

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

RACHEL MACE, M.D.

August 26, 2020

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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

RACHEL MACE, M.D.

AUGUST 26, 2020

** TAKEN VIA ZOOM VIDEOCONFERENCE **

SAMANTHA E. COHEN, RPR, CRR, LCR(TN)(MS)
RIVERSIDE REPORTING
Memphis, Tennessee
(901) 527-1100

The deposition of RACHEL MACE, M.D. is taken via Zoom videoconference on behalf of the Plaintiff, on this the 26th day of August, 2020, pursuant to notice and consent of counsel, beginning at approximately 2:00 p.m.

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

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

A P P E A R A N C E S

** ALL PARTIES APPEARED VIA ZOOM VIDEOCONFERENCE **

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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 video
4 deposition of Dr. Rachel Mace. This is 8/26 --
5 August 26, 2020. We are on the record at 2:05.
6 Counsel, would each of you please state your
7 appearances for the record which will then be
8 followed by the swearing in of the witness by the
9 court reporter.

10 MR. RILEY: David Riley on behalf of
11 Yates Hazlehurst.

12 MR. SIRI: Aaron Siri on behalf of Yates
13 Hazlehurst.

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

16 RACHEL MACE, M.D.,
17 Having been first duly sworn, was examined
18 and testified as follows:

19 EXAMINATION

20 BY MR. SIRI:

21 Q Good morning, Dr. Mace.

22 A Hi.

23 Q Well, good afternoon. We're in different
24 time zones. So Dr. Mace, can you kindly state

1 your full name for the record?

2 A Rachel Lenox Mace.

3 Q Have you ever been deposed before?

4 A I have.

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

6 A I've given a deposition just once.

7 Q Okay. And what was your role in that case?

8 A That was many years ago in the early 1990s.

9 My recollection is it was a custody dispute
10 between parents. I had provided care for their
11 child and they wanted some explanation of the
12 medical records.

13 Q Did it involve a vaccine issue?

14 A It did not.

15 Q Okay. Thank you. I'm going to go over a few
16 rules since it's been a while since you've been
17 deposed, which is a good thing, and, you know, if
18 you don't understand any of the rules, please let
19 me know.

20 A Okay.

21 Q Now, the court reporter has placed you under
22 oath, same as a court of law, meaning you're
23 testifying here today under penalty of perjury.

24 Do you understand what I mean when I say perjury?

1 A I do.

2 Q Okay. The court reporter is making a record
3 by typing up all the questions and your answers.

4 MR. SIRI: So I'll try not to go too
5 fast, Ms. Cohen.

6 Q (By Mr. Siri) And to do that though, when
7 you answer, kindly do so audibly. If you nod your
8 head, she can't take that down.

9 A Okay.

10 Q Okay. And also, uh-huhs, you know, are -- we
11 don't know if that means yes or no --

12 A Right.

13 Q -- when you read it, only when you hear it.
14 So if you could say yes or no instead of uh-huhs,
15 I'd appreciate it.

16 A I'll do my best.

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

20 A Okay.

21 Q All right. And please wait until I complete
22 asking the question before you answer. There will
23 definitely be times where you know what I'm about
24 to ask, but if I don't complete the question

1 before you answer, there's no complete record.

2 A Okay.

3 Q Okay. If you don't know an answer to a
4 question, you can say I don't know. That's
5 entirely fine. There will be probably questions
6 you don't know the answer to. You don't have to
7 guess or speculate. But if you don't know the
8 answer, you know, you could state -- but you
9 should provide your best recollection, you know,
10 even if it's partial or vague; okay?

11 A Okay.

12 Q All right. Now, as I mentioned yesterday,
13 this is now my second Zoom deposition, so under
14 normal conditions, I would be handing you
15 exhibits.

16 A Okay.

17 Q Instead, I'm going to put them on the screen,
18 and so you won't be able to manipulate them on
19 your end. If you want me to move up or down or
20 show you something, just let me know; okay?

21 A Yes.

22 Q Or if you can't see anything, you need me to
23 zoom in, or what have you. Okay. So I'm going to
24 start with a standard question, and it's -- are

1 you taking any medications -- medications or under
2 the influence of any other substance that might
3 affect your ability to testify today?

4 A I am not.

5 Q Okay. I'm not implying anything. Just a
6 normal question I ask. Thank you. All right. So
7 how did you prepare for today's deposition?

8 A I have reviewed records that were provided by
9 Attorney Sanders' office. I -- that includes the
10 medical record, some of the medical records for
11 Yates Hazlehurst, depositions of the parents, and
12 some of the depositions of expert witnesses. I
13 met with -- I had a couple phone conversations
14 with Mr. Sanders and met with him on one occasion
15 to review and make sure that I understood the
16 documents and didn't have any questions about what
17 I was reviewing.

18 Q Okay. And you just specifically had
19 discussions with regards to preparing for today's
20 deposition?

21 A We did.

22 Q Other than your discussions with Mr. Sanders,
23 did you talk with anybody else to -- with regards
24 to the deposition today?

1 A Not in any specific terms. Just, you know,
2 prepare the office, close the door, people don't
3 talk outside the room, that sort of thing.

4 Q Oh, so people just in your general vicinity,
5 in your office about not dropping in.

6 A Right. I'm at work and in my office in the
7 back and wanted to make sure that I don't have
8 interruptions for this.

9 Q Okay. Did you -- have you spoken to anyone
10 other than Mr. Sanders about this case at all?

11 A No. I -- I -- before agreeing to review the
12 case, I -- I notified our hospital risk management
13 office just to make sure that they thought that
14 that was okay.

15 Q Okay. Have you had any conversations with
16 Dr. Kathryn Edwards about this deposition?

17 A I have not.

18 Q Or about this case?

19 A I have not.

20 Q Okay. And well, you said you reviewed a
21 number of depositions. Were one of those that of
22 Dr. Kathryn Edwards?

23 A No, it wasn't.

24 Q Okay. And which depositions have you

1 reviewed?

2 A I have reviewed depositions from Carlton Hays
3 on September 12 and 13, a deposition of -- I'm
4 sorry, September 12 and 13 of 2006; LuAnn Upchurch
5 from June 29 of 2016; Robert Riikola,
6 September 21, 2015; Angela Hazlehurst,
7 September 12, 2006; Angela Hazlehurst, July 1,
8 2015; Rolf Hazlehurst, July 1, 2015 and May 13,
9 2016 -- 2016; Andrew Zimmerman from June 22, 2018;
10 Ramon Ramos, I don't have that date right -- right
11 handy; Elizabeth Munford, those are all the -- and
12 I'm sorry, Richard Kelley from November 7 of 2016.

13 Q And you reviewed all of those depositions?

14 A Yes.

15 Q Wow, okay. And besides those depositions,
16 you reviewed Yates' medical records?

17 A I reviewed medical records beginning from his
18 birth until -- the last record I have is an
19 evaluation from July 3, 2002.

20 Q Okay. Have -- so other than the deposition
21 transcripts and the medical records, were there
22 any other documents that you reviewed?

23 A Yes.

24 Q Okay.

1 A Let me get the correct notebook. I also
2 reviewed the complaint for damages and the answer
3 of the defendants.

4 Q Okay. You might be more prepared today than
5 me. Anything else?

6 A I reviewed medical literature that I thought
7 was pertinent to support my -- my beliefs with
8 regard to standard of care, just -- you know,
9 to -- to see where that -- where the information
10 came from that I base my practice on, so I -- I
11 reviewed specifically the 2000 Red Book because
12 that's a document that was in place at the time of
13 the -- of the vaccinations of Yates. I also
14 reviewed through the 2015 and the most current
15 Red Book, which is 2018 to 2021, because this is a
16 resource that I use regularly. I also looked at
17 some information about vaccinations and potential
18 complications like the question of whether autism
19 is caused by MMR vaccine. I looked a little bit
20 at the resources I typically use to get medical
21 information and information about mitochondrial
22 disorders as well.

23 Q Okay. Did you -- so you looked at the 2000
24 Red Book. Did you also look at any of the --

1 like, the 2000 CDC schedule or contraindication
2 lists as well?

3 A I was provided with a document from the CDC
4 that I had never seen before. I did look at a
5 little two-page document that's a -- that -- a
6 Xerox copy that's -- that indicates it's from the
7 CDC, and that, I think, was dated October of 2000.

8 Q But you -- so you looked at the 2000 Red Book
9 just to -- because that was the standard of care
10 back in 2000, provided for the standard of care in
11 2000?

12 A Yes.

13 Q Okay.

14 A That was -- that was a contribute -- a
15 contributor. You know, what I did in the year
16 2000 was based on my own training, my experiences
17 leading up to that point, and then the Red Book
18 would have been a resource that was readily
19 available. In case I had questions about things,
20 I could look at the Red Book for guidance.

21 Q Okay. So since the 2000 Red Book, I think --
22 so since the 2000 Red Book was part of, you're
23 saying, the standard of care in 2000, you looked
24 at it to refresh your memory of the standard of

1 care in 2000?

2 A Yes.

3 Q Okay. So and do you -- did anybody discuss
4 with you the topics that would be covered today
5 during the deposition?

6 A In general terms we talked about the standard
7 of care and questions about, you know, the --
8 what -- what is standard of care for a pediatric
9 patient with regard to immunizations, care for
10 otitis media, standard procedures in the office
11 with regard to vaccine information sheets and
12 information provided to families. We also talked
13 a little bit about -- a little bit about his
14 diagnosis of autism and the -- I'm aware that
15 there is -- there are some records or some
16 information about him possibly having a
17 mitochondrial disorder, which is why I looked at
18 that information.

19 Q Okay. Do you feel like you were -- you were
20 coached to give certain answers or do you -- are
21 you -- are you going to give your -- the testimony
22 that -- well, do you believe -- do you feel like
23 you were coached to give certain answers here
24 today during this deposition?

1 A No.

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

4 A No, I don't believe I was coached
5 specifically with certain answers. I was told
6 every time we had a conversation that I should say
7 what I believe.

8 Q (By Mr. Siri) Okay, wonderful. That was
9 going to be my next part of the question, so good.
10 So -- okay. So there are a lot of acronyms that
11 get thrown around in pediatrics practice; right?
12 So I'm -- and vaccinology, so I'm going to go
13 through a list of acronyms, and some of these will
14 be pretty obvious, like CDC, but I just will ask
15 you the acronym, and if you can tell me what the
16 name of the organization that it refers to just so
17 we have it on the record that we have a common
18 understanding of what those acronyms mean.

19 A Okay.

20 Q Okay. HHS.

21 A That would be the Department of Health and
22 Human Services.

23 Q Okay. Do you consider HHS to be a reliable
24 authority with regard to vaccines?

1 MR. SANDERS: Object to the form of the
2 question as overbroad. You can answer, Doctor, if
3 you have an answer.

4 A It's not a resource that I would generally
5 look to for information about -- in -- about
6 vaccinations. I don't go searching HHS
7 information.

8 Q (By Mr. Siri) Uh-huh. CDC.

9 A That's the Center for Disease Control.

10 Q And do you consider the CDC a reliable
11 authority for information regarding vaccines?

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

15 A I think generally the information we receive
16 from the CDC is reliable, but I wouldn't accept
17 everything that they say as absolute truth. I
18 would put it in context of other information.

19 Q (By Mr. Siri) Okay. Sometimes information
20 from the CDC is not reliable?

21 A Yes.

22 Q Okay. CDC is part of HHS; correct?

23 A I don't know.

24 Q Okay. FDA?

1 A The Food and Drug Administration.

2 Q Do you consider the FDA to be a reliable
3 source -- authority and source of information for
4 regard to vaccines?

5 MR. SANDERS: Same objection. You can
6 answer, Doctor.

7 A I -- I look at this -- the FDA as a -- I
8 believe they license drugs, so they decide what --
9 what medications or vaccines can be used and are
10 licensed in the United States, but I don't look at
11 them for information with regard to what
12 vaccinations should be administered.

13 Q (By Mr. Siri) Okay. Fair enough. So you
14 would consider them a reliable authority with
15 regards to the licensure of vaccines?

16 A Yes.

17 Q Okay. And NIH.

18 A National Institutes of Health.

19 Q Okay. And would you consider the NIH to be a
20 reliable authority of information regarding
21 vaccines?

22 MR. SANDERS: Same objection.

23 A I would make the same comment as well
24 about -- about this as well -- as with all of

1 these organizations. I would take the information
2 that they provide and put it in the context of
3 other information, including my own experience,
4 and find that -- you know, for the most part, I --
5 I would suspect they are reliable, but I wouldn't
6 view them as the ultimate authority and correct
7 about absolutely everything.

8 Q (By Mr. Siri) What would you view as the
9 ultimate authority with regards to vaccine
10 information?

11 MR. SANDERS: Same objection. You can
12 answer, Doctor.

13 A I would put at the top of my list the
14 American Academy of Pediatrics. I look at the
15 Red Book. In general, the -- my understanding is
16 that the American Academy of Pediatrics Committee
17 of Infectious Diseases that calls -- is the
18 Red Book works in conjunction with the advisory
19 committee of immunization practices at the CDC,
20 and most of the time through my career as a
21 pediatrician, they have agreed on recommended
22 vaccine schedules for infants and children, but
23 there have been exceptions to that, so when the
24 CDC and the American Academy of Pediatrics are not

1 in agreement, then I have to use my own judgment
2 to decide what's best in that situation.

3 Q (By Mr. Siri) Thank you. HRSA.

4 A I'd have to look that one up. I don't know
5 what that stands for.

6 Q You've heard of -- have you heard of that
7 agency before?

8 A I've heard of it, yes.

9 Q Okay. What's your understanding what that
10 agency does with regards to vaccines?

11 A I don't know what HRSA does.

12 Q Well, you'll have an opportunity to look it
13 up later, but it's the agency that's responsible
14 for defending claims and filings in vaccine court.
15 ACIP.

16 A ACIP?

17 Q Yes.

18 A A-C-I-P, Advisory Committee on Immunization
19 Practices, and I believe they're from the CD --
20 they are part of the CDC.

21 Q Okay. And ACIP is the committee within the
22 CDC, as you just said, that effectively decides
23 upon the CDC's childhood immunization schedule?

24 A Uh-huh.

1 Q Is that correct?

2 A Yes, that's what I understand. They -- they
3 make -- they don't decide. They -- they produce
4 guidelines for us as practicing physicians to help
5 us make decisions about what to do for our
6 patients.

7 Q Understood. And when -- and the CDC
8 publishes the recommended childhood immunization
9 schedule; correct?

10 A That's -- that's correct.

11 Q All right. And the pediatricians such as
12 yourself look to that schedule in deciding what
13 vaccines should be administered to children?

14 A We do use that schedule as a resource for
15 making decisions.

16 Q Okay. In deciding what vaccines to
17 administer, if -- is there anything else you would
18 look at other than the CDC's childhood
19 immunization schedule?

20 A I -- I look at the CDC schedule. I think
21 about the individual patients and -- and talk with
22 the family and consider multiple factors. Every
23 time I write orders for vaccines I think about
24 what's recommended, what -- if -- does that child

1 have a special condition, because there are
2 conditions in the recent CDC schedule where we
3 need to make alterations, but that -- so that
4 would be based on the CDC schedule, and I
5 communicate with the family about vaccines, and
6 then we make a decision about what's best to do.

7 Q Okay. Those conditions that prevent -- to
8 potentially consider before vaccinating, those are
9 contraindications and precautions? Is that
10 what -- that are -- can potentially exist in
11 administering a vaccine?

12 A Contraindications and precautions? There's
13 also a chart of complex health problems. For
14 example, I have patients who have undergone heart
15 transplantation, and because they're on
16 immunosuppressive drugs, I have to change the
17 vaccines that I order for that child compared to
18 other children, so those are just special
19 conditions that need to be considered. Much of
20 them have to do with immune deficiency.

21 Q Right. So what -- when you're trying -- so,
22 you know, you -- you look -- you will look at the
23 CDC, I understand, you know, immunization
24 schedule, but you look at other material, if I

1 understand you correctly, to then just determine
2 whether or not the vaccines are appropriate for
3 the child; correct?

4 A Most of time. If it's a healthy child who is
5 here for a routine health visit that does not have
6 complex health problems, I don't -- I don't stop
7 and consult other materials at that time. I
8 follow the routine recommended schedule for most
9 of my patients, but I have other resources
10 available to make decisions if the vaccine
11 schedule seems appropriate to do something
12 different.

