

**In the Matter Of:**  
HAZLEHURST vs  
HAYS, M.D., ET AL.

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**KATHRYN EDWARDS, M.D.**

*August 25, 2020*

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**riverside**  
R E P O R T I N G

22 North Second Street/Suite 303, Memphis, TN, 38103 (901) 527-1100



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.	)	DOCKET NO. C-19-38
	)	DIVISION II
E. CARLTON HAYS, M.D., and	)	JURY DEMANDED
THE JACKSON CLINIC PROFESSIONAL	)	
ASSOCIATION,	)	
	)	
Defendants.	)	

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

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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.

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A P P E A R A N C E S

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 ALSO PRESENT: ROLF HAZLEHURST  
 PATRICIA CHEN

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1 P R O C E E D I N G S

2 \* \* \* \* \*

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

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

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

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

21 KATHRYN EDWARDS, M.D.,  
22 Having been first duly sworn, was examined  
23 and testified as follows:  
24

1 EXAMINATION

2 BY MR. SIRI:

3 Q Good morning, Dr. Edwards.

4 A Good morning.

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

7 A Kathryn Margaret Edwards.

8 Q Have you been deposed before?

9 A Yes, sir, I have.

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

12 A Five or six.

13 Q And what did those matters typically involve?

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

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

20 A No, I was not, sir.

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

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

1 Q Okay. In the cases where you were a treating  
2 physician, you weren't a listed defendant?

3 A No, I was not.

4 Q Okay. Did any of those cases involve a  
5 vaccine?

6 A No, sir.

7 Q None of them involved an adverse reaction to  
8 a vaccine?

9 A No, sir.

10 Q I'm going to go through a few rules. Now,  
11 you've been deposed before, so you probably have  
12 heard this, but we'll do it nonetheless. The  
13 court reporter, as you know, has just placed you  
14 under oath. That is the same as a court of law,  
15 so you're testifying under penalty of perjury. Do  
16 you understand what I mean when I say perjury?

17 A I do, sir.

18 Q The court reporter is going to make a record  
19 by typing up all the questions and your answers.  
20 When answering questions, please speak audibly.  
21 The court reporter can't take down nods; okay?

22 A Yes, sir.

23 Q Okay. And also, you know, mm-hmms and the --  
24 you're familiar with that, those kind of verbal

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

4 A Yes, sir.

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

7 A Yes, sir.

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

14 A Yes, sir.

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

19 A Yes, sir.

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

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

4 A Yes, sir. Yes, sir.

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

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

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

12 A I do not.

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

15 A I reviewed the medical records and --  
16 reviewed the medical records and the medical  
17 literature.

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

21 A Yes, sir.

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

24 A Yes, sir.

1 Q Who provided you with medical records?

2 A Those were provided by Mr. Sanders.

3 Q Okay. And for what period of time did those  
4 medical records encompass approximately, or up  
5 until what age?

6 A The records that I have were -- provided  
7 information up until depositions in 2016. That's  
8 the last that I have.

9 Q Okay. And what were the -- what was the  
10 scientific literature that you reviewed?

11 A I reviewed the Red Book, I reviewed several  
12 articles about autism, that -- I reviewed the  
13 Danish study about autism and the lack of  
14 association with MMR, and those were the main ones  
15 I -- you know, I reviewed the literature  
16 extensively about all kinds of things, so, you  
17 know, I'm pretty much always reviewing the  
18 literature.

19 Q When you say you looked at the Red Book, what  
20 edition or year did you review?

21 A I reviewed the 2000 Red Book, I reviewed the  
22 2015 Red Book, and I reviewed the most recent Red  
23 Book.

24 Q And in terms of the autism articles, do you



1 recall specifically which ones you looked at?

2 A I'm sorry, sir, the authors of the articles  
3 that I reviewed?

4 Q Oh, no, I apologize. The autism articles  
5 that you looked at -- you mentioned autism  
6 articles. Do you recall which ones you looked at,  
7 titles? Or sometimes people refer to them by name  
8 of the first author.

9 A No, sir. I can pull them up if you would  
10 like me to and/or send you the PDFs if you'd like  
11 to review them.

12 Q Sure. We can do that after the deposition.  
13 We'd happily take copies of those. And then you  
14 reviewed the -- and then you said you reviewed the  
15 Danish study. That's -- that was a pretty recent  
16 study. Is that right?

17 A It was in 2019 in the Annals.

18 Q Yeah, okay. Anything else that you reviewed  
19 paper-wise or digitally?

20 A I -- not specifically that I recall, but I  
21 did review a number of articles, and that's kind  
22 of what I do all the time, so --

23 Q Yeah, understood. You've got a lot of  
24 published articles as well. Okay. Did you meet

1 with anybody to discuss this deposition?

2 A Mr. Sanders and I talked about sort of the  
3 mechanics of the deposition. I -- there were a  
4 couple of documents that -- that I wanted him to  
5 provide me which I didn't have, which he also did.

6 Q Okay. And did you meet in person or did you  
7 do it digitally?

8 A No, sir, we did not. We did not meet in  
9 person. We met by Zoom.

10 Q Okay. And then -- and other than  
11 Mr. Sanders, did you meet with anybody -- meet or  
12 talk with anybody else about today's --

13 A No, sir.

14 Q -- deposition?

15 A No, sir.

16 Q Okay. So before today, you didn't have  
17 discussions about this deposition or this case  
18 with anybody but Mr. Sanders?

19 A No, sir, I did not.

20 Q How did you first learn about this lawsuit?

21 A When Mr. Sanders contacted me to ask him --  
22 ask me if I would testify.

23 Q And since that time, the only person you've  
24 spoken to was Mr. Sanders about this lawsuit in

1 any way?

2 A That is correct. That is correct.

3 Q Okay. Just to close us up on that, you do  
4 not -- have not spoken or communicated in any way,  
5 either electronically or otherwise, with any of  
6 your colleagues who are infectious disease doctors  
7 or vaccinologists about this case in any way?

8 A No, sir.

9 Q Okay. I'm going to go through a list of  
10 acronyms, and for the record can you please state  
11 what you understand each stand for? This way  
12 we've -- as we use those acronyms in this  
13 deposition, or terms in this deposition, we have a  
14 baseline understanding. These will seem very  
15 obvious to you, but not necessarily to everybody.  
16 HHS.

17 A Health and Human Services.

18 Q All right. That's the United States  
19 Department of Health and Human Services; correct?

20 A That's correct.

21 Q The cabinet level department within the  
22 federal government? I'm sorry?

23 A That's correct, sir.

24 Q Okay. CDC.

- 1 A Centers for Disease Control and Prevention.
- 2 Q Okay. FDA.
- 3 A Food and Drug Administration.
- 4 Q NIH.
- 5 A National Institute of Health.
- 6 Q HRSA.
- 7 A HRSA?
- 8 Q Right.
- 9 A You --
- 10 Q I never -- I never use the full name either.
- 11 A You'll have to tell me and I'll say if that's
- 12 correct.
- 13 Q Health Resources and Services Administration.
- 14 A Yes, sir.
- 15 Q All right. Okay. It sounds right; right?
- 16 A Yes.
- 17 Q Okay. ACIP.
- 18 A Advisory Committee for Immunization
- 19 Practices.
- 20 Q Right. ACIP is the committee within the CDC
- 21 that effectively decides upon the CDC's childhood
- 22 immunization schedule; correct?
- 23 A For the use in the public sector, yes.
- 24 Q Right. Meaning what, you know,

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

4   A     Correct.

5   Q     And VRBPAC.

6   A     Vaccines and Related Biologic Products  
7   Advisory Committee.

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

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

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

19  A     They will vote.

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

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

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

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

13 A That's correct.

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

18 A No, sir, I'm not.

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

21 A Yes, sir.

22 Q Okay. What does IOM stand for?

23 A Institute of Medicine.

24 Q Okay. Do you consider the IOM and all the

1 agencies and committees we just listed as reliable  
2 authorities with regards to vaccines?

3 A I think that the reliability of each of the  
4 agencies must be judged on the specific question  
5 that you're asking.

6 Q All right. So there are instances in which,  
7 for example, the CDC is not reliable when it comes  
8 to vaccines?

9 A I think that you asked me a blanket question  
10 about all of the agencies and HHS, whether they're  
11 always efficient and effective, and that's really  
12 a very broad general statement. I think that the  
13 Centers for Disease Control have responsibility  
14 to -- to provide the guidelines once vaccines are  
15 licensed for how they will be used in the public  
16 sector. When they do that, they -- they use skill  
17 and they are the authoritative source for those  
18 recommendations.

19 Q So you would consider the CDC a reliable  
20 authority with regards to vaccines?

21 A Yes, sir.

22 MR. SANDERS: Object to -- object to the  
23 form of the --

24 A In general.

1 MR. SANDERS: -- question.

2 A In general.

3 Q (By Mr. Siri) In general. And you would  
4 consider the information that the CDC produces  
5 with regards to vaccines to be reliable, a  
6 reliable authority with regard to vaccines;  
7 correct?

8 A I think that there are so many  
9 recommendations. If you want to ask me about any  
10 specific ones, I will address whether I think that  
11 is reliable or not.

12 Q Okay. So you believe there are instances in  
13 which the CDC may not be reliable with regards to  
14 information provided regarding vaccines?

15 A The recommendations for the CDC are what's  
16 implemented and in general are reliable.

17 Q It sounds like you're saying that there could  
18 be exceptions. Is that right?

19 A Well, let me give you an example that's not  
20 vaccines. So at the beginning of the pandemic,  
21 the CDC said do not wear masks, you do not wear  
22 masks, you take the masks from the people and do  
23 not wear masks. So with additional information,  
24 the CDC says wear masks. So you're asking me to



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

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

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

17 Q Sure.

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

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

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

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

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

19 A In general, yes.

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

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

1 but in general, yes.

2 Q In general, you would consider those to be  
3 reliable authorities regarding vaccines?

4 A Yes.

5 Q What does GSK stand for?

6 A GlaxoSmithKline.

7 Q Okay. What is the National Childhood Vaccine  
8 Injury Act of 1986?

9 A It is a no-fault compensation system that is  
10 paid for by the -- the excise tax on vaccines. It  
11 is a system where special masters review the  
12 information related to an adverse event, and  
13 depending upon whether they're table injuries or  
14 injuries that are associated with adverse events,  
15 then if indeed the special masters and the -- and  
16 the process deems that an adverse event has  
17 occurred, then the -- then the plaintiffs will be  
18 compensated for the adverse event.

19 Q Right. So when it's a -- when you say table  
20 injury, what you're referring to is an injury in  
21 which it falls into certain specific -- certain  
22 injuries that occur in a certain period of time  
23 after certain vaccines, then the burden shifts to  
24 the government to show the vaccine didn't cause

1 the injury; correct?

2 A There's a table of injuries that are placed  
3 on -- and I don't have it in front of me. I  
4 certainly could pull it up.

5 Q I'm sorry for using some -- I'm sorry for the  
6 law lingo. Let me ask it -- let me ask you a  
7 simpler question, and we'll come back to the table  
8 of injuries. Right -- the National Childhood  
9 Vaccine Injury Act of 1986, I'll refer to that as  
10 the '86 Act; okay?

11 A '86 Act? Okay.

12 Q The 1986 Act.

13 A Okay.

14 Q Okay. So this way we can use that as  
15 shorthand. Now, this is the law -- and this is  
16 the law that in addition to creating the Vaccine  
17 Injury Compensation Program, as you mentioned, it  
18 also gave vaccine manufacturers immunity from  
19 economic liability for injuries caused by  
20 vaccines; correct?

21 A That is correct, sir.

22 Q Okay. In 1991, you became a professor of  
23 pediatrics in the division of infectious disease  
24 at Vanderbilt University School of Medicine;

1 correct?

2 A I think it was 1991. I don't have my CV in  
3 front of me. I came to Vanderbilt in '80.

4 Q Okay. But you still hold that position?

5 A I do, sir.

6 Q Okay. 2008 you became the chair of  
7 pediatrics at Vanderbilt University School of  
8 Medicine?

9 A No, I'm not the chair of pediatrics. I have  
10 an endowed chair, which is a chair that is -- that  
11 is funded by the endowment of the university that  
12 pays a portion of my salary. I am not in an -- I  
13 am not the chair of pediatrics.

14 Q Okay.

15 A I am a professor of pediatrics and have an  
16 endowed chair.

17 Q Thank you for that clarification. Okay. And  
18 in 2001 you became the vice chair for clinical  
19 research in the department of pediatrics at  
20 Vanderbilt University School of Medicine?

21 A Yes, sir.

22 Q In that year, you also became the director  
23 and the scientific director of the Vanderbilt  
24 Vaccine Research Program; correct?

1 A Yes, sir.

2 Q Okay. And you've received dozens of honors  
3 and awards related to your work in infectious  
4 disease, pediatrics, and vaccines?

5 A I've received some awards, yes.

6 Q I'm looking at your CV. You've got a --  
7 almost a full page of awards and honors, but I  
8 appreciate your modesty. You've been invited --  
9 you've been an invited speaker to over 250 events  
10 on these topics all over the world; correct?

11 A Yes, sir.

12 Q You have over 500 publications, most in  
13 peer-reviewed journals and most regarding or  
14 related to vaccinations or the infections they're  
15 intended to prevent?

16 A Yes, sir.

17 Q You've been a member of numerous committees,  
18 including at the FDA, CDC, and WHO that voted upon  
19 or related to national policy with regard to  
20 vaccinations; correct?

21 A Yes, sir.

22 Q You were on the editorial board for reviewer  
23 of some of the most prestigious journals regarding  
24 vaccines, including the journal Vaccines and

1 Clinical and Vaccine Immunology; correct?

2 A Yes, sir.

3 Q You're a member of the National Academy of  
4 Medicine, which was formerly known as the IOM;  
5 correct?

6 A Yes, sir.

7 Q Okay. And you are the principal investigator  
8 of the CDC's Clinical Immunization Safety  
9 Assessment Network?

10 A Yes, sir.

11 Q Okay. You conducted clinical trials to  
12 support the development for licensure of various  
13 vaccines; right?

14 A Yes, sir.

15 Q Okay. And you spent much of your career  
16 evaluating the safety and effectiveness of  
17 vaccines?

18 A That's correct.

19 Q You're an internationally recognized expert  
20 in vaccinology; correct?

21 A Yes, sir.

22 Q The medical textbook on vaccines is called  
23 Plotkin's Vaccines; correct?

24 A Yes, sir.

1 Q And it's got four names on the front of it;  
2 right?

3 A Yes, sir.

4 Q Okay. And you're -- what are those four  
5 names?

6 A Well, one of those is my name, so I'm an  
7 associate editor of Plotkin's Vaccine textbook.

8 Q And the other three individuals?

9 A As is Dr. Paul Offit, as is Dr. Walt  
10 Orenstein, and Stanley Plotkin is still an active  
11 member of that as well, and myself.

12 Q What's the name of the plaintiff in this  
13 case?

14 A Mr. Hazlehurst.

15 Q Okay. And what's the name of his child?

16 A I think his first name is William, but I  
17 think he goes by Yates.

18 Q Okay. Have you ever physically examined  
19 Yates?

20 A No, sir, I have not.

21 Q Have you ever met Yates?

22 A No, sir, I have not.

23 Q Is it your opinion that vaccines Yates  
24 received played a role in his -- no, a role in his



1 autism?

2 A I -- I'm of the opinion his vaccines played  
3 no role in his autism.

4 Q Is it your opinion that the vaccines Yates  
5 received collectively played no role in his  
6 autism?

7 A I believe that none of the vaccines played a  
8 role in his autism.

9 Q Neither individually, nor collectively?

10 A Neither individually, nor collectively.

11 Q Okay. What vaccines did Yates receive?

12 A He received a number of vaccines. I have his  
13 vaccine record here. I can read it for you. He  
14 received a DTP vacc -- DTaP vaccine, he received  
15 Hib vaccines, he received Prevnar vaccines, he  
16 received IPV vaccines, he received hepatitis B  
17 vaccines, he received MMR vaccines, and he  
18 received varicella vaccine.

19 Q Okay. Thank you. Who manufactures the  
20 varicella vaccine that Yates received?

21 A Merck.

22 Q Okay. And the MMR vaccine?

23 A Merck.

24 Q Okay. And the hepatitis B vaccine?

1 A There are two different manufacturers. Do  
2 you want me to look? I can read it. It's right  
3 here. I don't -- I don't --

4 Q Fine, please.

5 A SKB or GSK, SmithKline Beecham.

6 Q SKB stands for SmithKline Beecham?

7 A Correct.

8 Q And it -- you said or GSK because it became  
9 part of GSK; correct?

10 A That's correct.

11 Q Okay. And then the IPV vaccine he received?

12 A The IPV was from Connaught.

13 Q And that was merged into what company?

14 A Well, it's an international company now, and  
15 it -- it is part of an international  
16 conglomerative with Connaught and --

17 Q Sanofi; correct?

18 A Sanofi, yeah. Sanofi Pasteur, sorry.

19 Q No, no problem. And the brand name of the  
20 vaccine is IPOL; correct?

21 A Yeah, I believe so. It's just written down  
22 as the lot number and the name, but yeah.

23 Q Yeah. And the brand name for the HepB  
24 vaccine is Engerix-B; right?

1 A I guess, yeah.

2 Q Is it -- is it -- is that right?

3 A I believe so. I -- I don't -- yeah. I  
4 believe so. I -- I don't have the package inserts  
5 in front of me.

6 Q No, that's okay. I mean, it's -- I know,  
7 it's not uncommon that -- you know, most  
8 pediatricians and doctors don't -- you know, they  
9 typically refer to it by the manufacturer and not  
10 by the brand name. I -- but I just want to  
11 develop a complete record. So, right, SKB and  
12 GSK, they've got Engerix-B, right, and then Sanofi  
13 has a Hep -- excuse me, Merck has a HepB product.  
14 As you said, there were two. Engerix-B would be  
15 the one that's sold by GSK, formerly SKB; correct?

16 A Yes, sir.

17 Q Okay. By the way, the official brand name  
18 for the MMR vaccine is MMR2; correct?

19 A Yes, but I don't know whether the MMR2 was --  
20 was this -- whether MMR2 was what was given here  
21 or not. Let's see.

22 Q Wasn't MMR2 licensed in 1978?

23 A I don't know, sir, the exact year that it was  
24 licensed.

1 Q Okay. Well, take a look. If you think it  
2 might be the initial -- the first MMR, let me  
3 know.

4 A The MMR, it says MMR number one, but I think  
5 what that means is that they're -- they're just  
6 noting that there was the first MMR that was  
7 given. The -- the varicella vaccine, it says it's  
8 Merck here, and let's see the measles, it doesn't  
9 say the exact name.

10 Q That's all right. The initial MMR had a  
11 different rubella component; correct?

12 A I believe so.

13 Q If you --

14 A I'm not --

15 Q Go ahead.

16 A I'm not sure exactly what the difference is.

17 Q Okay. If you don't know, then say you don't  
18 know. That's fine.

19 A I do not know.

20 Q Okay. Are you aware that the initial MMR  
21 vaccine was licensed in 1971?

22 A I didn't know the exact year it was licensed,  
23 sir.

24 Q Okay. Are you aware that the initial MMR was

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

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

6 Q Okay. Yates received his MMR in the year  
7 2001; correct?

8 A That is correct, sir.

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

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

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

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

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

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

6 A Correct.

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

10 A Yes, sir.

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

13 A Yes, sir.

14 Q And who manufactured the Prevnar vaccine?

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

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

20 A Lederle. Wyeth Lederle, yes.

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

1 A That's correct, sir.

2 Q Okay. And the initial Prevnar was called  
3 Prevnar or sometimes referred to as Prevnar 7;  
4 correct?

5 A That's correct, because there were seven of  
6 the -- of the 100 serotypes of the pneumococcal  
7 organism, there were seven that caused most  
8 disease, so those were the vaccines that were  
9 included in this, the Prevnar 7. It currently now  
10 is 13, and there are efforts being made to make it  
11 20.

12 Q Right, because they're finding serotype  
13 replacement, right, meaning these serotypes are  
14 not in the vaccine, they're becoming more  
15 prominent as the older serotypes are being pushed  
16 out; correct?

17 A Correct.

18 Q Okay. Then you said he received a Hib  
19 vaccine.

20 A Uh-huh.

21 Q Well, who manufactured that one?

22 A There are several different kinds of Hib  
23 vaccines. The one that he received were Lederle.

24 Q Right.

1 A Because on the -- their differences are in  
2 what they are conjugated to, which --

3 Q Right.

4 A -- are -- what the capsular polysaccharides  
5 are conjugated to.

6 Q Okay. So Wyeth Lederle is the manufacturer  
7 of that vaccine and it was called HibTITER;  
8 correct?

9 A Correct.

10 Q Okay. And finally, he received a DTaP  
11 vaccine. And who manufactured that?

12 A That -- he received Tdap -- or excuse me,  
13 DTaP. It was Infanrix, which is GSK.

14 Q And at the time he received it though, it  
15 was -- it was by -- sold by Wyeth Lederle;  
16 correct?

17 A No, it wasn't, because it says Infanrix, and  
18 Infanrix is all -- is made by GSK. All of the GSK  
19 vaccines have rix at the end because they are all  
20 made in Rixensart, Netherlands, and so Infanrix  
21 was made by GSK at Rixensart.

22 Q Do you see in Yates' medical records it says  
23 Lederle next to the manufacturer of his DTaP  
24 vaccine?



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

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

10 A There is one -- there is one DTaP number one  
11 that says that it was made by Lederle, so that's  
12 4/07, so it looks like the first dose -- again,  
13 it -- it -- well, it looks -- it says on 4/7, 6/6,  
14 8/16 that the vaccine was made by Infanrix, and  
15 then there is one place where it says the DTaP was  
16 made by Lederle.

17 Q Okay. Are you looking at his --

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

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

1 A I'm looking at the handwritten and I'm also  
2 looking at a typed immunization record.

3 Q All right.

4 A So I'm looking at two different records.

5 Q Okay, understood. Okay. And you're correct,  
6 the first dose says Lederle and the other doses  
7 say SKB next to them, which became  
8 GlaxoSmithKline, as we talked about. Okay.

9 A No --

10 Q All right.

11 A -- SKB doesn't -- no, SKB doesn't become  
12 GlaxoSmithKline. SKB is GSK, and GSK makes  
13 Infanrix, and Infanrix is made in Rixensart, and  
14 it's never been a part of Lederle.

15 Q Perfect. Okay, great. Okay. So those are  
16 the seven vaccines, and I think we've established  
17 who made them, what their brand names are. With  
18 that, we'll move on. At what age -- what age did  
19 Yates receive his first vaccine?

20 THE VIDEOGRAPHER: Excuse me,  
21 Dr. Edwards, I don't think we -- did we hear that?

22 Q (By Mr. Siri) Oh, Dr. Edwards, you're muted.

23 A So, I'm sorry, would you ask the question  
24 again?

1 Q No problem. At what age did Yates receive  
2 his first vaccine?

3 A He received his first DTaP vaccine and his  
4 Hib and his IPV slightly less than two months of  
5 age.

6 Q Okay. And at what age did he receive his  
7 last vaccine?

8 A The last vaccine that I have record of was  
9 received on -- let's see. The last -- let's see.  
10 It would have been -- the last vaccine I have a  
11 record of would have been the varicella vaccine,  
12 which was 8/17/01. Now, whether there was  
13 another -- you know, that -- that's the  
14 immunization record that I have here.

15 Q Right. Based on the immunization records you  
16 have, the last vaccine was on August 17, 2001, and  
17 that would have made him around 18 months old;  
18 correct?

19 A That's correct.

20 Q Okay. Have you -- have you received any  
21 payments from Merck?

22 A I have served on one advisory board and I  
23 received some payments from Merck, but the  
24 advisory board -- I am not on the advisory board

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

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

6 A That is correct, sir.

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

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

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

24 A That is correct, sir.

1 Q And that's why it's often referred to as an  
2 independent DSMB as well; correct?

3 A That is correct.

4 Q Okay. And so what you're saying is you're  
5 going to be on the independent DSMB for one of the  
6 clinical trials that Merck is going to be  
7 conducting and that it will then, you know -- will  
8 you try to -- which clinical trial it will then --  
9 it hopes to submit to the FDA to license a  
10 product; correct?

11 A Well, that would be the ultimate goal of the  
12 evaluation of a vaccine would be that it would be  
13 licensed.

14 Q And this independent DSMB that you'll be  
15 sitting on, is this for a COVID vaccine?

16 A No. I'm actually on a number of data safety  
17 and monitoring committees. I'm on a COVID vaccine  
18 safe -- DSMB for Pfizer, I'm on an NIH DSMB for  
19 the use of monoclonal antibodies for the  
20 prevention of COVID infections, and I'm on an  
21 international DSMB from the Coalition for Epidemic  
22 Preparedness for a number of vaccines that are  
23 being studied in developing countries.

24 Q Okay. So for Pfizer, it's -- that's for the

1 COVID vaccine they're developing?

2 A That is correct.

3 Q That's the one that they're doing in  
4 conjunction with -- who was that?

5 A With a German manufacturer.

6 Q Is that BioNet?

7 A Yes, sir.

8 Q That's going to be an mRNA vaccine?

9 A It is an mRNA vaccine.

10 Q And the board, these independent DSMBs that  
11 you're sitting on, you said, for the -- outside of  
12 the U.S., are these also for vaccines?

13 A Yes, sir, they're for COVID vaccines.

14 Q They're all for COVID vaccines?

15 A Yes.

16 Q And which company's products are under review  
17 in those DSMBs?

18 A Oh, there --

19 Q Are the --

20 A There are a number of different companies  
21 that are being evaluated in that regard. We go  
22 over all of them. The one that I'm specifically  
23 working mostly with is an OVO, the DNA vaccine.

24 Q Okay. Okay. So going back to my specific

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

3 A I have received payments from Merck.

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

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

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

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

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

1 question where there's no privilege.

2 MR. SANDERS: It's not discoverable.

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

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

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

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

24 A Is --



1 Q Go ahead.

2 A I don't have an attorney for this case. I am  
3 simply being asked to be an expert witness.

4 Q That's right.

5 A I have -- I have -- have worked for some  
6 companies. I've worked for a number of companies,  
7 but not extensively and not until recently, and at  
8 the time that I was -- that these events happened,  
9 I was not -- I was not at all -- had not at all  
10 been paid to do anything for these companies, and  
11 I -- I do have a lot of expertise, I have a lot of  
12 experience, and they call upon me to provide  
13 information, and I don't do this extensively, but  
14 I -- I -- I do this, and if you -- you know, you  
15 can ask everyone that I'm -- that I -- I have  
16 integrity, I am looked upon as being a -- an  
17 objective, careful scientist, and the amount of  
18 money I have received is trivial.

19 Q Well, then how much was that?

20 MR. SANDERS: Dr. Edwards, you're free  
21 to answer if you want to. If you don't --

22 A You know, I really don't feel --

23 MR. SIRI: All right, counselor, she  
24 already characterized it.

1 Q (By Mr. Siri) You said trivial. How much  
2 was the amount?

3 A \$5,000.

4 Q All right. In your whole career?

5 A I -- yes.

6 Q Okay. How much did you receive, let's say,  
7 last year, in 2019?

8 MR. SANDERS: Same objection.

9 MR. SIRI: Your objection is noted,  
10 counselor, that's fine.

11 Q (By Mr. Siri) Please answer the question,  
12 Dr. Edwards.

13 A You know, I don't feel that my financial  
14 story is relevant to this.

15 Q But that's not for you to judge, so I'm  
16 asking you how much in 2019.

17 MR. SANDERS: Well, who are you --

18 A From Merck?

19 MR. SANDERS: -- asking from, Mr. Siri?

20 A From Merck?

21 Q (By Mr. Siri) From Merck.

22 A About \$5,000.

23 Q Okay. So you're saying the only payments  
24 you've ever received from Merck was in 2019?

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

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

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

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

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

1 Q So in -- so what you're saying is that, for  
2 example, when you were on VRBPAC, you weren't a  
3 consultant to any vaccine manufacturer?

4 A No, sir, that is correct.

5 Q Okay. And you weren't an advisor to any  
6 vaccine company?

7 A No, sir, that is correct.

8 Q And you weren't on any speakers' bureau for  
9 any vaccine company?

10 A I have never been on a speakers' bureau,  
11 thank you.

12 Q Uh-huh. You are currently an advisor to  
13 Merck; correct?

14 A I am not an advisor to Merck. I serve on  
15 their -- on a -- an upcoming DSMB, which has not  
16 yet begun.

17 Q I'm going to share my screen, and let me see  
18 if I can do this without messing it up. Okay.

19 MR. SIRI: Now, I'm going to mark this  
20 as Plaintiff's 1, Ms. Cohen, and I'll proceed. Is  
21 that okay? Okay.

22 THE COURT REPORTER: Yes.

23 MR. SIRI: Okay, thank you.

24 THE COURT REPORTER: Yes, sir.

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

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

7 A Yeah. I wrote it.

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

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

12 Q And this article was published this year;  
13 correct?

14 A That's correct.

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

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

21 Q Okay.

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

1 Q Okay.

2 A They have a pertussis vaccine that is  
3 genetically engineered, and I am an expert for  
4 that. I meet once a year to go over their  
5 portfolio with them with a bunch of other experts,  
6 including Dr. Plotkin.

7 Q Wonderful. Dr. Plotkin is an advisor and a  
8 consultant for all the big vaccine manufacturers.  
9 Now, are you paid fees for being an advisor to  
10 Merck? Were you paid fees for being an advisor to  
11 Merck?

12 A I told you that I was paid to be an advisor  
13 to Merck. I told you how much I was paid.

14 Q Okay. And, oh, so you were only paid in  
15 2019? You weren't paid in 2020?

16 A No, sir, that's correct. I was paid one  
17 time.

18 Q Okay. And you've been a consultant for  
19 Merck; correct?

20 A I am on their -- I'm going to be on their  
21 data safety and monitoring committee, which is  
22 different than being a consultant. I was a  
23 consultant at -- and an advisor at that time on  
24 that paper, but I am currently not.

1 Q Okay. So you were a consultant for Merck.  
2 Is that a yes or a no? I'm sorry.

3 A Yes.

4 Q Okay. And you received personal fees from  
5 Merck; correct?

6 A Yes.

7 Q Okay. And you've received research funding  
8 from Merck; correct?

9 A I -- I'd have to look over my CV to see  
10 whether I have in the past or not. I've done a  
11 lot of vaccine studies, and, you know, some of  
12 those are funded by the NIH. I've had a  
13 long-standing vaccine evaluation contract with  
14 that, but I also have done intermittent trials,  
15 and those are trials that support the nurses and  
16 the people that do the clinical trials, so I don't  
17 know. I would have to look at my CV. I can't  
18 remember for sure. I've been doing this for 40  
19 years.

20 Q Sure. By the way, do you recall how many  
21 lunches Merck paid for you to have in 2019?

22 A I had breakfast and lunch at the meeting. Do  
23 you want me to tell you what I ate?

24 Q I'm just asking if you recall how many

1 lunches in 2019 Merck paid for.

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

4 Q I'm going to share my screen.

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

7 (Whereupon, Exhibit No. 2  
8 was marked to the  
9 testimony of the  
10 witness.)

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

14 A Yes.

15 Q And this is information of Open Payments  
16 Data.

17 A Okay.

18 Q Are you familiar with this --

19 A This --

20 Q -- government database?

21 A No, I'm not, sir.

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



1 consulting fees that they pay to doctors?

2 A No, sir, I am not. This isn't something that  
3 I generally look at, thank you. But thank you for  
4 telling me.

5 Q No problem. So you can see the first two  
6 entries over here from 2019 provide around \$5,000,  
7 as you said. You said you had one meal, but when  
8 you scroll down, we can see there's far more than  
9 one meal; correct?

10 A Well, I don't -- I wasn't -- I was only there  
11 a night and a day, so I don't know how I could  
12 have eaten that much.

13 Q One, two, three --

14 A I'm a little --

15 Q -- four, five, six, seven --

16 A Well, I don't -- I don't -- I mean, I'm not a  
17 very big person, so I -- it's hard for me to  
18 imagine that I could have eaten several hundred  
19 dollars in a day, but I --

20 Q They reported that data. That doesn't mean  
21 they're happening that day.

22 A Okay. Well --

23 Q My picture, I'm pretty skinny, he eats a lot  
24 too. All right. Well, let me ask you -- okay.

1 You said you've never been on any speakers'  
2 bureau; correct?

3 A Not that I know about. I don't know what --  
4 I mean, I've given lectures for people that have  
5 asked me that maybe they said -- have had paid by  
6 a company, but I'm not on a speakers' bureau.

7 Q And what years were you sitting on VRBPAC?

8 A 2016 to 2018, I believe.

9 Q And weren't you also on VRBPAC between the  
10 years of 1996 and 2000?

11 A I believe so.

12 Q That's what it says on your CV. Would you  
13 like me to pull it up?

14 A Okay. No, I hope that you're being honest.

15 Q Well, I -- let's -- like, we can pull it up  
16 then, if you'd like.

17 A No, that's fine. That's fine.

18 Q Okay. I'm going to share my screen again.

19 A I think you do need to understand that  
20 sometimes people are asked to speak at various  
21 places, and it's not always clear how the  
22 financing for those places have arrived, so often,  
23 you know, people will ask me to come speak, and  
24 I'm not quite sure exactly how the compensation

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

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

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

8 Q Uh-huh. It was listed --

9 A Okay.

10 Q -- on your CV as well.

11 A Okay. Then I probably wrote it.

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

14 A Yeah.

15 Q And it was published in Pediatrics in Review?

16 A Yes, sir.

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

19 A Yes, sir.

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

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

24 Q Okay. Go down to the disclosures in this

1 article.

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

4 (Whereupon, Exhibit No. 3  
5 was marked to the  
6 testimony of the  
7 witness.)

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

10 A Yes, sir, I do.

11 Q Okay. Can you read that, please?

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

16 Q Okay. And this is from 1998; correct?

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

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

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

1 I'm sorry, I did not remember that.

2 Q And you said before this past year you didn't  
3 have involvement, you know, as a consultant with  
4 pharmaceutical -- any pharmaceutical company.

5 Does this refresh your memory that, in fact, you  
6 did have -- were a consultant for pharmaceutical  
7 companies before this past year? Let me -- let me  
8 ask it to you this way. Let me ask you again.

9 Before last year, have you been a consultant to a  
10 pharmaceutical company?

11 A I -- yes, I have, but I -- what I said before  
12 was I said that I was not a consultant to a  
13 pharmaceutical company when I was on VRBPAC  
14 recently. I hadn't reviewed my status when I was  
15 on VRBPAC before, so again, I'm -- I misspoke, so  
16 you've shown some information here that I was a  
17 consultant for them and that I had -- was on the  
18 speakers' bureau at that time.

19 Q All right. So while you were sitting on  
20 VRBPAC, you were on the speakers' bureau of at  
21 least two companies and a consultant for one of  
22 them; correct?

23 A I would have to look exactly at the dates,  
24 sir, because one of the things about these is that

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

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

6 A Connaught and Lederle-Praxis.

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

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

13 Q Okay.

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

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

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

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

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

1 Q Okay. Let me share the screen again. This  
2 is an article that you were an author on; correct?

3 A Yes, sir.

4 MR. SIRI: I'm going to mark this as  
5 Plaintiff's 4.

6 (Whereupon, Exhibit No. 4  
7 was marked to the  
8 testimony of the  
9 witness.)

10 Q (By Mr. Siri) This article is from 2000;  
11 correct?

12 A Yes, sir.

13 Q In the Journal of Pediatrics?

14 A Yes, sir.

15 Q Okay. Can you please read the item in  
16 yellow?

17 A Okay. Dr. Edwards is a consultant for and  
18 has vaccine trial contracts with Pasteur Mérieux  
19 Connaught, SmithKline Beecham, and Wyeth Lederle.  
20 She also gives lectures sponsored by Pasteur  
21 Mérieux Connaught and Wyeth Lederle, so yes, thank  
22 you so much for pointing that out. I didn't  
23 realize that I needed to go back and look for all  
24 of those in the past 40 years, but thank you so

1 much for doing that.

2 Q You're here today to testify about vaccines  
3 given to Yates in 2000 and 2001, and -- correct?

4 A Yes, sir, I am.

5 Q Okay. And including vaccines made by these  
6 specific companies; correct?

7 A Yes.

8 Q And you didn't think that your relationship  
9 with those companies were relevant?

10 A I --

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

13 A -- did not feel that --

14 MR. SANDERS: You can answer.

15 Q (By Mr. Siri) All right. I'll strike the  
16 question. I don't care. Now, were you a  
17 consultant for Sanofi after Connaught merged into  
18 Sanofi?

19 A Well, you seem to be able to find out whether  
20 I am or not, given my papers, so maybe you could  
21 just pull that up. Again, I -- I --

22 Q I'm asking you, were you a consultant for  
23 Sanofi after merging to Connaught?

24 A I don't remember, sir. I'm sorry.



1 Q That's fine. I'm -- if you don't remember,  
2 we can -- that's fine. You're an author in this  
3 article; correct?

4 A Yes, sir, I am.

5 Q It was published in 2005; correct?

6 A Yes, sir.

7 Q In the New England Journal of Medicine;  
8 right?

9 A Yes.

10 Q I'm sorry?

11 A Yes, sir, I am an author on the article,  
12 thank you.

13 Q Okay. Can you kind of read the yellow?

14 A Dr. Cherry and Dr. Edwards report having  
15 received consultation and lecture fees from  
16 GlaxoSmithKline and Pasteur Mérieux and grant  
17 support from Sanofi Pasteur.

