:2, 57:5, 60:3, 62:10, 93:20 surface 59:9 surrogate 27:20 survival 28:6, 28:7 sw 3:5 switching 61:3 sworn 6:3, 98:9 symptomatic 28:15 symptoms 28:16 synopsis 56:10, 57:14, 60:11 system 15:17, 36:8 systems 15:13 T t 4:12	table 50:4, 50:8, 70:4, 71:11, 75:7, 91:20, 92:8 tailored 31:3 tailoring 28:11 take 12:18, 41:19, 42:8, 46:22, 84:13, 86:14, 91:6, 97:12 taken 51:13, 98:10 takes 62:4 taking 41:3 talked 37:6 target 57:18 targeted 28:21 targeting 36:6, 73:3 task 85:20 team 81:7, 82:7, 82:13, 82:19 technical 30:18, 36:4, 40:3, 40:4, 40:6, 41:7, 42:6, 42:15, 44:4, 57:11 teleconference 63:17 tell 7:1, 7:3, 37:13, 37:17, 87:1 tells 80:10 ten 47:1
--	--	--	--

tenure 19:14, 21:5, 22:15, 23:15	18:12, 19:2, 22:14, 22:20, 37:10, 37:11, 37:12, 41:11, 42:7, 43:2, 44:6	today 7:3, 7:6, 7:9, 7:10, 14:14, 25:16, 28:4, 29:9, 29:18, 30:18, 36:3, 40:2, 40:4, 40:5, 40:9, 42:15, 44:9, 54:7, 54:17, 58:7, 59:5, 59:21, 75:15, 77:6, 78:1, 79:9, 80:2, 81:9, 82:9, 85:20, 89:12, 95:21	training 49:15, 49:16, 82:4
term 26:19, 50:19, 51:6, 52:22, 54:11, 60:14	therapy 18:15, 22:4, 22:6, 22:17, 22:19, 22:22, 23:12, 23:15, 37:7, 39:6, 39:9, 41:20, 45:6, 46:14	together 69:8, 80:6	transcript 5:7, 10:12, 10:14, 97:4, 97:5
terms 85:16, 94:9, 95:7	thereof 56:20	tolerability 32:7, 33:5, 33:22, 34:15	transferred 17:20
testified 6:4	thing 32:3, 33:15, 41:6	took 6:22, 90:19	treat 18:2
testimony 7:6, 7:8, 7:10, 10:17, 41:15, 43:10, 43:14, 76:3, 86:1, 86:4, 98:11	things 31:13, 93:1	tool 63:8	treated 33:4, 34:14, 44:17
th 2:8	think 11:9	topics 64:4	treatment 39:8, 90:5
thank 13:2, 52:15, 65:18, 65:21, 88:9, 96:19, 97:3, 97:14	thought 8:17, 29:16, 29:17, 45:6	totality 84:7, 86:8, 95:4	trial 1:2, 28:8, 28:10, 28:18, 30:22, 31:7, 40:13, 56:9, 60:12, 61:14, 64:20, 65:7, 67:18, 69:16, 76:10, 78:12, 80:8, 82:2, 83:6, 95:9
themselves 77:4, 95:17	three 34:6, 43:9, 77:22	toward 69:13, 71:11	trials 10:7, 28:20, 28:22, 30:19, 34:3, 46:6, 64:20, 65:2, 65:4, 74:16, 84:16, 95:6
therapeutic 22:9, 24:7, 24:8, 24:10, 24:11, 25:2, 25:6, 25:10, 25:14, 26:2, 26:17, 27:6, 27:9, 27:12, 27:14, 27:22, 28:1, 28:8, 28:22, 31:1, 31:2, 31:15, 36:6, 37:3, 40:8, 40:21, 41:1, 43:12, 43:15, 43:16, 43:21, 44:3, 44:6, 44:17, 45:1, 45:13, 46:14, 77:12	three-year 14:3	toxicologists 81:13	true 44:18, 45:13, 48:1, 52:14, 62:12, 74:1, 77:18, 79:3, 88:14, 98:11
therapies 18:9, 18:11,	through 47:19, 74:22, 75:2, 92:4, 92:5, 94:22	toxicology 21:21, 64:18, 85:11, 95:16	truth 7:1, 7:3
	time 12:17, 13:15, 13:19, 22:1, 22:3, 23:3, 28:4, 43:6, 46:1, 46:19, 47:13, 47:16, 51:4, 59:20, 74:20, 74:21, 75:22, 91:4, 96:19	trademark 1:1	truthful 69:13, 96:8
	times 12:15	trained 49:17	try 95:4
	title 53:14, 53:16		trying 40:21, 67:6,