13 Q Uh-huh. And so and before you administer,
14 you know, vaccines, you'll -- if the parents have
15 any questions, you'll answer those questions?

16 A That's correct.

17 Q All right. And before you administer
18 vaccines, you provide the parents a copy of the
19 vaccine information statement before you give the
20 vaccine?

21 A That's correct.

22 Q And if the parents have any questions about
23 the information they've read on the VIS, you would
24 answer those before you administered any vaccines

1 to the child?

2 A As long as they ask me beforehand, yes.

3 Q Of course. Now, the members of ACIP, they're
4 supposed to be independent of the pharmaceutical
5 companies whose products are being voted upon;
6 correct?

7 A I would imagine that's correct. I don't know
8 for a fact.

9 Q All right. Okay. Going back to the process
10 that you described in terms of, you know, before
11 you administer a vaccine, that's the process, I
12 presume, that you've been using for most of your
13 career?

14 A Yeah, yes.

15 Q Okay. And one you would consider the
16 standard of care?

17 A The -- the -- so you're referring to the
18 process of considering the individual child and
19 what's recommended and making a decision after
20 seeing if the parents have questions or concerns,
21 making a decision and then ordering vaccines.

22 Q Right. Providing them with the VIS and
23 answering any questions they have before you
24 administer the vaccines, that entire process,

1 would you consider that to be the standard of
2 care?

3 A I would say, yeah, we provide the VISs. I
4 believe that much of the time parents don't read
5 them and don't ask questions, but they are given
6 the opportunity to ask us questions and -- and,
7 you know, to read those forms, so yes, if they
8 have questions, I answer those questions.

9 Q All right. So the standard of care, you
10 know, that you employ, including that would have
11 been applicable when Yates was vaccinated, right,
12 you understand him to be the child at issue in
13 this case?

14 A Yes.

15 Q All right. The standard of care applicable
16 for the -- for vaccinating Yates and in your
17 current practice would be to provide a VIS to the
18 parents regarding before the child is vaccinated;
19 correct?

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

22 A Sure. So -- so our -- our procedures have --
23 have changed over the years. Just until -- you
24 know, we decide what -- we develop the protocols.

1 We decide what pieces of paper, supplemental
2 materials people need at their visits. In the
3 past, our -- our procedure was that the vaccine
4 information sheets were kept at the desk where the
5 nurses drew up the vaccines, so -- so the nurse
6 would -- would -- because we wanted to provide the
7 piece of paper that corresponded with the vaccines
8 that were being given that day and not by the
9 extraneous information that might not be
10 applicable to that day, so the vaccine information
11 sheets were brought by the staff member, the
12 nurse, with the vaccines in the room. They would
13 be given to the family, and then vaccines were
14 administered. If the family asked to review those
15 information sheets, certainly they would be given
16 an opportunity to review those information sheets,
17 but they weren't necessarily advised you must look
18 at this information sheet first and we have to go
19 over all of these questions before. Now -- now,
20 what I do though is when I'm ordering the
21 vaccines, I tell them about what I'm ordering and
22 I -- I tell them about, you know, common side
23 effects of those vaccines and ask them at that
24 time if they have any questions about the

1 vaccines, and then once we resolve that, that this
2 is what I'm ordering, this is why, this is what
3 it -- what the potential side effects may be, I
4 order the vaccines, then the nurse and -- would
5 bring in the vaccines and the vaccine information
6 sheet. We changed that in recent years. We
7 decided that because we're trying to really follow
8 the standard schedule for everyone, now those
9 information sheets are given at the beginning of
10 the visit, and again, parents often don't read
11 them or look at them.

12 Q So it sounds though that the standard of care
13 has remained, at least with regarding to the
14 VIS -- strike that. So providing the VIS prior to
15 vaccination, irrespective of duration of how long
16 before, but prior -- but providing the VIS before
17 administering the vaccines is the standard of care
18 that you currently employ and was the standard of
19 care applicable to Yates when he was vaccinated;
20 correct?

21 A Providing the VISs at the time of giving
22 vaccines.

23 Q Are you -- before giving the vaccines?

24 A Well, they're -- the papers are brought in

1 the room and the vaccine is brought in the room,
2 and -- so it's sort of simultaneous.

3 Q So the federal law requires that the VIS be
4 provided before the vaccine is administered. Are
5 you aware of that?

6 A I don't spend a lot of time reading federal
7 law. I know that we're required to provide VISs
8 to families and, you know, my practice is to tell
9 them what I'm vaccinating and then to be sure that
10 they have those, those forms.

11 Q Before --

12 A So sometimes it's simultaneous.

13 Q Okay. What would you consider -- you train
14 pediatricians; correct?

15 A I -- I did train pediatricians. Now I --
16 sure, I still do somewhat. I spent more time
17 teaching in the past than currently.

18 Q And some of your lectures have been recorded;
19 correct?

20 A I don't think so.

21 Q Okay. Well, we'll come back to that later.
22 Now, when you've given those lectures and you
23 explained, you know -- and in your, you know, your
24 rounds, did you -- what did you advise

1 pediatricians that you were training? Did you
2 advise them that they should provide the VIS
3 before giving the vaccines?

4 A So most of my teaching time was in the early
5 '90s. If you -- if you look at my CV, I was
6 director of the residency program and director of
7 the resident continuity clinic up until 1996. The
8 VISs were -- many were just becoming available
9 during that time frame, so we spent a lot of time
10 talking about -- and what doctors want to know or
11 what vaccines are needed, what vaccines are --
12 what are we preventing, what are the potential
13 side effects, the contraindications, the
14 precautions, what are the myths about those
15 things, that's what I spent my time teaching. Our
16 clinic set up procedures for how the VISs were
17 given to families, so I -- I -- I can't recall at
18 any time talking with my learners about this is
19 how you give the VIS. It's sort of the -- you
20 know, the VIS needs to be given is kind of the
21 extent of what I would have said. And I don't --
22 I wouldn't have focused on federal law says it
23 must be given this many minutes beforehand or
24 anything like that, just -- the VIS is an

1 important information sheet, families need to have
2 that.

3 Q So are you aware that the AAP Red Book
4 explains when the VIS should be given?

5 A I haven't looked at that specific piece of
6 information. I -- I -- you know, it's an
7 important document. We want to make sure families
8 receive that document, but again, we talk with
9 them about what -- what we do as standard of care
10 is talk with the family about what we're ordering,
11 why we're ordering it, what to watch out for, and
12 then we order the vaccines, and those sheets I
13 think are important. I would view it as a legal
14 document that they -- they need to be given. It's
15 required that they be given that, but I don't
16 think that that is an important part of -- usually
17 of our discussions or decision-making about the
18 vaccines.

19 Q So the standard of care applicable when Yates
20 was vaccinated and that you still employ though
21 would require having a discussion with the parents
22 about the risks and benefits of the vaccines and
23 answering any questions they have before the
24 vaccines are given; correct?

1 A I would say yes, we certainly give -- we
2 discuss, it may be a brief discussion or a longer
3 discussion depending -- but there's some
4 discussion about what's being ordered. They're,
5 you know, at a minimum informed these are the
6 vaccines that are being ordered. I like to talk
7 about what the diseases are because so many
8 families don't -- have never seen measles or -- I
9 mean, everybody knows chicken pox, but they've
10 never seen HIB or pneumococcus or other important
11 diseases, so I like to make sure I spend time on
12 that. But I would say that I probably spend extra
13 time talking about those things because it's a
14 topic that I think is so important. But I think
15 they need to be told what's being ordered and --
16 and what the potential risks are, you know, side
17 effects, and be given an opportunity to ask
18 questions. I mean, the whole visit is sort of
19 around parents. You know, our visit from start to
20 finish is an interactive process where parents are
21 given an opportunity at each step along the way to
22 ask questions. They're encouraged to ask
23 questions throughout the visit.

24 Q And one of the ways you help inform parents

1 is providing them a vaccine information statement;
2 correct?

3 A That is one of the ways we inform them, yes.

4 Q Right. And the AAP Red Book provides that
5 you should provide it prior to vaccination;
6 correct?

7 A As I said, I haven't looked at that
8 specific information. I can imagine that's
9 correct. Again, AAP I view as guidelines and
10 ideals, things that we should be aiming for.

11 Q And the CDC guidelines applicable when Yates
12 was vaccinated and today on their website clearly
13 state that the VIS materials need to be provided
14 prior to vaccination. Isn't that true?

15 A Well, I'll take your word for that. I
16 haven't looked at the CDC website for exactly how
17 they state that.

18 Q Okay. If the CDC guidance is to provide it
19 before vaccination and the AAP Red Book's guidance
20 is to provide the VISs before vaccination and
21 that's what's provided in the federal law, would
22 you consider providing VIS prior to vaccination to
23 be the standard of care that would be applicable
24 with regards to when the VIS needs to be provided?

1 A It is a wonderful ideal about what we -- you
2 know, it's a wonderful ideal. It's a guideline.
3 And in the practical day-to-day practice of
4 pediatrics, the VISs I think are given at the --
5 at the time that -- in many practices, including
6 our practice in the past, and in many practices,
7 they are given at the time that the nurse comes in
8 the room with the vaccines.

9 Q So the nurse comes in the room with the
10 vaccines and the VISs; correct?

11 A In --

12 Q Now, would she have -- does she have one hand
13 injecting the baby while the other hand is giving
14 the VIS? How are they done simultaneously?

15 A No. She lays the paper down on the table and
16 says here are the vaccines, and the parent helps,
17 you know, calm the child or hold the child, she
18 administers the vaccines, and the VIS sheets are
19 there, so, you know, just -- this -- it's just
20 sort of the day-to-day process of trying to not
21 keep our families waiting an extended period of
22 time, making sure that we're addressing their
23 concerns, so, you know, I'm the person who answers
24 the questions that the parents have about

1 vaccines. If they go in the room and the -- and
2 say to the nurse, wait, I have some questions,
3 then the nurse comes back, even though she's got
4 vaccines in hand, she would come back out of the
5 room and say, Dr. Mace, that mom has another
6 question for you, can you please go back in there,
7 and I would go in and address -- and maybe it was
8 about vaccines, maybe it was about some other
9 topic, but they -- you know, if a parent says,
10 wait, I have a question, then -- and that happens
11 from time to time.

12 Q So the nurse puts the VIS on the table?

13 A I'm not with the nurse when that happens, so
14 I'm imagining. I know the nurse goes in the room,
15 administer -- has the sheets in hand, has the
16 vaccines in hand, and when they come out of the
17 room, the parents have the child, they leave, the
18 nurse goes back in and completes her documentation
19 of the vaccines. Sometimes the VISs are left in
20 the room, sometimes the VISs -- you know, most of
21 the time the VISs go out the door with the
22 parents.

23 Q Are the nurses instructed to provide the VIS
24 and then administer the vaccines?

1 A I've not had a discussion with my nurses
2 about exactly what order they do things. We've
3 said these -- these sheets are important, the
4 parents need to receive them.

5 Q So do you believe the VIS provides important
6 information for the parents to receive?

7 A I do.

8 Q And, you know, they're prepared through the
9 limited process at the CDC; correct?

10 A I don't know what the process is. I know
11 it's an -- it's an extensive process. It takes a
12 lot of time to come up with the document. I know
13 there's -- in the past, the documents that were
14 produced were kind of lengthy and, you know, may
15 have contained too much information and it had to
16 be kind of reduced to provide just the most
17 important information, so I think the VIS sheets
18 are a good piece of information for families to
19 have.

20 Q Okay. And they explain the benefits of the
21 vaccine; correct?

22 A They do explain the benefits. I don't know
23 that they explain it in the same way as I can, as
24 a pediatrician who's actually cared for children

1 with some of these life-threatening infections.

2 Q And they explain risks of vaccinations as
3 well of the vaccine; correct?

4 A Yes.

5 Q Okay. And so if the VIS is not received by
6 the parent before vaccination, what you're saying
7 is you're providing even better information to the
8 parents orally before vaccination. Is that right?

9 A Sometimes I'm providing more extensive
10 information, sometimes I'm providing less
11 information. It depends on that family's needs.
12 If it's the very first set of vaccines, then I
13 spend more time. At the two-month visit I spend a
14 little more time explaining the diseases because I
15 think it's important. If it's a repeat of
16 vaccines they've had before, then I spend less
17 time, but parents are always given opportunities
18 to ask questions throughout the visit, including
19 when we tell them what vaccines we're ordering.

20 Q Have you ever had a parent ask you a question
21 about information on a VIS?

22 A Not -- you know, I can't -- I can't recall a
23 specific time that a parent looked at the VIS and
24 asked me a question about it.

1 Q Do you --

2 A Parents ask me lots of questions about
3 vaccines. It's a common topic. We talk about it
4 a lot, but I haven't had a parent who pulled out
5 the VIS and said tell me about this.

6 Q Uh-huh. Is it -- is it possible that the
7 questions were being asked because they did review
8 a VIS, they just didn't reference it?

9 A Is it possible? Sure.

10 Q So the VISs provide information of benefits
11 and risks, and you've indicated that, you know,
12 informing parents about the benefits and risks of
13 vaccinations and before vaccinating is important.
14 So then wouldn't it be important to give the VIS
15 prior to vaccinating?

16 A I view it as an additional document. I think
17 the information on there about the -- about the
18 National Child Injury Acts and the -- you know,
19 that information is that -- there's some phone
20 numbers in there, there's information that
21 families have. I would love for them to keep the
22 VISs. I sometimes tell families, particularly for
23 our live virus vaccines with delayed reactions,
24 I'll say, make sure you hang on to those

1 information sheets because if there's a fever or a
2 rash in 8 to 21 days, you may want to look back at
3 that, read through it again, but -- so I think --
4 I think it's got good information on it, but I
5 think that's a supplement to what I'm talking with
6 them about at the visits.

7 Q Okay. And would you agree that informed
8 consent would require that you explain the
9 benefits and the risks prior to administering the
10 vaccines?

11 A I -- I think informed consent does mean
12 getting -- giving them some information. Again,
13 the amount of detail varies, but giving them some
14 information about what the benefits are and, yes,
15 what the risks are before -- before -- I do that
16 before I order the vaccines.

17 Q So if you determine before you ordered the
18 vaccines that the child might have a precaution or
19 a contraindication to a vaccine, wouldn't you have
20 that discussion with the parent before
21 administering the vaccine?

22 A I would certainly have a discussion about
23 contraindications for sure. And with precautions,
24 we usually talk in general terms about that. For

1 example, you know, in this case, I know there's a
2 question about the ear infection, and I -- I can
3 think of many occasions when I'm -- I -- you know,
4 first we go in the room, we take a history, we
5 find out what's going on with the patient. Then
6 we examine. And sometimes they'll say, he's had a
7 little cold or I'm not sure the ear infection from
8 last time cleared up, and I quite -- because I
9 like to order my vaccines, I order the vaccines
10 generally before I examine the child so that the
11 nurse can be ready getting -- you know, getting
12 the vaccines prepared for the child, and I'll look
13 at the parent and say, even if I find that his ear
14 is still infected, even if I find, you know,
15 something, because this is a mild infection, it's
16 still safe for him to get vaccines today, so yes,
17 we talk about those things in general terms.

18 Q But you'll tell the parent beforehand about
19 that?

20 A I don't say this is listed as a precaution in
21 the Red Book or this is -- you know, this is a
22 vaccine precaution. I don't use that specific
23 word, but I -- but I -- I let them understand
24 that, you know, if their child has a cold, it's

1 certainly appropriate and important to go ahead
2 and vaccinate them while they're there for that
3 visit, if they have an ear infection it is
4 appropriate to go ahead and order the vaccine, it
5 is safe for their child to get their vaccine even
6 if they have an ear infection.

7 Q Does that include instances where the child
8 was -- received a prescription for Amoxil?

9 A Yes, for sure.

10 Q Uh-huh. And -- and you would tell the parent
11 the child has an ear infection, but we're going to
12 proceed with vaccination anyway.

13 A Because --

14 Q Correct?

15 A Yes, because it's safe and it's important to
16 not delay protecting their child against
17 potentially very serious or even deadly diseases.