18 Q Okay. So you were a consultant for Sanofi in  
19 2005; correct?

20 A That's what it says there, thank you.

21 Q Okay. And you received payments from Sanofi?

22 A I don't know what I received there. I guess  
23 I received lecture fees, so fees generally mean  
24 some money, so yes, I guess I did.

1 Q All right. And so -- and lecture fees  
2 usually means you're on the speakers' bureau;  
3 correct?

4 A Not necessarily at all, sir, thank you.

5 Q And you've received research funding from  
6 Sanofi through the years; correct?

7 A Yes, sir, I have.

8 Q Okay. Have you ever taken trips that were  
9 paid for by Sanofi?

10 A I have gone to meetings where I have been  
11 asked to participate in the conference and to  
12 provide information to do lectures and they have  
13 paid for my travel to those meetings, yes.

14 Q Okay. And where did these -- where did you  
15 go on these trips that Sanofi paid for?

16 A It depends to where the meeting was held. I  
17 would go to where they were held. Sanofi -- you  
18 know, Pasteur Mérieux has an office in France, so  
19 sometimes the meetings would be in France, and,  
20 you know, I was on a DSMB for a pertussis trial in  
21 the -- that was done in Senegal in West Africa in  
22 the 1990s. They -- for Pasteur, they paid me to  
23 go to Senegal, so I'm not taking pleasure trips  
24 that -- but I -- I'm -- what they're asking me to

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

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

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

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

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

17 Q And have they typically been about pertussis?

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

1 Q And Sanofi sells pertussis vaccines; correct?

2 A They do.

3 Q And after these meetings in these various  
4 foreign locations, there would often be a paper  
5 that would be published with regard to what  
6 transpired at the meeting; correct?

7 A Sometimes they would be, sometimes they would  
8 not be.

9 Q Isn't it true that when their papers are  
10 published, they almost universally call for  
11 expanding the use of pertussis vaccine or  
12 otherwise increasing pertussis vaccination rates?

13 A The articles that are generated, if my name  
14 is on them, must pass my scientific review, so if  
15 science is overstated or inappropriately stated, I  
16 would not put my name to that paper. I think that  
17 they're -- they're -- yeah.

18 Q I'm going to share my screen here for a  
19 second, and then we'll come back to the trips  
20 because -- we'll finish up that topic. Are you  
21 familiar with this -- with this paper?

22 A Yes, I am, sir.

23 Q Okay. This is a paper from Carnegie Mellon  
24 on a study on bias and physicians accepting money,

1 which was published by the AMA; correct?

2 A I can't see the lower publication.

3 Q Right there, American Medical Association.

4 A It looks like a JAMA editorial, yep.

5 Q Let me -- I'm going to read -- I'm going to  
6 read a portion of this and then ask you a  
7 question; okay?

8 A Yeah, I'm perfectly capable of reading as  
9 well, sir.

10 Q That's okay. I'll read it. The medical  
11 literature dealing with conflicts of interest  
12 bears similarities to the social science  
13 literature reviewed herein. Like the participants  
14 in the studies who did not view themselves as  
15 biased, physicians typically report that they are  
16 not biased by financial arrangements with  
17 pharmaceutical companies, although a large body of  
18 research suggests that they are. Although most  
19 physicians do not perceive themselves as biased,  
20 they do admit that conflicts of interest might  
21 compromise other physicians' decisions. A recent  
22 study of medical residents found that 61 percent  
23 reported that, quote, promotions don't influence  
24 my practice, end quote, while only 16 percent

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

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

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

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

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

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

1 Q Okay. I'm just -- I'm just trying to create  
2 a full record of what your interactions were with  
3 the companies that made the vaccines that my  
4 clients received. It's just -- this is typical of  
5 what occurs when an expert comes into a case.

6 Now, I asked you before, has Sanofi paid for  
7 your -- a trip that you took to Ireland in 2014?

8 A I don't know, sir. I can't remember.

9 Q All right.

10 A I've been, you know, all over the world, and  
11 I don't know. I think if they -- if they did, it  
12 was because I was going to go to a meeting to talk  
13 about a disease that they have an interest in --

14 Q Okay.

15 A -- because I'm an expert and they want me to  
16 be there because what I say is important and  
17 honest and noteworthy.

18 Q Is there somebody in the room with you,  
19 Dr. Edwards?

20 A My husband passes through. We're -- we're  
21 home.

22 Q Is there anybody who's assisting you in  
23 answering these questions, Dr. Edwards?

24 A No, sir. No, sir, there is not.

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

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

6 MR. SANDERS: I believe it's 5.

7 MR. SIRI: 5, thank you.

8 (Whereupon, Exhibit No. 5  
9 was marked to the  
10 testimony of the  
11 witness.)

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

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

24 Q Right. So this was six years ago though;



1 right?

2 A I thought it said 4 -- 2014.

3 Q Right. But you -- 2014 we should --

4 A About six -- yeah, six years ago. Yeah, six  
5 years ago.

6 Q So that, so you're saying, was a while ago.

7 Okay. Why don't -- let's -- what about in 2015,  
8 maybe that's sooner, do you recall if Sanofi paid  
9 for a trip for you to go to Amsterdam, Netherlands  
10 in 2015?

11 A There was a meeting in Amsterdam. It was  
12 about maternal immunizations, and I -- I don't  
13 remember who paid for me to go, but if you have  
14 records that it was Sanofi, then that's probably  
15 what happened.

16 MR. SIRI: I'm going to mark this as the  
17 next exhibit. That will be number 6.

18 (Whereupon, Exhibit No. 6  
19 was marked to the  
20 testimony of the  
21 witness.)

22 Q (By Mr. Siri) It says travel to Amsterdam in  
23 the amount of \$4,400, paid for by Sanofi; correct?

24 A That's what it says, sir.

1 Q All right. And do you recall that Sanofi  
2 paid for a trip for you to go to Cancún, Mexico in  
3 2017, which would have been three years ago?

4 A Yes, there was a pertussis meeting in Cancún.

5 Q Okay. And that -- and Sanofi paid for you to  
6 go to that meeting as well; correct?

7 A Yes, sir, they paid for my way to go to that  
8 meeting.

9 Q Okay.

10 A This is -- these are airfare and hotel room.  
11 There were no -- I did not accept any honorarium.

12 Q Uh-huh. Okay. The trip to Ireland, that was  
13 about pertussis?

14 A Yes, sir.

15 Q Okay. And -- and it was about promoting the  
16 use of pertussis vaccines; correct?

17 A It was about the appropriate use of pertussis  
18 vaccine, and -- yes, the appropriate use of  
19 pertussis vaccine.

20 Q Okay. To help increase pertussis vaccination  
21 rates; correct?

22 A It focused a lot on -- on the burden of  
23 pertussis in adolescents and babies. We -- we --  
24 because there were still a lot of children that

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

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

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

1 Q Okay.

2 A -- to reduce the burden of pertussis.

3 Q So these meetings collectively were about  
4 increasing vaccination of pertussis in pregnant  
5 women and in adolescents; correct?

6 A Yes.

7 Q When I said pertussis, I meant pertussis  
8 vaccination; right? You understood that?

9 A I presumed that's what you meant.

10 Q Thank you. Okay. And through the years,  
11 pertussis has paid for many meals that you've had;  
12 correct?

13 A Pertussis has -- I have spent a lot of my  
14 professional life working on pertussis, and I -- I  
15 started the initial trials that -- that compared  
16 the new vaccines to the old, and so pertussis,  
17 I've spent a lot of time working on pertussis.

18 Q So is the answer yes?

19 A What was your question again? I'm sorry.

20 Q I said, through the years has -- isn't it  
21 true that Sanofi has paid for many meals that  
22 you've had?

23 A Sanofi has paid for some food that I have  
24 eaten through the years, yes, thank you.

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

3 (Whereupon, Exhibit No. 7  
4 was marked to the  
5 testimony of the  
6 witness.)

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

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

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

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

23 (Brief recess.)

24 THE VIDEOGRAPHER: All right. We're

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

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

3 THE VIDEOGRAPHER: Oh, okay. I'm sorry.

4 Well, that would be good. I thought he -- let's  
5 see. I'm sorry. He went off and I had to admit  
6 him.

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

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

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

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

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

18 A Yes, it is.

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

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

1 not --

2 Q Yeah.

3 A -- a big eater, and so I have no idea  
4 about --

5 Q Yeah.

6 A -- what that cost was for.

7 Q Sure.

8 A Maybe it was wrong. You know, maybe it  
9 was -- you know, but I don't know. I cannot  
10 comment on that specifically.

11 Q Ahh, I gotcha. You think all of these  
12 charges -- well, strike that. All right. I  
13 was -- you know, having seen your profile picture,  
14 I was curious what -- I mean, I've eaten at Nobu,  
15 and I -- I'm a big eater, I never hit 300 bucks.  
16 Okay.

17 A I think that -- you know, I don't think you  
18 need to say that. I think that we -- I don't know  
19 the -- the content of that. I -- I don't know,  
20 and I think that I'm a very frugal person. Again,  
21 you know nothing about me as a person.

22 Q That's true. That's why we're here today to  
23 do is learn about it, and you know, you'll have  
24 your -- you know, the other side will have a

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

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

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

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

14 Q Under here it says personal fees; correct?

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



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

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

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

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

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

15 Q It's not on this form.

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

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

21 A Yes, sir, I do recall that.

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

1 for SmithKline Beecham; correct?

2 A At that time, that was the case, but what  
3 happens with these forms that you just went over  
4 is there is a time frame. It's not for 40 years.  
5 It's within a time span, so that was -- that  
6 article in the New England Journal of Medicine was  
7 a commentary about meningococcal vaccine that was  
8 published in 2019.

9 Q All right.

10 A So --

11 Q So far we've seen a -- you know, that you  
12 were a consultant for a pharma company in 1998,  
13 we've seen an article that you were a consultant  
14 in 2000, we've seen one from 2005, we've seen one  
15 from 2 -- 2020, and I think there was one other  
16 year; correct?

17 A You have shown a number of articles that list  
18 the conflicts, which I have provided.

19 Q Okay. Do you deny that those are accurate  
20 disclosures?

21 A No, they are not -- I do not deny that they  
22 are not. They are -- all right. They -- I --  
23 they published them so they are accurate.

24 Q Okay. While you were a consultant for SKB,

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

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

6 Q Absolutely.

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

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

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

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

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

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

22 A Yes, sir.

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

1 consultant for SmithKline Beecham; correct?

2 A Yes.

3 Q Okay. And then your -- your CV also  
4 discloses that you were conducting a trial for  
5 them at that same time in 2000; correct?

6 A If -- again, my CV says that and that's what  
7 it says here too. So again, I can't remember all  
8 of the trials that I've conducted for -- you know,  
9 for 40 years.

10 Q You were also a consultant for GSK after SKB  
11 merged with GSK; correct?

12 A Perhaps. I -- I don't know. Why don't you  
13 give me the specific examples or show me the paper  
14 so that you can confirm that's what I did.

15 Q So are the only industry positions,  
16 consultantships, adviserships fees that you  
17 believe you're going to recall during this  
18 deposition are ones that I can specifically prove?

19 A Sir, I am going to base my testimony on what  
20 I know to be medically factual. I'm going to use  
21 the literature that exists to discuss that, and if  
22 you -- you know, however you want to --

23 Q Right.

24 A -- to take that, then obviously that's how

1 you will do that.

2 Q So does that mean that you -- it doesn't  
3 answer my question. My question was, you know, do  
4 you believe the only conflicts that you have with  
5 pharmaceutical companies are ones -- the only  
6 conflict -- strike that. Do you believe the only  
7 conflicts with pharmaceutical companies that you  
8 will be able to recall today are ones that I can  
9 specifically prove?

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

12 A Sir, I'm happy to go through my CV with you.

13 Q (By Mr. Siri) Okay.

14 A I'm happy to go through the papers with you.  
15 I am happy to -- I obviously --

16 Q It's not a complicated question. I mean, I'm  
17 just asking you do you think you'll be able to  
18 recall any conflicts that you have with  
19 pharmaceutical companies today at all without a  
20 document being presented to you?

21 A I've listed several conflicts that I told you  
22 about.

23 Q Well, only after I've presented the documents  
24 to you, so, you know, this would go a lot quicker

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

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

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

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

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

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

18 Q Okay.

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

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

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

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

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

7 Q And this article was from 2019; correct?

8 A Right.

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

11 A That's correct, sir.

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

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

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

20 A Yes.

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

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

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

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

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



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

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

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

8 A Yes, sir, I can. Right there.

9 Q Okay. And this is from 2005; correct?

10 A I don't know. I --

11 Q Bottom right corner. Can you see that?

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

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

18 A Yeah. You've --

19 Q You're an author of this article?

20 A Yeah, that was Exhibit 1, I think.

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

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

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

16 Q Yeah.

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

18 Q Okay.

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

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

24 MR. SANDERS: Well --

1 Q (By Mr. Siri) -- that other stuff then.

2 MR. SANDERS: -- Mr. Siri, you do need  
3 to let her finish though her answers.

4 MR. SIRI: I respect that. I do. I  
5 just don't want to run out of time, and when she's  
6 going off on a -- on a -- you know, a bit of a  
7 tangent, respectfully, I just want to be efficient  
8 about it. I wouldn't want to have to go over to  
9 another day. Okay. So but absolutely, I -- I do  
10 certainly want to let her finish and I do want to  
11 get her complete answers. I agree with that.

12 Q (By Mr. Siri) Now, if you'll take a look at  
13 this article. I think we looked at this one  
14 earlier. All right. Just in case we didn't, this  
15 is your name, you're an author of this article;  
16 correct?

17 A Yes, sir. We just looked at this article.  
18 I --

19 Q Right. Now, it says you're on the advisory  
20 board of GSK; correct? And what is -- what is  
21 that board?

22 A I'm not -- I'm not exactly sure. I think  
23 that was for a flu -- that was for a flu trial,  
24 I'm pretty sure.

1 Q Okay. And what did you do on the board?

2 A Provided input in terms of the design of a  
3 flu study.

4 Q Okay. Have you ever received research  
5 funding from GSK?

6 A I'm pretty sure that I have, but again, I  
7 can't -- we could look at -- it's on the CV if I  
8 have.

9 Q Were you on a speakers' bureau for Wyeth  
10 Leder --

11 A Wyeth Lederle?

12 Q Lederle. I'll get that right one of these  
13 times, but no problems with -- yes, were you on a  
14 speakers' bureau for Wyeth Lederle?

15 A I can't recall, but that doesn't mean that I  
16 wasn't, so if you want to show me something else,  
17 I can read it for you.

18 Q We looked at this earlier. Dr. Edwards has  
19 funding for research from Connaught and Wyeth and  
20 Lederle and on their speakers' bureaus.

21 A Yeah, I think this was Exhibit 3 maybe. I  
22 think we've already looked at this.

23 Q Okay. So you were on the speakers' bureau  
24 for Wyeth Lederle?

1 A That's what it says. That's what it says,  
2 sir.

3 Q Okay. And you were a consultant for Wyeth  
4 Lederle; correct?

5 A That's what it says. I can't see it now  
6 because you took it away, but I think that's what  
7 it says. That's okay. I don't -- I think it's --

8 Q Were you a consultant for Wyeth Lederle?

9 A I think that's what it said, although I can't  
10 see because you took it away, but if that's what  
11 it said, then it's true.

12 Q Sorry. Let me show it to you.

13 A Lectures sponsored by Pasteur Mérieux,  
14 Connaught, and Wyeth. So I have delivered --  
15 that's slightly different than a speakers' bureau,  
16 but -- but that's --

17 Q We're not talking about a speakers' bureau  
18 anymore. That was the other exhibit. This one is  
19 about -- I asked you about whether you were a  
20 consultant for Wyeth Lederle.

21 A That's what it said, sir.

22 Q So were you a consultant?

23 A So if that's what it said, yes, that's true.

24 Q You had a contract with Wyeth Lederle for

1 \$255,022 per year from 1996 to 1998 to conduct a  
2 clinical trial for one of its vaccines. Is that  
3 correct?

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

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

17 A Yes.

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

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

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

1 an advisor to Pfizer this year?

2 A As I told you early on, I am on the data  
3 safety and monitoring committee for the Pfizer  
4 COVID-19 vaccine, yes, I am, but I -- yes, I am.

5 Q Are you paid for being an advisor?

6 A I'm paid for the time that I spend in the  
7 DSMB.

8 Q Who pays you?

9 A Pfizer pays me.

10 Q Now, being part of the speakers' bureau for a  
11 pharmaceutical company means you provide  
12 presentations regarding one or more of their  
13 products; correct?

14 A That's what being a -- on a speakers' bureau  
15 usually means, although sometimes the companies  
16 will -- will pay for vaccine -- or lectures about  
17 vaccines that are -- that are more general in  
18 terms of that, but -- but whenever I'm on a  
19 speakers' bureau, what I speak is my work. I do  
20 not allow anyone to make changes or alterations to  
21 what I say.

22 Q Are you familiar with the article entitled  
23 Academic Freedom and the Management of Promotional  
24 Speaking at Academic Medical Centers published out

1 of Tufts University School of Medicine?

2 A I think that I've read it, but I haven't  
3 recently reviewed it, thank you.

4 Q Let's take a look at it.

5 (Brief interruption in  
6 the proceedings.)

7 Q (By Mr. Siri) Dr. Edwards, who were you just  
8 speaking with?

9 A My husband asked me a question. I'm sorry, I  
10 won't --

11 Q No, that's okay. That's okay.

12 A He said --

13 Q I was just curious. It's fine.

14 A He has a telemedicine appointment, and I --  
15 he just asked me a question, so I'm sorry, I  
16 will be --

17 Q No, that's -- that's okay. I'm just -- just  
18 wondering because -- okay. So this was -- this is  
19 an article, I read the title before, and it was  
20 written by an associate professor of public health  
21 and community medicine and the assistant dean for  
22 conflicts of interest administration of Tufts  
23 University School of Medicine; correct?

24 A That's what it says, yes.



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

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

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

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

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

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

24 MR. SANDERS: Yeah, if you want to make

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

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

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

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

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

15 Q So is it --

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

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

1 A That's what's required, yes. Now, you know,  
2 whether there's one presentation that I have  
3 forgotten to do it, I -- you know, I can't say for  
4 that. I've done hundreds of these.

5 Q You're saying there might be some of them  
6 that you forgot to do it?

7 A There may be. Goodness, yes, there may be  
8 one or two or -- you know, I -- you know,  
9 obviously I am -- yeah, but I -- that's the goal  
10 is to have the title slide, to have the conflicts,  
11 and then to have the goal of the presentation.  
12 That's generally the format of my slides.

13 Q And the most important conflicts to disclose  
14 are typically ones with pharmaceutical companies  
15 whose products are implicated by the presentation;  
16 correct?

17 A That's correct, sir.

18 Q Okay. Now --

19 A And I --

20 Q -- let's get back --

21 A Wait, wait, wait, wait, wait. Time out.

22 Q Sure.

23 A So it is also imperative that any kind of  
24 presentation that is provide -- that provides

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

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

18 A Absolutely.

19 Q I'm sorry?

20 A Yes, sir, it is, thank you.

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

1 disclosed; right?

2 A That's correct.

3 Q Okay. Now, we discussed earlier that when an

4 A -- an ACIP votes to -- we discussed earlier

5 about, you know, when an ACIP votes to recommend a

6 childhood vaccine for universal use, you know, the

7 fact that we add it to the childhood immunization

8 schedule, my question is when it's added to the

9 schedule and if a child cannot -- or a parent of a

10 child cannot afford to pay for the vaccine --

11 A I can't hear what you're saying.

12 Q Oh, is that --

13 A The Internet is unstable. I can't understand

14 what you're talk -- I can't --

15 Q No problem. Can you hear me now?

16 A I can't understand your question because the

17 Internet was unstable.

18 Q No problem.

19 MR. SIRI: Rob, can you hear me?

20 THE VIDEOGRAPHER: Yes, Mr. Siri, I can.

21 It may be --

22 MR. SIRI: I'm wondering if it's on

23 Dr. Edwards' side.

24 THE VIDEOGRAPHER: Yeah, it may -- it

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

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

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

7 MR. SIRI: She appears frozen.

8 A I can hear you now. Can you --

9 Q (By Mr. Siri) Okay, great.

10 A -- hear?

11 Q Yes. Okay. Let's see if we can continue.

12 Now, ACIP, when it votes to add a vaccine to the  
13 childhood schedule, it would also vote to include  
14 it in the Vaccine for Children Program typically;  
15 correct?

16 A That's correct.

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

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



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

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

8 A As long as they are VFC eligible.

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

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

16 Q Okay. And you were a member of ACIP from  
17 1991 to 1995; correct?

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

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

23 A That's correct.

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

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

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

11 Q Okay. Let's take a look.

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

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

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

23 Q Okay. So does this look familiar,

24 Dr. Edwards?

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

3   (Whereupon, Exhibit No. 8  
4   was marked to the  
5   testimony of the  
6   witness.)

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

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

18 A     Yeah.

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

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

24 Q     All right. So between 1991 and 2000 while

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

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

7 Q No problem.

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

10 (Whereupon, Exhibit No. 9  
11 was marked to the  
12 testimony of the  
13 witness.)

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

17 A That's true.

18 Q Is there --

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

21 Q Okay. And the varicella vaccine was added?

22 A And we have IPV instead of OPV.

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

1 A Yes.

2 Q And rotavirus was added; correct?

3 A No, there's no rotavirus on here.

4 Hepatitis A was --

5 Q Oh, thank you, thank you, you're right. HepA  
6 vaccine was added?

7 A Yeah, that was for selected areas, however.  
8 That was for the native populations and it was not  
9 universal at that time.

10 Q Right. And then the Hib vaccine was added  
11 four doses; correct?

12 A Correct.

13 Q Are you aware that a June 15, 2000 report of  
14 the United States House of Representatives  
15 Committee and Government Form found that with  
16 regard to VRBPAC, quote, the overwhelming majority  
17 of members, both voting members and consultants,  
18 have substantial ties to the pharmaceutical  
19 industry?

20 A No, I'm not familiar with that document.

21 Q Okay. I assume then you're also not aware  
22 that this report concluded that ACIP reflects,  
23 quote, a system where government officials make  
24 crucial decisions affecting American children

1 without the advice and consent of the government.

2 A The ACIP is --

3 Q I'm just asking if you're aware of that  
4 quote.

5 A I'm sorry, where was that -- where is -- that  
6 quote was in the same article that you just --  
7 okay.

8 Q Yes. It's in this report.

9 MR. SIRI: And let's mark it so that  
10 Dr. Edwards will have an opportunity to review it  
11 before trial.

12 (Whereupon, Exhibit  
13 No. 10 was marked to the  
14 testimony of the  
15 witness.)

16 Q (By Mr. Siri) And so you'll have a chance to  
17 read this document. It's 25 pages, and you can  
18 read what the conflicts of interest and what the  
19 Majority Staff Report to the Committee on  
20 Government Reform, U.S. House of Representatives  
21 found with regard to VRBPAC and ACIP as of  
22 June 15, 2000, which was, you know, at the end of  
23 your tenure at ACIP and VRBPAC, from 1991 to 2000.  
24 Now, are you familiar with a vaccine named

1 RotaShield?

2 A Yes, sir, I am very familiar with RotaShield.

3 Q The RotaShield vaccine was manufactured and  
4 sold by Wyeth Le -- Leder --

5 A Lederle. Wyeth Lederle.

6 Q Lederle. Good God. Lederle. Vaccines in  
7 pediatrics; correct?

8 A Yes, sir, it was.

9 Q Okay. In February of 1998, you were on  
10 VRBPAC and voted to approve RotaShield for  
11 inclusion in the CDC's -- for inclusion -- excuse  
12 me. You were on VRBPAC and voted to recommend  
13 licensure of RotaShield by the FDA; correct?

14 A That is true, sir. I remember that very  
15 clearly.

16 Q Okay. When you voted to approve Wyeth  
17 Lederle's vaccine on VRBPAC, you also had a  
18 contract with Wyeth Lederle for 2,555 and 23 --  
19 \$255,023 per year from 1996 to 1998 for the study  
20 of another of its vaccines. Isn't that correct?

21 A I don't have my CV before me, but that may be  
22 correct. That probably was a pneumococcal vaccine  
23 and not the RotaShield vaccine, but that may be  
24 correct.

1 Q Okay.

2 A I voted for the rotavirus vaccine because it  
3 had an enormous impact on diarrheal disease and  
4 hospitalizations in children in the United States.

5 Q Please strike --

6 A It was licensed. We also had a big  
7 discussion about --

8 Q Dr. Edwards, there's no question pending, so  
9 I -- I've got a lot of material to go through, and  
10 you know, that's not -- we just have to get  
11 through this, and you -- you know, you're -- the  
12 attorney for the other side can ask you questions  
13 about other things, if you'd like. Now, at the  
14 same time, you were -- now, at the same time that  
15 you voted to recommend approval of the Wyeth  
16 Lederle vaccine, you were -- in addition to having  
17 a contract with them for a study, you also were on  
18 the Wyeth Lederle speakers' bureau; correct?

19 MR. SANDERS: You're muted, Dr. Edwards.

20 A I think you -- you showed information that  
21 that was on -- on one of the -- that -- that that  
22 was the case, I guess.

23 Q (By Mr. Siri) And you -- and as you said  
24 earlier, you don't deny that that's the case;



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

3 A That is correct.

4 Q Okay.

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

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

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

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

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

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

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

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

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

14 A Good.

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

17 A Yes, sir, I will, thank you.

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

23 A Yes, sir.

24 Q Would you agree that this threat of liability

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

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

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

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

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

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

1 Q (By Mr. Siri) Okay, that's fine. Would  
2 you -- would you agree that like -- government  
3 regulations are often intended to also help lead  
4 to safer products?

5 A That government regulations are intended for  
6 safer products? Is that your question?

7 Q Right, that government regulations can also  
8 help propel safer products on the market.

9 A Yeah, I think that that -- you know, the FDA  
10 has rigid standards and -- and going through and  
11 reviewing those are important, yes.

12 Q Are you aware that in the early 1980s  
13 pharmaceutical companies were being forced to exit  
14 the vaccine market due to high liability they  
15 faced from their vaccine products?

16 A Yes, sir, I am very aware of that.

17 Q Okay. And we've already discussed earlier  
18 how the 1986 Act provided immunity -- let me ask  
19 you this. Are you aware what court or person  
20 injured by a vaccine can bring a claim?

21 A Yes, I -- my understanding is that the -- the  
22 vaccine court -- that -- that claims need to first  
23 to -- go to the vaccine compensation court, and  
24 then if they are -- if after they're adjudicated

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

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

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

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

13 A That's correct.

14 Q Okay.

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

18 MR. SIRI: Thank you. I appreciate  
19 that.

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

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

1 answer.

2 A I'm not sure that the -- the number or the  
3 majority were table claims. I'm sorry, I don't --

4 Q (By Mr. Siri) That's okay. I -- that's  
5 totally fine. And are you aware that in the  
6 1990s, HHS amended the table such that now  
7 98 percent of the claim -- new claims are  
8 off-table claims?

9 A I am aware of that, yes, sir.

10 Q All right. And as we discussed earlier,  
11 off -- in off-table claims, the injured child must  
12 prove that the vaccine was the cause of the  
13 injury; correct?

14 A The actual determination of causation, I --  
15 I'm not quite sure exactly what the wording is,  
16 and so I would just have to defer to that wording.

17 Q That's fine. So what that would mean, of  
18 course, is that if HHS or any of its agencies  
19 admits or publishes any study that supports that a  
20 vaccine can cause a certain injury, the lawyers  
21 who represented people injured by vaccines would  
22 then use that as proof against HHS in vaccine  
23 court to establish liability; correct?

24 MR. SANDERS: Object to the form of the

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

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

6 Q (By Mr. Siri) No problem.

7 A I just --

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

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

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

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

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

9 A I --

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

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

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

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

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

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



1 that's --

2 Q Right.

3 A -- what you're talking about, yeah. Well,  
4 it's an advisory group that meets intermittently  
5 that advises the compensation system and -- and  
6 the meetings go over what's happening with the  
7 compensation system and any questions or any  
8 concerns that are -- that are going on.

9 Q And it's known as ACCV; correct?

10 A That's right.

11 Q Okay. Let's move on to something else. What  
12 is a vaccine information statement?

13 A The vaccine information statements are  
14 statements that are put together by the Centers  
15 for Disease Control. They're a part of the -- of  
16 the vaccine compensation system and they are --  
17 they are required to be given to -- to the  
18 recipients of the vaccines.

19 Q And they're often referred to as VISs;  
20 correct?

21 A That's correct. That's for vaccine  
22 information statements, yes, VIS.

23 Q Okay. And the CDC develops a VIS for each  
24 vaccine; correct?

1 A It does. It generally does it in  
2 consultation with others to make sure that they're  
3 clear and -- but -- but it does come from the CDC.

4 Q And are you aware that federal law requires  
5 each VIS to explain the risks of each vaccine?

6 A Yes, I'm aware.

7 MR. SANDERS: Object to the form of the  
8 question. You may answer.

9 Q (By Mr. Siri) Okay.

10 A I'm very aware of the content of the VIC --  
11 VIS.

12 Q And -- and only risks that are supported by  
13 available data and information may be included;  
14 correct?

15 A Correct.

16 Q Okay. The CDC routinely denies physicians to  
17 add risks to the VIS for various vaccines when  
18 there isn't evidence to support a causal  
19 relationship; correct?

20 A In order to say an adverse event happens,  
21 there has to be some documentation and  
22 confirmation that it -- that that is correct.

23 Q Right. So the VIS is -- so the CDC's policy  
24 is to only include risks on a VIS where there's

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

3 A That's correct.

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

7 A That's correct, sir.

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

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

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

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

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

20 Q Okay. And this is your profile; correct?

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

23 Q And it provides information about you on this  
24 page?

1 A It does.

2 Q It's intended to tell the public about what  
3 you do, correct, and who you are?

4 A Yes.

5 Q Okay. This profile states that you've  
6 received grants from the NIH; correct?

7 A Yes, sir.

8 Q And it says you've received grants from the  
9 CDC?

10 A Correct.

11 Q It says you're a frequent advisor to the NIH  
12 and the CDC on vaccine policy; correct?

13 A Correct.

14 Q And it states your affiliations to certain  
15 medical societies; correct?

16 A Yes, sir.

17 Q You remember those clearly; right?

18 A Those are pretty straightforward.

19 Q Okay.

20 A You know, I mean that -- some, you know,  
21 provide your funding for -- you know, those are a  
22 little different than individual pharma grants,  
23 so --

24 Q Each of these grants from the CDC and NIH,

1 those also have been by individual grants;  
2 correct?

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

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

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

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

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

10 A Absolutely not.

11 MR. SANDERS: But there --

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

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

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

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

24 A Most of them were one or two years, and

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

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

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

19 Q You've never reviewed this before?

20 A No, sir, I haven't.

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

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

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

3 MR. SIRI: Okay. Thank you.

4 (Whereupon, Exhibit  
5 No. 12 was marked to the  
6 testimony of the  
7 witness.)

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

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

12 THE WITNESS: Craig, was this a --

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

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

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

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



- 1 updated on August 14, 2019?
- 2 A That is correct, sir.
- 3 Q Okay. And this CV is 53 pages long?
- 4 A That's what it says, yep.
- 5 Q Okay. And it discloses your educational
- 6 affiliations; correct?
- 7 A It does.
- 8 Q Did you leave any out?
- 9 A Not that I deliberately -- did -- not that I
- 10 know.
- 11 Q The --
- 12 A My education is up, further up at the top,
- 13 and then -- and then my academic appointments are
- 14 after that.
- 15 Q And then these; right?
- 16 A Yes, sir.
- 17 Q Did you leave any educational affiliations or
- 18 academic appointments out?
- 19 A Not -- not that I know of, no.
- 20 Q Okay. I have almost a full page of honors
- 21 and awards; correct? A whole page of professional
- 22 activities; correct? Almost a full page?
- 23 A Yes, sir.
- 24 Q Okay.

1 A Yes, sir.

2 Q And your educational activities spans --  
3 let's see, it starts on Page 3 and it goes through  
4 4, 5, 6, 7, 8, 9. Would you say you were  
5 meticulous in documenting each one of your  
6 educational activities?

7 A No, I wouldn't. You know, it's -- I also  
8 have a job to do besides to keep my CV up, so I --  
9 there -- there maybe have been others that I  
10 didn't include on there, and their omission was  
11 not in any way deliberate. It's just a lot to  
12 keep all this up.

13 Q And it -- and there's another 40 pages or so  
14 on this CV; right?

15 A Yeah. I have a -- a number -- I have a lot  
16 of publications.

17 Q All right. Your CV does not disclose that  
18 you have been on the speakers' bureau of  
19 pharmaceutical companies; correct?

20 A I don't know, sir, what it -- what it says.

21 Q I --

22 A That's not -- that's not generally part of --  
23 you know, the CV is -- it's --

24 Q If you don't know that, that's fine. Your CV

1 does not disclose you received personal payments  
2 from two companies that sells vaccines; correct?

3 A No, sir, that is not part of the CV. The CV  
4 format is dictated by what the medical center  
5 wants one to include and it's generally used for  
6 purposes of -- of promotion and -- and that as  
7 well. It --

8 Q I'm sorry, who dictates what should be in  
9 your CV?

10 A Well, the format of the CV is generally what  
11 the university has -- has suggested and the  
12 content is, and it's generally driven by -- by  
13 promotions and -- and assessment of one's  
14 scholarly activities.

15 Q When you say promotions, what do you mean?

16 A Promotions from assistant to professor to  
17 full professor.

18 Q Okay. Now, we talked earlier how important,  
19 you know, disclosures are. This CV is intended to  
20 be provided to others, but you're saying your  
21 university policy and your university format  
22 doesn't provide in any way to disclose any  
23 consultancies you had with the pharmaceutical  
24 companies?

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

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

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

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

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

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

1 Q What's the goal of the CV?

2 A As I just commented, it's a document that  
3 puts together your academic portfolio, your  
4 education, your educational outreach, your grant  
5 funding, and your -- and the manuscripts that have  
6 been submitted to peer-reviewed journals.

7 Q And you provided this CV to counsel for the  
8 defendant in this case as part of being an expert  
9 witness; correct?

10 A Yes, sir.

11 Q That was one of the uses of this CV; correct?

12 A I was asked to provide my academic CV, which  
13 is what I did.

14 Q So you were asked specifically to only  
15 provide an academic -- about --

16 A No, I was asked to provide my CV. This is my  
17 CV. I've been providing this CV for 40 years and  
18 people have found it acceptable, so that's what I  
19 sent.

20 Q And nobody has ever asked you about  
21 pharmaceutical affiliations that were left off of  
22 this CV?

23 A No, sir, there --

24 MR. SANDERS: Object to the form of the

1 question. You may answer, Doctor.

2 A You're the first -- you're the first person,  
3 thank you.

4 Q (By Mr. Siri) This is the first case in  
5 which you appeared as an expert witness with  
6 regards to vaccines; correct?

7 A That's correct. I'm not -- I do not usually  
8 do this.

9 Q Okay. On July 29, 2020, you gave a  
10 presentation to ACIP regarding COVID-19 vaccine  
11 safety considerations; correct?

12 A Yes, sir, I did.

13 Q Okay. ACIP is expected to eventually vote  
14 regarding recommending a COVID-19 vaccine;  
15 correct?

16 A Yes, sir, that will be their goal.

17 Q Okay. Your presentation was intended to  
18 educate ACIP voting members about the COVID-19  
19 vaccine safety considerations; correct?

20 A Yes, sir.

21 Q And you began your presentation with a  
22 disclaimer; correct?

23 MR. SANDERS: You're muted, Dr. Edwards.

24 A I don't have my presentation in front of me.

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

2 (Brief pause in the

3 proceedings.)

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

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

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

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

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

15 MR. SIRI: Can everybody hear that?

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

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

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

23 MR. SIRI: Thank you.

24 THE VIDEOGRAPHER: -- it may say

1 accentuate or audio with -- play an audio.

2 MR. SIRI: Yep. I got it. I got it.

3 Thank you. Thank you. I appreciate that.

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

6 (Whereupon, a video clip  
7 was shown.)

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

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

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

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

23 A Not on this disclaimer, no, sir.

24 Q And many of those companies are also



1 developing COVID-19 vaccines; correct?

2 A The con -- they are, but the content of  
3 the -- the content of the talk was really a review  
4 of past information about safety and really about  
5 what was happening with the concerns about safety  
6 signals, so it's -- it appeared to be more  
7 relevant to the CISA contract that I was citing,  
8 and that's why I mentioned that.

9 Q Your presentation, as we discussed, was  
10 intended to help educate the ACIP committee  
11 regarding the safety, potential safety for various  
12 COVID vaccines under development; correct?