80:5, 94:16 turn 27:1, 53:1 turning 61:7, 73:5 two 8:7, 15:7, 26:20, 26:22, 27:3, 77:17, 79:2, 82:14, 97:5, 97:6, 97:8 tx 1:9 type 15:19, 23:18, 56:7, 74:22, 83:5 types 18:3, 18:12, 18:13, 22:8, 24:20, 25:3, 25:6, 30:20, 77:22, 82:18, 84:6, 95:12, 96:1 typical 29:21 typically 32:12, 32:15, 33:1, 34:3, 34:11, 34:22, 35:3, 35:10, 63:17, 94:5	86:17 understand 6:22, 10:8, 16:11, 16:17, 21:12, 36:14, 51:2, 67:6, 78:7, 81:4, 82:7, 82:13 understanding 10:10, 39:18, 40:11, 45:19, 54:12, 55:15, 55:17, 55:19, 60:5, 82:5, 90:18, 96:12 understood 58:11, 73:21 undertaken 24:18 undesirable 40:6, 40:20 undue 95:8 unique 81:15 unit 6:13 united 1:1, 6:14, 10:1, 13:16, 34:5, 49:18, 93:6, 93:7 university 13:4, 13:9, 13:21 unlike 24:11 unreasonable 67:14 until 47:3, 91:7 use 24:20, 70:21, 72:5, 73:13 useful 27:21 utilize 27:14	utilized 28:10 v vacation 12:16 vacations 12:18 vaccination 53:17 vaccine 10:6, 17:3, 19:21, 20:5, 20:19, 23:21, 24:2, 24:10, 24:11, 24:12, 26:2, 27:6, 27:9, 27:12, 27:15, 28:9, 29:2, 29:6, 29:19, 30:1, 30:14, 31:2, 31:10, 31:12, 32:9, 32:14, 32:16, 32:18, 32:20, 33:9, 34:2, 34:4, 34:19, 35:2, 35:4, 35:6, 35:7, 35:10, 35:18, 36:1, 36:6, 36:17, 38:15, 42:18, 47:7, 47:10, 47:12, 47:15, 47:18, 56:8, 60:13, 62:2, 65:11, 70:21, 71:13, 72:5, 73:3, 73:13, 73:21, 74:9, 74:11, 75:18, 76:13, 76:18, 76:22, 77:4, 77:12, 77:13, 77:16, 78:19, 79:15, 82:2, 88:12, 89:6,	89:11, 93:15, 93:16, 93:21, 94:2, 94:10, 95:6, 96:9 vaccine's 36:8, 75:13 vaccines 16:14, 16:20, 17:10, 17:12, 18:19, 19:9, 19:13, 21:2, 24:4, 24:7, 24:9, 24:16, 24:19, 24:20, 25:2, 25:10, 25:14, 25:15, 25:18, 25:20, 26:6, 26:10, 26:15, 26:17, 28:1, 28:22, 29:14, 30:20, 31:15, 31:20, 32:2, 32:12, 33:7, 33:15, 34:17, 34:21, 40:13, 47:22, 48:3, 48:10, 48:13, 48:17, 49:1, 49:4, 54:4, 54:10, 55:20, 70:20, 73:12, 73:22, 74:15, 76:12, 77:18, 78:13, 79:2, 79:16, 80:9, 80:12, 83:4, 83:5, 84:17, 88:4, 88:8, 89:21, 94:7 vaccinia 38:13 vaccinology 30:18, 36:4, 54:8, 82:10 value 94:16 variable 46:15
U uc 11:19, 11:21 ultimately 23:10, 60:12, 78:10, 88:4, 88:11, 88:12, 89:5, 90:5 under 19:11, 20:13, 29:18, 41:15, 50:22, 60:14, 74:1, 80:12, 83:7, 85:21,			

