In the Matter Of:

HAZLEHURST vs

HAYS, M.D., ET AL.

KATHRYN EDWARDS, M.D.

August 25, 2020

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IN THE CIRCUIT COURT OF MADISON COUNTY, TENNESSEE
FOR THE TWENTY-SIXTH JUDICIAL DISTRICT AT JACKSON

WILLIAM YATES HAZLEHURST, by and through his Conservator ROLF G.S. HAZLEHURST, Plaintiff, VS. E. CARLTON HAYS, M.D., and THE JACKSON CLINIC PROFESSIONAL ASSOCIATION, Defendants.	DOCKET NO. C-19-38 DIVISION II JURY DEMANDED

DEPOSITION
OF
KATHRYN EDWARDS, M.D.
AUGUST 25, 2020
** TAKEN VIA ZOOM VIDEOCONFERENCE **
SAMANTHA E. COHEN, RPR, CRR, LCR(TN)(MS)
RIVERSIDE REPORTING
Memphis, Tennessee
(901) 527-1100

The deposition of KATHRYN EDWARDS, M.D. is taken via Zoom videoconference on behalf of the Plaintiff, on this the 25th day of August, 2020, pursuant to notice and consent of counsel, beginning at approximately 8:00 a.m.

This deposition is taken pursuant to the terms and provisions of the Tennessee Rules of Civil Procedure.

All forms and formalities, excluding the signature of the witness, are waived and objections alone as to matters of competency, relevancy and materiality of the testimony are reserved, to be presented and disposed of at or before the hearing. Objections as to the form of the question must be made at the taking of the deposition.

A P P E A R A N C E S

** ALL PARTIES APPEARED VIA ZOOM VIDEOCONFERENCE **

FOR THE PLAINTIFF:
DAVID RILEY, ESQUIRE
Glassman, Wyatt, Tuttle & Cox
26 North Second Street
Memphis, Tennessee 38103
(901) 527-4673
AARON SIRI, ESQUIRE
Siri & Glimstad, LLP
200 Park Avenue
Seventeenth Floor
New York, New York 10166
(212) 532-1091

FOR THE DEFENDANTS:
CRAIG SANDERS, ESQUIRE
Rainey, Kizer, Reviere & Bell
105 South Highland Avenue
Jackson, Tennessee 38301
(731) 423-2414

VIDEOGRAPHER: ROB SAWYER, Law Media Productions
ALSO PRESENT: ROLF HAZLEHURST
PATRICIA CHEN

I N D E X

E X H I B I T S

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EXHIBITS - CONTINUED

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EXHIBITS - CONTINUED

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EXHIBITS - CONTINUED

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EXHIBITS - CONTINUED

P R O C E E D I N G S

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THE VIDEOGRAPHER: This is the Internet video deposition of Dr. Kathryn Edwards in the matter of Hazlehurst versus E. Carlton Hays, M.D., et al. in the Circuit Court of Madison County, Tennessee, Docket C-04-149. I'm Rob Sawyer of Law Media Productions. The court reporter is Samantha Cohen of Riverside Reporting. Today's date is August 25, 2020. We're on the record at 8:09 a.m. Central time. Counsel, will each of you identify yourselves for the record which will be followed by the swearing of the witness by the court reporter.

MR. RILEY: I am David Riley on behalf of Yates Hazlehurst.

MR. SIRI: Aaron Siri on behalf of Yates Hazlehurst as well.

MR. SANDERS: Craig Sanders on behalf of Dr. Carlton Hays and The Jackson Clinic.

KATHRYN EDWARDS, M.D.,

Having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SIRI:

Q Good morning, Dr. Edwards.

A Good morning.

Q For the record, could you please state your full name?

A Kathryn Margaret Edwards.

Q Have you been deposed before?

A Yes, sir, I have.

Q Okay. How many times have you been deposed before?

A Five or six.

Q And what did those matters typically involve?

A They involved adverse consequences of hospitalizations in patients with toxic shock, with infections, with other kinds of unfortunate events.

Q Were you a party, were you a defendant in any of those cases?

A No, I was not, sir.

Q Okay. Were you an expert witness in those cases?

A Yes, I was a treating physician in several and an expert witness in some.

Q Okay. In the cases where you were a treating physician, you weren't a listed defendant?
A No, I was not.
Q Okay. Did any of those cases involve a vaccine?
A No, sir.
Q None of them involved an adverse reaction to a vaccine?
A No, sir.
Q I'm going to go through a few rules. Now, you've been deposed before, so you probably have heard this, but we'll do it nonetheless. The court reporter, as you know, has just placed you under oath. That is the same as a court of law, so you're testifying under penalty of perjury. Do you understand what I mean when I say perjury?
A I do, sir.
Q The court reporter is going to make a record by typing up all the questions and your answers. When answering questions, please speak audibly. The court reporter can't take down nods; okay?
A Yes, sir.
Q Okay. And also, you know, mm-hmms and the -- you're familiar with that, those kind of verbal

incantations are also not -- they're not responsive, so yeses or nos or -- it sounds like you're familiar with that; right?

A Yes, sir.

Q Okay. If you don't understand the question, please let me know before answering; okay?

A Yes, sir.

Q All right. And, you know, I'm sure there are times where you will predict my question before I finish it, but I kindly ask that you wait until I finish the question so this -- just so we have a complete record of what I asked before you answer it; okay?

A Yes, sir.

Q All right. Now, you know, we're not asking you to speculate, and if you don't know the answer then state as much, but you should provide your best recollection even if vague or partial; okay?

A Yes, sir.

Q Okay. One special instruction is that under normal circumstances, if we were sitting in a room, I would hand you exhibits so you'd have an opportunity to flip through pages. In this format, I'll be putting the exhibits on the

screen, so if you'd like me to scroll up or down, just let me know, I'm happy to do that for you; okay?

A Yes, sir. Yes, sir.

Q Okay. All right. Are you taking any medications or under the influence of any other substance that might affect your ability to testify today?

A No. I'm on antihypertensives and Vitamin D.

Q Okay. Do you believe those would affect your ability to testify today?

A I do not.

Q Okay. How did you prepare for today's deposition?

A I reviewed the medical records and -- reviewed the medical records and the medical literature.

Q Okay. And you say you reviewed the medical records. I presume you mean the medical records of Yates Hazlehurst?

A Yes, sir.

Q Okay. Were those the only medical records you reviewed?

A Yes, sir.

Q Who provided you with medical records?
A Those were provided by Mr. Sanders.
Q Okay. And for what period of time did those medical records encompass approximately, or up until what age?
A The records that I have were -- provided information up until depositions in 2016. That's the last that I have.
Q Okay. And what were the -- what was the scientific literature that you reviewed?
A I reviewed the Red Book, I reviewed several articles about autism, that -- I reviewed the Danish study about autism and the lack of association with MMR, and those were the main ones I -- you know, I reviewed the literature extensively about all kinds of things, so, you know, I'm pretty much always reviewing the literature.
Q When you say you looked at the Red Book, what edition or year did you review?
A I reviewed the 2000 Red Book, I reviewed the 2015 Red Book, and I reviewed the most recent Red Book.
Q And in terms of the autism articles, do you

recall specifically which ones you looked at?
A I'm sorry, sir, the authors of the articles that I reviewed?
Q Oh, no, I apologize. The autism articles that you looked at -- you mentioned autism articles. Do you recall which ones you looked at, titles? Or sometimes people refer to them by name of the first author.
A No, sir. I can pull them up if you would like me to and/or send you the PDFs if you'd like to review them.
Q Sure. We can do that after the deposition. We'd happily take copies of those. And then you reviewed the -- and then you said you reviewed the Danish study. That's -- that was a pretty recent study. Is that right?
A It was in 2019 in the Annals.
Q Yeah, okay. Anything else that you reviewed paper-wise or digitally?
A I -- not specifically that I recall, but I did review a number of articles, and that's kind of what I do all the time, so --
Q Yeah, understood. You've got a lot of published articles as well. Okay. Did you meet

with anybody to discuss this deposition?
A Mr. Sanders and I talked about sort of the mechanics of the deposition. I -- there were a couple of documents that -- that I wanted him to provide me which I didn't have, which he also did.
Q Okay. And did you meet in person or did you do it digitally?
A No, sir, we did not. We did not meet in person. We met by Zoom.
Q Okay. And then -- and other than Mr. Sanders, did you meet with anybody -- meet or talk with anybody else about today's --
A No, sir.
Q -- deposition?
A No, sir.
Q Okay. So before today, you didn't have discussions about this deposition or this case with anybody but Mr. Sanders?
A No, sir, I did not.
Q How did you first learn about this lawsuit?
A When Mr. Sanders contacted me to ask him -- ask me if I would testify.
Q And since that time, the only person you've spoken to was Mr. Sanders about this lawsuit in

any way?
A That is correct. That is correct.
Q Okay. Just to close us up on that, you do not -- have not spoken or communicated in any way, either electronically or otherwise, with any of your colleagues who are infectious disease doctors or vaccinologists about this case in any way?
A No, sir.
Q Okay. I'm going to go through a list of acronyms, and for the record can you please state what you understand each stand for? This way we've -- as we use those acronyms in this deposition, or terms in this deposition, we have a baseline understanding. These will seem very obvious to you, but not necessarily to everybody. HHS.
A Health and Human Services.
Q All right. That's the United States Department of Health and Human Services; correct?
A That's correct.
Q The cabinet level department within the federal government? I'm sorry?
A That's correct, sir.
Q Okay. CDC.

A Centers for Disease Control and Prevention.
Q Okay. FDA.
A Food and Drug Administration.
Q NIH.
A National Institute of Health.
Q HRSA.
A HRSA?
Q Right.
A You --
Q I never -- I never use the full name either.
A You'll have to tell me and I'll say if that's correct.
Q Health Resources and Services Administration.
A Yes, sir.
Q All right. Okay. It sounds right; right?
A Yes.
Q Okay. ACIP.
A Advisory Committee for Immunization Practices.
Q Right. ACIP is the committee within the CDC that effectively decides upon the CDC's childhood immunization schedule; correct?
A For the use in the public sector, yes.
Q Right. Meaning what, you know,

pediatricians, for example, would typically use in their -- in -- to administer to children in private practices?

A Correct.

Q And VRBPAC.

A Vaccines and Related Biologic Products Advisory Committee.

Q And VRBPAC is the committee within the FDA that effectively decides upon which vaccines to license; correct?

A Not exactly. The VRBPAC committee answers questions that the FDA poses to the committee that are related to the effectiveness and the safety of the vaccines. The ultimate decision to license a vaccine is solely that of the FDA.

Q That's right. But the -- VRBPAC is the committee that will vote to make a recommendation on whether to -- for --

A They will vote.

Q -- whether the F -- let me -- I'm -- whether the FDA should or should not approve a vaccine for licensure; correct?

A The questions are posed does this vaccine -- is this vaccine efficacious, and they -- the

people vote on that. Is this vaccine safe, the people vote on that. So then those decisions are taken into account when the vaccines are licensed, so if a vaccine is safe and efficacious, the recommendations would be for VRBPAC that that vaccine could be licensed, but the FDA licenses them.

Q Right. The VRBPAC will make a recommendation to the FDA whether to license or not to license the vaccine, but it's up to ultimately the commissioner of the FDA to choose whether to license or not license; correct?

A That's correct.

Q Okay. Are you aware of any instance in which VRBPAC has made a recommendation to license a vaccine and the FDA commissioner did not license the vaccine?

A No, sir, I'm not.

Q Okay. Now, the CDC, FDA, NIH, HRSA, ACIP, and VRBPAC are all within or part of HHS; correct?

A Yes, sir.

Q Okay. What does IOM stand for?

A Institute of Medicine.

Q Okay. Do you consider the IOM and all the

agencies and committees we just listed as reliable authorities with regards to vaccines?
A I think that the reliability of each of the agencies must be judged on the specific question that you're asking.
Q All right. So there are instances in which, for example, the CDC is not reliable when it comes to vaccines?
A I think that you asked me a blanket question about all of the agencies and HHS, whether they're always efficient and effective, and that's really a very broad general statement. I think that the Centers for Disease Control have responsibility to -- to provide the guidelines once vaccines are licensed for how they will be used in the public sector. When they do that, they -- they use skill and they are the authoritative source for those recommendations.
Q So you would consider the CDC a reliable authority with regards to vaccines?
A Yes, sir.
MR. SANDERS: Object to -- object to the form of the --
A In general.

MR. SANDERS: -- question.
A In general.
Q (By Mr. Siri) In general. And you would consider the information that the CDC produces with regards to vaccines to be reliable, a reliable authority with regard to vaccines; correct?
A I think that there are so many recommendations. If you want to ask me about any specific ones, I will address whether I think that is reliable or not.
Q Okay. So you believe there are instances in which the CDC may not be reliable with regards to information provided regarding vaccines?
A The recommendations for the CDC are what's implemented and in general are reliable.
Q It sounds like you're saying that there could be exceptions. Is that right?
A Well, let me give you an example that's not vaccines. So at the beginning of the pandemic, the CDC said do not wear masks, you do not wear masks, you take the masks from the people and do not wear masks. So with additional information, the CDC says wear masks. So you're asking me to

answer a question that is inclusive of all time and all recommendations, and I'm not -- I don't feel that that is a focused enough question that I can answer it in an affirmative or a negative.

Q Understood. Fair enough. So what you're saying is that, for example, the CDC at one point said don't wear masks, now it said you can wear masks, and so, you know, it's possible the CDC gets things wrong in an area that wasn't vaccines and --

A It's not -- well, it's possible that a recommendation is made when there are inadequate facts to -- to make a definitive recommendation, so when more information is available, then one makes a recommendation in another way. Let me give you a vaccine example.

Q Sure.

A Same example would be oral polio vaccine. Oral polio vaccine was used for many years, was highly effective in preventing disease, but every year between four and eight children would get vaccine-acquired polio. Because that polio was eradicated from the hemisphere, it was decided that that would be a risk that was not acceptable

for the prevention of polio in the United States. So at that time, the CDC said, we will use IPV, inactivated polio. So if you say that the recommendations when we were using OPV are -- are correct, they were correct for that time, but the reason that we've changed them is that additional information becomes available. So if you want me to say something is authoritative and correct, I need to know what the question that you're asking me is.

Q Yeah, I wasn't asking about anything specifically. I was asking just generally do you consider the CDC a reliable authority with regards to vaccines.

A In general, yes, that's what I said before, thank you.

Q Okay. And -- and is that true of the FDA as well?

A In general, yes.

Q Yeah. In general, you consider it a reliable authority. Would that also be true of the NIH, HRSA, ACIP, VRBPAC, and HHS itself?

A Given the question that you're asking, I -- to be specific, I would need to know the question,

but in general, yes.
Q In general, you would consider those to be reliable authorities regarding vaccines?
A Yes.
Q What does GSK stand for?
A GlaxoSmithKline.
Q Okay. What is the National Childhood Vaccine Injury Act of 1986?
A It is a no-fault compensation system that is paid for by the -- the excise tax on vaccines. It is a system where special masters review the information related to an adverse event, and depending upon whether they're table injuries or injuries that are associated with adverse events, then if indeed the special masters and the -- and the process deems that an adverse event has occurred, then the -- then the plaintiffs will be compensated for the adverse event.
Q Right. So when it's a -- when you say table injury, what you're referring to is an injury in which it falls into certain specific -- certain injuries that occur in a certain period of time after certain vaccines, then the burden shifts to the government to show the vaccine didn't cause

the injury; correct?
A There's a table of injuries that are placed on -- and I don't have it in front of me. I certainly could pull it up.
Q I'm sorry for using some -- I'm sorry for the law lingo. Let me ask it -- let me ask you a simpler question, and we'll come back to the table of injuries. Right -- the National Childhood Vaccine Injury Act of 1986, I'll refer to that as the '86 Act; okay?
A '86 Act? Okay.
Q The 1986 Act.
A Okay.
Q Okay. So this way we can use that as shorthand. Now, this is the law -- and this is the law that in addition to creating the Vaccine Injury Compensation Program, as you mentioned, it also gave vaccine manufacturers immunity from economic liability for injuries caused by vaccines; correct?
A That is correct, sir.
Q Okay. In 1991, you became a professor of pediatrics in the division of infectious disease at Vanderbilt University School of Medicine;

correct?
A I think it was 1991. I don't have my CV in front of me. I came to Vanderbilt in '80.
Q Okay. But you still hold that position?
A I do, sir.
Q Okay. 2008 you became the chair of pediatrics at Vanderbilt University School of Medicine?
A No, I'm not the chair of pediatrics. I have an endowed chair, which is a chair that is -- that is funded by the endowment of the university that pays a portion of my salary. I am not in an -- I am not the chair of pediatrics.
Q Okay.
A I am a professor of pediatrics and have an endowed chair.
Q Thank you for that clarification. Okay. And in 2001 you became the vice chair for clinical research in the department of pediatrics at Vanderbilt University School of Medicine?
A Yes, sir.
Q In that year, you also became the director and the scientific director of the Vanderbilt Vaccine Research Program; correct?

A Yes, sir.
Q Okay. And you've received dozens of honors and awards related to your work in infectious disease, pediatrics, and vaccines?
A I've received some awards, yes.
Q I'm looking at your CV. You've got a -- almost a full page of awards and honors, but I appreciate your modesty. You've been invited -- you've been an invited speaker to over 250 events on these topics all over the world; correct?
A Yes, sir.
Q You have over 500 publications, most in peer-reviewed journals and most regarding or related to vaccinations or the infections they're intended to prevent?
A Yes, sir.
Q You've been a member of numerous committees, including at the FDA, CDC, and WHO that voted upon or related to national policy with regard to vaccinations; correct?
A Yes, sir.
Q You were on the editorial board for reviewer of some of the most prestigious journals regarding vaccines, including the journal Vaccines and

Clinical and Vaccine Immunology; correct?
A Yes, sir.
Q You're a member of the National Academy of Medicine, which was formerly known as the IOM; correct?
A Yes, sir.
Q Okay. And you are the principal investigator of the CDC's Clinical Immunization Safety Assessment Network?
A Yes, sir.
Q Okay. You conducted clinical trials to support the development for licensure of various vaccines; right?
A Yes, sir.
Q Okay. And you spent much of your career evaluating the safety and effectiveness of vaccines?
A That's correct.
Q You're an internationally recognized expert in vaccinology; correct?
A Yes, sir.
Q The medical textbook on vaccines is called Plotkin's Vaccines; correct?
A Yes, sir.

Q And it's got four names on the front of it; right?
A Yes, sir.
Q Okay. And you're -- what are those four names?
A Well, one of those is my name, so I'm an associate editor of Plotkin's Vaccine textbook.
Q And the other three individuals?
A As is Dr. Paul Offit, as is Dr. Walt Orenstein, and Stanley Plotkin is still an active member of that as well, and myself.
Q What's the name of the plaintiff in this case?
A Mr. Hazlehurst.
Q Okay. And what's the name of his child?
A I think his first name is William, but I think he goes by Yates.
Q Okay. Have you ever physically examined Yates?
A No, sir, I have not.
Q Have you ever met Yates?
A No, sir, I have not.
Q Is it your opinion that vaccines Yates received played a role in his -- no, a role in his

autism?
A I -- I'm of the opinion his vaccines played no role in his autism.
Q Is it your opinion that the vaccines Yates received collectively played no role in his autism?
A I believe that none of the vaccines played a role in his autism.
Q Neither individually, nor collectively?
A Neither individually, nor collectively.
Q Okay. What vaccines did Yates receive?
A He received a number of vaccines. I have his vaccine record here. I can read it for you. He received a DTP vacc -- DTaP vaccine, he received Hib vaccines, he received Prevnar vaccines, he received IPV vaccines, he received hepatitis B vaccines, he received MMR vaccines, and he received varicella vaccine.
Q Okay. Thank you. Who manufactures the varicella vaccine that Yates received?
A Merck.
Q Okay. And the MMR vaccine?
A Merck.
Q Okay. And the hepatitis B vaccine?

A There are two different manufacturers. Do you want me to look? I can read it. It's right here. I don't -- I don't --
Q Fine, please.
A SKB or GSK, SmithKline Beecham.
Q SKB stands for SmithKline Beecham?
A Correct.
Q And it -- you said or GSK because it became part of GSK; correct?
A That's correct.
Q Okay. And then the IPV vaccine he received?
A The IPV was from Connaught.
Q And that was merged into what company?
A Well, it's an international company now, and it -- it is part of an international conglomerative with Connaught and --
Q Sanofi; correct?
A Sanofi, yeah. Sanofi Pasteur, sorry.
Q No, no problem. And the brand name of the vaccine is IPOL; correct?
A Yeah, I believe so. It's just written down as the lot number and the name, but yeah.
Q Yeah. And the brand name for the HepB vaccine is Engerix-B; right?

A I guess, yeah.
Q Is it -- is it -- is that right?
A I believe so. I -- I don't -- yeah. I believe so. I -- I don't have the package inserts in front of me.
Q No, that's okay. I mean, it's -- I know, it's not uncommon that -- you know, most pediatricians and doctors don't -- you know, they typically refer to it by the manufacturer and not by the brand name. I -- but I just want to develop a complete record. So, right, SKB and GSK, they've got Engerix-B, right, and then Sanofi has a Hep -- excuse me, Merck has a HepB product. As you said, there were two. Engerix-B would be the one that's sold by GSK, formerly SKB; correct?
A Yes, sir.
Q Okay. By the way, the official brand name for the MMR vaccine is MMR2; correct?
A Yes, but I don't know whether the MMR2 was -- was this -- whether MMR2 was what was given here or not. Let's see.
Q Wasn't MMR2 licensed in 1978?
A I don't know, sir, the exact year that it was licensed.

Q Okay. Well, take a look. If you think it might be the initial -- the first MMR, let me know.
A The MMR, it says MMR number one, but I think what that means is that they're -- they're just noting that there was the first MMR that was given. The -- the varicella vaccine, it says it's Merck here, and let's see the measles, it doesn't say the exact name.
Q That's all right. The initial MMR had a different rubella component; correct?
A I believe so.
Q If you --
A I'm not --
Q Go ahead.
A I'm not sure exactly what the difference is.
Q Okay. If you don't know, then say you don't know. That's fine.
A I do not know.
Q Okay. Are you aware that the initial MMR vaccine was licensed in 1971?
A I didn't know the exact year it was licensed, sir.
Q Okay. Are you aware that the initial MMR was

replaced by MMR2 in 1978 when the rubella component was changed with the one developed by Dr. Stanley Plotkin?

A I didn't know what year it was, but thank you for telling me.

Q Okay. Yates received his MMR in the year 2001; correct?

A That is correct, sir.

Q Okay. Did -- do you -- is it your testimony that Yates could have received the initial MMR vaccine, the MMR1?

A No, sir. I think that -- I'm sorry, but all -- what I'm saying is that what the medical record says does not say any more about what kind of MMR other than it was provided by Merck, so if the MMR2 was available, then -- then I'm sure that's what he received. I just don't know which year those vaccines were changed.

Q Understood. Okay, fair enough. You just didn't know whether MMR1 was still being used?

A I don't know which MMR that Yates got because what it says is MMR number one. I trust that was the first dose, but I don't have any other characterization of the MMR vaccine that he

received from the medical record. I'm sure that it was the one that was approved and licensed, however.

Q Right. It presumably would be the one that was the only one in use in that year; correct?

A Correct.

Q Okay. The brand name for the varicella vaccine Merck makes is called VARIVAX. Is that right?

A Yes, sir.

Q Okay. And you also said that he received -- Yates received a Prevnar vaccine.

A Yes, sir.

Q And who manufactured the Prevnar vaccine?

A The -- it -- it's made by Wyeth. It was first licensed for use in 2000. Before that time there was not a pneumococcal conjugate vaccine.

Q All right. So the manufacturer was Wyeth Lederle, and then -- correct?

A Lederle. Wyeth Lederle, yes.

Q Lederle, thank you. This is what happens when you only read things and nobody ever -- you never speak them out loud. And then Wyeth Lederle then became part of Pfizer; correct?

A That's correct, sir.
Q Okay. And the initial Prevnar was called Prevnar or sometimes referred to as Prevnar 7; correct?
A That's correct, because there were seven of the -- of the 100 serotypes of the pneumococcal organism, there were seven that caused most disease, so those were the vaccines that were included in this, the Prevnar 7. It currently now is 13, and there are efforts being made to make it 20.
Q Right, because they're finding serotype replacement, right, meaning these serotypes are not in the vaccine, they're becoming more prominent as the older serotypes are being pushed out; correct?
A Correct.
Q Okay. Then you said he received a Hib vaccine.
A Uh-huh.
Q Well, who manufactured that one?
A There are several different kinds of Hib vaccines. The one that he received were Lederle.
Q Right.

A Because on the -- their differences are in what they are conjugated to, which --
Q Right.
A -- are -- what the capsular polysaccharides are conjugated to.
Q Okay. So Wyeth Lederle is the manufacturer of that vaccine and it was called HibTITER; correct?
A Correct.
Q Okay. And finally, he received a DTaP vaccine. And who manufactured that?
A That -- he received Tdap -- or excuse me, DTaP. It was Infanrix, which is GSK.
Q And at the time he received it though, it was -- it was by -- sold by Wyeth Lederle; correct?
A No, it wasn't, because it says Infanrix, and Infanrix is all -- is made by GSK. All of the GSK vaccines have rix at the end because they are all made in Rixensart, Netherlands, and so Infanrix was made by GSK at Rixensart.
Q Do you see in Yates' medical records it says Lederle next to the manufacturer of his DTaP vaccine?

A No. I see that -- that he has DTaP 1, 2, 3, and it says Infanrix. Now, there are -- he may have had boosters. No, I see on the next page that it's DTaP Infanrix 4. Now, there may have been another -- now, I don't see -- all that I see are Infanrix. There -- yeah, I see -- that's all that I see in that.

Q Understood. I'm going to share my screen for a moment.

A There is one -- there is one DTaP number one that says that it was made by Lederle, so that's 4/07, so it looks like the first dose -- again, it -- it -- well, it looks -- it says on 4/7, 6/6, 8/16 that the vaccine was made by Infanrix, and then there is one place where it says the DTaP was made by Lederle.

Q Okay. Are you looking at his --

A Lederle doesn't -- time out. Lederle does not make DTP vaccines at that point. They used to, but they don't any more. Now, whether they were still making it at that time, I'd have to check.

Q Okay. Are you looking at his handwritten immunization record?

A I'm looking at the handwritten and I'm also looking at a typed immunization record.
Q All right.
A So I'm looking at two different records.
Q Okay, understood. Okay. And you're correct, the first dose says Lederle and the other doses say SKB next to them, which became GlaxoSmithKline, as we talked about. Okay.
A No --
Q All right.
A -- SKB doesn't -- no, SKB doesn't become GlaxoSmithKline. SKB is GSK, and GSK makes Infanrix, and Infanrix is made in Rixensart, and it's never been a part of Lederle.
Q Perfect. Okay, great. Okay. So those are the seven vaccines, and I think we've established who made them, what their brand names are. With that, we'll move on. At what age -- what age did Yates receive his first vaccine?
THE VIDEOGRAPHER: Excuse me, Dr. Edwards, I don't think we -- did we hear that?
Q (By Mr. Siri) Oh, Dr. Edwards, you're muted.
A So, I'm sorry, would you ask the question again?

Q No problem. At what age did Yates receive his first vaccine?
A He received his first DTaP vaccine and his Hib and his IPV slightly less than two months of age.
Q Okay. And at what age did he receive his last vaccine?
A The last vaccine that I have record of was received on -- let's see. The last -- let's see. It would have been -- the last vaccine I have a record of would have been the varicella vaccine, which was 8/17/01. Now, whether there was another -- you know, that -- that's the immunization record that I have here.
Q Right. Based on the immunization records you have, the last vaccine was on August 17, 2001, and that would have made him around 18 months old; correct?
A That's correct.
Q Okay. Have you -- have you received any payments from Merck?
A I have served on one advisory board and I received some payments from Merck, but the advisory board -- I am not on the advisory board

now, and I will be being asked by Merck to be on their data safety and monitoring board for the evaluation of a new vaccine.

Q Data safety and monitoring board, otherwise known as a DSMB; correct?

A That is correct, sir.

Q And those are boards that review the safety and efficacy of the data that's produced during the course of a clinical trial; correct?

A That is correct. That is a member of an independent group of individuals who are deemed to be vaccine experts or statisticians that are -- are a part of the trial, but they're independent of the investigators and independent of the company. They review all of the adverse events that are associated with a vaccine under study, and they are at liberty to halt a study if there are adverse events that are -- are worrisome or there are concerns about the safety of the vaccines.

Q Right. So the members of the DSMB are independent of the company that's actually conducting the clinical trial?

A That is correct, sir.

Q And that's why it's often referred to as an independent DSMB as well; correct?
A That is correct.
Q Okay. And so what you're saying is you're going to be on the independent DSMB for one of the clinical trials that Merck is going to be conducting and that it will then, you know -- will you try to -- which clinical trial it will then -- it hopes to submit to the FDA to license a product; correct?
A Well, that would be the ultimate goal of the evaluation of a vaccine would be that it would be licensed.
Q And this independent DSMB that you'll be sitting on, is this for a COVID vaccine?
A No. I'm actually on a number of data safety and monitoring committees. I'm on a COVID vaccine safe -- DSMB for Pfizer, I'm on an NIH DSMB for the use of monoclonal antibodies for the prevention of COVID infections, and I'm on an international DSMB from the Coalition for Epidemic Preparedness for a number of vaccines that are being studied in developing countries.
Q Okay. So for Pfizer, it's -- that's for the

COVID vaccine they're developing?
A That is correct.
Q That's the one that they're doing in conjunction with -- who was that?
A With a German manufacturer.
Q Is that BioNet?
A Yes, sir.
Q That's going to be an mRNA vaccine?
A It is an mRNA vaccine.
Q And the board, these independent DSMBs that you're sitting on, you said, for the -- outside of the U.S., are these also for vaccines?
A Yes, sir, they're for COVID vaccines.
Q They're all for COVID vaccines?
A Yes.
Q And which company's products are under review in those DSMBs?
A Oh, there --
Q Are the --
A There are a number of different companies that are being evaluated in that regard. We go over all of them. The one that I'm specifically working mostly with is an OVO, the DNA vaccine.
Q Okay. Okay. So going back to my specific

question, so I believe you said you have received payments from Merck; correct?

A I have received payments from Merck.

Q Okay. Over the course of your career, what would you say total in terms of payments have you received from Merck?

MR. SANDERS: I'm going to object to that question. I don't think any specific amounts of money that Dr. Edwards or any of the defense experts receive beyond what they're paid in this case is discoverable.

MR. SIRI: She is here testifying regarding whether a product that Merck manufactures and sells didn't or did not -- did or didn't injure my client. Nothing could be more relevant than proffering an expert and the question of whether or not they received payment from the very company whose product is at issue in a case and caused an injury, so you're free to make that objection, you have it on the record.

MR. SANDERS: Yeah, she's not going to answer those questions. We can take that up --

MR. SIRI: That's not a -- there's no privilege. There's no basis for not answering a

question where there's no privilege.

MR. SANDERS: It's not discoverable.

MR. SIRI: Okay. Merck manufactures the MMR vaccine, Merck sells the MMR vaccine. She's here testifying that Merck's product didn't cause autism, the central question in this whole case, and you don't think the payments she may have gotten from Merck are relevant to whether or not she has any bias in this matter?

MR. SANDERS: Sir, I don't think it's discoverable in this case. We can take it up with the Court.

MR. SIRI: So let me get this straight. If you brought an expert on a car defect case regarding a Ford car and the expert -- the question of whether the expert got money from Ford is not discoverable?

Q (By Mr. Siri) Well, look, Dr. Edwards, Mr. Sanders here is not your attorney. He's the attorney for the defendant. You know, there is no -- are you asserting any privilege here? Did you have a discussion with your attorney? Is this -- is there any kind of --

A Is --

Q Go ahead.
A I don't have an attorney for this case. I am simply being asked to be an expert witness.
Q That's right.
A I have -- I have -- have worked for some companies. I've worked for a number of companies, but not extensively and not until recently, and at the time that I was -- that these events happened, I was not -- I was not at all -- had not at all been paid to do anything for these companies, and I -- I do have a lot of expertise, I have a lot of experience, and they call upon me to provide information, and I don't do this extensively, but I -- I -- I do this, and if you -- you know, you can ask everyone that I'm -- that I -- I have integrity, I am looked upon as being a -- an objective, careful scientist, and the amount of money I have received is trivial.
Q Well, then how much was that?
MR. SANDERS: Dr. Edwards, you're free to answer if you want to. If you don't --
A You know, I really don't feel --
MR. SIRI: All right, counselor, she already characterized it.

Q (By Mr. Siri) You said trivial. How much was the amount?
A $5,000.
Q All right. In your whole career?
A I -- yes.
Q Okay. How much did you receive, let's say, last year, in 2019?
MR. SANDERS: Same objection.
MR. SIRI: Your objection is noted, counselor, that's fine.
Q (By Mr. Siri) Please answer the question, Dr. Edwards.
A You know, I don't feel that my financial story is relevant to this.
Q But that's not for you to judge, so I'm asking you how much in 2019.
MR. SANDERS: Well, who are you --
A From Merck?
MR. SANDERS: -- asking from, Mr. Siri?
A From Merck?
Q (By Mr. Siri) From Merck.
A About $5,000.
Q Okay. So you're saying the only payments you've ever received from Merck was in 2019?

MR. SANDERS: Object to the form of the question.

Q (By Mr. Siri) Is that right, Dr. Edwards?

A I don't -- I don't have all of my financial records out to be able to say that, and I'm not going to perjure myself because I don't know. I don't think so, but I don't know. I think that this is the only money that I've received from Merck.

Q Okay. And you said that you've only recently been involved with receiving payments from these companies. Is that right?

A That's correct, because when I was on the VRBPAC, when I was chair of the FDA advisory committee, it was imperative that I had no conflicts, and I had no conflicts. This was two years ago, and I served on the committee for several years, so I had no conflicts at that time. The reason that I have been involved in recent conflicts is because we have a national pandemic. We are having -- and we need people who know how to evaluate vaccine safety, and I spend a lot of time doing that. I spend every day from morning until evening helping on that effort.

Q So in -- so what you're saying is that, for example, when you were on VRBPAC, you weren't a consultant to any vaccine manufacturer?
A No, sir, that is correct.
Q Okay. And you weren't an advisor to any vaccine company?
A No, sir, that is correct.
Q And you weren't on any speakers' bureau for any vaccine company?
A I have never been on a speakers' bureau, thank you.
Q Uh-huh. You are currently an advisor to Merck; correct?
A I am not an advisor to Merck. I serve on their -- on a -- an upcoming DSMB, which has not yet begun.
Q I'm going to share my screen, and let me see if I can do this without messing it up. Okay.
MR. SIRI: Now, I'm going to mark this as Plaintiff's 1, Ms. Cohen, and I'll proceed. Is that okay? Okay.
THE COURT REPORTER: Yes.
MR. SIRI: Okay, thank you.
THE COURT REPORTER: Yes, sir.

(Whereupon, Exhibit No. 1 was marked to the testimony of the witness.)

Q (By Mr. Siri) Dr. Edwards, are you -- are you familiar with this article?

A Yeah. I wrote it.

Q Okay. And that's your name on the first page; correct?

A That's my name, Kathryn M. Edwards. That's my name.

Q And this article was published this year; correct?

A That's correct.

Q Okay. And it says that you've served as an advisor for BioNet and Merck; correct?

A Okay. Yes, so this -- so this -- I have recently been removed as an advisor and now I'm on the DSMB, so as I testified to you before, I was an advisor to Merck.

Q Okay.

A But I am no longer an advisor to Merck. I am also an advisor to BioNet, which is a Thai pertussis vaccine manufacturer.

Q Okay.
A They have a pertussis vaccine that is genetically engineered, and I am an expert for that. I meet once a year to go over their portfolio with them with a bunch of other experts, including Dr. Plotkin.
Q Wonderful. Dr. Plotkin is an advisor and a consultant for all the big vaccine manufacturers. Now, are you paid fees for being an advisor to Merck? Were you paid fees for being an advisor to Merck?
A I told you that I was paid to be an advisor to Merck. I told you how much I was paid.
Q Okay. And, oh, so you were only paid in 2019? You weren't paid in 2020?
A No, sir, that's correct. I was paid one time.
Q Okay. And you've been a consultant for Merck; correct?
A I am on their -- I'm going to be on their data safety and monitoring committee, which is different than being a consultant. I was a consultant at -- and an advisor at that time on that paper, but I am currently not.

Q Okay. So you were a consultant for Merck. Is that a yes or a no? I'm sorry.
A Yes.
Q Okay. And you received personal fees from Merck; correct?
A Yes.
Q Okay. And you've received research funding from Merck; correct?
A I -- I'd have to look over my CV to see whether I have in the past or not. I've done a lot of vaccine studies, and, you know, some of those are funded by the NIH. I've had a long-standing vaccine evaluation contract with that, but I also have done intermittent trials, and those are trials that support the nurses and the people that do the clinical trials, so I don't know. I would have to look at my CV. I can't remember for sure. I've been doing this for 40 years.
Q Sure. By the way, do you recall how many lunches Merck paid for you to have in 2019?
A I had breakfast and lunch at the meeting. Do you want me to tell you what I ate?
Q I'm just asking if you recall how many

lunches in 2019 Merck paid for.

A I had one lunch -- one lunch and one breakfast.

Q I'm going to share my screen.

MR. SIRI: I'm going to mark this as Plaintiff's 2.

(Whereupon, Exhibit No. 2 was marked to the testimony of the witness.)

Q (By Mr. Siri) Taking a look at this list, this is -- this is you; correct? Kathryn M. Edwards?

A Yes.

Q And this is information of Open Payments Data.

A Okay.

Q Are you familiar with this --

A This --

Q -- government database?

A No, I'm not, sir.

Q Okay. You're not aware that this government database is one which pharmaceutical companies report all of the, you know, travel and meals and

consulting fees that they pay to doctors?
A No, sir, I am not. This isn't something that I generally look at, thank you. But thank you for telling me.
Q No problem. So you can see the first two entries over here from 2019 provide around $5,000, as you said. You said you had one meal, but when you scroll down, we can see there's far more than one meal; correct?
A Well, I don't -- I wasn't -- I was only there a night and a day, so I don't know how I could have eaten that much.
Q One, two, three --
A I'm a little --
Q -- four, five, six, seven --
A Well, I don't -- I don't -- I mean, I'm not a very big person, so I -- it's hard for me to imagine that I could have eaten several hundred dollars in a day, but I --
Q They reported that data. That doesn't mean they're happening that day.
A Okay. Well --
Q My picture, I'm pretty skinny, he eats a lot too. All right. Well, let me ask you -- okay.

You said you've never been on any speakers' bureau; correct?
A Not that I know about. I don't know what -- I mean, I've given lectures for people that have asked me that maybe they said -- have had paid by a company, but I'm not on a speakers' bureau.
Q And what years were you sitting on VRBPAC?
A 2016 to 2018, I believe.
Q And weren't you also on VRBPAC between the years of 1996 and 2000?
A I believe so.
Q That's what it says on your CV. Would you like me to pull it up?
A Okay. No, I hope that you're being honest.
Q Well, I -- let's -- like, we can pull it up then, if you'd like.
A No, that's fine. That's fine.
Q Okay. I'm going to share my screen again.
A I think you do need to understand that sometimes people are asked to speak at various places, and it's not always clear how the financing for those places have arrived, so often, you know, people will ask me to come speak, and I'm not quite sure exactly how the compensation

was provided, so -- but go ahead. Let's see what you're going to show.

Q Okay. Now, so this is an article in which -- Acellular Pertussis Vaccines; correct? Are you familiar with this article?

A I've written a lot about acellular pertussis. Is this one of my articles?

Q Uh-huh. It was listed --

A Okay.

Q -- on your CV as well.

A Okay. Then I probably wrote it.

Q Okay. And do you see the date, February 1998, that it was published?

A Yeah.

Q And it was published in Pediatrics in Review?

A Yes, sir.

Q And you're familiar with that journal; correct?

A Yes, sir.

Q How are you familiar with that journal, by the way?