13 A That's correct, sir.

14 Q I'm going to play you a short clip from that  
15 meeting, and then I'm going to ask you a question.

16 (Whereupon, an audio clip  
17 was shown.)

18 Q Dr. Edwards, that's you speaking in the  
19 video; correct?

20 A Yes, sir, that is me.

21 Q Okay. And you created a slide that was  
22 presented as part of this presentation?

23 A That's correct, I did.

24 Q Okay. Who decides what the background rate

1 is for each adverse event?

2 A Well, that's something that I'm also working  
3 on very hard with the -- you know, to try and help  
4 and understand. There's -- that is -- is  
5 determined by -- by -- by looking at the medical  
6 records, by looking at large-linked databases,  
7 and -- and trying to assess what that background  
8 rate is, so that is a -- a process that takes a  
9 lot of time and effort and statisticians and  
10 medical record experts and large-linked databases  
11 are addressed, but it can be a daunting effort.

12 Q Does that list get created before -- you  
13 know, like, before the trial starts, is there --  
14 let me -- I asked two questions at once. Doesn't  
15 a list of background rates already exist?

16 A There are a list of background rates. I  
17 think that we, however, have to make sure that  
18 those background rates are relevant. I think  
19 there -- they -- we need to make sure that those  
20 background rates are relevant to the population  
21 that's being studied, and I think that -- that we  
22 need to make sure that the background rates are  
23 relevant to -- to a time when COVID is  
24 circulating, and so there have been a lot of

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

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

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

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

16 A Yeah.

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

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

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

23 A Okay.

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

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

10 A That is the goal.

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

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

1 identified as a cause of the reaction.

2 Q And who decides whether the event is related  
3 to the experimental vaccine under study and  
4 clinical trial?

5 A Well, the assignment is generally by the  
6 investigator, and they -- they relate the adverse  
7 event and then they say that they think it's  
8 related or they think it's not related. I think  
9 that those -- those are -- you know, obviously  
10 they're usually in the -- in the position to do  
11 that most effectively because they have the whole  
12 picture there, but each of those are assessed  
13 individually by a DSMB, and if there's any  
14 question about the assignment of that, then there  
15 could be additional details that are asked for.

16 Q And when you say investigator, you mean  
17 the -- the -- the principal scientist who's  
18 conducting the trial on behalf of a pharmaceutical  
19 company's drug or vaccine that is under review;  
20 correct?

21 A It's the principal investigator, yes.

22 Q Yeah, and the principal investigator is  
23 compensated from the pharmaceutical company whose  
24 drug or vaccine is under review; correct?

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

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

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

18 Q Which are those?

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

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

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

3 A No, sir.

4 Q Oh.

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

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

17 A Yes, sir.

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

20 A That's correct.

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

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



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

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

21 A No, that's not correct.

22 Q Okay.

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

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

3 Q Okay.

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

21 Q Can you repeat the last part of that?

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

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

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

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

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

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

8 A It doesn't relate to the timing.

9 Q Okay.

10 A It relates to a definition.

11 Q Okay.

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

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

1 injury or they're just guidelines generally?

2 A These are guidelines for the definition of  
3 the adverse event. It does not assign causality.

4 Q Okay, understood. It's just to diagnose --  
5 it's just to assess whether or not the person, in  
6 fact, had the adverse events, had claimed to have  
7 occurred?

8 A It is to mix -- it's to assure the certainty  
9 of the diagnosis that you are making.

10 Q All right. And so if -- so if the three  
11 cases, and I'm going back to our example of -- of  
12 Guillain-Barre, were confirmed to, you know, meet  
13 the Brighton collaboration criteria for, in fact,  
14 being Guillain-Barre syndrome, and all three  
15 occurred in the experimental group and none  
16 occurred in the control group, would that be then  
17 used to determine -- to make a conclusion that the  
18 vaccine can cause Guillain-Barre or is there  
19 another process that occurs where that conclusion  
20 can be reached?

21 A I think causation is exceedingly difficult to  
22 prove, and I think one of the issues that you  
23 would need to make sure of is that there were  
24 not -- there was not another reason for that to

1 be -- to -- for Guillain-Barre to occur, so you  
2 have a case that is clearly defined, but the  
3 Brighton collaboration does not say that it is  
4 vaccine related. Now, how do you confirm that a  
5 vaccine causes an adverse event? Well, there are  
6 a couple ways. For instance, when we had polio,  
7 we could confirm that we had vaccine-acquired  
8 polio by isolation of the polio virus from the  
9 spinal fluid of the child that had the paralysis.  
10 We had -- we know that children that have severe  
11 immune deficiencies, which fortunately we're much  
12 better able to diagnose now with newborn  
13 screening, but we know, for instance, that some of  
14 those children would have dissemination of a virus  
15 and cause severe disease such as measles, and  
16 those -- and they would have virus isolated from  
17 their -- their blood or their lungs or their  
18 spinal fluid. So the actual determination of  
19 causation is often the exclusion of other -- other  
20 entities, but unless you have the ability to  
21 actually isolate that virus from a person who's  
22 ill, causation is more difficult to determine.  
23 Q And who makes the determination of whether or  
24 not there's some other potential explanation, for

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

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

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

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

1 certainly a study that has 200,000 children  
2 enrolled into it, which is a rotavirus study, has  
3 a lot more power to detect adverse events  
4 associated with vaccines than a study that enrolls  
5 1,000 people. The 30,000 COVID studies are going  
6 to have a lot greater power to look at adverse  
7 events than the 45 patients that was just reported  
8 in the New England Journal. But because adverse  
9 events may be so rare, it may be necessary to  
10 actually license the vaccine and then do post  
11 licensure studies to look at the rates of adverse  
12 events in that way.

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

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

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

22 A That's correct.

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



1 trial; correct?

2 A Well, I think that in order for a study -- a  
3 pivotal study that may be involved in licensure of  
4 the vaccine, there is a lot of discussion with the  
5 FDA what the control group would be, so if -- you  
6 know, so -- so the easiest control group is a  
7 placebo control group where someone just gives  
8 saline, and that's pretty straightforward, but  
9 that also is problematic because, you know, if  
10 you're giving a reactive vaccine and you're -- and  
11 the people are getting in -- the vaccine and the  
12 placebo group is getting saline and there's no  
13 reaction, then sometimes that can unblind the  
14 individuals in terms of I'm not so sure which --  
15 you know, I got the vaccine, so that -- so we want  
16 people to be blinded for the -- and we also need  
17 to make sure that the vaccine that is being  
18 studied does not have an impact on the disease  
19 you're looking for, so a great example would be  
20 the recent study by the Oxford group with their --  
21 with their adeno vector COVID vaccine, and what --  
22 and what they used in their control group was a  
23 meningococcal vaccine, so the meningococcal  
24 vaccine had reactions associated with it, so

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

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

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

17 Q Right.

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

20 Q Right.

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

1 people who do not receive any active agent.

2 Q And then this way you can actually compare  
3 the reaction rate between those that get the  
4 experimental vaccine and those that essentially  
5 are getting an inert substance; correct?

6 A Correct.

7 Q That's what a placebo is, it's an inert  
8 substance; correct?

9 A Yes.

10 Q Okay. And the pivotal clinical trials which  
11 you mentioned earlier, those are the trials that  
12 the FDA will typically rely upon to license a  
13 vaccine; correct?

14 A Yes, sir.

15 Q Okay. Now, if you were -- if you're going to  
16 design a clinical trial of a vaccine given to  
17 children 18 months or younger, how long would that  
18 clinical trial need to be to determine whether the  
19 vaccine caused autism?

20 A The -- in general, the -- autism is generally  
21 diagnosed somewhere within the first couple years  
22 of life, and -- and I think maybe the mean time is  
23 about two years depending upon the severity, so I  
24 think that that -- however, I think that -- that

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

16 Q You're talking about the Phase 4 trials?

17 A Yes, sir.

18 Q Okay. Post-licensure trial?

19 A That's correct.

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

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

23 Q All right. In 2 -- in 2000, in the year  
24 2000, children were typically diagnosed with

1 autism around four years of age. Is that correct?

2 A The diagnosis is made much -- much earlier  
3 than it used to be, yes.

4 Q Okay. Are you aware that in 2000, the  
5 typical age of diagnosis for autism was around  
6 four years of age?

7 A I don't know what -- the mean age. I -- I  
8 didn't review the literature from 2000 about  
9 autism, about the rates.

10 Q Let me share a study with you. This way you  
11 have it and you can have an opportunity also to  
12 review it for the trial. This is going to be --  
13 do you see the title of this article is Age Of  
14 Diagnosis For Autism: Individual and Community  
15 Factored Across 10 Birth Cohorts?

16 A Yes, sir.

17 Q And I'll scroll down to here, in which we can  
18 see Figure 1 displays the changing age of first  
19 autism diagnosis from the 1992 to 2001 birth  
20 cohorts. Do you see that?

21 A Yes, sir, but I -- you know, I -- I must say  
22 that -- you know, I've -- I've not reviewed this  
23 article, and I certainly will review, so I  
24 don't -- so you have a table and I have no idea

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

3 Q All right.

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

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

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

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

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

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

23 (Whereupon, Exhibit

24 Nos. 13 and 14 were

1 marked to the testimony  
2 of the witness.)

3 Q (By Mr. Siri) Now, for the vaccines  
4 licensed, you know, by the year -- by the year  
5 2000, how many children would you estimate need to  
6 be in those clinical trials to detect whether the  
7 vaccine caused autism by age 18 months and how  
8 long would the trial need to continue after 18  
9 months of age?

10 A I -- I can't give you those numbers off the  
11 top of my head exactly how they would be. And --

12 Q Okay.

13 A -- I think that that -- I think one of the --  
14 you know, when you have a rare event, although,  
15 you know, autism is now felt to be about  
16 1.5 percent of the population, when you have a  
17 rare event, and particularly when it was -- it --  
18 it might have been more difficult to diagnose  
19 earlier, in an earlier time, then I think it takes  
20 larger numbers, but I can't give you that number,  
21 sir, and again, I'm -- I'm not a -- an autism  
22 epidemiologist.

23 Q Okay. But given what you know about clinical  
24 trials, would you agree with me that the clinical

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

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

14 Q All right. The --

15 A Looking for adverse events that are  
16 associated with vaccines.

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

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



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

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

17 A Yes, sir.

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

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

1 understand what I'm saying.

2 Q Sure.

3 A I think that if an adverse event were to  
4 occur associated with vaccines that if it were an  
5 uncommon event and if it were -- if it was not  
6 diagnosed until later, then you would need a  
7 larger number sample size and a longer period to  
8 assess that. I am not saying, however, by  
9 answering yes to your questions that I believe  
10 autism -- that vaccines cause autism, so I just  
11 want to make sure that you understand what I'm  
12 saying.

13 Q I never asked that question. Absolutely. I  
14 think the record is clear on that. I -- I -- we  
15 are not trying to determine -- what I -- what I am  
16 trying to -- and hopefully so we can avoid going  
17 through each of the clinical trials, I am just  
18 trying to establish, and I -- you know, that  
19 because of the number of participants, the period  
20 the safety was reviewed and the control that was  
21 used, none of the pre-licensure clinical trials  
22 showed the vaccines Yates received were designed  
23 or capable of determining whether or not those  
24 products did or did not result in autism.

1 A Did not result in an adverse event.

2 Q The one at issue -- did not result in an  
3 adverse event of autism.

4 THE WITNESS: Mr. Sanders, I think  
5 that -- I want to make sure -- I think I'm  
6 getting -- I think he's trying to make me say  
7 things that I don't believe, so --

8 MR. SANDERS: Okay. Well, just listen  
9 to the --

10 THE WITNESS: How am I supposed to  
11 respond to the same question repeated times?

12 MR. SANDERS: Yeah, I think -- listen to  
13 the question, and if -- if you've already answered  
14 it, you can tell him I've already answered that.

15 Q (By Mr. Siri) All right. Well, so I --  
16 okay. Look, I -- let's -- let's take it piece by  
17 piece then. How long would -- how long would  
18 safety have to be tracked in the clinical trials  
19 relied upon to license the vaccine Yates received  
20 in order for them to have determined whether the  
21 vaccine caused autism?

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

1 A I'm not going to answer it. I've already  
2 answered the question.

3 Q (By Mr. Siri) I don't recall that -- you  
4 have not provided any period of time. Are you  
5 saying you don't know the --

6 A I said --

7 Q -- period of time?

8 A I said --

9 Q Please.

10 A I said that the studies that were involved in  
11 the licensure of MMR did not provide an adequate  
12 number of patients that had been followed for four  
13 years to determine the -- the -- a rare event that  
14 would happen four years after vaccination. That's  
15 what I'm saying.

16 Q Okay. And you consider autism to be a rare  
17 event?

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

20 A Yeah, the -- the CDC reports that the rate is  
21 about 1.5 percent.

22 Q (By Mr. Siri) You -- do you consider autism  
23 to be a rare event when those clinic trials for  
24 MMR occurred?

1 A It --

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

4 A It was a rarer event than it is now.

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

12 A Yes, sir.

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

15 A I am highly experienced conducting clinical  
16 trials.

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

21 A I am.

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

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

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

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

8 A Yes.

9 Q Thank you. All right.

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

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

17 MR. SANDERS: Sure.

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

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

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

1 THE WITNESS: Okay. So we'll meet then  
2 at quarter to twelve. Is that okay?

3 MR. SIRI: That's wonderful.

4 THE WITNESS: Okay, thank you.

5 MR. SIRI: Thank you, everybody.

6 THE VIDEOGRAPHER: All right. We are  
7 off the record at 11:26 a.m.

8 (Brief recess.)

9 THE VIDEOGRAPHER: All right. And we  
10 are back on the record at 11:47 a.m. Central time.

11 Q (By Mr. Siri) Thank you. Dr. Edwards, is  
12 silent transmission of pertussis within families,  
13 has that been demonstrated?

14 A Yes, it has been.

15 Q Okay.

16 A There have been --

17 Q Please continue.

18 A Yes, there has been.

19 Q Okay. Pertussis can be transmitted by  
20 breathing; correct?

21 A It's a respiratory pathogen. It can be  
22 transmitted by droplets.

23 Q Right. As well as by breathing; correct? I  
24 mean, the medical literature support -- had -- it

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

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

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

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



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

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

7 A That's correct and -- yeah.

8 Q It --

9 A That's correct.

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

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

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

23 A So maybe you --

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

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

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

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

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

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

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

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

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

7 A That's correct.

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

11 A Yes, sir.

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

14 A That's correct.

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

18 A That's correct.

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

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

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

1 two adolescent ones were both licensed in 2005;  
2 correct?

3 A I -- I can't remember exactly the year --

4 Q Okay.

5 A -- each of the vaccines are licensed.

6 Q Okay.

7 A Sorry, I can't do that.

8 Q That's fine. Now, pertussis vaccines can  
9 reduce the symptoms of pertussis; right?

10 A That's the goal for a vaccine, that you  
11 reduce the incidents of disease and the symptoms,  
12 so that's correct.

13 Q So the pertussis vaccine can reduce the  
14 symptoms of pertussis; correct?

15 A Yes. It's an effective vaccine.

16 Q Yeah. I was -- I thought that was a  
17 softball. I thought you'd agree with that one.  
18 Okay.

19 A I think that's --

20 Q I thought that was an easy one. All right.

21 A There are no easy questions.

22 Q Yep. Let's keep going. That's fair.  
23 Sometimes. So for decades, the medical orthodoxy  
24 was -- was that the vaccines could also prevent

1 infection and transmission; correct?

2 A Yes.

3 Q Okay. And but, you know, after spending of  
4 decades seeking to eradicate pertussis in first  
5 world countries, using acellular pertussis  
6 vaccine, the scientific community has recently  
7 come to understand that this vaccine can never  
8 accomplish that end; correct?

9 A I think that there are a number of  
10 deficiencies in the current acellular pertussis  
11 vaccine that could be improved upon.

12 Q Does the current pertussis vaccine have  
13 any -- can it exert any herd immunity effect?

14 A Probably, although that's been a little  
15 controversial as well. I think, you know,  
16 obviously we're all discussing herd immunity about  
17 everything, and just like with COVID there are  
18 some controversies about herd immunity. I think  
19 that an immunized community is what you would want  
20 to get, and certainly we know that if a highly --  
21 if a community is highly immunized, there's less  
22 pertussis. If there are a lot of people that are  
23 not immunized, there's more pertussis, so there is  
24 a role for herd immunity. The extent is still a

1 subject of debate.

2 Q And when you say pertussis, you mean the  
3 disease?

4 A Bordetella pertussis disease.

5 Q Right. But the pertussis vaccine, the  
6 scientific community now understands, does not  
7 prevent somebody who's received that vaccine from  
8 becoming infected with Bordetella pertussis and  
9 transmitting the pertussis; correct?

10 A It probably does. I think that we -- that we  
11 see the efficacy of the vaccine in young children,  
12 and it probably persists through the period until  
13 they get their booster. The efficacy of the  
14 pertussis vaccines and studies that we've been  
15 involved in is generally felt about 85 percent.  
16 We also know, however, that with the adolescents,  
17 there appears to be more of a problem with waiving  
18 immunity than we had appreciated before, so that  
19 is one of the areas that we're also working on.  
20 The other issue is I talked about before is  
21 maternal vaccination for prevention of disease in  
22 infants, so we --

23 Q Well, let -- I'd like -- let -- you know,  
24 I -- look, I appreciate, Doctor, that you are very

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

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

13 MS. CHEN: Yes, it's 15.

14 THE VIDEOGRAPHER: Thank you.

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

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

21 A Yes, sir.

22 Q And you're an author on this article?

23 A That's my name.

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

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

3 A That's correct.

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

9 A They were part of the authors, yeah.

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

12 A That's correct.

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

22 A Yes, sir, I certainly do.

23 Q Okay. Oh, sorry. Dr. Edwards?

24 A Yes, sir.



1 Q Okay. I think I froze. I didn't hear your  
2 last -- the answer to the last question.

3 A Yes, I agree that natural infection evokes  
4 both mucosal and systemic immune responses while  
5 acellular vaccines induce only a systemic immune  
6 response. I agree with that statement.

7 Q Okay. And then the next statement, mucosal  
8 immunity is essential to prevent colonization and  
9 transmission of Bordetella pertussis organisms.  
10 Do you agree with that statement?

11 A Yes, I agree with that statement, but it's  
12 not -- it does not exclude the role of systemic  
13 immunity as well.

14 Q Okay. And then the next sentence,  
15 preventative measures such as acellular pertussis  
16 vaccines that do not --

17 A I can't hear you, sir. I think that you're  
18 cutting out. I can't hear you.

19 MR. SANDERS: Mr. Siri, I cannot hear  
20 you either.

21 Q (By Mr. Siri) Let's give it a second. Okay.  
22 All right. Can you hear me now?

23 A Yes, sir.

24 Q Okay. So I was saying, the next sentence

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

6 A Yes.

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

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

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

20 A I --

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

1 study conducted by Warfel at the FDA; correct?

2 A Jason Warfel and Tod Merkel, yes.

3 Q Okay. And in that study, what they did is  
4 they -- they -- they had naive baboons, right,  
5 baboons that had never have been exposed to a  
6 pertussis; correct? They had one group, like, of  
7 naive baboons like that; right?

8 A Yes, sir.

9 Q And then they also had a group of baboons  
10 that had been vaccinated with acellular pertussis  
11 vaccine; correct?

12 A Yes.

13 Q And then -- then they had a third group that  
14 got whole-cell, but let's leave that one out,  
15 and then they got a fourth group of baboons that  
16 got -- that had been -- had had pertussis. They  
17 were convalescent; right?

18 A Yes, sir. I'm really familiar with the  
19 paper. I actually --

20 Q Then they --

21 A -- about it, so --

22 Q Well, what --

23 A So what is your question?

24 Q And all three baboons were then exposed --

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

3 A That's correct, sir.

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

9 A Yes, sir.

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

14 A Yes, sir.

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

19 A That's correct, sir. Yes.

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

1 A That's correct.

2 Q Okay. So I don't understand, how does that  
3 study support that pertussis vaccines -- how does  
4 that study change or add any qualifier to the  
5 statement in this study that acellular pertussis  
6 vaccines do not prevent colonization?

7 A So that's what it said, so --

8 Q Do you agree with that statement?

9 A I agree with that statement, yeah. I agree  
10 with that statement.

11 Q Okay. And then it says, consequently, they,  
12 meaning Bordetella -- excuse me, meaning acellular  
13 pertussis vaccines, do not reduce the circulation  
14 of Bordetella pertussis and do not exert any herd  
15 immunity effect; correct?

16 A It depend -- that's what it says. It depends  
17 on how you define herd immunity. So herd immunity  
18 in this situation prevents transmission from other  
19 people. Herd immunity can also define the  
20 penetrants of a virus or a bacteria in a  
21 population, so we know that in -- that populations  
22 that have very low rates of pertussis have much  
23 higher rates of pertussis disease, and those are  
24 papers that have come from data from California

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

7 Q What I --

8 A What --

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

19 A Yes, sir.

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

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

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

24 Q Look, I understand. You also want to point

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

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

15 Q Okay. Either stayed the same or gotten  
16 shorter?

17 A Yes.

18 Q What do you think, Doctor?

19 A I think both of those statements can be  
20 supported.

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

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



1 and to assist in ways that it can be controlled.

2 We know that most of the global population, we  
3 don't have very good surveillance information on  
4 pertussis in a lot of the global community, so  
5 that's what it's --

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

8 A Yes, sir.

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

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

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

24 A The recommendations for the use of pertussis

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

6 Q So the answer to my last question is yes?

7 A I kind of forgot what the question was.

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

12 A Yes.

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

15 A Yes.

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

18 A Yes.

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

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

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

1 A Yes, sir.

2 Q And those authors -- and those articles  
3 have -- because you're saying you want to reduce  
4 the burden of disease, have argued for expanded  
5 use of pertussis vaccine; correct?

6 A Yes.

7 Q Okay. There's also a group called the  
8 International Consensus Group on Pertussis  
9 Immunization; correct?

10 A I'm not -- I don't -- I don't know that I --  
11 and I hope I'm not a member of that. It's not  
12 something I recall.

13 Q You're not. You're not. You're off the hook  
14 right away. You're not.

15 A Okay.

16 Q That's the -- that's -- you're not aware that  
17 that's the GSK-funded equivalent of the Global  
18 Pertussis Initiative?

19 A No.

20 Q Okay. And the --

21 A Right, I --

22 Q You're not aware they did this -- engaged in  
23 the same type of sponsorship of meetings and --  
24 you know, and articles and so forth to encourage

1 pertussis vaccine?

2 A No, sir.

3 Q Okay. So in 2005, you said earlier you're  
4 not aware that Sanofi and GSK licensed their  
5 pertussis vaccine for adolescents in 2005;  
6 correct?

7 A I'm saying that I don't remember exactly what  
8 year those vaccines were licensed, but --

9 Q Okay.

10 A -- they did license those vaccines.

11 Q Okay. Are you aware that in 2006 the ACIP  
12 voted to add those vaccines to the recommended CDC  
13 childhood immunization schedule?

14 A They were added. I don't know which year  
15 they were added.

16 Q Okay. Okay. Are you -- so I assume you're  
17 not aware that in the ACIP documents in which that  
18 recommendation was made to add those vaccines, 34  
19 of the cited studies to support that  
20 recommendation from ACIP included one or more  
21 members from the Global Pertussis Initiative for  
22 the GSK-funded one?

23 A I think that one of the things -- you know,  
24 why are these people on these advisory boards?

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

3 Q But --

4 A -- for advice or for --

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

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

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

21 A You --

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

1 approximately 3,000 antigens; correct?

2 A Correct.

3 Q All right. The whole-cell pertussis vaccine  
4 that we used to use in the U.S. also had around  
5 3,000 antigens; correct?

6 A Correct.

7 Q The acellular pertussis vaccine has about,  
8 like you said earlier, three or four or five  
9 antigens in it; correct?

10 A Yes.

11 Q They're selected from the pertussis bacteria;  
12 right?

13 A They were selected for their role in disease  
14 prevention --

15 Q Selected to be -- yes. All right. Do you  
16 know what those five antigens are?

17 A Of course. They're pertussis toxin, they're  
18 filamentous hemagglutinin, they're FIM 1, they're  
19 FIM 2, and they're pertactin.

20 Q Okay. Is it FIM 1 or 2 or FIM 2 and 3? Has  
21 that changed over time?

22 A 2 and 3, I'm sorry. I'm -- 2 and 3, not 1  
23 and 2. Sorry.

24 Q That's no problem. I usually start counting

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

11 A Correct.

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

20 A Antibodies to the antigens.

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

24 A That is Dr. Cherry's hypothesis.

1 Q Okay. And that -- and that hypothesis is  
2 known as linked epitope suppression; correct?

3 A Correct.

4 Q But do you agree with that hypothesis?

5 A I'm not sure that it's been shown  
6 definitively. I think it's still a hypothesis.

7 Q Okay.

8 THE VIDEOGRAPHER: Excuse me. Mr. Siri,  
9 if you're done with that screen share, you might  
10 want to take it down.

11 MR. SIRI: Oh, thank you.

12 Q (By Mr. Siri) Okay. There was a time when  
13 immunity to pertussis was thought to be life long;  
14 correct?

15 A Yes, sir.

16 Q That's when adults were reexposed to  
17 pertussis and -- you know, after having it  
18 naturally and --

19 A I can't hear your question, sorry.

20 MR. SANDERS: Mr. Siri, you froze up  
21 again.

22 MR. SIRI: How about now? Hello?

23 THE WITNESS: Yeah.

24 MR. SANDERS: We can hear you again.



1 A I can hear you now. I just couldn't hear the  
2 question, so maybe --

3 Q (By Mr. Siri) No problem. Okay.

4 A Okay.

5 Q I -- given the issues, let's move on to  
6 another topic. Can varicella vaccine cause and  
7 result in pneumonia?

8 A The administration of varicella vaccine in  
9 immunocompromised subjects can result in  
10 pneumonia, yes.

11 Q Okay. What about non-immunocompromised  
12 subjects?

13 A Generally not, although there are always  
14 examples that may be not easy to understand, but  
15 in general, varicella vaccine does not cause  
16 pneumonia in normal healthy people.

17 Q But it -- it can cause pneumonia in normal  
18 healthy people sometimes?

19 A It may. I would -- in order to answer that  
20 definitively, I'd need to look in the literature  
21 or look in theirs.

22 Q Okay. So if -- are you aware that the IOM  
23 report about adverse events from vaccines in 2011  
24 did find a causally -- that the -- that the

1 pneumonia as a result from varicella vaccine was  
2 causally supported?

3 A In normal healthy people or in  
4 immunocompromised?

5 Q I'm not aware of it qualifying it to  
6 immunocompromised.

7 A Well, I would think probably they would do  
8 that, but again, I --

9 Q Okay. Can varicella vaccine cause and result  
10 in encephalitis?

11 A It can, particularly in immunocompromised or  
12 immunodeficient individuals.

13 Q Can varicella vaccine cause an infection of  
14 the brain?

15 A That's what encephalitis is, yes.

16 Q Okay. I didn't -- I just relate to lay talk.  
17 Can varicella vaccine cause and result in  
18 meningitis?

19 A Varicella vaccine in some subjects has been  
20 isolated from the spinal fluid, so that would be a  
21 definition of meningitis, yes.

22 Q So it -- it -- so varicella vaccine can  
23 sometimes cause and result in meningitis; yes?

24 A Yes.

1 Q Thank you. All right. Can varicella vaccine  
2 cause an infection of the spinal cord covering?

3 A That's the meninges, so that's the same  
4 question, and the answer remains the same, yes.

5 Q Thank you. Thank you for indulging. Can  
6 varicella vaccine cause seizures?

7 A It may be associated with seizures.  
8 Certainly you can get fever as well, and if there  
9 was encephalitis, it may indeed, although every  
10 time you have a seizure, I can't say that it was  
11 due to varicella.

12 Q But it can in some instances cause a seizure;  
13 correct?

14 A In very rare instances, and particularly in  
15 individuals who are not immunocompetent.

16 Q Okay. Can DTaP vaccine cause seizures?

17 A It can be associated with seizures in that it  
18 can cause fever and also sometimes -- so -- so  
19 yes, it can be associated with seizures.

20 Q Okay. Would you be surprised to know that  
21 the CDC has provided that a -- that -- has found  
22 that there can be a causal relationship between  
23 seizures and DTaP vaccine?

24 A That's not different from how I just answered

1 the question.

2 Q Okay. All right. Can DTaP cause nonstop  
3 crying for three hours or more?

4 A Yes, it can. It's called HHE.

5 Q Okay. Can DTaP cause long-term --

6 A It's also -- it's also called persistent  
7 crying or HHE, yes.

8 Q Thank you, Doctor. Can DTaP cause long-term  
9 seizures?

10 A No, sir.

11 Q Are you aware that the CDC has found that  
12 DTaP can cause long-term seizures, rarely, but  
13 that it can?

14 A No. I think that -- that I would disagree  
15 with that. It can cause it in patients that  
16 are -- have channelopathies, have Dravet syndrome,  
17 but that's not a normal healthy patient.

18 Q So it can cause seizures in patients that are  
19 not healthy?

20 A With a neurologic encephalopathy called  
21 Dravet's, yes.

22 Q Any other instances?

23 A No.

24 Q Okay. Are you aware -- would you be

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

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

8 Q Can DTaP cause coma?

9 A No, sir.

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

13 A Yes, I would, sir.

14 Q Okay. Can DTaP cause lowered consciousness?

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

20 Q Can DTaP cause permanent brain damage?

21 A No, sir.

22 Q Would you again be surprised if --

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

- 1 Q Then we'll come back to that.
- 2 A Good.
- 3 Q Can MMR cause encephalitis?
- 4 A Yes, and particularly in immunocompromised  
5 individuals.
- 6 Q Can MMR cause febrile seizures?
- 7 A Yes.
- 8 Q Can MMR cause chronic arthritis?
- 9 A I'm sorry, sir, I couldn't hear your --  
10 the --
- 11 Q No problem. Can MMR cause chronic arthritis?
- 12 A It can be associated with short-term  
13 arthritis, but generally not felt to be chronic.
- 14 Q Okay. Are you aware that the Institute of  
15 Medicine has found that chronic arthritis is  
16 causally related to MMR?
- 17 A Perhaps that's what they said.
- 18 Q Okay. If that is what they said, would you  
19 change your conclusion regarding whether MMR  
20 caused chronic arthritis?
- 21 A Probably not.
- 22 Q Okay. Can MMR cause acute arthritis?
- 23 A Cause true arthritis?
- 24 Q I'm sorry, acute.

1 A Oh. Yes.

2 Q Can MMR cause thrombocytopenia?

3 A Yes, definitely.

4 Q Okay. And that's an autoimmune disorder in  
5 which the body attacks a portion of the red blood  
6 cells; correct?

7 A Actually, it's not really autoimmune. It  
8 actually is -- is actually destruction of the  
9 platelets in the marrow, and then it goes away  
10 and -- and then it -- it -- so it -- it is an  
11 antibody-mediated function, but it's not an  
12 autoimmune in the classic way.

13 Q I appreciate that. Can MMR cause death?

14 A MMR can cause death in immunocompromised  
15 subjects, and we -- and that happens, and that's  
16 been reported and clearly outlined, and I just  
17 reviewed that last week for a conference.

18 Q Okay. What about non-immunocompromised  
19 subjects?

20 A Generally not, and I'm not aware of one  
21 isolated case that has been reported, but again, I  
22 didn't do a thorough search before you asked me  
23 the question.

24 Q Okay. Can MMR cause unusual bleeding or

1 bruising?

2 A Well, if it causes thrombocytopenia, then it  
3 will cause bleeding and bruise.

4 Q Can MMR cause deafness?

5 A I think it's not been well established. It's  
6 felt to be unlikely, but -- but I -- I would be --  
7 I would have to look for that again. I'm not  
8 sure.

9 Q Dr. Edwards, did you hear the question?

10 A No, sir, I did not hear the question.

11 Q Oh. Can MMR cause long-term seizures?

12 A Not in a normal host, no, sir.

13 Q So it can't cause it in healthy children?

14 A No.

15 Q Can it cause it in unhealthy children?

16 A I would think it probably could cause it in  
17 unhealthy children that have an immune compromise.

18 Q Into a coma?

19 A I'm sorry?

20 Q Can MMR cause a child to enter into a coma?

21 A Very unlikely unless they have  
22 immunocompromise.

23 Q Can MMR cause a child to have lowered  
24 consciousness?



1 A If they have a seizure associated with fever,  
2 then they would be postictal and it would cause  
3 lowered consciousness, yes, but not persistent  
4 lowered consciousness.

5 Q Can MMR cause brain damage?

6 A Not in a normal healthy subject without  
7 underlying problems.

8 Q So a child with underlying problems, MMR can  
9 cause brain damage; correct?

10 A I think I would have to assess each  
11 individual, the causality of each individual one.

12 Q So it's possible?

13 A I'm not sure. Not in a normal healthy  
14 person.

15 Q You're aware the CDC has specifically used  
16 the word brain damage as a possible cause from  
17 MMR?

18 A No, I am not aware of that.

19 Q Okay. Are you aware that the vaccine  
20 information statement for the MMR says -- that  
21 they list brain damage as a possible cause from  
22 the MMR vaccine?

23 A I'm -- I don't have that in front of me.  
24 Obviously if you do and that's what it says, then

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

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

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

12 MS. CHEN: Sixteen.

13 MR. SIRI: Sixteen, thank you.

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

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

21 A That's what it says.

22 Q Okay. And it's from the CDC?

23 A That's what it says.

24 Q Section 4 is the risks of a vaccine reaction;

1 correct?

2 A Yes.

3 Q And under severe events occurring very  
4 rarely, it lists brain damage; correct?

5 A Yes, it does.

6 Q Lowered consciousness?

7 A Yes.

8 Q Coma?

9 A Yes.

10 Q Long-term seizures?

11 A Yes.

12 Q Deafness?

13 A Yes.

14 Q Seizures?

15 A Yes.

16 Q Okay. Let's pull up one more and then  
17 we'll -- we'll move on. This is the vaccine  
18 information statement for DTaP.

19 A I think -- excuse me. Can I say one thing  
20 before you --

21 Q No. There's no question pending,  
22 Dr. Edwards. Your attorney can ask you questions.  
23 And I mean, and frankly, you know, we can hear  
24 somebody in the background. Being coached during

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

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

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

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

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

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

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

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

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

13 (Whereupon, Exhibit  
14 No. 17 was marked to the  
15 testimony of the  
16 witness.)

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

19 A I believe I've reviewed it.

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

22 A That's what it says, sir.

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

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

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

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

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

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

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

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

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

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

13 (Whereupon, Exhibit  
14 No. 18 was marked to the  
15 testimony of the  
16 witness.)

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

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

22 MR. SIRI: Patricia, is this one 18 or  
23 17?

24 A It's 18.

1 MS. CHEN: Eighteen.

2 MR. SIRI: Okay, thank you.

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

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

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

8 A Yes, sir.

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

10 A Yes, sir.

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

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

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



1 you surmise that it was given on those dates and  
2 for those vaccines?

3 A Yes, I would, sir.

4 Q Okay. And now what about the -- where  
5 there's those ellipses right below given, would  
6 you surmise that the VIS was given on those dates  
7 for those vaccines as well?

8 A I'm sorry. I can't understand your question.

9 Q Oh, I'm sorry. No problem. The ellipses  
10 right below given for some of the vaccines, do you  
11 see that?

12 A Yes.

13 Q Would you surmise that the VIS was given for  
14 some of those that --

15 A Yes.

16 Q You would --

17 A That's what that usually means, yes. I would  
18 surmise that, yes.

19 Q So you would surmise that the VIS was given  
20 for those vaccines on the dates listed; correct?

21 A Yes.

22 Q Okay. Now, for the ones that are blank,  
23 would you surmise that the VIS was not given to  
24 the -- to Yates' parents or guardian on the date

1 and for those vaccines listed on the --

2 A I could say that it was not recorded.

3 Whether it was given or not, I think that's a  
4 harder question.

5 Q Okay. So you don't know?

6 A I don't know, no. I'm sorry, I don't know.  
7 I don't know what happened there.

8 Q Okay. Similarly, for the ones that are  
9 listed as given, could those also be a mistake?

10 A I think it's -- it's unlikely those were a  
11 mistake. I think when we write things down that  
12 we do them, then we generally do them. I think  
13 sometimes we forget to write things down.

14 Q Got it. So if it's listed, it's highly  
15 unlikely that it wasn't given if it says given;  
16 correct?

17 A That's correct.

18 Q Meaning you give the vaccine, you fill out  
19 this chart right after the vaccine is given  
20 typically; correct?

21 A That's correct.

22 Q And you would know whether or not you gave a  
23 VIS; correct?

24 A I would think that you would know and it

1 would be part of your routine procedures.

2 Q Yeah. So, for example, let's take a look at  
3 Pevnar given on June 6, 2000. Do you see that  
4 row?

5 A Yes, sir, I do.

6 Q Okay. It states that the Pevnar vaccine was  
7 given, administered to Yates on June 6; correct?

8 A Yes, sir.

9 Q Okay. And it states clearly that the vaccine  
10 information statement was given to Yates' parents  
11 or guardian on that date; correct?