18 Q Have you ever been in the room with the nurse
19 when she's administered vaccines?

20 A A small number of times, yes. Generally not.
21 The nurses -- I'll say to the family, I'm leaving
22 now, and the nurse says Dr. Mace, you know,
23 doesn't want to be the bad guy, so I step out of
24 the room and generally move on to the next patient

1 while the nurse is doing her job.

2 Q And so in the few instances you've been in
3 the room, did the nurse provide the VIS to the
4 parents before or after vaccinating the child?

5 A I didn't pay any attention to that, except
6 that I'll say the nurse has to set the information
7 sheets down somewhere before she administers the
8 vaccines. She's not holding them, so I'm
9 imagining that she, you know, puts them on the
10 table, sometimes we, you know, hand people things
11 so they can stick it in their stroller or diaper
12 bag, and then she administers the vaccines.

13 Q So she puts it someplace the parents are, you
14 know, aware that this is for them; correct?

15 A I think, yes.

16 Q She doesn't shove it in some drawer
17 somewhere, I assume.

18 A No.

19 Q Right. She will set it someplace where they
20 will know this information is for them; correct?

21 A In general. But I'm -- I'm, again, always
22 surprised by the number of times there are
23 handouts that are left on the table or on a chair
24 in the room.

1 Q Well, just because a handout is left in the
2 room doesn't mean it wasn't provided prior to the
3 administration of vaccines; correct?

4 A That's correct.

5 Q Okay. So the nurse walks in the room, she
6 puts down the vaccine information statements
7 someplace where the parents are, you know, in --
8 with an intention that the parents are aware that
9 these are for them; correct?

10 A Yes.

11 Q Okay. And then the nurse will proceed to
12 inject the vaccines; correct?

13 A Yes.

14 Q Okay. And that -- and -- okay. Let's come
15 back to this topic because we -- we're, like,
16 halfway -- we'll talk about standard of care
17 later. We -- we've gotten on a tangent. Let's
18 keep going. So VRBPAC.

19 A I'm -- VRBPAC?

20 Q Yep.

21 A Can you spell that out for me?

22 Q Sure. V-R-B-P-H-C, Vaccines and Related
23 Biologics --

24 A I don't know what that is.

1 Q So VRBPAC, the -- they're ace -- there's a
2 committee within the CDC for recommending
3 vaccines, and there's also a committee within the
4 FDA for recommending licensure of vaccines;
5 correct?

6 MR. SANDERS: Object to the form of the
7 question. Go ahead, Doctor, if you have -- if you
8 know.

9 A Yeah, repeat the question.

10 Q (By Mr. Siri) No, no problem. I said,
11 within the CDC, there is a committee that exists
12 to decide on what vaccines should be recommended;
13 correct?

14 A If that is how you describe the ACIP, I would
15 think that -- yes.

16 Q Yeah, fair enough. I was saying, are you
17 aware that there's also a committee within the FDA
18 that votes on recommending which vaccines to
19 license?

20 A No. I don't know much about the inner
21 workings of the FDA.

22 Q Fair enough. Okay. IOM.

23 A Institute of Medicine.

24 Q Okay. And what is your understanding of the

1 Institute of Medicine?

2 A I think the Institute of Medicine is a highly
3 regarded organization of leaders within the field
4 of medicine who -- I -- I think they will consider
5 important topics and review topics and provide
6 guidance for healthcare professionals.

7 Q Okay. And the IOM issues a number of reports
8 regarding vaccinations; correct?

9 A I don't know that off the top of my head.

10 Q Okay. For the -- for reports that the IOM
11 would issue regarding vaccination, would you
12 consider those to be a generally reliable source
13 for information regarding vaccines?

14 A I would consider the Institute of Medicine
15 generally reliable with the understanding that I
16 would have to consider it in context of other
17 sources of information.

18 Q Sure. So generally you consider it a
19 reliable authority for information on vaccines?

20 MR. SANDERS: Object to the form of the
21 question. She just answered that.

22 MR. SIRI: Nope, it's different.

23 Q (By Mr. Siri) Please, Doctor.

24 A I view the Institute of Medicine as a

1 generally reliable source of information about
2 medical topics. It's not a place that I would
3 look to specifically for vaccination guidelines or
4 recommendations.

5 Q All right. Great, thank you. DSMB.

6 A Spell that again.

7 Q DSMB.

8 A DSMB? Okay.

9 Q Data safety monitoring board? I apologize.
10 DSMB is -- instead of just making up, you know,
11 David -- David -- data safety monitor -- data
12 safety monitoring board.

13 A So I'm aware of data safety monitoring
14 sheets. They're, you know, information sheets in
15 our office that are available in case we need the
16 information that's in the data safety monitoring
17 sheets. I'm not familiar with it beyond that.

18 Q Okay. Just to make sure that you didn't
19 mishear me, and I wasn't -- maybe I wasn't -- I
20 was saying DSMB, data safety monitoring board, not
21 sheet.

22 A Right. Right. So I --

23 Q Oh, you understood that. Okay. Then that's
24 fine.

1 A Yeah, so I'm not familiar with the data
2 safety monitoring board.

3 Q Okay.

4 A I --

5 Q No problem.

6 A I'm familiar with -- data safety monitoring
7 would be some information sheets that are kept in
8 a notebook in our office.

9 Q Okay. Have you heard of the National
10 Childhood Vaccine Injury Act of 1986?

11 A Yes, I have.

12 Q Okay. And that's the law that gave vaccine
13 manufacturers immunity from economic liability for
14 injuries caused by vaccines; correct?

15 A Say that again.

16 Q Sure. I'll say that's the law that provided
17 immunity for economic injury, liability if one of
18 their vaccine products injures somebody.

19 A I think that sounds like a reasonable
20 explanation of that, yes.

21 Q Okay.

22 A I mean, I -- I -- I'm not an expert, you
23 know, I haven't studied that act in detail to be
24 able to tell you exactly the description of what

1 it is.

2 Q Fair enough. During the deposition, I'll
3 refer to the National Childhood Vaccine Injury Act
4 of 1986 as the 1986 Act; okay?

5 A Okay.

6 Q All right. Okay. Can you please describe
7 your academic background?

8 A I graduated from Purdue University with a
9 degree in chemical engineering. I graduated from
10 Vanderbilt University School of Medicine with an
11 M.D. degree. I completed three years of residency
12 training in pediatrics. The first was in Memphis
13 at the University of Tennessee Center for Health
14 Sciences, and then the second and third years were
15 at Vanderbilt University Medical Center. I'm
16 board certified in general pediatrics. I've been
17 a member of the faculty at Vanderbilt University
18 Medical Center since 1989 starting as an
19 instructor, then assistant professor, and now
20 associate professor of clinical pediatrics. I was
21 director of the residency training program in
22 pediatrics from 1990 to 1996. I was co-director
23 of the combined internal medicine and pediatrics
24 residency program during that same time frame.

1 Q Okay. Did you have any other academic
2 appointments that involved vaccines or vaccination
3 that you didn't just describe?

4 A Any other academic appointments, no.

5 Q Okay. And you're certified with the American
6 Board of Pediatrics; correct?

7 A Correct.

8 Q And you've held that certification since
9 1989?

10 A That's correct.

11 Q Are there any professional organizations in
12 which you're involved that encourage or support
13 vaccination?

14 A Well, I'm a member of the American Academy of
15 Pediatrics, I'm a member of the Tennessee chapter
16 of the -- in addition to the AAP, the Tennessee
17 chapter of the American Academy of Pediatrics, and
18 then I'm a member at -- here in Nashville of the
19 Cumberland Pediatrics Foundation, which is an
20 organization of both community pediatricians and
21 academic specialty pediatricians, and that
22 organization provides continuing education
23 conferences for pediatricians that sometimes cover
24 the topic of immunizations.

1 Q Okay. Can you please describe the
2 professional activities in which you've been
3 engaged which relate or -- to vaccination?

4 A So I was -- as director of the resident
5 continuity clinic in the early '90s, I was
6 responsible for helping with the education of
7 residents in primary care, which would include
8 providing immunizations to children during that
9 time. I was also involved with the Nashville
10 Immunization Coalition at that time which was a
11 group of community members, as well as members
12 from the health department and Vanderbilt, to
13 promote better immunization coverage in the
14 community. I attended a conference in
15 Washington DC in the early to mid '90s where we
16 gave a presentation about building a coalition,
17 building a group to support immunizing children to
18 try to improve vaccine rates, particularly for
19 children under the age of two.

20 Q Uh-huh. Are there any committees in which
21 you've been a member that are involved in
22 supporting or encouraging vaccinations?

23 A Everything that -- everything that we do
24 is -- is -- you know, vaccinating is one of the

1 most important things, so I'm trying to think
2 about specific committees. I mean, I was a member
3 of the board of the Cumberland Pediatrics
4 Foundation. Committees, you know, I -- I'm really
5 thinking mostly about current committees. Most of
6 my time now is dedicated to patient care and
7 teaching medical students and sometimes residents
8 in the office, so from 1996 until present I've
9 been the founder and medical director of the
10 university pediatrics practice here at Vanderbilt,
11 and most of my time is not -- I can't think of a
12 committee that promotes vaccinations.

13 Q Okay. But the -- they -- they're supportive
14 of vaccinations. Would you agree with that?

15 A Sure. Everything I'm involved with is
16 supportive of childhood health --

17 Q Right, right.

18 A -- and therefore supportive of vaccinations.

19 Q I gotcha. Fair enough. And, you know, so
20 would you say that, you know, vaccinations and
21 providing vaccines and, you know, that information
22 regarding vaccines is a substantial portion of
23 your academic -- or professional career for the
24 last -- since 1989?

1 A Yes. I -- I -- providing vaccinations is one
2 of the most important things about my work.

3 Q Do you know what a speakers' bureau is?

4 A In general terms, yes.

5 Q Okay. What is it?

6 A A speakers' bureau, I would think, would be a
7 resource of people who are experts or have some --
8 have experience on a variety of topics and could
9 be provided to community groups perhaps that need
10 someone to come in and talk with them.

11 Q Okay. And speakers' bureaus are typically
12 funded by a specific pharmaceutical company;
13 correct?

14 A I don't know. I don't know about any
15 pharmaceutical-supported speakers' bureaus.

16 Q Oh, okay. Understood. You're talking about
17 a different form of speakers' bureau?

18 A Yes.

19 Q Yeah, okay. Are you familiar with
20 pharmaceutical-funded speakers' bureaus?

21 A No, I'm not.

22 Q Okay.

23 A I know that pharmaceutical companies will
24 provide information to groups and that they will

1 have physician experts who come and speak to those
2 groups, and I -- so I'm imagining a speakers'
3 bureau would be physicians or researchers who
4 engage in those types of educational activities.

5 Q Where the speaker is paid by the
6 pharmaceutical company to do that?

7 A Yes.

8 Q All right.

9 A That would be my understanding, yes.

10 Q I -- I'm assuming, and tell me if I'm wrong,
11 the conflict of interest policies at your -- where
12 you currently, you know, work and teach would
13 prohibit you from speaking, for example, at where
14 you work and teach if you were paid to do so by a
15 pharmaceutical company, if you were promoting
16 their product?

17 A They --

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

20 A There are very specific conflict of interest
21 guidelines that our academic institution has. We
22 sign a conflict of interest agreement every year.
23 Because I don't engage in that type of
24 professional education, I kind of skim through

1 those and -- and -- you know, but there are
2 definitely guidelines about that for my faculty
3 colleagues, for all of us. It doesn't really
4 apply to me.

5 Q (By Mr. Siri) So just a -- you're not a
6 consulted advisor, nor do you receive any personal
7 fees from any pharmaceutical company; correct?

8 A That's correct.

9 Q Why not?

10 A I like what I do. I take care of children
11 and I teach. I -- I love teaching medical
12 students about pediatrics, I love working with the
13 families and the staff members in our office and
14 find that a full job. I'm also not a researcher
15 who -- you know, I'm a general pediatrician, so
16 I'm not someone that probably would be sought out
17 necessarily by a pharmaceutical company, but if I
18 had been, I wouldn't be interested in that.

19 Q And why is that?

20 A My work and family life are full. I don't
21 need additional responsibilities.

22 Q Okay. Would you find that it might cause a
23 little bit of a conflict to, you know, speak at --
24 for pharmaceutical companies and at the same time

1 do the kind of work you do?

2 A Having never been in the position of making
3 that decision, I can't really say that it would be
4 a conflict. I think that anybody who makes a
5 decision to do that type of work is going to
6 consider very carefully whether it's a conflict
7 with their current work or not.

8 Q What's the name of the plaintiff in this
9 case?

10 A The plaintiff would be Yates Hazlehurst. I
11 don't know whether that would also include his
12 parents.

13 Q That's okay. And the name of the child at
14 issue in this case is -- you just said is Yates;
15 correct?

16 A Yes.

17 Q We went over that earlier. All right. Have
18 you ever physically examined Yates?

19 A No, I have not.

20 Q Have you ever met Yates?

21 A I have not.

22 Q Okay. Approximately how long would you
23 estimate you spent reviewing Yates' medical
24 records?

1 A I can give you an estimate. I -- I kept
2 notes. It was several -- it was several hours.
3 I --

4 Q Okay. That's fine. I don't need an exact
5 number.

6 A Okay.

7 Q Several hours is great. Now, is it your
8 opinion that they -- that the vaccines Yates
9 received played no role in his autism?

10 A Yes, that is my opinion.

11 Q Okay. Is it -- is it your opinion that none
12 of the vaccines that Yates received either
13 individually or collectively played no role in his
14 autism?

15 A Can you repeat --

16 MR. SANDERS: Object to the form of the
17 question. I think that was a double negative.

18 MR. SIRI: Yeah, it did. It did. I
19 didn't mean to do that. Let me do that again. It
20 doesn't have a double negative in how it's
21 written. Let me read it exactly as written.

22 Q (By Mr. Siri) Is your opinion that none of
23 the vaccines that Yates received either
24 individually or collectively -- I don't know how

1 to -- let me -- let me try that again. Let me
2 make -- let me make it simpler. Is it your
3 opinion that none of the vaccines that Yates
4 received played a role in his autism?

5 A Yes, it is -- that is my opinion.

6 Q Either -- and that includes for any
7 individual vaccine, correct, that he received?

8 A Correct.

9 Q As well as any combination of those vaccines
10 that he received; correct?

11 A Correct.

12 Q Okay. Now, without looking at any documents
13 that you have, okay, in your office, can you tell
14 me what vaccines did Yates receive?

15 A He received DTaP, he received HIB, he
16 received polio, hepatitis B, MMR, varicella. Did
17 I say pneumococcus already?

18 Q Nope.

19 A Pneumococcus.

20 Q Great. And without looking at any documents,
21 at approximately what age did Yates receive his
22 first set of vaccines?

23 A Two months.

24 Q Okay. And, again, without looking at

1 anything, at approximately what age did Yates
2 receive his last set of vaccines?

3 A It would be either 18 months or 24 months.

4 Q Okay. And finally without looking at any
5 documents, can you please describe any adverse
6 events that you are aware of that occurred after
7 Yates received any of his vaccines?

8 A Adverse events related to the vaccinations
9 specifically?

10 Q Well, adverse events following vaccinations,
11 yes.

12 A From the deposition of Rolf and Angela
13 Hazlehurst, they described some period of crying
14 following his six-month vaccination.

15 Q Uh-huh. Anything else?

16 A And after his 12-month MMR vaccine,
17 approximately two weeks later he developed a rash.

18 Q Anything else that you recall?

19 A That's all that I think of as adverse events
20 related within a time period of having been
21 vaccinated.

22 Q All right. Those are the only adverse events
23 that occurred that you can recall that occurred,
24 let's say, so we're on the same page, within two

1 weeks of any of the vaccines that he received?

2 A In terms of the timing that was reported,
3 yes.

4 Q Okay. Do you know Dr. Kathryn Edwards?

5 A I do.

6 Q Okay. How do you know her?

7 A She was a member of the faculty at Vanderbilt
8 School of Medicine from the time I was a medical
9 student through residency training and is a -- is
10 currently a faculty colleague.

11 Q Okay. So how long ago would that -- so when
12 did you first meet Dr. Edwards, how long ago would
13 that have been?

14 A 1984 or '85.

15 Q Okay. So when you first met her, what was
16 your respective roles vis-à-vis each other?

17 A I was a medical student, and she probably
18 doesn't remember but I asked her for advice as I
19 was considering a career in pediatrics. I
20 remember going into her office and asking her sort
21 of via faculty advisor in an informal way, so she
22 and I talked about residency training and programs
23 to apply to, that sort of thing.