A Because I wrote an article for the journal, sir.

Q Okay. Go down to the disclosures in this

article.

MR. SIRI: And we're going to mark this as Plaintiff's 3.

(Whereupon, Exhibit No. 3 was marked to the testimony of the witness.)

Q (By Mr. Siri) Do you see what it says in yellow?

A Yes, sir, I do.

Q Okay. Can you read that, please?

A Yeah. Dr. Edwards has funding for research from Connaught and Lederle-Praxis and is on their speakers' bureaus. She's also a consultant for SKB.

Q Okay. And this is from 1998; correct?

A That's what it says, sir, and I'm sorry, I just didn't remember that. As I said before, I've been doing this for 40 years, so I haven't been on a speakers' bureau recently, but -- and -- but obviously that's what it says, so --

Q So you have been on speakers' bureaus for pharmaceutical companies; correct?

A That's what it says there, sir, I guess, yes.

I'm sorry, I did not remember that.
Q And you said before this past year you didn't have involvement, you know, as a consultant with pharmaceutical -- any pharmaceutical company. Does this refresh your memory that, in fact, you did have -- were a consultant for pharmaceutical companies before this past year? Let me -- let me ask it to you this way. Let me ask you again. Before last year, have you been a consultant to a pharmaceutical company?
A I -- yes, I have, but I -- what I said before was I said that I was not a consultant to a pharmaceutical company when I was on VRBPAC recently. I hadn't reviewed my status when I was on VRBPAC before, so again, I'm -- I misspoke, so you've shown some information here that I was a consultant for them and that I had -- was on the speakers' bureau at that time.
Q All right. So while you were sitting on VRBPAC, you were on the speakers' bureau of at least two companies and a consultant for one of them; correct?
A I would have to look exactly at the dates, sir, because one of the things about these is that

you are often asked to do -- state what's happened in the last five years, so --

Q Now, while you were on the speakers' bureau for Connaught and Leder -- what -- can you kindly pronounce it for me again?

A Connaught and Lederle-Praxis.

Q Lederle. Okay. While you were on the speakers' bureau for these companies, you were also conducting clinical trials for their products; correct?

A That's correct, I believe. Again, sir, I -- I -- I can --

Q Okay.

A For my CV, if you want me to tell you when exact times that I conducted studies for all of these companies, I'm happy to do that. It's hard --

Q Well, that's what we're doing right now, Doctor. That's what we're doing right now. Now, you were a consultant for Connaught; correct?

A It doesn't say that here. This says SKB.

Q I'm asking you if you were a consultant for Connaught.

A I don't recall whether I was or not, sir.

Q Okay. Let me share the screen again. This is an article that you were an author on; correct?
A Yes, sir.
MR. SIRI: I'm going to mark this as Plaintiff's 4.
(Whereupon, Exhibit No. 4 was marked to the testimony of the witness.)
Q (By Mr. Siri) This article is from 2000; correct?
A Yes, sir.
Q In the Journal of Pediatrics?
A Yes, sir.
Q Okay. Can you please read the item in yellow?
A Okay. Dr. Edwards is a consultant for and has vaccine trial contracts with Pasteur Mérieux Connaught, SmithKline Beecham, and Wyeth Lederle. She also gives lectures sponsored by Pasteur Mérieux Connaught and Wyeth Lederle, so yes, thank you so much for pointing that out. I didn't realize that I needed to go back and look for all of those in the past 40 years, but thank you so

much for doing that.
Q You're here today to testify about vaccines given to Yates in 2000 and 2001, and -- correct?
A Yes, sir, I am.
Q Okay. And including vaccines made by these specific companies; correct?
A Yes.
Q And you didn't think that your relationship with those companies were relevant?
A I --
MR. SANDERS: Object to the form of the question.
A -- did not feel that --
MR. SANDERS: You can answer.
Q (By Mr. Siri) All right. I'll strike the question. I don't care. Now, were you a consultant for Sanofi after Connaught merged into Sanofi?
A Well, you seem to be able to find out whether I am or not, given my papers, so maybe you could just pull that up. Again, I -- I --
Q I'm asking you, were you a consultant for Sanofi after merging to Connaught?
A I don't remember, sir. I'm sorry.

Q That's fine. I'm -- if you don't remember, we can -- that's fine. You're an author in this article; correct?
A Yes, sir, I am.
Q It was published in 2005; correct?
A Yes, sir.
Q In the New England Journal of Medicine; right?
A Yes.
Q I'm sorry?
A Yes, sir, I am an author on the article, thank you.
Q Okay. Can you kind of read the yellow?
A Dr. Cherry and Dr. Edwards report having received consultation and lecture fees from GlaxoSmithKline and Pasteur Mérieux and grant support from Sanofi Pasteur.
Q Okay. So you were a consultant for Sanofi in 2005; correct?
A That's what it says there, thank you.
Q Okay. And you received payments from Sanofi?
A I don't know what I received there. I guess I received lecture fees, so fees generally mean some money, so yes, I guess I did.

Q All right. And so -- and lecture fees usually means you're on the speakers' bureau; correct?
A Not necessarily at all, sir, thank you.
Q And you've received research funding from Sanofi through the years; correct?
A Yes, sir, I have.
Q Okay. Have you ever taken trips that were paid for by Sanofi?
A I have gone to meetings where I have been asked to participate in the conference and to provide information to do lectures and they have paid for my travel to those meetings, yes.
Q Okay. And where did these -- where did you go on these trips that Sanofi paid for?
A It depends to where the meeting was held. I would go to where they were held. Sanofi -- you know, Pasteur Mérieux has an office in France, so sometimes the meetings would be in France, and, you know, I was on a DSMB for a pertussis trial in the -- that was done in Senegal in West Africa in the 1990s. They -- for Pasteur, they paid me to go to Senegal, so I'm not taking pleasure trips that -- but I -- I'm -- what they're asking me to

do is go and work in these areas, and they pay for me to get to where I have to work.

Q Did Sanofi pay for you to take a trip to Ireland?

A I don't recall that, but they -- it's not a trip. It's a meeting. I go to the meeting and -- and they pay for me to go to the meeting.

Q And these meetings are typically about, I presume, some -- how it relates to one of their products; correct?

A They're generally about vaccines or vaccine approaches or -- or thinking about what might be an important approach to vaccines. They're -- they're -- you know, obviously they're on products -- or they're on -- they're about diseases that they're interested in for sure.

Q And have they typically been about pertussis?

A Well, they certainly were about pertussis in the '90s, and so that was a lot that was -- you know, lot of meetings and efforts. There were several at the WHO in Geneva and -- as well, and -- but since that time, pertussis has been less of an issue and -- and some of the other vaccine preventable disease have been more issues.

Q And Sanofi sells pertussis vaccines; correct?
A They do.
Q And after these meetings in these various foreign locations, there would often be a paper that would be published with regard to what transpired at the meeting; correct?
A Sometimes they would be, sometimes they would not be.
Q Isn't it true that when their papers are published, they almost universally call for expanding the use of pertussis vaccine or otherwise increasing pertussis vaccination rates?
A The articles that are generated, if my name is on them, must pass my scientific review, so if science is overstated or inappropriately stated, I would not put my name to that paper. I think that they're -- they're -- yeah.
Q I'm going to share my screen here for a second, and then we'll come back to the trips because -- we'll finish up that topic. Are you familiar with this -- with this paper?
A Yes, I am, sir.
Q Okay. This is a paper from Carnegie Mellon on a study on bias and physicians accepting money,

which was published by the AMA; correct?
A I can't see the lower publication.
Q Right there, American Medical Association.
A It looks like a JAMA editorial, yep.
Q Let me -- I'm going to read -- I'm going to read a portion of this and then ask you a question; okay?
A Yeah, I'm perfectly capable of reading as well, sir.
Q That's okay. I'll read it. The medical literature dealing with conflicts of interest bears similarities to the social science literature reviewed herein. Like the participants in the studies who did not view themselves as biased, physicians typically report that they are not biased by financial arrangements with pharmaceutical companies, although a large body of research suggests that they are. Although most physicians do not perceive themselves as biased, they do admit that conflicts of interest might compromise other physicians' decisions. A recent study of medical residents found that 61 percent reported that, quote, promotions don't influence my practice, end quote, while only 16 percent

believed the same about other physicians' practices. Clearly, it cannot be true that most physicians are unbiased and that most other physicians are biased. Are you familiar with this?

A I -- no, sir. I don't remember reading this, but certainly I've heard this discussion before.

Q Do you agree with what I just read to you?

A This is a discussion of an article, so, you know, I -- I --

Q Do you agree with the substance of what I just read to you?

A I think that they have a point. I think you know nothing about me. You know nothing about what I have been doing for 40 years, and you are -- are trying to make it look like that I am -- I have conflicts and what I say is not true, so you -- you know, you can do whatever you want. I have a strong moral core and I think that I have integrity, and if you want to continue to do this, this is just fine. I'm just fine. I think you'll have to -- you know, you -- you will have to continue and I will just continue as well. I'm just fine with this.

Q Okay. I'm just -- I'm just trying to create a full record of what your interactions were with the companies that made the vaccines that my clients received. It's just -- this is typical of what occurs when an expert comes into a case. Now, I asked you before, has Sanofi paid for your -- a trip that you took to Ireland in 2014?
A I don't know, sir. I can't remember.
Q All right.
A I've been, you know, all over the world, and I don't know. I think if they -- if they did, it was because I was going to go to a meeting to talk about a disease that they have an interest in --
Q Okay.
A -- because I'm an expert and they want me to be there because what I say is important and honest and noteworthy.
Q Is there somebody in the room with you, Dr. Edwards?
A My husband passes through. We're -- we're home.
Q Is there anybody who's assisting you in answering these questions, Dr. Edwards?
A No, sir. No, sir, there is not.

Q Okay. Let me -- maybe -- all right. I'm going to share my screen.

MR. SIRI: And I'm going to mark this as the next plaintiff's exhibit, whatever that number is. If somebody knows, please announce it.

MR. SANDERS: I believe it's 5.

MR. SIRI: 5, thank you.

(Whereupon, Exhibit No. 5 was marked to the testimony of the witness.)

Q (By Mr. Siri) So this is from Open Payments Data and it shows a payment in 2014 for travel to Dublin, Ireland in the amount of $6,600. Does this refresh your memory of the trip that Sanofi paid for in 2014 for you to go to Ireland?

A I do -- I do remember that -- you know, that the meeting -- I -- it was -- you know, it was 15 years ago or so, so I don't remember exactly, you know, these. I do travel to the meetings and these -- and these expenses are paid for my travel. If I wouldn't be going, then they wouldn't be paid.

Q Right. So this was six years ago though;

right?
A I thought it said 4 -- 2014.
Q Right. But you -- 2014 we should --
A About six -- yeah, six years ago. Yeah, six years ago.
Q So that, so you're saying, was a while ago. Okay. Why don't -- let's -- what about in 2015, maybe that's sooner, do you recall if Sanofi paid for a trip for you to go to Amsterdam, Netherlands in 2015?
A There was a meeting in Amsterdam. It was about maternal immunizations, and I -- I don't remember who paid for me to go, but if you have records that it was Sanofi, then that's probably what happened.
MR. SIRI: I'm going to mark this as the next exhibit. That will be number 6.
(Whereupon, Exhibit No. 6 was marked to the testimony of the witness.)
Q (By Mr. Siri) It says travel to Amsterdam in the amount of $4,400, paid for by Sanofi; correct?
A That's what it says, sir.

Q All right. And do you recall that Sanofi paid for a trip for you to go to Cancún, Mexico in 2017, which would have been three years ago?
A Yes, there was a pertussis meeting in Cancún.
Q Okay. And that -- and Sanofi paid for you to go to that meeting as well; correct?
A Yes, sir, they paid for my way to go to that meeting.
Q Okay.
A This is -- these are airfare and hotel room. There were no -- I did not accept any honorarium.
Q Uh-huh. Okay. The trip to Ireland, that was about pertussis?
A Yes, sir.
Q Okay. And -- and it was about promoting the use of pertussis vaccines; correct?
A It was about the appropriate use of pertussis vaccine, and -- yes, the appropriate use of pertussis vaccine.
Q Okay. To help increase pertussis vaccination rates; correct?
A It focused a lot on -- on the burden of pertussis in adolescents and babies. We -- we -- because there were still a lot of children that

were getting infected with pertussis, and so I had been part of a large WHO study about pertussis and -- and so we needed to think a little bit about how we needed to better control pertussis, and so that meeting was about how we could control pertussis for the world's children.

Q Right. And the way you control pertussis, at least as discussed in that meeting, would have been to increase pertussis vaccination rates; correct?

A Well, I think that was one option, but one option that was begun to be discussed was whether -- was whether the babies that were -- that -- that were succumbing to pertussis, that if we could vaccinate their mothers and give them antibody at the time they were born, that there would be a reduction in the global death rate from pertussis, which we knew to be quite large. So that was also something that was not yet implemented broadly but was being discussed as well, so it was -- the meeting was to talk about how -- how global programs could be used and the vaccine could be used in different populations to --

Q Okay.
A -- to reduce the burden of pertussis.
Q So these meetings collectively were about increasing vaccination of pertussis in pregnant women and in adolescents; correct?
A Yes.
Q When I said pertussis, I meant pertussis vaccination; right? You understood that?
A I presumed that's what you meant.
Q Thank you. Okay. And through the years, pertussis has paid for many meals that you've had; correct?
A Pertussis has -- I have spent a lot of my professional life working on pertussis, and I -- I started the initial trials that -- that compared the new vaccines to the old, and so pertussis, I've spent a lot of time working on pertussis.
Q So is the answer yes?
A What was your question again? I'm sorry.
Q I said, through the years has -- isn't it true that Sanofi has paid for many meals that you've had?
A Sanofi has paid for some food that I have eaten through the years, yes, thank you.

MR. SIRI: Well, let's just -- I'm going to mark this as Plaintiff's -- I believe it's 7.

(Whereupon, Exhibit No. 7 was marked to the testimony of the witness.)

Q (By Mr. Siri) I'm going to ask you something. This is your -- the Open Payments Data for 2017 for -- well, it's frozen. Let's try that again. Okay. That's not good. I'm going to stop share and see if I can fix this problem. Give me just a moment, please. It looks like I'm having technical issues. Great.

MR. RILEY: Do we want to take a break and see if we can fix it? We're about an hour and a half in already.

MR. SIRI: Yeah, let's just take a -- just -- I'm just going to restart my computer, so let's come on back in just one minute. See you guys in one minute. I'm just going to reboot.

THE VIDEOGRAPHER: All right. We're off the record at 9:31 a.m. Central.

(Brief recess.)

THE VIDEOGRAPHER: All right. We're

back on the record at 9:37 a.m.

MR. RILEY: I don't see Mr. Siri.

THE VIDEOGRAPHER: Oh, okay. I'm sorry. Well, that would be good. I thought he -- let's see. I'm sorry. He went off and I had to admit him.

MR. SIRI: Here we are. Okay. All right. Well, I apologize for that technical issue. My computer just froze up. So I was sharing my screen and was trying to get an exhibit on there, here we go, and this will be Plaintiff's Exhibit Number -- I believe it's 8 [sic].

Q (By Mr. Siri) In any event, again, Dr. Edwards, that's your name; correct?

MR. SANDERS: Dr. Edwards, you're muted.

A That is my name, yes, sir, thank you.

Q (By Mr. Siri) And this is your address?

A Yes, it is.

Q Okay. So if we take a look down here, we can see there's a -- food and beverage for $322 on November 13, 2017. I was just curious, what's --

A I have no idea. I have no idea where that was. I have no idea, you know, the cost. I -- I have no idea. I -- as I said before, I -- I am

not --
Q Yeah.
A -- a big eater, and so I have no idea about --
Q Yeah.
A -- what that cost was for.
Q Sure.
A Maybe it was wrong. You know, maybe it was -- you know, but I don't know. I cannot comment on that specifically.
Q Ahh, I gotcha. You think all of these charges -- well, strike that. All right. I was -- you know, having seen your profile picture, I was curious what -- I mean, I've eaten at Nobu, and I -- I'm a big eater, I never hit 300 bucks. Okay.
A I think that -- you know, I don't think you need to say that. I think that we -- I don't know the -- the content of that. I -- I don't know, and I think that I'm a very frugal person. Again, you know nothing about me as a person.
Q That's true. That's why we're here today to do is learn about it, and you know, you'll have your -- you know, the other side will have a

chance to direct and say all the wonderful things that -- you know, that you want to say. Those are -- you're not -- you're not sharing time to interlace those comments. So now, you have also received personal fees from Sanofi; correct? You're muted, Doctor.

A I'm not quite sure what that means, whether that means payment for some -- I don't know what you're referring to, but I'm happy to see what you provided so I can address that.

Q All right. This is a disclosure form that you filled out; correct?

A Yes, I have filled out a number of those.

Q Under here it says personal fees; correct?

A Yes. I wasn't quite sure what you're referring to, but yes, and as -- those are outlined over here. I've already talked to you about those. I'm a scientific advisor for BioNet. It was not related to the meningococcal vaccine. I'm a scientific advisor for Merck, I was at that time, but it's not related to the meningococcal vaccine. I'm on DSMBs for Sanofi, for X4 Pharma, and if you go down, I think there's a couple others.

Q And you said that, you know, all your conflicts with pharma were in the last year and that you had done nothing with pharmaceutical companies before that; correct?

MR. SANDERS: Object to the form of the question. You can answer, Doctor.

A I think that you have presented evidence that I have had other interactions and I -- I -- so, you know, I -- I will address each one that you'd like to bring up, I'm happy to.

Q (By Mr. Siri) Sure. Were you a consultant for SmithKline Beecham, SKB?

A On this form, I don't know. Can you go down? I can't remember whether this is on this form.

Q It's not on this form.

A Okay. So I wasn't for them. I am truthful about what I do. I try and be truthful.

Q I'm going to mark this one as well as a plaintiff's exhibit. Do you recall we looked at this article?

A Yes, sir, I do recall that.

Q Now, we were discussing Connaught and the first two companies, but do you see the last sentence, it says that you're also a consultant

for SmithKline Beecham; correct?
A At that time, that was the case, but what happens with these forms that you just went over is there is a time frame. It's not for 40 years. It's within a time span, so that was -- that article in the New England Journal of Medicine was a commentary about meningococcal vaccine that was published in 2019.
Q All right.
A So --
Q So far we've seen a -- you know, that you were a consultant for a pharma company in 1998, we've seen an article that you were a consultant in 2000, we've seen one from 2005, we've seen one from 2 -- 2020, and I think there was one other year; correct?
A You have shown a number of articles that list the conflicts, which I have provided.
Q Okay. Do you deny that those are accurate disclosures?
A No, they are not -- I do not deny that they are not. They are -- all right. They -- I -- they published them so they are accurate.
Q Okay. While you were a consultant for SKB,

you were also conducting vaccine trials for SKB that SKB was -- then tried to use to license a vaccine. Isn't that true?

A I'm sorry. Could you -- I'm not sure that -- what you're saying. Could you please repeat that?

Q Absolutely.

A Please be specific because obviously I've done a lot of studies, and so I don't know exactly which one you're referring to. So if you can tell me the specific trial, the exact date, and then I will try and answer that.

Q My question is, have you ever conducted a vaccine trial for SKB while you were also a consultant for SKB?

A I may have. I just don't re -- I don't recall the specific trial, but I may have been, but that -- yeah, I may have been.

Q You're an author of this study; correct?

A Yes, I am, sir. I'm the senior author of the paper.

Q Okay. And this one is from 2000; right?

A Yes, sir.

Q It shows that you were a consultant for SmithKline Beecham. It discloses that you were a

consultant for SmithKline Beecham; correct?
A Yes.
Q Okay. And then your -- your CV also discloses that you were conducting a trial for them at that same time in 2000; correct?
A If -- again, my CV says that and that's what it says here too. So again, I can't remember all of the trials that I've conducted for -- you know, for 40 years.
Q You were also a consultant for GSK after SKB merged with GSK; correct?
A Perhaps. I -- I don't know. Why don't you give me the specific examples or show me the paper so that you can confirm that's what I did.
Q So are the only industry positions, consultantships, adviserships fees that you believe you're going to recall during this deposition are ones that I can specifically prove?
A Sir, I am going to base my testimony on what I know to be medically factual. I'm going to use the literature that exists to discuss that, and if you -- you know, however you want to --
Q Right.
A -- to take that, then obviously that's how

you will do that.
Q So does that mean that you -- it doesn't answer my question. My question was, you know, do you believe the only conflicts that you have with pharmaceutical companies are ones -- the only conflict -- strike that. Do you believe the only conflicts with pharmaceutical companies that you will be able to recall today are ones that I can specifically prove?
MR. SANDERS: Object to the form of the question. You may answer, Doctor.
A Sir, I'm happy to go through my CV with you.
Q (By Mr. Siri) Okay.
A I'm happy to go through the papers with you. I am happy to -- I obviously --
Q It's not a complicated question. I mean, I'm just asking you do you think you'll be able to recall any conflicts that you have with pharmaceutical companies today at all without a document being presented to you?
A I've listed several conflicts that I told you about.
Q Well, only after I've presented the documents to you, so, you know, this would go a lot quicker

if you, you know, just confirmed what those were, but let's -- let's move on. Let's move on. Now, I asked you have you -- were you a consultant for GSK, you know, after SKB merged with them, and this is an article that we looked at before, you confirmed that you authored it, it's from 2005, and as we saw earlier, it does say that you were receiving consultation and lecture fees from GlaxoSmithKline in 2005; correct?

A That's what it says there, yes, sir.

Q Okay. And you were a member of the speakers' bureau for GSK; correct?

A At that time, I -- I don't know. It doesn't say that there.

Q Okay. How about in 2000, before I pull up the article?

A Sir, I -- I'm sorry, but I cannot remember --

Q Okay.

A -- I -- all of these things, you know, and I'm happy to have you bring them up and have to discuss them, and I would have been happy to --

Q Dr. Edwards, we don't -- you know, we have -- we've got a lot to go through today. Have you ever been a member of any advisory board with GSK?

A I -- probably I have. I don't know. It says that I was consultation for GSK, and -- and Sanofi I've received grant support, so --

Q Are you familiar with this article? You're an author of this article; correct?

A Yes, sir, I am. I am, that's right.

Q And this article was from 2019; correct?

A Right.

Q It says you are -- it says KME. That's you; correct?

A That's correct, sir.

Q Been a consultant to Moderna, Roche, Sanofi, and X4 Pharmaceuticals; correct?

A Okay. And those are four DSMBs which I told you about before. Those are data safety and monitoring boards for all of those things.

Q Are -- in 2019, you're claiming you were on the data safety and monitoring board for these companies?

A Yes.

Q So you're saying when it says you were a consultant, it doesn't mean you were on the data -- you're saying that that meant you were on the data safety and monitoring boards?

A I was consulting that -- to them on the data safety and monitoring board, yes, that's correct. I have been on the data safety and monitoring boards for those. I currently also am still on those DSMBs.

Q Okay. So you're saying -- because, you know, there's lots of disclosures that specifically say data safety and monitoring board and separately there are disclosures that say you're a consultant. Are you claiming the term consultant here doesn't mean consultant, you're claiming it means that you're a member of the data safety and monitoring board?

A I think that it -- it's a little bit -- I think it's a little bit in terms of definitions, and so I -- I would say that -- that providing data safety and monitoring input to a -- for a study, it could be discerned as being a consultant, and so if that's how you would like to refer to it, I am fine with that.

Q Well, that is not -- my understanding is that's not the way it's referred to. So, for example, you know, as an example of how they're almost always listed separately, are you familiar

with this article? You're an author of this article; correct?

A Yes, sir. You know, I've written almost 600 articles. It's hard for me to remember exactly which one I --

Q But you can recognize your name; correct? That's your name?

A Yes, sir, I can. Right there.

Q Okay. And this is from 2005; correct?

A I don't know. I --

Q Bottom right corner. Can you see that?

A Yes, it is, sir. It's from the Pediatric Infectious Disease Journal.

Q Okay. There we go. One second. Oh, sorry, I pulled up the wrong one. I meant to pull up this one. Strike -- just strike that exhibit for now. That's your name; correct?

A Yeah. You've --

Q You're an author of this article?

A Yeah, that was Exhibit 1, I think.

Q Okay. So let's come back to it. So it says here, financial -- it says that -- looks at potential conflicts of interest. Dr. Edwards served as an advisor for BioNet and Merck; right?

So that's one category. And separately, and on the data safety and monitoring boards for Sanofi, X4 Pharmaceuticals, Seqirus, Moderna, and Pfizer. Do you see how they are distinguished in the conflicts of interest disclosure?

A Yeah, I think one of the problems sometimes, sir, is that the company -- that the journals will sometimes revise some of the -- of the statements in terms of that, so they may have -- and again, I don't remember exactly, but it may have been a possibility that they, you know, changed it in some way, and also, as you see in -- sometimes people classify things in different ways, so you looked into personal fees and the -- you know, in the -- and the right things and sometimes --

Q Yeah.

A -- things are put in different barrels, so --

Q Okay.

A -- it depends a little bit in terms of how --

Q Okay. Yes. You know, the attorney for the other side will have an opportunity to ask you questions and you can say all -- you know, you can talk about --

MR. SANDERS: Well --

Q (By Mr. Siri) -- that other stuff then.
MR. SANDERS: -- Mr. Siri, you do need to let her finish though her answers.
MR. SIRI: I respect that. I do. I just don't want to run out of time, and when she's going off on a -- on a -- you know, a bit of a tangent, respectfully, I just want to be efficient about it. I wouldn't want to have to go over to another day. Okay. So but absolutely, I -- I do certainly want to let her finish and I do want to get her complete answers. I agree with that.
Q (By Mr. Siri) Now, if you'll take a look at this article. I think we looked at this one earlier. All right. Just in case we didn't, this is your name, you're an author of this article; correct?
A Yes, sir. We just looked at this article. I --
Q Right. Now, it says you're on the advisory board of GSK; correct? And what is -- what is that board?
A I'm not -- I'm not exactly sure. I think that was for a flu -- that was for a flu trial, I'm pretty sure.

Q Okay. And what did you do on the board?
A Provided input in terms of the design of a flu study.
Q Okay. Have you ever received research funding from GSK?
A I'm pretty sure that I have, but again, I can't -- we could look at -- it's on the CV if I have.
Q Were you on a speakers' bureau for Wyeth Leder --
A Wyeth Lederle?
Q Lederle. I'll get that right one of these times, but no problems with -- yes, were you on a speakers' bureau for Wyeth Lederle?
A I can't recall, but that doesn't mean that I wasn't, so if you want to show me something else, I can read it for you.
Q We looked at this earlier. Dr. Edwards has funding for research from Connaught and Wyeth and Lederle and on their speakers' bureaus.
A Yeah, I think this was Exhibit 3 maybe. I think we've already looked at this.
Q Okay. So you were on the speakers' bureau for Wyeth Lederle?

A That's what it says. That's what it says, sir.
Q Okay. And you were a consultant for Wyeth Lederle; correct?
A That's what it says. I can't see it now because you took it away, but I think that's what it says. That's okay. I don't -- I think it's --
Q Were you a consultant for Wyeth Lederle?
A I think that's what it said, although I can't see because you took it away, but if that's what it said, then it's true.
Q Sorry. Let me show it to you.
A Lectures sponsored by Pasteur Mérieux, Connaught, and Wyeth. So I have delivered -- that's slightly different than a speakers' bureau, but -- but that's --
Q We're not talking about a speakers' bureau anymore. That was the other exhibit. This one is about -- I asked you about whether you were a consultant for Wyeth Lederle.
A That's what it said, sir.
Q So were you a consultant?
A So if that's what it said, yes, that's true.
Q You had a contract with Wyeth Lederle for

$255,022 per year from 1996 to 1998 to conduct a clinical trial for one of its vaccines. Is that correct?

A Sir, I -- I -- if it's on my CV, that is correct, but I -- again, I don't have my CV in front of me, and -- and probably the CV tells what -- the name of the vaccine that I was studying, so that is a contract that pays for the nurses, that pays for the study to be conducted with one of their vaccines, and -- and so if that's what it says on the CV, that's correct, sir.

Q And so while you were a consultant and on the speakers' bureau for Wyeth Lederle, you were also conducting trials for the same company for one of its vaccine products; correct?

A Yes.

Q Okay. And you're an advisor to Pfizer; correct?

A So when are you talking about that? At that time of that study or currently?

Q Well, Pfizer -- well, Wyeth Lederle eventually merged into Pfizer, so I'm talking about Pfizer. Let's say this year, have you been

an advisor to Pfizer this year?
A As I told you early on, I am on the data safety and monitoring committee for the Pfizer COVID-19 vaccine, yes, I am, but I -- yes, I am.
Q Are you paid for being an advisor?
A I'm paid for the time that I spend in the DSMB.
Q Who pays you?
A Pfizer pays me.
Q Now, being part of the speakers' bureau for a pharmaceutical company means you provide presentations regarding one or more of their products; correct?
A That's what being a -- on a speakers' bureau usually means, although sometimes the companies will -- will pay for vaccine -- or lectures about vaccines that are -- that are more general in terms of that, but -- but whenever I'm on a speakers' bureau, what I speak is my work. I do not allow anyone to make changes or alterations to what I say.
Q Are you familiar with the article entitled Academic Freedom and the Management of Promotional Speaking at Academic Medical Centers published out

of Tufts University School of Medicine?
A I think that I've read it, but I haven't recently reviewed it, thank you.
Q Let's take a look at it.
(Brief interruption in the proceedings.)
Q (By Mr. Siri) Dr. Edwards, who were you just speaking with?
A My husband asked me a question. I'm sorry, I won't --
Q No, that's okay. That's okay.
A He said --
Q I was just curious. It's fine.
A He has a telemedicine appointment, and I -- he just asked me a question, so I'm sorry, I will be --
Q No, that's -- that's okay. I'm just -- just wondering because -- okay. So this was -- this is an article, I read the title before, and it was written by an associate professor of public health and community medicine and the assistant dean for conflicts of interest administration of Tufts University School of Medicine; correct?
A That's what it says, yes.

Q Yeah, okay. As well as a few other individuals in that department, professors in that department. Now, I'm going to read you a portion highlighted in yellow and I'm going to ask you a question; okay? Numerous medical associations, such as the Association of American Medical Colleges, the American Board of Internal Medicine, and the Institute on Medicine as a Profession, and governing bodies such as the Institute of Medicine have recommended that medical schools and teaching hospitals prohibit or strongly discourage faculty from participating in so-called industry speakers' bureaus. Pharmaceutical company speakers' bureaus are a marketing enterprise wherein physicians and other professionals are engaged and trained by one or more companies to give a lecture about a medical condition or drug treatment to an audience of prescribers towards the end of promoting the company's drug which treats that condition. These speakers are generally required to use company-created or company-approved slides and are expected, prior to their presentation, to collaborate and review the slides with the company medical officers. The process is intended to

focus the speaker on the most positive aspects of a drug, thus increasing the familiarity and appeal of that drug to the speaker, as well as the company's marketing message. It is widely argued that physicians who participate in speakers' bureaus are essentially just paid marketers or spokespersons for an industry who use and indeed exploit their roles as physician leaders to influence their colleagues to prescribe the sponsored product. The sentiment that speakers' bureaus are promotional rather than educational are reinforced by the fact that the bureaus are funded through pharmaceutical companies' marketing budgets. Do you -- here's my question. Do you disagree with the finding of the experts in the Tufts University School of Medicine in this article?

A Yeah, I think that that -- as time has evolved, I think that speakers' bureaus have been looked down upon, and we at Vanderbilt University every year have to talk about a -- all conflicts of interest that we have, and I think over the years there have been increasing concerns, so we are -- are not -- we are not allowed to be on

speakers' bureaus any more, so again, I -- I don't remember exactly the time that I was no longer on a speakers' bureau from all of those articles, and you know, certainly could review that. But I think that is true, although I must say that -- and insist that there was never a time when you said the slides that the company made me provide, and I -- there was never a time that I said something that was not consistent with my research and my findings, so -- so I think that is a concern, but that is not how -- the way I personally operated, and I think that the -- that the speakers' bureau issues have become much more -- there's been concern about them, and they are -- are much, much less common than they used to be.

Q Are you willing to produce, you know, within a week of this deposition the slides that you used in your presentations on behalf of the pharma companies speakers' bureaus?

A That would be hundreds of slides, sir. I think that -- that -- you know, that would -- that's a lot, but I'm --

MR. SANDERS: Yeah, if you want to make

a request of anything, Mr. Siri, you need to do that through me.

MR. SIRI: I can also ask her if she'd like to do it, but I -- I sure can convert it into a formal request as well, counselor.

A I think if you just deal with Mr. Sanders, that would be helpful. That would be helpful.

Q (By Mr. Siri) I -- that's a separate question of whether you're willing to provide them. And you're saying they're hundreds of pages. How many presentations were there approximately?

A I -- I've given hundreds of presentations, sir --

Q So is it --

A -- in all kinds of venues, and I -- I don't remember the last time I gave a speakers' bureau. You know, just this week I've given three presentations to hundreds of people about COVID vaccines and about the vaccine safety assessment of COVID vaccines, so -- and I include, you know, my -- my conflicts on the slides.

Q And you always disclose your conflicts on the slides for each presentation?

A That's what's required, yes. Now, you know, whether there's one presentation that I have forgotten to do it, I -- you know, I can't say for that. I've done hundreds of these.
Q You're saying there might be some of them that you forgot to do it?
A There may be. Goodness, yes, there may be one or two or -- you know, I -- you know, obviously I am -- yeah, but I -- that's the goal is to have the title slide, to have the conflicts, and then to have the goal of the presentation. That's generally the format of my slides.
Q And the most important conflicts to disclose are typically ones with pharmaceutical companies whose products are implicated by the presentation; correct?
A That's correct, sir.
Q Okay. Now --
A And I --
Q -- let's get back --
A Wait, wait, wait, wait, wait. Time out.
Q Sure.
A So it is also imperative that any kind of presentation that is provide -- that provides

continuing medical education, that there is a conflict of interest statement that has to be provided to those that provide CME, so every time I give a CME, I disclose my conflicts, and those are reviewed by the CME agency to allow me to proceed. So whenever I give a lecture for a group, I am asked, you know, usually a month ahead for -- for me to put -- to put together what my goals would be, what I will be talking about, what my conflicts of interest will be, and those are reviewed by the CME group to make sure that there are not conflicts that should be -- that there are conflicts that would make the CME event not one that should be -- go forward, so that is a routine procedure.

Q Meaning it's a serious process to make sure that conflicts of interest are actually disclosed?

A Absolutely.

Q I'm sorry?

A Yes, sir, it is, thank you.

Q Okay. All right, good. And going through that whole process, it's really important to make sure that by the time a presentation happens that all of the conflicts that are relevant are

disclosed; right?
A That's correct.
Q Okay. Now, we discussed earlier that when an A -- an ACIP votes to -- we discussed earlier about, you know, when an ACIP votes to recommend a childhood vaccine for universal use, you know, the fact that we add it to the childhood immunization schedule, my question is when it's added to the schedule and if a child cannot -- or a parent of a child cannot afford to pay for the vaccine --
A I can't hear what you're saying.
Q Oh, is that --
A The Internet is unstable. I can't understand what you're talk -- I can't --
Q No problem. Can you hear me now?
A I can't understand your question because the Internet was unstable.
Q No problem.
MR. SIRI: Rob, can you hear me?
THE VIDEOGRAPHER: Yes, Mr. Siri, I can. It may be --
MR. SIRI: I'm wondering if it's on Dr. Edwards' side.
THE VIDEOGRAPHER: Yeah, it may -- it

may be a -- just a slowdown on her Internet possibly.

MR. SIRI: It looks that way because she's glitching a little bit.

Q (By Mr. Siri) Hey, Dr. Edwards, can you hear me now?

MR. SIRI: She appears frozen.

A I can hear you now. Can you --

Q (By Mr. Siri) Okay, great.

A -- hear?

Q Yes. Okay. Let's see if we can continue. Now, ACIP, when it votes to add a vaccine to the childhood schedule, it would also vote to include it in the Vaccine for Children Program typically; correct?

A That's correct.

Q And the Vaccine for Children Program assures that irrespective of the parent and child's ability to pay, the pharmaceutical -- that the company will still get paid for the sale -- for the use of that product; correct?

A I'm not -- I'm not exactly familiar with how the pharmaceutical companies are paid in the Vaccines for Children Program. I know it's an

entitlement program that allows children to be given the vaccines, but I'm not -- I -- I'm not familiar with how the -- the companies are paid for -- for the VFC vaccines.

Q But the VFC program, it does assure that every child will be able to get a vaccine irrespective of ability to pay; correct?

A As long as they are VFC eligible.

Q Of course. Meaning if they didn't have the ability to pay.

A Well, there's certain criteria in terms of the VFC eligibility, and so if the child is VFC eligible and the VFC doctor -- and the doctor is associated with VFC, then the vaccines can be given by VFC.

Q Okay. And you were a member of ACIP from 1991 to 1995; correct?

A I believe those are the years. Again, I -- I -- I don't have my CV in front of me, but if that's what my CV says, yes, I was, sir.

Q And as you discussed earlier, you were a member of VRBPAC from 1995 to 2000; correct?

A That's correct.

Q Okay. What vaccines -- now -- strike that.

When you joined VRBPAC in 1991, there were only three vaccines, effective vaccines that were recommended for universal use on the CDC childhood schedule; correct?

A I -- I believe, sir, but again, I -- you know, I -- I would have to look at that time for the schedule in 1991, and, you know, again, I -- I want to be truthful, so I have not looked at that, but if you're saying that's what the schedule said, then that's correct.

Q Okay. Let's take a look.

A It's also important for you to realize that with the CDC and the FDA, they also assess conflicts of the members of the committee as well, and if there is a conflict that is deemed to be disqualifying, then people are not -- cannot speak about that, so that's also another check that the CDC and the FDA have on conflicts.

Q All right. You can't speak about the recommendation, for example, for a potential product or vote on it too, I presume?

A If there's a significant conflict, yes, sir.

Q Okay. So does this look familiar, Dr. Edwards?

MR. SIRI: I'm going to mark this as Plaintiff --

(Whereupon, Exhibit No. 8 was marked to the testimony of the witness.)

A Well, it says 1989 childhood immunization schedule, so yes, that's helpful, so there's the DTaP, the aP has replace -- or the -- let's see. No, this is a DTP, so this is not aP. This is whole-cell. And the oral polio and MMR and then the Hib polysaccharide or the Hib polysaccharide conjugate vaccine and then TD -- yeah, so this is -- that's correct.

Q (By Mr. Siri) All right. Now, that Hib polysaccharide vaccine was found to not be efficacious, and particularly in --

A Yeah.

Q -- children under 18 months, so it was eventually replaced in 1991; correct?

A Correct. And so -- and this also says here that the conjugate is preferred over the polysaccharide at 18 months as well.

Q All right. So between 1991 and 2000 while

you were on ACIP and VRBPAC, what vaccines were licensed and added to the CDC vaccine schedule?

A Sir, I'm sorry, I can't tell you all of the ones I -- you probably have them listed, and I'll be able to -- happy to read them, but I just don't have that right in front of me.

Q No problem.

MR. SIRI: I'll add the -- the -- I'll add this as another plaintiff's exhibit.

(Whereupon, Exhibit No. 9 was marked to the testimony of the witness.)

Q (By Mr. Siri) Let me just -- let's just -- to do this efficiently, HepB vaccine was added to the schedule; correct? And that's --

A That's true.

Q Is there --

A Also DTaP was added, so we have whole-cell before now. This is acellular with it.

Q Okay. And the varicella vaccine was added?

A And we have IPV instead of OPV.

Q And we have IPV and the OPV, and the varicella was added; correct?