12 A That's correct.

13 Q Okay. Any reason to think that that's  
14 inaccurate?

15 A Well, I know that -- that the actual vaccine  
16 statement for Pevnar, the official one had not  
17 been published yet, so I know that you're  
18 concerned about that, and there are earlier forms  
19 that had -- are given to patients about vaccines,  
20 so if that's your question, I -- I -- I trust that  
21 some information was given to the family about the  
22 vaccine because that's what it said. Whether it  
23 was actually the official VIS because that hadn't  
24 yet been approved, I don't know, because it used

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

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

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

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

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

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

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

1 Q You don't -- right. So just to be clear,  
2 at -- the first VIS for Prevnar wasn't actually  
3 issued until July of 2000; correct?

4 A I believe that's correct.

5 Q Okay. So when I -- I asked you is it  
6 possible the VIS was provided on June 6, you're  
7 saying that it was possible that it was given on  
8 June 6 before it --

9 A That's --

10 Q -- was even in existence?

11 A That's not what I'm saying. What I'm saying  
12 is that the chart says that vaccine information  
13 materials were provided, so I don't know what was  
14 provided, but it -- unlikely it could be a VIS  
15 because that -- it wasn't official until after  
16 that time, so all I'm saying is that based on this  
17 record, some vaccine information materials were  
18 given.

19 Q But you don't know that; correct?

20 A It said -- this is what the chart says, so  
21 I'm being asked all the time to see patients and  
22 to assess patients based on what the medical chart  
23 says, so when that happens, I say the -- I -- I  
24 believe what the medical chart says. Now, the

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

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

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

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

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

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

22 A Okay.

23 Q -- on my statement.

24 A Okay.

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

2 (Whereupon, Exhibit

3 No. 19 was marked to the

4 testimony of the

5 witness.)

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

8 A Yes, I am.

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

14 A Yes, sir.

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

17 A 7/18/2000.

18 Q Okay.

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

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

24 A That's correct.

1 Q Okay. So it wasn't possible for the Prevnar  
2 VIS to have been given to Yates' parents or  
3 guardians on June 6, 2000 when he received the  
4 Prevnar vaccine; correct?

5 A That is correct, but that's not what the  
6 medical record states. It says vaccine  
7 information materials.

8 Q Okay.

9 A So vaccine information materials could be  
10 related or some other information that was  
11 provided, so he did not get a VIS, no, and if  
12 that's your question, he did not receive a VIS,  
13 but I do -- but it says he received some  
14 information.

15 Q You reviewed the medical records in this  
16 case; correct?

17 A Yes, sir.

18 Q And you reviewed Yates' medical records in  
19 particular; correct?

20 A Yes, sir.

21 Q Did you see any material in any of his  
22 medical records that would be something that would  
23 be provided to parents regarding the Prevnar  
24 vaccine and giving the risks and benefits of the



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

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

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

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

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

16 (Witness complying.)

17 Q Thank you. Okay.

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

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

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

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

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

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

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

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

19 A No, sir, I don't.

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

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

1 question -- or if you have an answer.

2 A I can -- I can say that Dr. Hays was one of  
3 our residents, and --

4 Q (By Mr. Siri) Was one of your what? I'm so  
5 sorry.

6 A He was one of our medicine pediatric  
7 residents.

8 Q Okay.

9 A And he has -- he was an excellent resident.  
10 The med peds residents are the smartest of the  
11 lot. They take -- they have -- it's very  
12 competitive, and I recall that at least in my  
13 interactions he had a strong moral core, so it  
14 would not be consistent with his behavior that he  
15 would alter something that was not correct.

16 Q Would you say he had the same moral core as  
17 you have, Dr. Edwards?

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

20 A I would hope so.

21 Q (By Mr. Siri) Okay. So tell me about your  
22 relationship with Dr. Hays.

23 A I was simply his teacher. I was not a  
24 memorable person. I think he cited in his

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

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

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

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

18 A Yes, sir, that's correct.

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

24 MR. SANDERS: Object.

1 A That's correct.

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

4 A That is correct.

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

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

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

15 A That's correct.

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

24 A Yes, sir, I do.

1 Q Okay. You have also repeatedly provided  
2 interviews in which you stated categorically that  
3 vaccines do not cause autism; correct?

4 A That's correct.

5 Q When you made those statements, did you mean  
6 that no vaccines cause autism?

7 A That's correct.

8 Q So it is your testimony that none of the  
9 vaccines that Yates received caused autism?

10 A That's correct.

11 Q Okay. It's your testimony that MMR vaccine  
12 cannot cause autism?

13 A That's correct.

14 Q It's your testimony that HepB vaccine cannot  
15 cause autism?

16 A That's correct.

17 Q It's your testimony that IPOL cannot cause  
18 autism?

19 A Yes.

20 Q It's your testimony that Hib vaccine cannot  
21 cause autism?

22 A Yes.

23 Q It's your testimony that varicella vaccine  
24 cannot cause autism?

1 A Yes.

2 Q It's your testimony that Prevnar vaccine  
3 cannot cause autism?

4 A Yes.

5 Q And it's your testimony that DTaP vaccine  
6 cannot cause autism?

7 A Yes.

8 Q How did the concern that vaccines can cause  
9 autism begin?

10 A It began with Andrew Wakefield in an article  
11 that he published in Lancet that suggested that a  
12 number of children that he reported had -- had  
13 developed autism after MMR vaccine, and then he  
14 made the claim that the MMR virus was seen in  
15 the -- in the biopsy of a number of the intestinal  
16 tissue from the patients.

17 Q You're talking about an article published by  
18 Andy Wakefield in 1998?

19 A Yes, sir.

20 Q Okay. So you're saying the concern that  
21 vaccines cause autism started with Andy Wakefield  
22 after publishing that article in 1998; correct?

23 A That's correct.

24 Q Before Wakefield's article regarding vaccines

1 as a potential cause of autism?

2 A I am not aware that others have brought forth  
3 that, I'm -- that hypothesis, no, but maybe they  
4 have. I -- I don't know. I -- I'm not -- I know  
5 certainly that Dr. Wakefield really advanced that  
6 hypothesis.

7 Q Are you aware that stakeholders, including  
8 parents, were claiming and clamoring that  
9 pertussis-containing vaccines caused autism over a  
10 decade before the Wakefield article?

11 A Yes, but what you -- what you asked me, at  
12 least I thought you did, was about measles, so  
13 about MMR. So again, yes, there have been a  
14 number of false claims about autism from a number  
15 of different vaccines, but the MMR is -- I thought  
16 you were talking about Wakefield, so there were --  
17 obviously there were concerns about the whole-cell  
18 pertussis vaccine, it was very reactive, and  
19 that's certainly worked to get a -- one that was  
20 less associated, so yes, I was aware. I'm sorry.

21 Q No problem. And when you say false claims,  
22 you mean parents were claiming that based on their  
23 experience with their child, a particular vaccine  
24 caused their child's autism, but the science was



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

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

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

12 A Yes, sir.

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

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

23 Q And so one of the conditions that the  
24 1986 Act -- one of the ten conditions of the

1 1986 Act required HHS to review was whether or not  
2 a pertussis-containing vaccine caused autism;  
3 correct?

4 A Yes, sir.

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

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

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

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

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

22 A Was it --

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

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

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

8 Q Sure.

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

11 (Whereupon, Exhibit  
12 No. 20 was marked to the  
13 testimony of the  
14 witness.)

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

17 A Yes, I have this book in my office.

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

20 A Yes, 30 years ago.

21 Q Right. In 1991; correct?

22 A That's correct.

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

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

4 A Yes, sir.

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

8 A That's correct.

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

13 A That's correct.

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

16 A No, sir.

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

24 A That's what the chart says, yes.

1 Q But it doesn't -- that's not what they  
2 reached regarding autism; right?

3 A That's correct.

4 Q Okay. And they could have also reached the  
5 conclusion that the evidence does not indicate a  
6 causal relation, meaning that the evidence  
7 supports it's not causally related; correct?

8 A I'm sorry, it says, no evidence bearing on a  
9 causal relationship. The opposite would that --  
10 be evidence indicates a causal relationship. So  
11 what is the question?

12 Q Right. I was reading number three. I was  
13 just -- I just wanted to go through the five  
14 categories so that we could really understand what  
15 the first category meant. The third category  
16 meaning -- they found evidence to show that it  
17 wasn't caused by a vaccine; right?

18 A Yes.

19 Q And the second category was that they  
20 couldn't find enough information to reach a  
21 conclusion one way or another; correct?

22 A Correct.

23 Q And the first category is that they literally  
24 couldn't find any evidence whatsoever whether or

1 not the vaccine did or did not cause the  
2 condition; correct?

3 A That's correct.

4 Q Okay.

5 A So this is 30 years ago. This is 30 years  
6 ago.

7 Q We're going to -- we're going to take this in  
8 pieces. I -- that's the only way I can do it,  
9 Dr. Edwards. Okay. So 1991, there -- and in 1986  
10 there was enough concern that pertussis-containing  
11 vaccines caused autism that it was included in the  
12 1986 Act and it was even an issue reviewed by the  
13 Institute of Medicine; correct?

14 A Correct.

15 Q That's many years before Wakefield's article;  
16 correct?

17 A That's correct, but I -- I didn't say -- I  
18 said that -- that MMR was for Wakefield's article.

19 Q I --

20 A Not pertussis.

21 Q I never said MMR though when I asked you the  
22 question; correct?

23 A I don't recall. I guess you could ask the  
24 court reporter to repeat it again, but --

1 Q It's in the record. All right. How --  
2 according to the CDC's childhood vaccine schedule,  
3 how many times is a baby injected with DTaP during  
4 the first year of life?

5 A Three times. Two, four, six months of age  
6 and at 12 to 18 months.

7 Q Yes, ma'am, and --

8 A Four times within the first 18 months.

9 Q And how many times did you -- how many doses  
10 of DTaP did Yates receive in that time period?

11 A I believe he received four. In one of the  
12 records it said he received three, and then on the  
13 other record it said he received four, so four.

14 Q So four shots. So Yates received four shots  
15 of DTaP by 18 months of age; correct?

16 A Yes, sir.

17 Q Okay. Now, as -- we're going to  
18 fast-forward, as I know you want to do. Let's go  
19 all the way now to 2011. In 2011, the IOM issued  
20 another report regarding looking at various  
21 claimed adverse reactions and whether they're  
22 causally or not causally connected to certain  
23 vaccines; correct?

24 A Yes.

1 Q Okay. And that report was paid for by the  
2 HRSA and the CDC; correct?

3 A I don't know who supported that report, I'm  
4 sorry.

5 Q So let's pull it up. This is the report from  
6 the IOM from 2011; correct?

7 A Yes. I think that is correct.

8 MR. SIRI: Okay. I'm going to mark this  
9 as Plaintiff's 20 [sic].

10 (Whereupon, Exhibit  
11 No. 21 was marked to the  
12 testimony of the  
13 witness.)

14 Q (By Mr. Siri) It's entitled Adverse Effects  
15 of Vaccines: Evidence and Causality. Can you  
16 hear me, Doctor?

17 A Yes.

18 Q Yes.

19 A That is what it said. That's what this says.

20 Q And it's issued by the Institute of Medicine;  
21 right?

22 A That's correct. That is what it says.

23 Q And it -- these reports, as they typically  
24 do, start with the charge to the committee;



1 correct?

2 A That's correct. I've -- so -- I'm on a  
3 number of these committees, so I'm fully aware of  
4 how it's set up.

5 Q Wonderful. And the committee is a committee  
6 within the Institute of Medicine that's set up to  
7 answer the question that's in the charge provided  
8 by whoever is paying for the report; correct?

9 A Yeah. This -- the Institute of Medicine was  
10 set up by -- by Abraham Lincoln to provide the  
11 government with expert --

12 Q Well, okay, I -- respectfully, we don't need  
13 you to go through the whole history of the IOM.  
14 I -- you can certainly talk about that afterwards.  
15 Yes, it was set up by Congress, it was supposed to  
16 be the advisor to Congress, but as it stands in  
17 2011, the IOM issues reports upon the commission  
18 by others to do so; correct.

19 A Correct.

20 Q Okay. You said correct?

21 A Correct, correct.

22 Q Okay. This report was commissioned by the  
23 Health Resources and Services Administration;  
24 correct?

1 A Correct.

2 Q And if you look down at Footnote 4, isn't  
3 it -- and funding for this was also provided by  
4 the CDC and the National Vaccine Program Office;  
5 correct?

6 A Yes, sir.

7 Q Okay. And the -- and the -- the adverse  
8 events that the IOM is asked to look at in 2011  
9 were described by HRSA, the one who is  
10 commissioning the report, as the vast majority of  
11 adverse events in the claims for compensation that  
12 were occurring in the vaccine court; correct?

13 A That's correct.

14 Q All right. Meaning what -- what HRSA was  
15 asking was is they wanted the IOM to review the  
16 existing scientific literature to determine were  
17 these commonly claimed injuries in vaccine court,  
18 were they or were they not caused by vaccines;  
19 correct?

20 A That's correct.

21 Q Okay. And, you know, the HRSA is also the  
22 agency that defends against vaccine claims in  
23 vaccine court; correct?

24 A That is.

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

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

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

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

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

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

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

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

24 A No, sir.

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

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

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

9 MS. CHEN: Yes.

10 MR. SIRI: Thank you.

11 (Whereupon, Exhibit  
12 No. 22 was marked to the  
13 testimony of the  
14 witness.)

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

18 A Yes, sir.

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

23 A Yes, sir.

24 Q And here it's examining the question of

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

3 A That's correct.

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

6 A Yes.

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

10 A That's correct.

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

14 A Yes, sir.

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

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

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

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

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

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

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

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

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

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

3 Q Okay.

4 A -- want me to review it --

5 Q The --

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

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

15 A Correct. It lacked scientific rigor.

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

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

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

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

22 Q I like looking at the primary sources too, so  
23 we're -- we're simpatico in that regard, Doctor.

24 So why don't you take a moment to look at that and



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

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

16 Q All right.

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

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

1 antigens alone or in combination; correct?  
2 Meaning it did not find -- meaning the IOM did not  
3 find any literature one way or another bearing on  
4 that -- that would allow it to reach any  
5 conclusion regarding -- on the basis of  
6 mechanistic evidence of whether DTaP vaccine  
7 causes autism; correct?

8 A I think that it did not identify any  
9 literature explaining that -- how that this could  
10 be caused, so the conclusion was the -- that they  
11 assessed the mechanistic evidence, and there was  
12 no information that they could say that could  
13 provide a mechanistic -- a mechanism. That's  
14 exactly what they're saying. And based --

15 Q Right.

16 A Okay. So we agree on that, great.

17 Q Right. And similarly, they didn't find any  
18 evidence that showed -- that -- that would support  
19 that it didn't cause autism either. It just --  
20 they couldn't find any mechanistic evidence one  
21 way or another. We can agree on that; right?

22 A Yes, but I think it's more important to find  
23 evidence, biologic evidence to support something  
24 than to -- than to refute, but --

1 Q Sure.

2 A Yes.

3 Q But the -- but you need to conduct the  
4 studies to look for, right, mechanistic cause  
5 evidence, meaning somebody's got to -- you know,  
6 experimental evidence, for example, somebody who's  
7 engaged in those experiments to see is there a  
8 connection, you know, is the aluminum adjuvant in  
9 the DTaP vaccine problematic, is one of the  
10 ingredients, is the -- or the way it's  
11 administered, is it in combination, whatever.  
12 There's probably a lot of experiments. You could  
13 do it in animal models, you could inject mice,  
14 right, and you can look to see do they develop  
15 autistic-like features. There's all types of  
16 studies that you could do, and all they're saying  
17 is they don't find any one way or another.

18 A That's correct.

19 Q You -- right. Okay. Well, and here's the  
20 causality conclusion. All right. And because  
21 they couldn't find any evidence whatsoever, they  
22 said -- would you like to read it? You're muted,  
23 Doctor.

24 A The evidence is inadequate to accept or

1 reject a causal relationship between DTP and  
2 autism.

3 Q Meaning they don't know; correct?

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

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

9 A That's correct.

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

13 A That's correct.

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

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

19 Q (By Mr. Siri) Okay.

20 A We can't -- you cannot --

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

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

24 MR. SIRI: There's no question.

1 THE WITNESS: Sir, just --

2 MR. SANDERS: No, she's answering.

3 She's clarifying the question. Dr. Edwards, go  
4 ahead.

5 MR. SIRI: Sure.

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

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

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

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

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

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

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

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

6 Q Okay.

7 A I --

8 MR. RILEY: Mr. Sanders, let me  
9 interject, if I don't -- if you don't mind. Can  
10 somebody explain to me, why does Dr. Edwards  
11 continue to mute her microphone? I'm just -- I  
12 want to make --

13 THE WITNESS: I'm sorry, sir. I am  
14 sorry, sir. I am sorry. It just -- it --  
15 sometimes I mute because I -- I want to make sure  
16 that I can hear what's being -- and I don't want  
17 to create any other noise, so I will -- do you --  
18 I will stop muting the phone.

19 MR. RILEY: Okay. Thank you, Doctor. I  
20 just was -- just making sure we're all on the same  
21 page.

22 THE WITNESS: Craig, I just feel like  
23 I'm getting badgered.

24 MR. SANDERS: Okay. Why don't we go off

1 the record for a minute and take a break and the  
2 attorneys can talk for a minute.

3 MR. SIRI: I've got a few more questions  
4 and then we can take a break. I -- there is  
5 nothing that is badgering. These are -- you know,  
6 I understand that the doctor never --

7 THE WITNESS: I'd like to take a break.  
8 I'd like to take a break.

9 MR. RILEY: Let's -- Mr. Siri, let's --  
10 let's do this, Mr. Siri. Let's take a break just  
11 a second; okay? And we'll -- we'll talk and let  
12 Dr. Edwards regroup and we'll come back and we'll  
13 start again; okay?

14 MR. SIRI: What time should we start?  
15 Five minutes?

16 MR. SANDERS: I think we need to talk  
17 for a minute, David.

18 MR. RILEY: That's fine. We'll talk.

19 THE WITNESS: I would like to talk. I  
20 would not like -- I'd like until the bottom of the  
21 hour. And Mr. Sanders, if you could give me a  
22 call, that would be very helpful. Thank you.

23 THE VIDEOGRAPHER: And we're off the  
24 record --

1 MR. SIRI: Let the record -- no, no, no.  
2 We're not going off the record yet.

3 Mr. Sanders -- Sawyer -- Mr. Sawyer?

4 THE VIDEOGRAPHER: That's fine. I'm --

5 MR. SIRI: I want to make a statement  
6 before we go off the record. I would like to make  
7 a statement on the record that, you know, I  
8 understand that Dr. Edwards is not used to being  
9 challenged about her vaccine knowledge, she's  
10 never been an expert witness. None of the  
11 questions here are badgering. They're all  
12 directly relevant to the question of vaccines  
13 causing autism. She may not like to have to give  
14 the answers she's giving, but that's not an excuse  
15 to pause the deposition, nor is it an excuse to  
16 force a break when we've just had a break fairly  
17 recently, you know. It -- you know, this clearly  
18 is taking an opportunity to coach the witness in  
19 the middle of a line of questioning that clearly  
20 the defense finds troubling, so with that, we can  
21 take our break.

22 MR. SANDERS: I'd like to make a  
23 statement, Mr. Sawyer, before you go off. We've  
24 been going now for over five hours. Mr. Siri has



1 repeatedly tried to cut the witness off, not allow  
2 her to answer questions. We've only taken two  
3 very short breaks within that time. There's no  
4 problem whatsoever with the witness needing to  
5 take a break. We've not broke for lunch at all  
6 and it's 1:20 here Central time. I don't know how  
7 Mr. Siri does it in New York or California where  
8 he practices, but that's not how we do it here in  
9 Tennessee, in which we, you know, treat the  
10 witnesses with respect, and if they need to take a  
11 break, take one. I certainly agree that if  
12 there's a question pending, we wouldn't do that,  
13 and I don't -- Dr. Edwards, I'm not going to call  
14 you, I don't plan to talk to you during the  
15 deposition, I'll talk to you afterwards, but I  
16 will let you know that you can take a break at any  
17 time, you just -- just speak up and let the  
18 attorneys know. If there's a question pending,  
19 you can answer that first, and I'm going to make  
20 sure throughout the rest of this deposition that  
21 Mr. Siri allows you to provide an answer and  
22 allows you to take a break at any time that you  
23 need one.

24 THE WITNESS: Okay. I will --

1           MR. SIRI: I'll just -- before we -- one  
2 second. Before we go off, so I -- I --  
3 Mr. Sanders, I fully appreciate that when a  
4 witness needs a break, I -- it's been always my  
5 custom to provide a break. I've got no issue with  
6 that. But when the break is preceded by an  
7 insinuation that I am badgering, or as you've just  
8 said, doing something improper, that changes the  
9 tone and texture. I -- I have tried to let  
10 Dr. Edwards answer every question fully and  
11 completely. There have been times where she's  
12 decided to go just start providing information  
13 that I felt was a little off topic, but for the  
14 most part I believe I have. If you think there is  
15 a time where I've not let her complete a question,  
16 Mr. Sanders, I very much -- and I believe you  
17 pointed out once or twice and I believe I -- you  
18 know, I said absolutely, I'd like for her to  
19 finish, and I do want her to actually finish her  
20 answers to every question, so that's different  
21 than starting to talk when there's no question on  
22 the table, and that has happened, and in those  
23 instances, I certainly -- it's been my practice,  
24 and I think it's been my practice in all courts I

1 practice in to -- you know, to say, hey, there's  
2 no question on the table, so I -- I very much --  
3 you know, and also -- so I have no issues with  
4 breaks. I just -- you know, when they're made in  
5 the context of these kind of insinuations of --  
6 that -- that's a very different tenor in which  
7 they're asked for. Other than that, I have no  
8 issue with giving breaks or stopping obviously  
9 when there's no question pending, so I think we  
10 were on the same page, Mr. Sanders. Would you  
11 agree?

12 MR. SANDERS: I think we move forward.  
13 I would appreciate you, you know, letting her have  
14 an opportunity to respond, and --

15 MR. SIRI: Absolutely.

16 MR. SANDERS: -- and all I would request  
17 is that you treat her with respect and dignity and  
18 be kind to her throughout the deposition and give  
19 her a chance to respond to your questions.

20 MR. SIRI: Well, I'm -- I certainly am  
21 trying to do that. I -- you know, I've not -- I  
22 think the only disparaging adjectives have been  
23 tossed in my direction so far. I've -- and maybe  
24 like I've said, maybe the substance of my

1 questions are uncomfortable, but that's -- you  
2 know, that's -- I -- I try to be as respectful in  
3 the context as I can. I think the record reflects  
4 that. The other thing too is that, you know, as  
5 far as I'm aware, you know, depositions are eight  
6 hours, that's the normal, and, you know, they  
7 continue from day to day. Now, that's one of the  
8 other things, which is, you know, I'm trying to  
9 move things along, but if there's going to be, you  
10 know, long soliloquies provided that are  
11 nonresponsive to the question, that's just going  
12 to take -- that just makes the deposition longer.  
13 You, of course, can read the -- you can direct and  
14 ask her anything afterwards. You know, I'd just  
15 like to get through my outline, and, you know, I  
16 ask simple questions and I get two-minute  
17 responses. That's -- if you could -- you know, if  
18 you could ask her to just answer the questions on  
19 the table and that you will come back to her later  
20 for anything that's needed, that would certainly  
21 move this along, and that's been my experience  
22 usually.

23 MR. SANDERS: I -- and I certainly  
24 will -- Dr. Edwards, let you know to give -- to,

1 you know, answer the question and then you -- and  
2 explain to the extent you need to, and I -- I  
3 don't agree, Mr. Siri, that all the questions are  
4 simple and that there's a simple answer to them,  
5 so sometimes I think there has to be some  
6 explanation.

7 MR. SIRI: I agree with that too.  
8 Certainly not. Some of these questions are not  
9 simple. No argument. But there are many that are  
10 simple, but yet, you know, there's a lot of -- of  
11 information provided that's not relevant to the  
12 questions, so if we could just, you know, for the  
13 questions that are not simple, and certainly  
14 where, you know, there's information provided that  
15 are not relevant to the question, if we can just  
16 answer the question, we can get through this  
17 relatively quickly. But if every question, you  
18 know, is answered and then with a story with it,  
19 that's just going to take us longer, and I  
20 certainly don't want to have to continue this  
21 another day, you know. I understand, like, a  
22 number of jurisdictions where I practice, I've  
23 done cases in -- you know, this is a -- Tennessee  
24 is a day-to-day jurisdiction, so I would like to

1 finish up today, and I think that that will depend  
2 on whether we can move through, you know, the  
3 questions and answers without a lot of additional  
4 information. I mean, you'll have the opportunity  
5 to get that additional information. Anyway, we'll  
6 leave it at that.

7 MR. RILEY: How about I interject just a  
8 second, Craig. This is --

9 MR. SANDERS: We're not going to have a  
10 second day, I can say that, so whatever you need  
11 to do, you need to get through today.

12 MR. RILEY: Let's -- okay. Let's -- let  
13 me just interject for just a second. Craig, the  
14 whole purpose of me opening my big mouth during  
15 the deposition was I noticed that Dr. Edwards, the  
16 witness, was muting her microphone after every  
17 question, and if I'm wrong about that, I'm  
18 mistaken. That is simply what was shown on Zoom  
19 on my screen, and so I was just simply asking if  
20 she would just prevent from muting her microphone  
21 so that everyone over Zoom understood that she was  
22 hearing the questions and providing the -- her own  
23 answers to the questions. That was the only --  
24 the only --

1 MR. SANDERS: Sure.

2 MR. RILEY: -- basis for me  
3 interjecting, and that's all I simply would ask,  
4 and we -- we should take a break right now for --  
5 for a few minutes and regroup and come back, if  
6 that's okay with everybody. That's what I think  
7 we ought to do and maybe come back whatever --  
8 what time are y'all thinking?

9 MR. SANDERS: Yeah, David, I -- I think  
10 that's a reasonable request, and -- and as far as  
11 I know, no one is there with Dr. Edwards other  
12 than, you know, she said her husband passed  
13 through the room once or twice. I would suggest a  
14 15-minute break, perhaps. Is that too long,  
15 Mr. Siri?

16 MR. SIRI: That's fine. Eleven --  
17 excuse me. 1:40 then.

18 MR. SANDERS: Okay. That sounds good.

19 MR. RILEY: 1:40. Thank you.

20 THE VIDEOGRAPHER: All right. And we  
21 are off the record at 1:25 Central time.

22 (Brief recess.)

23 THE VIDEOGRAPHER: Yeah, we are back on  
24 the record at 1:41.

1 MR. SIRI: Great. Thank you.

2 Q (By Mr. Siri) All right. So Dr. Edwards, is  
3 there a study that supports that DTaP vaccine does  
4 not cause autism?

5 A The assessment of the IOM report shows that  
6 there is not a study that refutes that  
7 association. It is hard to prove a negative. And  
8 also -- so there is not a study that says a  
9 negative.

10 Q The IOM though has concluded that, for  
11 example, MMR vaccine -- that the evidence supports  
12 that an MMR vaccine does not cause autism;  
13 correct?

14 A That's correct because there -- there are  
15 more studies that have been looking -- that have  
16 looked at that in a larger group. However, there  
17 are no studies that support that association.

18 Q Right. So it is possible to have a causality  
19 conclusion on whether a vaccine causes or doesn't  
20 cause autism; correct?

21 A It is impossible for the DTaP. They did not  
22 come up with a causality association --

23 Q Okay. So --

24 A -- or --



1 Q Right, because they couldn't find any study  
2 one way or another with regards to whether DTaP  
3 causes autism; right?

4 A That's correct.

5 Q Are you aware of any study -- strike that.  
6 So then let me ask you this. Strike that. Are  
7 you aware of any study that supports that DTaP  
8 does not cause autism?

9 A No, but I'm also not aware of any study that  
10 says that it does.

11 Q Fair enough. Well, Geier and Geier, but it  
12 was -- it was deemed not reliable; right?

13 A Right, correct.

14 Q Given that the current state of the science  
15 is that there aren't sufficient studies, or any  
16 studies potentially, to support that DTaP does not  
17 cause autism, isn't it premature to make the  
18 sweeping statement that all vaccines do not cause  
19 autism?

20 A No, sir, I do not think that that is a -- an  
21 inadequate or inappropriate statement. I think we  
22 are ignoring a lot of information in the  
23 literature that tells us that autism is really a  
24 prenatal event, that the -- the abnormalities that

1 are seen on the ultrasound assessing the size of  
2 the brain and the -- those differences in children  
3 with autism are becoming more and more apparent  
4 and becoming more and more established. We also  
5 have specific genetic defects, so there is likely  
6 an environmental cause, but I think focusing on  
7 the vaccine link is not a productive  
8 investigation.

9 Q All right. But parents back in '86 were  
10 concerned that pertussis-containing vaccines  
11 caused autism; correct?

12 A Yes, sir, and --

13 Q Who are -- please.

14 A And so because of the adverse events  
15 associated with vaccines, we made a vaccine that  
16 was -- was less reactogenic. Now, obviously I  
17 don't think either of them caused autism, but I  
18 think that the -- that the -- the safety profile  
19 of the acellular vaccines are less reactogenic  
20 than the whole-cell.

21 Q But parents continued to complain that  
22 pertussis-containing vaccines might be a cause of  
23 their children's autism, and hence the IOM again  
24 in 2011 reviewed whether pertussis-containing --

1 including tetanus and diphtheria-containing  
2 vaccines caused autism; correct?

3 A There is inadequate evidence to suggest  
4 there's a causation.

5 Q All right. So if there isn't enough evidence  
6 to support -- to reach a conclusion, not saying  
7 vaccines cause autism, I'm certainly not asking  
8 you to say that, all I'm asking is as a matter of  
9 science, as a matter of logic, if you don't have  
10 the proof that DTaP doesn't cause autism, not  
11 saying it does, but you don't have the proof yet  
12 that it doesn't; right? Is it --

13 A Okay. I --

14 Q Let me just finish. Thank you. Isn't it  
15 premature to say that all vaccines do not cause  
16 autism?

17 A No, I do not believe that that is the case,  
18 sir. I feel that I've answered this question  
19 repeatedly. I do not feel that vaccines cause  
20 autism.

21 Q Okay. And do you have a study that supports  
22 that DTaP doesn't cause autism?

23 A I have -- I do not have a study that -- that  
24 DTaP causes autism, so I don't have either.

1 Q Fair enough. Do you have any study one way  
2 or another of whether IPOL causes autism?

3 A I -- no, I do not, sir.

4 Q Do you have any study one way or another of  
5 whether Engerix-B causes autism?

6 A I do not have any evidence that it causes  
7 autism, nor that it does not.

8 Q And what about HibTITERs vaccine, any  
9 evidence one way or another whether it causes  
10 autism?

11 A No. I think that's really not been  
12 associated with it. I don't think there are  
13 reports of that, but I -- but the evidence is the  
14 same. It's neither conclusive or -- as I have  
15 mentioned before.

16 Q Okay. And what about the Prevnar vaccine?  
17 Any evidence one way or another?

18 A No, sir. No, sir. But Prevnar is used all  
19 over the world, and there have been no reports of  
20 that in the large-linked databases.

21 Q Are there published studies that say that?

22 A I'm not sure whether there's specific or not,  
23 right.

24 Q Okay. And how about varicella vaccines, let

1 me just finish, are there any studies one way or  
2 another that support whether it does or doesn't  
3 cause autism?

4 A Part of MMR, but not as varicella by itself,  
5 no, sir. No studies that say it does or no  
6 studies that say it doesn't.

7 Q All right. There have been studies that have  
8 found an association between hepatitis B vaccine  
9 and autism; correct?

10 A Not studies that I feel are credible.

11 Q Okay. Which study -- which study do you --  
12 are you referring to when you say that?

13 A Well, why don't you show me the study and  
14 then I'll say whether I agree with it.

15 Q Okay. Why don't we just do one and then  
16 we'll move on. Okay. This is going -- this is --  
17 oops. This is not the right study. Sorry.

18 MR. SIRI: While I'm looking for this,  
19 this is going to be 20 -- Plaintiff's Exhibit 22?  
20 Is that right?

21 MS. CHEN: So I think it's actually 23.  
22 I think somewhere along 17 and 18 we got a little  
23 jumbled up.

24 MR. SIRI: Okay.

1 MS. CHEN: So I think it's actually 23,  
2 but please correct me if I'm wrong.

3 MR. SIRI: I -- we'll floss it out  
4 afterwards, thank you.

5 (Whereupon, Exhibit  
6 No. 23 was marked to the  
7 testimony of the  
8 witness.)

9 Q (By Mr. Siri) Okay. So this is going to be  
10 Plaintiff's Exhibit 23, and are you familiar with  
11 this study?

12 A No, sir, I'm not.

13 Q Okay. This study was by Carolyn Gallagher  
14 and Melody Goodman; correct?

15 A That's what it says, sir.

16 Q Are you familiar with these researchers?

17 A No, sir, I'm not.

18 Q Okay. Are you familiar with the -- the Ph.D.  
19 Program in Population Health and Clinical Outcomes  
20 Research at the Stony Brook University Medical  
21 Center, Health Sciences Center?

22 A No, sir, I'm not.

23 Q Are you familiar with the graduate program in  
24 public health there?

1 A No, I don't -- I -- I don't know the academic  
2 programs at Stony Brook.

3 Q Okay, great. So this study found that boys  
4 vaccinated as neonates had three-fold greater odds  
5 for autism diagnosis compared to boys never  
6 vaccinated or vaccinated after the first month of  
7 life, and it was specifically looking at whether  
8 they received HepB or did not receive HepB. Have  
9 you ever heard about that conclusion?

10 A I'm not -- I haven't reviewed the study, sir.  
11 I don't know where the -- where the database is.  
12 I would be happy to review it at another time. I  
13 think there are a couple points that -- you know,  
14 certainly it is more common to have boys have  
15 autism than girls. I think whenever you have such  
16 a study, you have to make sure that there are not  
17 any confounders. What is the database for which  
18 this was taken, please?

19 Q I believe it was based on a --

20 A Would you go to the methods, please?

21 Q Sure, absolutely.

22 A Okay. So that's NHIS, a complex study design  
23 that -- stratification, clustering, and -- so the  
24 parent sample contained 15,000 children, and in

1 each of those years, the outcome variable was  
2 autism yes or no, I don't know exactly how the  
3 diagnosis was made and what the diagnostic  
4 criteria were. Can you move down a little bit  
5 so --

6 Q Yeah, I want to make sure you can see it all.  
7 Can you see it all now, Dr. Edwards?

8 A I --

9 Q And if you need me to scroll to the next  
10 page, just let me know.

11 A Okay. So these included boys with a  
12 vaccination record that were available, and this  
13 domain to birth prior -- and was restricted to  
14 birth prior to 1999. The vaccination with  
15 hepatitis B was determined by subtracting birth  
16 month and year. The birth month -- so I guess one  
17 question would be whether we have documentation of  
18 the actual birth record for this and make sure  
19 that the confirmation that the vaccine was  
20 received, so I -- so I can't see that that's -- I  
21 can't see that that has been documented. The  
22 outcome variable was yes or no, and -- and so SAS  
23 was used to look at the statistics. Could you go  
24 to the next slide, please?



- 1 Q Sure. That's it under the results.
- 2 A Okay.
- 3 Q So is this one of the studies that you  
4 indicated earlier you found to be unreliable?
- 5 A No. I -- I -- I have not assessed this  
6 study.
- 7 Q Study -- what --
- 8 A I can't -- I can't say, sir. I'd need a  
9 little bit -- a few more minutes to look --
- 10 Q You --
- 11 A -- at -- for --
- 12 Q Absolutely. You know what, this will be  
13 marked, you'll have a copy, and we can revisit it  
14 at trial.
- 15 A Thank you very much.
- 16 Q Okay. Now, one thing though is you're  
17 familiar with the Agency for Health Research and  
18 Quality?
- 19 A Yes, sir.
- 20 Q It's referred to as AHRQ; correct?
- 21 A I'm -- I am familiar, yes, thank you.
- 22 Q Part of HHS? It's part of HHS, Doctor?
- 23 A Yes. Yes, sir. Yes, sir, it is. Yes.
- 24 Q And you're aware AHRQ issued a review in 2014

1 entitled Safety of Vaccines Used For Routine  
2 Immunization in the United States?

3 A I believe I reviewed that, but you can pull  
4 it up so I can look at it again.

5 Q Okay. As I'm pulling it up, let me ask you  
6 this. Are you aware that HHS describes this  
7 report as the most comprehensive review to date of  
8 published studies on the safety of routine  
9 vaccines recommended for children in the  
10 United States?

11 A No, I didn't know what they had claimed.

12 MR. SIRI: Okay. Okay. So this is  
13 going to be marked as 24, Plaintiff's 24.

14 (Whereupon, Exhibit  
15 No. 24 was marked to the  
16 testimony of the  
17 witness.)