24 Q What did she -- what advice did she give you?

1 A She gave me great advice, to definitely go
2 into pediatrics.

3 Q Okay. And so she was your -- you were a
4 medical student and she was one of your
5 professors?

6 A Correct.

7 Q Okay. And then as you continued through your
8 career, has it typically been that she has been in
9 a -- you know, a role where -- a role where she
10 was, you know, somebody who was either your
11 supervisor or mentor?

12 A Not supervisor. During my residency training
13 period she would have been a supervisor, so for
14 the -- as a student, and then two years of
15 residency were done at Vanderbilt.

16 Q Okay.

17 A And then --

18 Q Oh, please.

19 A Yeah, after that, we were faculty colleagues,
20 although certainly she was, you know, much more
21 advanced. She -- she's someone who is a very
22 respected -- an incredibly respected infectious
23 disease expert at Vanderbilt.

24 Q Okay. Is she also an incredibly respected

1 expert in vaccinology?

2 A I would say yes. When we -- when we want to
3 know about a new vaccine or changes, you know,
4 there's a change in the vaccine schedule, we have
5 a question about things, she would absolutely be a
6 colleague that we would turn to and be very happy
7 to receive information from her about her thoughts
8 about something.

9 Q Would she be, like, the main go-to expert at
10 Vanderbilt on, you know, any, like, difficult
11 vaccine question?

12 A One of a number. Vanderbilt has a really
13 strong pediatric infectious disease division, and
14 we have a number of colleagues that we can turn to
15 for that, but certainly she is, you know, one of
16 the -- the very most respected.

17 Q Have you ever considered her a mentor?

18 A In an informal way I would say yes. As a --
19 as a pediatrician, she -- and also as a -- a
20 professional mom, she, you know, has a family and
21 we've had brief conversations about raising
22 children.

23 Q It's tough on dads too, I promise.

24 A I'm sorry?

1 Q It's tough on dads too, I promise.

2 A Okay.

3 Q So have you -- my wife is an attorney as
4 well. Have you -- so, you know, so you were a
5 medical student, and I assume, you know, she'd be
6 somebody who you learned -- she's one of the
7 people who educated you about vaccines. Is that
8 correct?

9 A I would think, yes.

10 Q Okay.

11 A You know, I don't ever recall a specific
12 lecture or setting, but certainly she's provided
13 continuing education. Even in my -- in my role as
14 a faculty member, I try to attend continuing
15 education conferences and lectures and she's been
16 involved in that for sure.

17 Q And what are the lectures that she typically
18 gives? What are the -- what's the topic of those
19 lectures?

20 A I -- you know, I can't give you a -- I --
21 I've attended lectures on -- let me think. When
22 she -- there -- there may have been a Cumberland
23 Pediatrics -- Cumberland Pediatrics Foundation
24 meeting a year or so ago about there was a measles

1 outbreak and concern -- concern about measles in
2 the U.S., and she may have been a speaker at that
3 particular CPF evening event.

4 Q Have you attended any of her lectures
5 regarding vaccine safety?

6 A I can't recall a specific time that I
7 attended a lecture on vaccine safety, but any
8 lecture that talks about vaccines in general is --
9 I would think would certainly include discussion
10 about safety.

11 Q Okay. And have you been to many of her
12 lectures regarding -- that involved vaccines?

13 A Again, I -- I attend lectures in a variety of
14 different settings, and I can't tell you numbers
15 or dates, but in general, if I saw her on the
16 schedule and I was able to go, she would be
17 somebody that I would be interested in hearing.

18 Q Okay. In your estimation, how often does she
19 lecture at Vanderbilt with regards to vaccines?

20 A In a formal way, I -- I would think a couple
21 times a year.

22 Q Okay.

23 A I -- I don't -- I don't know the -- I
24 certainly don't know the details of her schedule.

1 Q Understood. Would it be fair to say that
2 Dr. Edwards has helped train, you know, a number
3 of generations of pediatricians that have come
4 through Vanderbilt with regards to vaccines?

5 A Yes.

6 Q Okay. And that would include vaccine safety;
7 correct?

8 A Yes.

9 Q And part of her influence is her extensive
10 experience in the area of vaccines; correct?

11 A Yes.

12 Q Are you aware, for example, that she receives
13 funding from federal health agencies relating to
14 some of her vaccine work?

15 A I'm not aware of the details, but certainly
16 research needs to be funded and research is funded
17 I'm -- I know from both federal grants as well as
18 by pharmaceutical companies.

19 Q And were you aware that she was a member of a
20 federal committee related to vaccines?

21 A I'm not aware of any of those sorts of
22 details.

23 Q Uh-huh. Are you familiar with CIS -- CISA?

24 A C-E-S-A?

1 Q C-I-S-A, Clinical Immunization Safety
2 Assessment Network.

3 A No.

4 Q Okay. Are you familiar with the medical
5 textbook Plotkin's Vaccines?

6 A I have some -- vague, but I don't have a copy
7 of it. I don't know that I've ever consulted it.

8 Q What would you consider the -- you know,
9 the -- the authority -- if you have an opinion on
10 this, you know, if -- if -- what would you
11 consider to be authoritative, a medical textbook
12 with regards to vaccines?

13 MR. SANDERS: I'm going to object to the
14 form of the question. You can answer, Doctor, if
15 you have an answer.

16 A Well, I look at -- I mean, I use the Red Book
17 as -- as my resource, but I think you're asking a
18 different question.

19 Q (By Mr. Siri) Yeah, that's okay. You're
20 talking about practice. I just meant about, you
21 know, medical knowledge. That's okay. Let's --
22 we can move on. But I presume, is it your
23 understanding that Dr. Edwards has published
24 hundreds of articles relating to vaccines?

1 A I would imagine, yes, but I don't have -- you
2 know, I don't -- I've not reviewed her CV.

3 Q Would it be fair to say that she has a
4 substantial influence in the field of vaccinology?

5 A Yes.

6 Q Okay. To your knowledge, has Dr. Edwards
7 been an advisor to Merck?

8 A I don't know.

9 Q To your knowledge, has Dr. Edwards received
10 payments or personal fees from Merck?

11 A I don't know.

12 Q To your knowledge, has Dr. Edwards been a
13 consultant to Merck?

14 A I don't know.

15 Q To your knowledge, has Dr. Edwards received
16 research funding from Merck?

17 A I don't know.

18 Q To your knowledge, has Dr. Edwards been on
19 the speakers' bureau of any pharmaceutical company
20 that sells vaccines?

21 A I don't know.

22 Q To your knowledge, has Dr. Edwards been a
23 consultant for Sanofi?

24 A I don't know.

1 Q To your knowledge, has Dr. Edwards been a
2 consultant for Connaught?

3 A I don't know.

4 Q To your knowledge, has Dr. Edwards ever
5 received payment from Sanofi for giving lectures?

6 A I don't know.

7 Q To your knowledge, has Dr. Edwards ever
8 received research funding from Sanofi?

9 A It's possible that there was a live
10 intranasal flu vaccine study looking -- comparing
11 the live attenuated influenza vaccine to the
12 standard killed virus vaccine, and I'm not certain
13 at all, but you told me to tell you what I -- to
14 do my best, and I think that --

15 Q That's correct.

16 A -- Sanofi may have had -- played a role in
17 the funding for that particular study.

18 Q All right. Thank you. To your knowledge,
19 has Dr. Edwards traveled to numerous foreign
20 destinations that were paid for by Sanofi?

21 A I have no knowledge of that.

22 Q To your knowledge, has Dr. Edwards received
23 personal fees from Sanofi?

24 A I have no knowledge of that.

1 Q To your knowledge, has Dr. Edwards been a
2 consultant for SmithKline Beecham?

3 A I don't know.

4 Q To your knowledge, was Dr. Edwards a
5 consultant for GSK?

6 A I don't know.

7 Q When I say GSK, do you know what that means?

8 A GlaxoSmithKline Beecham or just
9 GlaxoSmithKline.

10 Q Perfect. To your knowledge, was Dr. Edwards
11 receiving payments from GSK for giving lectures?

12 A I don't know.

13 Q To your knowledge, was -- has Dr. Edwards
14 been a member of the speakers' bureau for GSK?

15 A I don't know.

16 Q To your knowledge, has Dr. Edwards been on an
17 advisory board within GSK?

18 A I don't know.

19 Q To your knowledge, has Dr. Edwards received
20 research funding from GSK?

21 A I don't know.

22 Q To your knowledge, has Dr. Edwards been a
23 member of the speakers' bureau for Wyeth Lederle?

24 A I don't know.

1 Q To your knowledge, was Dr. Edwards a
2 consultant for Wyeth Lederle?

3 A I don't know.

4 Q To your knowledge, was Dr. Edwards an advisor
5 to Pfizer?

6 A I don't know.

7 Q Were you aware that Dr. Edwards was on the
8 speakers' bureau of Connaught and Lederle at the
9 same time that she was on the FDA's advisory
10 committee that voted in favor of licensing one or
11 more of their products?

12 A No, I was not.

13 Q If that were true, what would you think about
14 that?

15 A Well, I think that when we have advisory
16 committees, the good thing is that they are
17 committees, and, you know, that it considers many
18 people's opinions, and I think that most of the
19 time physicians are -- and researchers are
20 required to disclose any conflict of interest that
21 they have, so I think Dr. Edwards is a very
22 reliable physician and I would trust her to
23 disclose her potential conflict of interest to the
24 group and that that would be taken into

1 consideration with decisions that are made.

2 Q And what would you say if those conflicts
3 were not disclosed when she was sitting on that
4 FDA committee and voted?

5 A Well, I don't know what the procedures are in
6 those types of committees when that type of
7 information is asked for and -- and released, but
8 in general, in medical literature and -- and in
9 giving lectures and other things, people are
10 always asked to reveal conflict -- potential
11 conflicts of interest.

12 Q It's a very important thing to do; correct?

13 A Yes, that's important.

14 Q Were you aware that Dr. Edwards was a
15 consultant for SmithKline Beecham while she was a
16 member of the FDA's federal advisory committee
17 regarding vaccines?

18 A No, I was not.

19 Q Were you aware that Dr. Edwards was a
20 consultant for SmithKline Beecham while she was a
21 member of the FDA's federal advisory committee on
22 vaccines?

23 A No.

24 Q Were you aware that Dr. Edwards was

1 conducting a clinical trial for Wyeth Lederle
2 while she was a member of the FDA's advisory
3 committee on vaccines?

4 A No.

5 Q Okay. Are you familiar with the New England
6 Journal of Medicine?

7 A Yes.

8 Q Okay. Is it considered one of the world's
9 leading and most prestigious medical journals?

10 A It is.

11 Q Okay. Have you ever heard of a Dr. Marcia
12 Angell?

13 A No.

14 Q Okay. You're not aware that she was the
15 first woman to serve as the editor in chief of the
16 New England Journal of Medicine?

17 A No.

18 Q Okay. Does that refresh your recollection at
19 all? No? That's okay. I -- you know, being the
20 editor in chief of the New England Medical Journal
21 I presume you would consider to be a prestigious
22 and important position with regards to the --
23 the -- the medical -- strike that. Are you --
24 I -- I assume you're not aware that Dr. Marcia

1 Angell is now a professor at Harvard Medical
2 School; correct?

3 A I am not. Can you spell her last name?

4 Q Sure. It's A-n-g-e-l-l. I'm going to read
5 you a quote from Dr. Angell and then I'm going to
6 ask you a question; okay?

7 A Okay.

8 Q Conflicts of interest and biases exist in
9 virtually every field of medicine, particularly
10 those that rely heavily on drugs or devices. It
11 is no longer possible to believe much of the
12 clinical research that is published or to rely on
13 the judgment of trusted physicians or
14 authoritative medical guidelines. I take no
15 pleasure in this conclusion, which I reached
16 slowly and reluctantly over my two decades as the
17 editor in chief of the New England Journal of
18 Medicine. Have you ever heard that quote before?

19 A I have not.

20 Q Have you ever read that before?

21 A I have not.

22 Q All right. I'm going to read you one more
23 quote and then ask you a question, this one also
24 from Dr. Angell. Okay. And this is what she

1 blames is -- for the eradication of truth in
2 medical publishing. She said or -- you know,
3 individuals that use legitimacy that led me to
4 push basically pharmaceutical company's agenda,
5 and she says, quote, they serve as consultants to
6 the same companies whose products they evaluate,
7 they join corporate advisory boards and speakers'
8 bureaus, enter into patent and royalty
9 arrangements, agree to be the listed authors of
10 articles ghostwritten by interested companies,
11 promote drugs and devices at company-sponsored
12 symposia, and allow themselves to be plied with
13 expensive gifts and trips to luxurious settings.
14 Have you ever heard that quote before?

15 A I have not.

16 Q Have you ever read that quote any place?

17 A I have not.

18 Q Okay. Do you have any reason to disagree
19 with what Dr. Marcia Angell has written and what I
20 have read to you?

21 A I think that her statements are general terms
22 and are important statements, but need to be -- I
23 don't think that that's something that makes all
24 medical research, particularly in the area of

1 vaccinations, invalid. I think vaccines are
2 incredibly important and children need to be
3 protected, so -- so --

4 Q Right. Children should certainly be
5 protected; correct?

6 A Children should be protected from these
7 deadly and, you know, very harmful diseases, yes.

8 Q Uh-huh. And -- and doctor -- absolutely,
9 Dr. Marcia Angell is not saying that all medical
10 literature is not to be trusted; correct?

11 A Yes, I --

12 Q All right. She's --

13 A That --

14 Q She's saying -- oh, please.

15 A She's bringing up a problem, it's an
16 important problem. It doesn't mean that
17 everything that's published is invalid by any
18 means.

19 Q I -- I -- yes. I think what she's saying
20 is -- she's saying that when literature is
21 published and it's done by, you know, individuals
22 who have these kinds of serious conflicts that
23 she's written, she says, you know, it can create a
24 very serious problem with regards to the

1 reliability of the studies that are published by
2 those individuals; correct?

3 A Yes. She's saying it creates a potential
4 problem, yes.

5 Q Okay. And she -- and, you know, this is from
6 somebody who was the editor in chief of the New
7 England Medical Journal for 20 years. Would
8 that -- would that give her opinion about the
9 reliability of medical literature published by
10 such individuals more weight in your eyes?

11 A It's a very important statement. I don't
12 think that it can necessarily be applied just in
13 general terms to -- to all published studies and
14 all individuals.

15 Q Are you aware of the number of doctors that
16 have written books which present evidence for why
17 the risks of vaccination outweigh the benefits for
18 some or all people?

19 A I'm aware that there -- there are
20 publications that -- read the statement again.

21 Q Sure. Are you aware that there are a
22 number -- that there are numerous doctors that
23 have written books which present evidence for why
24 the risks of vaccination outweigh the benefits for

1 some or all people?

2 A So I would say no. I'm -- I'm not aware of
3 books that present evidence that would meet the
4 standards of -- of -- of -- that we expect of
5 research studies that we rely upon to make our
6 decisions about vaccines. I think there's a lot
7 of anecdotal information out there about the risks
8 of vaccinations that -- in -- in some cases is
9 incorrect and not backed by evidence.

10 Q Have you ever read the book by Dr. Richard
11 Moskowitz, M.D., entitled Vaccines: And Re --
12 A Reappraisal, who's been practicing medicine for
13 50 years, and wrote, quote, I cannot keep silent
14 about the major epidemic of vaccine-related
15 suffering and disability, sufficient to break any
16 heart, that continues unabated, remains -- and
17 remains largely unacknowledged, end quote?

18 A I have not read that book.

19 Q Okay. Have you read the book, for example,
20 by Dr. Thomas Cowan, M.D., called Vaccine
21 Autoimmunity and the Changing Nature of Childhood
22 Illness?

23 A I have not read that book.

24 Q Okay. Are you certain that the evidence

1 provided in those books are just, as you've
2 characterized, anecdotal?

3 A Having --

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

6 A Having not read those books, I can't make any
7 statement, and I certainly don't have any
8 certainty about what they say.

9 Q (By Mr. Siri) Fair enough. Febrile seizures
10 sometimes will happen in temporal relation to
11 receiving an MMR vaccine; correct?