A Yes.
Q And rotavirus was added; correct?
A No, there's no rotavirus on here.
Hepatitis A was --
Q Oh, thank you, thank you, you're right. HepA vaccine was added?
A Yeah, that was for selected areas, however. That was for the native populations and it was not universal at that time.
Q Right. And then the Hib vaccine was added four doses; correct?
A Correct.
Q Are you aware that a June 15, 2000 report of the United States House of Representatives Committee and Government Form found that with regard to VRBPAC, quote, the overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry?
A No, I'm not familiar with that document.
Q Okay. I assume then you're also not aware that this report concluded that ACIP reflects, quote, a system where government officials make crucial decisions affecting American children

without the advice and consent of the government.
A The ACIP is --
Q I'm just asking if you're aware of that quote.
A I'm sorry, where was that -- where is -- that quote was in the same article that you just -- okay.
Q Yes. It's in this report.
MR. SIRI: And let's mark it so that Dr. Edwards will have an opportunity to review it before trial.
(Whereupon, Exhibit No. 10 was marked to the testimony of the witness.)
Q (By Mr. Siri) And so you'll have a chance to read this document. It's 25 pages, and you can read what the conflicts of interest and what the Majority Staff Report to the Committee on Government Reform, U.S. House of Representatives found with regard to VRBPAC and ACIP as of June 15, 2000, which was, you know, at the end of your tenure at ACIP and VRBPAC, from 1991 to 2000. Now, are you familiar with a vaccine named

RotaShield?
A Yes, sir, I am very familiar with RotaShield.
Q The RotaShield vaccine was manufactured and sold by Wyeth Le -- Leder --
A Lederle. Wyeth Lederle.
Q Lederle. Good God. Lederle. Vaccines in pediatrics; correct?
A Yes, sir, it was.
Q Okay. In February of 1998, you were on VRBPAC and voted to approve RotaShield for inclusion in the CDC's -- for inclusion -- excuse me. You were on VRBPAC and voted to recommend licensure of RotaShield by the FDA; correct?
A That is true, sir. I remember that very clearly.
Q Okay. When you voted to approve Wyeth Lederle's vaccine on VRBPAC, you also had a contract with Wyeth Lederle for 2,555 and 23 -- $255,023 per year from 1996 to 1998 for the study of another of its vaccines. Isn't that correct?
A I don't have my CV before me, but that may be correct. That probably was a pneumococcal vaccine and not the RotaShield vaccine, but that may be correct.

Q Okay.
A I voted for the rotavirus vaccine because it had an enormous impact on diarrheal disease and hospitalizations in children in the United States.
Q Please strike --
A It was licensed. We also had a big discussion about --
Q Dr. Edwards, there's no question pending, so I -- I've got a lot of material to go through, and you know, that's not -- we just have to get through this, and you -- you know, you're -- the attorney for the other side can ask you questions about other things, if you'd like. Now, at the same time, you were -- now, at the same time that you voted to recommend approval of the Wyeth Lederle vaccine, you were -- in addition to having a contract with them for a study, you also were on the Wyeth Lederle speakers' bureau; correct?
MR. SANDERS: You're muted, Dr. Edwards.
A I think you -- you showed information that that was on -- on one of the -- that -- that that was the case, I guess.
Q (By Mr. Siri) And you -- and as you said earlier, you don't deny that that's the case;

correct? You -- you said that if the -- if the article discloses it, you were on the --

A That is correct.

Q Okay.

A I do not deny it if it's in print, thank you.

Q Okay. And while you were at VRBPAC, you were also a consultant for Wyeth Lederle as we saw before; correct?

A I believe that was the case, although obviously you're -- that wasn't listed in one of the conflicts of -- of the -- right there.

Q Okay. So does the document need to be directly in front of you for you to confer with what we've -- all right. Just strike that. Look, we've already confirmed it earlier. Let me ask you this; okay? You said earlier that, you know, conflicts are critically important, that especially when VRBPAC is voting they make sure that nobody can vote that has a conflict. Strike that. Let me ask you this. To your knowledge, has your name ever appeared in a congressional report regarding vaccines?

A Not that I know of, but it looks like it did appear here, my name was in this since you

highlighted it, so I guess, yeah. I don't generally read the congressional reports, so --

Q Are you aware that this congressional report only identified one of the conflicts with Wyeth Lederle, the contract you had to conduct a vaccine trial, but that they completely missed that you were a consultant for this company, that you were on the speakers' bureau -- and that you were on a speakers' bureau?

A Well, obviously I had never seen this before, so I -- I'm not -- I wasn't aware of that, no.

Q Okay. Well, you'll have an opportunity to review this document before trial.

A Good.

Q Okay. And I presume you will do that; correct?

A Yes, sir, I will, thank you.

Q Okay. Now, you're aware that when companies -- strike that. Are you aware that when companies make a product that injures someone, the company may get sued for the harm on the basis of product liability?

A Yes, sir.

Q Would you agree that this threat of liability

often drives companies to ensure their products are safe before they are put on the market?

MR. SANDERS: Object to the form of the question. You can answer, Doctor, if you have an answer.

A I think that -- that all of us in vaccines from pharma to investigators to pediatricians, we know the power of vaccines and we -- we -- but we -- and we know that they have a great impact on disease, but we also want to make sure that the vaccines are safe, because if there is an adverse event, then -- then depending upon the frequency and severity, that -- that -- the risks of the vaccine must be weighed, so all of us want safe and effective vaccines.

Q (By Mr. Siri) Would you agree that the threat of liability that a pharmaceutical would have for an injury caused by one of their vaccines would help ensure that the products are safe?

MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have an answer.

A I'm not a lawyer, sir. I -- I don't know what their --

Q (By Mr. Siri) Okay, that's fine. Would you -- would you agree that like -- government regulations are often intended to also help lead to safer products?
A That government regulations are intended for safer products? Is that your question?
Q Right, that government regulations can also help propel safer products on the market.
A Yeah, I think that that -- you know, the FDA has rigid standards and -- and going through and reviewing those are important, yes.
Q Are you aware that in the early 1980s pharmaceutical companies were being forced to exit the vaccine market due to high liability they faced from their vaccine products?
A Yes, sir, I am very aware of that.
Q Okay. And we've already discussed earlier how the 1986 Act provided immunity -- let me ask you this. Are you aware what court or person injured by a vaccine can bring a claim?
A Yes, I -- my understanding is that the -- the vaccine court -- that -- that claims need to first to -- go to the vaccine compensation court, and then if they are -- if after they're adjudicated

there, if the claimant is not happy with the results, then they -- then the claim can go to the -- to the regular courts.

Q All right. Now, when it goes to the regular court, okay, can they sue the pharmaceutical company for design defect claims, meaning for claims that the vaccine could be made safer?

A I don't know, sir. I'm not a lawyer.

Q That's fine. Now, in vaccine court, as you mentioned it, the respondent, the defendant, so to speak, is the secretary of the United States Department of Health and Human Services; correct?

A That's correct.

Q Okay.

THE VIDEOGRAPHER: Excuse me, Mr. Siri, you might want to stop the screen share if you're not sharing the screen.

MR. SIRI: Thank you. I appreciate that.

Q (By Mr. Siri) All right. Are you aware that when the 1986 Act was passed, most of the claims were table claims and settled quickly?

MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have an

answer.
A I'm not sure that the -- the number or the majority were table claims. I'm sorry, I don't --
Q (By Mr. Siri) That's okay. I -- that's totally fine. And are you aware that in the 1990s, HHS amended the table such that now 98 percent of the claim -- new claims are off-table claims?
A I am aware of that, yes, sir.
Q All right. And as we discussed earlier, off -- in off-table claims, the injured child must prove that the vaccine was the cause of the injury; correct?
A The actual determination of causation, I -- I'm not quite sure exactly what the wording is, and so I would just have to defer to that wording.
Q That's fine. So what that would mean, of course, is that if HHS or any of its agencies admits or publishes any study that supports that a vaccine can cause a certain injury, the lawyers who represented people injured by vaccines would then use that as proof against HHS in vaccine court to establish liability; correct?
MR. SANDERS: Object to the form of the

question. You can answer, Doctor, if you have an answer.

A Yeah, I'm not a lawyer, sir. I -- you know, I'm sorry that I just don't know all the nuances of --

Q (By Mr. Siri) No problem.

A I just --

Q So if the CDC conducted a study that showed that a vaccine caused a certain injury, do you think that evidence could be used in vaccine court to show that the vaccine caused that injury?

MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have an answer.

A Yeah, I think that -- that what's important is that one takes a body of literature that -- that addresses an issue, and as we see, there can be individual studies that may suggest some kind of event, and when it is looked at in additional populations, when it is looked at in more inclusive studies that it isn't shown, and I think that's one of the issues that we often find with -- with the -- the large-linked databases in terms of adverse events, is sometimes signals will

be seen, but then when we have larger numbers, there are not.

Q (By Mr. Siri) I'm just asking -- I'm just asking you if the CDC admits in a study or a court that a vaccine causes a certain injury, would that be -- do you -- do you believe that could be used against CDC -- against HHS in vaccine court to establish liability?

A I --

MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have an answer.

A I will refrain from answering. I think I've answered the question already.

Q (By Mr. Siri) So you -- you're -- well, you haven't answered the question, but we'll come back to it later. Oh, what did I do? Oops. Can you still see that on your end?

A I can see a list of files that you have in your computer. Now I can't see them.

Q Yeah, okay. So what is the Advisory Commission on Childhood Vaccines?

A It's a -- an advisory -- you're talking about the advisory group to the compensation system,

that's --
Q Right.
A -- what you're talking about, yeah. Well, it's an advisory group that meets intermittently that advises the compensation system and -- and the meetings go over what's happening with the compensation system and any questions or any concerns that are -- that are going on.
Q And it's known as ACCV; correct?
A That's right.
Q Okay. Let's move on to something else. What is a vaccine information statement?
A The vaccine information statements are statements that are put together by the Centers for Disease Control. They're a part of the -- of the vaccine compensation system and they are -- they are required to be given to -- to the recipients of the vaccines.
Q And they're often referred to as VISs; correct?
A That's correct. That's for vaccine information statements, yes, VIS.
Q Okay. And the CDC develops a VIS for each vaccine; correct?

A It does. It generally does it in consultation with others to make sure that they're clear and -- but -- but it does come from the CDC.
Q And are you aware that federal law requires each VIS to explain the risks of each vaccine?
A Yes, I'm aware.
MR. SANDERS: Object to the form of the question. You may answer.
Q (By Mr. Siri) Okay.
A I'm very aware of the content of the VIC -- VIS.
Q And -- and only risks that are supported by available data and information may be included; correct?
A Correct.
Q Okay. The CDC routinely denies physicians to add risks to the VIS for various vaccines when there isn't evidence to support a causal relationship; correct?
A In order to say an adverse event happens, there has to be some documentation and confirmation that it -- that that is correct.
Q Right. So the VIS is -- so the CDC's policy is to only include risks on a VIS where there's

evidence of a causal relationship between the vaccine and a listed reaction; correct?

A That's correct.

Q Now, we -- we talked about earlier your -- you work at the Vanderbilt University Medical Center; correct?

A That's correct, sir.

Q Okay. I'm going to pull up your profile.

MR. SIRI: I'm going to mark this as another plaintiff's exhibit.

(Whereupon, Exhibit No. 11 was marked to the testimony of the witness.)

Q (By Mr. Siri) This is your profile from the Vanderbilt University Medical Center page; correct?

A It's from one of the websites. This is a -- this is a -- one of the Vanderbilt websites.

Q Okay. And this is your profile; correct?

A That's my picture and that's what I'm -- I'm a professor of pediatrics.

Q And it provides information about you on this page?

A It does.
Q It's intended to tell the public about what you do, correct, and who you are?
A Yes.
Q Okay. This profile states that you've received grants from the NIH; correct?
A Yes, sir.
Q And it says you've received grants from the CDC?
A Correct.
Q It says you're a frequent advisor to the NIH and the CDC on vaccine policy; correct?
A Correct.
Q And it states your affiliations to certain medical societies; correct?
A Yes, sir.
Q You remember those clearly; right?
A Those are pretty straightforward.
Q Okay.
A You know, I mean that -- some, you know, provide your funding for -- you know, those are a little different than individual pharma grants, so --
Q Each of these grants from the CDC and NIH,

those also have been by individual grants; correct?

A When the NIH and the CDC issues requests for proposals, and then as a part of that response, then an investigator works with their medical center to propose a response to that request, so with the NIH vaccine evaluation center, that was a multi-million-dollar contract that involved a lot of parts and generally was several hundred pages in length in terms of what was included in that, and that was sort of the mainstay of -- of most of my funding, was the NIH funding. In addition, over the past two -- or a decade and a half, we've had a major input in terms of vaccine safety with a large CDC grant. I also had a very large CDC grant to look at pneumonia, the cause of pneumonia, and -- and the outcomes of pneumonia in children and adults, so -- so I've had a large -- I've had a number of very large contracts from the NIH and CDC, and those were supplemented by -- by smaller grants from -- from pharma, but the bulk and the majority of my funding was from the NIH and CDC.

Q Well, I'm going to make a request that all

your funding contracts for all your grants, you know, be produced so that we can substantiate that assertion. And we'll -- we'll make that in writing, you know, but --

MR. SANDERS: Yeah, you can present any of those to me, Mr. Siri.

Q (By Mr. Siri) All right. And I assume, Doctor, you have no problem producing that; correct?

A Absolutely not.

MR. SANDERS: But there --

A Absolutely not, other than the work that it will require to do that in the midst of a COVID outbreak, but other than that --

Q (By Mr. Siri) But you -- you have -- you have had multi-year contracts with pharma companies to conduct trials for their vaccines; correct?

A As we've talked about before, I do have -- I did have pharma contracts as well.

Q And those spanned -- some of those spanned -- conducting clinical trials over a number of years; correct?

A Most of them were one or two years, and

certainly the amount of funding that was provided by those was substantially less than the NIH and CDC contracts.

Q Is it -- that the reason that on your profile page you don't disclose any of the grants you received from pharmaceutical companies?

A Yes, sir, because it's -- you know, this is -- this is a vignette of what -- what I've done, and certainly there are many parts that -- you know, many large grants that I -- I haven't talked about the pneumonia study, I haven't talked about pertussis. I mean, I haven't talked about lots of other things, so this is -- and I didn't write this. Somebody just took this from, you know, what -- what they had -- you know, so again, I -- it wasn't I selected to be in this. Someone else wrote this, and this is just a summary of the work that I've been doing for 40 years.

Q You've never reviewed this before?

A No, sir, I haven't.

Q Now, I'm going to mark your CV as plaintiff's exhibit whatever the next number is.

MR. SIRI: Patricia, what's that number so I can try to be more --

MS. CHEN: Right now I have this exhibit as Plaintiff's 12.

MR. SIRI: Okay. Thank you.

(Whereupon, Exhibit No. 12 was marked to the testimony of the witness.)

Q (By Mr. Siri) So looking at Plaintiff's Exhibit 12, this is your CV, Dr. Edwards. Is that correct?

A And can you give me the date that this was --

THE WITNESS: Craig, was this a --

A Okay. All right. So -- so this is -- it's a year behind, yeah, but -- yeah.

Q (By Mr. Siri) Okay. This would be the -- so August 14, 2019, would that be the last time this CV was updated?

A Of course not. I have a current CV which I can send you or Mr. Sanders can send you after this deposition.

Q I'd appreciate that. But in terms of the CV that I was provided, this -- this CV that we're looking at right now that's been marked Plaintiff's 12 for this deposition, it was last

updated on August 14, 2019?
A That is correct, sir.
Q Okay. And this CV is 53 pages long?
A That's what it says, yep.
Q Okay. And it discloses your educational affiliations; correct?
A It does.
Q Did you leave any out?
A Not that I deliberately -- did -- not that I know.
Q The --
A My education is up, further up at the top, and then -- and then my academic appointments are after that.
Q And then these; right?
A Yes, sir.
Q Did you leave any educational affiliations or academic appointments out?
A Not -- not that I know of, no.
Q Okay. I have almost a full page of honors and awards; correct? A whole page of professional activities; correct? Almost a full page?
A Yes, sir.
Q Okay.

A Yes, sir.
Q And your educational activities spans -- let's see, it starts on Page 3 and it goes through 4, 5, 6, 7, 8, 9. Would you say you were meticulous in documenting each one of your educational activities?
A No, I wouldn't. You know, it's -- I also have a job to do besides to keep my CV up, so I -- there -- there maybe have been others that I didn't include on there, and their omission was not in any way deliberate. It's just a lot to keep all this up.
Q And it -- and there's another 40 pages or so on this CV; right?
A Yeah. I have a -- a number -- I have a lot of publications.
Q All right. Your CV does not disclose that you have been on the speakers' bureau of pharmaceutical companies; correct?
A I don't know, sir, what it -- what it says.
Q I --
A That's not -- that's not generally part of -- you know, the CV is -- it's --
Q If you don't know that, that's fine. Your CV

does not disclose you received personal payments from two companies that sells vaccines; correct?
A No, sir, that is not part of the CV. The CV format is dictated by what the medical center wants one to include and it's generally used for purposes of -- of promotion and -- and that as well. It --
Q I'm sorry, who dictates what should be in your CV?
A Well, the format of the CV is generally what the university has -- has suggested and the content is, and it's generally driven by -- by promotions and -- and assessment of one's scholarly activities.
Q When you say promotions, what do you mean?
A Promotions from assistant to professor to full professor.
Q Okay. Now, we talked earlier how important, you know, disclosures are. This CV is intended to be provided to others, but you're saying your university policy and your university format doesn't provide in any way to disclose any consultancies you had with the pharmaceutical companies?

A Yes, but it's done in a different way. There are conflicts of interest statements that we need to -- that are prepared and we submit every year to the medical center, so they are aware of what we -- what we're doing.

Q Uh-huh. And so you're saying there's a university format that would preclude you from including your -- well, your consultantships, adviserships, affiliations, personal payments, and speakers' bureaus' involvement with pharmaceutical companies on the CV?

MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have an answer.

A It would not preclude what else you wanted to put in your CV, but 53 pages is a lot, and -- and you know, some people when I send my CV say it's too long, so again, I'm just trying to be parsimonious with space and -- but I'm not trying to be deceptive.

Q (By Mr. Siri) You're not trying to be selective by leaving out every single consultancy or advisership?

A That's not the goal of the CV, sir.

Q What's the goal of the CV?
A As I just commented, it's a document that puts together your academic portfolio, your education, your educational outreach, your grant funding, and your -- and the manuscripts that have been submitted to peer-reviewed journals.
Q And you provided this CV to counsel for the defendant in this case as part of being an expert witness; correct?
A Yes, sir.
Q That was one of the uses of this CV; correct?
A I was asked to provide my academic CV, which is what I did.
Q So you were asked specifically to only provide an academic -- about --
A No, I was asked to provide my CV. This is my CV. I've been providing this CV for 40 years and people have found it acceptable, so that's what I sent.
Q And nobody has ever asked you about pharmaceutical affiliations that were left off of this CV?
A No, sir, there --
MR. SANDERS: Object to the form of the

question. You may answer, Doctor.
A You're the first -- you're the first person, thank you.
Q (By Mr. Siri) This is the first case in which you appeared as an expert witness with regards to vaccines; correct?
A That's correct. I'm not -- I do not usually do this.
Q Okay. On July 29, 2020, you gave a presentation to ACIP regarding COVID-19 vaccine safety considerations; correct?
A Yes, sir, I did.
Q Okay. ACIP is expected to eventually vote regarding recommending a COVID-19 vaccine; correct?
A Yes, sir, that will be their goal.
Q Okay. Your presentation was intended to educate ACIP voting members about the COVID-19 vaccine safety considerations; correct?
A Yes, sir.
Q And you began your presentation with a disclaimer; correct?
MR. SANDERS: You're muted, Dr. Edwards.
A I don't have my presentation in front of me.

Q (By Mr. Siri) Okay. Well, let's pull it up.

(Brief pause in the proceedings.)

Q Why are we doing this over Zoom? Almost there.

A Would you like me to pull up my own slides?

Q Sure, if you've got the disclaimer slide, that's great. In the meantime -- well, let's -- well, let's see who gets the --

A Well, I guess I'll just -- I'm afraid I'll lose my Zoom, so you can just pull it up. I'm sure you're capable of that.

Q Sure. Well, whether I'm capable of it is about to be tested.

MR. SIRI: Can everybody hear that?

MR. SANDERS: I can see it. I can't hear it.

MR. SIRI: Rob, remind me again what I need to do so that everybody can hear it.

THE VIDEOGRAPHER: All right. Just before you hit share screen, you'll need to check the box that says audio or --

MR. SIRI: Thank you.

THE VIDEOGRAPHER: -- it may say

accentuate or audio with -- play an audio.

MR. SIRI: Yep. I got it. I got it. Thank you. Thank you. I appreciate that.

Q (By Mr. Siri) All right. Here we go. Let's try this one more time.

(Whereupon, a video clip was shown.)

Q (By Mr. Siri) Okay. So, Dr. Edwards, that was your disclaim -- disclosures of conflict for that presentation; correct?

MR. SANDERS: Object to the form of the question. You can answer, Doctor, if you have an answer.

A That was my disclosure, and it was in reference to -- to the fact that -- that I wanted to address that -- any potential conflicts because I was speaking at the CDC and I was being funded by the CDC, so those were the contexts in which I was -- I presented the disclaimer.

Q (By Mr. Siri) And you didn't disclose your current and prior affiliations with pharmaceutical companies that sell vaccines; correct?

A Not on this disclaimer, no, sir.

Q And many of those companies are also

developing COVID-19 vaccines; correct?
A The con -- they are, but the content of the -- the content of the talk was really a review of past information about safety and really about what was happening with the concerns about safety signals, so it's -- it appeared to be more relevant to the CISA contract that I was citing, and that's why I mentioned that.
Q Your presentation, as we discussed, was intended to help educate the ACIP committee regarding the safety, potential safety for various COVID vaccines under development; correct?
A That's correct, sir.
Q I'm going to play you a short clip from that meeting, and then I'm going to ask you a question.
(Whereupon, an audio clip was shown.)
Q Dr. Edwards, that's you speaking in the video; correct?
A Yes, sir, that is me.
Q Okay. And you created a slide that was presented as part of this presentation?
A That's correct, I did.
Q Okay. Who decides what the background rate

is for each adverse event?
A Well, that's something that I'm also working on very hard with the -- you know, to try and help and understand. There's -- that is -- is determined by -- by -- by looking at the medical records, by looking at large-linked databases, and -- and trying to assess what that background rate is, so that is a -- a process that takes a lot of time and effort and statisticians and medical record experts and large-linked databases are addressed, but it can be a daunting effort.
Q Does that list get created before -- you know, like, before the trial starts, is there -- let me -- I asked two questions at once. Doesn't a list of background rates already exist?
A There are a list of background rates. I think that we, however, have to make sure that those background rates are relevant. I think there -- they -- we need to make sure that those background rates are relevant to the population that's being studied, and I think that -- that we need to make sure that the background rates are relevant to -- to a time when COVID is circulating, and so there have been a lot of

implications with social distancing for other kinds of respiratory events and other kind of infections, so it looks very much like the -- that social distancing is reducing the burden of a lot of diseases, and so we will need to assess those in the context of a -- of a pandemic, and so that will be important in terms of how that -- that is assessed as well.

Q Like, for example, the mortality amongst infants has gone down dramatically during this period of social distancing.

A Well, not -- not necessarily. I think what I'm saying is that --

Q No, I know, I'm just ask -- you said there are changes --

A Yeah.

Q -- that have occurred. I'm just saying that's an example of a change; correct?

A I think changes -- again, I'm not aware of exactly what the mortality --

Q Oh, then that -- then that's fine. Let's -- let me just move on.

A Okay.

Q If you don't know it, let's move on. So --

but so let's do something more specific to what you're saying. For example, you said that the background rate needs to be relevant to the population under study in the trial, so for example, if the study only includes healthy adults, you would need to know what is the background rate for the particular condition of interest in that -- in a group of healthy adults for the relevant time period; correct?

A That is the goal.

Q Yeah. Okay. Well, who decides -- who ends up actually deciding what the background rate is when these trials are conducted?

A Well, I think that -- that those are -- are rates that we have some general idea about, and -- and then as time goes on, as we gather more data, they may be assessed with -- with different rates, but I think we have to take the rates that we currently have. We also have to assess whether there are unusual reactions, whether there are reactions that we would see that we haven't seen before, so it's not only the frequency, but it's the character of the -- of the reaction, and it's also whether other kinds of events can be

identified as a cause of the reaction.
Q And who decides whether the event is related to the experimental vaccine under study and clinical trial?
A Well, the assignment is generally by the investigator, and they -- they relate the adverse event and then they say that they think it's related or they think it's not related. I think that those -- those are -- you know, obviously they're usually in the -- in the position to do that most effectively because they have the whole picture there, but each of those are assessed individually by a DSMB, and if there's any question about the assignment of that, then there could be additional details that are asked for.
Q And when you say investigator, you mean the -- the -- the principal scientist who's conducting the trial on behalf of a pharmaceutical company's drug or vaccine that is under review; correct?
A It's the principal investigator, yes.
Q Yeah, and the principal investigator is compensated from the pharmaceutical company whose drug or vaccine is under review; correct?

A That is how it generally is funded, although as you're probably aware with COVID, that has been somewhat different in that their Operation Warp Speed has provided funding for a number of the vaccine studies, so -- so that's a little bit different in terms of Warp Speed.

Q That's true; right? It's definitely -- it's a deviation from the past and that's far enough -- has -- and HHS and the U.S. Government have provided funding directly to the pharmaceutical companies for conducting these clinical trials. The pharmaceutical companies then spend the money that they're provided to pay for the clinical trials; correct?

A That's -- for those vaccines that are evaluated within that process. There are some that are being evaluated outside that process.

Q Which are those?

A Pfizer is being funded by Pfizer, not by the government, although the manufacturing of the vaccine, if it's proven to be safe and effective, is provided by Pfizer -- or by --

Q Okay. So if the Pfizer vaccine, the payments, a lot like the principal investigator is

saying, are going directly from the government to the principal investigator?

A No, sir.

Q Oh.

A The Operation Desert Storm COVID vaccine studies that are run through the NIH are being paid for by BARDA to the investigators. The independent studies, such as Pfizer, is -- is funding this study itself. However, Pfizer has been given money to build manufacturing capabilities for the vaccine if it were to be proven effective.

Q Okay. Now, in a clinical trial, you have the individuals that are receiving the vaccine under investigation, and that's typically called the experimental group; correct?

A Yes, sir.

Q And then you'll have a control group that is not receiving that vaccine; correct?

A That's correct.

Q Okay. So going back to background rates, why not just compare the rate between -- of the adverse event between the experimental group and the control group?

A Certainly that is -- that is being done all the time so that you're comparing the adverse events that occur with the vaccine and with the control group, but you're also -- I mean, this is a 30,000 people study, so it -- you know, it's a large study, and so you will also be looking at -- let's say there was an episode of Guillain-Barre, and you would say, well, you know, what is the expected Guillain-Barre rate in that population, and if it were consistent with the overall rate, then you would say, well -- you know, well, we may need to assess -- it seems that it could be a chance occurrence because in that particular population with this number of people vaccinated, you could see Guillain-Barre as a background rate, and the reason that this is important is because we not -- we need to make sure that an event is indeed causative, and if we're going to stop a study, which is -- which can certainly be done if there's an adverse event or a hospitalization or a death, certainly we -- we need to consider that, but we also need to consider whether that may just be a chance occurrence, and so -- and certainly we know that every -- that the more time that we

delay the licensure of a vaccine, that there are downsides as well, so this is done, you know, so we compare both vaccine groups, but we also have an understanding or an assessment of what is the overall background rate of that adverse event in the population.

Q So what you're saying is, for example, if there are, let's say, three instances of Guillain-Barre in the experimental group and zero instances of Guillain-Barre in the control group, that doesn't end the analysis. It's not that that means that -- let me just finish the example. That doesn't mean that the vaccine caused Guillain-Barre. That's not what the -- that's -- this study just doesn't stop. It then -- the principal investigator, you're saying, will then look at the background rates and make a determination of whether or not they believe the Guillain-Barre is actually causally related to the vaccine that's being studied?

A No, that's not correct.

Q Okay.

A I'm -- so what you would do in that situation is if there is a cluster of adverse events in the

vaccine group, and there are none that are seen in the control group, so --

Q Okay.

A -- that would be very worrisome, the unequal distribution of the adverse events. So that would -- that would trigger a DSMB to say, wait a second, you know, this looks -- you know, looks suspicious, but we also have to realize that there are specific criteria for the diagnosis of an adverse event, so there is a collaboration called the Brighton collaboration that -- that makes diagnoses a different way so that we can say that Guillain-Barre is indeed the case. So if we have three cases of Guillain-Barre that are diagnosed with the proper qualifications in the vaccine group and none in the control group, then we would be concerned about that, and regardless of the background rate, that would be a cause of concern, and if indeed that is the case, then the study may be stopped.

Q Can you repeat the last part of that?

A I'm saying that if indeed three cases of documented Guillain-Barre with all the criteria that established the diagnosis clearly would

happen in the -- in the vaccine group and none in the control group, then it's likely that the vaccine study would be stopped by the DSMB.

Q So the Brighton collaboration is establishing the criteria for making the diagnosis for various conditions?

A The Brighton collaboration is a very interesting group that has been in existence in over a decade that actually works very closely to make a definition of an adverse event so that everyone will agree with it, and there are various levels; one, two, three, and four. One is a level that everyone would agree that -- that the definition is correct. And so -- so it's important when you say that the adverse events are indeed adverse events that you have confirmed that that's not -- that's what the case -- so let me give you an example. Right now we're looking at background rates in some large databases, and we look at background rates and it comes up in the medical record that all these people have Guillain-Barre or have had Guillain-Barre, so when we -- in the medical record. So then when we look in the medical record, the diagnosis was history

of Guillain-Barre, and so it -- the patient does not currently have it. So there are criteria for making the diagnosis, and if we're going to clearly associate a vaccine with an adverse event, we want to make sure that the diagnosis of that adverse event is correct.

Q So that relates to the timing, but it's --

A It doesn't relate to the timing.

Q Okay.

A It relates to a definition.

Q Okay.

A So it relates to the symptoms that you had, it relates to a spinal fluid protein, it relates to -- you know, to the exclusion of other ongoing events such as Campylobacter or other kind of viral infections. These are rigid diagnoses that everyone would agree that this is Guillain-Barre. These are -- and this is very important to make sure that you are diagnosing things appropriately. So the Brighton collaboration has a number of these guidelines they are currently working on adverse events for COVID for guidelines as well.

Q And so these guidelines are specific to assess whether a vaccine causes a particular

injury or they're just guidelines generally?
A These are guidelines for the definition of the adverse event. It does not assign causality.
Q Okay, understood. It's just to diagnose -- it's just to assess whether or not the person, in fact, had the adverse events, had claimed to have occurred?
A It is to mix -- it's to assure the certainty of the diagnosis that you are making.
Q All right. And so if -- so if the three cases, and I'm going back to our example of -- of Guillain-Barre, were confirmed to, you know, meet the Brighton collaboration criteria for, in fact, being Guillain-Barre syndrome, and all three occurred in the experimental group and none occurred in the control group, would that be then used to determine -- to make a conclusion that the vaccine can cause Guillain-Barre or is there another process that occurs where that conclusion can be reached?
A I think causation is exceedingly difficult to prove, and I think one of the issues that you would need to make sure of is that there were not -- there was not another reason for that to

be -- to -- for Guillain-Barre to occur, so you have a case that is clearly defined, but the Brighton collaboration does not say that it is vaccine related. Now, how do you confirm that a vaccine causes an adverse event? Well, there are a couple ways. For instance, when we had polio, we could confirm that we had vaccine-acquired polio by isolation of the polio virus from the spinal fluid of the child that had the paralysis. We had -- we know that children that have severe immune deficiencies, which fortunately we're much better able to diagnose now with newborn screening, but we know, for instance, that some of those children would have dissemination of a virus and cause severe disease such as measles, and those -- and they would have virus isolated from their -- their blood or their lungs or their spinal fluid. So the actual determination of causation is often the exclusion of other -- other entities, but unless you have the ability to actually isolate that virus from a person who's ill, causation is more difficult to determine.

Q And who makes the determination of whether or not there's some other potential explanation, for

example, those three cases of Guillain-Barre in our example?

A Yeah, well, I think that -- that the DSMB would have to look at that. I think that, for instance, they may be asked, for instance, of -- let's say one of the patients had diarrhea and you -- and you could say that, you know, there is an entity called campylobacter, which is associated with Guillain-Barre, so if you found that that individual had campylobacter in their stool and they had Guillain-Barre, then you would be worried. But again, it was -- these -- these are not easy things to do, and I think that you try and get as much information to exclude things, but sometimes when an adverse event happens, it's so after the adverse event that some of these things cannot be tested for, such as campylobacter.

Q So when a -- you know, what you're saying is -- I mean, when a clinical trial is conducted for a vaccine, it has limitations on what adverse events it can determine before licensure; correct?

A Yes, it does, and it's dependent upon the number of people enrolled in the study, so

certainly a study that has 200,000 children enrolled into it, which is a rotavirus study, has a lot more power to detect adverse events associated with vaccines than a study that enrolls 1,000 people. The 30,000 COVID studies are going to have a lot greater power to look at adverse events than the 45 patients that was just reported in the New England Journal. But because adverse events may be so rare, it may be necessary to actually license the vaccine and then do post licensure studies to look at the rates of adverse events in that way.

Q So one of the factors on whether or not a clinical trial can detect an adverse event is the number of participants, which you're referring to as how powered the study is; correct?

A That's correct. That's called the sample size.

Q Thank you. And then another factor would be the duration that safety is reviewed after administering the product; correct?

A That's correct.

Q Okay. And I assume a third factor would also be whether or not -- what the control is in the

trial; correct?
A Well, I think that in order for a study -- a pivotal study that may be involved in licensure of the vaccine, there is a lot of discussion with the FDA what the control group would be, so if -- you know, so -- so the easiest control group is a placebo control group where someone just gives saline, and that's pretty straightforward, but that also is problematic because, you know, if you're giving a reactive vaccine and you're -- and the people are getting in -- the vaccine and the placebo group is getting saline and there's no reaction, then sometimes that can unblind the individuals in terms of I'm not so sure which -- you know, I got the vaccine, so that -- so we want people to be blinded for the -- and we also need to make sure that the vaccine that is being studied does not have an impact on the disease you're looking for, so a great example would be the recent study by the Oxford group with their -- with their adeno vector COVID vaccine, and what -- and what they used in their control group was a meningococcal vaccine, so the meningococcal vaccine had reactions associated with it, so

people were less clear what they got, but again, there's -- the meningococcal had -- vaccine had no impact on COVID, so those are some of the nuances.

Q So if you're going to use the Pfizer vaccine in the experimental group, the COVID Pfizer vaccine in the experimental group, and you're going to use the meningococcal vaccine, right, which would be Menveo in the United States in the experiment -- in the -- excuse me, the control group, then the meningococcal vaccine needs to have previously been licensed to determine that it doesn't cause a certain reaction in order to make an assessment of whether or not the experimental vaccine does or does not cause that same reaction; correct?

A Yeah. But the COVID studies are going to --

Q Right.

A Most of them are going to have a control of saline.

Q Right.

A Because it's hard to get two vaccines that are given within a month apart, so most all of those will be very clear, and the benefit of having a true placebo will be that you will have

people who do not receive any active agent.
Q And then this way you can actually compare the reaction rate between those that get the experimental vaccine and those that essentially are getting an inert substance; correct?
A Correct.
Q That's what a placebo is, it's an inert substance; correct?
A Yes.
Q Okay. And the pivotal clinical trials which you mentioned earlier, those are the trials that the FDA will typically rely upon to license a vaccine; correct?
A Yes, sir.
Q Okay. Now, if you were -- if you're going to design a clinical trial of a vaccine given to children 18 months or younger, how long would that clinical trial need to be to determine whether the vaccine caused autism?
A The -- in general, the -- autism is generally diagnosed somewhere within the first couple years of life, and -- and I think maybe the mean time is about two years depending upon the severity, so I think that that -- however, I think that -- that

most of the going theories would suggest that autism is really a prenatal event and not an event that happens after the child is born. So I think that that -- that what you're asking me is a little bit of a loaded question, and so I will answer -- I will ask you -- or I will answer in that -- that the -- that the vaccine trials that are -- that are conducted always have a tail of about a year that is required for -- for the manufacturers to follow the patients. With the more recent licensure of new vaccines, there is also generally a longer tail with post-marketing surveillance, which may then include two or three years to look at any adverse event that may occur in that population.

Q You're talking about the Phase 4 trials?

A Yes, sir.

Q Okay. Post-licensure trial?

A That's correct.

Q Okay. That occurs after the product is already on the market; correct?

A That's after the vaccine is licensed, yes.

Q All right. In 2 -- in 2000, in the year 2000, children were typically diagnosed with

autism around four years of age. Is that correct?
A The diagnosis is made much -- much earlier than it used to be, yes.
Q Okay. Are you aware that in 2000, the typical age of diagnosis for autism was around four years of age?
A I don't know what -- the mean age. I -- I didn't review the literature from 2000 about autism, about the rates.
Q Let me share a study with you. This way you have it and you can have an opportunity also to review it for the trial. This is going to be -- do you see the title of this article is Age Of Diagnosis For Autism: Individual and Community Factored Across 10 Birth Cohorts?
A Yes, sir.
Q And I'll scroll down to here, in which we can see Figure 1 displays the changing age of first autism diagnosis from the 1992 to 2001 birth cohorts. Do you see that?
A Yes, sir, but I -- you know, I -- I must say that -- you know, I've -- I've not reviewed this article, and I certainly will review, so I don't -- so you have a table and I have no idea

where this table came from. I'm not saying that it's not correct --

Q All right.

A -- or anything, but, you know, for you -- for -- I -- I think this --

Q That's entirely fair, entirely fair. That was why I wanted to mark it and you have an opportunity to review it later. Absolutely. You didn't write it and you've never seen it before, and I -- I -- no question. I just wanted to mark it as -- so that will be Plaintiff's Exhibit, I believe, 14. Okay. Now --

MR. SANDERS: I have it as 13, Mr. Siri, but it -- you may be right.

MR. SIRI: Well, I have the -- I don't know how we're going to do this, but we have the video.

MR. SANDERS: Okay. That was 13 then. Okay.

MR. SIRI: Yeah. Look at that, I finally got a number right. Okay. So I think the video is 13, this will be 14.

(Whereupon, Exhibit Nos. 13 and 14 were

marked to the testimony
of the witness.)
Q (By Mr. Siri) Now, for the vaccines licensed, you know, by the year -- by the year 2000, how many children would you estimate need to be in those clinical trials to detect whether the vaccine caused autism by age 18 months and how long would the trial need to continue after 18 months of age?
A I -- I can't give you those numbers off the top of my head exactly how they would be. And --
Q Okay.
A -- I think that that -- I think one of the -- you know, when you have a rare event, although, you know, autism is now felt to be about 1.5 percent of the population, when you have a rare event, and particularly when it was -- it -- it might have been more difficult to diagnose earlier, in an earlier time, then I think it takes larger numbers, but I can't give you that number, sir, and again, I'm -- I'm not a -- an autism epidemiologist.
Q Okay. But given what you know about clinical trials, would you agree with me that the clinical

trials relied upon to license the vaccines given to -- for Yates were not designed to determine whether these products caused autism when given to an infant or child or at or below the age of 18 months?

A I think those trials were likely not powered, to answer that question. I don't recall the actual number that were enrolled in the -- in the MMR vaccine trials, and so I can't -- I can't say that definitively, that -- you know, but I would trust that it likely was not large enough, and that's why large database studies are needed to really assess that in a Phase 4 assessment.

Q All right. The --

A Looking for adverse events that are associated with vaccines.

Q Okay. And then they would also -- in addition to needing to be -- have enough participants to be properly powered, they would also need to actually track the children in the clinical trial for long enough so that enough of them could actually get an autism diagnosis such that an assessment can be made; correct?

A Yes, or you could do those studies in a --

you could also do those studies in a large-linked database, which has been done since that time looking at children that --

Q Well, we'll get to the post licensure after. Let's -- I'm trying to do this systematically. Let's talk about pre licensure now. We'll certainly get to those, the post-licensure period. Sticking with the pre-licensure period, so -- so it sounds like, you know, you would agree there weren't -- they probably, as you said, are unlikely to have been properly powered and they would have needed to review safety long enough as well to determine -- to capture enough children in the experimental and control group that had or didn't have autism in order to make an assessment of whether the product caused autism; correct?