18 Q (By Mr. Siri) Have you seen this study  
19 before?

20 A I believe I've looked at this document, yes.

21 Q Okay. And one of the -- one of the -- it --  
22 one of the things they reviewed was whether  
23 hepatitis B vaccine causes autism; correct?

24 A That's what is highlighted there in this

1 article. It says autism and it's referring to the  
2 article that you've just mentioned, and -- and so  
3 I -- yeah.

4 Q Okay. And this is the only study that they  
5 found; correct?

6 A I don't -- I don't know whether they did. I  
7 haven't -- I didn't review this before the  
8 deposition to see whether they found any. I -- if  
9 this is the only one -- if this is the only  
10 paragraph, then it's apparently the one that  
11 they -- they saw, so I -- I was not aware that  
12 there were associations as to --

13 Q I --

14 A -- that report.

15 Q Well, we'll mark this and so you'll have a  
16 chance to review it before trial, which is -- it's  
17 been marked, and I'm going to now mark this one.  
18 It's a different excerpt from the same report.

19 MR. SIRI: We'll call this Plaintiff's  
20 25.

21 (Whereupon, Exhibit  
22 No. 25 was marked to the  
23 testimony of the  
24 witness.)

1 Q (By Mr. Siri) Are you -- do you recall that  
2 you were a technical expert for this report?

3 A I guess I must have reviewed it, so I guess  
4 that I -- I must have and forgotten about that  
5 article, so I -- I've read -- you know, probably  
6 read since that time -- since 24 -- I've probably  
7 read 5,000 articles. I read about three or four a  
8 day, so I'm sorry that I don't recall it, but I  
9 certainly will review it again.

10 Q And what -- and what association does it  
11 provide under your name here?

12 A Vanderbilt Vaccine Research Program. That's  
13 the name of the program that I used to lead at  
14 Vanderbilt.

15 Q Okay. It doesn't disclose any of your  
16 affiliations with pharmaceutical companies;  
17 correct?

18 A I don't know, sir. I can't -- since I forgot  
19 about the one article that they mentioned, I don't  
20 know what it says, so I guess you'll have to look.

21 Q Okay. And this is --

22 A I'm sure if it did, you'd show me.

23 Q And this is a government report; correct?

24 A It's AHRQ. They're a part of the government.

1 Q Yeah, okay. Let me show you an article here.  
2 I'm going to pull up one of your articles,  
3 Dr. Edwards.

4 MR. SIRI: And I'm going to mark this as  
5 26.

6 (Whereupon, Exhibit  
7 No. 26 was marked to the  
8 testimony of the  
9 witness.)

10 A Yeah, my name is spelled wrong also, but it  
11 is me.

12 Q (By Mr. Siri) Yeah, I noticed that. Now,  
13 Dr. Edwards, this was -- so you're familiar with  
14 this study; correct?

15 A I remember reading it. I don't remember all  
16 the details of it. I have about 600 articles, but  
17 if you show me what you want me to look at, I'd be  
18 delighted to do it.

19 Q Thank you, Dr. Edwards. Now, this, as it's  
20 titled, Causality Assessment of Adverse Events  
21 Reported to the Vaccine Adverse Events Reporting  
22 System.

23 A Correct.

24 Q This -- this was a study in which you --

1 about a hundred reports were selected and  
2 reviewers then looked at the medical records that  
3 were available for those individuals who submitted  
4 the adverse event report to VAERS to --

5 A Could you make it a little -- could you make  
6 it a little bigger so I can read it, please?  
7 Thank you so much.

8 Q Absolutely.

9 A Okay. So the abstract, if you could just  
10 move it up and so I can read it, thank you.

11 Q Sure. You've got it. Is that better?

12 A Yeah. So this is part of -- of our vaccine  
13 CISA studies and this was a hundred VAERS reports,  
14 and a number of people reviewed them.

15 Q Okay. And what were they reviewing for?

16 A We were just trying to establish whether --  
17 how we could establish -- whether we could  
18 establish causality and whether we could establish  
19 temporality, so that was -- we were just trying  
20 to -- to look at -- at that with it -- I'm kind of  
21 getting dizzy. Can you stop moving it and make it  
22 a little bigger, please?

23 Q I'm sorry. I thought I would help you out  
24 here by moving to what I think you're talking

1 about, which is the five different causality  
2 groups that they would have assigned. I was  
3 trying to be helpful.

4 A So could I look at the abstract just very  
5 quickly again? I'm sorry.

6 Q Absolutely. It's -- like I said at the  
7 beginning, it's awkward because normally you'd  
8 just have this in front of you, and, you know,  
9 you'd look at it and -- but like I said at the  
10 beginning, I'm happy to scroll to any place that  
11 you'd like. Please.

12 (Whereupon, the witness  
13 is reading the document.)

14 A Yeah, so these -- these VAERS reports were  
15 distributed. There was a lot of people on the --  
16 on the -- the group that reviewed them, and so we  
17 sorted them into whether we thought definite,  
18 probable, possibly, unlikely, or unrelated in  
19 terms of causality, so that was how it was done,  
20 and there's probably a results section that --  
21 that I'm sure you're going to show, so you might  
22 want to return to that, to the results table.

23 Q Yes, ma'am. All right. And as you just  
24 said, these are the five potential, right,

1 definite, probable, possible, unlikely, unrelated,  
2 and here was the -- and then these were the --  
3 these were the 100 reported that were reviewed;  
4 correct?

5 A So there were 100 reports, and in those 100  
6 reports, there were 108 adverse events associated  
7 with the -- with vaccines, adverse events  
8 following immunizations, so there were -- yeah, so  
9 these are the -- those that were -- these are just  
10 the reports. These are not assessment of  
11 causality.

12 Q Absolutely. These are just the reports, and  
13 these were the conditions that were looked at, and  
14 in six -- in six of the reports, there was a claim  
15 of autism being caused by vaccines; correct?

16 A That's what it says. I didn't remember how  
17 many that had autism, but that's what it says, so  
18 I'm sure it's right.

19 Q Okay. It doesn't mean that the vaccines  
20 caused autism in those six reports; right? It was  
21 just reported to VAERS by a manufacturer or a  
22 doctor or a parent; right?

23 A That it -- that's correct.

24 Q All right.



1 A That's correct.

2 Q So what this study was going to do, it was  
3 going to review the existing literature, the  
4 existing medical records of these 100 children,  
5 and the doctors were going to try to make a  
6 causality assessment with regards to whether in  
7 these six instances the vaccines caused autism;  
8 correct?

9 A That's correct.

10 Q Okay. Now, let's scroll down, and you can  
11 see there were -- these are the causality  
12 conclusions. Now, Dr. Edwards, okay, what was the  
13 causality conclusion regarding these six cases of  
14 autism?

15 A I have -- I have no idea, sir. I'm sorry, I  
16 didn't pull this paper to review it, so I -- I  
17 don't know what the assessments were. You'll have  
18 to tell me.

19 Q Well, you know, based on -- going back to --  
20 please. Go ahead.

21 A Can I say something or do you want to finish  
22 and then I'll say --

23 Q No, no, go ahead. You go, please.

24 A So -- so one of the things that you have to

1 understand with the VAERS reports are that some  
2 reports are better than others. Some reports are  
3 more comprehensive than others. So what we did in  
4 this study was we assessed whether we could --  
5 whether a causation could be assessed, so I'm  
6 sorry, I don't remember each six cases, I do not  
7 remember the adequacy of the medical records for  
8 each of those, and I don't remember exactly what  
9 we came up with, but I could be pretty sure that  
10 none of them were definitely caused by vaccines,  
11 but again, that's what -- what I would recall and  
12 I -- I would have to read the article if it says  
13 specifically about those cases.

14 Q Fair enough. Would you be willing to produce  
15 the records showing what the causality conclusion  
16 were for those six autism cases?

17 A So this study was done -- in what year was  
18 this, sir? It was published in 2010?

19 Q I think it was '12. Let me look at the --

20 A Okay. So this study was led by -- in Boston,  
21 Anita Loughlin, and --

22 Q Okay.

23 A Okay. Could you put the authors back up so I  
24 can just --

1 Q Oh, absolutely.

2 A Okay. So this study was led -- so this study  
3 was led -- led by Anita Loughlin who is at Boston  
4 University Medical Center. She no longer works  
5 there. Her boss, who was on -- who was the second  
6 author, Colin Marchant, has retired. So whether  
7 I -- I do not have the primary data for this  
8 study, and -- and so I'm not sure how we could get  
9 the primary data, but I -- and I don't even know  
10 how to reach Anita, but I can do what I can, but I  
11 just -- you know, I -- I have a lot of studies  
12 and -- that I'm on, and I do not have the database  
13 for this. She would have that or someone at -- at  
14 Boston. I could see whether they have any of this  
15 information.

16 Q I'd appreciate that. You know, I've seen a  
17 number of these studies, and usually it will, you  
18 know, break it down on a more granular level what  
19 the causality conclusion is for each one of these  
20 conditions that are reviewed. Any -- any  
21 recollection you have of why that information  
22 wasn't provided in this study on a granular level,  
23 instead they provided this flow chart where you  
24 have to engage in some kind of, you know, logic

- 1 game to try and sort of figure out what --
- 2 A No, sir, I --
- 3 Q You --
- 4 A No, sir. No, sir. I -- you know, it  
5 certainly wasn't designed to confuse people. You  
6 know, it's not the New England Journal. This  
7 isn't my best paper, and I'm not the first author  
8 or the senior author on this, so I'm sure that I  
9 didn't disagree with what it said, but I really  
10 wasn't in charge of this study.
- 11 Q Got it. Fair enough. Now, many vaccines  
12 contain aluminum adjuvant; correct?
- 13 A Yes, sir.
- 14 Q Okay. There are generally three types of  
15 aluminum adjuvant used in vaccines?
- 16 A Yes, sir.
- 17 Q Do you know what those are?
- 18 A Yes. Aluminum hydroxide, aluminum phosphate,  
19 and alum, which is a formulation of aluminum, so  
20 those are the three forms.
- 21 Q All right. The third one is amorphous  
22 aluminum --
- 23 A It just --
- 24 Q -- hydroxyphosphate sulfate? Is that the one

1 you're referring to?

2 A Yeah, which is part of alum.

3 Q It's part of alum, right. I mean,  
4 generally -- these are generally referred to as  
5 aluminum adjuvants; right?

6 A That's correct.

7 Q Okay. Sometimes I'll ask you questions I  
8 know that seem very simple to you, but, you know,  
9 not simple to the --

10 A I appreciate --

11 Q -- rest of us.

12 A I appreciate simple straightforward questions  
13 that I can answer yes or no, thank you.

14 Q Okay. Have you ever published any studies  
15 regarding the effects of aluminum adjuvants?

16 A Yes, I have.

17 Q Okay.

18 A Probably more than a single one and, you  
19 know, I'm sure that -- I'd be happy to look at  
20 which one you've chosen.

21 Q Well, we -- we couldn't identify any, so I  
22 was asking --

23 A Oh, okay. Well, I'll tell you some studies  
24 that we've done. We've actually --

1 Q Sure.

2 A We've actually looked at the effect of  
3 different kinds of aluminum on our pertussis  
4 studies, so if you go to the pertussis studies,  
5 you'll see different forms of aluminum on the  
6 chart, you'll see different -- different  
7 assessments of aluminum. I also published several  
8 papers about adverse local events due to  
9 hypersensitivity of aluminum, and -- and because  
10 aluminum can cause sterile abscesses, so -- so I  
11 have several of those papers that I have studied  
12 aluminum and aluminum adjuvants.

13 Q And are any of those intended to assess the  
14 overall safety of aluminum adjuvants when injected  
15 into the body?

16 A They are -- they are studies to look at the  
17 effect of the aluminum on the immune response  
18 for -- and also in one complication of an adverse  
19 event with aluminum associated with  
20 hypersensitivity. They are not large database  
21 studies to look at aluminum.

22 Q Okay. And how many people were involved in  
23 those typically?

24 A The studies of pertussis were several

1 thousand people and the studies of the -- of their  
2 local abscesses were just a few patients. I can't  
3 remember the exact number.

4 Q Got it. And the pertussis studies were  
5 comparing a vaccine with one type of adjuvant with  
6 a vaccine with a different kind of adjuvant. Is  
7 that right?

8 A Yes. And they were also comparing them to  
9 whole-cell vaccines.

10 Q Which also has aluminum adjuvant in it?

11 A That's correct.

12 Q Okay. Do you have any studies that compare a  
13 group that got aluminum adjuvant with those that  
14 didn't get aluminum adjuvant?

15 A I believe. I can't recall exactly. We had  
16 13 acellular vaccines and one whole-cell. I think  
17 there may -- perhaps one of them was recombinant  
18 and did not include alum, but I can't say for  
19 sure. I would have to check that. And that was  
20 published in the '90s.

21 Q Okay. Is that on your CV? You don't --

22 A Yes, sir, it is.

23 Q It is?

24 A Yes.

1 Q Do you recall the title, by any chance?

2 A It's the Multi-Center Acellular Pertussis  
3 Vaccine Studies Immunogenicity. It was  
4 published -- there was a big -- a big syllabus  
5 that had all the acellular vaccine studies, and it  
6 was the immunogenicity, and it was published in  
7 the 1990s. I was the first author on that.

8 Q All right. Could you just repeat the title  
9 again? Multi-Center Acellular --

10 A Pertussis, MAPT, Multi-Center Acellular  
11 Pertussis Trial on Immunogenicity. It was  
12 published in Pediatrics.

13 Q Okay, thank you.

14 A There's also a paper that looks at the safety  
15 of those as well, and that -- the lead author on  
16 that paper is Michael Decker, D-e-c-k-e-r.

17 Q Were you an author on that one?

18 A Yes, I was. There were about seven papers  
19 from that work, and I was an author on all of  
20 those.

21 Q Got it. And I can find those in your CV?

22 A Yes, sir.

23 Q All right, thank you. Okay. So which -- and  
24 so just to -- just to close the loop on that, so



1 you've done studies regarding comparing different  
2 aluminum adjuvants -- comparing different  
3 pertussis vaccines with different kinds of  
4 aluminum adjuvants, you think maybe one of them  
5 that had a group that didn't get aluminum  
6 adjuvant, and then separately you have some  
7 studies regarding local reactions to aluminum  
8 adjuvants. Is that right?

9 A That's correct.

10 Q Any other aluminum adjuvant studies?

11 A Well, obviously there's other studies I've  
12 done that had -- have had aluminum in their --  
13 have had aluminum adjuvants. There are some of  
14 the studies I've done with pneumococcal vaccines,  
15 you know, or other vaccines, or -- so -- so again,  
16 that's part of some of the vaccines and it's not a  
17 part of the others.

18 Q So which -- which studies were that -- so  
19 which -- which studies would those be?

20 A Sir, I can't -- I can't tell you which of  
21 the --

22 Q That's okay. I'm only asking for your best  
23 memory. You don't have to make -- if you don't  
24 remember, that's fine. That's totally fine. I

1 was impressed you remembered the other  
2 multi-center study. Okay. Got it. So some of  
3 the others -- some of the other studies of  
4 vaccines, you're saying, you know, one group got  
5 one vaccine with aluminum and the other group got  
6 a vaccine without aluminum.

7 A Not necessarily. I would have to go through,  
8 you know, all of them. In general, the focus on  
9 the studies that looked at various vaccines was  
10 are they immunogenic, what kind of adverse events  
11 are they associated with, and -- and is there any  
12 interactions in the immune responses when you  
13 administer that vaccine with other vaccines, so  
14 the focus was not on comparing the adjuvants, the  
15 aluminum adjuvants, but some of them had adjuvants  
16 of different types.

17 Q Understood. Meaning it wasn't like a -- a --  
18 it wasn't a primary, you know, outcome that you  
19 were looking to assess, but you could maybe, you  
20 know, infer safety of adjuvants from those  
21 studies, you're thinking, you think. You'd have  
22 to look.

23 A Well, there -- they were between 2 and 3,000  
24 babies, and so we --

1 Q Okay.

2 A -- we assessed the safety there.

3 Q All right. We'll take -- we'll take a look  
4 for that, and hopefully we'll just find them on  
5 our own. Thank you for explaining.

6 A If you want after this, I can send the PDFs  
7 for that, if you'd like.

8 Q I would appreciate that, thank you. Okay.  
9 Now, do you know which of Yates' vaccines  
10 contained aluminum adjuvant?

11 A Yeah, certainly the DTP and -- and again,  
12 I -- I'd have to -- sometimes I have to refresh my  
13 memory whether -- which of the vaccines other than  
14 DTP contain that, so certainly the DTP did as  
15 well, and I can pull up the package inserts for  
16 the other vaccines if you'd like me to.

17 Q Okay. Do you know whether Engerix-B had  
18 aluminum adjuvant in it?

19 A I -- I'm not -- I can't remember for sure.

20 Q Okay. You conducted clinical trials for GSK  
21 with the Engerix-B vaccine; correct?

22 A It may -- it hasn't been a primary focus over  
23 the studies. It may have been a concomitantly  
24 administered vaccine. You know, I -- you've asked

1 me a lot of questions, and I -- you know, I tried  
2 to remember everything, but I -- my -- my memory  
3 is not encyclopedic.

4 Q That's -- and that's entirely fine. If you  
5 don't remember, you just say so. It's -- it's  
6 fine not to remember. Now, what's the part of the  
7 typical particle size of each piece of aluminum  
8 adjuvant in each vaccine typically?

9 A You're kidding. That --

10 Q If you don't know, that's fine.

11 A Thank you for the levity. I -- I'm impressed  
12 that you thought that I would know that.

13 Q Okay. Were you aware that each vaccine that  
14 contains aluminum adjuvant typically contains tens  
15 of thousands of pieces of aluminum adjuvant  
16 between 1 to 10 microns in size?

17 A I wasn't aware of the physical  
18 characteristics of each particle of an aluminum,  
19 no.

20 Q Okay. And 1 micron would be about a million  
21 times larger than a single ion of aluminum;  
22 correct?

23 A I don't know, sir.

24 Q Okay. Now, you said you looked at injection

1 site reactions to aluminum adjuvant; correct?

2 A Yes, sir.

3 Q Okay. So approximately how many individual  
4 pieces of aluminum adjuvant would be present at  
5 the injection site directly after an injection of  
6 aluminum adjuvant vaccine?

7 A I don't know, sir.

8 Q Okay. You've never heard that it would be  
9 tens of thousands of individual aluminum adjuvant  
10 particles?

11 A I've never heard whether that's -- that is  
12 correct or not, no.

13 Q Okay.

14 A I've -- I have not. I have not read anything  
15 about the number and the size of the particles.

16 Q Okay. And what's the purpose of including  
17 aluminum adjuvants in many of the vaccines on a  
18 childhood schedule?

19 A Aluminum is added as an adjuvant. An  
20 adjuvant means that it enhances the immune  
21 response to the vaccine.

22 Q Okay. And does it bind to the antigen in the  
23 vaccine?

24 A Well, it depends in terms of whether it's --

1 it's -- you know, it's -- it's an emulsion or  
2 whether it's alum and the physical characteristics  
3 of each of the doses of the vaccine and its  
4 relationship to the aluminum in the vaccine. I am  
5 not aware of how many pieces of aluminum is in  
6 each injection or the actual physical charac --  
7 physical characterization of the combining of the  
8 adjuvant and the aluminum.

9 Q Got it. Now, without the aluminum adjuvant,  
10 there would be a very weak immune response in the  
11 vaccine that contained aluminum adjuvant. Is that  
12 correct?

13 A Well, sometimes it's -- it's interesting.  
14 You know, with some of the vaccines that I've  
15 studied over the years, some are really enhanced  
16 with the aluminum and others are not, so it's kind  
17 of a -- it sort of depends upon the antigen.

18 Q Uh-huh. So, for example, in the Infanrix or  
19 the Engerix-B vaccines, would it be accurate to  
20 say that without aluminum adjuvant they wouldn't  
21 generate a sufficient immune response to make  
22 the -- such that the vaccine would be effective at  
23 preventing the diseases for which its vaccination  
24 is provided?

1 A Yeah, that's generally correct. And what  
2 usually happens in the Phase 1 and Phase 2 trials  
3 is that the vaccines are usually administered with  
4 or without adjuvants, and then in that -- in that  
5 scenario, then if it's found that the -- the  
6 vaccine doesn't need an adjuvant and the vaccine  
7 response is adequate, then it would not be added,  
8 so I think it's fair to say that vaccines that  
9 have adjuvants in them have been shown in the  
10 studies, in the early studies, and then confirmed  
11 in the later studies that they -- in order to be  
12 optimally immunogenic and protective, they need to  
13 have alum.

14 MR. SIRI: Okay. I'm going to mark this  
15 as Exhibit 27, Plaintiff's Exhibit 27.

16 (Whereupon, Exhibit  
17 No. 27 was marked to the  
18 testimony of the  
19 witness.)

20 Q (By Mr. Siri) You're familiar with this  
21 book, Dr. Edwards; correct?

22 A Yeah, I spent a lot of hours writing this  
23 book and enter -- in this book.

24 Q Okay. And I'm going to read you a sentence

1 from Page 21 of this book, the chapter --

2 A Yeah, this is an article that's written by  
3 Claire-Anne Siegrist, who is an immunologist in  
4 Geneva.

5 Q Okay. So she wrote, most non-live vaccines  
6 require their formulation with specific adjuvants  
7 to induce danger signals and trigger a sufficient  
8 activation of the innate system. Do you agree  
9 with that statement?

10 A I do, but I think you're taking it out of  
11 context. You're taking it out of the context of  
12 what she's talking about, and she's -- she's one  
13 of the most eloquent persons to discuss what  
14 happens with immune responses, and so what she's  
15 saying is that that -- an adjuvant or a --  
16 aluminum, in this case, or other adjuvants will  
17 engender a -- more of a local response and maybe  
18 be associated with some local irritation or even  
19 some fever, and because of that, then the immune  
20 system is triggered, and I think with the COVID  
21 vaccine studies now, which that's exactly what  
22 we're seeing, we're seeing adjuvants that are  
23 added or -- that are added to the vaccines and  
24 we're seeing reactions that are danger signals, it



1 says I need to make an immune response to this, so  
2 this is -- is a -- is danger signals, but it  
3 doesn't say it's dangerous.

4 Q Ahh. I never said that. I -- but it does  
5 create a danger signal so that the vaccine, when  
6 injected, will assist in producing, you know,  
7 various kinds of cytokines; correct?

8 A It will -- it will cause a sufficient  
9 activation of the innate immune system, just as  
10 she said.

11 Q Right. And the antigens, when they're  
12 absorbed onto aluminum adjuvant, they're then  
13 taken up by macrophages and dendritic cells;  
14 correct?

15 A That's correct.

16 Q Okay. So the den -- the macrophages and  
17 dendritic cells absorb -- they do phagocytosis,  
18 right, they basically eat not only the antigen,  
19 but also the aluminum adjuvant; correct?

20 A That's correct.

21 Q Okay. Now, you know, part of the -- as we  
22 discussed, you know, the aluminum adjuvant helps  
23 create a danger signal that in this instance is  
24 viewed as a good one so that the immune system

1 reacts; correct?

2 A Yes, sir.

3 Q Okay. And -- and to -- to helping -- help  
4 it, you know, release cytokines, including IL-1,  
5 IL-2, IL-6, or IL-17; correct?

6 A Yes, sir.

7 Q Okay. Now, once the aluminum adjuvant, the  
8 antigen balancing the aluminum adjuvant is taken  
9 up by the macrophages, where do they travel in the  
10 body?

11 A Well, they generally stay localized and -- or  
12 the macrophages will begin to degrade them, and  
13 the -- and if the macrophages are in the  
14 circulation, then they will do that as they  
15 circulate in the body.

16 Q You're saying that -- it's your testimony  
17 that macrophages have the ability to degrade  
18 aluminum adjuvant?

19 A Well, they -- they degrade the actual -- the  
20 actual antigen antibody com -- or the antigen  
21 complex and -- so they -- they do act to process  
22 the aluminum, and some of the aluminum stays  
23 locally as well.

24 Q Okay. Are you aware that there are numerous

1 studies starting in 1997 at the CDC going all the  
2 way up to the present that have injected various  
3 animals with aluminum adjuvant and then sacrificed  
4 the animals to find where the aluminum adjuvant  
5 traveled in the body?

6 A Yes, sir, I am, and those actually began a  
7 long time ago with Freund and the use of  
8 adjuvants, so yes, I am, sir.

9 Q Are you aware that those studies have  
10 universally found that the adjuvant travels to  
11 various organs and in particular the brain?

12 A I have not reviewed the animal studies, but,  
13 you know, certainly things happen in animals that  
14 don't happen in people, and I'm not aware of  
15 studies of, you know, post autopsy in human brains  
16 showing aluminum.

17 Q So you're not aware of any study that shows,  
18 for example, high levels of aluminum in the brains  
19 of post autopsy children that had autism?

20 A Well, I guess if you want me to comment on a  
21 certain paper, I'm not aware of that paper, so if  
22 you'd like me to review that again, you can show  
23 me the paper and I'll look at it and see whether I  
24 think it's credible.

1 Q Okay. But you have -- you said you have seen  
2 the studies where they injected animals with  
3 aluminum adjuvant, sacrificed them, and have found  
4 universally aluminum adjuvant in the brain of  
5 those animals?

6 A I have seen those papers in reference to, but  
7 again, I can't recall the detail and the specifics  
8 about the -- those -- each of those papers, sir.

9 Q Okay.

10 A I'd be happy to look at them if you'd like me  
11 to.

12 Q Okay. Well, we could gladly provide you  
13 copies of those. I'll just -- but I don't want to  
14 spend the time marking them now because there's a  
15 lot of them. Okay. So now, as you indicated,  
16 vaccines cause immune activation; right? That's  
17 what they do. They activate the immune system;  
18 correct?

19 A That's correct.

20 Q Okay. Now, if the aluminum adjuvant is bound  
21 to antigen, were to travel to and remain in the  
22 brain, it could cause sustained immune activation  
23 in the brain; correct?

24 A I don't -- I -- no, sir, I -- I have no

1 evidence to suggest that I would -- I would agree  
2 with that statement.

3 Q Now, do you have no evidence to suggest that  
4 it would travel to the brain or do you have no  
5 evidence to suggest that it would cause --

6 A I have no --

7 Q -- sustained immune reaction -- activation in  
8 the brain?

9 A I have no evidence to address either of the  
10 portions of your biphasic question.

11 Q Fair enough. What about the animal studies  
12 we have just discussed? Do you believe that would  
13 provide evidence?

14 A Provide evidence for what?

15 Q That aluminum adjuvant upon injection can  
16 travel to the brain.

17 A Again, sir, I'd have to look at those papers  
18 and see whether I agree. And again, I'm sorry, I  
19 haven't -- I didn't review those for the  
20 deposition.

21 Q That's no problem.

22 MR. SIRI: You know, let's just mark  
23 them quickly so that we can -- this way  
24 Dr. Edwards has them and has an opportunity to

1 review them. Let me just share my screen. We  
2 will quickly mark them. I want to make sure that  
3 you have copies. Okay. So we're going to mark  
4 this study as Exhibit Number -- is it 29?

5 MS. CHEN: 28.

6 MR. SIRI: 28, thank you.

7 (Whereupon, Exhibit  
8 No. 28 was marked to the  
9 testimony of the  
10 witness.)

11 MR. SIRI: And we're going to mark --  
12 and this is a study of rabbits injected with  
13 aluminum and dissected and aluminum found in the  
14 brain. I believe it's CDC related. This is a  
15 study from -- sorry. This is a study from 2009  
16 involving mice. We're going to mark this as  
17 Exhibit Number 29.

18 (Whereupon, Exhibit  
19 No. 29 was marked to the  
20 testimony of the  
21 witness.)

22 MR. SIRI: This is a study from 2012 and  
23 we're going to mark it as Exhibit 30. This one  
24 actually shows the macrophages can act as a Trojan

1 horse carrying material to the brain.

2 (Whereupon, Exhibit  
3 No. 30 was marked to the  
4 testimony of the  
5 witness.)

6 MR. SIRI: We're going to mark this one  
7 as Exhibit Number 31. It's from 2013. It's  
8 another mice one, and it's got actually pictures  
9 of the aluminum in the brain of the mice, so you  
10 can take a quick look at that.

11 (Whereupon, Exhibit  
12 No. 31 was marked to the  
13 testimony of the  
14 witness.)

15 MR. SIRI: And then here's another one  
16 from -- this one is from 2015. We're going to  
17 mark it as Exhibit 32. This one again is 155  
18 mice. Again, it's lots of images of the brains of  
19 the mice.

20 (Whereupon, Exhibit  
21 No. 32 was marked to the  
22 testimony of the  
23 witness.)

24 MR. SIRI: This is a study from 2016,

1 we're going to mark as Exhibit 33. This one shows  
2 the macrophages actually acting as Trojan horses  
3 carrying the loads to the brain. You know, in  
4 the -- in any event, you'll read the study.

5 (Whereupon, Exhibit  
6 No. 33 was marked to the  
7 testimony of the  
8 witness.)

9 MR. SIRI: Thirty -- Exhibit Number 34,  
10 and then -- let's just do one more and that should  
11 be enough. This one is from 2006 as well, and  
12 we'll mark that as Exhibit 34.

13 (Whereupon, Exhibit  
14 No. 34 was marked to the  
15 testimony of the  
16 witness.)

17 Q (By Mr. Siri) So obviously you have not had  
18 a chance to look at these. I'm not going to ask  
19 you questions about them at the moment. That's  
20 not going to be fair. You will have an  
21 opportunity to review those and we can revisit it  
22 at trial. Now, coming back to this, immune  
23 activation in the brain can lead to  
24 neurodevelopmental disorders. Isn't that true?



1 A Sir, I think that -- that you're asking me to  
2 comment on things that -- I am not a neurologist.

3 Q Oh.

4 A Nor am I a -- so I'm just saying that --  
5 that, you know, if you want me to discuss what the  
6 effect of the -- of specific questions about  
7 animal models or that -- that's really not my area  
8 of expertise.

9 Q So okay, that's fine. If you don't know,  
10 that's fine. So you're -- the -- you don't know  
11 whether immune activation in the brain can lead to  
12 neurodevelopmental disorders?

13 A I have not reviewed the paper that you're  
14 taking that from. That is not my understanding,  
15 but I would be happy to read it and review it.  
16 But again, I -- I don't -- it's hard for me to  
17 know what you're talking about sometimes.

18 Q Okay.

19 A Which specific paper you're talking about.

20 Q Well, I wasn't actually talking about any  
21 paper.

22 A Okay.

23 Q I mean, there are many -- there are hundreds  
24 of NIH-funded papers that -- you know, out of

1 Cal Tech and so forth that study immune activation  
2 during pregnancy and during, you know, early  
3 phases of childhood development in infants and  
4 toddlers, and, you know, finding that immune  
5 activation can lead to neurodevelopmental  
6 disorders, and I was just curious if you were  
7 familiar with that body of literature in general,  
8 and it sounds to me that your answer is no. Is  
9 that correct?

10 A Yes.

11 Q Okay. Are you aware that aluminum adjuvant  
12 injected into the body can cause an increase in  
13 IL-6 in the brain?

14 A No, sir, I am not, and I -- if that is the  
15 case and if there's a specific paper, please let  
16 me review that. I think if you want me to review  
17 something that I am not familiar with, I am happy  
18 to do that.

19 Q Well, I obviously have to ask first to know  
20 whether you're familiar with it, and I'm very  
21 happy to give you a copy of it. So 2013 -- what  
22 exhibit number is this? All right. Well, I will  
23 mark this. Again, I can't find one, but I'll mark  
24 one of them, which is -- so let me just share my

1 screen. I'll mark this one so you'll have an  
2 opportunity to review it, and I believe I have one  
3 more, and you can have an opportunity to review  
4 that one for trial as well, 102.

5 MR. SIRI: So we're going to mark this  
6 one as Exhibit -- is it 35?

7 MS. CHEN: Yes.

8 MR. SIRI: Okay, thank you. And we will  
9 actually mark this one as Exhibit 36.

10 (Whereupon, Exhibit  
11 Nos. 35 and 36 were  
12 marked to the testimony  
13 of the witness.)

14 Q (By Mr. Siri) Okay. Are you aware that  
15 there are studies that show that an increase in  
16 IL-6 has been shown to induce autism-like features  
17 in lab animals?

18 A Sir, I am not familiar with the -- with the  
19 animal aluminum literature in regarding to -- so  
20 you can keep asking me. I'm totally fine with  
21 answering that I am not familiar with the paper,  
22 so --

23 Q Yeah.

24 A And I'll find -- I'll just say that send it

1 to me, I'll be happy to look at it, but I don't  
2 want to comment on something that I have not  
3 reviewed.

4 Q And I absolute -- I -- that is absolutely  
5 fair and you shouldn't and I'm not asking you to,  
6 but obviously, again, it's okay to say you don't  
7 know or you haven't reviewed it, but I don't know  
8 if you don't know it until I ask you about it, so  
9 if you don't know, that's totally fine.

10 MR. SIRI: We're going to mark this one  
11 as 37 and we're going to mark this one as 38.  
12 Okay.

13 (Whereupon, Exhibit  
14 Nos. 37 and 38 were  
15 marked to the testimony  
16 of the witness.)

17 MR. SIRI: Patricia, are you able to see  
18 the exhibit numbers on these as I'm opening them?

19 MS. CHEN: Yes.

20 MR. SIRI: Okay, great. I just wanted  
21 to make sure because I don't see them on my side.

22 Q (By Mr. Siri) Okay. Now, let's just do this  
23 one. So have you ever seen --

24 MR. SIRI: I'm going to mark this one

1 as -- what are we up to, 30 -- 30 what?

2 MS. CHEN: 39.

3 MR. SIRI: 39.

4 (Whereupon, Exhibit  
5 No. 39 was marked to the  
6 testimony of the  
7 witness.)

8 Q (By Mr. Siri) Have you ever seen this paper,  
9 Dr. Edwards?

10 A No, sir.

11 MR. SIRI: Okay. I'm going to mark this  
12 one as 40.

13 (Whereupon, Exhibit  
14 No. 40 was marked to the  
15 testimony of the  
16 witness.)

17 Q (By Mr. Siri) Have you ever seen this letter  
18 from a Professor Romain Gherardi regarding his  
19 opinion regarding whether aluminum adjuvants in  
20 vaccines can contribute to causing ASD?

21 A No, I -- I have not, sir. I -- I am not  
22 familiar with this letter, nor was it actually  
23 addressed to me, so I haven't read it.

24 Q Fair enough. Let's see. It was in 2017 and

1 it was addressed to HHS, NIH, and FDA. In 2017  
2 you were sitting on VRBPAC, correct, at the FDA?

3 A Yes, sir.

4 Q Okay. And this is another letter from  
5 Professor Christopher Exley, who is considered an  
6 expert in aluminum, and again it was in 2017  
7 addressed to the FDA when you were sitting on  
8 VRBPAC. Have you ever seen this letter in which  
9 he discusses what he believes is the role of  
10 aluminum adjuvant in causing autism spectrum  
11 disorder?

12 A I -- not -- not that I -- not that I  
13 remember, sir.

14 Q Okay. Well, so both of these papers provide  
15 an extensive list of studies regarding aluminum  
16 adjuvant, as well as Dr. Gherardi's, you know,  
17 that they say support that aluminum adjuvant in  
18 vaccines can trigger and then add to ASD, so I  
19 just want to point that out to you. Okay. Now,  
20 earlier you stated you're not aware of any study  
21 in which, you know, a high -- aluminum adjuvants  
22 found in the brain of autistic individuals or  
23 children.

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

1 Exhibit Number 41, is it?

2 MS. CHEN: If the letter from Dr. Exley  
3 was supposed to be 41, then you're on 42, but if  
4 not, then this current one is 41.

5 MR. SIRI: Yeah, Dr. Exley will be  
6 Exhibit Number 41, thank you, and this will be  
7 Exhibit Number 42.

8 (Whereupon, Exhibit  
9 Nos. 41 and 42 were  
10 marked to the testimony  
11 of the witness.)

12 Q (By Mr. Siri) And so I'll provide you this  
13 as well to review. This is a study conducted by  
14 Dr. Exley, in which he looked at the brains of  
15 autistic children and found the highest levels of  
16 aluminum that he has found in any of the numerous  
17 cohorts of brains that he's ever looked at,  
18 including for various other ailments. You'll have  
19 an opportunity to look at that as well. Okay. So  
20 are -- do -- do you know of any specific study  
21 involving injection of aluminum into humans or  
22 animals, all right, and what -- that showed  
23 aluminum adjuvants are safe?

24 MR. SANDERS: Object to the form of the

1 question. You can answer, Doctor.

2 A Yeah, it really is such a ridiculous  
3 question, I'm not going to answer it.

4 Q (By Mr. Siri) It's ridiculous to ask whether  
5 you're aware of any studies that looked at the  
6 injection of aluminum adjuvant on whether it's  
7 safe? Okay. Are you familiar with the HPV  
8 Gardasil clinical trials?

9 A Yes, sir, I am.

10 Q Okay. What did the control group in the  
11 clinical trials to license Gardasil, Gardasil 4,  
12 what did virtually everybody, the thousands of  
13 young girls and boys and middle-aged girls and  
14 boys, women and men, what did they receive an  
15 injection of in those clinical trials?