12 A Any cause of fever in a child who's prone to
13 febrile seizures, so any -- any -- anything that
14 causes fever, including an infection or a vaccine,
15 could possibly cause a febrile seizure in a child.

16 Q And what temperature, you know, would --
17 whether -- for any cause, right, from an MMR
18 vaccine or from an infection or from any other
19 cause, okay, what level -- let me -- yeah, I
20 apologize. Let me -- I want to get the question
21 on the record. What temperature, you know, in a
22 child could cause febrile seizure?

23 A There's not a temperature threshold. It has
24 to do with the -- the rate of the rise of the

1 temperature, so if -- a child who develops a
2 sudden onset fever who is prone to febrile
3 seizures may have a seizure at 102, for example.
4 They could rise slowly to 104 and not experience a
5 seizure, so it's -- it has to do with the rate of
6 rise of the temperature, from what I understand,
7 not that -- how high it goes.

8 Q Understood. And so if it quickly rose to
9 101, the child could have a febrile seizure?

10 A I would think possibly so.

11 Q Yeah. Okay. Now, I assume you're familiar
12 with the MMR vaccine; correct?

13 A Yes.

14 Q Okay. Now, have you ever ordered the
15 administration of the MMR vaccine?

16 A Yes.

17 Q Okay. Some of my questions will be
18 simplistic, but I -- it's about laying a
19 foundation. There's all these funny videos on
20 YouTube you can maybe see where they -- the lawyer
21 is asking silly questions. You can make a montage
22 out of those for me too sometimes. All right.
23 How many times approximately have you administered
24 the MMR vaccine? Or let me rephrase that. I

1 apologize. How many times approximately have you
2 ordered the administration of the MMR vaccine?

3 A Certainly hundreds. Possibly -- possibly in
4 the thousands. Just thinking about the number of
5 patients for whom I've provided primary care
6 over -- over my 30-year career as a pediatrician.

7 Q Uh-huh. And so you've ordered hundreds and
8 potentially thousands of MMR -- the administration
9 of MM -- strike that. So over the last 30 years,
10 you've ordered hundreds and potentially thousands
11 of administrations of MMR vaccine during that
12 period?

13 A Yes.

14 Q I think you said that the first time. Okay.
15 And -- and have doctors who you've been
16 supervising also ordered the administration of MMR
17 vaccines?

18 A In that time period when I was supervising
19 doctors up until 1996, yes. Since 1996, I have
20 been doing patient care directly, so not generally
21 supervising resident doctors.

22 Q Okay. So how many doses of MMR vaccine would
23 you say were administered under your supervision?

24 A Certainly thousands.

1 Q Okay. So in total, between MMR vaccines that
2 you ordered to be administered directly or that
3 were ordered by other doctors who you've
4 supervised, it's been thousands of administrations
5 of the MMR vaccine; correct?

6 A Yes.

7 Q Okay. Have you ever administered the MMR
8 vaccine yourself?

9 A I've not administered an MMR.

10 Q You're familiar with the varicella chicken
11 pox vaccine Varivax; correct?

12 A Yes.

13 Q Okay. And have you ever ordered the
14 administration of the Varivax vaccine?

15 A Yes.

16 Q Okay. How many times approximately have you
17 ordered the administration of this vaccine?

18 A Thousands.

19 Q Okay. And over what period of time did that
20 occur?

21 A Over -- let's see. Twenty-five years in my
22 own practice at Vanderbilt and then six years --
23 yeah, so 24 and six as a supervising physician, so
24 30 years.

1 Q And how many doses of Varivax have been
2 administered by other doctors who were under your
3 supervision?

4 A Ordered by other doctors, I included all of
5 that in the thousands.

6 Q Understood. So and are you familiar with the
7 hepatitis B vaccine Engerix-B?

8 A Yes.

9 Q Are you familiar with the polio vaccine IPOL?

10 A Yes.

11 Q Are you familiar with the pneumococcal
12 vaccine Prevnar?

13 A Yes.

14 Q Are you familiar with the DTaP vaccine
15 Infanrix?

16 A Yes.

17 Q And are you familiar with the HIB vaccine
18 HibTITER?

19 A Yes.

20 Q Is it also true that you either ordered
21 directly or -- or supervised doctors -- other
22 doctors who've ordered the administration of a few
23 thousand doses of each one of these vaccines over
24 the course of your career?

1 A Yes, that's correct.

2 Q Okay. Vaccines come in packages; correct?

3 A Yes.

4 Q Okay. In fact, each one of those packages
5 will have a package insert; correct?

6 A Yes.

7 Q The package insert provides information with
8 regards to the vaccine; correct?

9 A Yes.

10 Q Including providing information regarding its
11 clinical trial experience; correct?

12 A Yes.

13 Q Okay. Now, the FDA decides whether to
14 license a vaccine based on a review of the pivotal
15 clinical trial conducted for the vaccine; correct?

16 A Yes, I believe that's correct.

17 Q Okay. And the clinical trial will compare a
18 group receiving the vaccine with a group not
19 receiving the vaccine; correct?

20 A Generally speaking, yes.

21 Q But not always?

22 A Well, I -- I don't go back to all of the
23 original studies and read all of them, but I would
24 think that -- I mean, vaccines go through many,

1 many different layers of both effectiveness and
2 safety trials, so at some -- some -- and figuring
3 out what doses to use, so I'm sure some component
4 of it compares --

5 Q Right.

6 A -- vaccinated to not vaccinated individuals.

7 Q Right. But the trials that are relied upon
8 to license vaccines are the larger Phase 3 trials
9 often referred to as the pivotal clinical trials;
10 correct?

11 A That sounds correct.

12 Q Okay. Not your area?

13 A Not my area, right.

14 Q Fair enough. But, you know, I assume your
15 general understanding is that a clinical trial
16 would have an experimental group, which is the
17 group that are seeking the experimental vaccine;
18 correct?

19 A Yes.

20 Q And then there's a group that receives --
21 there's a control group that will receive whatever
22 the control is, assuming there is a control group;
23 correct?

24 A Correct.

1 Q And what does placebo control mean?

2 A Placebo control means that a patient is
3 administered something that does not contain
4 material being tested so that we can compare
5 whether -- for example, with a vaccine, it might
6 be an injection that doesn't contain the vaccine
7 so that we can determine if there are any side
8 effects that are due to just receiving the
9 vaccine -- receiving an injection itself, did the
10 needle or the -- the liquid that it's contained in
11 cause any type of problem.

12 Q So and for that reason, a placebo is an inert
13 substance, like a saline injection; correct?

14 A In most cases, yes.

15 Q Okay. I mean, the definition of the -- of a
16 placebo by the CDC and FDA means a substance that
17 has no effect on the human body; correct? Or, you
18 know --

19 A I -- yeah, I haven't looked at how they
20 define it. We certainly do know that in some
21 things placebos can have effects as well.

22 Q Ahh. The placebo effect, true. The
23 psycho -- which is viewed as the psychological
24 effect; right? But the -- but in terms of the

1 physical -- like, what a placebo is, it's -- it is
2 by definition an inert substance.

3 A We're choosing something that you hope has no
4 effect at all, so --

5 Q Right.

6 A -- the effect of your vaccine or medication
7 to the effect of --

8 Q Right. The hope is that the saline injection
9 has no effect.

10 A Right.

11 Q Okay. Or sugar pill. Hopefully not too much
12 sugar; right?

13 A Right.

14 Q Okay. Now, what does properly powered mean
15 in relation to a clinical trial?

16 A Properly powered is -- would be a statistical
17 phrase that talks about enrolling enough patients
18 to make sure that the effects that are seen in
19 that trial are -- I'm trying to think of the right
20 term. That they're relied upon.

21 Q Okay. All right. It means that there's
22 enough people in the trial to assess whether what
23 you're seeing is by chance or actually
24 statistically significant?

1 A Statistically significant, that's what I was
2 looking for.

3 Q Okay.

4 A Yes.

5 Q Right. But -- but, you know, having an
6 appropriate control and being properly powered
7 isn't enough. You also need to have review safety
8 for sufficient duration during a trial; correct?

9 A That makes sense, yes.

10 Q Okay. And so, like, for example, if you
11 wanted to determine whether a product causes
12 asthma, which is typically diagnosed at five years
13 of age, the clinic trial would typically need to
14 track children until at least around that age;
15 correct?

16 A If you're giving me an example of something
17 that's diagnosed at age five and we're trying to
18 determine if something prevents it, then yes, you
19 would need to follow until at least age five.

20 Q All right. So if you were going to try -- if
21 you were going to conduct a clinical trial to try
22 to determine whether a vaccine, for example, does
23 or doesn't cause autism, you would need any
24 vaccinated children, let's say, up to 18 months,

1 you would need to track those children, assuming
2 there were enough of them and assuming it was
3 properly controlled, you'd need to track them for
4 long enough so that the kids will get to an age
5 where they're likely to get an autism diagnosis;
6 correct?

7 A That makes sense, yes.

8 Q Okay. Are you aware that in 2000, children
9 were typically diagnosed with autism at around
10 four years of age?

11 A I would agree that the autism diagnosis in
12 2000 was later than it currently is. I don't know
13 at what age it was typically made.

14 Q Okay. And what currently is the typical age
15 of diagnosis for autism?

16 A We screen children at 18 months and at two
17 years for autism symptoms. Some of my patients
18 who have autism are -- are identified well before
19 12 months of age, and some of my patients with
20 autism have much more subtle features and
21 sometimes we don't make a diagnosis until they're
22 high school age, so it's a -- it's a very broad
23 range.

24 Q So how much later was the diagnosis

1 approximately made on average in 2000 and that --
2 you know, as compared to now?

3 A I don't have any data on that. We -- I don't
4 think in 2000 we were doing the routine screening
5 questionnaires, the screening questionnaires that
6 we do now at 18 months and two years. And I'll
7 say even with those, sometimes we -- there are
8 children with very mild autism that are not -- you
9 know, that pass those screening questionnaires,
10 but I think, you know, it -- it can be a very,
11 very obvious diagnosis and it can also be a very
12 subtle diagnosis.

13 THE COURT REPORTER: This is the court
14 reporter. Can you guys hear me?

15 MR. SANDERS: Yes.

16 MR. SIRI: I can.

17 THE COURT REPORTER: Okay. It says that
18 the host has turned off my video, and I can't turn
19 it back on, and I just wanted to make sure that
20 you guys knew I'm still here. I just -- can
21 you -- you can't see me, can you?

22 MR. SANDERS: No. I just see your name.

23 THE COURT REPORTER: Okay. Okay. Now
24 it says the host has asked to start my video.

1 Okay. Sorry. I was here the whole time and I
2 heard everything, but I just wanted to let you
3 know.

4 MR. SIRI: Welcome back. Welcome back
5 in person.

6 THE COURT REPORTER: It just made me
7 nervous thinking you guys think I might've just
8 disappeared.

9 MR. SIRI: All right. Can you --
10 Mr. Lawson, can you kindly activate my screen
11 sharing?

12 Q (By Mr. Siri) Okay. Dr. Mace, I'm going to
13 mark this article as Plaintiff's Exhibit 1.

14 (Whereupon, Exhibit No. 1
15 was marked to the
16 testimony of the
17 witness.)

18 Q (By Mr. Siri) Dr. Mace, are you familiar
19 with this article? Have you ever seen it?

20 A I have not read this specific article.

21 Q Okay. Well, it's been marked and you'll have
22 an opportunity to review it before trial. I'll
23 just direct you to the bottom of Page 3 where
24 there's a chart of the -- entitled displays the

1 changing age of first autism diagnosis for the
2 1992 to 2001 birth cohorts, and you can see for
3 the year 2000 what it provided the average age was
4 with a 95 percent confidence interval, you know,
5 banded up and -- up and down right there, so, you
6 know, a little below and before 3.6 years of age.
7 Okay. Okay. So let me ask you, if you were going
8 to design a clinical trial of a vaccine given to
9 children at 18 months or younger, how long would
10 you say the clinical trial needs to be to
11 determine whether a vaccine caused autism?

12 A I'm sorry. There was a noise that -- that --

13 Q No -- no problem. If you were going to
14 design a clinical trial, a vaccine in the year
15 2000 given to a child 18 months or younger, how
16 long would the clinical trial need to be to
17 determine whether the vaccine caused autism?

18 A A specific clinical trial that is a
19 prospective study it would seem would need to last
20 until we, you know, reach at least the median age
21 of the autism diagnosis and I would think a little
22 while past that.

23 Q Okay. And how many children would you
24 estimate are needed to be in a clinical trial to

1 detect whether a vaccine causes the autism?

2 A I can't answer that. I don't know.

3 Q Okay. Probably a statistician is a lot
4 smarter than us and can figure that out; right?

5 Okay. And based -- now, based on the duration of
6 the trials, the control use and the size of
7 trials, is it accurate to state that the clinical
8 trials relied upon to license the vaccines given
9 to Yates were not designed to determine whether
10 these products caused autism when given to an
11 infant or toddler at or below the age of 18
12 months?

13 A I can't comment on the trials that were used
14 to license the MMR vaccine because I haven't
15 studied those.

16 Q Okay. What about the rest of the vaccines
17 that Yates received?

18 A I haven't studied -- I -- you know, as we
19 talked about earlier with the package insert, I
20 don't go back to the original research studies and
21 look at those. I rely on -- on -- on the FDA's
22 approval of -- and licensing of drugs and the AAP
23 and ACIP vaccine schedules. I have those package
24 inserts available so that I can consult with them

1 if I have a question, but I have not reviewed the
2 original research that led to the approval of the
3 vaccines.

4 Q Okay. But you've read the package inserts?

5 A I've looked at -- I look at the package
6 inserts when I have a specific question that I
7 want to have answered, yes.

8 Q What -- you know, what is your understanding
9 of the typical duration that safety is reviewed
10 after injection in clinical trials typically
11 relied upon to license most vaccines?

12 A I'm not an expert on vaccine licensure, so I
13 can't comment on that.

14 Q Okay. Are you aware of whether any of the
15 clinical trials relied upon to license the vaccine
16 Yates received included a placebo control group?

17 A I'm not aware one way or the other.

18 Q Okay. Now, if they didn't include a placebo
19 control or a vaccine control that was itself
20 determined not to cause autism, that alone would
21 make it impossible for the clinical trial to have
22 determined whether or not the product caused
23 autism; correct?

24 MR. SANDERS: Object to the form of the

1 question. You can answer it, Dr. Mace, if you
2 have an answer.

3 A Well, I think there are lots of -- that's --
4 I mean, there are lots of different types of ways
5 of looking at the question about whether or not
6 vaccines cause autism, you know, retrospective
7 studies, large cohort studies. Again, I'm not an
8 expert on statistics, but --

9 Q (By Mr. Siri) Uh-huh.

10 A -- I -- you can't -- can't specifically
11 answer that question.

12 Q All right. Let me just add in there that you
13 just -- you know, you basically rely on what the
14 CDC, the FDA, and the AAP, you know, say is safe
15 and reliable.

16 A In general we do. I mean, we look to those
17 organizations because they include a panel of
18 experts. I like things that are recommended by
19 consensus, by committees, because they often have
20 experts who understand the details of the
21 statistics and the way clinical trials are
22 conducted, and I'm -- I come to my conclusions
23 based on those recommendations. I put some trust
24 in those organizations to study those details

1 and -- and especially when a vaccine is licensed
2 that it's been looked at carefully.

3 Q To give you -- you know, and so you -- you
4 give trust to the, you know, their -- their
5 conclusions and their recommendations regarding
6 the vaccines that you administer; correct?

7 A I -- I look at a lot of sources and rely upon
8 those committees and consensus groups to give me
9 advice on the issue of safety, yes.

10 Q So other than the AAP, the FDA, and the CDC,
11 is there any other source you look at?

12 A I look at a resource online currently that's
13 called UpToDate, and UpToDate is a peer-reviewed
14 web-based resource that covers topics, a wide
15 range of topics, and often they -- they -- in
16 their peer review, they include references that I
17 can also, you know, click on the references and
18 dig in a little bit more deeply, but I use
19 UpToDate as a resource for a lot of health
20 information for making decisions about patient
21 care.