A Yes, sir.

Q Okay. So if -- you know, if the safety review period, you know, was no longer than -- let's say, was 42 days, and assessing whether the vaccine caused a child that received the product at 18 months caused autism, that wouldn't be long enough; correct?

A I want to make sure that it's clear that you

understand what I'm saying.
Q Sure.
A I think that if an adverse event were to occur associated with vaccines that if it were an uncommon event and if it were -- if it was not diagnosed until later, then you would need a larger number sample size and a longer period to assess that. I am not saying, however, by answering yes to your questions that I believe autism -- that vaccines cause autism, so I just want to make sure that you understand what I'm saying.
Q I never asked that question. Absolutely. I think the record is clear on that. I -- I -- we are not trying to determine -- what I -- what I am trying to -- and hopefully so we can avoid going through each of the clinical trials, I am just trying to establish, and I -- you know, that because of the number of participants, the period the safety was reviewed and the control that was used, none of the pre-licensure clinical trials showed the vaccines Yates received were designed or capable of determining whether or not those products did or did not result in autism.

A Did not result in an adverse event.
Q The one at issue -- did not result in an adverse event of autism.
THE WITNESS: Mr. Sanders, I think that -- I want to make sure -- I think I'm getting -- I think he's trying to make me say things that I don't believe, so --
MR. SANDERS: Okay. Well, just listen to the --
THE WITNESS: How am I supposed to respond to the same question repeated times?
MR. SANDERS: Yeah, I think -- listen to the question, and if -- if you've already answered it, you can tell him I've already answered that.
Q (By Mr. Siri) All right. Well, so I -- okay. Look, I -- let's -- let's take it piece by piece then. How long would -- how long would safety have to be tracked in the clinical trials relied upon to license the vaccine Yates received in order for them to have determined whether the vaccine caused autism?
MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have an answer.

A I'm not going to answer it. I've already answered the question.
Q (By Mr. Siri) I don't recall that -- you have not provided any period of time. Are you saying you don't know the --
A I said --
Q -- period of time?
A I said --
Q Please.
A I said that the studies that were involved in the licensure of MMR did not provide an adequate number of patients that had been followed for four years to determine the -- the -- a rare event that would happen four years after vaccination. That's what I'm saying.
Q Okay. And you consider autism to be a rare event?

MR. SANDERS: Object to the form of the question. You may answer, Doctor.

A Yeah, the -- the CDC reports that the rate is about 1.5 percent.
Q (By Mr. Siri) You -- do you consider autism to be a rare event when those clinic trials for MMR occurred?

A It --

MR. SANDERS: Object to the form of the question. You may answer, Doctor.

A It was a rarer event than it is now.

Q (By Mr. Siri) You say you answered the question, but I -- I'm -- you're not -- you're not really answering the question. I just -- you know, you say you conduct -- you've done -- according to your profile, you have done most of the clinical trials relied upon to license many of the vaccines, correct, on the market?

A Yes, sir.

Q Okay. So you're highly experienced at conducting clinical trials; correct?

A I am highly experienced conducting clinical trials.

Q All right. And you're familiar with many of the clinical trials that -- relied upon to license many of the vaccines currently on the market; correct?

A I am.

Q Okay. In your opinion, did the clinical trials relied upon to license the vaccines that Yates received, many of which are still on the

market today, were they designed to rule out that the vaccine causes autism?

A No. You've badgered me into answering the question the way you want me to, but I -- I think that -- that I've -- that's probably the answer.

Q Is it -- is that your accurate and truthful testimony?

A Yes.

Q Thank you. All right.

MR. SANDERS: Mr. Siri, can we take a break at some point? We've been going about three and a half hours. Whenever you get to a stopping point.

MR. SIRI: Absolutely. Let me just -- just a few more minutes and then we'll take a break. Does that sound good?

MR. SANDERS: Sure.

MR. SIRI: Okay. You know what, why don't we -- do you want -- do we want to take a five-minute break?

THE WITNESS: I think I need a little more than five minutes. I'd like to have fifteen minutes, if that's okay.

MR. SIRI: Oh, absolutely, Dr. Edwards.

THE WITNESS: Okay. So we'll meet then at quarter to twelve. Is that okay?
MR. SIRI: That's wonderful.
THE WITNESS: Okay, thank you.
MR. SIRI: Thank you, everybody.
THE VIDEOGRAPHER: All right. We are off the record at 11:26 a.m.
(Brief recess.)
THE VIDEOGRAPHER: All right. And we are back on the record at 11:47 a.m. Central time.
Q (By Mr. Siri) Thank you. Dr. Edwards, is silent transmission of pertussis within families, has that been demonstrated?
A Yes, it has been.
Q Okay.
A There have been --
Q Please continue.
A Yes, there has been.
Q Okay. Pertussis can be transmitted by breathing; correct?
A It's a respiratory pathogen. It can be transmitted by droplets.
Q Right. As well as by breathing; correct? I mean, the medical literature support -- had -- it

specifically supports that; correct? I'm not saying it's the only -- let me -- I know that you want to qualify everything. I'm not saying it's the only way it spreads. I'm asking you is it a way that it can spread.

A Pertussis is most generally spread by people that are coughing, but it can be asymptomatically spread, and there are studies of challenged models where monkeys or primates are put in together and in separate cages right to each other, and one monkey can -- one primate, one baboon can infect the other. So if you say breathing in terms of generation of droplets, yes.

Q All right. And also when somebody transmits it asymptomatically, that means they transmit it when they weren't coughing; correct?

A Yeah. It's not the usual method, and you know, for many years we didn't believe that that actually happened, and then there were some data that would suggest that perhaps adolescents were able to transmit. Most of the time, however, those people that transmit have some type of symptoms, and that's why the organism is so efficient because you cough, and cough generates

droplets and aerosols that infect other people, so that -- so in general, not like COVID, most people that are infected with pertussis have some symptoms.

Q Or they can be paucisymptomatic, meaning they just have some symptoms.

A That's correct and -- yeah.

Q It --

A That's correct.

Q They don't realize -- they're not sick enough to stay home; correct? They're not -- let me rephrase. Strike that. They're not sick enough where they think -- where they would normally stay home and in bed; correct?

A Generally not. And again, the most serious pertussis is in babies before they're vaccinated, and they -- and then they can die of that.

Q Right. Babies under one year of age are at risk if they get pertussis, they can develop a whoop by which they're known -- they can't -- you're the expert. You know what, let's strike that. Let's strike that.

A So maybe you --

Q Let's just move -- let's just move on. No

question on the table. No question on the table. Okay. So long-held assumptions by the medical community regarding pertussis vaccine have recently been shown to -- by more recent science to show the -- not being correct; correct? Is that right?

A Knowledge evolves in all fields and so it should be based on science.

Q Absolutely. That's why you would agree with the statement, I believe, quote, if we knew what we were doing, it wouldn't be called research; correct?

A Yes. That is actually on my wall in my office.

Q Oh. The only pertussis vaccine used in the United States and the one Yates received is known as acellular pertussis vaccine; correct?

A Acellular pertussis vaccines are a group of vaccines. It's not a vaccine. The acellular pertussis vaccines consist of three or four antigens. The Infanrix consists of three antigens, but Sanofi Pasteur consists of four antigens. They are combined with diphtheria toxin and tetanus toxin. All of the vaccines that are

used in the United States are acellular. However, acellular vaccines are not used all over the world and whole-cell vaccines also are used.

Q But in the United States, since 2000, we have used in the United States exclusively acellular pertussis vaccine, not --

A That's correct.

Q Okay. Thank you. And I think you mentioned that -- giving acellular pertussis vaccines to adolescents; correct?

A Yes, sir.

Q And that -- that would be what's known as the Tdap vaccine; correct?

A That's correct.

Q All right. Versus the DTaP vaccine, which is only licensed up until seven years of age; correct?

A That's correct.

Q Okay. And there are two adolescent acellular pertussis vaccines; correct?

A Right. There's two -- for the primary series there's two for the adolescent. They are made by Sanofi Pasteur and by GSK.

Q All right. Thank you. And the -- and the

two adolescent ones were both licensed in 2005; correct?
A I -- I can't remember exactly the year --
Q Okay.
A -- each of the vaccines are licensed.
Q Okay.
A Sorry, I can't do that.
Q That's fine. Now, pertussis vaccines can reduce the symptoms of pertussis; right?
A That's the goal for a vaccine, that you reduce the incidents of disease and the symptoms, so that's correct.
Q So the pertussis vaccine can reduce the symptoms of pertussis; correct?
A Yes. It's an effective vaccine.
Q Yeah. I was -- I thought that was a softball. I thought you'd agree with that one. Okay.
A I think that's --
Q I thought that was an easy one. All right.
A There are no easy questions.
Q Yep. Let's keep going. That's fair. Sometimes. So for decades, the medical orthodoxy was -- was that the vaccines could also prevent

infection and transmission; correct?
A Yes.
Q Okay. And but, you know, after spending of decades seeking to eradicate pertussis in first world countries, using acellular pertussis vaccine, the scientific community has recently come to understand that this vaccine can never accomplish that end; correct?
A I think that there are a number of deficiencies in the current acellular pertussis vaccine that could be improved upon.
Q Does the current pertussis vaccine have any -- can it exert any herd immunity effect?
A Probably, although that's been a little controversial as well. I think, you know, obviously we're all discussing herd immunity about everything, and just like with COVID there are some controversies about herd immunity. I think that an immunized community is what you would want to get, and certainly we know that if a highly -- if a community is highly immunized, there's less pertussis. If there are a lot of people that are not immunized, there's more pertussis, so there is a role for herd immunity. The extent is still a

subject of debate.
Q And when you say pertussis, you mean the disease?
A Bordetella pertussis disease.
Q Right. But the pertussis vaccine, the scientific community now understands, does not prevent somebody who's received that vaccine from becoming infected with Bordetella pertussis and transmitting the pertussis; correct?
A It probably does. I think that we -- that we see the efficacy of the vaccine in young children, and it probably persists through the period until they get their booster. The efficacy of the pertussis vaccines and studies that we've been involved in is generally felt about 85 percent. We also know, however, that with the adolescents, there appears to be more of a problem with waiving immunity than we had appreciated before, so that is one of the areas that we're also working on. The other issue is I talked about before is maternal vaccination for prevention of disease in infants, so we --
Q Well, let -- I'd like -- let -- you know, I -- look, I appreciate, Doctor, that you are very

knowledgeable, but -- I mean, you're a vaccinologist, you're world renowned, you know a lot of information. I just -- I need to get information in smaller bites, and you know, you've given me a lot of information, which is great, but obviously I can't address it all. I just need to take it in pieces. With that said, I want to go back to my question, which was, does it prevent infection and transmission of pertussis.

MR. SIRI: And what I'd like to do is -- I'm going to -- I'm going to mark this as Plaintiff's Exhibit -- is it 15?

MS. CHEN: Yes, it's 15.

THE VIDEOGRAPHER: Thank you.

(Whereupon, Exhibit No. 15 was marked to the testimony of the witness.)

Q (By Mr. Siri) This is an article in the Frontiers in Immunology; correct?

A Yes, sir.

Q And you're an author on this article?

A That's my name.

Q And along with 19 -- not -- many other what

are considered, I guess, you know, experts in pertussis and pertussis vaccine; correct?

A That's correct.

Q And also the World Association of Infectious Diseases and Immunological Disorders as well as the Vaccine Study Group of European Society of Clinical Microbiology and Infectious Diseases also signed on to this study; correct?

A They were part of the authors, yeah.

Q Okay. So and this study was published just this past summer, July 2019; correct?

A That's correct.

Q Okay. Let's scroll down there. And you reviewed and confirmed -- strike that. We can come back to that later if we need to. I'm going to read you a few sentences from this and I'd like to ask you a question. So the study says, natural infection with pertussis evokes both mucosal and systemic immune responses, while acellular pertussis vaccine induce only a systemic immune response. Do you agree with that statement?

A Yes, sir, I certainly do.

Q Okay. Oh, sorry. Dr. Edwards?

A Yes, sir.

Q Okay. I think I froze. I didn't hear your last -- the answer to the last question.
A Yes, I agree that natural infection evokes both mucosal and systemic immune responses while acellular vaccines induce only a systemic immune response. I agree with that statement.
Q Okay. And then the next statement, mucosal immunity is essential to prevent colonization and transmission of Bordetella pertussis organisms. Do you agree with that statement?
A Yes, I agree with that statement, but it's not -- it does not exclude the role of systemic immunity as well.
Q Okay. And then the next sentence, preventative measures such as acellular pertussis vaccines that do not --
A I can't hear you, sir. I think that you're cutting out. I can't hear you.
MR. SANDERS: Mr. Siri, I cannot hear you either.
Q (By Mr. Siri) Let's give it a second. Okay. All right. Can you hear me now?
A Yes, sir.
Q Okay. So I was saying, the next sentence

says, preventative measures such as acellular pertussis vaccines that do not induce a valid mucosal response can prevent disease but cannot avoid infection and transmission. Do you agree with that statement?

A Yes.

Q Okay. Next highlighted yellow, it says, acellular pertussis vaccines do not prevent colonization. Do you agree with that statement?

A They do not totally prevent colonization. They have a small role and that's been shown in baboon studies. I think what you're doing is you're taking -- I have written almost 600 papers. You're taking a sentence and you're wanting me to say whether that sentence is true or not, so --

Q That's -- that's what I'm asking you because it's in a paper that you authored and at the bottom of which the paper says everybody read it and agreed to it. So are --

A I --

Q So acellular -- it says, acellular pertussis do not prevent colonization. Now, you said there was a baboon study that would seem to indicate. Now, in the baboon study, you're talking about the

study conducted by Warfel at the FDA; correct?
A Jason Warfel and Tod Merkel, yes.
Q Okay. And in that study, what they did is they -- they -- they had naive baboons, right, baboons that had never have been exposed to a pertussis; correct? They had one group, like, of naive baboons like that; right?
A Yes, sir.
Q And then they also had a group of baboons that had been vaccinated with acellular pertussis vaccine; correct?
A Yes.
Q And then -- then they had a third group that got whole-cell, but let's leave that one out, and then they got a fourth group of baboons that got -- that had been -- had had pertussis. They were convalescent; right?
A Yes, sir. I'm really familiar with the paper. I actually --
Q Then they --
A -- about it, so --
Q Well, what --
A So what is your question?
Q And all three baboons were then exposed --

all three groups of baboons were then exposed to pertussis; correct?

A That's correct, sir.

Q And then they -- they -- they used a swab up the baboon's nose to see if they could culture a pertussis -- Bordetella pertussis from the baboons after they were up for -- were challenged with Bordetella pertussis; correct?

A Yes, sir.

Q And what they found was that the baboons that were naive, as well as the baboons -- what they found was the baboons that were naive, they had symptoms, they were coughing; correct?

A Yes, sir.

Q But the baboons that had received acellular pertussis, they had less than -- they still had some symptoms, but they had a lot less symptoms; correct?

A That's correct, sir. Yes.

Q But they both were able -- but the -- but Warfel and his colleagues were able to retrieve Bordetella pertussis from the -- their nasal pharynx for this same duration of time after exposure; correct?

A That's correct.
Q Okay. So I don't understand, how does that study support that pertussis vaccines -- how does that study change or add any qualifier to the statement in this study that acellular pertussis vaccines do not prevent colonization?
A So that's what it said, so --
Q Do you agree with that statement?
A I agree with that statement, yeah. I agree with that statement.
Q Okay. And then it says, consequently, they, meaning Bordetella -- excuse me, meaning acellular pertussis vaccines, do not reduce the circulation of Bordetella pertussis and do not exert any herd immunity effect; correct?
A It depend -- that's what it says. It depends on how you define herd immunity. So herd immunity in this situation prevents transmission from other people. Herd immunity can also define the penetrants of a virus or a bacteria in a population, so we know that in -- that populations that have very low rates of pertussis have much higher rates of pertussis disease, and those are papers that have come from data from California

and those papers have -- have been authored by -- by a number of epidemiologists that -- so again, the problem is that I wish you would just ask me what you want me -- to ask. Where are you going with this? You know, what are you trying to say? So I'm --

Q What I --

A What --

Q What I'm just trying to establish here is, you know, because I don't think if I ask directly you'd agree, is that, you know, there are long-held assumptions or established principles in vaccinology that can go on for 30 years. All right. In this instance, there was a 30-year worldwide campaign to vaccinate children, adolescents, pregnant, expanding the circles of vaccination in an attempt to reduce infection and transmission of pertussis; correct?

A Yes, sir.

Q But science, vaccinology has finally caught up, the sciences caught up, and we now know that, in fact, the acellular pertussis vaccine cannot prevent transmission infection, right, which is why you're developing -- trying to develop a

better vaccine, right, a nasally-inhaled one that will also prevent infection and transmission; right? It's kind of like the COVID vaccine. The Oxford one appears to maybe prevent disease, but it doesn't -- it doesn't appear to stop infection and transmission. So, you know, what I'm asking you is, I just want to -- I thought I asked a simple question, which is can acellular pertussis vaccine prevent infection and transmission. Had you said no, we could have moved on. So let me -- I mean, can a -- acellular pertussis vaccine does not prevent infection and transmission, just as you've written in this article; correct?

A Acellular pertussis vaccines have a major role in prevention of disease. We -- the children -- babies used to die of pertussis, and because of acellular vaccines, we have -- we don't -- we have a reduction in infant deaths. We do not have a vaccine that reduces colonization. So when you say -- when you ask me a question, I want to make sure that I'm answering the question completely so that you don't take what I said and change it into something that I haven't said.

Q Look, I understand. You also want to point

out the benefit of the vaccine, not just potentially an issue. I understand that. We're here today to talk about a potential injury from a vaccine, so obviously today is going to focus on those items, and I know that's, you know, not something that -- you've never appeared as an expert before, you've never had to be challenged in this way, I understand that, but that is the role today. Look, moving on, let me ask you this. The interepidemic intervals for pertussis in the United States have actually gotten shorter over the last two decades; correct?

A Some people think they have. Other people think they've stayed three to four years.

Q Okay. Either stayed the same or gotten shorter?

A Yes.

Q What do you think, Doctor?

A I think both of those statements can be supported.

Q Fair. Okay. What is the Global Pertussis Initiative?

A It's an initiative that is funded by Sanofi Pasteur to assess the global burden of pertussis

and to assist in ways that it can be controlled. We know that most of the global population, we don't have very good surveillance information on pertussis in a lot of the global community, so that's what it's --

Q And you were a member of the Global Pertussis Initiative; correct?

A Yes, sir.

Q All right. And so, for example, as you pointed out, there isn't good surveillance. The point in increasing surveillance of pertussis is to make sure that more people get the pertussis vaccine in various countries around the world; correct?

A The goal of pertussis surveillance is to see how much pertussis that we have in the world.

Q It's also to -- isn't it true that there are many articles published through the Global Pertussis Initiative including which you're an author in which the -- there's argument for expanded use of pertussis among, you know, adolescents, pregnant women, and -- and other -- and increasing the rate among children?

A The recommendations for the use of pertussis

vaccine in each of those populations is supported, so yes, if the -- if the country pro -- if the country has immunization recommendations for pertussis, those are supported, yes, that -- so with the ultimate goal to reduce disease.

Q So the answer to my last question is yes?

A I kind of forgot what the question was.

Q No problem. I just -- well, I'll make it simpler. I'm just saying the Global Pertussis Initiative has convened many meetings of pertussis which is -- with experts; correct?

A Yes.

Q And the Global Pertussis Initiative is funded by Sanofi; correct?

A Yes.

Q And those meetings and the Global Pertussis Initiative has produced many papers; correct?

A Yes.

Q Okay. And in those -- those started in 2000 when the initiative was first started by Sanofi; correct?

A I don't know the year that it started.

Q Okay. And you've been an author on a number of those papers; right?

A Yes, sir.
Q And those authors -- and those articles have -- because you're saying you want to reduce the burden of disease, have argued for expanded use of pertussis vaccine; correct?
A Yes.
Q Okay. There's also a group called the International Consensus Group on Pertussis Immunization; correct?
A I'm not -- I don't -- I don't know that I -- and I hope I'm not a member of that. It's not something I recall.
Q You're not. You're not. You're off the hook right away. You're not.
A Okay.
Q That's the -- that's -- you're not aware that that's the GSK-funded equivalent of the Global Pertussis Initiative?
A No.
Q Okay. And the --
A Right, I --
Q You're not aware they did this -- engaged in the same type of sponsorship of meetings and -- you know, and articles and so forth to encourage

pertussis vaccine?
A No, sir.
Q Okay. So in 2005, you said earlier you're not aware that Sanofi and GSK licensed their pertussis vaccine for adolescents in 2005; correct?
A I'm saying that I don't remember exactly what year those vaccines were licensed, but --
Q Okay.
A -- they did license those vaccines.
Q Okay. Are you aware that in 2006 the ACIP voted to add those vaccines to the recommended CDC childhood immunization schedule?
A They were added. I don't know which year they were added.
Q Okay. Okay. Are you -- so I assume you're not aware that in the ACIP documents in which that recommendation was made to add those vaccines, 34 of the cited studies to support that recommendation from ACIP included one or more members from the Global Pertussis Initiative for the GSK-funded one?
A I think that one of the things -- you know, why are these people on these advisory boards?

Because we're the experts. You don't -- you know, you don't ask people --

Q But --

A -- for advice or for --

Q Because they're supposed to be independent; correct? They're supposed to be independent of the pharma companies; correct? Okay. Well, you said it earlier. Strike the question. We already have an answer. Okay. What is linked epitope suppression?

A Linked epitope suppression is when you -- actually you have seen a certain epitope on an antigen and that when you've seen it then you're introduced again and there's some suppression of that particular response to that epitope.

Q Is there a suppression of the response of that same epitope that's already seen and for which there's immunity or is it suppression of a response to other antigens that usually come along -- let's --

A You --

Q Let's take it in pieces. It's going to be complicated; right? We'll take it in quick little pieces. So the pertussis bacteria has

approximately 3,000 antigens; correct?
A Correct.
Q All right. The whole-cell pertussis vaccine that we used to use in the U.S. also had around 3,000 antigens; correct?
A Correct.
Q The acellular pertussis vaccine has about, like you said earlier, three or four or five antigens in it; correct?
A Yes.
Q They're selected from the pertussis bacteria; right?
A They were selected for their role in disease prevention --
Q Selected to be -- yes. All right. Do you know what those five antigens are?
A Of course. They're pertussis toxin, they're filamentous hemagglutinin, they're FIM 1, they're FIM 2, and they're pertactin.
Q Okay. Is it FIM 1 or 2 or FIM 2 and 3? Has that changed over time?
A 2 and 3, I'm sorry. I'm -- 2 and 3, not 1 and 2. Sorry.
Q That's no problem. I usually start counting

from one to two, so I totally -- you know, it now -- now it's been found that those that are vaccinated, as we've discussed, based on the pertussis vaccine, kids still become infected with pertussis, you know, because they're only generating a vigorous immune response to the five antigens, and whereby previously with the whole-cell or with natural infection it would have developed -- they would have generated an immune response to all 3,000 antigens; correct?

A Correct.

Q Okay. And I believe, you know, Dr. Cherry, among others, has found that those vaccinated with acellular pertussis vaccine, when they generate an immune response to the five antigens in the vaccine, or three or four, when they actually encounter pertussis, their body develops the vigorous immune response by developing antigens to those five antigens.

A Antibodies to the antigens.

Q Antibodies to -- thank you. But there's a suppression in generating antibodies to the other approximately 2,995 antigens; correct?

A That is Dr. Cherry's hypothesis.

Q Okay. And that -- and that hypothesis is known as linked epitope suppression; correct?
A Correct.
Q But do you agree with that hypothesis?
A I'm not sure that it's been shown definitively. I think it's still a hypothesis.
Q Okay.
THE VIDEOGRAPHER: Excuse me. Mr. Siri, if you're done with that screen share, you might want to take it down.
MR. SIRI: Oh, thank you.
Q (By Mr. Siri) Okay. There was a time when immunity to pertussis was thought to be life long; correct?
A Yes, sir.
Q That's when adults were reexposed to pertussis and -- you know, after having it naturally and --
A I can't hear your question, sorry.
MR. SANDERS: Mr. Siri, you froze up again.
MR. SIRI: How about now? Hello?
THE WITNESS: Yeah.
MR. SANDERS: We can hear you again.

A I can hear you now. I just couldn't hear the question, so maybe --
Q (By Mr. Siri) No problem. Okay.
A Okay.
Q I -- given the issues, let's move on to another topic. Can varicella vaccine cause and result in pneumonia?
A The administration of varicella vaccine in immunocompromised subjects can result in pneumonia, yes.
Q Okay. What about non-immunocompromised subjects?
A Generally not, although there are always examples that may be not easy to understand, but in general, varicella vaccine does not cause pneumonia in normal healthy people.
Q But it -- it can cause pneumonia in normal healthy people sometimes?
A It may. I would -- in order to answer that definitively, I'd need to look in the literature or look in theirs.
Q Okay. So if -- are you aware that the IOM report about adverse events from vaccines in 2011 did find a causally -- that the -- that the

pneumonia as a result from varicella vaccine was causally supported?
A In normal healthy people or in immunocompromised?
Q I'm not aware of it qualifying it to immunocompromised.
A Well, I would think probably they would do that, but again, I --
Q Okay. Can varicella vaccine cause and result in encephalitis?
A It can, particularly in immunocompromised or immunodeficient individuals.
Q Can varicella vaccine cause an infection of the brain?
A That's what encephalitis is, yes.
Q Okay. I didn't -- I just relate to lay talk. Can varicella vaccine cause and result in meningitis?
A Varicella vaccine in some subjects has been isolated from the spinal fluid, so that would be a definition of meningitis, yes.
Q So it -- it -- so varicella vaccine can sometimes cause and result in meningitis; yes?
A Yes.

Q Thank you. All right. Can varicella vaccine cause an infection of the spinal cord covering?
A That's the meninges, so that's the same question, and the answer remains the same, yes.
Q Thank you. Thank you for indulging. Can varicella vaccine cause seizures?
A It may be associated with seizures. Certainly you can get fever as well, and if there was encephalitis, it may indeed, although every time you have a seizure, I can't say that it was due to varicella.
Q But it can in some instances cause a seizure; correct?
A In very rare instances, and particularly in individuals who are not immunocompetent.
Q Okay. Can DTaP vaccine cause seizures?
A It can be associated with seizures in that it can cause fever and also sometimes -- so -- so yes, it can be associated with seizures.
Q Okay. Would you be surprised to know that the CDC has provided that a -- that -- has found that there can be a causal relationship between seizures and DTaP vaccine?
A That's not different from how I just answered

the question.
Q Okay. All right. Can DTaP cause nonstop crying for three hours or more?
A Yes, it can. It's called HHE.
Q Okay. Can DTaP cause long-term --
A It's also -- it's also called persistent crying or HHE, yes.
Q Thank you, Doctor. Can DTaP cause long-term seizures?
A No, sir.
Q Are you aware that the CDC has found that DTaP can cause long-term seizures, rarely, but that it can?
A No. I think that -- that I would disagree with that. It can cause it in patients that are -- have channelopathies, have Dravet syndrome, but that's not a normal healthy patient.
Q So it can cause seizures in patients that are not healthy?
A With a neurologic encephalopathy called Dravet's, yes.
Q Any other instances?
A No.
Q Okay. Are you aware -- would you be

surprised to learn that the CDC's conclusion that DTaP could cause long-term seizures was not qualified in the manner you just stated?

A I'd be happy to look at what you just said to make sure that I understand what you're asking me. I'm not sure just you reading it makes me comfortable that that's what it said.

Q Can DTaP cause coma?

A No, sir.

Q Okay. Again, would you be surprised if the CDC has concluded there is a causal relationship between DTaP and coma?

A Yes, I would, sir.

Q Okay. Can DTaP cause lowered consciousness?

A Well, if there was a seizure you had with it and you were postictal, then that would cause lowered consciousness, and then also the HHE episodes are associated with -- with less responsiveness, so yes.

Q Can DTaP cause permanent brain damage?

A No, sir.

Q Would you again be surprised if --

A I would be exceedingly surprised because no one believes that.

Q Then we'll come back to that.
A Good.
Q Can MMR cause encephalitis?
A Yes, and particularly in immunocompromised individuals.
Q Can MMR cause febrile seizures?
A Yes.
Q Can MMR cause chronic arthritis?
A I'm sorry, sir, I couldn't hear your -- the --
Q No problem. Can MMR cause chronic arthritis?
A It can be associated with short-term arthritis, but generally not felt to be chronic.
Q Okay. Are you aware that the Institute of Medicine has found that chronic arthritis is causally related to MMR?
A Perhaps that's what they said.
Q Okay. If that is what they said, would you change your conclusion regarding whether MMR caused chronic arthritis?
A Probably not.
Q Okay. Can MMR cause acute arthritis?
A Cause true arthritis?
Q I'm sorry, acute.

A Oh. Yes.
Q Can MMR cause thrombocytopenia?
A Yes, definitely.
Q Okay. And that's an autoimmune disorder in which the body attacks a portion of the red blood cells; correct?
A Actually, it's not really autoimmune. It actually is -- is actually destruction of the platelets in the marrow, and then it goes away and -- and then it -- it -- so it -- it is an antibody-mediated function, but it's not an autoimmune in the classic way.
Q I appreciate that. Can MMR cause death?
A MMR can cause death in immunocompromised subjects, and we -- and that happens, and that's been reported and clearly outlined, and I just reviewed that last week for a conference.
Q Okay. What about non-immunocompromised subjects?
A Generally not, and I'm not aware of one isolated case that has been reported, but again, I didn't do a thorough search before you asked me the question.
Q Okay. Can MMR cause unusual bleeding or

bruising?
A Well, if it causes thrombocytopenia, then it will cause bleeding and bruise.
Q Can MMR cause deafness?
A I think it's not been well established. It's felt to be unlikely, but -- but I -- I would be -- I would have to look for that again. I'm not sure.
Q Dr. Edwards, did you hear the question?
A No, sir, I did not hear the question.
Q Oh. Can MMR cause long-term seizures?
A Not in a normal host, no, sir.
Q So it can't cause it in healthy children?
A No.
Q Can it cause it in unhealthy children?
A I would think it probably could cause it in unhealthy children that have an immune compromise.
Q Into a coma?
A I'm sorry?
Q Can MMR cause a child to enter into a coma?
A Very unlikely unless they have immunocompromise.
Q Can MMR cause a child to have lowered consciousness?

A If they have a seizure associated with fever, then they would be postictal and it would cause lowered consciousness, yes, but not persistent lowered consciousness.
Q Can MMR cause brain damage?
A Not in a normal healthy subject without underlying problems.
Q So a child with underlying problems, MMR can cause brain damage; correct?
A I think I would have to assess each individual, the causality of each individual one.
Q So it's possible?
A I'm not sure. Not in a normal healthy person.
Q You're aware the CDC has specifically used the word brain damage as a possible cause from MMR?
A No, I am not aware of that.
Q Okay. Are you aware that the vaccine information statement for the MMR says -- that they list brain damage as a possible cause from the MMR vaccine?
A I'm -- I don't have that in front of me. Obviously if you do and that's what it says, then

that's what it says. That's not been my experience.

Q All right. And as we discussed earlier, the CDC only puts things on the VIS -- well, let's take a look at it. And as we discussed earlier, as you testified earlier, the CDC only puts things on the VIS if there's evidence to support that it's causally related to the vaccine. This is the vaccine -- oops, sorry.

MR. SIRI: Okay. So I'm going to mark this as Plaintiff's Exhibit -- what is it, please?

MS. CHEN: Sixteen.

MR. SIRI: Sixteen, thank you.

(Whereupon, Exhibit No. 16 was marked to the testimony of the witness.)

Q (By Mr. Siri) So this is the vaccine information statement for the MMR vaccine, correct, Dr. Edwards?

A That's what it says.

Q Okay. And it's from the CDC?

A That's what it says.

Q Section 4 is the risks of a vaccine reaction;

correct?
A Yes.
Q And under severe events occurring very rarely, it lists brain damage; correct?
A Yes, it does.
Q Lowered consciousness?
A Yes.
Q Coma?
A Yes.
Q Long-term seizures?
A Yes.
Q Deafness?
A Yes.
Q Seizures?
A Yes.
Q Okay. Let's pull up one more and then we'll -- we'll move on. This is the vaccine information statement for DTaP.
A I think -- excuse me. Can I say one thing before you --
Q No. There's no question pending, Dr. Edwards. Your attorney can ask you questions. And I mean, and frankly, you know, we can hear somebody in the background. Being coached during

a deposition is not appropriate. This is the -- this is the vaccine information statement. You know what, here's what we're going to do. I mean, I've never had a deposition over Zoom and, you know, coaching a witness while a deposition is not --

A No one is coaching me. No one is coaching me. My husband just walked through. I will ask him to leave the room. I'm sorry.

Q That's -- that's fine. I mean, because we can hear somebody saying something and then you want to add something. That's just, you know, not the way that this works. Now, as an expert in vaccinology, you're familiar with how doctors record in a patient -- record in a patient's medical records that a vaccine was administered; correct?

A Yes, sir, and that -- I have that in front of me, sir.

Q Okay. Do you know if the doctors are required to record whether the parent or guardian received the VIS?

A Well, on some -- on some forms, it does have that information, and that's -- it does have in --

in some of the -- the forms that -- that are -- but I don't -- I don't think that it's absolutely mandated, and I actually see a number of vaccine records that come to me from adverse events that I'm asked to re -- to review. And I think that -- that in general, it's not always on there, so I think it can be for some and not all -- and others it's not on there, and so I think it's -- it's -- it's both ways.

Q Uh-huh. Are you -- have you ever --

MR. SIRI: I'm going to mark this as Plaintiff's 17.

(Whereupon, Exhibit No. 17 was marked to the testimony of the witness.)

Q (By Mr. Siri) Have you seen this document before?

A I believe I've reviewed it.

Q Okay. And this is facts about vaccine information statements from the CDC; correct?

A That's what it says, sir.

Q I'm going to read the bottom in yellow. In addition to distributing VISs, as described above,

providers are required to record specific information in the patient's medical record or in a permanent office log. Number one, bullet point number one, the edition date of the VIS found on the back at the right bottom corner, and the date that the VIS is provided, the date of the visit when the vaccine is administered. So is a vaccine provider required, as the CDC states, to record giving a VIS to the parent or guardian of a child before giving the vaccine?

A So what it states is that in addition to distributing, providers are required to record in the patient's chart or in a permanent office log. So if, indeed, there might be in a permanent office log the standard procedures of what is always done, that would seem to me to suffice.

Q So as long as it's recorded somewhere in the medical records in the office, whether it's in a patient's medical records or in a permanent office log, that would meet the CDC requirement; correct?

A That's what happens, although as I often say -- see, I don't always see that in the records that I review from doctors all over the United States, so that's what is supposed to be

done. Whether it's always done, I don't think it always is.

Q But if a doctor asked you if it's required to record that information somewhere in a medical record or in a permanent office log, what would you tell that doctor?

A I would say that those are the guidelines that the CDC provides.

Q Now, I believe you said you've seen this before.

MR. SIRI: I'm going to mark this as number 18, Plaintiff's Exhibit 18.

(Whereupon, Exhibit No. 18 was marked to the testimony of the witness.)

Q (By Mr. Siri) You have that in front of you; correct?

A Yeah, I do. I thought it was 17. I guess we're at 18, huh? Okay. Yeah, okay. Yeah, I have it in front of me.

MR. SIRI: Patricia, is this one 18 or 17?

A It's 18.

MS. CHEN: Eighteen.

MR. SIRI: Okay, thank you.

Q (By Mr. Siri) Did I say 18 or did I say --

A You said -- you said it correct and I was incorrect.

Q Okay. So looking -- you've seen this record before; correct?

A Yes, sir.

Q You've reviewed it as part of your review?

A Yes, sir.

Q Okay. From reviewing this record, can you tell me if Yates' parents or guardian did not receive a VIS for any of the vaccines Yates received?

A Well, it's recorded that it's given and then a -- you know, a -- in a number of them, but it's not recorded in all of them. Now, whether this is -- if it's a standard operating procedure that's documented and how this is done in the office, then I trust that it was given, but it doesn't say that it was given here. It says that it was given on a number of which it was noting.

Q Okay. So would you surmise that it was given on the -- for the ones where it says given, would

you surmise that it was given on those dates and for those vaccines?
A Yes, I would, sir.
Q Okay. And now what about the -- where there's those ellipses right below given, would you surmise that the VIS was given on those dates for those vaccines as well?
A I'm sorry. I can't understand your question.
Q Oh, I'm sorry. No problem. The ellipses right below given for some of the vaccines, do you see that?
A Yes.
Q Would you surmise that the VIS was given for some of those that --
A Yes.
Q You would --
A That's what that usually means, yes. I would surmise that, yes.
Q So you would surmise that the VIS was given for those vaccines on the dates listed; correct?
A Yes.
Q Okay. Now, for the ones that are blank, would you surmise that the VIS was not given to the -- to Yates' parents or guardian on the date

and for those vaccines listed on the --
A I could say that it was not recorded. Whether it was given or not, I think that's a harder question.
Q Okay. So you don't know?
A I don't know, no. I'm sorry, I don't know. I don't know what happened there.
Q Okay. Similarly, for the ones that are listed as given, could those also be a mistake?
A I think it's -- it's unlikely those were a mistake. I think when we write things down that we do them, then we generally do them. I think sometimes we forget to write things down.
Q Got it. So if it's listed, it's highly unlikely that it wasn't given if it says given; correct?
A That's correct.
Q Meaning you give the vaccine, you fill out this chart right after the vaccine is given typically; correct?
A That's correct.
Q And you would know whether or not you gave a VIS; correct?
A I would think that you would know and it

would be part of your routine procedures.
Q Yeah. So, for example, let's take a look at Prevnar given on June 6, 2000. Do you see that row?
A Yes, sir, I do.
Q Okay. It states that the Prevnar vaccine was given, administered to Yates on June 6; correct?
A Yes, sir.
Q Okay. And it states clearly that the vaccine information statement was given to Yates' parents or guardian on that date; correct?
A That's correct.
Q Okay. Any reason to think that that's inaccurate?
A Well, I know that -- that the actual vaccine statement for Prevnar, the official one had not been published yet, so I know that you're concerned about that, and there are earlier forms that had -- are given to patients about vaccines, so if that's your question, I -- I -- I trust that some information was given to the family about the vaccine because that's what it said. Whether it was actually the official VIS because that hadn't yet been approved, I don't know, because it used

to take several months, and as I said before, the Prevnar vaccine was licensed in 2000, so it was a new vaccine.

Q So what you're saying is they might have written given under the vaccine information materials publication date column even though it may have been a -- not been a VIS, it may have been some other materials; correct?

A Yeah. What it states is vaccine information materials. It doesn't say VIS. It says materials.

Q Uh-huh. And so what you're saying is that when given was written there, it's possible that a -- some other materials were provided. Is that right?

A That's correct. It does say that materials were given, so that's how I'm reading it.

Q But you would agree that a VIS was not given; correct?

A I don't know that, sir. I have no idea. That's just what I -- I understand is a question because I read, you know, the concerns of everyone, and so that was something I just was going to respond to, so I don't --

Q You don't -- right. So just to be clear, at -- the first VIS for Prevnar wasn't actually issued until July of 2000; correct?
A I believe that's correct.
Q Okay. So when I -- I asked you is it possible the VIS was provided on June 6, you're saying that it was possible that it was given on June 6 before it --
A That's --
Q -- was even in existence?
A That's not what I'm saying. What I'm saying is that the chart says that vaccine information materials were provided, so I don't know what was provided, but it -- unlikely it could be a VIS because that -- it wasn't official until after that time, so all I'm saying is that based on this record, some vaccine information materials were given.
Q But you don't know that; correct?
A It said -- this is what the chart says, so I'm being asked all the time to see patients and to assess patients based on what the medical chart says, so when that happens, I say the -- I -- I believe what the medical chart says. Now, the

medical chart doesn't always say -- answer all my questions, but if it has said something, I take it that it is factual.

Q I just want to make sure that I'm clear on this. But you're -- is it your testimony that it was possible for the VIS for Prevnar to be provided on June 6, 2000 to Yates' parents or guardian?