16 A I can't remember what they received in the  
17 control group. If you want to remind me, I'll --  
18 that would be great. I -- I --

19 Q That's fine.

20 A I just don't remember that, per se.

21 Q Okay. Okay. If a study involving injecting  
22 aluminum existed to support its safety, do you  
23 think the NIH -- Office of Intramural Research at  
24 the NIH defines such a study?



1 A I think that they -- the NIH would fund  
2 studies that have a testable hypothesis --

3 Q Okay.

4 A -- that would allow the sample size and the  
5 study conduct to come up with a meaningful  
6 conclusion, but obviously I -- I'm not in charge  
7 of the purse strings at NIH, so I would have to --  
8 they would have to look at the studies.

9 Q All right. I'm not -- I -- I apologize.  
10 I -- I -- maybe -- I must have not said my  
11 question clearly. I meant if -- do you think that  
12 they have the ability to resources to find if they  
13 were to search, not conduct, but to search the  
14 literature and find any study that would support  
15 the safety of injecting -- that involved the  
16 injection of aluminum that supported safety?

17 A Well, the NIH is not really in the position  
18 to evaluate the literature in terms of -- you  
19 know, the way the NIH is set up is that they -- if  
20 they have a question that they want to address,  
21 then they issue an RFP, which I told you kind of  
22 about how that works.

23 Q Uh-huh.

24 A And if an investigator is -- has a hypothesis

1 that they want to test and they submit it, there  
2 is a specific group or pot of money that is set  
3 aside for studies on vaccine safety within the  
4 NIH.

5 Q So you're saying if a request were made to  
6 the -- for example, the National Institute of  
7 Allergies and Infectious Diseases and they said  
8 that they had searched for a study that supported  
9 the safety of injecting aluminum adjuvant, you're  
10 saying that they wouldn't conduct such a review?

11 I'm not sure I --

12 A I -- all right. I'm really --

13 Q All --

14 A I can't answer. I don't know what you're  
15 saying, I'm sorry. I -- I'm just -- I -- I'm  
16 sorry, I can't answer that.

17 Q That's no problem. Let me ask it to you this  
18 way. If the National Institute of Allergy and  
19 Infectious Disease and the -- you know, the Eunice  
20 Kennedy Shriver National Institute of Child Health  
21 and Human Development and the NIH Office of  
22 Intramural Research all looked for a study of  
23 whether or not alum -- injecting aluminum adjuvant  
24 were safe, do you think they would be able to find

1 such a study?

2 A I don't know, sir. I don't know what their  
3 capabilities are in searching the literature, and  
4 I don't know the answer to that question, so I  
5 can't answer yes or no. I just can't answer that,  
6 and -- you know, I'm sorry that I -- it's just not  
7 something that I can answer.

8 Q No problem.

9 MR. SIRI: Let me mark this as 40 --  
10 what is it? 44? Is it 44, Patricia?

11 A I can't count that high.

12 MR. SIRI: Well, until somebody tells me  
13 otherwise, I'll assume it's Plaintiff's 44.

14 (Whereupon, Exhibit  
15 No. 44 was marked to the  
16 testimony of the  
17 witness.)

18 Q (By Mr. Siri) Now, this was the response  
19 from the Department of Health and Human Services.  
20 You'll have an opportunity to review it. I just  
21 want to mark it here so you have the benefit of it  
22 for trial, and this is a letter that was sent to  
23 my firm, and it says, you know, this is the final  
24 response to your Freedom of Information Act

1 request addressed to the FOIA office at the  
2 National Institute of Health. You requested  
3 copies of any human or animal studies involving  
4 the subcutaneous or intramuscular injection of  
5 aluminum adjuvant relied upon by the NIH to  
6 establish the safety of injecting infants and  
7 children with aluminum hydroxide, aluminum  
8 phosphate, and AAHS. And it says that the OIR,  
9 NIAID, and NICHD searched their files and no  
10 records responsive to your request were located.  
11 You can have a -- take a look at that at another  
12 time. A similar response was received by the CDC  
13 as well. But we can mark for identification --  
14 let's just move on though. All right. So let's  
15 just take a -- just take a quick look at the  
16 Gardasil trial. Now, when -- this is the package  
17 insert for Gardasil; correct?

18 A Yes, sir, it is.

19 MR. SIRI: Okay. We're going to mark  
20 this as Plaintiff's 45.

21 (Whereupon, Exhibit  
22 No. 45 was marked to the  
23 testimony of the  
24 witness.)

1 Q (By Mr. Siri) Now, take a look at Table 9  
2 and -- take a look at Table 9. All right. So  
3 this is the summary of the girls and women 9  
4 through 26 years of age who reported an incident  
5 condition potentially indicative of a systemic  
6 autoimmune disorder after enrolling in the  
7 clinical trials for Gardasil regardless of  
8 causality; correct?

9 A That's what it appears to show, yes, sir.

10 Q And it shows that it had an AAH control and a  
11 saline placebo control; correct?

12 A That's what it says, yes.

13 Q AAH means -- is an aluminum adjuvant; right?

14 A Amorphous aluminum hydroxyphosphate sulfate,  
15 which is what it says at the bottom.

16 Q All right. Are you aware that -- that of the  
17 9,412 women and girls that received either an AAHS  
18 control or saline placebo, virtually all of them  
19 received the AAHS control?

20 A I'm not aware of the distribution. I do now  
21 remember that the -- that the control in some of  
22 them was the aluminum, so thank you for refreshing  
23 my memory. I don't know what the distribution  
24 between those two are, but if you could --

1 probably it's somewhere and so you could show that  
2 to me.

3 Q Sure. Well, I mean, go back to Table 1.

4 A So --

5 Q Yeah, please.

6 A Again, I don't know whether that's precisely  
7 the same study because the numbers, I don't know  
8 whether they add up, but I --

9 Q Yeah, that's fair enough. There is --  
10 obviously in clinical trials, like the saline  
11 placebo study, is reported; all right? And I'll  
12 just pull that up quickly.

13 MR. SIRI: Mark this as 40 --  
14 Exhibit 46, I think.

15 (Whereupon, Exhibit  
16 No. 46 was marked to the  
17 testimony of the  
18 witness.)

19 A You know, you're throwing certain studies up,  
20 and I don't -- I can't confirm with a number that  
21 what you're showing me is the same, so I'm not  
22 trying to be difficult, but --

23 Q (By Mr. Siri) You're not. Fair enough.

24 A It's something -- I just -- you've got to go

1 slow enough that I know what you're talking about.

2 Q No problem. I -- you know, I'm going to --  
3 I'll mark these, and you'll have a chance to look  
4 at them before trial, but I think that's going to  
5 be fair.

6 A Great. I'll take a couple weeks' vacation  
7 and look at all these things.

8 Q All right. Let's just go and -- I'll take a  
9 look at this -- this placebo and -- you know what,  
10 if we have time at the end, we'll come back to  
11 this.

12 A What -- if you have a specific question about  
13 it, maybe that --

14 Q Yeah, okay. Well, that would be great. I  
15 just -- I don't want to spend too much time on it,  
16 but you know, here you can see that, you know,  
17 there's 320 girls in the placebo group and 274  
18 boys in the placebo group, saline placebo group;  
19 correct? And then if we go here, this is the --  
20 this is the study of Gardasil in preadolescents  
21 and adolescents that's recorded com -- filed as  
22 the 018 trial, because there's a number of them,  
23 as you know. This is the only one that included a  
24 saline placebo, and when you go down, you can see

1 the number of participants that adds up to 561,  
2 the same number of boys and girls, and you can  
3 look through here and, you know, you can see what  
4 adverse reactions were reported. Now, this is  
5 very difficult to do over Zoom. This is why  
6 I'm -- it's very complicated. If you had this in  
7 your hand, you could look at it and you could flip  
8 through the pages and I would ask you is there any  
9 systemic autoimmune issues reported here, but  
10 doing this over Zoom, I'd have to scroll through  
11 it and it's very difficult. You'll have a chance  
12 to look at it. What you'll find is that there are  
13 none, and then, you know, what I would have asked  
14 you, and we can do this again at trial, is -- so  
15 you're prepared for it, you see in the Gardasil  
16 group, within six months, right, of starting --  
17 of -- of the injection, 2.3 percent of the  
18 previous healthy girls developed -- reported  
19 incidences in a condition potentially indicative  
20 of systemic autoimmune disorder; correct?

21 A You know, I -- it's -- I'm trying to -- as  
22 quickly as I can, so which of the things do you  
23 want me to look at, lupus or do you want me to  
24 look at all of these? Okay. You want me to look



1 at the numbers comparing the Gardasil and the  
2 control. Okay. So the total number of events and  
3 the percentage of events were comparable.

4 Q Right. But isn't it possible that the  
5 Gardasil vaccine caused these 2.3 percent in girls  
6 to develop systemic autoimmune disorder as well --  
7 and that the AAH control, the AAH adjuvant that  
8 was in the Gardasil is what caused the 2.3 percent  
9 of girls to develop a systemic autoimmune disorder  
10 in the control group?

11 A No. That -- you can't deduce that because  
12 there's a couple of other things you have to  
13 consider. First of all, you have to consider what  
14 the incidents of these autoimmune conditions is in  
15 the population, in the unimmunized population.  
16 Lupus, scleroderma, inflammatory bowel disease,  
17 many of these things are diagnosed during this  
18 time, this preadolescent, adolescent early  
19 adulthood time. So the fact that you have equal  
20 numbers doesn't mean that either causes the  
21 adverse event. The interpretation could be that  
22 neither of them do, and this is the background  
23 rate of that adverse event, so this is -- is  
24 not -- you can't make that conclusion from this,

1 at least if you're knowledgeable you can't.

2 Q So these were previously healthy participants  
3 in the trial; correct?

4 A They are previously healthy participants, but  
5 previously healthy participants can develop lupus,  
6 they can develop other things, so the fact that  
7 you see these in the population does not mean that  
8 they're caused by this.

9 Q Do you believe if you looked at the  
10 background rate you would find that during every  
11 six-month period, 2.3 percent of previous healthy  
12 girls and women in America would develop a  
13 systemic autoimmune disorder?

14 A I would have to look at that and see. I do  
15 not have that at the top of my -- you know, and  
16 certainly that would be -- if you're on a data  
17 safety monitoring committee, that's what you would  
18 do.

19 Q Right. Because, I mean, if it's 2.3 percent  
20 every six months, that's 4.6 percent every year,  
21 over ten years that would be 46 percent of all  
22 previously healthy women --

23 A Yeah.

24 Q -- and --

1 A Yeah, that -- that -- it doesn't say that  
2 it's additive. That's for -- that's full -- or  
3 whatever. It's wrong.

4 Q But this is showing within six months how  
5 many previously healthy girls that's -- prior --  
6 previously didn't have systemic autoimmune  
7 disorder reported a systemic autoimmune disorder;  
8 correct?

9 A That's correct. It's -- it says, to have one  
10 in the Gardasil group out of 10,000 and you have  
11 three out of 10,000 in the placebo group, so I  
12 don't know, you know, what the rate is in this  
13 population, but that seems -- you know, one in  
14 the -- in 10,000 isn't very much.

15 Q Well, no, it's 245 in the Gardasil group out  
16 of 10,000.

17 A No, I said for lupus. I said for lupus. You  
18 have to look at all of these individual issues.

19 Q Ahh.

20 A And I'm just saying that for lupus, there's  
21 one in 10,000 in the -- in the vaccine group and  
22 there's three in slightly less than 10,000 in the  
23 placebo group, so I would have to look at the  
24 background rates in that population, and it

1 doesn't mean that it's going to be additive,  
2 there's data to suggest that in six more months  
3 you're going to have double, and that just isn't  
4 the way it works.

5 Q You just don't know, right, because this  
6 study, they may have looked at it for six months.  
7 You have the data that you have. Why -- but if  
8 they had just compared Gardasil to a strictly  
9 saline placebo group, then there wouldn't be this  
10 unknown of did the adjuvant cause it, did it not;  
11 correct?

12 A But it goes back to what I tried to make  
13 clear a number of hours ago, and that is that when  
14 you have a trial, if you -- if you have a -- as a  
15 placebo, a real placebo, then patients often will  
16 know what they have received. Now, you may say  
17 that they would -- they would say that they're --  
18 they don't care whether they receive vaccine, and  
19 actually, if you look at the information, the --  
20 the actual administration of an HPV vaccine has no  
21 impact on people's sexual activity, but you could  
22 say, well, if they realized that they got placebo,  
23 they wouldn't have sex and they wouldn't get HPV,  
24 so this is all part of the complexities of

1 clinical trials. If you choose a placebo that's  
2 placebo, it's hard to -- hard to make sure that  
3 your participants do not know what you're getting.

4 Q So what you're saying is -- you're saying  
5 that you should abandon the gold standard of  
6 clinical trials, you should double-blind --

7 A No.

8 Q -- give up control -- let me just finish my  
9 question -- the double-blind placebo controlled  
10 studies because those in the placebo group are not  
11 going to have, you know, reactions in a way that  
12 let's say giving them another vaccine would have,  
13 and then they're going to -- you know, when they  
14 don't have a reaction, they're going to be, like,  
15 whoa, I know now I got a placebo. I mean, you  
16 know, why is it -- what you're saying is the  
17 assumption is vaccines will all cause reactions,  
18 and so we have to give -- we always have to  
19 compare giving vaccines to giving vaccines, then  
20 you'll never know what the safety profile of any  
21 vaccine is.

22 MR. SANDERS: Object to the form of the  
23 question. You can answer it, Doctor, if  
24 you understand the question.

1 A I'm not going to answer that. I'm not going  
2 to answer that. I think --

3 Q (By Mr. Siri) Fair enough if you don't want  
4 to answer it.

5 A I think the answers to my questions -- to  
6 your questions in general are quite clear, so I  
7 think that I've answered that question.

8 Q Now, the package insert for each vaccine in  
9 Section 6 will list adverse reactions to the  
10 vaccine; correct?

11 A I can't see Section 6, so if you want to show  
12 me Section 6, I'm happy to look at that.

13 Q No, I just mean in general, package inserts  
14 for all vaccines have typically -- you know, they  
15 list in Section 6 of the package insert adverse  
16 reactions to the vaccine; correct?

17 A There is always a section. I didn't know  
18 that it was always Section 6, so now I -- I know,  
19 thank you.

20 Q Okay, great. You know, we can pull up --

21 A I believe you. I just didn't know it was 6.

22 Q No, that's fine. Right. But you're aware  
23 there's -- there's a section that lists the  
24 clinical trial experience and the adverse events

1 in each --

2 A Absolutely. I just don't know the numbers  
3 which each of those is assigned.

4 Q Right. Are you aware that under federal law  
5 the package insert is supposed to include in  
6 Section 6, quote, only those adverse events for  
7 which there is some basis to believe there is a  
8 causal relationship between the drug and the  
9 occurrence of the adverse event, end quote?

10 A I am aware that's what it states, but I think  
11 that a lot of the inclusions in package inserts  
12 have really not shown a causation, they have just  
13 been reported in the clinical trials, so -- so  
14 those package inserts tend to be quite inclusive.

15 Q Now, the adverse events typically are what  
16 are actually post-marketing adverse events;  
17 correct?

18 A No, not necessarily. The adverse events are  
19 those that are captured both in the assessment of  
20 the vaccine evaluation during the Phase 1, 2, and  
21 3 trials, but also post marketing. Now, it may  
22 label, for instance, those charts that you showed.  
23 There's charts that -- those are -- those are --  
24 are studies that were done part of the -- of the

1 actual -- of the licensure, I would think, but  
2 they're generally both studies that -- that --  
3 results of studies pre and post licensure are in  
4 the package insert.

5 Q So what you're saying is that even though the  
6 federal law is clear that the manufacturer is  
7 supposed to only provide the adverse events for  
8 which they believe there's a causal relationship,  
9 is it your testimony that they're not complying  
10 with that law and listing adverse events that  
11 are -- also don't have a -- they don't have a  
12 reason to believe they're causally related?

13 MR. SANDERS: Object to the form of the  
14 question. You can answer, Doctor, if you  
15 understood the question.

16 A I'm not sure that I understood the question,  
17 but I will answer what I -- what I -- I -- what  
18 happens with the package insert. As the paper  
19 that showed you with VAERS, I think in general we  
20 are often left not being able to assess a  
21 causation definitively with a vaccine and an  
22 adverse event, so given that difficulty, if there  
23 is an adverse event that happens in a clinical  
24 study and it is associated with -- with -- and



1 frequently enough, it will appear in the package  
2 insert, so -- so every single thing that's in the  
3 package insert has not been established without  
4 reasonable doubt that it's causative.

5 Q (By Mr. Siri) Oh, so -- so the adverse  
6 reactions that are listed in the package insert  
7 are only included when there is, you know, a basis  
8 to believe that there is a causal connection  
9 between the adverse event and the vaccine;  
10 correct?

11 A That's not what I said.

12 Q Okay. I --

13 A That's opposite of what I said.

14 Q I -- please.

15 A So please listen to what I say so you don't  
16 have to ask again. So what I'm saying is that if  
17 an adverse event is seen in a Phase -- in a  
18 Phase 1, 2, and 3 trial or in a post-licensure  
19 trial, it is often included in the package insert  
20 whether or not you can prove causation because as  
21 I showed you in that VAERS, it's very difficult to  
22 prove definitive causation, so if there's any  
23 question of a relationship between the adverse  
24 event and the vaccine, it is put in the package

1 insert.

2 MR. SIRI: I'm going to mark this as  
3 Exhibit -- Plaintiff's Exhibit 47.

4 MS. CHEN: 47.

5 MR. SIRI: Thank you.

6 (Whereupon, Exhibit  
7 No. 47 was marked to the  
8 testimony of the  
9 witness.)

10 Q (By Mr. Siri) Now, are you familiar with  
11 this regulation, Dr. Edwards?

12 A It's a CFR Title 21. I don't know all the --  
13 that's included in it, so if there's something  
14 you'd like me to address, I'd be happy to read it.

15 Q Okay. All right. This is Section 201.57,  
16 specific requirements on content and format of  
17 labeling for human prescription drugs and  
18 biological products. This would be the section  
19 that would govern what should go in a package  
20 insert; correct?

21 A I trust it, so -- although I can only see a  
22 portion of it.

23 Q Fair enough. Let's go down to what it  
24 provides for Section 6. So this would be

1 Section 6, adverse reactions that would be  
2 reported. Can you read the yellow, please?

3 A Yes. This section must describe the overall  
4 adverse reaction profile of the drug based on the  
5 entire safety database. This definition -- I  
6 don't know which definition you're referring to, I  
7 guess adverse reactions -- does not include all  
8 the adverse events observed during the use of the  
9 drug, only those for which there's some basis to  
10 believe there is a causal relationship. This is  
11 not what you said. This is not -- it's to say it  
12 does not have to be a proved causal relationship.  
13 And if there is any question about the  
14 relationship or any question about this, it is  
15 included in the package insert. So this does not  
16 establish that there is a causal relationship  
17 between the drug and the AEFI.

18 Q Okay. But you would agree that the package  
19 insert only includes adverse events that meet this  
20 definition as required by federal law?

21 A I think that what companies put in the  
22 package insert is often when there has not been  
23 clear establishment of the causal relationship, as  
24 I've said three times now.

1 Q Fine. But they -- would they put something  
2 in when there is -- when there isn't some basis to  
3 believe there's a causal relationship?

4 MR. SANDERS: Object to the form of the  
5 question. Asked and answered several times.

6 A I'm not going to answer it again.

7 Q (By Mr. Siri) Okay. It's not clear to me,  
8 but -- I mean, I'm -- I think that -- I think what  
9 I'm understanding is you're saying that they'll  
10 put adverse events into the package insert even if  
11 they haven't established causation, but you're  
12 not --

13 A That is correct.

14 Q But you're not --

15 A That is correct.

16 Q Absolutely. Right. They'll only put it in  
17 when there's -- but they'll only put it in when  
18 there's some basis to believe there is a causal  
19 relationship as required by the Code of Federal  
20 Regulations.

21 MR. SANDERS: Object to the form of the  
22 question. Asked and answered.

23 MR. SIRI: That hasn't been ans -- that  
24 has not been asked and answered.

1 Q (By Mr. Siri) Please, Dr. Edwards.

2 A I'm not going to answer it because I've  
3 already answered it.

4 Q Okay. Well, you haven't clarified what the  
5 minimum standard is, so let me ask a question I  
6 think you'll find easier. Do you believe that  
7 there are adverse events in package inserts that  
8 are put in for which there is no basis to believe  
9 there's a causal relationship?

10 A Yes.

11 Q Okay. And what's that -- what do you base  
12 that opinion on?

13 A Well, I think if you look at the adverse  
14 events of package inserts, they contain a lot of  
15 adverse events, some of which I have not seen  
16 associated with the vaccine, so I think that every  
17 single thing that is listed in a package insert  
18 does not mean that that particular vaccine causes,  
19 causes that adverse event, no, and that's what my  
20 answer is.

21 Q Right, sure. It just means that as a -- that  
22 there's some basis to believe that it causes it,  
23 not that it actually causes it; right? Let's use  
24 something specific. Now, of course, it's the

1 manufacturer that's adding these adverse events to  
2 the insert; correct?

3 A Yes, sir, that's correct.

4 Q Okay. And you're not in -- are you privy to  
5 all of the data and information that the  
6 manufacturers each have when they're adding the  
7 adverse events to the package insert?

8 A Of course not. You know, certainly, I'm not  
9 privy to that. The FDA is privy to that.

10 Q Okay. Now, here is a letter --

11 MR. SIRI: We'll mark this as 50 --  
12 Exhibit 57 [sic].

13 (Whereupon, Exhibit  
14 No. 48 was marked to the  
15 testimony of the  
16 witness.)

17 Q (By Mr. Siri) This is a letter to the FDA  
18 from Merck; correct? I'm sorry, yes, this is a  
19 letter from the FDA to Merck; correct?

20 A That's what it appears to be.

21 Q Okay. Have you ever seen a supplemental  
22 approval letter like this before?

23 A No, sir. I don't work for pharma.

24 Q Okay. But you've consulted for

1 pharmaceutical companies; correct?

2 A I think we've already answered that question.

3 Q Okay. Now, in this, the FDA -- please take a  
4 moment to read the first paragraph. Let me know  
5 when you're done.

6 A I'm finished.

7 Q Okay. So in this, the FDA is approving the  
8 amendment to the package insert for MMR; correct?

9 A That's correct.

10 Q And Merck in 2017 decided to add into their  
11 package insert the disclosure of adverse events  
12 for these two adverse -- potential adverse events;  
13 correct?

14 A Yes, sir.

15 Q Okay. And why do you believe they did that?

16 A Well, they probably had -- these adverse  
17 events had been reported in their -- in the use of  
18 some of the vaccines. However, as part of my CISA  
19 role, I have actually done extensive reviews of  
20 HSP with vaccines, and the data is clearly not --  
21 does not establish causation, so they must have  
22 seen this in certain patients, I don't know how  
23 many patients, maybe it says later, but they just  
24 wanted to include it in the package insert. I

1 think sometimes things are included in the package  
2 insert that you -- that you don't really know for  
3 sure that are related and sometimes they can be  
4 very helpful, so, for instance, the whole  
5 rotavirus and intussusception, that was included  
6 in the package insert and then people began to see  
7 that, so I think it's prudent to put in things  
8 that you think may be associated even if you're  
9 not, but the fact that it's in the package insert  
10 does not mean that that adverse event is caused by  
11 the vaccine, and I think I've said that several  
12 times.

13 Q I know. Are you aware that under the  
14 1986 Act one of the exceptions where you could sue  
15 a vaccine manufacturer is if they know a vaccine  
16 causes certain injury and they don't disclose it?

17 A I think I remember that. Whether that was --  
18 I don't -- you know, I don't know whether -- I  
19 think that certainly the -- pharma is very -- you  
20 know, would rather add things to the package  
21 insert than omit them.

22 Q Do you think that might explain why they  
23 added these two conditions to the MMR, why Merck  
24 added these two conditions to the MMR package



1 insert?

2 A I think you'd have to ask Merck. I'm not  
3 familiar with their motivation for that.

4 Q Fair enough. What's encephalitis?

5 A It's an inflammation of the brain.

6 Q And what's encephalopathy?

7 A It's an abnormality of the brain. It means a  
8 pathologic brain, so there is a difference.  
9 Encephalitis is a cause of encephalopathy, but  
10 there are other causes of encephalopathy besides  
11 encephalitis.

12 Q All right. Encephalitis means basically  
13 brain swelling and encephalopathy means actual  
14 damage to the brain; correct?

15 A No, that's not what I said. Encephalitis,  
16 anything that has an itis after it is  
17 inflammation, so inflammation of the encephal,  
18 which means the brain, means there is an  
19 inflammation in the brain. There are brain  
20 inflammations that occur every year in people that  
21 have no long-term damage. Those are called  
22 aseptic meningitis from the enteroviruses.  
23 Encephalopathy is abnormality of the brain or  
24 pathology in the brain. The -- encephalopathy can

1 be mild or it can be severe. Just because it says  
2 encephalopathy does -- has no prognostic  
3 implication on its long-term impact on an  
4 individual.

5 Q Okay. Does the package insert for Infanrix  
6 list encephalopathy within seven days of a prior  
7 pertussis-containing vaccine as a contraindication  
8 to injecting further doses of this product?

9 A I think that contraindications for the use of  
10 DTaP basically are encephalopathy, acute  
11 encephalopathy, and anaphylaxis. However,  
12 encephalopathy, and the definition in this, is  
13 that it has to be persistent for 24 hours, and  
14 generally the people have to be hospitalized. So  
15 encephalopathy in that definition is quite -- is  
16 quite severe.

17 Q All right. So meaning if you've -- if that  
18 kind of severe reaction happened from a prior dose  
19 of Infanrix, the manufacturer's package insert  
20 says don't administer that vaccine again.

21 A If it's -- just as I said. If it meets that  
22 definition, the vaccine is contraindicated to be  
23 administered again.

24 Q Does the package insert for Infanrix list

1 encephalopathy in Section 6?

2 A I don't know, sir. You'll have to pull up  
3 Section 6. I think that's a little unreasonable  
4 for me to know exactly.

5 Q Well, that's fine. You don't know is a  
6 perfectly fine answer. Does the package insert  
7 for Engerix-B list encephalitis and encephalopathy  
8 in Section 6?

9 A I would trust that it does, but I don't know  
10 that it does, so I can't answer that, sir. If you  
11 would like to pull up the package insert, I am  
12 happy to read it.

13 Q Does the package insert for VARIVAX, the  
14 chicken pox vaccine, list encephalitis in  
15 Section 6?

16 A Probably does.

17 Q Does the package insert for MMR list --

18 A That question -- you also asked me that  
19 question before, which I answered.

20 Q Thank you. Does the package insert for MMR  
21 list encephalitis, encephalopathy,  
22 acute disseminated encephalomyelitis, and subacute  
23 sclerosing panencephalitis, SSPE, in Section 6?

24 A I believe that it does, although SSPE has not

1 been documented to occur with vaccine-associated  
2 virus. Are you waiting for me to answer?

3 Q Oh, no, no.

4 MR. SIRI: I'm going to mark this as  
5 plaintiff's Exhibit 40 -- is it 8?

6 MS. CHEN: 49.

7 MR. SIRI: 49, thank you.

8 (Whereupon, Exhibit  
9 No. 49 was marked to the  
10 testimony of the  
11 witness.)

12 Q (By Mr. Siri) And this is the -- a report  
13 from the CDC, the MMWR; correct?

14 A Yes.

15 Q Okay. And it is regarding SSPE, which is  
16 what we were just talking about; correct?

17 A Yes, sir.

18 Q Okay. And you're saying that SSPE cannot  
19 be -- is not caused by the measles vaccine;  
20 correct?

21 A That is -- that is the conclusion. Now, this  
22 study, I don't know whether -- you know, whether  
23 this is older and they didn't find the virus and  
24 whether -- you also have to make sure that it's

1 not the measles virus from the natural -- make  
2 sure that it's vaccine-associated.

3 Q Well, let's take a look at what it says. So  
4 can you please -- please read the portion in  
5 yellow out loud.

6 A The estimated risk of SSPE following natural  
7 measles is averaged by 8.5 cases per million.  
8 Estimated risk of following measles averaged 0.7  
9 per million of the live virus vaccine distributed.  
10 However, you have to make sure that in that time  
11 when those reported from '63 to '74 that each of  
12 those viruses was sequenced to make sure that  
13 it's -- that it is indeed a measles virus, and I  
14 don't know whether that was done in this paper.

15 Q Okay. But the CDC here is estimating and it  
16 is stating that the -- is indicating that SSPE can  
17 be caused by measles vaccination; correct?

18 A This is -- this paper was published a long  
19 time ago, and my understanding is that this has  
20 not been confirmed with the actual isolation of  
21 the virus from the -- from --

22 Q So the CDC's information here -- well, strike  
23 that.

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

1 Exhibit -- Plaintiff's 4 -- 49.

2 MS. CHEN: 50.

3 MR. SIRI: 50, sorry. 50.

4 (Whereupon, Exhibit  
5 No. 50 was marked to the  
6 testimony of the  
7 witness.)

8 Q (By Mr. Siri) Dr. Edwards, have you seen  
9 this before?

10 A I've not seen this result. I've seen the  
11 interpretation of the result by your expert and  
12 by -- by another geneticist.

13 Q Okay.

14 A And again, I am not a mitochondrial expert.

15 Q Got it. So you're not in a position to opine  
16 on the accuracy or the meaning of this result.

17 A No, other than the fact that I read an expert  
18 said that they didn't feel that this documented  
19 that, so I can -- obviously and one expert said  
20 that it did, so I'm not the person to say whether  
21 this is what the definitive diagnosis of this --  
22 of the mitochondrial problem is.

23 Q Understood. Let me just clear out some of  
24 these exhibits. Have you -- have you read this

1 affidavit from --

2 A Yes, I have, sir.

3 Q -- Dr. Kelley?

4 A I have, sir. Yes, I have, sir.

5 MR. SIRI: I'm going to mark this as  
6 Exhibit 51.

7 (Whereupon, Exhibit  
8 No. 51 was marked to the  
9 testimony of the  
10 witness.)

11 Q (By Mr. Siri) It is -- do you -- do you have  
12 any basis to contest the conclusion in this  
13 report?

14 MR. SANDERS: Object to the form of the  
15 question. It's overbroad. You can answer,  
16 Doctor, if you have an answer.

17 A Yeah, I -- I guess that I would sort of  
18 prefer if you had a specific question. I don't  
19 want to, you know, sort of jam an entire -- a  
20 physician for -- you know, for anything, and so if  
21 there's a specific question, I'm happy to answer  
22 it.

23 Q (By Mr. Siri) Do you disagree with  
24 Dr. Kelley's conclusion in this report?

1 A Why don't you show me his report -- his  
2 conclusion so that I am sure that I can address  
3 exactly what you want me to disagree with.

4 Q Well, why don't you read the summary portion.

5 A So first of all, I don't -- I don't -- I  
6 can't say that the first conclusion is correct  
7 because an expert on the other side said that the  
8 biochemical abnormalities are not -- are not  
9 consistent with that, so I can't comment on that  
10 particular -- I think it's -- it's something -- an  
11 issue of controversy. I think that the degree of  
12 medical -- that the set of immunizations at  
13 11 months of age while he was ill, that the  
14 immediate cause of his autistic regression to  
15 further impair the ability of his weakened  
16 mitochondria so by adequate amounts of energy, the  
17 highest energy consuming tissue in the body, I  
18 would not agree with that conclusion.

19 Q Are you a mitochondrial expert?

20 A I am not a mitochondrial expert. However, I  
21 feel that that -- while he was ill would be an  
22 immediate cause of getting his immunizations, I  
23 think that he was not -- was not seriously ill.  
24 He was -- he had a respiratory illness and had



1 otitis. I don't feel that there -- and he was  
2 actually closer to 12 months than he was 11  
3 months, I think it was three days from 12 months,  
4 so I disagree that he was 11 months old, and --  
5 and I think that -- that what he is stating in the  
6 last sentence is solely anecdotal. It's his  
7 experience.

8 Q And on -- how would you determine whether or  
9 not Yates' otitis media was severe or not severe  
10 when he received his immunizations at 11 months?

11 A Because I have read very carefully and I --  
12 and the -- in my clinical judgment, this child  
13 in -- should have been given the vaccinations, and  
14 I see no reason for him not to have received the  
15 vaccinations.

16 Q Have you ever treated any children with  
17 mitochondrial disorders?

18 A I have been involved in discussions about  
19 vaccines with children with mitochondrial  
20 disorders, so I -- yes, and I'm also quite  
21 familiar with children with mitochondrial  
22 disorders have a lot of problems when they have  
23 infections, real infections that are vaccine  
24 preventable, so -- so I think that is also a very

1 important thing to take into account is the -- is  
2 the fact that children with mitochondrial  
3 disorders have difficulties with infections that  
4 can be vaccine preventable.

5 Q Okay. Have you published any studies with  
6 regards to that?

7 A I don't believe so. I think those have been  
8 mostly in the individual case evaluations of the  
9 CISA, and those are not published. Those are --  
10 those are confidential because they involve  
11 individual patients.

12 Q Do you do any clinical study -- have you  
13 done -- performed any clinical studies with  
14 regards to mitochondrial disorders?

15 A Well, I have -- I have one paper where  
16 Cameron Schlegel is the first author where  
17 we've -- we've looked actually at some inborn  
18 errors of metabolism, and we've looked at -- at  
19 vaccines in relationship to their -- to their  
20 adverse outcomes, and this was a urea cycle  
21 defect, and so what we showed there was that the  
22 vaccines were not associate -- the administration  
23 of vaccines were not associated with adverse  
24 events in that particular population, so we have

1 studied high-risk people, but this was not  
2 specifically a mitochondrial population.

3 Q All right. Does Yates have a urea disorder?

4 A Sir, I said that we used another genetic  
5 condition. I was not saying that he had a urea  
6 cycle disorder. I'm just saying that I have  
7 experience in doing studies in populations that  
8 have genetic defects to look at the safety of  
9 vaccines.

10 MR. SIRI: Okay. I'm going to mark this  
11 as 52, Plaintiff's Exhibit 52.

12 (Whereupon, Exhibit  
13 No. 52 was marked to the  
14 testimony of the  
15 witness.)

16 Q (By Mr. Siri) Have you had a chance to  
17 review this document?

18 A No, sir, I haven't.

19 MR. SIRI: I'm going to mark this as  
20 Plaintiff's Exhibit 53.

21 (Whereupon, Exhibit  
22 No. 53 was marked to the  
23 testimony of the  
24 witness.)

1 Q (By Mr. Siri) Have you ever reviewed this  
2 study?

3 A Yes, I have, sir.

4 Q Okay. Do you agree with the conclusion in  
5 this study with regards to what caused Hannah  
6 Poling's autism?

7 A I -- I do not agree with all the conclusions  
8 in this study.

9 Q Okay. What don't you agree with?

10 MR. SANDERS: Object to the form of the  
11 question. Overbroad. You can answer, Doctor, if  
12 you can.

13 A I'm not going to answer until I know what the  
14 question is.

15 Q (By Mr. Siri) In this study, which you said  
16 you reviewed, the authors conducted a -- provide  
17 their case report with regard to Hannah Poling a  
18 discussion and then, you know, they reach a  
19 conclusion with regards to what led to Hannah  
20 Poling's autism. Do you dispute the finding that  
21 vaccines given to Hannah Poling caused her autism?

22 A I think that the -- there was a temporal  
23 association. Whether it was causative, I don't  
24 know. And again, as I said before, I'm not a

1 mitochondrial expert.

2 MR. SIRI: I'm going to play a video, I  
3 guess, which will be marked as Exhibit 54.

4 (Whereupon, Exhibit  
5 No. 54 was marked to the  
6 testimony of the  
7 witness.)

8 MR. SANDERS: Mr. Siri, may I ask you a  
9 question? We're well over seven hours into the  
10 deposition. Do you have an estimate about how  
11 much longer we will be?

12 MR. SIRI: We shouldn't be that much  
13 longer. We're getting there, I think. Rob, how  
14 long -- Mr. Sawyer, how many hours are we on  
15 record?

16 THE WITNESS: It's 20 minutes after  
17 3:00.

18 THE VIDEOGRAPHER: Right. I don't have  
19 the exact record time, but I know we took two  
20 15-minute breaks.

21 THE COURT REPORTER: I have the exact  
22 time, if you need it.

23 MR. SIRI: Sure. What --

24 THE VIDEOGRAPHER: Great, thank you.

1 THE COURT REPORTER: Yes, no problem.

2 The exact time has been six hours and almost 32  
3 minutes.

4 MR. SIRI: Okay. Thank you.

5 Q (By Mr. Siri) Okay. I'm about -- I'm going  
6 to try to wrap this up today, believe me. I think  
7 we all would like that. Okay. So let me play  
8 this video. Can you hear that?

9 A No, sir, I cannot.

10 Q Okay. Yeah, I think I know the issue. Let  
11 me just try that again.

12 (Whereupon, a video clip  
13 was shown.)