22 Q I understand. So to just wrap up this
23 discussion, and it's totally fine if you don't
24 know, but what you're saying is you don't know

1 enough about the clinical trials relied upon to
2 license the vaccines that Yates received to say
3 whether or not they were designed in a manner that
4 would have permitted them to determine one way or
5 another whether those products caused or didn't
6 cause autism; correct?

7 A Read that -- say that --

8 Q No -- no problem. Is it your testimony that
9 you're not -- you don't have enough -- you
10 don't -- strike that. Is it your testimony that
11 you are -- strike that. Is it your testimony that
12 you don't know enough about the clinical trials
13 relied upon to license the vaccines that Yates
14 received to be able to say whether they were
15 designed in a manner that would have permitted
16 them to determine one way or another whether those
17 vaccines did or did not cause autism?

18 A I personally don't have enough knowledge or
19 expertise in statistics to --

20 Q Okay.

21 A Yes.

22 Q By the way, in a context of a clinical trial,
23 what is your understanding of the term safety
24 review period?

1 A I'm -- I can tell you just from a common
2 sense standpoint that -- what safety review period
3 would mean, but I don't have any specific
4 technical knowledge of that terminology.

5 Q And so in common sense parlance, what would
6 it mean to you?

7 A It means that we need to allow some time to
8 make sure that -- that a treatment is safe and
9 that there aren't unexpected consequences, adverse
10 consequences of a treatment. The period means a
11 period of time.

12 Q A period of time in which safety is reviewed.
13 Would that be fair?

14 A Yeah.

15 Q Okay. Now, the package inserts for each of
16 the vaccines that are provided with -- strike
17 that. With each of the, you know, pack -- you
18 know, packets of vaccines that -- that are
19 distributed by manufacturers, we discussed earlier
20 there -- they each include a package insert;
21 correct?

22 A Yes.

23 Q Okay. And the package inserts will each
24 describe the clinical trial experience relied upon

1 by the FDA to license the vaccine; correct?

2 A I don't know if it's an exhaustive list of
3 all the clinical trials, but there is certainly
4 trial information in the package insert.

5 Q Are you aware that the Code of Federal
6 Regulations require that the -- the full database
7 of safety from those clinical trials be
8 represented within Section 6 of those package
9 inserts?

10 A I'm not an expert on federal regulations.

11 Q Fair enough. I'm just going to share this
12 for a moment just because that's -- it's worth
13 taking a quick look at.

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

16 (Whereupon, Exhibit No. 2
17 was marked to the
18 testimony of the
19 witness.)

20 Q (By Mr. Siri) Okay. You'll have a chance to
21 look at it, Dr. Mace. Have you ever seen this
22 section of the Code of Federal Regulations before,
23 Section 201.57 entitled specific requirements on
24 content and format of labeling for human

1 prescription drug and biological products?

2 A I have not ever seen this.

3 Q Okay. And biological products means --
4 includes vaccines; correct?

5 A I would think, yes.

6 Q Okay. And labeling would -- would include --
7 is it -- do you -- are you aware that labeling
8 would include package inserts?

9 A You know, I don't study these types of
10 regulations, so I don't know -- I can't comment on
11 the specific meanings of the terminology of this.

12 Q That's entirely fair, absolutely. If you
13 don't know, it's -- just say -- it's totally fine.
14 You could probably show me medical stuff and I
15 would be a deer in the headlights, so -- okay. So
16 here it is, Section 6, adverse reactions, these
17 are the requirements of what needs to be on the
18 package insert, Section 6. I'm going to read it
19 out loud and then we'll just move on and you'll
20 have a copy of it for trial. It says, this
21 section must describe the overall adverse reaction
22 profile of the drug based on the entire safety
23 database. All right. For purposes of
24 prescription drug labeling, an adverse reaction is

1 an undesirable effect, reasonably associated with
2 use of a drug, that may occur as part of the
3 pharmacological action of the drug or may be
4 unpredictable in its occurrence. This definition
5 does not include all adverse events observed
6 during use of a drug, only those adverse events
7 for which there is some basis to believe there is
8 a causal relationship between the drug and the
9 occurrence of the adverse event. Now, let me ask
10 you, at -- has it been your understanding when
11 you've looked at package inserts that the adverse
12 events listed therein are only those for which the
13 manufacturer has some basis to believe there's a
14 causal relationship between the vaccine and the
15 occurrence of the adverse event?

16 A That wouldn't necessarily be my understanding
17 of that.

18 Q What has been your understanding?

19 A You know, I -- when I'm consulting the
20 package inserts, I have a general -- because I
21 have other sources of education about adverse
22 reactions to vaccinations, that's generally not
23 the part of the package insert that I'm reading.
24 I'm reviewing things like dosage and timing and

1 any special circumstances, so I haven't -- I don't
2 sit down and read through the adverse reactions
3 section. It's not something that I've -- that's
4 not a source that I look to for information about
5 adverse reactions.

6 Q Would you consider the company that actually
7 makes the product though probably a good source of
8 information on where to look for what adverse
9 reactions might be causally related to the
10 vaccine?

11 A My impression generally is that drug
12 companies are going to tell us every possible
13 reaction that has occurred, that has ever been
14 reported by someone using that drug so that it's
15 on the list and that it's not necessary -- general
16 drug company literature I think doesn't
17 necessarily indicate to me a causal relationship.

18 Q Uh-huh. Right. But here, as we talked about
19 earlier, under the 1986 Act, generally the vaccine
20 manufacturers, they're immune from liability for
21 injuries caused by their vaccines, so do they
22 really have the same incentive to just list any
23 possible adverse reaction in the package insert?

24 MR. SANDERS: Object. Object to the

1 form of the question. You can answer, Dr. Mace,
2 if you have an answer.

3 A I don't really have an answer to that
4 question.

5 Q (By Mr. Siri) Okay. Are you aware that
6 under the 1986 Act vaccine manufacturers actually
7 can be held liable for a vaccine injury if they
8 knew that the vaccine caused that injury and
9 didn't disclose it to the public?

10 A I haven't studied the details of that act, so
11 I can't comment specifically on that.

12 Q Fair enough. And do you think that vaccine
13 manufacturers would violate this federal legal
14 provision by not only listing only those adverse
15 reactions for which there is some basis to believe
16 there's a causal relationship, but, in fact, just
17 listing adverse reactions for which they have no
18 basis to believe there's a causal relationship?

19 A I haven't studied the topic enough to be able
20 to answer that question.

21 Q Not in a position to make -- draw any, you
22 know, opinion based on your experience about -- to
23 reach a conclusion or opinion about that question?

24 A I -- yes, I agree with that. I agree with

1 you saying that I don't have enough data to draw a
2 conclusion to answer your question.

3 Q Fair enough. Now, how long is the safety
4 review period for -- after each dose of Engerix-B
5 in the clinical trials that were relied upon to
6 license this vaccine?

7 A I don't know the answer to that.

8 MR. SIRI: Okay. I'm going to mark this
9 as Plaintiff's 3.

10 (Whereupon, Exhibit No. 3
11 was marked to the
12 testimony of the
13 witness.)

14 Q (By Mr. Siri) Dr. Mace, what is the document
15 that I've just placed on the screen?

16 A It looks like information -- prescribing
17 information for Engerix-B, for the hepatitis B
18 vaccine.

19 Q And this is the package insert for the
20 Engerix-B vaccine; correct?

21 A That's what it looks like to me.

22 Q Okay. Now, and you -- I -- I'm assuming
23 you've seen this -- you know, most package inserts
24 have a similar first page. I assume you've seen

1 this format for a table of contents for a package
2 insert before?

3 A Yes. In general terms, I have.

4 Q You've administered or supervised
5 administration of this product thousands of times;
6 correct?

7 A Engerix-B?

8 Q Yes.

9 A I don't order vaccines by brand name, so I've
10 ordered the hepatitis B vaccine thousands of
11 times.

12 Q Okay. And so -- and it's -- how many HepB
13 vaccines are there on the market?

14 A I don't know. I really don't study brand
15 names. I order a vaccine by its generic term, so
16 I don't know the answer to that.

17 Q So when you're looking at a package insert of
18 a product that you have ordered for a patient, if
19 you don't know the brand name, how do you look up
20 the package insert?

21 A Well, I have the brand name on the vaccine in
22 our refrigerator, so I know that if I order -- if
23 I want to look at the rotavirus vaccine package
24 insert, that's the one that we buy and that's the

1 one that's in the refrigerator, so I know I'm
2 looking at the right package insert for the
3 vaccine that we stock in our clinic and that I'm
4 ordering for that patient. I just don't -- I --
5 you know, our nurses, I suspect, know brand names,
6 but I -- because they're pulling it out of the
7 fridge. I order by generic terminology.

8 Q You order hepatitis B?

9 A Correct.

10 Q So if you're ordering a vaccine for a
11 one-year-old baby, you'll write hepatitis B
12 vaccine; right?

13 A That's not the age I give hepatitis B, but --

14 Q Or a -- a -- at birth?

15 A Right.

16 Q Not one day. Not one day. Did I say -- did
17 I say one year or one day? I'm sorry. At birth
18 you'll order hepatitis B vaccine; correct?

19 A Correct.

20 Q And there's -- are you aware there are only
21 two standalone hepatitis B vaccines licensed in
22 the United States?

23 A I -- again, I order the vaccine and our --
24 our hospital, our clinic orders -- our pharmacy,

1 you know, makes -- contracts with which drug
2 product they're going to buy.

3 Q So does the -- if I say the name Engerix-B
4 and Recombivax HB, do those names ring a bell?

5 A They certainly sound familiar.

6 Q Okay. So you're not sure if those are or
7 aren't the two licensed hepatitis B vaccines that
8 are available to give to newborn babies?

9 A Recombivax B and Engerix-B, they sound like
10 hepatitis B vaccines. Again, I order by a generic
11 name.

12 Q Okay. Are you aware that for a two-year
13 period of time recently Merck, which makes
14 Recombivax HB, was having a production issue and
15 hence Recombivax HB wasn't available for a period
16 of time, and the only HepB vaccine available for
17 newborns would have been Engerix-B?

18 A I'm not aware of that.

19 Q Okay. Now, as you can see here in the table
20 of contents, the adverse reactions are listed in
21 Section 6; correct?

22 A Yes.

23 Q Okay. And you've seen that before on other
24 package inserts?

1 A Normally I unfold the package insert and
2 scroll through to find what I'm looking for, so
3 I'm sure I've seen it.

4 Q So in all the times that you've done that for
5 HepB vaccine, have you ever looked at the section,
6 the Section 6.1, the clinical trial experience,
7 the clinical trials that were relied upon to
8 license the Engerix-B vaccine?

9 A I have not read that section on Engerix-B.

10 Q Okay. What would you think would be the
11 period of time that safety was reviewed after
12 injecting Engerix-B in the clinical trials relied
13 upon to license that product?

14 A I'm not an expert on clinical trials for
15 licensing, so I can't really give you an opinion
16 about that.

17 Q What would you guess?

18 MR. SANDERS: Object to the form of the
19 question. You can answer, Dr. Mace, if you have
20 an answer.

21 A I think it depends on what type of adverse
22 reaction we're looking at.

23 Q (By Mr. Siri) How about any and all adverse
24 reactions.

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

3 A I really am not an expert in vaccine research
4 and how long one should be extending the safety
5 review period.

6 Q (By Mr. Siri) Well, would you say that, you
7 know, two years sounds like a reasonable period of
8 time?

9 MR. SANDERS: Object to the form of the
10 question. It's been asked and answered.

11 A I -- I really -- I don't know whether shorter
12 than that is appropriate or longer than that is
13 appropriate.

14 Q (By Mr. Siri) Okay. Would it sound like a
15 conspiracy theory if I told you it was only four
16 days?

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

19 A Would it sound like a conspiracy theory? No,
20 because I don't believe in conspiracy theories.

21 Q (By Mr. Siri) Fair enough. Would it sound
22 like some kind of, you know, one of the -- I
23 forgot the exact wording you used, but, you know,
24 one of these ad hominem attacks that are made on

1 vaccines to just -- to say that safety was only
2 reviewed for four days after administration to
3 license this product?

4 A I --

5 MR. SANDERS: Same objection.

6 A I can't really comment on that.

7 Q (By Mr. Siri) Okay. Well, why don't we
8 scroll down to Section 6.1.? Here is Section 6.1,
9 the clinical trials experience. All right.

10 A Uh-huh, yes.

11 Q Let me scroll out and I'll give you a moment
12 to read. Take a moment to read the whole thing so
13 you've had a chance to review it.

14 (Whereupon, the witness
15 is reading the document.)

16 A Okay.

17 Q Okay. How long does the package insert say
18 the clinical trial relied upon to license
19 Engerix-B reviewed safety after administration?

20 A This indicates that looking for adverse
21 reactions subjects were monitored for four days
22 post administration.

23 Q Okay. Is four days long enough to see what
24 adverse events occurred seven days after

1 administration?

2 A No.

3 Q Okay. Is four days long enough to assess
4 whether this vaccine could cause autism?

5 A No, but this is why we have post-marketing
6 studies and we have systems for reporting. We
7 have great systems for reporting adverse events,
8 and while I can't explain all of the details of
9 it, we all know about the rotavirus vaccine and
10 that there were adverse events reported after that
11 that changed -- that resulted in the changes in
12 policies about the safety of that -- that
13 particular vaccination.

14 Q Well, we'll certainly get to the
15 post-licensure safety --

16 A Yes.

17 Q -- as well, Dr. Mace, for sure. That's
18 critically important to it, and we will get there.
19 First I want to go through the pre-licensure
20 clinical trial, and you've brought up rotavirus,
21 which I assume you're talking about RotaShield;
22 correct?

23 A Correct.

24 Q And intussepsis is the issue that arose after

1 licensure. That's what you're referring to?

2 A Intussusception.

3 Q Thank you. See? Now, intussusception --
4 that's what happens when you're only reading
5 things and you don't say them. Intussusception is
6 something that happens within 21 days of receiving
7 typically a rotavirus vaccine; right?

8 A Intussusception can occur in settings that
9 are unrelated to vaccines, and probably more of
10 the children I've seen with intussusception had it
11 occur not in relationship to vaccination.

12 Q Okay.

13 A So I -- I can't tell you the exact, but it --
14 maybe that they attribute one happening within
15 21 days following the vaccine as --

16 Q I didn't mean to say that at all that
17 intussusception occurs from vaccination. I just
18 said that if intussusception were to occur, if it
19 were to occur from a rotavirus vaccine, it would
20 usually happen within the first 21 days after
21 getting that vaccine; correct?

22 A I would want to look at what the guidelines
23 say about that.

24 Q Okay. That's fair. You'll -- and I think

1 you'll find that that's the number. And it is --
2 and intussusception is not a loosely-defined
3 neurological disorder; right? Intussusception is
4 not a loosely-defined neurological disorder. It's
5 a very clearly marked, you know, issue with the
6 intestines where there's a blockage and there's a
7 clearly-defined, you know, diagnosable physical
8 issue with the child; correct?

9 A It's a specific event, yes.

10 Q Yeah, okay. So, you know, I'm just going to
11 scroll to the end here just so that, you know, you
12 can see that this is the full section of 6.1, and
13 again, you can -- this is a trial that included
14 adults and you -- you know, not children. With
15 adults, just to show you, that they did review
16 serious adverse events for 30 days following the
17 last vaccine, but that wasn't children; right?
18 That's adults with type 2 diabetes. Very
19 different group; correct?

20 A I see that, yes.

21 Q Okay. And by the way, you can see that there
22 were a number of subjects that had serious adverse
23 events, but it says no SAEs were deemed related
24 to -- oh, sorry -- Engerix-B. Isn't it true that

1 it's the principal investigator who's paid by the
2 sponsor that makes that determination typically?

3 A I don't know who is responsible for making
4 that statement.

5 Q No problem. Fair enough. Okay. Just to --
6 okay. Are you aware that the FDA also issues a
7 summary basis of approval separate from this
8 document when it approves each new vaccine?

9 A No, I'm not.

10 Q Okay. So you're not aware that the FDA
11 summary basis of approval for Engerix-B also makes
12 clear that the safety was only reviewed for four
13 days?

14 A I'm not aware of that.

15 Q Are you aware that there's also typically a
16 peer-reviewed study that would be published that
17 the -- you know, summarizes and describes clinical
18 trials, not always, but typically, after they're
19 concluded?