A That's not what I said, sir. I said --

Q No, I know that. I'm asking you, is it -- I'm not asking what you have said. I'm just trying to make the record clear. Was it -- let me ask it to you directly. Was it possible for a VIS for Prevnar to be provided to Yates' parents or guardians on June 6, 2000?

A So when did you say that the VIS was officially put out? What -- July what? This is July 6. When did you say -- July -- what July -- what time?

Q Let's pull up the document. You don't need to rely --

A Okay.

Q -- on my statement.

A Okay.

MR. SIRI: Let's mark this as 19.

(Whereupon, Exhibit No. 19 was marked to the testimony of the witness.)

Q (By Mr. Siri) Are you familiar with this document, Dr. Edwards?

A Yes, I am.

Q Okay. So let's scroll down to the Prevnar, or maybe it's pneumococcal, I don't know how they list it. Yeah, pneumococcal. All right. This would be the VIS issuance dates for the Prevnar vaccine; correct?

A Yes, sir.

Q And when was the first VIS for Prevnar issued by the CDC?

A 7/18/2000.

Q Okay.

A So it would have been after the vaccine was administered.

Q That would have been after the vaccine to Yates -- the Prevnar vaccine was administered to Yates on June 6, 2000; correct?

A That's correct.

Q Okay. So it wasn't possible for the Prevnar VIS to have been given to Yates' parents or guardians on June 6, 2000 when he received the Prevnar vaccine; correct?
A That is correct, but that's not what the medical record states. It says vaccine information materials.
Q Okay.
A So vaccine information materials could be related or some other information that was provided, so he did not get a VIS, no, and if that's your question, he did not receive a VIS, but I do -- but it says he received some information.
Q You reviewed the medical records in this case; correct?
A Yes, sir.
Q And you reviewed Yates' medical records in particular; correct?
A Yes, sir.
Q Did you see any material in any of his medical records that would be something that would be provided to parents regarding the Prevnar vaccine and giving the risks and benefits of the

vaccine that could have been given to the parents or guardians of Yates on June 6, 2000?

A I did see -- let's see. There was one record that said information was given. Let's see here. There was one -- yeah. So -- let's see here. There were handouts. So this would have been at -- was this -- this would have been at four months; right?

Q Would you mind -- I -- it would have been at four months, yes.

A Yeah, yeah. So on page -- well, I don't know what page it is. It's G -- or it's -- it's -- it's --

Q Would you mind holding it up to the camera, Doctor?

(Witness complying.)

Q Thank you. Okay.

A At the bottom, it says, handouts, four month.

Q Okay. All right. What's the number on that document, Doctor? Doctor? Dr. Edwards, you said there was a number on that document. Can you kindly --

A ACJ -- JC, dash, C8, dash, 67.

Q Is it possible -- going back to plaintiff's

Exhibit 17, Yates' medical records, is it possible that this vaccine record was altered after the fact to make it appear as if a VIS or vaccine information materials were given for Prevnar or potentially other vaccines when in reality they weren't?

MR. SANDERS: Object to the form of the question. You may answer, Doctor.

A Yeah, I see absolutely no indication that that's the case. I have looked at hundreds of vaccine records and they all look like this, so I would believe this vaccine record. There's no reason that it would be altered. Why would one alter a vaccine record?

Q (By Mr. Siri) Well, when somebody is facing potential liability and a lawsuit, do you think that that might incentivize a doctor to change a medical record?

A No, sir, I don't.

Q Okay. So in your opinion, doctors will never modify medical records potentially to avoid liability?

MR. SANDERS: Object to the form of the question. You may answer, Doctor, if you have a

question -- or if you have an answer.
A I can -- I can say that Dr. Hays was one of our residents, and --
Q (By Mr. Siri) Was one of your what? I'm so sorry.
A He was one of our medicine pediatric residents.
Q Okay.
A And he has -- he was an excellent resident. The med peds residents are the smartest of the lot. They take -- they have -- it's very competitive, and I recall that at least in my interactions he had a strong moral core, so it would not be consistent with his behavior that he would alter something that was not correct.
Q Would you say he had the same moral core as you have, Dr. Edwards?
MR. SANDERS: Object to the form of the question. You may answer, Doctor.
A I would hope so.
Q (By Mr. Siri) Okay. So tell me about your relationship with Dr. Hays.
A I was simply his teacher. I was not a memorable person. I think he cited in his

deposition a number of the people he remembered. It wasn't me obviously, but I do know the residents and I do interact with them and I have a sense of their -- of them as people, and obviously, you know, that was a long time ago, but I -- he was well-trained.

Q Okay. Now, a significant proportion of parents with an autistic child over the years have continued to identify vaccines as a cause of their child's autism; correct?

A Have -- said that -- what's the cause of their autism?

Q I said when -- you know, there are a number of peer-reviewed studies that have looked at and surveyed parents of autistic children with regards to what they blame as a cause of their child's autism; correct?

A Yes, sir, that's correct.

Q Okay. And many of those studies have come back with results that show that a significant proportion of parents of autistic children continue to blame vaccines as a potential cause of their child's autism; correct?

MR. SANDERS: Object.

A That's correct.

MR. SANDERS: Object to the form of the question.

A That is correct.

Q (By Mr. Siri) Yeah. I mean, that continues to happen even though public health authorities have loudly and repeatedly claimed that vaccines do not cause autism; correct?

A There are a number of -- of misinformed state -- misinformed concepts that many of -- many people have, including people in high places.

Q Okay. But public health authorities have loudly and repeatedly claimed that vaccines do not cause autism; correct?

A That's correct.

Q Okay. Now, in the expert disclosures for this case, it asserts that among other things you will testify that, quote, the issue of whether vaccines cause autism has been thoroughly researched and rejected, end quote. Let me ask you, do you believe the issue of whether vaccines cause autism have been thoroughly researched and rejected?

A Yes, sir, I do.

Q Okay. You have also repeatedly provided interviews in which you stated categorically that vaccines do not cause autism; correct?
A That's correct.
Q When you made those statements, did you mean that no vaccines cause autism?
A That's correct.
Q So it is your testimony that none of the vaccines that Yates received caused autism?
A That's correct.
Q Okay. It's your testimony that MMR vaccine cannot cause autism?
A That's correct.
Q It's your testimony that HepB vaccine cannot cause autism?
A That's correct.
Q It's your testimony that IPOL cannot cause autism?
A Yes.
Q It's your testimony that Hib vaccine cannot cause autism?
A Yes.
Q It's your testimony that varicella vaccine cannot cause autism?

A Yes.
Q It's your testimony that Prevnar vaccine cannot cause autism?
A Yes.
Q And it's your testimony that DTaP vaccine cannot cause autism?
A Yes.
Q How did the concern that vaccines can cause autism begin?
A It began with Andrew Wakefield in an article that he published in Lancet that suggested that a number of children that he reported had -- had developed autism after MMR vaccine, and then he made the claim that the MMR virus was seen in the -- in the biopsy of a number of the intestinal tissue from the patients.
Q You're talking about an article published by Andy Wakefield in 1998?
A Yes, sir.
Q Okay. So you're saying the concern that vaccines cause autism started with Andy Wakefield after publishing that article in 1998; correct?
A That's correct.
Q Before Wakefield's article regarding vaccines

as a potential cause of autism?
A I am not aware that others have brought forth that, I'm -- that hypothesis, no, but maybe they have. I -- I don't know. I -- I'm not -- I know certainly that Dr. Wakefield really advanced that hypothesis.
Q Are you aware that stakeholders, including parents, were claiming and clamoring that pertussis-containing vaccines caused autism over a decade before the Wakefield article?
A Yes, but what you -- what you asked me, at least I thought you did, was about measles, so about MMR. So again, yes, there have been a number of false claims about autism from a number of different vaccines, but the MMR is -- I thought you were talking about Wakefield, so there were -- obviously there were concerns about the whole-cell pertussis vaccine, it was very reactive, and that's certainly worked to get a -- one that was less associated, so yes, I was aware. I'm sorry.
Q No problem. And when you say false claims, you mean parents were claiming that based on their experience with their child, a particular vaccine caused their child's autism, but the science was

then done to confirm that that vaccine could not cause autism?

A I'm saying that there are no scientific documentations that the vaccines cause autism. I'm not saying that parents did not say that they thought that the vaccines cause autism.

Q All right. Okay. Are you familiar -- are you aware that the 1986 Act required that HHS conduct studies on regard to whether pertussis-containing vaccines caused certain conditions?

A Yes, sir.

Q Okay. And that's because parents were loudly claiming and complaining that they believe their children -- those conditions were caused by pertussis-containing vaccines?

A Yes. The pertussis vaccines were very reactive. They were associated with a lot of seizures, and they were -- and parents were really, you know, very worried about the vaccines, and so -- so there was an effort to make safer vaccines for pertussis.

Q And so one of the conditions that the 1986 Act -- one of the ten conditions of the

1986 Act required HHS to review was whether or not a pertussis-containing vaccine caused autism; correct?

A Yes, sir.

Q Okay. Are you aware that the IOM reviewed whether pertussis-containing vaccine caused autism and issued a report in 1991 with their conclusion?

A I was, and there's also been subsequent discussions about that as well.

Q We'll go through all of them. But in 1991, the IOM did issue a report on whether pertussis-containing vaccines can cause autism; correct?

A I believe so. I don't remember exactly what the content of that report was, but I'm sure you have it so you can pull it up and I can look at it.

Q Good. We'll do that. But -- let's do that right now. I presume you're not aware of what the causality conclusion was in that IOM report regarding --

A Was it --

Q -- pertussis -- let me finish my question -- pertussis vaccine caused autism. We just need a

complete record. I presume you're not aware of what the causality conclusion was with regard to whether pertussis vaccine causes autism.

A I think you're going to put it up so then I can just review it. I think it was not definitive in terms of the -- but again, I -- I'm sorry, but I just have to look.

Q Sure.

MR. SIRI: I'm going to mark this as Plaintiff's Exhibit 19 [sic].

(Whereupon, Exhibit No. 20 was marked to the testimony of the witness.)

Q (By Mr. Siri) Are you familiar with this report?

A Yes, I have this book in my office.

Q Okay, wonderful. And this is a report issued by the Institute of Medicine; correct?

A Yes, 30 years ago.

Q Right. In 1991; correct?

A That's correct.

Q And this is a table summarizing the conclusion with regard to whether

pertussis-containing vaccines can cause autism, DPT, or a rubella vaccine can cause certain other conditions; correct?

A Yes, sir.

Q And for each condition reviewed, they -- there was one of five conclusions that the IOM could have reached; correct?

A That's correct.

Q So starting at the bottom, they could have reached the conclusion that evidence indicates a causal relationship; right? That it -- the vaccine actually causes it; correct?

A That's correct.

Q But they didn't reach that conclusion regarding autism; right?

A No, sir.

Q Okay. Then they looked at what evidence is consistent with the causal relationship that there is -- evidence is consistent with a causal relationship, and they found that acute encephalopathy was -- that that -- that DPT -- that the evidence was consistent that DPT vaccine could cause acute encephalopathy; correct?

A That's what the chart says, yes.

Q But it doesn't -- that's not what they reached regarding autism; right?
A That's correct.
Q Okay. And they could have also reached the conclusion that the evidence does not indicate a causal relation, meaning that the evidence supports it's not causally related; correct?
A I'm sorry, it says, no evidence bearing on a causal relationship. The opposite would that -- be evidence indicates a causal relationship. So what is the question?
Q Right. I was reading number three. I was just -- I just wanted to go through the five categories so that we could really understand what the first category meant. The third category meaning -- they found evidence to show that it wasn't caused by a vaccine; right?
A Yes.
Q And the second category was that they couldn't find enough information to reach a conclusion one way or another; correct?
A Correct.
Q And the first category is that they literally couldn't find any evidence whatsoever whether or

not the vaccine did or did not cause the condition; correct?
A That's correct.
Q Okay.
A So this is 30 years ago. This is 30 years ago.
Q We're going to -- we're going to take this in pieces. I -- that's the only way I can do it, Dr. Edwards. Okay. So 1991, there -- and in 1986 there was enough concern that pertussis-containing vaccines caused autism that it was included in the 1986 Act and it was even an issue reviewed by the Institute of Medicine; correct?
A Correct.
Q That's many years before Wakefield's article; correct?
A That's correct, but I -- I didn't say -- I said that -- that MMR was for Wakefield's article.
Q I --
A Not pertussis.
Q I never said MMR though when I asked you the question; correct?
A I don't recall. I guess you could ask the court reporter to repeat it again, but --

Q It's in the record. All right. How -- according to the CDC's childhood vaccine schedule, how many times is a baby injected with DTaP during the first year of life?
A Three times. Two, four, six months of age and at 12 to 18 months.
Q Yes, ma'am, and --
A Four times within the first 18 months.
Q And how many times did you -- how many doses of DTaP did Yates receive in that time period?
A I believe he received four. In one of the records it said he received three, and then on the other record it said he received four, so four.
Q So four shots. So Yates received four shots of DTaP by 18 months of age; correct?
A Yes, sir.
Q Okay. Now, as -- we're going to fast-forward, as I know you want to do. Let's go all the way now to 2011. In 2011, the IOM issued another report regarding looking at various claimed adverse reactions and whether they're causally or not causally connected to certain vaccines; correct?
A Yes.

Q Okay. And that report was paid for by the HRSA and the CDC; correct?
A I don't know who supported that report, I'm sorry.
Q So let's pull it up. This is the report from the IOM from 2011; correct?
A Yes. I think that is correct.
MR. SIRI: Okay. I'm going to mark this as Plaintiff's 20 [sic].
(Whereupon, Exhibit No. 21 was marked to the testimony of the witness.)
Q (By Mr. Siri) It's entitled Adverse Effects of Vaccines: Evidence and Causality. Can you hear me, Doctor?
A Yes.
Q Yes.
A That is what it said. That's what this says.
Q And it's issued by the Institute of Medicine; right?
A That's correct. That is what it says.
Q And it -- these reports, as they typically do, start with the charge to the committee;

correct?
A That's correct. I've -- so -- I'm on a number of these committees, so I'm fully aware of how it's set up.
Q Wonderful. And the committee is a committee within the Institute of Medicine that's set up to answer the question that's in the charge provided by whoever is paying for the report; correct?
A Yeah. This -- the Institute of Medicine was set up by -- by Abraham Lincoln to provide the government with expert --
Q Well, okay, I -- respectfully, we don't need you to go through the whole history of the IOM. I -- you can certainly talk about that afterwards. Yes, it was set up by Congress, it was supposed to be the advisor to Congress, but as it stands in 2011, the IOM issues reports upon the commission by others to do so; correct.
A Correct.
Q Okay. You said correct?
A Correct, correct.
Q Okay. This report was commissioned by the Health Resources and Services Administration; correct?

A Correct.
Q And if you look down at Footnote 4, isn't it -- and funding for this was also provided by the CDC and the National Vaccine Program Office; correct?
A Yes, sir.
Q Okay. And the -- and the -- the adverse events that the IOM is asked to look at in 2011 were described by HRSA, the one who is commissioning the report, as the vast majority of adverse events in the claims for compensation that were occurring in the vaccine court; correct?
A That's correct.
Q All right. Meaning what -- what HRSA was asking was is they wanted the IOM to review the existing scientific literature to determine were these commonly claimed injuries in vaccine court, were they or were they not caused by vaccines; correct?
A That's correct.
Q Okay. And, you know, the HRSA is also the agency that defends against vaccine claims in vaccine court; correct?
A That is.

Q Yeah, along with the DOJ; correct?
A That's correct.
Q Okay. So --
A But let me just say one thing.
Q All right.
A The people that are selected for these committee -- committees are not all necessarily members of the Institute of Medicine, and they are totally independent of -- of the government, and each of these people on this particular evaluation have absolutely no conflicts or funding from pharma.
Q You've sat on IOM committees like this; correct?
A Yes, but not about vaccine injuries or things that -- that -- besides -- there are -- there have been committees that I have been -- I have not been able to participate because of conflicts, so yes, the conflict of interest issue was very carefully scrutinized.
Q But you have been on IOM committees relating to vaccines; correct?
A Yes.
Q Okay. Now -- okay. Did this report -- did

the IOM in 2011 issue -- report review whether one or more vaccines can cause autism? You're muted.

A Why don't you pull up the tables that summarize their findings and -- and, you know, I -- my -- I have to remember a lot of things, and so I would like to look at the data actually.

Q Do you -- but you -- to your -- best of your recollection --

A I -- I'm not -- I want to look at the data, so could I look at the data, please?

Q I will pull it up, but I -- you know, as this is a deposition, I'm asking just your best recollection. Do you recall whether or not the report looked at whether -- whether the IOM looked at whether or not, for example, DTaP vaccine causes autism?

A I believe that it did. I -- I -- I'm certain that it looked at tetanus and a number of -- HPV and others, but I can't -- I can't recall exactly the extent to which pertussis was assessed.

Q Understood. And I assume that means you also don't recall its causality conclusion regarding whether pertussis vaccine causes autism?

A No, sir.

Q Okay. Thank you. This is an excerpt from that report. Let's look towards the top. You can see it's the same title; correct?

MR. SANDERS: You've got to share your screen, Mr. Siri.

MR. SIRI: Oh, sorry. Thank you. Okay. This is going to be marked as Plaintiff's -- are we at 21 [sic]?

MS. CHEN: Yes.

MR. SIRI: Thank you.

(Whereupon, Exhibit No. 22 was marked to the testimony of the witness.)

Q (By Mr. Siri) So -- so this is an excerpt from the 2011 IOM report, correct, Dr. Edwards? I'm sorry, Dr. Edwards, you're muted.

A Yes, sir.

Q Thank you. Okay. And so -- and this is in the section relating to diphtheria tetanus, tetanus, and acellular pertussis-containing vaccines; correct?

A Yes, sir.

Q And here it's examining the question of

whether any of those vaccines, which would include particularly DTaP, cause autism; correct?

A That's correct.

Q Okay. So 2011 is about 20 years after 1991; correct?

A Yes.

Q And so they're again looking at whether pertussis-containing vaccine causes autism. The IOM is again looking at this question; right?

A That's correct.

Q Okay. So first they're going to look at the potential of what epidemiological evidence is available; right?

A Yes, sir.

Q Did they find any evidence whatsoever to support that DTaP does not cause autism?

A So it's always challenging when the sentence has double negatives. So what they decided here was that there was one study that was an epidemiologic study by the Geiers. It was not felt to be of a -- to providing adequate data, so their summary was the epidemiologic evidence is insufficient or absent to assess the association. The fact that you can't assess the association

doesn't mean that -- that it -- it -- that there is no association, but what they're just saying here is this particular evidence could not address that given the -- the publications that were present at that time.

Q Right. It's saying since there's no studies, as you've just said, it could be there is some association, they just don't know.

A It could be there isn't or it could be there is. This information is inadequate to make that decision.

Q Absolutely, that's right. Now, the -- one study they did find, Geier and Geier, it did find actually an association between autism and DTaP vaccine; correct?

A Yes, but the quality of that manuscript is certainly one that was deemed not to be of -- epidemiologically rigorous.

Q Because it -- it was based on VAERS data, which is a passive surveillance system where the -- where the number of -- let's put it this way, where the denominator is unknown; correct?

A Yeah, I -- I -- in terms of reviewing the Geier and Geier paper, it's been a few years, so I

would have to -- I know that -- what the bottom line was, but if you --

Q Okay.

A -- want me to review it --

Q The --

A -- before the trial, I would be delighted to do that.

Q Okay. Bottom line is that they only found one paper, it supported actually -- it -- the paper concluded that DTaP was associated with autism, but the IOM committee found that it was not reliable and hence didn't consider it in making a causality assessment regarding whether DTaP causes autism; correct?

A Correct. It lacked scientific rigor.

Q Okay. Then it looked at mechanistic evidence; correct?

A That's what you're showing me, thank you.

Q Absolutely. Well, you asked to look directly at it, so --

A I know. I -- no, I appreciate it.

Q I like looking at the primary sources too, so we're -- we're simpatico in that regard, Doctor. So why don't you take a moment to look at that and

then you can answer the question of isn't it true that the IOM was not able to then find any mechanistic evidence one way or another that would help them answer the question of whether DTaP vaccine causes autism.

A Well, I think that mechanistic evidence is actually more associated with establishing a correlation, so in general, what you need to do when you assess an adverse event is does it make biologic plausibility, and basically what they're saying here is that the mechanistic evidence or the pathology of autism regarding the association is lacking, so there is no mechanistic biologic evidence to suggest that there is a -- that -- that there is this association.

Q All right.

A That's different actually than what you're saying.

Q Well, let's -- let's read it. It says the -- let's read it. The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis

antigens alone or in combination; correct?
Meaning it did not find -- meaning the IOM did not find any literature one way or another bearing on that -- that would allow it to reach any conclusion regarding -- on the basis of mechanistic evidence of whether DTaP vaccine causes autism; correct?
A I think that it did not identify any literature explaining that -- how that this could be caused, so the conclusion was the -- that they assessed the mechanistic evidence, and there was no information that they could say that could provide a mechanistic -- a mechanism. That's exactly what they're saying. And based --
Q Right.
A Okay. So we agree on that, great.
Q Right. And similarly, they didn't find any evidence that showed -- that -- that would support that it didn't cause autism either. It just -- they couldn't find any mechanistic evidence one way or another. We can agree on that; right?
A Yes, but I think it's more important to find evidence, biologic evidence to support something than to -- than to refute, but --

Q Sure.
A Yes.
Q But the -- but you need to conduct the studies to look for, right, mechanistic cause evidence, meaning somebody's got to -- you know, experimental evidence, for example, somebody who's engaged in those experiments to see is there a connection, you know, is the aluminum adjuvant in the DTaP vaccine problematic, is one of the ingredients, is the -- or the way it's administered, is it in combination, whatever. There's probably a lot of experiments. You could do it in animal models, you could inject mice, right, and you can look to see do they develop autistic-like features. There's all types of studies that you could do, and all they're saying is they don't find any one way or another.
A That's correct.
Q You -- right. Okay. Well, and here's the causality conclusion. All right. And because they couldn't find any evidence whatsoever, they said -- would you like to read it? You're muted, Doctor.
A The evidence is inadequate to accept or

reject a causal relationship between DTP and autism.

Q Meaning they don't know; correct?

A There is no scientific evidence to support or refute, just as it says.

Q All right. There is no scientific evidence to support that DTaP causes autism that they could find; correct?

A That's correct.

Q And there's no scientific evidence to support that it doesn't cause autism that they could find; correct?

A That's correct.

MR. SIRI: Did you catch that, that she said it's not correct -- that it is correct?

A I just said exactly what it said. The evidence is inadequate to accept or reject a causal relationship.

Q (By Mr. Siri) Okay.

A We can't -- you cannot --

Q There's no -- Doctor -- Doctor --

MR. SANDERS: Mr. Siri, you need to let her answer the question.

MR. SIRI: There's no question.

THE WITNESS: Sir, just --

MR. SANDERS: No, she's answering. She's clarifying the question. Dr. Edwards, go ahead.

MR. SIRI: Sure.

A There is no evidence to accept or reject a causal relationship. The fact that there is no evidence to accept or reject the causal association does not mean that there is a causal relationship.

Q (By Mr. Siri) I -- sure. Fine. I -- not what was asked. Okay. Okay. So -- so given the IOM's conclusion regarding DTaP vaccine and autism, isn't it false to claim that vaccines do not cause autism?

A No, sir, because we have a lot of additional information since that time that bears on this question, that definitively doesn't address the question.

Q Okay. So there -- there has been a study that has shown that DTaP vaccine does not cause autism?

A I think that -- that the assessment of autism and relationship to vaccine has been assessed in a

number of studies and do -- does not show that there is a relationship.

Q Is there a study that shows that DTaP vaccines does not cause autism? You're muted.

A I know I'm muted. I'm thinking.

Q Okay.

A I --

MR. RILEY: Mr. Sanders, let me interject, if I don't -- if you don't mind. Can somebody explain to me, why does Dr. Edwards continue to mute her microphone? I'm just -- I want to make --

THE WITNESS: I'm sorry, sir. I am sorry, sir. I am sorry. It just -- it -- sometimes I mute because I -- I want to make sure that I can hear what's being -- and I don't want to create any other noise, so I will -- do you -- I will stop muting the phone.

MR. RILEY: Okay. Thank you, Doctor. I just was -- just making sure we're all on the same page.

THE WITNESS: Craig, I just feel like I'm getting badgered.

MR. SANDERS: Okay. Why don't we go off

the record for a minute and take a break and the attorneys can talk for a minute.

MR. SIRI: I've got a few more questions and then we can take a break. I -- there is nothing that is badgering. These are -- you know, I understand that the doctor never --

THE WITNESS: I'd like to take a break. I'd like to take a break.

MR. RILEY: Let's -- Mr. Siri, let's -- let's do this, Mr. Siri. Let's take a break just a second; okay? And we'll -- we'll talk and let Dr. Edwards regroup and we'll come back and we'll start again; okay?

MR. SIRI: What time should we start? Five minutes?

MR. SANDERS: I think we need to talk for a minute, David.

MR. RILEY: That's fine. We'll talk.

THE WITNESS: I would like to talk. I would not like -- I'd like until the bottom of the hour. And Mr. Sanders, if you could give me a call, that would be very helpful. Thank you.

THE VIDEOGRAPHER: And we're off the record --

MR. SIRI: Let the record -- no, no, no. We're not going off the record yet. Mr. Sanders -- Sawyer -- Mr. Sawyer?

THE VIDEOGRAPHER: That's fine. I'm --

MR. SIRI: I want to make a statement before we go off the record. I would like to make a statement on the record that, you know, I understand that Dr. Edwards is not used to being challenged about her vaccine knowledge, she's never been an expert witness. None of the questions here are badgering. They're all directly relevant to the question of vaccines causing autism. She may not like to have to give the answers she's giving, but that's not an excuse to pause the deposition, nor is it an excuse to force a break when we've just had a break fairly recently, you know. It -- you know, this clearly is taking an opportunity to coach the witness in the middle of a line of questioning that clearly the defense finds troubling, so with that, we can take our break.

MR. SANDERS: I'd like to make a statement, Mr. Sawyer, before you go off. We've been going now for over five hours. Mr. Siri has

repeatedly tried to cut the witness off, not allow her to answer questions. We've only taken two very short breaks within that time. There's no problem whatsoever with the witness needing to take a break. We've not broke for lunch at all and it's 1:20 here Central time. I don't know how Mr. Siri does it in New York or California where he practices, but that's not how we do it here in Tennessee, in which we, you know, treat the witnesses with respect, and if they need to take a break, take one. I certainly agree that if there's a question pending, we wouldn't do that, and I don't -- Dr. Edwards, I'm not going to call you, I don't plan to talk to you during the deposition, I'll talk to you afterwards, but I will let you know that you can take a break at any time, you just -- just speak up and let the attorneys know. If there's a question pending, you can answer that first, and I'm going to make sure throughout the rest of this deposition that Mr. Siri allows you to provide an answer and allows you to take a break at any time that you need one.

THE WITNESS: Okay. I will --

MR. SIRI: I'll just -- before we -- one second. Before we go off, so I -- I -- Mr. Sanders, I fully appreciate that when a witness needs a break, I -- it's been always my custom to provide a break. I've got no issue with that. But when the break is preceded by an insinuation that I am badgering, or as you've just said, doing something improper, that changes the tone and texture. I -- I have tried to let Dr. Edwards answer every question fully and completely. There have been times where she's decided to go just start providing information that I felt was a little off topic, but for the most part I believe I have. If you think there is a time where I've not let her complete a question, Mr. Sanders, I very much -- and I believe you pointed out once or twice and I believe I -- you know, I said absolutely, I'd like for her to finish, and I do want her to actually finish her answers to every question, so that's different than starting to talk when there's no question on the table, and that has happened, and in those instances, I certainly -- it's been my practice, and I think it's been my practice in all courts I

practice in to -- you know, to say, hey, there's no question on the table, so I -- I very much -- you know, and also -- so I have no issues with breaks. I just -- you know, when they're made in the context of these kind of insinuations of -- that -- that's a very different tenor in which they're asked for. Other than that, I have no issue with giving breaks or stopping obviously when there's no question pending, so I think we were on the same page, Mr. Sanders. Would you agree?

MR. SANDERS: I think we move forward. I would appreciate you, you know, letting her have an opportunity to respond, and --

MR. SIRI: Absolutely.

MR. SANDERS: -- and all I would request is that you treat her with respect and dignity and be kind to her throughout the deposition and give her a chance to respond to your questions.

MR. SIRI: Well, I'm -- I certainly am trying to do that. I -- you know, I've not -- I think the only disparaging adjectives have been tossed in my direction so far. I've -- and maybe like I've said, maybe the substance of my

questions are uncomfortable, but that's -- you know, that's -- I -- I try to be as respectful in the context as I can. I think the record reflects that. The other thing too is that, you know, as far as I'm aware, you know, depositions are eight hours, that's the normal, and, you know, they continue from day to day. Now, that's one of the other things, which is, you know, I'm trying to move things along, but if there's going to be, you know, long soliloquies provided that are nonresponsive to the question, that's just going to take -- that just makes the deposition longer. You, of course, can read the -- you can direct and ask her anything afterwards. You know, I'd just like to get through my outline, and, you know, I ask simple questions and I get two-minute responses. That's -- if you could -- you know, if you could ask her to just answer the questions on the table and that you will come back to her later for anything that's needed, that would certainly move this along, and that's been my experience usually.

MR. SANDERS: I -- and I certainly will -- Dr. Edwards, let you know to give -- to,

you know, answer the question and then you -- and explain to the extent you need to, and I -- I don't agree, Mr. Siri, that all the questions are simple and that there's a simple answer to them, so sometimes I think there has to be some explanation.

MR. SIRI: I agree with that too. Certainly not. Some of these questions are not simple. No argument. But there are many that are simple, but yet, you know, there's a lot of -- of information provided that's not relevant to the questions, so if we could just, you know, for the questions that are not simple, and certainly where, you know, there's information provided that are not relevant to the question, if we can just answer the question, we can get through this relatively quickly. But if every question, you know, is answered and then with a story with it, that's just going to take us longer, and I certainly don't want to have to continue this another day, you know. I understand, like, a number of jurisdictions where I practice, I've done cases in -- you know, this is a -- Tennessee is a day-to-day jurisdiction, so I would like to

finish up today, and I think that that will depend on whether we can move through, you know, the questions and answers without a lot of additional information. I mean, you'll have the opportunity to get that additional information. Anyway, we'll leave it at that.

MR. RILEY: How about I interject just a second, Craig. This is --

MR. SANDERS: We're not going to have a second day, I can say that, so whatever you need to do, you need to get through today.

MR. RILEY: Let's -- okay. Let's -- let me just interject for just a second. Craig, the whole purpose of me opening my big mouth during the deposition was I noticed that Dr. Edwards, the witness, was muting her microphone after every question, and if I'm wrong about that, I'm mistaken. That is simply what was shown on Zoom on my screen, and so I was just simply asking if she would just prevent from muting her microphone so that everyone over Zoom understood that she was hearing the questions and providing the -- her own answers to the questions. That was the only -- the only --

MR. SANDERS: Sure.

MR. RILEY: -- basis for me interjecting, and that's all I simply would ask, and we -- we should take a break right now for -- for a few minutes and regroup and come back, if that's okay with everybody. That's what I think we ought to do and maybe come back whatever -- what time are y'all thinking?

MR. SANDERS: Yeah, David, I -- I think that's a reasonable request, and -- and as far as I know, no one is there with Dr. Edwards other than, you know, she said her husband passed through the room once or twice. I would suggest a 15-minute break, perhaps. Is that too long, Mr. Siri?

MR. SIRI: That's fine. Eleven -- excuse me. 1:40 then.

MR. SANDERS: Okay. That sounds good.

MR. RILEY: 1:40. Thank you.

THE VIDEOGRAPHER: All right. And we are off the record at 1:25 Central time.

(Brief recess.)

THE VIDEOGRAPHER: Yeah, we are back on the record at 1:41.

MR. SIRI: Great. Thank you.

Q (By Mr. Siri) All right. So Dr. Edwards, is there a study that supports that DTaP vaccine does not cause autism?

A The assessment of the IOM report shows that there is not a study that refutes that association. It is hard to prove a negative. And also -- so there is not a study that says a negative.

Q The IOM though has concluded that, for example, MMR vaccine -- that the evidence supports that an MMR vaccine does not cause autism; correct?

A That's correct because there -- there are more studies that have been looking -- that have looked at that in a larger group. However, there are no studies that support that association.

Q Right. So it is possible to have a causality conclusion on whether a vaccine causes or doesn't cause autism; correct?

A It is impossible for the DTaP. They did not come up with a causality association --

Q Okay. So --

A -- or --

Q Right, because they couldn't find any study one way or another with regards to whether DTaP causes autism; right?
A That's correct.
Q Are you aware of any study -- strike that. So then let me ask you this. Strike that. Are you aware of any study that supports that DTaP does not cause autism?
A No, but I'm also not aware of any study that says that it does.
Q Fair enough. Well, Geier and Geier, but it was -- it was deemed not reliable; right?
A Right, correct.
Q Given that the current state of the science is that there aren't sufficient studies, or any studies potentially, to support that DTaP does not cause autism, isn't it premature to make the sweeping statement that all vaccines do not cause autism?
A No, sir, I do not think that that is a -- an inadequate or inappropriate statement. I think we are ignoring a lot of information in the literature that tells us that autism is really a prenatal event, that the -- the abnormalities that

are seen on the ultrasound assessing the size of the brain and the -- those differences in children with autism are becoming more and more apparent and becoming more and more established. We also have specific genetic defects, so there is likely an environmental cause, but I think focusing on the vaccine link is not a productive investigation.

Q All right. But parents back in '86 were concerned that pertussis-containing vaccines caused autism; correct?

A Yes, sir, and --

Q Who are -- please.

A And so because of the adverse events associated with vaccines, we made a vaccine that was -- was less reactogenic. Now, obviously I don't think either of them caused autism, but I think that the -- that the -- the safety profile of the acellular vaccines are less reactogenic than the whole-cell.

Q But parents continued to complain that pertussis-containing vaccines might be a cause of their children's autism, and hence the IOM again in 2011 reviewed whether pertussis-containing --

including tetanus and diphtheria-containing vaccines caused autism; correct?
A There is inadequate evidence to suggest there's a causation.
Q All right. So if there isn't enough evidence to support -- to reach a conclusion, not saying vaccines cause autism, I'm certainly not asking you to say that, all I'm asking is as a matter of science, as a matter of logic, if you don't have the proof that DTaP doesn't cause autism, not saying it does, but you don't have the proof yet that it doesn't; right? Is it --
A Okay. I --
Q Let me just finish. Thank you. Isn't it premature to say that all vaccines do not cause autism?
A No, I do not believe that that is the case, sir. I feel that I've answered this question repeatedly. I do not feel that vaccines cause autism.
Q Okay. And do you have a study that supports that DTaP doesn't cause autism?
A I have -- I do not have a study that -- that DTaP causes autism, so I don't have either.

Q Fair enough. Do you have any study one way or another of whether IPOL causes autism?
A I -- no, I do not, sir.
Q Do you have any study one way or another of whether Engerix-B causes autism?
A I do not have any evidence that it causes autism, nor that it does not.
Q And what about HibTITERs vaccine, any evidence one way or another whether it causes autism?
A No. I think that's really not been associated with it. I don't think there are reports of that, but I -- but the evidence is the same. It's neither conclusive or -- as I have mentioned before.
Q Okay. And what about the Prevnar vaccine? Any evidence one way or another?
A No, sir. No, sir. But Prevnar is used all over the world, and there have been no reports of that in the large-linked databases.
Q Are there published studies that say that?
A I'm not sure whether there's specific or not, right.
Q Okay. And how about varicella vaccines, let

me just finish, are there any studies one way or another that support whether it does or doesn't cause autism?

A Part of MMR, but not as varicella by itself, no, sir. No studies that say it does or no studies that say it doesn't.

Q All right. There have been studies that have found an association between hepatitis B vaccine and autism; correct?

A Not studies that I feel are credible.

Q Okay. Which study -- which study do you -- are you referring to when you say that?

A Well, why don't you show me the study and then I'll say whether I agree with it.

Q Okay. Why don't we just do one and then we'll move on. Okay. This is going -- this is -- oops. This is not the right study. Sorry.

MR. SIRI: While I'm looking for this, this is going to be 20 -- Plaintiff's Exhibit 22? Is that right?

MS. CHEN: So I think it's actually 23. I think somewhere along 17 and 18 we got a little jumbled up.

MR. SIRI: Okay.

MS. CHEN: So I think it's actually 23, but please correct me if I'm wrong.

MR. SIRI: I -- we'll floss it out afterwards, thank you.

(Whereupon, Exhibit No. 23 was marked to the testimony of the witness.)

Q (By Mr. Siri) Okay. So this is going to be Plaintiff's Exhibit 23, and are you familiar with this study?

A No, sir, I'm not.

Q Okay. This study was by Carolyn Gallagher and Melody Goodman; correct?

A That's what it says, sir.

Q Are you familiar with these researchers?

A No, sir, I'm not.

Q Okay. Are you familiar with the -- the Ph.D. Program in Population Health and Clinical Outcomes Research at the Stony Brook University Medical Center, Health Sciences Center?

A No, sir, I'm not.

Q Are you familiar with the graduate program in public health there?

A No, I don't -- I -- I don't know the academic programs at Stony Brook.
Q Okay, great. So this study found that boys vaccinated as neonates had three-fold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life, and it was specifically looking at whether they received HepB or did not receive HepB. Have you ever heard about that conclusion?
A I'm not -- I haven't reviewed the study, sir. I don't know where the -- where the database is. I would be happy to review it at another time. I think there are a couple points that -- you know, certainly it is more common to have boys have autism than girls. I think whenever you have such a study, you have to make sure that there are not any confounders. What is the database for which this was taken, please?
Q I believe it was based on a --
A Would you go to the methods, please?
Q Sure, absolutely.
A Okay. So that's NHIS, a complex study design that -- stratification, clustering, and -- so the parent sample contained 15,000 children, and in

each of those years, the outcome variable was autism yes or no, I don't know exactly how the diagnosis was made and what the diagnostic criteria were. Can you move down a little bit so --

Q Yeah, I want to make sure you can see it all. Can you see it all now, Dr. Edwards?

A I --

Q And if you need me to scroll to the next page, just let me know.

A Okay. So these included boys with a vaccination record that were available, and this domain to birth prior -- and was restricted to birth prior to 1999. The vaccination with hepatitis B was determined by subtracting birth month and year. The birth month -- so I guess one question would be whether we have documentation of the actual birth record for this and make sure that the confirmation that the vaccine was received, so I -- so I can't see that that's -- I can't see that that has been documented. The outcome variable was yes or no, and -- and so SAS was used to look at the statistics. Could you go to the next slide, please?

Q Sure. That's it under the results.
A Okay.
Q So is this one of the studies that you indicated earlier you found to be unreliable?
A No. I -- I -- I have not assessed this study.
Q Study -- what --
A I can't -- I can't say, sir. I'd need a little bit -- a few more minutes to look --
Q You --
A -- at -- for --
Q Absolutely. You know what, this will be marked, you'll have a copy, and we can revisit it at trial.
A Thank you very much.
Q Okay. Now, one thing though is you're familiar with the Agency for Health Research and Quality?
A Yes, sir.
Q It's referred to as AHRQ; correct?
A I'm -- I am familiar, yes, thank you.
Q Part of HHS? It's part of HHS, Doctor?
A Yes. Yes, sir. Yes, sir, it is. Yes.
Q And you're aware AHRQ issued a review in 2014

entitled Safety of Vaccines Used For Routine Immunization in the United States?

A I believe I reviewed that, but you can pull it up so I can look at it again.

Q Okay. As I'm pulling it up, let me ask you this. Are you aware that HHS describes this report as the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States?

A No, I didn't know what they had claimed.

MR. SIRI: Okay. Okay. So this is going to be marked as 24, Plaintiff's 24.

(Whereupon, Exhibit No. 24 was marked to the testimony of the witness.)