14 A I can't see this. This -- I can't see this.  
15 I can't see this.

16 Q Oh, you can't --

17 A Did you want me to listen or look?

18 Q I -- I wanted both. I mean --

19 MR. SANDERS: I'm not able to see it  
20 either, Mr. Siri. I just see a list of your  
21 exhibits on your computer as of now.

22 MR. SIRI: Oh, jeez. I shared the  
23 wrong -- I appreciate that. Luckily I didn't  
24 share a more inappropriate screen, huh? All

1 right. Give me a moment. There we go. All  
2 right. Let's try that again. Well, no, that's  
3 not going to work either. I need to do this, I  
4 need to click that and do this. Okay. And here  
5 we go. Oh, for God's sake. I did the wrong  
6 screen again.

7 A I guess I'm fine. It's Sanjay Gupta. If you  
8 want to just let me listen to Sanjay, I'm happy to  
9 listen to him. I also know Julie Gerberding quite  
10 well, so if you'd like me to listen, I'm happy to  
11 do that, but I can't see.

12 Q (By Mr. Siri) Okay. Last time. Are you  
13 ready? And -- there we go.

14 (Whereupon, a video clip  
15 was shown.)

16 Q Dr. Edwards, do you have any basis to  
17 disagree with what the CDC director just said on  
18 that video?

19 A I think if you listened very closely to what  
20 Julie said, Julie said she hadn't really had the  
21 ability to look at the case, to evaluate the case.  
22 I think that what she said, a lot of what she said  
23 was correct in that patients that have  
24 dysfunctional mitochondria, if they are stressed,

1 then they can have more difficulties. I think  
2 stress can come from the administration of a  
3 vaccine with fever, but stress also comes with a  
4 disease, so I think that this is a situation where  
5 you have to decide what the risks and the benefits  
6 of a vaccine are, and this is what you -- what you  
7 have to -- have to decide when there is a patient  
8 with this definitively diagnosed disorder, which  
9 I -- I don't think that I can convincingly say  
10 that your patient has, and -- but again, I think  
11 that you have to talk to the neurologist about  
12 that.

13 Q But so what you're saying is that if a child  
14 does have this serious mitochondrial disorder,  
15 they -- having an infection or having the vaccine,  
16 either of those could actually cause a stress on  
17 the body that could potentially lead to autism?

18 A If indeed you had that disorder, that -- that  
19 is hypothesized, so there's one case that -- that  
20 that's been shown in.

21 Q Okay. Based on the Poling and other cases,  
22 there is a known causal association between  
23 vaccines and regressive autism; correct?

24 MR. SANDERS: Object to the form of the



1 question. You may answer, Doctor.

2 A I -- I don't -- could you repeat the  
3 question, please?

4 Q (By Mr. Siri) Sure. Based on the Poling  
5 case, there is a known causal association between  
6 vaccines and regressive autism; correct?

7 MR. SANDERS: Same objection.

8 A Yeah, I don't think you can definitively say  
9 that, sir. I -- I don't think I could say an  
10 answer yes to that or -- or no, I can't -- I can't  
11 say that.

12 Q (By Mr. Siri) But you can't rule it out  
13 either; correct?

14 A I don't -- other than the -- the Hannah  
15 Poling case, I'm not familiar with any other cases  
16 that have suggested that to be the case.

17 Q What about this case?

18 A I can't see it.

19 Q Okay. So when that --

20 A It depends on --

21 Q Oh.

22 A Okay. It depends a little bit on the  
23 diagnosis, so again, I think that you show me a  
24 case and I want to -- you know, I don't know

1 whether the -- the mitochondrial dysfunction has  
2 been definitively diagnosed, so I think that if  
3 you show me something, I can't say for sure  
4 because I don't know for sure whether they have --  
5 what they have.

6 Q Okay.

7 A And I think it's probably something that you  
8 might want to talk about with -- to the  
9 neurologist.

10 Q Okay. Yates was diagnosed with regressive  
11 autism; correct?

12 A I didn't hear the first part of the question,  
13 sir.

14 Q Oh, no problem. I said, Yates was diagnosed  
15 with regressive autism; correct?

16 A Well, I -- I did review the report from --  
17 from the Vanderbilt CDC and it said autism. I  
18 wasn't familiar -- I don't -- I didn't see any  
19 other characterization and I'm not familiar with  
20 how one distinguishes that from another.

21 Q Okay. You're not --

22 A A diagnosis of autism, but I can't say that  
23 he has regressive autism.

24 Q You don't know though one way or another?

1 A I do not know whether he has regressive  
2 autism one way or another, yes, that's correct,  
3 sir.

4 Q Do you have any evidence of what caused  
5 Yates' autism?

6 A Yeah, I -- autism is a -- is a -- a neuro  
7 abnormality. I think that it was likely  
8 associated with some prenatal event and I do not  
9 think it's -- was due to his vaccines.

10 Q Do you have any evidence that Yates' autism  
11 was caused by some prenatal event?

12 A I think that -- that those -- those things  
13 are always hard to know. I think you -- you know,  
14 you -- I don't know the -- the mother, father's  
15 maternal age, there's about -- in terms of --  
16 there's factors about infections during pregnancy,  
17 and I'm not aware of any of those, so I think  
18 that -- that I'm not fully aware of the prenatal  
19 situation. I'm just saying that the articles on  
20 autism say that it's generally a prenatal event,  
21 and so that's what I'm saying.

22 Q So sitting here today, you don't actually  
23 have any evidence of what might have caused Yates'  
24 regressive autism; correct?

1 MR. SANDERS: Object to the form of the  
2 question. It mischaracterizes her testimony.

3 MR. SIRI: I didn't -- I'm not -- I'm  
4 not trying to characterize her testimony at all.  
5 I'm asking her --

6 Q (By Mr. Siri) Sitting here today, do you have  
7 any evidence of what caused Yates' regressive  
8 autism?

9 MR. SANDERS: Object to the form of the  
10 question. I --

11 MR. SIRI: Let me rephrase that because  
12 she never said regressive autism.

13 Q (By Mr. Siri) Sitting here today, do you  
14 have any evidence for what caused Yates' autism?

15 A I have no confirmation of what caused Yates'  
16 autism except that I know that it's not from his  
17 vaccine receipt.

18 Q Now, would you disagree that the best  
19 available evidence reflects that Yates has a  
20 serious mitochondrial disorder?

21 MR. SANDERS: Object to the form of the  
22 question. Asked and answered.

23 A I feel that -- that -- that the -- that the  
24 discussion from the neurologist and the geneticist

1 that addressed that shed considerable doubt on the  
2 diagnosis, so I -- I -- but again, I'm not an  
3 expert, I haven't looked at the mitochondria, and  
4 I wouldn't know a dysfunctional mitochondria from  
5 another looking under the microscope, so I'm not  
6 an expert in the mitochondrial diagnosis.

7 Q (By Mr. Siri) CDC --

8 A I think that -- I can't hear your question.

9 MR. SANDERS: Mr. Siri, you've frozen on  
10 us.

11 MR. SIRI: It says I'm unstable. Okay.  
12 And -- okay, I'm back.

13 Q (By Mr. Siri) Now, did you attend the  
14 Wellcome Trust London Vaccine Safety Meeting in  
15 2019?

16 A I sure did.

17 Q Okay. And who were you invited there by?

18 A I was invited by Wellcome Trust.

19 Q Okay. Did the invitation come from a  
20 specific person such as Dr. Stanley Plotkin?

21 A I think it probably came from Stanley.

22 Q Okay. And the meeting was intended to  
23 discuss gaps in the vaccine safety that needed to  
24 be addressed?

1 A That's correct.

2 Q Okay. And one of the topics discussed was  
3 the gap in safety data with regard to vaccination  
4 of children with mitochondrial disorders; correct?

5 A I can't -- I can't remember specifically  
6 whether that was on the program. I know there was  
7 a discussion of autism, and Fombonne did that, and  
8 then there was also the presentation by the Danish  
9 group. So if it was part of that, I can't  
10 remember. I don't recall that there was a  
11 specific person that talked about that, but maybe  
12 if you have the -- the calendar there, I could  
13 look at that. I -- I just can't quite remember  
14 for sure.

15 MR. SIRI: All right. I'm going to mark  
16 this as Exhibit 55. Patricia?

17 MS. CHEN: Correct, 55.

18 MR. SIRI: 55, thank you.

19 (Whereupon, Exhibit  
20 No. 55 was marked to the  
21 testimony of the  
22 witness.)

23 Q (By Mr. Siri) This is an e-mail chain  
24 regarding the Wellcome Trust London Vaccine Safety

1 Meeting in which you were on the chain; correct?

2 A I don't know. I can't -- I'm trying to find  
3 whether -- I don't see that I'm on the chain.

4 Yeah, there I am. Okay, yeah, I'm on the chain.

5 Q Okay. And does this document look familiar  
6 to you, the summary of ideas for future studies  
7 proposed by attendees at the Wellcome Trust London  
8 Vaccine Safety Meeting?

9 A Probably.

10 Q Okay.

11 A I -- I know there was such a discussion.

12 Q Okay. Do you recall if --

13 A Are these comment -- are these my comments  
14 from Dr. Plotkin? Is this -- is this -- is this  
15 something that I've responded to Dr. Plotkin? Is  
16 that -- are those comments, are those mine?

17 Q You'll have to tell me, frankly.

18 A Okay.

19 Q Because they redacted it when the --

20 A Okay.

21 Q -- government provided it, but --

22 A Okay.

23 Q Do you see here that this is one of the -- do  
24 you recall -- does this help remind you of one of

1 the things that was discussed at that meeting?

2 A Uh-huh, yeah. It says to look at reactions  
3 in patients with confirmed mitochondrial diseases  
4 or metabolic diseases.

5 Q All right. And to create a registry of such  
6 reactions; right?

7 A Yes, sir. That's what it says.

8 Q Okay. And that's in order to better  
9 understand, you know, what injuries or issues  
10 vaccines could potentially cause with individuals  
11 with mitochondrial disease or metabolic disease;  
12 correct?

13 A I think it's to better understand reactions  
14 to vaccines in patients with mitochondrial disease  
15 or metabolic diseases, as it says.

16 Q Was Yates receiving vaccines up to 18 months  
17 as recommended by the CDC childhood vaccine  
18 schedule?

19 A Yes, sir, he was.

20 Q Okay. Now, the number of vaccines in -- on  
21 the CDC schedule increased from six vaccines in  
22 1985 to a total of 20 in 2000; correct?

23 A There have been -- there has been an  
24 increase, yes.



1 MR. SIRI: I'll mark this as number 56.

2 MS. CHEN: 56?

3 (Whereupon, Exhibit  
4 No. 56 was marked to the  
5 testimony of the  
6 witness.)

7 A Again, this is from somebody's slide. I  
8 guess that's me. You've got a picture of me.

9 Q (By Mr. Siri) That's -- it's on YouTube. I  
10 didn't have to go far. So does this remind you of  
11 how many injections there were in 1985 versus  
12 2000?

13 A Well, that's my slide, so hopefully it's  
14 authoritative.

15 Q Okay. So between 1985 and 2000, the number  
16 of injections has gone from six to 20; correct?

17 A Yes. I got -- I'm not quite sure what the  
18 little cross is, but I guess --

19 Q Oh, that's just my mouse.

20 A Oh, okay.

21 Q Don't count -- don't count the -- don't count  
22 the mouse.

23 A Okay. I thought, oh, I don't remember that  
24 cross. Okay.

1 Q That's fair.

2 A I don't remember this slide even, but that's  
3 okay.

4 Q Has there ever been a study which looked at  
5 the total of the children following the CDC  
6 vaccine schedule such as Yates to 18 months and  
7 those that have not received these products,  
8 meaning they were completely unvaccinated?

9 A I think that there have been studies looking  
10 at vaccines and vaccine receipt and not vaccine  
11 receipt. I think it's problematic because, as you  
12 know, most of the individuals -- most children  
13 receive the vaccines, so about 95 percent of them  
14 do. I think those that don't receive vaccine  
15 are -- are often -- there's a reason that they're  
16 not being vaccinated, and so one of -- excuse me.  
17 One of the things that you would have to make sure  
18 of is that the underlying epidemiologic  
19 characteristics of the children that were  
20 vaccinated are comparable to those that are not  
21 vaccinated, so that's one of the issues is  
22 indeed are they comparable, and so that's been --  
23 you know, obviously a lot of people, you know,  
24 say, well, why don't we study people that don't

1 get vaccines instead of people that do, but the  
2 problem is that they're not often the right -- the  
3 same populations, and then more so it's hard to  
4 study something that's recommended, and so  
5 those -- those studies are problematic in terms of  
6 numbers and comparability of the -- of the  
7 population groups.

8 Q All the studies relied upon to say that MMR  
9 vaccine doesn't cause autism are retrospective,  
10 right, the studies; correct?

11 A This -- the bulk of the MMR studies, as we  
12 talked about before, are database studies, and  
13 there have been repeated database studies that  
14 have addressed the rates of autism in those  
15 populations, so those are the most powerful  
16 studies that we have because they have great  
17 sample sizes and they have larger ability -- they  
18 have a longer time to assess the -- the long-term  
19 outcomes.

20 Q So in the same way that they can do  
21 retrospective studies comparing those, you know,  
22 children who are fully vaccinated with MMR and  
23 fully vaccinated without MMR, why can't you just  
24 do a study comparing fully vaccinated with those

1 receiving no vaccine in those same databases, such  
2 as, for example, the Vaccine Safety Datalink,  
3 which the IOM said is possible to do?

4 A Because I just told you why. I told you that  
5 those -- first of all, the sample sizes are not  
6 comparable. Secondly, the underlying  
7 characteristics of the population that are not  
8 vaccinated are often not the same as those that  
9 are vaccinated. The delivery of care is often not  
10 the same, and some of the databases that do exist  
11 are parts of health so that would select for  
12 vaccinated children. If you want to put a study  
13 in VAERS, VAERS is an interesting database, and I  
14 have spent a lot of time looking in VAERS. VAERS  
15 is a hypothesis generator, you know, often you  
16 don't have the information that's necessary to  
17 have a complete understanding of what's going on,  
18 so there hasn't been a -- so the issues are that  
19 it's very problematic because the study design  
20 does not have comparable groups to compare.

21 Q Right. Meaning you're concerned about  
22 confounders; correct? Right?

23 A There's concern about confounders in mice.

24 Q Okay. So tell me what -- which -- what --

1 what is the difference in the characteristics  
2 between those who receive vaccines and those who  
3 don't, such that, you know, you -- that you  
4 wouldn't be able to control for?

5 A Well, first of all, you'd have to decide  
6 which database you're going to use. The second  
7 would be you have -- you would have to make sure  
8 that the -- that the populations are comparable in  
9 terms of age. You'd have to make sure that  
10 they're comparable in terms of underlying  
11 comorbidities. You'd have to make sure that  
12 they're comparable in the -- in the -- in the care  
13 that they received, in their socioeconomic status,  
14 in their -- in their access to -- to the ability  
15 to be immunized, and all of those would need to be  
16 looked into, and also you would have to make sure  
17 that -- for instance, that -- that the vaccine  
18 records are confirmed. So, you know, you may have  
19 someone that says that they haven't been  
20 vaccinated, but how do you confirm something that  
21 hasn't happened, you know. You're sort of asking  
22 as to --

23 Q Well --

24 A -- how to confirm -- can I finish?

1 Q Yeah, yeah, please.

2 A You're asking me how to confirm something  
3 that's not recorded, so how can I confirm that  
4 they haven't been vaccinated. So that's another  
5 problem in terms of how do you confirm that they  
6 have not been vaccinated and some of those issues  
7 as well, and again, the issue was in terms of  
8 sample sizes.

9 Q Okay. Well, then let's take those backwards.  
10 So let's start with confirming that they are not  
11 vaccinated. Isn't it true that there's an ICD-9  
12 that -- ICD-10 codes for when a child -- when a  
13 parent refuses a vaccine including for religious  
14 reasons; correct?

15 A Well, there has been, but you know, that is  
16 not -- it's not -- you'd do an audit to make sure  
17 that that's correct.

18 Q All right. And that -- please.

19 A I'm trying to answer the question, sir.

20 Q Yeah, please.

21 A So what you would have to do in that  
22 situation is that you would have to go back to the  
23 chart, and if they say they didn't get the  
24 vaccine, you would have to confirm that they

1 didn't get the vaccine. So you would do that in  
2 the chart. There also are some vaccine databases  
3 that exist that you would have to go into, so the  
4 State of Tennessee has a database called TWIS so  
5 you would go back and you'd make sure that Susie  
6 Smith never got a vaccine through the database,  
7 but again, it's hard to confirm something that  
8 isn't done.

9 Q But again, are -- are you -- so are you aware  
10 of the White Paper that was produced by the CDC  
11 with regards to comparing the vaxxed versus  
12 unvaccinated population within the VSD in which  
13 they did identify almost 2,000 children who were  
14 not vaccinated and they confirmed their ICD-9  
15 codes for a large portion of them indicated that  
16 they weren't, and then they went and they did a  
17 sample size to confirm, meaning they looked at  
18 their entire medical records and they found a  
19 very, very high confidence that if a child has an  
20 ICD-9, 10 code that the parents, you know, for  
21 parent refusal to vaccinate for one -- for  
22 religious or other reasons, that the child, in  
23 fact, was not vaccinated?

24 A So I -- I -- I'm not familiar with the paper,

1 so I'm happy to look at the paper.

2 Q We'll send it to you.

3 A Again, out -- 2 --

4 Q Yeah.

5 A Can I speak or do you want to just interrupt?

6 Q Oh, no, go ahead.

7 A Okay. So 2,000 people is not very many  
8 people. 2,000 unvaccinated people is not very  
9 many people. How -- how -- what are we using for  
10 the safety database for COVID? 15,000. So 2,000,  
11 great, but it's not very large.

12 Q Well, wouldn't it be enough to look at it --  
13 an issue, for example, asthma, which is very  
14 common in one in six kids today?

15 A It depends upon what the -- it depends upon  
16 what -- what you're looking for, sir.

17 Q So then if -- from what you're saying then,  
18 if you don't know -- if you can't rely on the  
19 vaccination records in all of the databases, then  
20 how are any vaccine retrospective studies  
21 reliable? Because how do you know if the kid got  
22 an MMR or didn't get an MMR in any database?

23 A You can confirm the receipt of the vaccine,  
24 you can go over the chart, you can look at the



1 chart and say that the pediatrician gave the  
2 vaccine, you can look at the vaccine record, you  
3 can look at TWIS. There's a number of different  
4 ways to do that.

5 Q So couldn't they do that here as well in a  
6 study that compared vaxxed versus unvaxxed  
7 children?

8 A Well, that's what you told me that they were  
9 just doing, and they can do it, but it's harder --  
10 you know, it's harder -- so it's the same argument  
11 that you're giving about this vaccine record.  
12 You're saying that because it doesn't say that  
13 somebody got something, it didn't happen, so, you  
14 know, the records are not always perfect,  
15 unfortunately.

16 Q I --

17 A So --

18 Q Look --

19 A You would have to -- please stop.

20 Q Yeah, go ahead.

21 A I -- I think this is not appropriate. This  
22 is rude.

23 Q I'm not sure what's rude about it. Look,  
24 I -- you know, I've asked vaccinologists before

1 and pediatricians this question, and I -- I can  
2 tell you I always find it surprising that with the  
3 medical brain trust that exists in this country,  
4 all the resources that there are, that for some  
5 reason, you know, there seems to be an incredible  
6 opposition to performing this analysis, which by  
7 the way, the Institute of Medicine, and I can show  
8 you their 2013 report, said it's -- the comparison  
9 is possible to do, which is why the CDC  
10 commissioned a White Paper on it. All right.

11 Look --

12 MR. SANDERS: Object to the -- to the  
13 attorney colloquy there. You know, if you have a  
14 question, feel free to ask it, Mr. Siri, but we  
15 don't need to be lectured.

16 MR. SIRI: Fair enough.

17 Q (By Mr. Siri) All right. There are -- there  
18 is, in fact, a study that compared vaccinated  
19 versus unvaccinated children that does exist, but  
20 I -- from your answer to your prior question, I  
21 believe you've never seen it. Is that correct?

22 A I don't know which question -- which paper  
23 you're talking about. I may have seen it. As you  
24 know, I've -- I've -- you know --

1 Q Yeah.

2 A So if you want me to see whether I know about  
3 it, please show it to me.

4 Q Sure. Have you seen this paper before,  
5 Dr. Edwards?

6 A No, I don't believe I have, sir.

7 Q Okay. Well, I'll highlight something for you  
8 and so you have an opportunity to look at it after  
9 this. You can see that it's from the professors  
10 at the Department of Epidemiology and  
11 Biostatistics School of Public Health.

12 A I can't -- you're cutting out, sir.

13 Q Oh, sorry. Let -- I just want to make sure  
14 that I highlight -- do you see here that -- over  
15 here it found that the unvaccinated children had  
16 higher -- statistically significant higher rates  
17 of chicken pox?

18 A Yes, sir.

19 Q And do you see that the unvaccinated children  
20 had statistically significant higher rates of  
21 whooping cough?

22 A Yes, sir.

23 Q Okay. Do you see here though that it also  
24 found that the children had a statistically

1 significant higher rate -- vaccinated children had  
2 a statistically significant higher rate of autism?

3 A I don't know what the diagnosis is. I don't  
4 know the denominator or the population. I'd be  
5 happy to look at this, but I -- I'm not going to  
6 sign on to something that I haven't reviewed, and  
7 I'm not familiar with this.

8 Q Yeah, it's a pilot study and you should have  
9 an opportunity to review it. I just wanted to  
10 highlight those portions for you.

11 A This -- yeah, this isn't probably the most  
12 prominent journal, but --

13 Q Sure. But, you know, some -- sometimes, you  
14 know, what --

15 A A paper does --

16 Q Please.

17 A Paper doesn't refuse ink.

18 Q Paper doesn't -- I'm sorry?

19 A Paper does not refuse ink.

20 Q Fair enough. But at least there's some ink.

21 MR. SIRI: We'll mark this 50 --

22 MS. CHEN: 57.

23 MR. SIRI: Thank you. And we'll mark

24 this one 58 so that you have an opportunity to

1 review it for trial as well.

2 (Whereupon, Exhibit  
3 Nos. 57 and 58 were  
4 marked to the testimony  
5 of the witness.)

6 Q (By Mr. Siri) They found similar issues with  
7 preterm babies, you know, higher rates.

8 A What's the database, sir? Can you give me  
9 the database, please? So go to the methods,  
10 please. Move to the methods.

11 Q This is based on parental surveys. It was  
12 based on parental recall, so, you know, it's not  
13 the best study --

14 A That's not good.

15 Q -- for --

16 A That's not good. If you're going to do a  
17 study, you don't remember parental recall.

18 Q It would be better to do it with, I assume,  
19 like, medical records; right?

20 A Oh, absolutely. This record -- this -- I  
21 mean, if I was -- I'm a journal editor. This  
22 paper would never see the light of day.

23 Q There are --

24 MR. SIRI: So I'll also mark this one,

1 which is -- that is number 59, is it?

2 MS. CHEN: Yes.

3 (Whereupon, Exhibit  
4 No. 59 was marked to the  
5 testimony of the  
6 witness.)

7 Q (By Mr. Siri) So this -- this is a study  
8 that looked at medical records in three pediatric  
9 practices, and have you ever seen this one before?

10 A No, sir.

11 Q Okay. It was just published this year, so  
12 you'll have an opportunity to look at it. We'll  
13 look at one more and then we'll just move on.

14 MR. SANDERS: Mr. Siri, I want to state,  
15 a lot -- most of the articles, or quite a few of  
16 the articles you've been using have never been  
17 disclosed in the case, and discovery has long  
18 since been over in the case in regards to  
19 production, so I just want a standing objection as  
20 to any use at trial of these exhibits, and we can  
21 take that up at a later time. I just want to put  
22 that on the record.

23 MR. SIRI: Yeah, well, we'll just agree  
24 to take that up at a later time then.

1 Q (By Mr. Siri) And then this is -- have you  
2 ever seen this article?

3 A I've seen -- I've reviewed a lot of work from  
4 Peter Aaby, so I've not -- I don't know that I've  
5 seen this particular paper, but Peter Aaby looks  
6 at the non-specific effects of immunity with the  
7 DTP and OPV in -- in African populations.

8 Q And he's a respected scientist?

9 A He's a controversial scientist.

10 Q Ahh, okay.

11 A Some of his work we publish in this -- in the  
12 journal that I'm an editor, so we -- it depends  
13 upon the study that he does.

14 Q Have you seen this study before? I  
15 apologize. I don't recall your answer.

16 A I don't know that I've seen this specific  
17 study. I've seen a number of other studies from  
18 Peter Aaby.

19 Q Okay. Well, in this study, you'll have an  
20 opportunity to review it, he found that children  
21 receiving DTP vaccine in the first six months of  
22 life died at ten times the rate as those who  
23 received no DT -- no vaccines in the first six  
24 months of life. Have you ever heard that before?

1 A I'm aware of his studies about DTP, and these  
2 are in African countries. This is in  
3 Guinea-Bissau in the 1980s, so I -- how this is  
4 related to -- to the U.S. I think is a question  
5 that, you know, we have to address.

6 Q Are you aware that in 1994 the IOM stated  
7 that, quote, the committee was able to identify  
8 little information pertaining to why some  
9 individuals react adversely to vaccines when most  
10 do not, end quote?

11 A I think that's probably a true statement. I  
12 wasn't aware that that appeared in there, but I  
13 think there is a variability and -- and  
14 reactogenicity.

15 (Whereupon, Exhibit  
16 No. 60 was marked to the  
17 testimony of the  
18 witness.)

19 MR. SIRI: Okay. Let's take a  
20 five-minute break and we'll come back. It's --  
21 well, let's make it seven minutes. We'll come  
22 back at 3:55 and see if we can wrap this thing up.  
23 All right. Thank you.

24 (Brief recess.)



1 THE VIDEOGRAPHER: All right. We are  
2 back on the record at 3:57 p.m. Central time.

3 MR. SIRI: Okay, thank you.

4 Q (By Mr. Siri) Dr. Edwards, do you believe  
5 that parents should be able to object to vaccines  
6 on religious grounds?

7 A I think that parents should have -- I think  
8 that -- I think parents need to be informed about  
9 what are the religious restrictions about vaccines  
10 or what their concerns are there, but I think that  
11 if they choose to say they do not want to be  
12 vaccinated and they have the questions answered  
13 for religious reasons, then I think that is -- is  
14 acceptable.

15 Q Okay. So what you're saying is that once  
16 they've been informed of the benefits and the  
17 risks, if they still want to object on religious  
18 grounds, your opinion is they should be able to  
19 withhold vaccination from their children?

20 A I think that -- that you're -- that's not  
21 exactly what I said. I said --

22 Q I apologize.

23 A -- there are --

24 MR. SANDERS: Go ahead, Dr. Edwards.

1 A So there are concerns, for instance, let me  
2 give you an example. The COVID vaccine that is  
3 made by AstraZeneca is made in a cell line that  
4 some people say was from aborted fetus. The  
5 Catholic church has said that that is not a  
6 prohibition to the use of vaccines, and -- and so  
7 if people are not aware of that, then they can be  
8 informed of that. And I think that with the  
9 measles, you know, there were some issues  
10 regarding the use of the vaccine in religious  
11 communities, and so I think that that -- that it's  
12 important to answer the questions, to give  
13 authoritative data about what their beliefs are to  
14 make sure that those are indeed correct. If they  
15 continue to believe that, then religious  
16 objections, I think, can be -- can be grounds for  
17 not being vaccinated, although obviously it puts  
18 their children and other children at risk.

19 Q (By Mr. Siri) So after being informed in the  
20 manner you just said, if a parent still wants to  
21 not vaccinate for religious reasons, you would --  
22 you would agree that the child -- that the  
23 parent -- that the child -- that the parent's  
24 decision should stand and the child shouldn't be

1 vaccinated?

2 A I think that that patient, if it was in my  
3 practice, I would continue to discuss the  
4 dialogue, but at that particular time if they did  
5 not want to give the vaccines, I might try and  
6 explain it. The other option that some people do  
7 is that they feel that it poses a risk to the  
8 other patients, and they may no longer keep them  
9 in the practice but respect their opinion that  
10 they not be vaccinated.

11 Q Would you exclude a child from your practice  
12 if their parents didn't want to vaccinate the  
13 child after giving them all the information that  
14 you say you'd like to give them?

15 A I think that there are a number of factors  
16 involved in that. One, if I'm the only doctor in  
17 the area and the patient has no other access to a  
18 doctor, no, I would not. If there are other  
19 doctors that -- that would -- would -- would do  
20 that and I've repeatedly talked to them and they  
21 are not accepting of it, I may. But I think that  
22 most of the time I try and provide information and  
23 have a dialogue so that people understand why  
24 vaccines are necessary.

1 MR. SIRI: I'd like to mark this as  
2 Plaintiff's 50 --

3 MS. CHEN: 61.

4 MR. SIRI: Thank --

5 THE WITNESS: We're in the 60s. We're  
6 in the 60s.

7 MS. CHEN: We're on 61.

8 MR. SIRI: 61, thank you.

9 (Whereupon, Exhibit  
10 No. 61 was marked to the  
11 testimony of the  
12 witness.)

13 Q (By Mr. Siri) So this is Plotkin's Vaccine,  
14 Sixth -- Fifth Edition. I'm going to read you a  
15 sentence from here and see -- and ask you a  
16 question. The issue of purity becomes magnified  
17 in adjuvated vaccines. The adjuvant is added to  
18 enhance immune response; it will do so  
19 nonspecifically in many cases to the target  
20 antigen, as well as to any impurities or  
21 by-products of the manufacturing process. Do you  
22 agree with that statement?

23 A First of all, I don't know exactly where this  
24 is in the book. I hope that -- you know, and --

1 and I don't know whether this is a chapter that I  
2 edited or not. I think that there's probably  
3 sentences in the book that I edited. It's -- you  
4 know, I think it's a thousand pages or so, 1,400  
5 pages, so I think that that -- if there is an  
6 impurity, it can be magnified with adjuvated  
7 vaccines, but again, I -- this -- you're taking  
8 one sentence out of a context of 1,400 pages.

9 Q Okay. Is it -- okay. So let me just ask you  
10 directly. Isn't it --

11 A Well, which chapter is this and who wrote  
12 this chapter, please, so I can tell whether this  
13 is one I edited. I can't remember.

14 Q It -- you'll have a copy of this. You can  
15 look it up later. I have no more questions about  
16 this exhibit. I'll just ask you the question  
17 directly. Isn't it true that an adjuvant will  
18 bind not only to the target antigen, but also to  
19 impurities and by-products of the manufacturing  
20 process?

21 A Yes, sir, it is.

22 Q Okay. And, you know, once bound to the  
23 impurities and by-products, the body may also  
24 develop antibodies to the -- to the impurities and

1 by-products in the vaccine; correct?

2 A I can't say -- I -- I do not know  
3 specifically any antibodies that have been looked  
4 at to be impurities, so I can't give you a paper  
5 that says yes or no.

6 Q Fair enough. You know, you're a doctor;  
7 correct? You're a medical doctor; right?

8 A That's what my CV said, and I -- I'm not an  
9 imposter.

10 Q All right. And you've -- and you have a lot  
11 of familiarity with reviewing medical records;  
12 right?

13 A Yes, sir, as I've stated before, I've  
14 reviewed a lot of medical records.

15 Q You know how to read and understand medical  
16 records, okay. So --

17 A I do know how to read, yes, I do.

18 Q Okay. Like I said, some of the questions you  
19 may find to be very basic, but -- you know, we  
20 have to provide a foundation for some of the other  
21 questions that we provide. Now, have you seen  
22 this medical record before, which I'm going to  
23 mark as Plaintiff's 52, I believe.

24 MS. CHEN: It's 62.

1 MR. SIRI: All right. 62.

2 (Whereupon, Exhibit

3 No. 62 was marked to the

4 testimony of the

5 witness.)

6 Q (By Mr. Siri) Dr. Edwards?

7 MR. SANDERS: There's nothing up there,

8 Mr. Siri.

9 A There's nothing up there, sir.

10 Q (By Mr. Siri) Oh.

11 A If you could give me a page, I can look on my  
12 medical records, so if you would like -- if that's  
13 easier. What page would you like me to look at?

14 Q There we go. It's right there. Have you  
15 seen this medical record before?

16 A Yes, I have, but it's a -- yeah, can you make  
17 it a little bigger, please?

18 Q Sure. Okay. What is the -- the date of the  
19 medical record?

20 A 2/08/01, excuse me.

21 Q Okay. And how much did Yates weigh on that  
22 date according to this medical record?

23 A He weighed 24 pounds and 2 ounces.

24 Q Okay. Which would be about 11 kilograms?

1 A Yes, and I've looked very carefully at his  
2 growth chart, and that's here too, so his growth  
3 has been quite -- quite adequate both in height  
4 and weight and he stayed on his growth chart, so  
5 that was very reassuring as well.

6 Q Okay. Now -- now, on that date as well, he  
7 was diagnosed with otitis media; correct?

8 A So let me look at my chart because you're  
9 cutting it off. So the date -- let me get mine so  
10 I can make sure that I -- I -- so that -- okay.  
11 So -- okay. Okay.

12 Q Was he -- was -- based on this medical  
13 record, was Yates diagnosed with otitis media on  
14 February 8, 2001?

15 A Yes, he was, sir.

16 Q Okay. And what was he prescribed?

17 A Amoxicillin.

18 Q Okay. Looking at the amount of Amoxicillin  
19 prescribed, do you know whether that would have  
20 been for a mild or moderate form of otitis media  
21 or for a severe form of otitis media?

22 A That was a -- that was the prescribed amount.  
23 It's 40 milligrams per kilogram and he weighs  
24 11 kilos, so that's -- that's 400. The CDC in



1 a -- because of the issues regarding otitis and  
2 because of the emergence of more resistant  
3 streptococcus pneumoniae, the CDC made a guidance  
4 document that it was important to increase the  
5 dose of Amoxicillin for all cases of otitis, so  
6 the -- the dose for -- of 40 milligrams for  
7 Amoxicillin was the recommended dose for garden  
8 variety otitis media.

9 Q Has that CDC guidance document been produced  
10 in this case?

11 A I don't know. I was part of the guidance  
12 document and so I -- I participated in that  
13 discussion, and that's the standard dose. In  
14 general, looking at the PDR is not generally where  
15 you find the most definitive information about the  
16 doses. Certainly the PDR gives you other  
17 information. But the doses that are recommended  
18 are often not the best found in the PDR.

19 Q And when was the CDC guidance document which  
20 you refer issued?

21 A I'm not sure. It was around this time  
22 because we had a lot of problems with pneumococcal  
23 otitis and so the guidance document was -- was  
24 issued about -- for the treatment of otitis media,

1 and it was 40 milligrams per kilogram of  
2 Amoxicillin.

3 (Whereupon, Exhibit  
4 No. 63 was marked to the  
5 testimony of the  
6 witness.)

7 Q (By Mr. Siri) Okay. And so you're saying --  
8 do you know if Dr. Hays reviewed that guidance  
9 document before he prescribed Amoxil to Yates?

10 A Well, pretty much everyone knew that the dose  
11 of Amoxicillin was 40 milligrams per kilogram,  
12 which is exactly what he gave here, that that's  
13 the standard treatment of otitis media.

14 Q Okay.

15 A Getting out the PDR, and I just said the PDR  
16 does -- is not -- you know, does not provide the  
17 guidance that you need for specific instances.

18 Q Understood. But had the guidance of the PDR  
19 been looked at for prescribing the amount given of  
20 40 milligrams per kilogram per day would have  
21 fallen into the severe category for otitis media;  
22 correct?

23 A Because it's wrong. This does not mean by  
24 giving 40 milligrams per kilogram for Amoxicillin

1 that it's severe. This is wrong.

2 Q Now, this CDC guidance document that you're  
3 referring, are you willing to provide a copy of  
4 it?

5 A I would be delighted.

6 Q Okay. Now -- now, generally speaking, do  
7 physicians look to the PDR to determine what  
8 dosage to provide patients?

9 A Not any that I know of.

10 Q Okay. So how does a pediatrician typically  
11 decide how much of a particular, you know,  
12 antibiotic, for example, to give one of their  
13 patients?

14 A Well, I think there's several ways.  
15 Certainly people use UpToDate. I think there  
16 are -- there's something called a Harriet Lane  
17 Handbook, which is a handbook that is updated  
18 every year by Harriet Lane at the -- at Johns  
19 Hopkins, and it gives doses of medication. We  
20 used to always have that. I felt it was like  
21 my -- you know, it was an appendage and that --  
22 but, you know, now we have computers, so most  
23 people don't get out their old Harriet Lane. So  
24 that's an -- that's another way. The Red Book can

1 be another way, but you know, otitis media is  
2 really common and so, you know, any -- anybody  
3 who's finished a pediatric residency would know  
4 what the dose is, and that's exactly what we would  
5 give is 40 per kilo.