variables 28:11	vis-à-vis 40:15	whether 27:14, 35:18,	43:7, 49:19,
variety 18:4, 19:1,	vision 23:19	36:1, 43:10,	50:14, 78:7,
19:7, 22:9,	vitae 11:12, 39:2	60:6, 62:17,	86:21, 88:1,
41:13, 82:18,	volunteer 21:9, 84:15	62:19, 67:10,	93:17, 93:21,
89:15, 90:20	volunteers 19:9, 33:2,	67:14, 67:16,	94:11
various 15:21, 43:17,	34:12	77:4, 79:1,	worked
59:16, 69:6,	von 38:9	80:8, 82:12,	15:5, 16:5,
71:1, 72:7,	vs 1:8	85:17, 88:2,	16:7, 17:21,
73:15, 80:20,		90:12, 93:16,	18:6, 18:9,
89:18, 95:2		93:21, 94:10	18:12, 18:14,
vast 45:21, 75:6		wide 22:9, 89:15	18:22, 19:7,
vehicle 75:17	W	willebrand 38:9	20:7, 21:1,
version 8:11, 71:15	want 7:16, 7:21,	williams 3:4	22:20, 22:22,
versions 94:7	39:3, 45:7,	wilmer 4:5	23:12, 37:9,
versus 7:20	45:9, 51:20,	wish 73:7	43:8
vetted 31:7	95:19	withdraw 37:1, 51:22,	working
via 63:17	washington 1:23, 2:9, 3:6,	55:7	12:15, 14:7,
view 35:15	3:15	within 15:7, 17:15,	14:17, 14:19,
viii 39:5, 39:16,	way 18:14, 26:3,	18:4, 19:16,	17:17, 18:1,
45:6	63:10, 65:17,	21:17, 22:17,	22:12, 24:9,
viral 19:1, 21:4,	99:5	61:9, 64:14,	43:9
22:10, 56:12,	we'll 97:12	67:4, 74:3,	wouldn't
56:14, 57:5,	we're 75:2, 97:3	75:14	85:21
60:20	we've 73:18, 74:4,	without 57:2, 87:6	writing
virologist 59:14	81:8, 83:9,	witness 69:18, 71:5,	12:13
virus 58:12, 58:14,	84:3, 91:10	72:14, 85:3,	written
58:17, 59:16,	web 91:5	98:7, 98:12,	12:7, 63:18
59:18, 60:18,	week 97:8, 97:11	99:8	Y
70:22, 71:16,	weeks 97:6	wong 4:4	yeah
72:6, 72:11,	west 6:13	wong@wilmerhale 4:10	31:19, 55:2,
73:3, 73:14,	whereof 99:8	word 26:21, 48:19,	73:10
89:11		67:19	year
viruses 22:11		words 27:1, 27:3	11:19, 21:13,
		work 11:21, 14:8,	71:17
			years
			18:7, 43:7,
			43:8, 68:8
			yourself
			6:10, 14:15
			Z
			zemaira
			38:5
			zika
			71:13, 71:16,
			72:11, 73:3
			.
			.1700
			2:10

.1948 3:16 .6243 4:8	99:15 16 63:7 17 32:5, 33:20, 63:7, 64:9 18 32:21, 34:9 182 73:10 1893 73:1, 73:2 19 32:10, 34:20, 58:10, 89:12 1973 11:16 1978 13:6, 13:9 198 72:3 1985 14:17, 14:20, 15:2, 16:5	202 3:7 202.551 2:10, 3:16 2020 21:11, 21:14, 47:11 2023 1:13, 1:16, 8:9, 8:10 2024 1:24, 98:20, 99:9 2028 99:15 2050 2:7, 3:14, 5:17, 69:17, 69:21, 70:3, 72:11, 73:19, 91:17, 91:18, 92:8, 92:14 2051 5:18, 71:4, 71:7, 71:10, 71:19, 72:2, 73:19 2052 5:19, 72:13, 72:16, 72:18, 72:19, 73:7, 73:11 2056 56:7, 56:20, 57:2, 57:14, 58:6, 60:11 2057 53:5, 53:8, 53:11, 53:15, 53:16 219 72:3 2200 5:20, 9:4, 9:5 23 70:1, 97:16, 98:21 28 92:1, 92:7	
0			3
01358 1:13, 8:9 01359 1:16 02109 4:7			3 64:19 30 61:4, 61:6, 61:17 32 63:19 33 64:9 33139 6:14 34 43:8, 65:1, 68:8 35 61:18, 65:8 37 65:22 38 47:3
1			4
1 64:16 10 32:4, 32:22, 33:20, 34:10, 47:3 10,702,600 1:14 10,933,127 1:17 100 60:3 11 2:8, 32:10, 32:22, 34:10, 35:9, 91:7 1164 5:16, 8:1, 8:2, 8:12, 37:21 12 91:7, 97:16, 98:21 13 51:1, 91:7 1325 70:2, 71:9, 71:13, 71:16, 72:12, 91:19 1330 6:13 1359 8:10 15 61:7, 61:17,	2 64:17 2-component 70:16, 71:2, 71:22, 72:8, 73:16 2.3 73:10 2.4 70:19 20 18:7, 35:8 20024 3:6 20036 2:9, 3:15 2012 70:12, 71:3, 72:9, 73:17, 79:17 2016 70:2, 91:19		5
			5033 3:7 506 6:13 54 39:2 555080 1:26 57 91:7

6 60 4:6 617.526 4:8 64 70:9 680 3:5 69 5:17 7 71 5:18 72 5:19 8 82 73:9 9 9 1:25, 98:21 91 71:20, 72:3 99 1:27 9th 99:9	
--	--