Q (By Mr. Siri) Have you seen this study before?

A I believe I've looked at this document, yes.

Q Okay. And one of the -- one of the -- it -- one of the things they reviewed was whether hepatitis B vaccine causes autism; correct?

A That's what is highlighted there in this

article. It says autism and it's referring to the article that you've just mentioned, and -- and so I -- yeah.

Q Okay. And this is the only study that they found; correct?

A I don't -- I don't know whether they did. I haven't -- I didn't review this before the deposition to see whether they found any. I -- if this is the only one -- if this is the only paragraph, then it's apparently the one that they -- they saw, so I -- I was not aware that there were associations as to --

Q I --

A -- that report.

Q Well, we'll mark this and so you'll have a chance to review it before trial, which is -- it's been marked, and I'm going to now mark this one. It's a different excerpt from the same report.

MR. SIRI: We'll call this Plaintiff's 25.

(Whereupon, Exhibit No. 25 was marked to the testimony of the witness.)

Q (By Mr. Siri) Are you -- do you recall that you were a technical expert for this report?
A I guess I must have reviewed it, so I guess that I -- I must have and forgotten about that article, so I -- I've read -- you know, probably read since that time -- since 24 -- I've probably read 5,000 articles. I read about three or four a day, so I'm sorry that I don't recall it, but I certainly will review it again.
Q And what -- and what association does it provide under your name here?
A Vanderbilt Vaccine Research Program. That's the name of the program that I used to lead at Vanderbilt.
Q Okay. It doesn't disclose any of your affiliations with pharmaceutical companies; correct?
A I don't know, sir. I can't -- since I forgot about the one article that they mentioned, I don't know what it says, so I guess you'll have to look.
Q Okay. And this is --
A I'm sure if it did, you'd show me.
Q And this is a government report; correct?
A It's AHRQ. They're a part of the government.

Q Yeah, okay. Let me show you an article here. I'm going to pull up one of your articles, Dr. Edwards.

MR. SIRI: And I'm going to mark this as 26.

(Whereupon, Exhibit No. 26 was marked to the testimony of the witness.)

A Yeah, my name is spelled wrong also, but it is me.

Q (By Mr. Siri) Yeah, I noticed that. Now, Dr. Edwards, this was -- so you're familiar with this study; correct?

A I remember reading it. I don't remember all the details of it. I have about 600 articles, but if you show me what you want me to look at, I'd be delighted to do it.

Q Thank you, Dr. Edwards. Now, this, as it's titled, Causality Assessment of Adverse Events Reported to the Vaccine Adverse Events Reporting System.

A Correct.

Q This -- this was a study in which you --

about a hundred reports were selected and reviewers then looked at the medical records that were available for those individuals who submitted the adverse event report to VAERS to --

A Could you make it a little -- could you make it a little bigger so I can read it, please? Thank you so much.

Q Absolutely.

A Okay. So the abstract, if you could just move it up and so I can read it, thank you.

Q Sure. You've got it. Is that better?

A Yeah. So this is part of -- of our vaccine CISA studies and this was a hundred VAERS reports, and a number of people reviewed them.

Q Okay. And what were they reviewing for?

A We were just trying to establish whether -- how we could establish -- whether we could establish causality and whether we could establish temporality, so that was -- we were just trying to -- to look at -- at that with it -- I'm kind of getting dizzy. Can you stop moving it and make it a little bigger, please?

Q I'm sorry. I thought I would help you out here by moving to what I think you're talking

about, which is the five different causality groups that they would have assigned. I was trying to be helpful.

A So could I look at the abstract just very quickly again? I'm sorry.

Q Absolutely. It's -- like I said at the beginning, it's awkward because normally you'd just have this in front of you, and, you know, you'd look at it and -- but like I said at the beginning, I'm happy to scroll to any place that you'd like. Please.

(Whereupon, the witness is reading the document.)

A Yeah, so these -- these VAERS reports were distributed. There was a lot of people on the -- on the -- the group that reviewed them, and so we sorted them into whether we thought definite, probable, possibly, unlikely, or unrelated in terms of causality, so that was how it was done, and there's probably a results section that -- that I'm sure you're going to show, so you might want to return to that, to the results table.

Q Yes, ma'am. All right. And as you just said, these are the five potential, right,

definite, probable, possible, unlikely, unrelated, and here was the -- and then these were the -- these were the 100 reported that were reviewed; correct?

A So there were 100 reports, and in those 100 reports, there were 108 adverse events associated with the -- with vaccines, adverse events following immunizations, so there were -- yeah, so these are the -- those that were -- these are just the reports. These are not assessment of causality.

Q Absolutely. These are just the reports, and these were the conditions that were looked at, and in six -- in six of the reports, there was a claim of autism being caused by vaccines; correct?

A That's what it says. I didn't remember how many that had autism, but that's what it says, so I'm sure it's right.

Q Okay. It doesn't mean that the vaccines caused autism in those six reports; right? It was just reported to VAERS by a manufacturer or a doctor or a parent; right?

A That it -- that's correct.

Q All right.

A That's correct.
Q So what this study was going to do, it was going to review the existing literature, the existing medical records of these 100 children, and the doctors were going to try to make a causality assessment with regards to whether in these six instances the vaccines caused autism; correct?
A That's correct.
Q Okay. Now, let's scroll down, and you can see there were -- these are the causality conclusions. Now, Dr. Edwards, okay, what was the causality conclusion regarding these six cases of autism?
A I have -- I have no idea, sir. I'm sorry, I didn't pull this paper to review it, so I -- I don't know what the assessments were. You'll have to tell me.
Q Well, you know, based on -- going back to -- please. Go ahead.
A Can I say something or do you want to finish and then I'll say --
Q No, no, go ahead. You go, please.
A So -- so one of the things that you have to

understand with the VAERS reports are that some reports are better than others. Some reports are more comprehensive than others. So what we did in this study was we assessed whether we could -- whether a causation could be assessed, so I'm sorry, I don't remember each six cases, I do not remember the adequacy of the medical records for each of those, and I don't remember exactly what we came up with, but I could be pretty sure that none of them were definitely caused by vaccines, but again, that's what -- what I would recall and I -- I would have to read the article if it says specifically about those cases.

Q Fair enough. Would you be willing to produce the records showing what the causality conclusion were for those six autism cases?

A So this study was done -- in what year was this, sir? It was published in 2010?

Q I think it was '12. Let me look at the --

A Okay. So this study was led by -- in Boston, Anita Loughlin, and --

Q Okay.

A Okay. Could you put the authors back up so I can just --

Q Oh, absolutely.
A Okay. So this study was led -- so this study was led -- led by Anita Loughlin who is at Boston University Medical Center. She no longer works there. Her boss, who was on -- who was the second author, Colin Marchant, has retired. So whether I -- I do not have the primary data for this study, and -- and so I'm not sure how we could get the primary data, but I -- and I don't even know how to reach Anita, but I can do what I can, but I just -- you know, I -- I have a lot of studies and -- that I'm on, and I do not have the database for this. She would have that or someone at -- at Boston. I could see whether they have any of this information.
Q I'd appreciate that. You know, I've seen a number of these studies, and usually it will, you know, break it down on a more granular level what the causality conclusion is for each one of these conditions that are reviewed. Any -- any recollection you have of why that information wasn't provided in this study on a granular level, instead they provided this flow chart where you have to engage in some kind of, you know, logic

game to try and sort of figure out what --
A No, sir, I --
Q You --
A No, sir. No, sir. I -- you know, it certainly wasn't designed to confuse people. You know, it's not the New England Journal. This isn't my best paper, and I'm not the first author or the senior author on this, so I'm sure that I didn't disagree with what it said, but I really wasn't in charge of this study.
Q Got it. Fair enough. Now, many vaccines contain aluminum adjuvant; correct?
A Yes, sir.
Q Okay. There are generally three types of aluminum adjuvant used in vaccines?
A Yes, sir.
Q Do you know what those are?
A Yes. Aluminum hydroxide, aluminum phosphate, and alum, which is a formulation of aluminum, so those are the three forms.
Q All right. The third one is amorphous aluminum --
A It just --
Q -- hydroxyphosphate sulfate? Is that the one

you're referring to?
A Yeah, which is part of alum.
Q It's part of alum, right. I mean, generally -- these are generally referred to as aluminum adjuvants; right?
A That's correct.
Q Okay. Sometimes I'll ask you questions I know that seem very simple to you, but, you know, not simple to the --
A I appreciate --
Q -- rest of us.
A I appreciate simple straightforward questions that I can answer yes or no, thank you.
Q Okay. Have you ever published any studies regarding the effects of aluminum adjuvants?
A Yes, I have.
Q Okay.
A Probably more than a single one and, you know, I'm sure that -- I'd be happy to look at which one you've chosen.
Q Well, we -- we couldn't identify any, so I was asking --
A Oh, okay. Well, I'll tell you some studies that we've done. We've actually --

Q Sure.
A We've actually looked at the effect of different kinds of aluminum on our pertussis studies, so if you go to the pertussis studies, you'll see different forms of aluminum on the chart, you'll see different -- different assessments of aluminum. I also published several papers about adverse local events due to hypersensitivity of aluminum, and -- and because aluminum can cause sterile abscesses, so -- so I have several of those papers that I have studied aluminum and aluminum adjuvants.
Q And are any of those intended to assess the overall safety of aluminum adjuvants when injected into the body?
A They are -- they are studies to look at the effect of the aluminum on the immune response for -- and also in one complication of an adverse event with aluminum associated with hypersensitivity. They are not large database studies to look at aluminum.
Q Okay. And how many people were involved in those typically?
A The studies of pertussis were several

thousand people and the studies of the -- of their local abscesses were just a few patients. I can't remember the exact number.

Q Got it. And the pertussis studies were comparing a vaccine with one type of adjuvant with a vaccine with a different kind of adjuvant. Is that right?

A Yes. And they were also comparing them to whole-cell vaccines.

Q Which also has aluminum adjuvant in it?

A That's correct.

Q Okay. Do you have any studies that compare a group that got aluminum adjuvant with those that didn't get aluminum adjuvant?

A I believe. I can't recall exactly. We had 13 acellular vaccines and one whole-cell. I think there may -- perhaps one of them was recombinant and did not include alum, but I can't say for sure. I would have to check that. And that was published in the '90s.

Q Okay. Is that on your CV? You don't --

A Yes, sir, it is.

Q It is?

A Yes.

Q Do you recall the title, by any chance?
A It's the Multi-Center Acellular Pertussis Vaccine Studies Immunogenicity. It was published -- there was a big -- a big syllabus that had all the acellular vaccine studies, and it was the immunogenicity, and it was published in the 1990s. I was the first author on that.
Q All right. Could you just repeat the title again? Multi-Center Acellular --
A Pertussis, MAPT, Multi-Center Acellular Pertussis Trial on Immunogenicity. It was published in Pediatrics.
Q Okay, thank you.
A There's also a paper that looks at the safety of those as well, and that -- the lead author on that paper is Michael Decker, D-e-c-k-e-r.
Q Were you an author on that one?
A Yes, I was. There were about seven papers from that work, and I was an author on all of those.
Q Got it. And I can find those in your CV?
A Yes, sir.
Q All right, thank you. Okay. So which -- and so just to -- just to close the loop on that, so

you've done studies regarding comparing different aluminum adjuvants -- comparing different pertussis vaccines with different kinds of aluminum adjuvants, you think maybe one of them that had a group that didn't get aluminum adjuvant, and then separately you have some studies regarding local reactions to aluminum adjuvants. Is that right?

A That's correct.

Q Any other aluminum adjuvant studies?

A Well, obviously there's other studies I've done that had -- have had aluminum in their -- have had aluminum adjuvants. There are some of the studies I've done with pneumococcal vaccines, you know, or other vaccines, or -- so -- so again, that's part of some of the vaccines and it's not a part of the others.

Q So which -- which studies were that -- so which -- which studies would those be?

A Sir, I can't -- I can't tell you which of the --

Q That's okay. I'm only asking for your best memory. You don't have to make -- if you don't remember, that's fine. That's totally fine. I

was impressed you remembered the other multi-center study. Okay. Got it. So some of the others -- some of the other studies of vaccines, you're saying, you know, one group got one vaccine with aluminum and the other group got a vaccine without aluminum.

A Not necessarily. I would have to go through, you know, all of them. In general, the focus on the studies that looked at various vaccines was are they immunogenic, what kind of adverse events are they associated with, and -- and is there any interactions in the immune responses when you administer that vaccine with other vaccines, so the focus was not on comparing the adjuvants, the aluminum adjuvants, but some of them had adjuvants of different types.

Q Understood. Meaning it wasn't like a -- a -- it wasn't a primary, you know, outcome that you were looking to assess, but you could maybe, you know, infer safety of adjuvants from those studies, you're thinking, you think. You'd have to look.

A Well, there -- they were between 2 and 3,000 babies, and so we --

Q Okay.
A -- we assessed the safety there.
Q All right. We'll take -- we'll take a look for that, and hopefully we'll just find them on our own. Thank you for explaining.
A If you want after this, I can send the PDFs for that, if you'd like.
Q I would appreciate that, thank you. Okay. Now, do you know which of Yates' vaccines contained aluminum adjuvant?
A Yeah, certainly the DTP and -- and again, I -- I'd have to -- sometimes I have to refresh my memory whether -- which of the vaccines other than DTP contain that, so certainly the DTP did as well, and I can pull up the package inserts for the other vaccines if you'd like me to.
Q Okay. Do you know whether Engerix-B had aluminum adjuvant in it?
A I -- I'm not -- I can't remember for sure.
Q Okay. You conducted clinical trials for GSK with the Engerix-B vaccine; correct?
A It may -- it hasn't been a primary focus over the studies. It may have been a concomitantly administered vaccine. You know, I -- you've asked

me a lot of questions, and I -- you know, I tried to remember everything, but I -- my -- my memory is not encyclopedic.

Q That's -- and that's entirely fine. If you don't remember, you just say so. It's -- it's fine not to remember. Now, what's the part of the typical particle size of each piece of aluminum adjuvant in each vaccine typically?

A You're kidding. That --

Q If you don't know, that's fine.

A Thank you for the levity. I -- I'm impressed that you thought that I would know that.

Q Okay. Were you aware that each vaccine that contains aluminum adjuvant typically contains tens of thousands of pieces of aluminum adjuvant between 1 to 10 microns in size?

A I wasn't aware of the physical characteristics of each particle of an aluminum, no.

Q Okay. And 1 micron would be about a million times larger than a single ion of aluminum; correct?

A I don't know, sir.

Q Okay. Now, you said you looked at injection

site reactions to aluminum adjuvant; correct?
A Yes, sir.
Q Okay. So approximately how many individual pieces of aluminum adjuvant would be present at the injection site directly after an injection of aluminum adjuvant vaccine?
A I don't know, sir.
Q Okay. You've never heard that it would be tens of thousands of individual aluminum adjuvant particles?
A I've never heard whether that's -- that is correct or not, no.
Q Okay.
A I've -- I have not. I have not read anything about the number and the size of the particles.
Q Okay. And what's the purpose of including aluminum adjuvants in many of the vaccines on a childhood schedule?
A Aluminum is added as an adjuvant. An adjuvant means that it enhances the immune response to the vaccine.
Q Okay. And does it bind to the antigen in the vaccine?
A Well, it depends in terms of whether it's --

it's -- you know, it's -- it's an emulsion or whether it's alum and the physical characteristics of each of the doses of the vaccine and its relationship to the aluminum in the vaccine. I am not aware of how many pieces of aluminum is in each injection or the actual physical charac -- physical characterization of the combining of the adjuvant and the aluminum.

Q Got it. Now, without the aluminum adjuvant, there would be a very weak immune response in the vaccine that contained aluminum adjuvant. Is that correct?

A Well, sometimes it's -- it's interesting. You know, with some of the vaccines that I've studied over the years, some are really enhanced with the aluminum and others are not, so it's kind of a -- it sort of depends upon the antigen.

Q Uh-huh. So, for example, in the Infanrix or the Engerix-B vaccines, would it be accurate to say that without aluminum adjuvant they wouldn't generate a sufficient immune response to make the -- such that the vaccine would be effective at preventing the diseases for which its vaccination is provided?

A Yeah, that's generally correct. And what usually happens in the Phase 1 and Phase 2 trials is that the vaccines are usually administered with or without adjuvants, and then in that -- in that scenario, then if it's found that the -- the vaccine doesn't need an adjuvant and the vaccine response is adequate, then it would not be added, so I think it's fair to say that vaccines that have adjuvants in them have been shown in the studies, in the early studies, and then confirmed in the later studies that they -- in order to be optimally immunogenic and protective, they need to have alum.

MR. SIRI: Okay. I'm going to mark this as Exhibit 27, Plaintiff's Exhibit 27.

(Whereupon, Exhibit No. 27 was marked to the testimony of the witness.)

Q (By Mr. Siri) You're familiar with this book, Dr. Edwards; correct?

A Yeah, I spent a lot of hours writing this book and enter -- in this book.

Q Okay. And I'm going to read you a sentence

from Page 21 of this book, the chapter --
A Yeah, this is an article that's written by Claire-Anne Siegrist, who is an immunologist in Geneva.
Q Okay. So she wrote, most non-live vaccines require their formulation with specific adjuvants to induce danger signals and trigger a sufficient activation of the innate system. Do you agree with that statement?
A I do, but I think you're taking it out of context. You're taking it out of the context of what she's talking about, and she's -- she's one of the most eloquent persons to discuss what happens with immune responses, and so what she's saying is that that -- an adjuvant or a -- aluminum, in this case, or other adjuvants will engender a -- more of a local response and maybe be associated with some local irritation or even some fever, and because of that, then the immune system is triggered, and I think with the COVID vaccine studies now, which that's exactly what we're seeing, we're seeing adjuvants that are added or -- that are added to the vaccines and we're seeing reactions that are danger signals, it

says I need to make an immune response to this, so this is -- is a -- is danger signals, but it doesn't say it's dangerous.

Q Ahh. I never said that. I -- but it does create a danger signal so that the vaccine, when injected, will assist in producing, you know, various kinds of cytokines; correct?

A It will -- it will cause a sufficient activation of the innate immune system, just as she said.

Q Right. And the antigens, when they're absorbed onto aluminum adjuvant, they're then taken up by macrophages and dendritic cells; correct?

A That's correct.

Q Okay. So the den -- the macrophages and dendritic cells absorb -- they do phagocytosis, right, they basically eat not only the antigen, but also the aluminum adjuvant; correct?

A That's correct.

Q Okay. Now, you know, part of the -- as we discussed, you know, the aluminum adjuvant helps create a danger signal that in this instance is viewed as a good one so that the immune system

reacts; correct?
A Yes, sir.
Q Okay. And -- and to -- to helping -- help it, you know, release cytokines, including IL-1, IL-2, IL-6, or IL-17; correct?
A Yes, sir.
Q Okay. Now, once the aluminum adjuvant, the antigen balancing the aluminum adjuvant is taken up by the macrophages, where do they travel in the body?
A Well, they generally stay localized and -- or the macrophages will begin to degrade them, and the -- and if the macrophages are in the circulation, then they will do that as they circulate in the body.
Q You're saying that -- it's your testimony that macrophages have the ability to degrade aluminum adjuvant?
A Well, they -- they degrade the actual -- the actual antigen antibody com -- or the antigen complex and -- so they -- they do act to process the aluminum, and some of the aluminum stays locally as well.
Q Okay. Are you aware that there are numerous

studies starting in 1997 at the CDC going all the way up to the present that have injected various animals with aluminum adjuvant and then sacrificed the animals to find where the aluminum adjuvant traveled in the body?

A Yes, sir, I am, and those actually began a long time ago with Freund and the use of adjuvants, so yes, I am, sir.

Q Are you aware that those studies have universally found that the adjuvant travels to various organs and in particular the brain?

A I have not reviewed the animal studies, but, you know, certainly things happen in animals that don't happen in people, and I'm not aware of studies of, you know, post autopsy in human brains showing aluminum.

Q So you're not aware of any study that shows, for example, high levels of aluminum in the brains of post autopsy children that had autism?

A Well, I guess if you want me to comment on a certain paper, I'm not aware of that paper, so if you'd like me to review that again, you can show me the paper and I'll look at it and see whether I think it's credible.

Q Okay. But you have -- you said you have seen the studies where they injected animals with aluminum adjuvant, sacrificed them, and have found universally aluminum adjuvant in the brain of those animals?

A I have seen those papers in reference to, but again, I can't recall the detail and the specifics about the -- those -- each of those papers, sir.

Q Okay.

A I'd be happy to look at them if you'd like me to.

Q Okay. Well, we could gladly provide you copies of those. I'll just -- but I don't want to spend the time marking them now because there's a lot of them. Okay. So now, as you indicated, vaccines cause immune activation; right? That's what they do. They activate the immune system; correct?

A That's correct.

Q Okay. Now, if the aluminum adjuvant is bound to antigen, were to travel to and remain in the brain, it could cause sustained immune activation in the brain; correct?

A I don't -- I -- no, sir, I -- I have no

evidence to suggest that I would -- I would agree with that statement.

Q Now, do you have no evidence to suggest that it would travel to the brain or do you have no evidence to suggest that it would cause --

A I have no --

Q -- sustained immune reaction -- activation in the brain?

A I have no evidence to address either of the portions of your biphasic question.

Q Fair enough. What about the animal studies we have just discussed? Do you believe that would provide evidence?

A Provide evidence for what?

Q That aluminum adjuvant upon injection can travel to the brain.

A Again, sir, I'd have to look at those papers and see whether I agree. And again, I'm sorry, I haven't -- I didn't review those for the deposition.

Q That's no problem.

MR. SIRI: You know, let's just mark them quickly so that we can -- this way Dr. Edwards has them and has an opportunity to

review them. Let me just share my screen. We will quickly mark them. I want to make sure that you have copies. Okay. So we're going to mark this study as Exhibit Number -- is it 29?

MS. CHEN: 28.

MR. SIRI: 28, thank you.

(Whereupon, Exhibit No. 28 was marked to the testimony of the witness.)

MR. SIRI: And we're going to mark -- and this is a study of rabbits injected with aluminum and dissected and aluminum found in the brain. I believe it's CDC related. This is a study from -- sorry. This is a study from 2009 involving mice. We're going to mark this as Exhibit Number 29.

(Whereupon, Exhibit No. 29 was marked to the testimony of the witness.)

MR. SIRI: This is a study from 2012 and we're going to mark it as Exhibit 30. This one actually shows the macrophages can act as a Trojan

horse carrying material to the brain.

(Whereupon, Exhibit No. 30 was marked to the testimony of the witness.)

MR. SIRI: We're going to mark this one as Exhibit Number 31. It's from 2013. It's another mice one, and it's got actually pictures of the aluminum in the brain of the mice, so you can take a quick look at that.

(Whereupon, Exhibit No. 31 was marked to the testimony of the witness.)

MR. SIRI: And then here's another one from -- this one is from 2015. We're going to mark it as Exhibit 32. This one again is 155 mice. Again, it's lots of images of the brains of the mice.

(Whereupon, Exhibit No. 32 was marked to the testimony of the witness.)

MR. SIRI: This is a study from 2016,

we're going to mark as Exhibit 33. This one shows the macrophages actually acting as Trojan horses carrying the loads to the brain. You know, in the -- in any event, you'll read the study.

(Whereupon, Exhibit No. 33 was marked to the testimony of the witness.)

MR. SIRI: Thirty -- Exhibit Number 34, and then -- let's just do one more and that should be enough. This one is from 2006 as well, and we'll mark that as Exhibit 34.

(Whereupon, Exhibit No. 34 was marked to the testimony of the witness.)

Q (By Mr. Siri) So obviously you have not had a chance to look at these. I'm not going to ask you questions about them at the moment. That's not going to be fair. You will have an opportunity to review those and we can revisit it at trial. Now, coming back to this, immune activation in the brain can lead to neurodevelopmental disorders. Isn't that true?

A Sir, I think that -- that you're asking me to comment on things that -- I am not a neurologist.
Q Oh.
A Nor am I a -- so I'm just saying that -- that, you know, if you want me to discuss what the effect of the -- of specific questions about animal models or that -- that's really not my area of expertise.
Q So okay, that's fine. If you don't know, that's fine. So you're -- the -- you don't know whether immune activation in the brain can lead to neurodevelopmental disorders?
A I have not reviewed the paper that you're taking that from. That is not my understanding, but I would be happy to read it and review it. But again, I -- I don't -- it's hard for me to know what you're talking about sometimes.
Q Okay.
A Which specific paper you're talking about.
Q Well, I wasn't actually talking about any paper.
A Okay.
Q I mean, there are many -- there are hundreds of NIH-funded papers that -- you know, out of

Cal Tech and so forth that study immune activation during pregnancy and during, you know, early phases of childhood development in infants and toddlers, and, you know, finding that immune activation can lead to neurodevelopmental disorders, and I was just curious if you were familiar with that body of literature in general, and it sounds to me that your answer is no. Is that correct?

A Yes.

Q Okay. Are you aware that aluminum adjuvant injected into the body can cause an increase in IL-6 in the brain?

A No, sir, I am not, and I -- if that is the case and if there's a specific paper, please let me review that. I think if you want me to review something that I am not familiar with, I am happy to do that.

Q Well, I obviously have to ask first to know whether you're familiar with it, and I'm very happy to give you a copy of it. So 2013 -- what exhibit number is this? All right. Well, I will mark this. Again, I can't find one, but I'll mark one of them, which is -- so let me just share my

screen. I'll mark this one so you'll have an opportunity to review it, and I believe I have one more, and you can have an opportunity to review that one for trial as well, 102.

MR. SIRI: So we're going to mark this one as Exhibit -- is it 35?

MS. CHEN: Yes.

MR. SIRI: Okay, thank you. And we will actually mark this one as Exhibit 36.

(Whereupon, Exhibit Nos. 35 and 36 were marked to the testimony of the witness.)

Q (By Mr. Siri) Okay. Are you aware that there are studies that show that an increase in IL-6 has been shown to induce autism-like features in lab animals?

A Sir, I am not familiar with the -- with the animal aluminum literature in regarding to -- so you can keep asking me. I'm totally fine with answering that I am not familiar with the paper, so --

Q Yeah.

A And I'll find -- I'll just say that send it

to me, I'll be happy to look at it, but I don't want to comment on something that I have not reviewed.

Q And I absolute -- I -- that is absolutely fair and you shouldn't and I'm not asking you to, but obviously, again, it's okay to say you don't know or you haven't reviewed it, but I don't know if you don't know it until I ask you about it, so if you don't know, that's totally fine.

MR. SIRI: We're going to mark this one as 37 and we're going to mark this one as 38. Okay.

(Whereupon, Exhibit Nos. 37 and 38 were marked to the testimony of the witness.)

MR. SIRI: Patricia, are you able to see the exhibit numbers on these as I'm opening them?

MS. CHEN: Yes.

MR. SIRI: Okay, great. I just wanted to make sure because I don't see them on my side.

Q (By Mr. Siri) Okay. Now, let's just do this one. So have you ever seen --

MR. SIRI: I'm going to mark this one

as -- what are we up to, 30 -- 30 what?

MS. CHEN: 39.

MR. SIRI: 39.

(Whereupon, Exhibit No. 39 was marked to the testimony of the witness.)

Q (By Mr. Siri) Have you ever seen this paper, Dr. Edwards?

A No, sir.

MR. SIRI: Okay. I'm going to mark this one as 40.

(Whereupon, Exhibit No. 40 was marked to the testimony of the witness.)

Q (By Mr. Siri) Have you ever seen this letter from a Professor Romain Gherardi regarding his opinion regarding whether aluminum adjuvants in vaccines can contribute to causing ASD?

A No, I -- I have not, sir. I -- I am not familiar with this letter, nor was it actually addressed to me, so I haven't read it.

Q Fair enough. Let's see. It was in 2017 and

it was addressed to HHS, NIH, and FDA. In 2017 you were sitting on VRBPAC, correct, at the FDA?

A Yes, sir.

Q Okay. And this is another letter from Professor Christopher Exley, who is considered an expert in aluminum, and again it was in 2017 addressed to the FDA when you were sitting on VRBPAC. Have you ever seen this letter in which he discusses what he believes is the role of aluminum adjuvant in causing autism spectrum disorder?

A I -- not -- not that I -- not that I remember, sir.

Q Okay. Well, so both of these papers provide an extensive list of studies regarding aluminum adjuvant, as well as Dr. Gherardi's, you know, that they say support that aluminum adjuvant in vaccines can trigger and then add to ASD, so I just want to point that out to you. Okay. Now, earlier you stated you're not aware of any study in which, you know, a high -- aluminum adjuvants found in the brain of autistic individuals or children.

MR. SIRI: I'm going to mark this as --

Exhibit Number 41, is it?

MS. CHEN: If the letter from Dr. Exley was supposed to be 41, then you're on 42, but if not, then this current one is 41.

MR. SIRI: Yeah, Dr. Exley will be Exhibit Number 41, thank you, and this will be Exhibit Number 42.

(Whereupon, Exhibit Nos. 41 and 42 were marked to the testimony of the witness.)

Q (By Mr. Siri) And so I'll provide you this as well to review. This is a study conducted by Dr. Exley, in which he looked at the brains of autistic children and found the highest levels of aluminum that he has found in any of the numerous cohorts of brains that he's ever looked at, including for various other ailments. You'll have an opportunity to look at that as well. Okay. So are -- do -- do you know of any specific study involving injection of aluminum into humans or animals, all right, and what -- that showed aluminum adjuvants are safe?

MR. SANDERS: Object to the form of the

question. You can answer, Doctor.
A Yeah, it really is such a ridiculous question, I'm not going to answer it.
Q (By Mr. Siri) It's ridiculous to ask whether you're aware of any studies that looked at the injection of aluminum adjuvant on whether it's safe? Okay. Are you familiar with the HPV Gardasil clinical trials?
A Yes, sir, I am.
Q Okay. What did the control group in the clinical trials to license Gardasil, Gardasil 4, what did virtually everybody, the thousands of young girls and boys and middle-aged girls and boys, women and men, what did they receive an injection of in those clinical trials?
A I can't remember what they received in the control group. If you want to remind me, I'll -- that would be great. I -- I --
Q That's fine.
A I just don't remember that, per se.
Q Okay. Okay. If a study involving injecting aluminum existed to support its safety, do you think the NIH -- Office of Intramural Research at the NIH defines such a study?

A I think that they -- the NIH would fund studies that have a testable hypothesis --
Q Okay.
A -- that would allow the sample size and the study conduct to come up with a meaningful conclusion, but obviously I -- I'm not in charge of the purse strings at NIH, so I would have to -- they would have to look at the studies.
Q All right. I'm not -- I -- I apologize. I -- I -- maybe -- I must have not said my question clearly. I meant if -- do you think that they have the ability to resources to find if they were to search, not conduct, but to search the literature and find any study that would support the safety of injecting -- that involved the injection of aluminum that supported safety?
A Well, the NIH is not really in the position to evaluate the literature in terms of -- you know, the way the NIH is set up is that they -- if they have a question that they want to address, then they issue an RFP, which I told you kind of about how that works.
Q Uh-huh.
A And if an investigator is -- has a hypothesis

that they want to test and they submit it, there is a specific group or pot of money that is set aside for studies on vaccine safety within the NIH.

Q So you're saying if a request were made to the -- for example, the National Institute of Allergies and Infectious Diseases and they said that they had searched for a study that supported the safety of injecting aluminum adjuvant, you're saying that they wouldn't conduct such a review? I'm not sure I --

A I -- all right. I'm really --

Q All --

A I can't answer. I don't know what you're saying, I'm sorry. I -- I'm just -- I -- I'm sorry, I can't answer that.

Q That's no problem. Let me ask it to you this way. If the National Institute of Allergy and Infectious Disease and the -- you know, the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH Office of Intramural Research all looked for a study of whether or not alum -- injecting aluminum adjuvant were safe, do you think they would be able to find

such a study?
A I don't know, sir. I don't know what their capabilities are in searching the literature, and I don't know the answer to that question, so I can't answer yes or no. I just can't answer that, and -- you know, I'm sorry that I -- it's just not something that I can answer.
Q No problem.
MR. SIRI: Let me mark this as 40 -- what is it? 44? Is it 44, Patricia?
A I can't count that high.
MR. SIRI: Well, until somebody tells me otherwise, I'll assume it's Plaintiff's 44.
(Whereupon, Exhibit No. 44 was marked to the testimony of the witness.)
Q (By Mr. Siri) Now, this was the response from the Department of Health and Human Services. You'll have an opportunity to review it. I just want to mark it here so you have the benefit of it for trial, and this is a letter that was sent to my firm, and it says, you know, this is the final response to your Freedom of Information Act

request addressed to the FOIA office at the National Institute of Health. You requested copies of any human or animal studies involving the subcutaneous or intramuscular injection of aluminum adjuvant relied upon by the NIH to establish the safety of injecting infants and children with aluminum hydroxide, aluminum phosphate, and AAHS. And it says that the OIR, NIAID, and NICHD searched their files and no records responsive to your request were located. You can have a -- take a look at that at another time. A similar response was received by the CDC as well. But we can mark for identification -- let's just move on though. All right. So let's just take a -- just take a quick look at the Gardasil trial. Now, when -- this is the package insert for Gardasil; correct?

A Yes, sir, it is.

MR. SIRI: Okay. We're going to mark this as Plaintiff's 45.

(Whereupon, Exhibit No. 45 was marked to the testimony of the witness.)

Q (By Mr. Siri) Now, take a look at Table 9 and -- take a look at Table 9. All right. So this is the summary of the girls and women 9 through 26 years of age who reported an incident condition potentially indicative of a systemic autoimmune disorder after enrolling in the clinical trials for Gardasil regardless of causality; correct?

A That's what it appears to show, yes, sir.

Q And it shows that it had an AAH control and a saline placebo control; correct?

A That's what it says, yes.

Q AAH means -- is an aluminum adjuvant; right?

A Amorphous aluminum hydroxyphosphate sulfate, which is what it says at the bottom.

Q All right. Are you aware that -- that of the 9,412 women and girls that received either an AAHS control or saline placebo, virtually all of them received the AAHS control?

A I'm not aware of the distribution. I do now remember that the -- that the control in some of them was the aluminum, so thank you for refreshing my memory. I don't know what the distribution between those two are, but if you could --

probably it's somewhere and so you could show that to me.

Q Sure. Well, I mean, go back to Table 1.

A So --

Q Yeah, please.

A Again, I don't know whether that's precisely the same study because the numbers, I don't know whether they add up, but I --

Q Yeah, that's fair enough. There is -- obviously in clinical trials, like the saline placebo study, is reported; all right? And I'll just pull that up quickly.

MR. SIRI: Mark this as 40 -- Exhibit 46, I think.

(Whereupon, Exhibit No. 46 was marked to the testimony of the witness.)

A You know, you're throwing certain studies up, and I don't -- I can't confirm with a number that what you're showing me is the same, so I'm not trying to be difficult, but --

Q (By Mr. Siri) You're not. Fair enough.

A It's something -- I just -- you've got to go

slow enough that I know what you're talking about.
Q No problem. I -- you know, I'm going to -- I'll mark these, and you'll have a chance to look at them before trial, but I think that's going to be fair.
A Great. I'll take a couple weeks' vacation and look at all these things.
Q All right. Let's just go and -- I'll take a look at this -- this placebo and -- you know what, if we have time at the end, we'll come back to this.
A What -- if you have a specific question about it, maybe that --
Q Yeah, okay. Well, that would be great. I just -- I don't want to spend too much time on it, but you know, here you can see that, you know, there's 320 girls in the placebo group and 274 boys in the placebo group, saline placebo group; correct? And then if we go here, this is the -- this is the study of Gardasil in preadolescents and adolescents that's recorded com -- filed as the 018 trial, because there's a number of them, as you know. This is the only one that included a saline placebo, and when you go down, you can see

the number of participants that adds up to 561, the same number of boys and girls, and you can look through here and, you know, you can see what adverse reactions were reported. Now, this is very difficult to do over Zoom. This is why I'm -- it's very complicated. If you had this in your hand, you could look at it and you could flip through the pages and I would ask you is there any systemic autoimmune issues reported here, but doing this over Zoom, I'd have to scroll through it and it's very difficult. You'll have a chance to look at it. What you'll find is that there are none, and then, you know, what I would have asked you, and we can do this again at trial, is -- so you're prepared for it, you see in the Gardasil group, within six months, right, of starting -- of -- of the injection, 2.3 percent of the previous healthy girls developed -- reported incidences in a condition potentially indicative of systemic autoimmune disorder; correct?

A You know, I -- it's -- I'm trying to -- as quickly as I can, so which of the things do you want me to look at, lupus or do you want me to look at all of these? Okay. You want me to look

at the numbers comparing the Gardasil and the control. Okay. So the total number of events and the percentage of events were comparable.

Q Right. But isn't it possible that the Gardasil vaccine caused these 2.3 percent in girls to develop systemic autoimmune disorder as well -- and that the AAH control, the AAH adjuvant that was in the Gardasil is what caused the 2.3 percent of girls to develop a systemic autoimmune disorder in the control group?

A No. That -- you can't deduce that because there's a couple of other things you have to consider. First of all, you have to consider what the incidents of these autoimmune conditions is in the population, in the unimmunized population. Lupus, scleroderma, inflammatory bowel disease, many of these things are diagnosed during this time, this preadolescent, adolescent early adulthood time. So the fact that you have equal numbers doesn't mean that either causes the adverse event. The interpretation could be that neither of them do, and this is the background rate of that adverse event, so this is -- is not -- you can't make that conclusion from this,

at least if you're knowledgeable you can't.
Q So these were previously healthy participants in the trial; correct?
A They are previously healthy participants, but previously healthy participants can develop lupus, they can develop other things, so the fact that you see these in the population does not mean that they're caused by this.
Q Do you believe if you looked at the background rate you would find that during every six-month period, 2.3 percent of previous healthy girls and women in America would develop a systemic autoimmune disorder?
A I would have to look at that and see. I do not have that at the top of my -- you know, and certainly that would be -- if you're on a data safety monitoring committee, that's what you would do.
Q Right. Because, I mean, if it's 2.3 percent every six months, that's 4.6 percent every year, over ten years that would be 46 percent of all previously healthy women --
A Yeah.
Q -- and --

A Yeah, that -- that -- it doesn't say that it's additive. That's for -- that's full -- or whatever. It's wrong.
Q But this is showing within six months how many previously healthy girls that's -- prior -- previously didn't have systemic autoimmune disorder reported a systemic autoimmune disorder; correct?
A That's correct. It's -- it says, to have one in the Gardasil group out of 10,000 and you have three out of 10,000 in the placebo group, so I don't know, you know, what the rate is in this population, but that seems -- you know, one in the -- in 10,000 isn't very much.
Q Well, no, it's 245 in the Gardasil group out of 10,000.
A No, I said for lupus. I said for lupus. You have to look at all of these individual issues.
Q Ahh.
A And I'm just saying that for lupus, there's one in 10,000 in the -- in the vaccine group and there's three in slightly less than 10,000 in the placebo group, so I would have to look at the background rates in that population, and it

doesn't mean that it's going to be additive, there's data to suggest that in six more months you're going to have double, and that just isn't the way it works.

Q You just don't know, right, because this study, they may have looked at it for six months. You have the data that you have. Why -- but if they had just compared Gardasil to a strictly saline placebo group, then there wouldn't be this unknown of did the adjuvant cause it, did it not; correct?

A But it goes back to what I tried to make clear a number of hours ago, and that is that when you have a trial, if you -- if you have a -- as a placebo, a real placebo, then patients often will know what they have received. Now, you may say that they would -- they would say that they're -- they don't care whether they receive vaccine, and actually, if you look at the information, the -- the actual administration of an HPV vaccine has no impact on people's sexual activity, but you could say, well, if they realized that they got placebo, they wouldn't have sex and they wouldn't get HPV, so this is all part of the complexities of

clinical trials. If you choose a placebo that's placebo, it's hard to -- hard to make sure that your participants do not know what you're getting.

Q So what you're saying is -- you're saying that you should abandon the gold standard of clinical trials, you should double-blind --

A No.