6 Q So other than the Harriet Lane Handbook or  
7 the Red Book or the PDR or this --

8 A I -- I said --

9 Q Is there any --

10 A -- not PDR. I said I don't use the PDR.

11 Q Okay. And you're saying that in your  
12 experience physicians in Tennessee wouldn't have  
13 used -- around 2000, 2001 wouldn't have used the  
14 PDR to determine what to prescribe a child with an  
15 infection?

16 A Not if they were well informed.

17 Q Okay. And so what would -- you're saying  
18 they would normally look at the Harriet Lane  
19 Handbook?

20 A I think they would look at the Red Book, they  
21 would look at Harriet Lane, they would look at --  
22 now, obviously they didn't have UpToDate then, and  
23 they might look in a textbook and they might look  
24 at -- or -- you know, and they also go to CMEs and

1 they -- you know, this is a very common diagnosis.  
2 Every child has otitis sometimes, so this is a  
3 very common diagnosis, and this particular amount  
4 of antibiotic is very standard.

5 Q Okay. When you say textbooks, what are you  
6 referring to?

7 A Yeah, there's textbooks of pediatrics that  
8 are published, and they talk about otitis media  
9 and the -- and the dosage used for that. There  
10 are textbooks of infectious diseases that -- that  
11 are -- that exist, and they give doses of  
12 antibiotics. There's -- you know, there's a lot  
13 of textbooks. There's a lot of sources for  
14 information.

15 Q Are you familiar with the normal hemoglobin  
16 ranges in a baby?

17 A Yes, sir, I am.

18 Q Okay. So what would be the normal range for  
19 hemoglobin in a baby?

20 A Well, it depends a little bit on how -- the  
21 age of the baby. The baby can't -- you know,  
22 babies are -- they're very hemoconcentrated, so  
23 when babies are born, they can have hemoglobins  
24 in, you know, 16, 17, 18 because they have -- you

1 know, they have a lot of -- of hemoglobin, and so  
2 they have a lot of blood cells, and over the first  
3 few weeks of life, then -- then there is less  
4 production of red cells and then children -- you  
5 know, the blood count will go down, so children  
6 are born with higher levels of hemoglobin than --

7 Q So after the -- so by the time they're two  
8 months old, what would be the normal range  
9 approximately?

10 A Well, maybe 14, 16, 12, 14. I -- I don't  
11 know, sir. I'd have to just look at each age  
12 range, and I can do that. Again, you know, I'm  
13 not a general pediatrician.

14 Q I just asked for your best memory. If you  
15 don't remember, that's fine. How about at four  
16 months old?

17 A Well, it depends also about issues related to  
18 diet, it depends whether they've been in the  
19 hospital, if they -- it depends whether they've  
20 been premature, it depends whether they've had a  
21 lot of blood drawn in the unit, and so it's very  
22 dependent upon -- I can't -- I can say in a normal  
23 that it may be 10 to 14, something of that nature.

24 Q Okay. And that's also true for a

1 six-month-old?

2 A Well, the six -- and by six months old, then  
3 what you begin to do is you start making your own  
4 new blood cells, and if you are nutritionally  
5 replete and you have the amount of iron that you  
6 need in your formula, then you begin to make your  
7 blood cells, so again, it's -- it's a little  
8 variable. There's always a range.

9 Q What was your under -- what is your  
10 understanding of Yates' medical condition when he  
11 received his six-month vaccines?

12 A So your question is what was -- what --  
13 how -- what was it six months of age?

14 Q Yeah, like -- it's what is your understanding  
15 of Yates' medical condition when he received his  
16 six-month vaccines.

17 A Okay. So let me just pull up his six-month  
18 vaccines because I reviewed that, and I just would  
19 never want to guess, misstate it, so here's at  
20 four months, here's his six -- let's see. Here is  
21 his six months. So it said the parents voiced  
22 concern about congestion, some green discharge,  
23 no current concerns for the eyes, ears, nose,  
24 throat, cardiovascular, respiratory, GI, and

1 endocrinology, allergic, neurologic, or  
2 immunology, so they had some concern about a  
3 congestion and some green discharge.

4 Q Was Dr. Carlton Hays the healthcare provider  
5 under whose authority Yates was vaccinated?

6 A I believe so. That's what -- his name is at  
7 the top, so I think that would mean that he was  
8 the one who did this.

9 Q Okay. And I presume you would agree that the  
10 standard of care applicable when Yates was  
11 vaccinated was to provide written materials  
12 including VISs at each vaccination visit?

13 A I think we've gone over that before.  
14 That's -- we talked about that. We also talked  
15 about that it didn't have a little ditto sign  
16 underneath it, so --

17 Q Ma'am, I'm ask -- this is a different  
18 question. I'm asking if you agree that the  
19 standard of care applicable when Yates was  
20 vaccinated was to provide written materials  
21 including a VIS at each vaccination visit to  
22 inform the parents of the benefits and risks of  
23 vaccination before the child was vaccinated.

24 A Yes, that's what we talked about before.



1 Q Okay. The CDC issues a recommended childhood  
2 immunization schedule annually; correct?

3 A Yes, sir.

4 Q Pediatricians look to this schedule to  
5 determine what vaccines to administer; correct?

6 A They do. They also look to the -- to the Red  
7 Book, the COID.

8 Q Okay. But you would agree that the standard  
9 of care when applicable to vaccinating Yates would  
10 have been to follow the CDC's recommendations for  
11 which vaccines to provide to Yates; correct?

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

14 A It's a guideline for the administration of  
15 vaccines.

16 Q (By Mr. Siri) Okay.

17 A Sometimes we do -- we administer vaccines in  
18 slightly different ways if there has been a --  
19 perhaps a fever or some other reaction to a  
20 vaccine, sometimes we separate them, so these are  
21 guidelines. They're not The Ten Commandments.

22 Q Right. So sometimes the CDC also has  
23 guidelines for when not to vaccinate; correct?

24 A They make suggestions, although the -- the --

1 well, they make suggestions.

2 Q Okay. And when a -- back when Yates was  
3 vaccinated, when a pediatrician --

4 A Is there a dog somewhere that barks?

5 Q Nope. I didn't hear a dog.

6 MR. SIRI: Anybody hear a dog?

7 MR. SANDERS: I think it may have been  
8 your chair hitting the wall or something.

9 THE WITNESS: Oh, okay.

10 MR. SANDERS: It was loud.

11 MR. SIRI: It's a better pet than a dog.  
12 I don't have to feed it at least or deal with  
13 cleaning anything up.

14 Q (By Mr. Siri) All right. Anyhow, the --  
15 when Yates was vaccinated, what would Dr. Hays  
16 have looked to as the -- to determine what  
17 vaccines to administer to Yates?

18 A Well, I think we just talked about that. He  
19 would have looked at the guidelines for -- for --  
20 from the CDC and the American Academy of  
21 Pediatrics.

22 Q And those would have been the standard of  
23 care applicable for what vaccines to give or not  
24 to give to Yates when he was vaccinated by

1 Dr. Hays; correct?

2 MR. SANDERS: Object to the form of the  
3 question. She's already asked -- been asked and  
4 answered that.

5 MR. SIRI: No, she hasn't. No, she  
6 hasn't.

7 Q (By Mr. Siri) Please answer the question.

8 A What is the question? What is the question  
9 and how does it differ from the question you just  
10 asked me before that I answered?

11 Q Okay. So the question you answered before,  
12 you're -- so you're saying that you've already  
13 answered that, the standard of care applicable for  
14 when to vaccinate or not to vaccinate Yates by  
15 Dr. Hays can be found in the CDC schedule and  
16 case -- contraindication and precaution list and  
17 the Red Book that were in effect at that time. Is  
18 that correct?

19 A Those are the guidelines, yes, sir.

20 Q And that would have been the standard of care  
21 applicable for that --

22 A It would have been -- but -- but what you  
23 have to --

24 MR. SANDERS: Go ahead, Dr. Edwards.

1 You can finish.

2 A What you have to understand is that there is  
3 some ability to use discretion and medical  
4 judgment, and so there may be times when you  
5 choose not to do exactly what is said in the --  
6 you may choose to delay one, you may choose to  
7 give -- you know, the vaccines are -- the DTaP can  
8 be given at six weeks or two months, so if you  
9 give it at six weeks, it's fine. If you give it  
10 at two months, it's fine. Or if you want to wait  
11 a little longer to 10, that's not what it says,  
12 but it's not malpractice.

13 Q (By Mr. Siri) Would the standard of care  
14 include parents having an opportunity to review  
15 the materials provided with the risks and benefits  
16 and ask any questions they may have after  
17 reviewing those materials?

18 A It's important that -- that -- parents  
19 certainly should be able to ask questions, and I  
20 think that -- that often doctors prepare parents  
21 for subsequent visits by talking about what will  
22 be coming up at the next visit so that they're  
23 able to think about what's happening, and  
24 certainly with -- if you look at -- at the -- at

1 the visit at -- at -- at the four-month visit,  
2 you -- it says that handouts were provided, and  
3 then it said -- it said reviewed with the parents,  
4 the next visit is in two months, immunizations  
5 will be due. So those are opportunities that  
6 families will ask, and they -- if they have  
7 specific questions, then those will be addressed.

8 Q All right. And so the standard of care would  
9 be providing the parents an opportunity to review  
10 the material before the child is administered the  
11 vaccine and ask any questions about it; correct?

12 A I think that -- that the -- if you give the  
13 VIC later, I don't think that's -- is -- is any  
14 way not the standard of care. What -- I think a  
15 lot of the dialogue that happens with -- with  
16 parents is is about questions that they have about  
17 the vaccine and discussion of the vaccine. So the  
18 fact that a person has not had the VIC, like  
19 before the -- the visit or something of that  
20 nature, I don't think that's -- that's a -- that  
21 that's a -- that that is inappropriate practice.

22 Q Just to make sure I understand you, federal  
23 law requires that the -- that the parent or  
24 guardian be provided the VIS by the person

1 administering the vaccine prior to the giving of  
2 the vaccine. I assume you would agree that that  
3 is the standard of care, that the VIS must be  
4 provided prior to the administration of the  
5 vaccine; correct?

6 A Yes.

7 Q And that would be a -- would have been  
8 applicable to vaccinating Yates; correct?

9 A Yes, but it doesn't mean that --

10 Q Okay.

11 A -- it's simply based on that. There's also  
12 an open dialogue about immunizations that is  
13 not -- is not part of the VIS as well.

14 Q And that would be the part of the standard of  
15 care as well?

16 A To address the questions that the parents  
17 had.

18 Q So that -- so it -- that would have been part  
19 of the standard of care for vaccinating Yates as  
20 well, correct, what you just said?

21 A Yeah. If they had questions, then the  
22 questions should be addressed.

23 Q Okay. What is CISA?

24 A Center for Immunization Safety Assessment.

1 It's CISA.

2 Q Oh, thank you.

3 MR. SIRI: I'm getting close to  
4 finishing here. Let me -- I'm going to -- let's  
5 take a five-minute break. Let me take a quick  
6 look, and hopefully we'll be -- get this wrapped  
7 up today. I'll --

8 MR. SANDERS: Hang on. Mr. Siri, when  
9 you say you're getting close, can you give us a  
10 little more of a --

11 MR. SIRI: Yeah, it looks like we'll be  
12 done in less than eight hours. Ms. Cohen, how --  
13 how far are we in?

14 THE WITNESS: Actually, it's already  
15 been 8 hours, I think.

16 MR. SANDERS: Yeah. I think Ms. Cohen  
17 can tell us we're probably really close.

18 MR. SIRI: Yeah.

19 THE COURT REPORTER: According to my  
20 digital recorder, it's 7 hours and 29 minutes.

21 MR. SIRI: Okay. We're close. We're  
22 very close. All right. So should we -- it's  
23 2:23. Why don't we -- excuse me. It's 4:23. Why  
24 don't we reconvene at -- at 4:30 instead of in

1 seven minutes, and we'll -- we can finish this up.

2 MR. SANDERS: Okay.

3 THE VIDEOGRAPHER: All right. We're off  
4 the record at 4:23 Central time.

5 (Brief recess.)

6 THE VIDEOGRAPHER: All right. We are  
7 back on the record at 4:32 p.m. Central time.

8 Q (By Mr. Siri) All right, thank you.

9 Dr. Edwards, if a -- do vaccine reactions only --  
10 if one were to occur, only occur within the first  
11 15 minutes after getting a vaccine?

12 A I'm sorry, the dog barked again. What did --  
13 would you say --

14 Q I'm sorry. I leaned back. Okay. I was  
15 saying, are there -- are there vaccine reactions  
16 that occur after the first 15 minutes of receiving  
17 a vaccine?

18 A Yes, sir, there are.

19 Q Okay. Can you give a few examples?

20 A Yeah. A sore arm, a swollen leg after a  
21 vaccination. Usually those local reactions don't  
22 happen within 15 minutes, they generally happen  
23 within the first 20 -- 12 to 24 hours, so I think  
24 what you might be referring to are the more severe



1 reactions that occur, and those are generally  
2 anaphylactic reactions, and those reactions  
3 generally would occur within 15 minutes, and those  
4 are more severe. They need to -- often need to be  
5 treated with epinephrine or something of that  
6 nature, so -- but yes, there are a number of  
7 reactions that happen after 15 minutes.

8 Q There are also some severe adverse reactions  
9 that occur beyond 15 minutes as well; correct?

10 A Yes, but not contraindications to  
11 vaccination.

12 Q Not -- without discussing whether it's a  
13 contraindication or not, just -- you know, we  
14 reviewed some adverse reactions earlier that, you  
15 know, had a -- there was a basis to say, you know,  
16 sometimes rarely or -- were caused by vaccines.  
17 Some of those are serious and some of those can  
18 arise beyond the first 15 minutes after the  
19 vaccination; right?

20 A Yes, sir, that's correct.

21 Q Some -- some of them would -- some of them,  
22 in fact, only arise a week or two after  
23 vaccination; correct?

24 A It depends on what the vaccine is, so when

1 the adverse of -- if it happens a week later may  
2 be associated with a measles vaccine, but it's  
3 very unlikely to be associated with a DTP vaccine.

4 Q Dr. Edwards, what is your husband's name?

5 A William Edwards.

6 Q And what is his profession?

7 A He's a teacher. He's retired now.

8 Q Is he a medical doctor as well?

9 A No, sir, he's not.

10 Q Does he have any medical training?

11 A No, sir, he does not, although he's lived  
12 with me for 50 years and he's heard me talk about  
13 a lot of things and he's quite a patient listener.

14 Q That's great. And did he teach at the  
15 university level or --

16 A No, sir, he taught at high school level.

17 Q And what did he teach?

18 A He taught history.

19 Q Okay. Has he recommended any responses,  
20 regardless of how minimal you feel that it was, to  
21 any of the deposition questions asked of you  
22 today?

23 A No, sir. He's not a vaccinologist.

24 Q Okay. Has anyone recommended any responses,

1 regardless of how minimal you feel that it was, to  
2 any of the questions asked of you in this  
3 deposition today?

4 A No, sir.

5 Q Okay. During this deposition, did anyone  
6 ever speak to you while your microphone was muted  
7 about any question that was asked of you during  
8 this deposition?

9 A Yeah, probably. I think my husband asked me  
10 if I needed anything when he went to Wal-Mart, so  
11 I didn't think you really wanted to hear what  
12 he -- what -- he asked me about going to Wal-Mart,  
13 so I muted that. He asked me if -- he asked me  
14 something about whether I wanted some water, and I  
15 said yes, I would like some water. He -- I don't  
16 know what else he asked me. I -- you know, he's  
17 here and he asked me a question, and so I muted it  
18 when he said it so you couldn't hear that he was  
19 talking about Wal-Mart. But I -- if he talks  
20 about Wal-Mart now, I will certainly let you hear  
21 it.

22 Q Okay, wonderful. Have you been to Wal-Mart  
23 or any grocery stores in the last two months?

24 A I have not been to Wal-Mart. I've been to

1 the grocery store hardly any.

2 Q Have you been to the -- any hospital in the  
3 last two months?

4 A Yes, I've been to Vanderbilt on several  
5 occasions.

6 Q Okay. Have you met or treated any patients  
7 while you were there?

8 A No, sir, I have not.

9 Q Did you meet with anybody --

10 A I've talked about patients, but I have not  
11 treated any patients.

12 Q Understood. All right. So you met with  
13 other physicians while you were there?

14 A Yes.

15 Q How much have you been paid for your services  
16 in this case by --

17 A I haven't been paid for anything at this  
18 point.

19 Q Okay. What is it that you are charging per  
20 hour for being an expert in this case?

21 A \$500, but I'm going to be giving this to --  
22 to people that have had difficulties during this  
23 pandemic. I'm not going to take any of this money  
24 myself.

1 Q That's very honorable of you. Going back to  
2 the -- my -- let's see if I can pronounce this  
3 correctly. Is it CISA?

4 A Correct.

5 Q Okay. And what does that stand for?

6 A Center for Immunization Safety Assessment.

7 Q Okay. And CISA assesses serious adverse  
8 events in specific cases following immunization;  
9 correct?

10 A Serious -- or excuse me. CISA assesses  
11 reactions after vaccination, yes.

12 Q Okay. And it is part of the CDC Immunization  
13 Vaccine Safety Network. Is that right?

14 A Yes.

15 Q Okay. It's part of the immunization --  
16 Vaccine Immunization Safety Office within the CDC  
17 that's responsible for vaccine safety; correct?

18 A Yes.

19 Q Okay. It's Bible, so to speak, for doing --  
20 for reviewing whether or not an adverse event is  
21 caused by a vaccine is a process described in an  
22 article entitled, quote, Comprehensive Assessment  
23 of Serious Adverse Events Following Immunization  
24 by Healthcare Providers. Is that correct?

1 A Yes, but we also assess some that are not as  
2 serious as well, so -- so the severity of them  
3 depends upon -- you know, depends upon the  
4 question.

5 Q Understood. But when it is a serious adverse  
6 event, the guidance document that's used is the  
7 document I just -- whose title I just referenced;  
8 correct?

9 A No. When -- when we are -- so these are  
10 questions that doctors ask. There is a line that  
11 doctors assess. They call the CDC and then we  
12 assess the assessment, so -- so -- so this is a  
13 paper that was written by Elizabeth Williams who  
14 is one of my fellows, and -- and so it talks about  
15 the process by which we assess reactions, so, you  
16 know, not all of them are serious, but many of  
17 them are, and so it goes through a series of  
18 steps, which you've obviously highlighted.

19 Q Okay. And this would be how -- these are the  
20 steps that would be undertaken within CISA to  
21 determine whether or not a serious adverse event  
22 following immunization might be causally related  
23 to the vaccination; correct?

24 A That's correct, yes.

1 Q Okay. And so in step one, it says to  
2 establish a clear diagnosis of what the potential  
3 injury might be; correct?

4 A To establish a clear diagnosis of what the  
5 adverse event is, correct.

6 Q Okay. And then in step two, it's to consider  
7 whether the timing of the adverse event following  
8 immunizations is consistent with prior knowledge  
9 and known biological mechanisms; correct?

10 A Correct.

11 Q Okay. And so then an example is provided;  
12 right? It says, for example, if a child  
13 experiences a febrile seizure three days after the  
14 receipt of a measles, mumps, and rubella vaccine,  
15 a parent might consider the immunization to be the  
16 cause of the seizure; right?

17 A Actually, it's -- actually, this is a little  
18 early. Most of the seizures that are associated  
19 with MMR are a little later than this. Generally  
20 they're five to seven days in terms of that  
21 because it mimics a reaction, but you may indeed  
22 see a seizure, and sometimes when the Prevnar is  
23 given with the MMR, that was a seizure that was  
24 seen within three days.

1 Q Uh-huh.

2 A So and again, I just say however -- if it  
3 occurs one to two weeks after vaccination, a  
4 period of elevated risk for febrile seizure and  
5 after an MMR is usually seven to ten. Thus --  
6 thus it is improbable that a febrile seizure  
7 occurring three days after immunization was caused  
8 by MMR. That's exactly what I just said.

9 Q All right. So just to make sure I understand  
10 it, what you're saying is is that if the child has  
11 a fever after MMR vaccine, it can cause a seizure,  
12 but that --

13 A It can cause a seizure, yes.

14 Q Right. And the thinking is, and correct me  
15 if I'm wrong, that had the child had a fever maybe  
16 from a certain other reason, the child would have  
17 also had a seizure.

18 A No, that doesn't say that at all.

19 Q Oh, okay.

20 A That's --

21 Q Well, that's why I asked it. Correct --  
22 please.

23 A Well, that's not correct. What you said is  
24 wrong.



1 Q So it's arguing -- so is it that -- is it  
2 saying that it's improbable that a febrile seizure  
3 will occur in the first three days after  
4 immunization because fevers don't occur from MMR  
5 in the first three days after vaccination?

6 A That's what it says, sir.

7 Q Okay. And has -- in this example, we -- you  
8 stop at step two and you don't go further in this  
9 example because MMR, you know, has not been shown  
10 to cause fever in the first three days after  
11 vaccination, and hence couldn't have resulted in  
12 febrile, meaning seizure -- which means a seizure  
13 with fever; correct?

14 A Yes, sir. However, however, we also have to  
15 consider were there other vaccines that were given  
16 at the same time, so if there were other vaccines  
17 that were given at the same time, like a DTP, then  
18 maybe the -- a febrile seizure could occur a  
19 little earlier, although generally those are  
20 between day one and day two, so having an  
21 understanding of when you expect to see the  
22 adverse -- excuse me, I've got the hiccups --  
23 adverse events is very important.

24 Q Understood. All right. And here, knowing

1 that MMR, you know, has -- has not been associated  
2 with fever in the first three days after  
3 vaccination permitted being able to conclude the  
4 febrile seizure in this example was not caused by  
5 MMR.

6 A That's correct.

7 Q Okay. Are you familiar with the clinical  
8 trials relied upon to license the MMR vaccine?

9 A I'm sure there were clinical trials and, you  
10 know, it was -- it's been a few years ago, but if  
11 you want to bring up the paper, I'd be delighted  
12 to look at it.

13 Q Sure.

14 MR. SIRI: So the last one would be  
15 marked as 60 --

16 MS. CHEN: Sixty-four.

17 MR. SIRI: Thank you. And we'll mark  
18 this one as 65.

19 (Whereupon, Exhibit  
20 Nos. 64 and 65 were  
21 marked to the testimony  
22 of the witness.)

23 Q (By Mr. Siri) And so if you take a look  
24 here, have you seen this document before issued by

1 the Department of Health, Education, and Welfare  
2 granting licensure for the MMR vaccine  
3 occurring --

4 A In 1978, no, sir. I -- this went to the FDA.  
5 I have not seen this letter.

6 Q Do you know who Maurice Hilleman is?

7 A I sure do. He's the -- a vaccine guru that  
8 has -- was at Merck for many years.

9 Q Okay. And you'll have an opportunity to  
10 review this, but if you see, it provides that this  
11 is the -- for the combined MMR measles line --  
12 measles, mumps, and rubella vaccine, and this is  
13 for the purpose of supporting a licensure to  
14 manufacture and sell, signed by Maurice Hilleman  
15 from Merck. Do you see that?

16 A Sir, I --

17 MR. SANDERS: Can you enlarge it a  
18 little bit, Mr. Siri, please?

19 MR. SIRI: Absolutely.

20 MR. SANDERS: Thank you.

21 MR. SIRI: Is that better?

22 MR. SANDERS: Yes.

23 A Yes.

24 Q (By Mr. Siri) And just going back to the

1 first page, this is, you know, from the Bureau of  
2 Biologics, and it says, this is to inform you that  
3 the amendments to your product license  
4 applications to include the use of RA 27/3 strain  
5 rubella virus grown in human diploid cells have  
6 been accepted for manufacture of the following  
7 products, and it's -- includes the measles, mumps,  
8 rubella vaccine. All right. It also included a  
9 stand-alone rubella and a stand -- and a measles  
10 mumps vaccine, which we no longer use. Let's  
11 just -- as is typical of these clinical trial  
12 reports submitted to the FDA, which I presume  
13 you're very familiar with, this is a -- usually  
14 there's a summary of the clinical trials that were  
15 conducted; correct?

16 A Yes.

17 Q Okay. And does this look like what you would  
18 expect to see of a summary of the clinical trials  
19 that were conducted when submitting them, what  
20 would now be called the BSA application to license  
21 the vaccine?

22 A Well, it lists the number of studies, it  
23 lists the age of the subjects. It doesn't say  
24 whether there's any other concomitant vaccines.

1 It talks about the -- the seroconversion, the  
2 number that's seroconverted over the number that  
3 was seronegative for the mumps, measles, and  
4 rubella --

5 Q All right.

6 A -- vaccine. And then it gives a geometric  
7 mean titre. I don't know what RA means. One,  
8 two, three, four, five, six, seven -- I have no  
9 idea. There's no --

10 Q Yeah. Those are just reference numbers. But  
11 in the first -- in the first column, it provides a  
12 study number; right? Each of these clinical  
13 trials is provided a study number; correct?

14 A Yes, sir. That's correct.

15 Q And then there's a -- there's also a row that  
16 provides a number of vaccinees. It's a total of  
17 834 vaccinees; correct?

18 A Yes, sir.

19 Q Okay. So, you know, 442 is the first one,  
20 you know, listed. I'm going to scroll down and  
21 what -- you know, what this document has done is  
22 it's excerpted all the tables that have fever in  
23 them and they -- the results of fever in children.  
24 Do you see here for study 442 in the first four

1 days -- well, the first day and the -- and the  
2 next presumably three days after vaccination that  
3 there -- 25.6 percent of the children did have a  
4 fever in this trial?

5 A Yeah, but that's not a fever that's high  
6 enough to cause a febrile seizure.

7 Q What would be high enough?

8 A Usually 103, 104, and there's one of those.  
9 But you also have not provided me with any  
10 information about what else is happening in this  
11 patient, so I think that -- that it may indeed be  
12 something else that's going on with that child  
13 that may be causing the fever. So the fact that  
14 there's one child with fever to 103, 104, does not  
15 mean that that was caused by the vaccine. That  
16 doesn't mean that it wasn't and there was -- you  
17 know, but I have no other information. I have no  
18 information whether other studies were done,  
19 whether the child had a rash, whether he had other  
20 findings, so the finding of one person that had a  
21 reaction after a vaccine does not mean that it's  
22 caused by the vaccine.

23 Q Okay. Let's go to the next study. So this  
24 is study 443. This is, you know, another group of

1 individuals, and you can see that 30 percent of  
2 them in the first four days had a fever between 99  
3 and 100.9. 8 percent had a fever between 101 and  
4 102.9. And then one, as you just said, had a  
5 fever between 103 to 104.9 in this study. So --

6 A Yeah, I don't know whether -- I don't know  
7 whether this study was conducted in the winter  
8 when flu was around. I know other -- you know, so  
9 I'm just saying that -- that the typical pattern  
10 for a fever after MMR is not within the first  
11 three days, which is what we stated, first three  
12 days.

13 Q It's usually between the fifth and twelfth  
14 day; correct?

15 A That's what I said.

16 Q Right. And you can see that those rates are  
17 also provided, and they're relatively comparable  
18 to the first four days; correct?

19 A No. I think that they're -- they're more.  
20 There's seven as opposed to thirteen, five as  
21 opposed to nine. Those are almost double, so  
22 those are different.

23 Q Okay.

24 A The numbers are so small that you could not

1 say that there's probably a statistical difference  
2 between them.

3 Q All right. Well, when they designed the  
4 study, they only included a total of 800 and  
5 something kids with all the -- so, you know, this  
6 is the data that existed.

7 A I know, but you're separating out each of the  
8 individual studies, so each of the individual  
9 studies probably has no more than 80 subjects.

10 Q Well, yeah, I mean, and that's -- that's the  
11 way they designed it. Like, here's another one,  
12 right, and so again, you know, there are children  
13 that had in the first four days fevers, and this  
14 one as well; correct?

15 A Yeah, there's -- there's one in both of those  
16 groups, one.

17 Q Right. Just like there was only one in the  
18 five to twelve days that --

19 A I know, but there's five -- but there's five  
20 in the five to twelve.

21 Q All right. But you -- you said that it's --  
22 fevers of 103 to 104, that would cause a febrile  
23 fever -- seizure.

24 A They are -- febrile seizures are associated



1 with higher fevers.

2 Q Right. So in this instance, there's one in  
3 each in this category right here, which you said  
4 is the category where one would expect to get a  
5 febrile seizure. Let's take a look at another --  
6 you know, look at another one where here's one and  
7 there's none here and you're saying, you know --  
8 so I mean, based on the clinical trials that were  
9 done for the MMR vaccine, do you believe it was  
10 accurate to state that it was improbable? Let's  
11 go -- that -- that a --

12 A Yes, I do, sir. Yes, I do. You're taking  
13 one study from 1978, you're not telling me  
14 anything else that happened in each of those  
15 individual patients, you're taking studies that  
16 have no more than 80 people a thing, and then  
17 you're looking at the numbers. There's no  
18 statistics here, there's no comparability. You're  
19 asking -- you're just looking at numbers, and  
20 that's just not the way that you do things.

21 Q Those are the clinical trials relied upon to  
22 license the MMR vaccine though; correct?

23 A They were relied upon to license the MMR  
24 vaccine, but they were not the ones that --

1 that -- that -- that characterized large numbers  
2 of patients with reactions that -- that are  
3 associated with the MMR. A larger study with more  
4 power would be able to define more clearly what  
5 the time you would see fever, and when that has  
6 been done, it's been five to seven days. That  
7 doesn't mean there's one or two patients. You  
8 know, this is kind of quibbling over irrelevance.

9 Q So but the study that you said would be  
10 needed to really even determine what time periods  
11 are -- fevers are associated with MMR, you're  
12 saying the clinical trials relied upon to license  
13 MMR weren't even powered to do that.

14 A That's correct.

15 Q Okay. I just have a few more questions for  
16 you.

17 A I'm sorry, you have no more questions? Is  
18 that what you --

19 Q No, I just -- I just have a few more for you  
20 and we're done. So vaccines are grown on various  
21 growth mediums; correct?

22 A Yes.

23 Q And those growth mediums are removed from the  
24 vaccines by the end of the manufacturing process

1 so that as part of the vaccination process  
2 antibodies to these substances are then generated;  
3 correct?

4 A Well, we've already talked about that. These  
5 are impurities in the vaccine, and we -- and  
6 you're asking me to comment on all vaccines, so  
7 that's not -- I can't be very precise.

8 Q Okay. How about bovine -- how about calf  
9 bovine serum? That's used as a growth medium for  
10 some vaccines; correct?

11 A Cells need to be supported by -- by  
12 nutrients, so both the -- and serralbumin can be  
13 added as a grow -- to help support the cells that  
14 would then support viral growth.

15 Q Okay. But the calf bovine serum that's used  
16 as a growth medium would be removed from the final  
17 product so that the body would instead develop  
18 antibodies to calf bovine serum; correct?

19 A Yes, that would be the goal.

20 Q Okay. And it's, you know, similarly --  
21 there's caseins from cow milk that's used as a  
22 growth medium in some -- at least one vaccine, and  
23 that also is removed from the final formulation of  
24 the product; correct?

1 A Yeah, the -- the products are purified as --  
2 to have as pure product to be in. Whether there's  
3 a microgram of BSA, you know, I can't comment on  
4 the final -- final -- excuse me, amount of each of  
5 the impurities that are in the vaccine. That's in  
6 the package insert, but I -- I don't remember all  
7 of those.

8 Q Okay. Fair enough. Final topic. You  
9 lecture to doctors about vaccine safety; correct?

10 A Yes, sir.

11 Q You provided a -- have you provided a -- how  
12 many times have you provided lectures in rooms  
13 with doctors in them about vaccine safety would  
14 you estimate?

15 A I do it in so many formats that I can't even  
16 comment. I lecture on this on the wards when I  
17 take care of patients, I lecture to the medical  
18 students, I lecture in -- and they're not always  
19 in formal lectures. I give lectures to -- to the  
20 fellows, and I give lectures to large groups of  
21 doctors, and so I can't tell you. I probably have  
22 talked to thousands of doctors about vaccine  
23 safety.

24 Q Okay. And the purpose is to educate them

1 about vaccine safety; correct?

2 A Of course.

3 Q To frame the way that they think about  
4 vaccine safety; correct?

5 A To educate them so that how they think about  
6 vaccine safety is informed by research and data.  
7 I do not try and brainwash people.

8 Q Okay. Are you -- are you -- are you aware  
9 that there is one of these lectures available on  
10 YouTube that you gave to a room full of doctors at  
11 the Vanderbilt Kennedy Center on January 12, 2011?

12 A Yeah, I think you got some pictures from  
13 that. It was one of the earlier ones, yeah.

14 Q Do you recall -- do you recall that  
15 presentation?

16 A I recall giving that presentation. I don't  
17 recall what was included in that presentation.

18 Q Okay. So -- well, let me ask before I play  
19 it. Do you recall stating that the -- that an  
20 article that we looked at earlier with regard  
21 to Poling -- regarding the Poling case brought up  
22 the whole controversy of whether vaccines are safe  
23 in vulnerable children?

24 A I -- I don't know that I said that. That

1 sounds like something that I may have said.

2 Q Do you think that the Hannah Poling case  
3 brought up the whole controversy regarding whether  
4 vaccines are safe in vulnerable children?

5 A I think that it -- it -- yeah, I think it was  
6 a topic of intensive discussion.

7 MR. SANDERS: Ms. Cohen, can you tell us  
8 the time that we've been in again, please?

9 THE COURT REPORTER: Seven minutes -- I  
10 mean seven hours and 56 minutes.

11 MR. SANDERS: Thank you.

12 MR. SIRI: Four minutes left. All  
13 right.

14 Q (By Mr. Siri) Do you recall telling the  
15 doctors that, quote, I'm going to go over this  
16 morning the process of vaccine licensure so that  
17 you can understand how comprehensive it is so that  
18 you can explain that to your patients?

19 A That sounds like something I would say.

20 Q Okay. And do you believe that you said that?

21 A Well, sir, I think it's something I said. I  
22 don't remember whether I said that 20 or 15 years  
23 ago during that lecture, but it sounds like  
24 something I would say. So that sounds like a

1 reasonable statement, but whether I said it in  
2 that lecture, I don't know.

3 Q Fair enough. I'm going to play you one clip  
4 since we're pretty much out of time.

5 (Whereupon, a video clip  
6 was shown.)

7 Q Dr. Edwards, isn't it true that most VAERS  
8 reports are not filed by parents?

9 A I don't know the distribution. I think  
10 probably most VAERS reports are filed by the  
11 manufacturers, but I don't know the exact  
12 distribution of the reports.

13 Q Your implication though was that -- let me --  
14 let's pull up a document. So --

15 A I don't think that my statement had any  
16 implications. I'm just saying that the people --  
17 a lot of different people can report adverse  
18 events.

19 Q But isn't it true that most are not filed by  
20 teachers? Isn't it true that approximately  
21 80 percent of VAERS reports are filed by doctors  
22 and pharmaceutical companies and health -- and  
23 health -- and health -- state health agencies?

24 A That's probably correct, but I didn't say --

1 I said -- well --

2 Q Yeah. So most are not filed by neighbors;  
3 correct?

4 A No, but some of them are.

5 Q Okay. And most are not filed by grandma;  
6 right?

7 A No, but some of them are. Particularly, I'm  
8 a grandma, and I file them, so yeah, I file them.

9 Q Uh-huh. What percentage of adverse reactions  
10 are reported to VAERS approximately according to a  
11 study conducted by AHRQ, if you're familiar with  
12 it?

13 A I would say -- I -- I would say if -- a  
14 fairly low percentage. I don't know what that  
15 paper says. You can probably tell me so I can  
16 read that again before I prepare for the trial.

17 MR. SIRI: Okay. How much time is left?  
18 Are we -- are we at eight hours, Ms. Cohen?

19 THE COURT REPORTER: We're at seven  
20 hours, 59 minutes, and 18 seconds.

21 MR. SIRI: Okay. Well, I --  
22 Dr. Edwards, you and I could probably spend  
23 another two days together, but our time together  
24 has come to a close until the trial. And thank



1 you for sitting with me today and answering our  
2 questions. So I assume at that point, you know --  
3 you know, I've got more questions, but if we are  
4 going to close it out at eight hours, then we'll  
5 close it out right now.

6 MR. SANDERS: I don't have any  
7 questions. Dr. Edwards, we'll go off the record  
8 and then you can click out.

9 THE VIDEOGRAPHER: All right. That  
10 concludes the videotape testimony of Dr. Kathryn  
11 Edwards, and we are off the record at 5:03 p.m.

12 (Whereupon, the  
13 deposition of Kathryn  
14 Edwards, M.D.,  
15 concluded.)

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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



My Commission Expires:  
June 4, 2022

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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:

\_\_\_\_\_

<b>Exhibits</b>	<b>Kathryn Edw ards - Exhibit 12</b> 126:4,5,9	<b>Kathryn Edw ards - Exhibit 24</b> 264:14,15	<b>Kathryn Edw ards - Exhibit 35</b> Kathryn Edw ards - <b>Exhibit 36</b> 297:9	<b>Kathryn Edw ards - Exhibit 48</b> 324:13,14	<b>Kathryn Edw ards - Exhibit 61</b> 370:9,10
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