20 A That seems like a reasonable process.

21 Q Okay. And -- and I assume then you're also
22 not aware when you read that the peer-reviewed
23 study summarizing clinical trials for hepatitis B,
24 for Engerix-B, it also again reconfirms that

1 safety was only reviewed for four days. Are you
2 surprised to learn that the safety was only
3 reviewed for four days in the clinical -- after
4 administering Engerix-B in the clinical trial that
5 the FDA relied upon to license this product?

6 A No, I don't know about what was licensed
7 before Engerix-B, what other hepatitis B vaccines
8 were approved, what -- what other research there
9 was prior to this exact product being developed,
10 so I would need to know a lot more information
11 before I could tell you about the four-day period
12 or not. I mean, if they're just looking at
13 reactions to the injection, four days seems
14 reasonable, but if -- you know, I just don't know
15 enough about prior studies prior to the
16 development and licensure of Engerix-B.

17 Q And you know what, fair enough. Why don't we
18 take a look. That's -- that's a fair -- that's a
19 fair comment and I think we should look. Well,
20 before we go there, was there any control group in
21 this clinical trial?

22 A I don't know.

23 Q Okay. So let me just pull up -- just bear
24 with me just a moment here. I appreciate it.

1 Okay.

2 MR. SIRI: So I'm going to mark this as
3 Plaintiff's 4.

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

8 Q (By Mr. Siri) Now, let's take a look at
9 hepatitis B, and, you know, so we can see here,
10 this is from the CDC Pink Book. You're familiar
11 with that, I assume?

12 A It's not a resource that I -- I know it
13 exists. It's not a resource that I go to to --

14 Q Okay.

15 A -- to get information.

16 Q Okay. And this is Table 1, U.S. Vaccines.
17 Do you have -- and then over here, you can see
18 that it provides the hepatitis B vaccines
19 available in the United States. Do you see that?

20 A Yes.

21 Q Okay. And you can see here's Engerix-B made
22 by GlaxoSmithKline. That was licensed in 1989;
23 correct?

24 A Yes, that's what it says.

1 Q And so you said, well, maybe there was a HepB
2 vaccine licensed before that. Well, there was,
3 you were right, there is, and that's Recombivax HB
4 which we mentioned earlier; correct?

5 A Yes.

6 Q Okay. Well, you know, it could be, you're
7 right. Maybe the safety review period for
8 Recombivax HB was, you know, three years, and
9 so -- and it's -- maybe it's just a -- like a
10 knockoff of Engerix-B and so they figured they
11 didn't need to do three years for that one too;
12 right? Well, let's -- why don't we take a look.
13 Okay. And so here is the FDA website, vaccines
14 licensed in United States; correct?

15 A Yes.

16 Q Okay. So let's take a look. Here we go.
17 There was two HepB vaccines, right, Engerix-B and
18 Recombivax HB, and there's more recently the
19 HEPLISAV-B, but that's only licensed for
20 individuals 18 years and over; correct?

21 A I don't know about that one. I can't tell
22 you about it.

23 Q Fair enough. You're a pediatrician. You're
24 not normally vaccinating adults; correct?

1 A Correct.

2 Q Okay. So -- and let's take a look at
3 Recombivax HB. Click on it, and we can go to the
4 package insert; right? And again, it's going to
5 have a section, all right, so here it is,
6 Recombivax HB; right? You would agree this is the
7 package insert for Recombivax HB?

8 A That's what it looks like, yes.

9 Q And Section 6.1 is going to be the clinical
10 trial experience; right?

11 A Yes.

12 Q Okay. So let's scroll down. And why don't
13 you take a moment to read the summary of the
14 clinical trials that were relied upon to license
15 Engerix-B -- Recombivax HB. Excuse me on that.
16 Sorry. I'm going to save it as an exhibit so we
17 can mark it.

18 MS. CHEN: Aaron, this will be marked as
19 Exhibit Number 5.

20 MR. SIRI: Thank you.

21 (Whereupon, Exhibit No. 5
22 was marked to the
23 testimony of the
24 witness.)

1 Q (By Mr. Siri) Okay. Let me know when you're
2 done reviewing that.

3 (Whereupon, the witness
4 is reading the document.)

5 Q Dr. Mace?

6 A Yes.

7 Q Okay. Sorry. I heard no -- I wanted to make
8 sure I didn't lose you. Okay. Do you --

9 A Okay. I've generally reviewed it.

10 Q Okay. Wonderful. So I'm going to pull up a
11 PDF version of it just so that I can highlight
12 things. And again, this is Plaintiff's 5. So
13 let's take a look here, and it says, in three
14 clinical studies, 434 doses of Recombivax HB,
15 5 micrograms, were administered to 147 infants and
16 children up to 10 years of age and were monitored
17 for five days after each dose. Do you see that?

18 A I do.

19 Q Okay. And I assume -- maybe I shouldn't
20 assume. Are you aware that the summary basis of
21 approval for the FDA and the peer-reviewed
22 literature regarding this study confirmed that the
23 vaccine safety was only reviewed for five days
24 after its dose?

1 A I'm not aware of the literature.

2 Q So, you know, you brought up a good point,
3 maybe the vaccine for HepB before Engerix-B had a
4 longer safety review period, but, in fact, it only
5 reviewed safety for five days; correct?

6 A For this Recombivax HB, yes.

7 Q Okay. And going back to the -- do you have
8 any reason to doubt that Table 1 in the CDC Pink
9 Book is not accurate with regards to which
10 hepatitis B vaccines are currently licensed for
11 pediatric use in the United States?

12 A No, but my question is was there another
13 hepatitis B vaccine that preceded the recombinant
14 vaccines.

15 Q You might be aware that there was a plasma
16 vaccine, were you aware of that, which is a
17 completely different type of technology?

18 A Right. Right. There was a -- there was a
19 hepatitis B vaccine that preceded these two
20 vaccines.

21 Q And it was made using actual human blood;
22 correct?

23 A I don't have a strong recollection of it, but
24 that sounds correct.

1 Q Right. And those were withdrawn from the
2 market, weren't they?

3 A I don't know the details. I think my
4 recollection would be that these vaccines were
5 felt to be safer and better and that's why they
6 were developed instead of the human product
7 vaccine.

8 Q And they determined they were safer by
9 studying them for four or five days respectively?

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

13 A Well, they probably already knew a lot about
14 hepatitis B vaccination, and in this case we were
15 removing some of the risks by using a recombinant
16 vaccine rather than a human blood product. That
17 would be my understanding of the development of
18 these vaccines.

19 Q (By Mr. Siri) Uh-huh. And so you're saying
20 they just assumed they were safe maybe because the
21 completely different HepB vaccines that, you know,
22 had a -- that were -- based on using human blood
23 were withdrawn from the market let them have an
24 assumption such that they only reviewed safety for

1 four or five days?

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

5 A I don't believe that vaccine researchers
6 would make a -- would make assumptions. I think
7 they would come to their conclusions based on data
8 and evidence, and they have a much better
9 understanding than I do about their reasons that
10 they needed to study for a certain period of time.

11 Q (By Mr. Siri) So meaning you're just -- you
12 don't actually know if they had a reason. You're
13 just -- you're speculating that they had some way
14 to know safety, let's say, on day six after giving
15 these vaccines; correct?

16 A I believe that they had data about safety of
17 hepatitis B vaccinations --

18 Q Okay.

19 A -- that would have been applicable in this
20 situation with a new vaccine and would have made
21 decisions on how long to monitor based on a lot of
22 data.

23 Q Isn't -- you know, isn't that the criticism
24 that is being leveled everywhere against -- you

1 know, about folks who have a -- you know, opinions
2 about vaccines, that their opinions are based on
3 belief rather than science, rather than evidence?

4 A No, I -- I think they had evidence. I think
5 that I -- I believe that they had evidence that
6 led them to know how long a reasonable period of
7 time would be for the safety monitoring period
8 after these new vaccines were developed.

9 Q But that's just your belief; correct?

10 A Well, my beliefs are based on reading things
11 and thinking things through, based on training,
12 and based on experience. I have 30 years of
13 experience as a pediatrician. I have vaccinated
14 children almost every day in my work life and have
15 not seen children with serious adverse effects.
16 Heart -- you mentioned -- you said earlier
17 something about heartbreaking effects. I
18 vaccinate children every day. I did take care of
19 children who had devastating diseases in my
20 training period before we had the Prevnar vaccine
21 and before we had the HIB vaccine in particular.
22 I cared for children who suffered brain damage,
23 hearing loss, long-term disability by diseases
24 that were at that time not preventable by

1 vaccines, and I saw those diseases go away as the
2 population became vaccinated against those
3 diseases, so I have 30 years of experience, so
4 it's more than just a belief. It is experience
5 that tells me this.

6 Q So your argument, just to make sure I
7 understand it, is that over the last 30 years, we
8 should trust you, you know, because you're a
9 pediatrician, you've been dealing with children
10 for 30 years, and over the last 30 years the
11 health of children in this country has improved.
12 But isn't it true that 30 years ago, according to
13 the CDC, about 12 percent of children had a
14 chronic health condition, where the most recent
15 CDC data shows that closer to 45 to 50 percent of
16 children today have a chronic health condition? I
17 mean, it seems to me that over the last 30 years
18 we've seen an explosion in the amount of chronic
19 health issues, and if you're vaccinating babies
20 from day zero and you haven't conducted studies
21 before you license them to see their long-term
22 effects and there's no, as you I'm sure know,
23 studies that compare completely unvaccinated with
24 vaccinated children, it's hard for me to see how

1 you make your claim. It seems to me like this is,
2 you know, a belief. Do you disagree with that?

3 A That's a --

4 MR. SANDERS: Object to the form of the
5 question. Go ahead, Dr. Mace.

6 A That's a really long question loaded for --

7 Q (By Mr. Siri) Sure, it is.

8 A -- depositions, so I would have to say, no,
9 I'm not going to agree with that long question.

10 Q Okay. Let me ask you this. Because I
11 don't -- I don't want to get too far off the topic
12 of what we're here today to talk about, which is
13 why -- let's just -- we'll cut it short. Let's
14 just say -- let's just put it this way. You know,
15 if your experience is what's important and your
16 belief, you know, isn't it true that something in
17 the order -- isn't it true that there are a number
18 of peer-reviewed studies that look at -- survey
19 parents who have autistic children for what they
20 believe caused their child's autism?

21 A I -- I'm sure there are. I can't quote you
22 any specifics though.

23 Q And based on -- and those studies, based on
24 their experience with their child, are you aware

1 that those studies show that many -- that
2 somewhere in the order of 40 to 50 percent, it
3 depends on the study, of children [sic] of an
4 autistic child believe, based on their experience,
5 that -- that their experience that the vaccines
6 were a cause of their child's autism often
7 identifying many different types of vaccines?

8 A So you're asking me if because -- because
9 I --

10 Q I'm asking if you're aware of those studies.
11 That's all.

12 A Okay. I'm aware -- I'm aware of -- that
13 there are studies and that parents -- parents do
14 have concerns that -- that their child's autism
15 was -- was caused by MMR vaccine.

16 Q Are you aware that there are -- that there
17 are studies that when they've surveyed parents and
18 they asked them which vaccines, they don't just
19 blame MMR, they blame pretty much -- it depends on
20 the survey, but various vaccines given in the
21 first year of life?

22 A I am not aware of specific studies and
23 exactly what those studies say.

24 Q Okay. Are you aware that many parents also

1 believe that vaccines cause all kinds of
2 autoimmune conditions as well based on their
3 experience and as well as neurological issues
4 based on their experience?

5 A I can see that your concern is that I used
6 the word believe, that I believe that research
7 studies were done to lead the researchers of the
8 Engerix-B and Recombivax B to believe -- to know
9 that they had enough data to determine that those
10 were safe vaccines. So I -- you know, I think
11 that -- that my experience and my reading of
12 literature and my training and my consultation
13 with experts and my consultation with the American
14 Academy of Pediatrics literature is based on
15 experience, it's based on evidence, it's based on
16 lots. It boils down though to me in the end
17 deciding what is the right course of action and
18 that a vaccine is safe for a child and writing an
19 order for that vaccine, and I don't think that
20 that -- that -- that we can say that -- that
21 people's anecdotal experiences necessarily add up
22 to the same as me believing that I'm doing the
23 right thing when I order a vaccine because it's --
24 it's much more than a belief. It is based on lots

1 of data and training and evidence and discussions
2 and conferences and -- so it's more than just I
3 believe. Sorry, I used an imprecise term.

4 Q Well, my -- I don't think you were imprecise.
5 I think you said that you believed, and I think
6 you meant it as believed, that you believe that
7 there is some, you know, data or studies that you
8 don't know if it exists that led the Merck and
9 GlaxoSmithKline when they conducted their trials
10 for Engerix-B and Recombivax HB to believe that
11 four days and five days were appropriate safety
12 review periods; right?

13 A I can agree with that, yes.

14 Q But you don't know that there's -- that data
15 exists; correct? You're just guessing.

16 A I haven't reviewed that data. I haven't gone
17 out and looked for it --

18 Q Okay.

19 A -- to find out.

20 Q And until right now, in the 30 -- in the last
21 45 minutes is the first time you've ever learned
22 that the clinical trials relied upon to license
23 Recombivax HB and Engerix-B didn't review safety
24 for more than five days after injection in the --

1 in the clinical trials used to license it. Isn't
2 that true?

3 A It's true that I hadn't reviewed that data in
4 the -- in the vaccine package insert, and so --
5 right. I'm not an expert on how long trials were
6 done, for sure.

7 Q This information is not hidden someplace,
8 Dr. Mace, is it? It's in the package insert
9 that's in every single box for the vaccine you
10 said you -- one or -- well, it's only in those two
11 vaccines that you said you've given thousands of
12 times; correct?

13 A I --

14 MR. SANDERS: Object to the form of the
15 question. Compound. Go ahead, Dr. Mace.

16 A I have given the routine childhood vaccines
17 to thousands of children, so I've ordered
18 thousands of doses of all of the vaccines.

19 Q (By Mr. Siri) But let me ask you this.
20 Maybe we -- let's find -- let's find common
21 ground. We -- can we agree that conclusions
22 should be based on well-supported scientific
23 evidence?

24 A Yes.

1 Q Including conclusions about safety?

2 A Yes.

3 Q Not based on beliefs or anecdotal stories?

4 A I agree with you.

5 Q Okay. Because human beings have biases;
6 right?

7 A Yes.

8 Q For example, if somebody engaged -- devoted
9 their career to helping children, which is an
10 honorable thing to do, part of their self-schema
11 is that they want to help children; correct?

12 A Part of --

13 Q A big part of their self-schema is that
14 they've been helping children; correct?

15 A That's something that's very important to
16 them, yes.

17 Q All right. And obviously, if there's
18 evidence that either may exist or could exist that
19 would undermine that the bevy of pharmaceutical
20 products they've been injecting into babies and
21 children maybe cause harm, do you think they might
22 be a bit biased in how they absorb that
23 information potentially? Like, for example, if
24 they just learned that there's only four or five

1 days of safety review after a clinical trial for
2 the two vaccines given to babies on -- right after
3 birth, that maybe instead of taking a moment to
4 think about that, their immediate reaction is, oh,
5 there must be some other -- I believe there's some
6 other data they know nothing about or maybe
7 doesn't exist? Because your first excuse when I
8 showed you Engerix-B, Doctor, was you said, well,
9 maybe there's a vaccine right before it, which we
10 looked at, Recombivax HB. That's the very first
11 recombinant vaccine ever, which is an entirely new
12 technology and ushered in in many ways the
13 current, you know, vaccine age. Would you agree
14 with that?

15 MR. SANDERS: Object to the form of the
16 question. I -- that's compound in numerous
17 respects.

18 MR. SIRI: It certainly -- it certainly
19 is. I'll agree with you, counsel.

20 Q (By Mr. Siri) Please, Dr. Mace.

21 A So, again, I'm not -- I'm not an expert in
22 research on vaccines, so I don't know that
23 Recombivax was the first recombinant vaccine that
24 was ever developed. I just don't have those sorts

1 of things memorized. You know, I learn -- we
2 learned those in our education. I will say
3 that --

4 Q Fair enough. Fair enough, yeah.

5 A We consider very carefully the risk of harm
6 to children. We stop and think and -- you know,
7 over and over have looked at the studies that --
8 that are -- the studies and the summaries of
9 studies and the consensus statements about the
10 harm of vaccines because we absolutely don't want
11 to do something that harms children. So we stop
12 and we listen and we think, and then we look at
13 the preponderance of evidence and also the
14 benefits of vaccination, which is incredibly
15 important to consider in this. Keeping children
16 vaccinated protects not just that child, but it
17 also protects other children in our practice who
18 cannot be vaccinated because of health problems.
19 So we take it very seriously. I think we
20 recognize that people have biases, but we really
21 try to set aside the bias and listen carefully and
22 make sure we're making the right decision for each
23 and every child.