Q -- give up control -- let me just finish my question -- the double-blind placebo controlled studies because those in the placebo group are not going to have, you know, reactions in a way that let's say giving them another vaccine would have, and then they're going to -- you know, when they don't have a reaction, they're going to be, like, whoa, I know now I got a placebo. I mean, you know, why is it -- what you're saying is the assumption is vaccines will all cause reactions, and so we have to give -- we always have to compare giving vaccines to giving vaccines, then you'll never know what the safety profile of any vaccine is.

MR. SANDERS: Object to the form of the question. You can answer it, Doctor, if you understand the question.

A I'm not going to answer that. I'm not going to answer that. I think --
Q (By Mr. Siri) Fair enough if you don't want to answer it.
A I think the answers to my questions -- to your questions in general are quite clear, so I think that I've answered that question.
Q Now, the package insert for each vaccine in Section 6 will list adverse reactions to the vaccine; correct?
A I can't see Section 6, so if you want to show me Section 6, I'm happy to look at that.
Q No, I just mean in general, package inserts for all vaccines have typically -- you know, they list in Section 6 of the package insert adverse reactions to the vaccine; correct?
A There is always a section. I didn't know that it was always Section 6, so now I -- I know, thank you.
Q Okay, great. You know, we can pull up --
A I believe you. I just didn't know it was 6.
Q No, that's fine. Right. But you're aware there's -- there's a section that lists the clinical trial experience and the adverse events

in each --
A Absolutely. I just don't know the numbers which each of those is assigned.
Q Right. Are you aware that under federal law the package insert is supposed to include in Section 6, quote, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event, end quote?
A I am aware that's what it states, but I think that a lot of the inclusions in package inserts have really not shown a causation, they have just been reported in the clinical trials, so -- so those package inserts tend to be quite inclusive.
Q Now, the adverse events typically are what are actually post-marketing adverse events; correct?
A No, not necessarily. The adverse events are those that are captured both in the assessment of the vaccine evaluation during the Phase 1, 2, and 3 trials, but also post marketing. Now, it may label, for instance, those charts that you showed. There's charts that -- those are -- those are -- are studies that were done part of the -- of the

actual -- of the licensure, I would think, but they're generally both studies that -- that -- results of studies pre and post licensure are in the package insert.

Q So what you're saying is that even though the federal law is clear that the manufacturer is supposed to only provide the adverse events for which they believe there's a causal relationship, is it your testimony that they're not complying with that law and listing adverse events that are -- also don't have a -- they don't have a reason to believe they're causally related?

MR. SANDERS: Object to the form of the question. You can answer, Doctor, if you understood the question.

A I'm not sure that I understood the question, but I will answer what I -- what I -- I -- what happens with the package insert. As the paper that showed you with VAERS, I think in general we are often left not being able to assess a causation definitively with a vaccine and an adverse event, so given that difficulty, if there is an adverse event that happens in a clinical study and it is associated with -- with -- and

frequently enough, it will appear in the package insert, so -- so every single thing that's in the package insert has not been established without reasonable doubt that it's causative.

Q (By Mr. Siri) Oh, so -- so the adverse reactions that are listed in the package insert are only included when there is, you know, a basis to believe that there is a causal connection between the adverse event and the vaccine; correct?

A That's not what I said.

Q Okay. I --

A That's opposite of what I said.

Q I -- please.

A So please listen to what I say so you don't have to ask again. So what I'm saying is that if an adverse event is seen in a Phase -- in a Phase 1, 2, and 3 trial or in a post-licensure trial, it is often included in the package insert whether or not you can prove causation because as I showed you in that VAERS, it's very difficult to prove definitive causation, so if there's any question of a relationship between the adverse event and the vaccine, it is put in the package

insert.

MR. SIRI: I'm going to mark this as Exhibit -- Plaintiff's Exhibit 47.

MS. CHEN: 47.

MR. SIRI: Thank you.

(Whereupon, Exhibit No. 47 was marked to the testimony of the witness.)

Q (By Mr. Siri) Now, are you familiar with this regulation, Dr. Edwards?

A It's a CFR Title 21. I don't know all the -- that's included in it, so if there's something you'd like me to address, I'd be happy to read it.

Q Okay. All right. This is Section 201.57, specific requirements on content and format of labeling for human prescription drugs and biological products. This would be the section that would govern what should go in a package insert; correct?

A I trust it, so -- although I can only see a portion of it.

Q Fair enough. Let's go down to what it provides for Section 6. So this would be

Section 6, adverse reactions that would be reported. Can you read the yellow, please?

A Yes. This section must describe the overall adverse reaction profile of the drug based on the entire safety database. This definition -- I don't know which definition you're referring to, I guess adverse reactions -- does not include all the adverse events observed during the use of the drug, only those for which there's some basis to believe there is a causal relationship. This is not what you said. This is not -- it's to say it does not have to be a proved causal relationship. And if there is any question about the relationship or any question about this, it is included in the package insert. So this does not establish that there is a causal relationship between the drug and the AEFI.

Q Okay. But you would agree that the package insert only includes adverse events that meet this definition as required by federal law?

A I think that what companies put in the package insert is often when there has not been clear establishment of the causal relationship, as I've said three times now.

Q Fine. But they -- would they put something in when there is -- when there isn't some basis to believe there's a causal relationship?

MR. SANDERS: Object to the form of the question. Asked and answered several times.

A I'm not going to answer it again.

Q (By Mr. Siri) Okay. It's not clear to me, but -- I mean, I'm -- I think that -- I think what I'm understanding is you're saying that they'll put adverse events into the package insert even if they haven't established causation, but you're not --

A That is correct.

Q But you're not --

A That is correct.

Q Absolutely. Right. They'll only put it in when there's -- but they'll only put it in when there's some basis to believe there is a causal relationship as required by the Code of Federal Regulations.

MR. SANDERS: Object to the form of the question. Asked and answered.

MR. SIRI: That hasn't been ans -- that has not been asked and answered.

Q (By Mr. Siri) Please, Dr. Edwards.
A I'm not going to answer it because I've already answered it.
Q Okay. Well, you haven't clarified what the minimum standard is, so let me ask a question I think you'll find easier. Do you believe that there are adverse events in package inserts that are put in for which there is no basis to believe there's a causal relationship?
A Yes.
Q Okay. And what's that -- what do you base that opinion on?
A Well, I think if you look at the adverse events of package inserts, they contain a lot of adverse events, some of which I have not seen associated with the vaccine, so I think that every single thing that is listed in a package insert does not mean that that particular vaccine causes, causes that adverse event, no, and that's what my answer is.
Q Right, sure. It just means that as a -- that there's some basis to believe that it causes it, not that it actually causes it; right? Let's use something specific. Now, of course, it's the

manufacturer that's adding these adverse events to the insert; correct?
A Yes, sir, that's correct.
Q Okay. And you're not in -- are you privy to all of the data and information that the manufacturers each have when they're adding the adverse events to the package insert?
A Of course not. You know, certainly, I'm not privy to that. The FDA is privy to that.
Q Okay. Now, here is a letter --
MR. SIRI: We'll mark this as 50 -- Exhibit 57 [sic].
(Whereupon, Exhibit No. 48 was marked to the testimony of the witness.)
Q (By Mr. Siri) This is a letter to the FDA from Merck; correct? I'm sorry, yes, this is a letter from the FDA to Merck; correct?
A That's what it appears to be.
Q Okay. Have you ever seen a supplemental approval letter like this before?
A No, sir. I don't work for pharma.
Q Okay. But you've consulted for

pharmaceutical companies; correct?
A I think we've already answered that question.
Q Okay. Now, in this, the FDA -- please take a moment to read the first paragraph. Let me know when you're done.
A I'm finished.
Q Okay. So in this, the FDA is approving the amendment to the package insert for MMR; correct?
A That's correct.
Q And Merck in 2017 decided to add into their package insert the disclosure of adverse events for these two adverse -- potential adverse events; correct?
A Yes, sir.
Q Okay. And why do you believe they did that?
A Well, they probably had -- these adverse events had been reported in their -- in the use of some of the vaccines. However, as part of my CISA role, I have actually done extensive reviews of HSP with vaccines, and the data is clearly not -- does not establish causation, so they must have seen this in certain patients, I don't know how many patients, maybe it says later, but they just wanted to include it in the package insert. I

think sometimes things are included in the package insert that you -- that you don't really know for sure that are related and sometimes they can be very helpful, so, for instance, the whole rotavirus and intussusception, that was included in the package insert and then people began to see that, so I think it's prudent to put in things that you think may be associated even if you're not, but the fact that it's in the package insert does not mean that that adverse event is caused by the vaccine, and I think I've said that several times.

Q I know. Are you aware that under the 1986 Act one of the exceptions where you could sue a vaccine manufacturer is if they know a vaccine causes certain injury and they don't disclose it?

A I think I remember that. Whether that was -- I don't -- you know, I don't know whether -- I think that certainly the -- pharma is very -- you know, would rather add things to the package insert than omit them.

Q Do you think that might explain why they added these two conditions to the MMR, why Merck added these two conditions to the MMR package

insert?
A I think you'd have to ask Merck. I'm not familiar with their motivation for that.
Q Fair enough. What's encephalitis?
A It's an inflammation of the brain.
Q And what's encephalopathy?
A It's an abnormality of the brain. It means a pathologic brain, so there is a difference. Encephalitis is a cause of encephalopathy, but there are other causes of encephalopathy besides encephalitis.
Q All right. Encephalitis means basically brain swelling and encephalopathy means actual damage to the brain; correct?
A No, that's not what I said. Encephalitis, anything that has an itis after it is inflammation, so inflammation of the encephal, which means the brain, means there is an inflammation in the brain. There are brain inflammations that occur every year in people that have no long-term damage. Those are called aseptic meningitis from the enteroviruses. Encephalopathy is abnormality of the brain or pathology in the brain. The -- encephalopathy can

be mild or it can be severe. Just because it says encephalopathy does -- has no prognostic implication on its long-term impact on an individual.

Q Okay. Does the package insert for Infanrix list encephalopathy within seven days of a prior pertussis-containing vaccine as a contraindication to injecting further doses of this product?

A I think that contraindications for the use of DTaP basically are encephalopathy, acute encephalopathy, and anaphylaxis. However, encephalopathy, and the definition in this, is that it has to be persistent for 24 hours, and generally the people have to be hospitalized. So encephalopathy in that definition is quite -- is quite severe.

Q All right. So meaning if you've -- if that kind of severe reaction happened from a prior dose of Infanrix, the manufacturer's package insert says don't administer that vaccine again.

A If it's -- just as I said. If it meets that definition, the vaccine is contraindicated to be administered again.

Q Does the package insert for Infanrix list

encephalopathy in Section 6?
A I don't know, sir. You'll have to pull up Section 6. I think that's a little unreasonable for me to know exactly.
Q Well, that's fine. You don't know is a perfectly fine answer. Does the package insert for Engerix-B list encephalitis and encephalopathy in Section 6?
A I would trust that it does, but I don't know that it does, so I can't answer that, sir. If you would like to pull up the package insert, I am happy to read it.
Q Does the package insert for VARIVAX, the chicken pox vaccine, list encephalitis in Section 6?
A Probably does.
Q Does the package insert for MMR list --
A That question -- you also asked me that question before, which I answered.
Q Thank you. Does the package insert for MMR list encephalitis, encephalopathy, acute disseminated encephalomyelitis, and subacute sclerosing panencephalitis, SSPE, in Section 6?
A I believe that it does, although SSPE has not

been documented to occur with vaccine-associated virus. Are you waiting for me to answer?

Q Oh, no, no.

MR. SIRI: I'm going to mark this as plaintiff's Exhibit 40 -- is it 8?

MS. CHEN: 49.

MR. SIRI: 49, thank you.

(Whereupon, Exhibit No. 49 was marked to the testimony of the witness.)

Q (By Mr. Siri) And this is the -- a report from the CDC, the MMWR; correct?

A Yes.

Q Okay. And it is regarding SSPE, which is what we were just talking about; correct?

A Yes, sir.

Q Okay. And you're saying that SSPE cannot be -- is not caused by the measles vaccine; correct?

A That is -- that is the conclusion. Now, this study, I don't know whether -- you know, whether this is older and they didn't find the virus and whether -- you also have to make sure that it's

not the measles virus from the natural -- make sure that it's vaccine-associated.

Q Well, let's take a look at what it says. So can you please -- please read the portion in yellow out loud.

A The estimated risk of SSPE following natural measles is averaged by 8.5 cases per million. Estimated risk of following measles averaged 0.7 per million of the live virus vaccine distributed. However, you have to make sure that in that time when those reported from '63 to '74 that each of those viruses was sequenced to make sure that it's -- that it is indeed a measles virus, and I don't know whether that was done in this paper.

Q Okay. But the CDC here is estimating and it is stating that the -- is indicating that SSPE can be caused by measles vaccination; correct?

A This is -- this paper was published a long time ago, and my understanding is that this has not been confirmed with the actual isolation of the virus from the -- from --

Q So the CDC's information here -- well, strike that.

MR. SIRI: I'm going to mark this as

Exhibit -- Plaintiff's 4 -- 49.

MS. CHEN: 50.

MR. SIRI: 50, sorry. 50.

(Whereupon, Exhibit No. 50 was marked to the testimony of the witness.)

Q (By Mr. Siri) Dr. Edwards, have you seen this before?

A I've not seen this result. I've seen the interpretation of the result by your expert and by -- by another geneticist.

Q Okay.

A And again, I am not a mitochondrial expert.

Q Got it. So you're not in a position to opine on the accuracy or the meaning of this result.

A No, other than the fact that I read an expert said that they didn't feel that this documented that, so I can -- obviously and one expert said that it did, so I'm not the person to say whether this is what the definitive diagnosis of this -- of the mitochondrial problem is.

Q Understood. Let me just clear out some of these exhibits. Have you -- have you read this

affidavit from --
A Yes, I have, sir.
Q -- Dr. Kelley?
A I have, sir. Yes, I have, sir.
MR. SIRI: I'm going to mark this as Exhibit 51.
(Whereupon, Exhibit No. 51 was marked to the testimony of the witness.)
Q (By Mr. Siri) It is -- do you -- do you have any basis to contest the conclusion in this report?
MR. SANDERS: Object to the form of the question. It's overbroad. You can answer, Doctor, if you have an answer.
A Yeah, I -- I guess that I would sort of prefer if you had a specific question. I don't want to, you know, sort of jam an entire -- a physician for -- you know, for anything, and so if there's a specific question, I'm happy to answer it.
Q (By Mr. Siri) Do you disagree with Dr. Kelley's conclusion in this report?

A Why don't you show me his report -- his conclusion so that I am sure that I can address exactly what you want me to disagree with.
Q Well, why don't you read the summary portion.
A So first of all, I don't -- I don't -- I can't say that the first conclusion is correct because an expert on the other side said that the biochemical abnormalities are not -- are not consistent with that, so I can't comment on that particular -- I think it's -- it's something -- an issue of controversy. I think that the degree of medical -- that the set of immunizations at 11 months of age while he was ill, that the immediate cause of his autistic regression to further impair the ability of his weakened mitochondria so by adequate amounts of energy, the highest energy consuming tissue in the body, I would not agree with that conclusion.
Q Are you a mitochondrial expert?
A I am not a mitochondrial expert. However, I feel that that -- while he was ill would be an immediate cause of getting his immunizations, I think that he was not -- was not seriously ill. He was -- he had a respiratory illness and had

otitis. I don't feel that there -- and he was actually closer to 12 months than he was 11 months, I think it was three days from 12 months, so I disagree that he was 11 months old, and -- and I think that -- that what he is stating in the last sentence is solely anecdotal. It's his experience.

Q And on -- how would you determine whether or not Yates' otitis media was severe or not severe when he received his immunizations at 11 months?

A Because I have read very carefully and I -- and the -- in my clinical judgment, this child in -- should have been given the vaccinations, and I see no reason for him not to have received the vaccinations.

Q Have you ever treated any children with mitochondrial disorders?

A I have been involved in discussions about vaccines with children with mitochondrial disorders, so I -- yes, and I'm also quite familiar with children with mitochondrial disorders have a lot of problems when they have infections, real infections that are vaccine preventable, so -- so I think that is also a very

important thing to take into account is the -- is the fact that children with mitochondrial disorders have difficulties with infections that can be vaccine preventable.

Q Okay. Have you published any studies with regards to that?

A I don't believe so. I think those have been mostly in the individual case evaluations of the CISA, and those are not published. Those are -- those are confidential because they involve individual patients.

Q Do you do any clinical study -- have you done -- performed any clinical studies with regards to mitochondrial disorders?

A Well, I have -- I have one paper where Cameron Schlegel is the first author where we've -- we've looked actually at some inborn errors of metabolism, and we've looked at -- at vaccines in relationship to their -- to their adverse outcomes, and this was a urea cycle defect, and so what we showed there was that the vaccines were not associate -- the administration of vaccines were not associated with adverse events in that particular population, so we have

studied high-risk people, but this was not specifically a mitochondrial population.

Q All right. Does Yates have a urea disorder?

A Sir, I said that we used another genetic condition. I was not saying that he had a urea cycle disorder. I'm just saying that I have experience in doing studies in populations that have genetic defects to look at the safety of vaccines.

MR. SIRI: Okay. I'm going to mark this as 52, Plaintiff's Exhibit 52.

(Whereupon, Exhibit No. 52 was marked to the testimony of the witness.)

Q (By Mr. Siri) Have you had a chance to review this document?

A No, sir, I haven't.

MR. SIRI: I'm going to mark this as Plaintiff's Exhibit 53.

(Whereupon, Exhibit No. 53 was marked to the testimony of the witness.)

Q (By Mr. Siri) Have you ever reviewed this study?
A Yes, I have, sir.
Q Okay. Do you agree with the conclusion in this study with regards to what caused Hannah Poling's autism?
A I -- I do not agree with all the conclusions in this study.
Q Okay. What don't you agree with?
MR. SANDERS: Object to the form of the question. Overbroad. You can answer, Doctor, if you can.
A I'm not going to answer until I know what the question is.
Q (By Mr. Siri) In this study, which you said you reviewed, the authors conducted a -- provide their case report with regard to Hannah Poling a discussion and then, you know, they reach a conclusion with regards to what led to Hannah Poling's autism. Do you dispute the finding that vaccines given to Hannah Poling caused her autism?
A I think that the -- there was a temporal association. Whether it was causative, I don't know. And again, as I said before, I'm not a

mitochondrial expert.

MR. SIRI: I'm going to play a video, I guess, which will be marked as Exhibit 54.

(Whereupon, Exhibit No. 54 was marked to the testimony of the witness.)

MR. SANDERS: Mr. Siri, may I ask you a question? We're well over seven hours into the deposition. Do you have an estimate about how much longer we will be?

MR. SIRI: We shouldn't be that much longer. We're getting there, I think. Rob, how long -- Mr. Sawyer, how many hours are we on record?

THE WITNESS: It's 20 minutes after 3:00.

THE VIDEOGRAPHER: Right. I don't have the exact record time, but I know we took two 15-minute breaks.

THE COURT REPORTER: I have the exact time, if you need it.

MR. SIRI: Sure. What --

THE VIDEOGRAPHER: Great, thank you.

THE COURT REPORTER: Yes, no problem. The exact time has been six hours and almost 32 minutes.

MR. SIRI: Okay. Thank you.

Q (By Mr. Siri) Okay. I'm about -- I'm going to try to wrap this up today, believe me. I think we all would like that. Okay. So let me play this video. Can you hear that?

A No, sir, I cannot.

Q Okay. Yeah, I think I know the issue. Let me just try that again.

(Whereupon, a video clip was shown.)

A I can't see this. This -- I can't see this. I can't see this.

Q Oh, you can't --

A Did you want me to listen or look?

Q I -- I wanted both. I mean --

MR. SANDERS: I'm not able to see it either, Mr. Siri. I just see a list of your exhibits on your computer as of now.

MR. SIRI: Oh, jeez. I shared the wrong -- I appreciate that. Luckily I didn't share a more inappropriate screen, huh? All

right. Give me a moment. There we go. All right. Let's try that again. Well, no, that's not going to work either. I need to do this, I need to click that and do this. Okay. And here we go. Oh, for God's sake. I did the wrong screen again.

A I guess I'm fine. It's Sanjay Gupta. If you want to just let me listen to Sanjay, I'm happy to listen to him. I also know Julie Gerberding quite well, so if you'd like me to listen, I'm happy to do that, but I can't see.

Q (By Mr. Siri) Okay. Last time. Are you ready? And -- there we go.

(Whereupon, a video clip was shown.)

Q Dr. Edwards, do you have any basis to disagree with what the CDC director just said on that video?

A I think if you listened very closely to what Julie said, Julie said she hadn't really had the ability to look at the case, to evaluate the case. I think that what she said, a lot of what she said was correct in that patients that have dysfunctional mitochondria, if they are stressed,

then they can have more difficulties. I think stress can come from the administration of a vaccine with fever, but stress also comes with a disease, so I think that this is a situation where you have to decide what the risks and the benefits of a vaccine are, and this is what you -- what you have to -- have to decide when there is a patient with this definitively diagnosed disorder, which I -- I don't think that I can convincingly say that your patient has, and -- but again, I think that you have to talk to the neurologist about that.

Q But so what you're saying is that if a child does have this serious mitochondrial disorder, they -- having an infection or having the vaccine, either of those could actually cause a stress on the body that could potentially lead to autism?

A If indeed you had that disorder, that -- that is hypothesized, so there's one case that -- that that's been shown in.

Q Okay. Based on the Poling and other cases, there is a known causal association between vaccines and regressive autism; correct?

MR. SANDERS: Object to the form of the

question. You may answer, Doctor.
A I -- I don't -- could you repeat the question, please?
Q (By Mr. Siri) Sure. Based on the Poling case, there is a known causal association between vaccines and regressive autism; correct?
MR. SANDERS: Same objection.
A Yeah, I don't think you can definitively say that, sir. I -- I don't think I could say an answer yes to that or -- or no, I can't -- I can't say that.
Q (By Mr. Siri) But you can't rule it out either; correct?
A I don't -- other than the -- the Hannah Poling case, I'm not familiar with any other cases that have suggested that to be the case.
Q What about this case?
A I can't see it.
Q Okay. So when that --
A It depends on --
Q Oh.
A Okay. It depends a little bit on the diagnosis, so again, I think that you show me a case and I want to -- you know, I don't know

whether the -- the mitochondrial dysfunction has been definitively diagnosed, so I think that if you show me something, I can't say for sure because I don't know for sure whether they have -- what they have.

Q Okay.

A And I think it's probably something that you might want to talk about with -- to the neurologist.

Q Okay. Yates was diagnosed with regressive autism; correct?

A I didn't hear the first part of the question, sir.

Q Oh, no problem. I said, Yates was diagnosed with regressive autism; correct?

A Well, I -- I did review the report from -- from the Vanderbilt CDC and it said autism. I wasn't familiar -- I don't -- I didn't see any other characterization and I'm not familiar with how one distinguishes that from another.

Q Okay. You're not --

A A diagnosis of autism, but I can't say that he has regressive autism.

Q You don't know though one way or another?

A I do not know whether he has regressive autism one way or another, yes, that's correct, sir.
Q Do you have any evidence of what caused Yates' autism?
A Yeah, I -- autism is a -- is a -- a neuro abnormality. I think that it was likely associated with some prenatal event and I do not think it's -- was due to his vaccines.
Q Do you have any evidence that Yates' autism was caused by some prenatal event?
A I think that -- that those -- those things are always hard to know. I think you -- you know, you -- I don't know the -- the mother, father's maternal age, there's about -- in terms of -- there's factors about infections during pregnancy, and I'm not aware of any of those, so I think that -- that I'm not fully aware of the prenatal situation. I'm just saying that the articles on autism say that it's generally a prenatal event, and so that's what I'm saying.
Q So sitting here today, you don't actually have any evidence of what might have caused Yates' regressive autism; correct?

MR. SANDERS: Object to the form of the question. It mischaracterizes her testimony.

MR. SIRI: I didn't -- I'm not -- I'm not trying to characterize her testimony at all. I'm asking her --

Q (By Mr. Siri) Siting here today, do you have any evidence of what caused Yates' regressive autism?

MR. SANDERS: Object to the form of the question. I --

MR. SIRI: Let me rephrase that because she never said regressive autism.

Q (By Mr. Siri) Sitting here today, do you have any evidence for what caused Yates' autism?

A I have no confirmation of what caused Yates' autism except that I know that it's not from his vaccine receipt.

Q Now, would you disagree that the best available evidence reflects that Yates has a serious mitochondrial disorder?

MR. SANDERS: Object to the form of the question. Asked and answered.

A I feel that -- that -- that the -- that the discussion from the neurologist and the geneticist

that addressed that shed considerable doubt on the diagnosis, so I -- I -- but again, I'm not an expert, I haven't looked at the mitochondria, and I wouldn't know a dysfunctional mitochondria from another looking under the microscope, so I'm not an expert in the mitochondrial diagnosis.

Q (By Mr. Siri) CDC --

A I think that -- I can't hear your question.

MR. SANDERS: Mr. Siri, you've frozen on us.

MR. SIRI: It says I'm unstable. Okay. And -- okay, I'm back.

Q (By Mr. Siri) Now, did you attend the Wellcome Trust London Vaccine Safety Meeting in 2019?

A I sure did.

Q Okay. And who were you invited there by?

A I was invited by Wellcome Trust.

Q Okay. Did the invitation come from a specific person such as Dr. Stanley Plotkin?

A I think it probably came from Stanley.

Q Okay. And the meeting was intended to discuss gaps in the vaccine safety that needed to be addressed?

A That's correct.
Q Okay. And one of the topics discussed was the gap in safety data with regard to vaccination of children with mitochondrial disorders; correct?
A I can't -- I can't remember specifically whether that was on the program. I know there was a discussion of autism, and Fombonne did that, and then there was also the presentation by the Danish group. So if it was part of that, I can't remember. I don't recall that there was a specific person that talked about that, but maybe if you have the -- the calendar there, I could look at that. I -- I just can't quite remember for sure.

MR. SIRI: All right. I'm going to mark this as Exhibit 55. Patricia?

MS. CHEN: Correct, 55.

MR. SIRI: 55, thank you.

(Whereupon, Exhibit No. 55 was marked to the testimony of the witness.)

Q (By Mr. Siri) This is an e-mail chain regarding the Wellcome Trust London Vaccine Safety

Meeting in which you were on the chain; correct?
A I don't know. I can't -- I'm trying to find whether -- I don't see that I'm on the chain. Yeah, there I am. Okay, yeah, I'm on the chain.
Q Okay. And does this document look familiar to you, the summary of ideas for future studies proposed by attendees at the Wellcome Trust London Vaccine Safety Meeting?
A Probably.
Q Okay.
A I -- I know there was such a discussion.
Q Okay. Do you recall if --
A Are these comment -- are these my comments from Dr. Plotkin? Is this -- is this -- is this something that I've responded to Dr. Plotkin? Is that -- are those comments, are those mine?
Q You'll have to tell me, frankly.
A Okay.
Q Because they redacted it when the --
A Okay.
Q -- government provided it, but --
A Okay.
Q Do you see here that this is one of the -- do you recall -- does this help remind you of one of

the things that was discussed at that meeting?
A Uh-huh, yeah. It says to look at reactions in patients with confirmed mitochondrial diseases or metabolic diseases.
Q All right. And to create a registry of such reactions; right?
A Yes, sir. That's what it says.
Q Okay. And that's in order to better understand, you know, what injuries or issues vaccines could potentially cause with individuals with mitochondrial disease or metabolic disease; correct?
A I think it's to better understand reactions to vaccines in patients with mitochondrial disease or metabolic diseases, as it says.
Q Was Yates receiving vaccines up to 18 months as recommended by the CDC childhood vaccine schedule?
A Yes, sir, he was.
Q Okay. Now, the number of vaccines in -- on the CDC schedule increased from six vaccines in 1985 to a total of 20 in 2000; correct?
A There have been -- there has been an increase, yes.

MR. SIRI: I'll mark this as number 56.
MS. CHEN: 56?
(Whereupon, Exhibit No. 56 was marked to the testimony of the witness.)

A Again, this is from somebody's slide. I guess that's me. You've got a picture of me.
Q (By Mr. Siri) That's -- it's on YouTube. I didn't have to go far. So does this remind you of how many injections there were in 1985 versus 2000?
A Well, that's my slide, so hopefully it's authoritative.
Q Okay. So between 1985 and 2000, the number of injections has gone from six to 20; correct?
A Yes. I got -- I'm not quite sure what the little cross is, but I guess --
Q Oh, that's just my mouse.
A Oh, okay.
Q Don't count -- don't count the -- don't count the mouse.
A Okay. I thought, oh, I don't remember that cross. Okay.

Q That's fair.
A I don't remember this slide even, but that's okay.
Q Has there ever been a study which looked at the total of the children following the CDC vaccine schedule such as Yates to 18 months and those that have not received these products, meaning they were completely unvaccinated?
A I think that there have been studies looking at vaccines and vaccine receipt and not vaccine receipt. I think it's problematic because, as you know, most of the individuals -- most children receive the vaccines, so about 95 percent of them do. I think those that don't receive vaccine are -- are often -- there's a reason that they're not being vaccinated, and so one of -- excuse me. One of the things that you would have to make sure of is that the underlying epidemiologic characteristics of the children that were vaccinated are comparable to those that are not vaccinated, so that's one of the issues is indeed are they comparable, and so that's been -- you know, obviously a lot of people, you know, say, well, why don't we study people that don't

get vaccines instead of people that do, but the problem is that they're not often the right -- the same populations, and then more so it's hard to study something that's recommended, and so those -- those studies are problematic in terms of numbers and comparability of the -- of the population groups.

Q All the studies relied upon to say that MMR vaccine doesn't cause autism are retrospective, right, the studies; correct?

A This -- the bulk of the MMR studies, as we talked about before, are database studies, and there have been repeated database studies that have addressed the rates of autism in those populations, so those are the most powerful studies that we have because they have great sample sizes and they have larger ability -- they have a longer time to assess the -- the long-term outcomes.

Q So in the same way that they can do retrospective studies comparing those, you know, children who are fully vaccinated with MMR and fully vaccinated without MMR, why can't you just do a study comparing fully vaccinated with those

receiving no vaccine in those same databases, such as, for example, the Vaccine Safety Datalink, which the IOM said is possible to do?

A Because I just told you why. I told you that those -- first of all, the sample sizes are not comparable. Secondly, the underlying characteristics of the population that are not vaccinated are often not the same as those that are vaccinated. The delivery of care is often not the same, and some of the databases that do exist are parts of health so that would select for vaccinated children. If you want to put a study in VAERS, VAERS is an interesting database, and I have spent a lot of time looking in VAERS. VAERS is a hypothesis generator, you know, often you don't have the information that's necessary to have a complete understanding of what's going on, so there hasn't been a -- so the issues are that it's very problematic because the study design does not have comparable groups to compare.

Q Right. Meaning you're concerned about confounders; correct? Right?

A There's concern about confounders in mice.

Q Okay. So tell me what -- which -- what --

what is the difference in the characteristics between those who receive vaccines and those who don't, such that, you know, you -- that you wouldn't be able to control for?

A Well, first of all, you'd have to decide which database you're going to use. The second would be you have -- you would have to make sure that the -- that the populations are comparable in terms of age. You'd have to make sure that they're comparable in terms of underlying comorbidities. You'd have to make sure that they're comparable in the -- in the -- in the care that they received, in their socioeconomic status, in their -- in their access to -- to the ability to be immunized, and all of those would need to be looked into, and also you would have to make sure that -- for instance, that -- that the vaccine records are confirmed. So, you know, you may have someone that says that they haven't been vaccinated, but how do you confirm something that hasn't happened, you know. You're sort of asking as to --

Q Well --

A -- how to confirm -- can I finish?

Q Yeah, yeah, please.
A You're asking me how to confirm something that's not recorded, so how can I confirm that they haven't been vaccinated. So that's another problem in terms of how do you confirm that they have not been vaccinated and some of those issues as well, and again, the issue was in terms of sample sizes.
Q Okay. Well, then let's take those backwards. So let's start with confirming that they are not vaccinated. Isn't it true that there's an ICD-9 that -- ICD-10 codes for when a child -- when a parent refuses a vaccine including for religious reasons; correct?
A Well, there has been, but you know, that is not -- it's not -- you'd do an audit to make sure that that's correct.
Q All right. And that -- please.
A I'm trying to answer the question, sir.
Q Yeah, please.
A So what you would have to do in that situation is that you would have to go back to the chart, and if they say they didn't get the vaccine, you would have to confirm that they

didn't get the vaccine. So you would do that in the chart. There also are some vaccine databases that exist that you would have to go into, so the State of Tennessee has a database called TWIS so you would go back and you'd make sure that Susie Smith never got a vaccine through the database, but again, it's hard to confirm something that isn't done.

Q But again, are -- are you -- so are you aware of the White Paper that was produced by the CDC with regards to comparing the vaxxed versus unvaccinated population within the VSD in which they did identify almost 2,000 children who were not vaccinated and they confirmed their ICD-9 codes for a large portion of them indicated that they weren't, and then they went and they did a sample size to confirm, meaning they looked at their entire medical records and they found a very, very high confidence that if a child has an ICD-9, 10 code that the parents, you know, for parent refusal to vaccinate for one -- for religious or other reasons, that the child, in fact, was not vaccinated?

A So I -- I -- I'm not familiar with the paper,

so I'm happy to look at the paper.
Q We'll send it to you.
A Again, out -- 2 --
Q Yeah.
A Can I speak or do you want to just interrupt?
Q Oh, no, go ahead.
A Okay. So 2,000 people is not very many people. 2,000 unvaccinated people is not very many people. How -- how -- what are we using for the safety database for COVID? 15,000. So 2,000, great, but it's not very large.
Q Well, wouldn't it be enough to look at it -- an issue, for example, asthma, which is very common in one in six kids today?
A It depends upon what the -- it depends upon what -- what you're looking for, sir.
Q So then if -- from what you're saying then, if you don't know -- if you can't rely on the vaccination records in all of the databases, then how are any vaccine retrospective studies reliable? Because how do you know if the kid got an MMR or didn't get an MMR in any database?
A You can confirm the receipt of the vaccine, you can go over the chart, you can look at the

chart and say that the pediatrician gave the vaccine, you can look at the vaccine record, you can look at TWIS. There's a number of different ways to do that.

Q So couldn't they do that here as well in a study that compared vaxxed versus unvaxxed children?

A Well, that's what you told me that they were just doing, and they can do it, but it's harder -- you know, it's harder -- so it's the same argument that you're giving about this vaccine record. You're saying that because it doesn't say that somebody got something, it didn't happen, so, you know, the records are not always perfect, unfortunately.

Q I --

A So --

Q Look --

A You would have to -- please stop.

Q Yeah, go ahead.

A I -- I think this is not appropriate. This is rude.

Q I'm not sure what's rude about it. Look, I -- you know, I've asked vaccinologists before

and pediatricians this question, and I -- I can tell you I always find it surprising that with the medical brain trust that exists in this country, all the resources that there are, that for some reason, you know, there seems to be an incredible opposition to performing this analysis, which by the way, the Institute of Medicine, and I can show you their 2013 report, said it's -- the comparison is possible to do, which is why the CDC commissioned a White Paper on it. All right. Look --

MR. SANDERS: Object to the -- to the attorney colloquy there. You know, if you have a question, feel free to ask it, Mr. Siri, but we don't need to be lectured.

MR. SIRI: Fair enough.

Q (By Mr. Siri) All right. There are -- there is, in fact, a study that compared vaccinated versus unvaccinated children that does exist, but I -- from your answer to your prior question, I believe you've never seen it. Is that correct?

A I don't know which question -- which paper you're talking about. I may have seen it. As you know, I've -- I've -- you know --

Q Yeah.
A So if you want me to see whether I know about it, please show it to me.
Q Sure. Have you seen this paper before, Dr. Edwards?
A No, I don't believe I have, sir.
Q Okay. Well, I'll highlight something for you and so you have an opportunity to look at it after this. You can see that it's from the professors at the Department of Epidemiology and Biostatistics School of Public Health.
A I can't -- you're cutting out, sir.
Q Oh, sorry. Let -- I just want to make sure that I highlight -- do you see here that -- over here it found that the unvaccinated children had higher -- statistically significant higher rates of chicken pox?
A Yes, sir.
Q And do you see that the unvaccinated children had statistically significant higher rates of whooping cough?
A Yes, sir.
Q Okay. Do you see here though that it also found that the children had a statistically

significant higher rate -- vaccinated children had a statistically significant higher rate of autism?

A I don't know what the diagnosis is. I don't know the denominator or the population. I'd be happy to look at this, but I -- I'm not going to sign on to something that I haven't reviewed, and I'm not familiar with this.

Q Yeah, it's a pilot study and you should have an opportunity to review it. I just wanted to highlight those portions for you.

A This -- yeah, this isn't probably the most prominent journal, but --

Q Sure. But, you know, some -- sometimes, you know, what --

A A paper does --

Q Please.

A Paper doesn't refuse ink.

Q Paper doesn't -- I'm sorry?

A Paper does not refuse ink.

Q Fair enough. But at least there's some ink.

MR. SIRI: We'll mark this 50 --

MS. CHEN: 57.

MR. SIRI: Thank you. And we'll mark this one 58 so that you have an opportunity to

review it for trial as well.

(Whereupon, Exhibit Nos. 57 and 58 were marked to the testimony of the witness.)

Q (By Mr. Siri) They found similar issues with preterm babies, you know, higher rates.

A What's the database, sir? Can you give me the database, please? So go to the methods, please. Move to the methods.

Q This is based on parental surveys. It was based on parental recall, so, you know, it's not the best study --

A That's not good.

Q -- for --

A That's not good. If you're going to do a study, you don't remember parental recall.

Q It would be better to do it with, I assume, like, medical records; right?

A Oh, absolutely. This record -- this -- I mean, if I was -- I'm a journal editor. This paper would never see the light of day.

Q There are --

MR. SIRI: So I'll also mark this one,

which is -- that is number 59, is it?

MS. CHEN: Yes.

(Whereupon, Exhibit No. 59 was marked to the testimony of the witness.)

Q (By Mr. Siri) So this -- this is a study that looked at medical records in three pediatric practices, and have you ever seen this one before?

A No, sir.

Q Okay. It was just published this year, so you'll have an opportunity to look at it. We'll look at one more and then we'll just move on.

MR. SANDERS: Mr. Siri, I want to state, a lot -- most of the articles, or quite a few of the articles you've been using have never been disclosed in the case, and discovery has long since been over in the case in regards to production, so I just want a standing objection as to any use at trial of these exhibits, and we can take that up at a later time. I just want to put that on the record.

MR. SIRI: Yeah, well, we'll just agree to take that up at a later time then.

Q (By Mr. Siri) And then this is -- have you ever seen this article?
A I've seen -- I've reviewed a lot of work from Peter Aaby, so I've not -- I don't know that I've seen this particular paper, but Peter Aaby looks at the non-specific effects of immunity with the DTP and OPV in -- in African populations.
Q And he's a respected scientist?
A He's a controversial scientist.
Q Ahh, okay.
A Some of his work we publish in this -- in the journal that I'm an editor, so we -- it depends upon the study that he does.
Q Have you seen this study before? I apologize. I don't recall your answer.
A I don't know that I've seen this specific study. I've seen a number of other studies from Peter Aaby.
Q Okay. Well, in this study, you'll have an opportunity to review it, he found that children receiving DTP vaccine in the first six months of life died at ten times the rate as those who received no DT -- no vaccines in the first six months of life. Have you ever heard that before?

A I'm aware of his studies about DTP, and these are in African countries. This is in Guinea-Bissau in the 1980s, so I -- how this is related to -- to the U.S. I think is a question that, you know, we have to address.

Q Are you aware that in 1994 the IOM stated that, quote, the committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not, end quote?

A I think that's probably a true statement. I wasn't aware that that appeared in there, but I think there is a variability and -- and reactogenicity.

(Whereupon, Exhibit No. 60 was marked to the testimony of the witness.)

MR. SIRI: Okay. Let's take a five-minute break and we'll come back. It's -- well, let's make it seven minutes. We'll come back at 3:55 and see if we can wrap this thing up. All right. Thank you.

(Brief recess.)

THE VIDEOGRAPHER: All right. We are back on the record at 3:57 p.m. Central time.

MR. SIRI: Okay, thank you.

Q (By Mr. Siri) Dr. Edwards, do you believe that parents should be able to object to vaccines on religious grounds?

A I think that parents should have -- I think that -- I think parents need to be informed about what are the religious restrictions about vaccines or what their concerns are there, but I think that if they choose to say they do not want to be vaccinated and they have the questions answered for religious reasons, then I think that is -- is acceptable.

Q Okay. So what you're saying is that once they've been informed of the benefits and the risks, if they still want to object on religious grounds, your opinion is they should be able to withhold vaccination from their children?

A I think that -- that you're -- that's not exactly what I said. I said --

Q I apologize.

A -- there are --

MR. SANDERS: Go ahead, Dr. Edwards.

A So there are concerns, for instance, let me give you an example. The COVID vaccine that is made by AstraZeneca is made in a cell line that some people say was from aborted fetus. The Catholic church has said that that is not a prohibition to the use of vaccines, and -- and so if people are not aware of that, then they can be informed of that. And I think that with the measles, you know, there were some issues regarding the use of the vaccine in religious communities, and so I think that that -- that it's important to answer the questions, to give authoritative data about what their beliefs are to make sure that those are indeed correct. If they continue to believe that, then religious objections, I think, can be -- can be grounds for not being vaccinated, although obviously it puts their children and other children at risk.

Q (By Mr. Siri) So after being informed in the manner you just said, if a parent still wants to not vaccinate for religious reasons, you would -- you would agree that the child -- that the parent -- that the child -- that the parent's decision should stand and the child shouldn't be

vaccinated?
A I think that that patient, if it was in my practice, I would continue to discuss the dialogue, but at that particular time if they did not want to give the vaccines, I might try and explain it. The other option that some people do is that they feel that it poses a risk to the other patients, and they may no longer keep them in the practice but respect their opinion that they not be vaccinated.
Q Would you exclude a child from your practice if their parents didn't want to vaccinate the child after giving them all the information that you say you'd like to give them?
A I think that there are a number of factors involved in that. One, if I'm the only doctor in the area and the patient has no other access to a doctor, no, I would not. If there are other doctors that -- that would -- would -- would do that and I've repeatedly talked to them and they are not accepting of it, I may. But I think that most of the time I try and provide information and have a dialogue so that people understand why vaccines are necessary.

MR. SIRI: I'd like to mark this as Plaintiff's 50 --

MS. CHEN: 61.

MR. SIRI: Thank --

THE WITNESS: We're in the 60s. We're in the 60s.

MS. CHEN: We're on 61.

MR. SIRI: 61, thank you.

(Whereupon, Exhibit No. 61 was marked to the testimony of the witness.)

Q (By Mr. Siri) So this is Plotkin's Vaccine, Sixth -- Fifth Edition. I'm going to read you a sentence from here and see -- and ask you a question. The issue of purity becomes magnified in adjuvated vaccines. The adjuvant is added to enhance immune response; it will do so nonspecifically in many cases to the target antigen, as well as to any impurities or by-products of the manufacturing process. Do you agree with that statement?

A First of all, I don't know exactly where this is in the book. I hope that -- you know, and --

and I don't know whether this is a chapter that I edited or not. I think that there's probably sentences in the book that I edited. It's -- you know, I think it's a thousand pages or so, 1,400 pages, so I think that that -- if there is an impurity, it can be magnified with adjuvated vaccines, but again, I -- this -- you're taking one sentence out of a context of 1,400 pages.

Q Okay. Is it -- okay. So let me just ask you directly. Isn't it --

A Well, which chapter is this and who wrote this chapter, please, so I can tell whether this is one I edited. I can't remember.

Q It -- you'll have a copy of this. You can look it up later. I have no more questions about this exhibit. I'll just ask you the question directly. Isn't it true that an adjuvant will bind not only to the target antigen, but also to impurities and by-products of the manufacturing process?

A Yes, sir, it is.

Q Okay. And, you know, once bound to the impurities and by-products, the body may also develop antibodies to the -- to the impurities and

by-products in the vaccine; correct?
A I can't say -- I -- I do not know specifically any antibodies that have been looked at to be impurities, so I can't give you a paper that says yes or no.
Q Fair enough. You know, you're a doctor; correct? You're a medical doctor; right?
A That's what my CV said, and I -- I'm not an imposter.
Q All right. And you've -- and you have a lot of familiarity with reviewing medical records; right?
A Yes, sir, as I've stated before, I've reviewed a lot of medical records.
Q You know how to read and understand medical records, okay. So --
A I do know how to read, yes, I do.
Q Okay. Like I said, some of the questions you may find to be very basic, but -- you know, we have to provide a foundation for some of the other questions that we provide. Now, have you seen this medical record before, which I'm going to mark as Plaintiff's 52, I believe.
MS. CHEN: It's 62.

MR. SIRI: All right. 62.

(Whereupon, Exhibit No. 62 was marked to the testimony of the witness.)

Q (By Mr. Siri) Dr. Edwards?

MR. SANDERS: There's nothing up there, Mr. Siri.

A There's nothing up there, sir.

Q (By Mr. Siri) Oh.

A If you could give me a page, I can look on my medical records, so if you would like -- if that's easier. What page would you like me to look at?

Q There we go. It's right there. Have you seen this medical record before?

A Yes, I have, but it's a -- yeah, can you make it a little bigger, please?

Q Sure. Okay. What is the -- the date of the medical record?

A 2/08/01, excuse me.

Q Okay. And how much did Yates weigh on that date according to this medical record?

A He weighed 24 pounds and 2 ounces.

Q Okay. Which would be about 11 kilograms?

A Yes, and I've looked very carefully at his growth chart, and that's here too, so his growth has been quite -- quite adequate both in height and weight and he stayed on his growth chart, so that was very reassuring as well.
Q Okay. Now -- now, on that date as well, he was diagnosed with otitis media; correct?
A So let me look at my chart because you're cutting it off. So the date -- let me get mine so I can make sure that I -- I -- so that -- okay. So -- okay. Okay.
Q Was he -- was -- based on this medical record, was Yates diagnosed with otitis media on February 8, 2001?
A Yes, he was, sir.
Q Okay. And what was he prescribed?
A Amoxicillin.
Q Okay. Looking at the amount of Amoxicillin prescribed, do you know whether that would have been for a mild or moderate form of otitis media or for a severe form of otitis media?
A That was a -- that was the prescribed amount. It's 40 milligrams per kilogram and he weighs 11 kilos, so that's -- that's 400. The CDC in

a -- because of the issues regarding otitis and because of the emergence of more resistant streptococcus pneumoniae, the CDC made a guidance document that it was important to increase the dose of Amoxicillin for all cases of otitis, so the -- the dose for -- of 40 milligrams for Amoxicillin was the recommended dose for garden variety otitis media.

Q Has that CDC guidance document been produced in this case?

A I don't know. I was part of the guidance document and so I -- I participated in that discussion, and that's the standard dose. In general, looking at the PDR is not generally where you find the most definitive information about the doses. Certainly the PDR gives you other information. But the doses that are recommended are often not the best found in the PDR.

Q And when was the CDC guidance document which you refer issued?

A I'm not sure. It was around this time because we had a lot of problems with pneumococcal otitis and so the guidance document was -- was issued about -- for the treatment of otitis media,

and it was 40 milligrams per kilogram of Amoxicillin.

(Whereupon, Exhibit No. 63 was marked to the testimony of the witness.)

Q (By Mr. Siri) Okay. And so you're saying -- do you know if Dr. Hays reviewed that guidance document before he prescribed Amoxil to Yates?

A Well, pretty much everyone knew that the dose of Amoxicillin was 40 milligrams per kilogram, which is exactly what he gave here, that that's the standard treatment of otitis media.

Q Okay.

A Getting out the PDR, and I just said the PDR does -- is not -- you know, does not provide the guidance that you need for specific instances.

Q Understood. But had the guidance of the PDR been looked at for prescribing the amount given of 40 milligrams per kilogram per day would have fallen into the severe category for otitis media; correct?

A Because it's wrong. This does not mean by giving 40 milligrams per kilogram for Amoxicillin

that it's severe. This is wrong.
Q Now, this CDC guidance document that you're referring, are you willing to provide a copy of it?
A I would be delighted.
Q Okay. Now -- now, generally speaking, do physicians look to the PDR to determine what dosage to provide patients?
A Not any that I know of.
Q Okay. So how does a pediatrician typically decide how much of a particular, you know, antibiotic, for example, to give one of their patients?
A Well, I think there's several ways. Certainly people use UpToDate. I think there are -- there's something called a Harriet Lane Handbook, which is a handbook that is updated every year by Harriet Lane at the -- at Johns Hopkins, and it gives doses of medication. We used to always have that. I felt it was like my -- you know, it was an appendage and that -- but, you know, now we have computers, so most people don't get out their old Harriet Lane. So that's an -- that's another way. The Red Book can

be another way, but you know, otitis media is really common and so, you know, any -- anybody who's finished a pediatric residency would know what the dose is, and that's exactly what we would give is 40 per kilo.

Q So other than the Harriet Lane Handbook or the Red Book or the PDR or this --

A I -- I said --

Q Is there any --

A -- not PDR. I said I don't use the PDR.

Q Okay. And you're saying that in your experience physicians in Tennessee wouldn't have used -- around 2000, 2001 wouldn't have used the PDR to determine what to prescribe a child with an infection?

A Not if they were well informed.

Q Okay. And so what would -- you're saying they would normally look at the Harriet Lane Handbook?

A I think they would look at the Red Book, they would look at Harriet Lane, they would look at -- now, obviously they didn't have UpToDate then, and they might look in a textbook and they might look at -- or -- you know, and they also go to CMEs and

they -- you know, this is a very common diagnosis. Every child has otitis sometimes, so this is a very common diagnosis, and this particular amount of antibiotic is very standard.

Q Okay. When you say textbooks, what are you referring to?

A Yeah, there's textbooks of pediatrics that are published, and they talk about otitis media and the -- and the dosage used for that. There are textbooks of infectious diseases that -- that are -- that exist, and they give doses of antibiotics. There's -- you know, there's a lot of textbooks. There's a lot of sources for information.

Q Are you familiar with the normal hemoglobin ranges in a baby?

A Yes, sir, I am.

Q Okay. So what would be the normal range for hemoglobin in a baby?

A Well, it depends a little bit on how -- the age of the baby. The baby can't -- you know, babies are -- they're very hemoconcentrated, so when babies are born, they can have hemoglobins in, you know, 16, 17, 18 because they have -- you

know, they have a lot of -- of hemoglobin, and so they have a lot of blood cells, and over the first few weeks of life, then -- then there is less production of red cells and then children -- you know, the blood count will go down, so children are born with higher levels of hemoglobin than --

Q So after the -- so by the time they're two months old, what would be the normal range approximately?

A Well, maybe 14, 16, 12, 14. I -- I don't know, sir. I'd have to just look at each age range, and I can do that. Again, you know, I'm not a general pediatrician.

Q I just asked for your best memory. If you don't remember, that's fine. How about at four months old?

A Well, it depends also about issues related to diet, it depends whether they've been in the hospital, if they -- it depends whether they've been premature, it depends whether they've had a lot of blood drawn in the unit, and so it's very dependent upon -- I can't -- I can say in a normal that it may be 10 to 14, something of that nature.

Q Okay. And that's also true for a

six-month-old?
A Well, the six -- and by six months old, then what you begin to do is you start making your own new blood cells, and if you are nutritionally replete and you have the amount of iron that you need in your formula, then you begin to make your blood cells, so again, it's -- it's a little variable. There's always a range.
Q What was your under -- what is your understanding of Yates' medical condition when he received his six-month vaccines?
A So your question is what was -- what -- how -- what was it six months of age?
Q Yeah, like -- it's what is your understanding of Yates' medical condition when he received his six-month vaccines.
A Okay. So let me just pull up his six-month vaccines because I reviewed that, and I just would never want to guess, misstate it, so here's at four months, here's his six -- let's see. Here is his six months. So it said the parents voiced concern about congestion, some green discharge, no current concerns for the eyes, ears, nose, throat, cardiovascular, respiratory, GI, and

endocrinology, allergic, neurologic, or immunology, so they had some concern about a congestion and some green discharge.

Q Was Dr. Carlton Hays the healthcare provider under whose authority Yates was vaccinated?

A I believe so. That's what -- his name is at the top, so I think that would mean that he was the one who did this.

Q Okay. And I presume you would agree that the standard of care applicable when Yates was vaccinated was to provide written materials including VISs at each vaccination visit?

A I think we've gone over that before. That's -- we talked about that. We also talked about that it didn't have a little ditto sign underneath it, so --

Q Ma'am, I'm ask -- this is a different question. I'm asking if you agree that the standard of care applicable when Yates was vaccinated was to provide written materials including a VIS at each vaccination visit to inform the parents of the benefits and risks of vaccination before the child was vaccinated.

A Yes, that's what we talked about before.

Q Okay. The CDC issues a recommended childhood immunization schedule annually; correct?
A Yes, sir.
Q Pediatricians look to this schedule to determine what vaccines to administer; correct?
A They do. They also look to the -- to the Red Book, the COID.
Q Okay. But you would agree that the standard of care when applicable to vaccinating Yates would have been to follow the CDC's recommendations for which vaccines to provide to Yates; correct?
MR. SANDERS: Object to the form of the question. You may answer, Doctor.
A It's a guideline for the administration of vaccines.
Q (By Mr. Siri) Okay.
A Sometimes we do -- we administer vaccines in slightly different ways if there has been a -- perhaps a fever or some other reaction to a vaccine, sometimes we separate them, so these are guidelines. They're not The Ten Commandments.
Q Right. So sometimes the CDC also has guidelines for when not to vaccinate; correct?
A They make suggestions, although the -- the --

well, they make suggestions.
Q Okay. And when a -- back when Yates was vaccinated, when a pediatrician --
A Is there a dog somewhere that barks?
Q Nope. I didn't hear a dog.
MR. SIRI: Anybody hear a dog?
MR. SANDERS: I think it may have been your chair hitting the wall or something.
THE WITNESS: Oh, okay.
MR. SANDERS: It was loud.
MR. SIRI: It's a better pet than a dog. I don't have to feed it at least or deal with cleaning anything up.
Q (By Mr. Siri) All right. Anyhow, the -- when Yates was vaccinated, what would Dr. Hays have looked to as the -- to determine what vaccines to administer to Yates?
A Well, I think we just talked about that. He would have looked at the guidelines for -- for -- from the CDC and the American Academy of Pediatrics.
Q And those would have been the standard of care applicable for what vaccines to give or not to give to Yates when he was vaccinated by

Dr. Hays; correct?

MR. SANDERS: Object to the form of the question. She's already asked -- been asked and answered that.

MR. SIRI: No, she hasn't. No, she hasn't.

Q (By Mr. Siri) Please answer the question.

A What is the question? What is the question and how does it differ from the question you just asked me before that I answered?

Q Okay. So the question you answered before, you're -- so you're saying that you've already answered that, the standard of care applicable for when to vaccinate or not to vaccinate Yates by Dr. Hays can be found in the CDC schedule and case -- contraindication and precaution list and the Red Book that were in effect at that time. Is that correct?

A Those are the guidelines, yes, sir.

Q And that would have been the standard of care applicable for that --

A It would have been -- but -- but what you have to --

MR. SANDERS: Go ahead, Dr. Edwards.

You can finish.
A What you have to understand is that there is some ability to use discretion and medical judgment, and so there may be times when you choose not to do exactly what is said in the -- you may choose to delay one, you may choose to give -- you know, the vaccines are -- the DTaP can be given at six weeks or two months, so if you give it at six weeks, it's fine. If you give it at two months, it's fine. Or if you want to wait a little longer to 10, that's not what it says, but it's not malpractice.
Q (By Mr. Siri) Would the standard of care include parents having an opportunity to review the materials provided with the risks and benefits and ask any questions they may have after reviewing those materials?
A It's important that -- that -- parents certainly should be able to ask questions, and I think that -- that often doctors prepare parents for subsequent visits by talking about what will be coming up at the next visit so that they're able to think about what's happening, and certainly with -- if you look at -- at the -- at

the visit at -- at -- at the four-month visit, you -- it says that handouts were provided, and then it said -- it said reviewed with the parents, the next visit is in two months, immunizations will be due. So those are opportunities that families will ask, and they -- if they have specific questions, then those will be addressed.

Q All right. And so the standard of care would be providing the parents an opportunity to review the material before the child is administered the vaccine and ask any questions about it; correct?

A I think that -- that the -- if you give the VIC later, I don't think that's -- is -- is any way not the standard of care. What -- I think a lot of the dialogue that happens with -- with parents is is about questions that they have about the vaccine and discussion of the vaccine. So the fact that a person has not had the VIC, like before the -- the visit or something of that nature, I don't think that's -- that's a -- that that's a -- that that is inappropriate practice.

Q Just to make sure I understand you, federal law requires that the -- that the parent or guardian be provided the VIS by the person

administering the vaccine prior to the giving of the vaccine. I assume you would agree that that is the standard of care, that the VIS must be provided prior to the administration of the vaccine; correct?

A Yes.

Q And that would be a -- would have been applicable to vaccinating Yates; correct?

A Yes, but it doesn't mean that --

Q Okay.

A -- it's simply based on that. There's also an open dialogue about immunizations that is not -- is not part of the VIS as well.

Q And that would be the part of the standard of care as well?

A To address the questions that the parents had.

Q So that -- so it -- that would have been part of the standard of care for vaccinating Yates as well, correct, what you just said?

A Yeah. If they had questions, then the questions should be addressed.

Q Okay. What is CISA?

A Center for Immunization Safety Assessment.

It's CISA.

Q Oh, thank you.

MR. SIRI: I'm getting close to finishing here. Let me -- I'm going to -- let's take a five-minute break. Let me take a quick look, and hopefully we'll be -- get this wrapped up today. I'll --

MR. SANDERS: Hang on. Mr. Siri, when you say you're getting close, can you give us a little more of a --

MR. SIRI: Yeah, it looks like we'll be done in less than eight hours. Ms. Cohen, how -- how far are we in?

THE WITNESS: Actually, it's already been 8 hours, I think.

MR. SANDERS: Yeah. I think Ms. Cohen can tell us we're probably really close.

MR. SIRI: Yeah.

THE COURT REPORTER: According to my digital recorder, it's 7 hours and 29 minutes.

MR. SIRI: Okay. We're close. We're very close. All right. So should we -- it's 2:23. Why don't we -- excuse me. It's 4:23. Why don't we reconvene at -- at 4:30 instead of in

seven minutes, and we'll -- we can finish this up.

MR. SANDERS: Okay.

THE VIDEOGRAPHER: All right. We're off the record at 4:23 Central time.

(Brief recess.)

THE VIDEOGRAPHER: All right. We are back on the record at 4:32 p.m. Central time.

Q (By Mr. Siri) All right, thank you.

Dr. Edwards, if a -- do vaccine reactions only -- if one were to occur, only occur within the first 15 minutes after getting a vaccine?

A I'm sorry, the dog barked again. What did -- would you say --

Q I'm sorry. I leaned back. Okay. I was saying, are there -- are there vaccine reactions that occur after the first 15 minutes of receiving a vaccine?

A Yes, sir, there are.

Q Okay. Can you give a few examples?

A Yeah. A sore arm, a swollen leg after a vaccination. Usually those local reactions don't happen within 15 minutes, they generally happen within the first 20 -- 12 to 24 hours, so I think what you might be referring to are the more severe

reactions that occur, and those are generally anaphylactic reactions, and those reactions generally would occur within 15 minutes, and those are more severe. They need to -- often need to be treated with epinephrine or something of that nature, so -- but yes, there are a number of reactions that happen after 15 minutes.

Q There are also some severe adverse reactions that occur beyond 15 minutes as well; correct?

A Yes, but not contraindications to vaccination.

Q Not -- without discussing whether it's a contraindication or not, just -- you know, we reviewed some adverse reactions earlier that, you know, had a -- there was a basis to say, you know, sometimes rarely or -- were caused by vaccines. Some of those are serious and some of those can arise beyond the first 15 minutes after the vaccination; right?

A Yes, sir, that's correct.

Q Some -- some of them would -- some of them, in fact, only arise a week or two after vaccination; correct?

A It depends on what the vaccine is, so when

the adverse of -- if it happens a week later may be associated with a measles vaccine, but it's very unlikely to be associated with a DTP vaccine.

Q Dr. Edwards, what is your husband's name?

A William Edwards.

Q And what is his profession?

A He's a teacher. He's retired now.

Q Is he a medical doctor as well?

A No, sir, he's not.

Q Does he have any medical training?

A No, sir, he does not, although he's lived with me for 50 years and he's heard me talk about a lot of things and he's quite a patient listener.

Q That's great. And did he teach at the university level or --

A No, sir, he taught at high school level.

Q And what did he teach?

A He taught history.

Q Okay. Has he recommended any responses, regardless of how minimal you feel that it was, to any of the deposition questions asked of you today?

A No, sir. He's not a vaccinologist.

Q Okay. Has anyone recommended any responses,

regardless of how minimal you feel that it was, to any of the questions asked of you in this deposition today?

A No, sir.

Q Okay. During this deposition, did anyone ever speak to you while your microphone was muted about any question that was asked of you during this deposition?

A Yeah, probably. I think my husband asked me if I needed anything when he went to Wal-Mart, so I didn't think you really wanted to hear what he -- what -- he asked me about going to Wal-Mart, so I muted that. He asked me if -- he asked me something about whether I wanted some water, and I said yes, I would like some water. He -- I don't know what else he asked me. I -- you know, he's here and he asked me a question, and so I muted it when he said it so you couldn't hear that he was talking about Wal-Mart. But I -- if he talks about Wal-Mart now, I will certainly let you hear it.

Q Okay, wonderful. Have you been to Wal-Mart or any grocery stores in the last two months?

A I have not been to Wal-Mart. I've been to

the grocery store hardly any.
Q Have you been to the -- any hospital in the last two months?
A Yes, I've been to Vanderbilt on several occasions.
Q Okay. Have you met or treated any patients while you were there?
A No, sir, I have not.
Q Did you meet with anybody --
A I've talked about patients, but I have not treated any patients.
Q Understood. All right. So you met with other physicians while you were there?
A Yes.
Q How much have you been paid for your services in this case by --
A I haven't been paid for anything at this point.
Q Okay. What is it that you are charging per hour for being an expert in this case?
A $500, but I'm going to be giving this to -- to people that have had difficulties during this pandemic. I'm not going to take any of this money myself.

Q That's very honorable of you. Going back to the -- my -- let's see if I can pronounce this correctly. Is it CISA?
A Correct.
Q Okay. And what does that stand for?
A Center for Immunization Safety Assessment.
Q Okay. And CISA assesses serious adverse events in specific cases following immunization; correct?
A Serious -- or excuse me. CISA assesses reactions after vaccination, yes.
Q Okay. And it is part of the CDC Immunization Vaccine Safety Network. Is that right?
A Yes.
Q Okay. It's part of the immunization -- Vaccine Immunization Safety Office within the CDC that's responsible for vaccine safety; correct?
A Yes.
Q Okay. It's Bible, so to speak, for doing -- for reviewing whether or not an adverse event is caused by a vaccine is a process described in an article entitled, quote, Comprehensive Assessment of Serious Adverse Events Following Immunization by Healthcare Providers. Is that correct?

A Yes, but we also assess some that are not as serious as well, so -- so the severity of them depends upon -- you know, depends upon the question.
Q Understood. But when it is a serious adverse event, the guidance document that's used is the document I just -- whose title I just referenced; correct?
A No. When -- when we are -- so these are questions that doctors ask. There is a line that doctors assess. They call the CDC and then we assess the assessment, so -- so -- so this is a paper that was written by Elizabeth Williams who is one of my fellows, and -- and so it talks about the process by which we assess reactions, so, you know, not all of them are serious, but many of them are, and so it goes through a series of steps, which you've obviously highlighted.
Q Okay. And this would be how -- these are the steps that would be undertaken within CISA to determine whether or not a serious adverse event following immunization might be causally related to the vaccination; correct?
A That's correct, yes.

Q Okay. And so in step one, it says to establish a clear diagnosis of what the potential injury might be; correct?
A To establish a clear diagnosis of what the adverse event is, correct.
Q Okay. And then in step two, it's to consider whether the timing of the adverse event following immunizations is consistent with prior knowledge and known biological mechanisms; correct?
A Correct.
Q Okay. And so then an example is provided; right? It says, for example, if a child experiences a febrile seizure three days after the receipt of a measles, mumps, and rubella vaccine, a parent might consider the immunization to be the cause of the seizure; right?
A Actually, it's -- actually, this is a little early. Most of the seizures that are associated with MMR are a little later than this. Generally they're five to seven days in terms of that because it mimics a reaction, but you may indeed see a seizure, and sometimes when the Prevnar is given with the MMR, that was a seizure that was seen within three days.

Q Uh-huh.
A So and again, I just say however -- if it occurs one to two weeks after vaccination, a period of elevated risk for febrile seizure and after an MMR is usually seven to ten. Thus -- thus it is improbable that a febrile seizure occurring three days after immunization was caused by MMR. That's exactly what I just said.
Q All right. So just to make sure I understand it, what you're saying is is that if the child has a fever after MMR vaccine, it can cause a seizure, but that --
A It can cause a seizure, yes.
Q Right. And the thinking is, and correct me if I'm wrong, that had the child had a fever maybe from a certain other reason, the child would have also had a seizure.
A No, that doesn't say that at all.
Q Oh, okay.
A That's --
Q Well, that's why I asked it. Correct -- please.
A Well, that's not correct. What you said is wrong.

Q So it's arguing -- so is it that -- is it saying that it's improbable that a febrile seizure will occur in the first three days after immunization because fevers don't occur from MMR in the first three days after vaccination?
A That's what it says, sir.
Q Okay. And has -- in this example, we -- you stop at step two and you don't go further in this example because MMR, you know, has not been shown to cause fever in the first three days after vaccination, and hence couldn't have resulted in febrile, meaning seizure -- which means a seizure with fever; correct?
A Yes, sir. However, however, we also have to consider were there other vaccines that were given at the same time, so if there were other vaccines that were given at the same time, like a DTP, then maybe the -- a febrile seizure could occur a little earlier, although generally those are between day one and day two, so having an understanding of when you expect to see the adverse -- excuse me, I've got the hiccups -- adverse events is very important.
Q Understood. All right. And here, knowing

that MMR, you know, has -- has not been associated with fever in the first three days after vaccination permitted being able to conclude the febrile seizure in this example was not caused by MMR.

A That's correct.

Q Okay. Are you familiar with the clinical trials relied upon to license the MMR vaccine?

A I'm sure there were clinical trials and, you know, it was -- it's been a few years ago, but if you want to bring up the paper, I'd be delighted to look at it.

Q Sure.

MR. SIRI: So the last one would be marked as 60 --

MS. CHEN: Sixty-four.

MR. SIRI: Thank you. And we'll mark this one as 65.

(Whereupon, Exhibit Nos. 64 and 65 were marked to the testimony of the witness.)

Q (By Mr. Siri) And so if you take a look here, have you seen this document before issued by

the Department of Health, Education, and Welfare granting licensure for the MMR vaccine occurring --

A In 1978, no, sir. I -- this went to the FDA. I have not seen this letter.

Q Do you know who Maurice Hilleman is?

A I sure do. He's the -- a vaccine guru that has -- was at Merck for many years.

Q Okay. And you'll have an opportunity to review this, but if you see, it provides that this is the -- for the combined MMR measles line -- measles, mumps, and rubella vaccine, and this is for the purpose of supporting a licensure to manufacture and sell, signed by Maurice Hilleman from Merck. Do you see that?

A Sir, I --

MR. SANDERS: Can you enlarge it a little bit, Mr. Siri, please?

MR. SIRI: Absolutely.

MR. SANDERS: Thank you.

MR. SIRI: Is that better?

MR. SANDERS: Yes.

A Yes.

Q (By Mr. Siri) And just going back to the

first page, this is, you know, from the Bureau of Biologics, and it says, this is to inform you that the amendments to your product license applications to include the use of RA 27/3 strain rubella virus grown in human diploid cells have been accepted for manufacture of the following products, and it's -- includes the measles, mumps, rubella vaccine. All right. It also included a stand-alone rubella and a stand -- and a measles mumps vaccine, which we no longer use. Let's just -- as is typical of these clinical trial reports submitted to the FDA, which I presume you're very familiar with, this is a -- usually there's a summary of the clinical trials that were conducted; correct?

A Yes.

Q Okay. And does this look like what you would expect to see of a summary of the clinical trials that were conducted when submitting them, what would now be called the BSA application to license the vaccine?

A Well, it lists the number of studies, it lists the age of the subjects. It doesn't say whether there's any other concomitant vaccines.

It talks about the -- the seroconversion, the number that's seroconverted over the number that was seronegative for the mumps, measles, and rubella --

Q All right.

A -- vaccine. And then it gives a geometric mean titre. I don't know what RA means. One, two, three, four, five, six, seven -- I have no idea. There's no --

Q Yeah. Those are just reference numbers. But in the first -- in the first column, it provides a study number; right? Each of these clinical trials is provided a study number; correct?

A Yes, sir. That's correct.

Q And then there's a -- there's also a row that provides a number of vaccinees. It's a total of 834 vaccinees; correct?

A Yes, sir.

Q Okay. So, you know, 442 is the first one, you know, listed. I'm going to scroll down and what -- you know, what this document has done is it's excerpted all the tables that have fever in them and they -- the results of fever in children. Do you see here for study 442 in the first four

days -- well, the first day and the -- and the next presumably three days after vaccination that there -- 25.6 percent of the children did have a fever in this trial?

A Yeah, but that's not a fever that's high enough to cause a febrile seizure.

Q What would be high enough?

A Usually 103, 104, and there's one of those. But you also have not provided me with any information about what else is happening in this patient, so I think that -- that it may indeed be something else that's going on with that child that may be causing the fever. So the fact that there's one child with fever to 103, 104, does not mean that that was caused by the vaccine. That doesn't mean that it wasn't and there was -- you know, but I have no other information. I have no information whether other studies were done, whether the child had a rash, whether he had other findings, so the finding of one person that had a reaction after a vaccine does not mean that it's caused by the vaccine.

Q Okay. Let's go to the next study. So this is study 443. This is, you know, another group of

individuals, and you can see that 30 percent of them in the first four days had a fever between 99 and 100.9. 8 percent had a fever between 101 and 102.9. And then one, as you just said, had a fever between 103 to 104.9 in this study. So --

A Yeah, I don't know whether -- I don't know whether this study was conducted in the winter when flu was around. I know other -- you know, so I'm just saying that -- that the typical pattern for a fever after MMR is not within the first three days, which is what we stated, first three days.

Q It's usually between the fifth and twelfth day; correct?

A That's what I said.

Q Right. And you can see that those rates are also provided, and they're relatively comparable to the first four days; correct?

A No. I think that they're -- they're more. There's seven as opposed to thirteen, five as opposed to nine. Those are almost double, so those are different.

Q Okay.

A The numbers are so small that you could not

say that there's probably a statistical difference between them.

Q All right. Well, when they designed the study, they only included a total of 800 and something kids with all the -- so, you know, this is the data that existed.

A I know, but you're separating out each of the individual studies, so each of the individual studies probably has no more than 80 subjects.

Q Well, yeah, I mean, and that's -- that's the way they designed it. Like, here's another one, right, and so again, you know, there are children that had in the first four days fevers, and this one as well; correct?

A Yeah, there's -- there's one in both of those groups, one.

Q Right. Just like there was only one in the five to twelve days that --

A I know, but there's five -- but there's five in the five to twelve.

Q All right. But you -- you said that it's -- fevers of 103 to 104, that would cause a febrile fever -- seizure.

A They are -- febrile seizures are associated

with higher fevers.
Q Right. So in this instance, there's one in each in this category right here, which you said is the category where one would expect to get a febrile seizure. Let's take a look at another -- you know, look at another one where here's one and there's none here and you're saying, you know -- so I mean, based on the clinical trials that were done for the MMR vaccine, do you believe it was accurate to state that it was improbable? Let's go -- that -- that a --
A Yes, I do, sir. Yes, I do. You're taking one study from 1978, you're not telling me anything else that happened in each of those individual patients, you're taking studies that have no more than 80 people a thing, and then you're looking at the numbers. There's no statistics here, there's no comparability. You're asking -- you're just looking at numbers, and that's just not the way that you do things.
Q Those are the clinical trials relied upon to license the MMR vaccine though; correct?
A They were relied upon to license the MMR vaccine, but they were not the ones that --

that -- that -- that characterized large numbers of patients with reactions that -- that are associated with the MMR. A larger study with more power would be able to define more clearly what the time you would see fever, and when that has been done, it's been five to seven days. That doesn't mean there's one or two patients. You know, this is kind of quibbling over irrelevance.

Q So but the study that you said would be needed to really even determine what time periods are -- fevers are associated with MMR, you're saying the clinical trials relied upon to license MMR weren't even powered to do that.

A That's correct.

Q Okay. I just have a few more questions for you.

A I'm sorry, you have no more questions? Is that what you --

Q No, I just -- I just have a few more for you and we're done. So vaccines are grown on various growth mediums; correct?

A Yes.

Q And those growth mediums are removed from the vaccines by the end of the manufacturing process

so that as part of the vaccination process antibodies to these substances are then generated; correct?

A Well, we've already talked about that. These are impurities in the vaccine, and we -- and you're asking me to comment on all vaccines, so that's not -- I can't be very precise.

Q Okay. How about bovine -- how about calf bovine serum? That's used as a growth medium for some vaccines; correct?

A Cells need to be supported by -- by nutrients, so both the -- and seralbumin can be added as a grow -- to help support the cells that would then support viral growth.

Q Okay. But the calf bovine serum that's used as a growth medium would be removed from the final product so that the body would instead develop antibodies to calf bovine serum; correct?

A Yes, that would be the goal.

Q Okay. And it's, you know, similarly -- there's caseins from cow milk that's used as a growth medium in some -- at least one vaccine, and that also is removed from the final formulation of the product; correct?

A Yeah, the -- the products are purified as -- to have as pure product to be in. Whether there's a microgram of BSA, you know, I can't comment on the final -- final -- excuse me, amount of each of the impurities that are in the vaccine. That's in the package insert, but I -- I don't remember all of those.

Q Okay. Fair enough. Final topic. You lecture to doctors about vaccine safety; correct?

A Yes, sir.

Q You provided a -- have you provided a -- how many times have you provided lectures in rooms with doctors in them about vaccine safety would you estimate?

A I do it in so many formats that I can't even comment. I lecture on this on the wards when I take care of patients, I lecture to the medical students, I lecture in -- and they're not always in formal lectures. I give lectures to -- to the fellows, and I give lectures to large groups of doctors, and so I can't tell you. I probably have talked to thousands of doctors about vaccine safety.

Q Okay. And the purpose is to educate them

about vaccine safety; correct?
A Of course.
Q To frame the way that they think about vaccine safety; correct?
A To educate them so that how they think about vaccine safety is informed by research and data. I do not try and brainwash people.
Q Okay. Are you -- are you -- are you aware that there is one of these lectures available on YouTube that you gave to a room full of doctors at the Vanderbilt Kennedy Center on January 12, 2011?
A Yeah, I think you got some pictures from that. It was one of the earlier ones, yeah.
Q Do you recall -- do you recall that presentation?
A I recall giving that presentation. I don't recall what was included in that presentation.
Q Okay. So -- well, let me ask before I play it. Do you recall stating that the -- that an article that we looked at earlier with regard to Poling -- regarding the Poling case brought up the whole controversy of whether vaccines are safe in vulnerable children?
A I -- I don't know that I said that. That

sounds like something that I may have said.
Q Do you think that the Hannah Poling case brought up the whole controversy regarding whether vaccines are safe in vulnerable children?
A I think that it -- it -- yeah, I think it was a topic of intensive discussion.
MR. SANDERS: Ms. Cohen, can you tell us the time that we've been in again, please?
THE COURT REPORTER: Seven minutes -- I mean seven hours and 56 minutes.
MR. SANDERS: Thank you.
MR. SIRI: Four minutes left. All right.
Q (By Mr. Siri) Do you recall telling the doctors that, quote, I'm going to go over this morning the process of vaccine licensure so that you can understand how comprehensive it is so that you can explain that to your patients?
A That sounds like something I would say.
Q Okay. And do you believe that you said that?
A Well, sir, I think it's something I said. I don't remember whether I said that 20 or 15 years ago during that lecture, but it sounds like something I would say. So that sounds like a

reasonable statement, but whether I said it in that lecture, I don't know.

Q Fair enough. I'm going to play you one clip since we're pretty much out of time.

(Whereupon, a video clip was shown.)

Q Dr. Edwards, isn't it true that most VAERS reports are not filed by parents?

A I don't know the distribution. I think probably most VAERS reports are filed by the manufacturers, but I don't know the exact distribution of the reports.

Q Your implication though was that -- let me -- let's pull up a document. So --

A I don't think that my statement had any implications. I'm just saying that the people -- a lot of different people can report adverse events.

Q But isn't it true that most are not filed by teachers? Isn't it true that approximately 80 percent of VAERS reports are filed by doctors and pharmaceutical companies and health -- and health -- and health -- state health agencies?

A That's probably correct, but I didn't say --

I said -- well --
Q Yeah. So most are not filed by neighbors; correct?
A No, but some of them are.
Q Okay. And most are not filed by grandma; right?
A No, but some of them are. Particularly, I'm a grandma, and I file them, so yeah, I file them.
Q Uh-huh. What percentage of adverse reactions are reported to VAERS approximately according to a study conducted by AHRQ, if you're familiar with it?
A I would say -- I -- I would say if -- a fairly low percentage. I don't know what that paper says. You can probably tell me so I can read that again before I prepare for the trial.
MR. SIRI: Okay. How much time is left? Are we -- are we at eight hours, Ms. Cohen?
THE COURT REPORTER: We're at seven hours, 59 minutes, and 18 seconds.
MR. SIRI: Okay. Well, I -- Dr. Edwards, you and I could probably spend another two days together, but our time together has come to a close until the trial. And thank

you for sitting with me today and answering our questions. So I assume at that point, you know -- you know, I've got more questions, but if we are going to close it out at eight hours, then we'll close it out right now.

MR. SANDERS: I don't have any questions. Dr. Edwards, we'll go off the record and then you can click out.

THE VIDEOGRAPHER: All right. That concludes the videotape testimony of Dr. Kathryn Edwards, and we are off the record at 5:03 p.m.

(Whereupon, the deposition of Kathryn Edwards, M.D., concluded.)

C E R T I F I C A T E

STATE OF TENNESSEE:

COUNTY OF SHELBY:

I, SAMANTHA COHEN, Registered Professional Reporter, Certified Realtime Reporter, and Notary Public for the State of Tennessee at Large, do hereby certify that I reported in machine shorthand the above-captioned proceedings.

I HEREBY CERTIFY that the foregoing pages contain a full, true, and correct transcript of my said Stenotype notes then and there taken.

I FURTHER CERTIFY that I am not an attorney or counsel of any of the parties, nor a relative or employee of any of the parties, nor am I a relative or employee of any attorney or counsel connected with the action, nor am I financially interested in the action.

I FURTHER CERTIFY that in order for this document to be authentic and genuine, it must bear my original signature and my embossed notarial seal and that any reproduction in whole or in part of this document is not allowed or condoned and that such reproductions should be deemed a forgery.

THEREFORE, witness my hand and my official seal in the State of Tennessee on September 25, 2020.

Samantha Cohen

SAMANTHA E. COHEN, RPR, CRR
Tennessee LCR #405
Mississippi LCR #1935
Notary Public at Large

SAMANTHA COHEN STATE OF TENNESSEE NOTARY PUBLIC SHELBY COUNTY

My Commission Expires:
June 4, 2022

SIGNATURE OF THE WITNESS

STATE OF TENNESSEE:

COUNTY OF SHELBY:

_____
KATHRYN EDWARDS, M.D.

Subscribed and sworn to by me on this the _____ day of _____, 2020.

_____
Notary Public

My Commission Expires:

_____

Q

T

Z