24 Q Well, that's the issue with biases, isn't it?

1 Right. That's the problem. The biases are --
2 well, strike that. So let's -- let's turn this
3 conversation into something specific to this case.
4 So, for example --

5 MR. SANDERS: Mr. Siri, sorry to
6 interrupt, but we've been going about two and a
7 half hours. Whenever you get to a stopping point
8 for a short break, could you please let us know?

9 MR. SIRI: Okay. Fair enough.

10 Q (By Mr. Siri) I'll just do just a few more
11 questions on that and then we'll take a break.

12 A Okay.

13 Q So, for example, you say that, you know, very
14 careful about the science. Now, parents have been
15 complaining that vaccines cause autism; correct?
16 Strike that. Parents have been complaining that
17 they believe vaccines their children receive cause
18 autism; correct?

19 A That concern is raised by parents.

20 Q Fair enough. And so what you're saying is is
21 that the issue has been studied; correct?

22 A The issue has been studied.

23 Q All right. Right. So have you reviewed any
24 study, for example, that showed a hepatitis B

1 vaccine doesn't cause autism?

2 A I have not.

3 Q Okay. Because no such study exists, does it?

4 Isn't that true?

5 A I am not aware.

6 Q Are you familiar with the Agency for Health
7 Research and Quality?

8 A Not exactly, no.

9 Q Are you familiar with the report that they
10 issued in 2014 regarding vaccine safety that HHS
11 has said is the most comprehensive report on
12 vaccine safety issue to date?

13 A I'm not aware of that. I might have seen it,
14 but --

15 Q Okay. And you're -- and you're -- so you've
16 never seen that study?

17 A I don't know whether I've seen it or not.
18 I've looked at a lot of studies.

19 Q Okay. We can pull it up. And that they
20 looked at whether Hep -- they looked at HepB and
21 autism. Why don't we pull it up.

22 MR. SIRI: And then we'll take a break,
23 counsel.

24 MR. SANDERS: Thank you.

1 MR. SIRI: I'm going to share my screen.
2 Okay. So I want to mark this as Plaintiff's
3 Exhibit 6?

4 MS. CHEN: 6.

5 MR. SIRI: Thank you, Patricia.
6 (Whereupon, Exhibit No. 6
7 was marked to the
8 testimony of the
9 witness.)

10 Q (By Mr. Siri) So have you seen this report
11 before?

12 A I have not.

13 Q Okay. And you've -- I assume you've never
14 seen the HHS letter from 2018 that would describe
15 this as the most comprehensive report on vaccine
16 safety that they believe was -- was done as of at
17 least 2018?

18 A As I said, I've reviewed a lot of literature
19 and a lot of reports. I don't have a specific
20 recollection of seeing either this report or that
21 letter.

22 Q All right. Fair enough. So this is Page 114
23 of the report, and here they're looking at
24 hepatitis B vaccine, and I'm going to -- you've

1 never seen this before, so we'll -- you know, I
2 won't -- you'll have an opportunity to review
3 this, but basically they only found one study, and
4 it found that children that received -- result was
5 significant for the risk of autism in children who
6 received their first dose of hepatitis B vaccine
7 during the first month of life. The odds ratio
8 were three times the risk, meaning that babies
9 that got HepB versus the babies that didn't get
10 HepB on the first day of -- first dose of HepB in
11 the first month of life had three times the rate
12 of autism and a statistically significant
13 confidence interval. All right. Well, look, you
14 haven't seen this, so it's not fair. Why don't
15 you -- you know, you'll have an opportunity to
16 discuss that further at trial.

17 MR. SIRI: What are we looking at for a
18 break here? Do you want to take 10 minutes?
19 Should we come back at -- 11 minutes, come back at
20 4:40?

21 MR. SANDERS: Dr. Mace, is that enough
22 time for you to get a short break?

23 THE WITNESS: Come back at 4:50? Is
24 that what we're --

1 MR. SANDERS: Yes.

2 MR. SIRI: Yes. Is that okay with you,
3 Dr. Mace?

4 THE WITNESS: That's fine, yes, thank
5 you.

6 MR. SIRI: Okay. Well, thank you.

7 THE VIDEOGRAPHER: Okay. We are off the
8 record at 4:40.

9 (Brief recess.)

10 THE VIDEOGRAPHER: We are now back on
11 the record at 4:51.

12 Q (By Mr. Siri) Okay. All right. So
13 Dr. Mace, well, let's move on to -- we were
14 talking about clinical trials relied upon to
15 license the vaccines that Yates received, and
16 we'll move on to another vaccine. Now, why don't
17 we talk about varicella. Okay. So varicella
18 vaccine, VARIVAX, sold by Merck, that's the --
19 that's the first and only vaccine licensed for
20 chicken pox in the United States; correct?

21 A As far as I know, yes, that's correct.

22 Q Okay. There was never a chicken pox vaccine
23 before VARIVAX; correct?

24 A You know, I order my vaccines by generic

1 name, not brand name, so that's probably correct,
2 but I -- I don't order by brand name.

3 Q Okay. Are you aware of any vaccine for
4 chicken pox other than the one that's sold by
5 Merck?

6 A I don't even pay attention to which company
7 it comes from.

8 Q Okay.

9 A It's what I have memorized in my brain.

10 Q But you do understand vaccines are made and
11 sold by pharmaceutical companies; correct?

12 A Yes.

13 Q All right. And that they -- you know, and do
14 you -- are you aware that they sell over
15 30 billion dollars worth of vaccines every year?

16 A I have no idea what the number is.

17 Q Okay. But you are aware that they --
18 pharmaceutical companies make billions of dollars
19 in profits from the sale of vaccines; correct?

20 A I don't know --

21 Q Okay.

22 A -- what magnitude their profits would be from
23 vaccinations.

24 Q Fair enough. Now, since there was no --

1 let's just assume that there was no -- let's take
2 a quick look at the Pink Book for a second. So
3 going back to this exhibit that was previously
4 marked, I'm going to share my -- can you --

5 MR. SIRI: Mr. Lawson, could you kindly
6 share --

7 THE VIDEOGRAPHER: Yeah, you came back
8 in, so --

9 MR. SIRI: Not a problem.

10 THE VIDEOGRAPHER: All right. You
11 should have the power now.

12 MR. SIRI: Thank you.

13 THE VIDEOGRAPHER: You bet.

14 Q (By Mr. Siri) Okay. So -- all right. So we
15 looked at HepB, and now we'll go to varicella
16 right here. According to the CDC, there's only
17 one vaccine for chicken pox; correct?

18 A Yes, I see that.

19 Q Do you have any reason to doubt that this
20 information is accurate?

21 A I don't have any reason to doubt it.

22 Q Okay. So assuming the vaccine VARIVAX was
23 the first licensed chicken pox vaccine in the
24 United States, okay, was there any reason, any

1 ethical reason not to use a control group
2 receiving a placebo in the clinical trials relied
3 upon to license this product?

4 A Well, I'm not an expert on designing clinical
5 trials for vaccines, so I can't answer
6 specifically, you know, how they made their
7 decisions about what to do with this particular
8 vaccine, but I can't think of an ethical reason
9 not to include a placebo -- a placebo group. But
10 this is really outside of my area of expertise in
11 terms of clinical trials for vaccines.

12 Q Well, you're -- you're here testifying that
13 vaccines that my client received didn't cause
14 autism; correct?

15 A Yes.

16 Q Okay. And so to determine the safety of
17 those products that my client received, we would
18 want to look at the pre-licensure and
19 post-licensure studies that reviewed safety;
20 correct?

21 A Yes.

22 Q Okay. So looking at the pre-licensure
23 clinical trials for these products would be
24 relevant to answering the question of whether or

1 not the vaccines Yates received causes autism.

2 Would you agree with that?

3 A I would agree, but I also need to look at the
4 clinical trials in the context of, you know, there
5 may be other pieces of information that -- that
6 aren't being presented at this point that could
7 also influence my answer to those questions, so
8 it's hard to answer a question about a specific
9 clinical trial under these circumstances without,
10 you know, having the time to look at other
11 resources and information.

12 Q But you've already reached your conclusion
13 though, haven't you, with regards to whether the
14 vaccine Yates received caused his autism?

15 A So I have looked at general guidelines about
16 vaccines and autism in studies that have been
17 reported and -- and find no evidence that vaccines
18 cause autism.

19 Q Well, we'll get to that evidence a bit later.
20 Let's continue on with the pre-licensure clinical
21 trials. Let's see if we can do this quickly and
22 so we can -- we can move on. If the Varivax
23 vaccine only reviewed safety for 42 days in its
24 pre-licensure clinical trials, would you agree

1 that that wouldn't have been long enough to
2 determine whether when giving it to an
3 18-month-old baby in 2000 it would have caused
4 autism?

5 A So I -- I think if we're looking at -- at
6 whether varicella vaccine could cause autism,
7 42 days is not -- wouldn't seem to me long enough
8 to make a determination for sure on that, but --
9 but licensure of vaccines is not -- you know, the
10 reasons that go into the decisions about how long
11 to do that is not my area of expertise.

12 Q Do you ever inject neomycin into children or
13 babies?

14 A Neomycin?

15 Q Yes.

16 A I believe there's neomycin in some vaccines.

17 Q Right. I'm asking you separate from
18 vaccination, do you ever inject neomycin, the
19 antibiotic, as an antibiotic into children?

20 A I can't think of any occasion that I would
21 have ordered a neomycin injection.

22 Q Okay. Is it licensed to -- is neomycin
23 licensed to be injected into babies and children?

24 A It -- it's not something that I've ever

1 looked into because I've never felt the need to
2 order neomycin for a patient for injection.

3 Q Fair enough. Now, Yates received IPOL that's
4 produced by Sanofi. Are you aware that the IPOL
5 vaccine currently used in the United States and
6 sold by Sanofi is very different than the polio
7 vaccine that was developed by Jonas Salk?

8 A I get the Salk and the Sabin vaccines
9 confused and I always have to go back and look at
10 those.

11 Q No problem. So would it -- would it jog your
12 memory if I said that Jonas Salk developed the
13 inactivated polio vaccine, IPV, in 1955, whereas
14 Sabin developed the oral polio vaccine that --

15 A Yes.

16 Q Does that jog your memory of which vaccine
17 Jonas Salk created?

18 A Sure, that's helpful.

19 Q Okay. So Jonas Salk was the developer of the
20 inactivated polio vaccine licensed in 1955;
21 correct?

22 A I -- I don't know what year it was licensed,
23 but Jonas Salk, yes, I agree, developed the
24 original inactivated polio vaccine.

1 Q Are you aware that the polio vaccine that
2 Yates received, IPOL, is a very different product
3 than the polio vaccine that was developed by Jonas
4 Salk many years prior?

5 A It -- it wouldn't surprise me because
6 vaccines are -- as all medicines, are researched
7 and hopefully improved over time.

8 Q All right. Are you aware that the -- that
9 the polio vaccine IPOL that Yates received was
10 licensed in 1988?

11 A I don't know the year of licensure.

12 Q Okay. Are you aware that IPOL is -- that the
13 poliovirus used in the IPOL vaccine is grown on
14 substrate monkey kidney cells known as vero?

15 A I don't know the details of how that vaccine
16 is developed.

17 Q So you're not aware that Jonas Salk used a
18 different substrate?

19 A That's correct.

20 Q Okay. And I presume you're not aware that
21 the culturing techniques as well as the amount of
22 the different types of antigen are different in
23 the two products?

24 A That's correct.

1 Q Okay. Are you aware that the safety review
2 period in the clinical trials relied to license
3 IPOL was only 48 hours after injection?

4 A I'm not aware of that.

5 MR. SIRI: I'm going to mark this as
6 Plaintiff's 7.

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

11 Q (By Mr. Siri) Now, the only IPV, inactivated
12 polio vaccine, used in the United States is IPOL,
13 this product, since 2 -- since the '90s; correct?

14 A That seems correct to me.

15 Q Okay. And it even notes over here, for
16 example, it describes that with regards to this
17 product, it says, this culture technique and
18 improvements in purification, concentration, and
19 standardization of poliovirus antigen produce a
20 more potent and consistent immunogenic vaccine
21 than the inactivated polio vaccine available in
22 the U.S. prior to 1988. Do you see that?

23 A I do see that.

24 Q Do you have any reason to doubt that that's

1 not accurate?

2 A No, I don't.

3 Q Okay. So, you know, why don't we scroll down
4 to the section that discusses the adverse
5 reactions and the clinical trials that were relied
6 upon, and you can see here how long the safety was
7 reviewed. Do you see that?

8 A I do see what you've highlighted in yellow.

9 Q Okay. But you've never looked at this
10 portion of this package insert before?

11 A That's correct.

12 Q Okay. In the 30 years that you've been
13 administering polio vaccines, this would have been
14 the only package -- this would have been the
15 package insert that would have been contained in
16 all of those products -- okay. Strike that. Now
17 you have it, you'll have a chance to review the
18 entire adverse reaction section before trial.
19 It's -- you know, it's got a few clinical trials
20 and you'll see the safety review duration in all
21 of them, so -- all right. That's -- do you
22 believe that reviewing the safety of IPOL for
23 48 hours after giving this product to a
24 nine-month-old would have been long enough to

1 determine whether or not it caused autism?

2 A A 48-hour period of observation would not be
3 enough to determine whether or not something
4 caused autism.

5 Q Do you know the duration safety was reviewed
6 after injection of HibTITER in a pre-licensure
7 clinical trial relied upon to license that
8 product?

9 A Are you asking me a question?

10 Q Yeah, I'm sorry. I said are you -- are you
11 aware of the -- how long safety was reviewed in
12 the clinical trials relied upon to license
13 HibTITER?

14 A I do not know the duration of safety
15 monitoring.

16 Q Okay. This is the package insert for
17 HibTITER. Is that correct?

18 A It looks like a package insert for HibTITER.

19 MR. SIRI: And I'm going to mark it as
20 Plaintiff's Exhibit 8.

21 (Whereupon, Exhibit No. 8
22 was marked to the
23 testimony of the
24 witness.)

1 Q (By Mr. Siri) You'll -- have you seen this
2 package insert before?

3 A I haven't -- I haven't looked at specifically
4 this -- I -- you know, I've looked at package
5 inserts, but I -- I don't recall the specifics of
6 seeing this.

7 Q Okay. Well, you'll have a chance to review
8 it. If it provides that safety was only reviewed
9 for 30 days in the clinical trials relied upon to
10 license this product, would you agree that the
11 clinical trials to license HibTITER would not have
12 determined whether giving this product to an
13 11-month-old --

14 A So -- so again, I'll say I'm not an expert on
15 what the requirements are to -- to be printed in
16 this information. My understanding is that
17 these -- they come pre and post-licensure safety
18 monitoring that -- that adequate amounts of time
19 are -- are provided for determining serious and
20 significant adverse events.

21 Q You're saying pre licensure or post
22 licensure? I apologize.

23 A The combination of studies. And I, you know,
24 don't -- again, I don't know about other studies

1 that -- that were done in the preliminary stages
2 of these vaccines in terms of the -- you know, but
3 maybe this is reporting, I don't know, Phase 3
4 studies only, but we've had Phase 1 and Phase 2
5 and other types of studies that are not reported
6 in the package insert. Again, this is beyond my
7 area of expertise in terms of the steps that are
8 taken and the studies that are done for licensure.

9 Q Are you aware that Phase 1 and Phase 2 types
10 of studies are almost always shorter than Phase 3
11 studies, the pivotal trials actually relied upon
12 to license the vaccine?

13 A I don't know what the duration are, the
14 requirements are for those phases.

15 Q Are you aware that the Phase 1 and Phase 2
16 studies have far less people in them typically
17 than a Phase 3 study because they want to first
18 make sure there isn't an immediate reaction to the
19 product?

20 A Yes, I am.

21 Q Okay. You talked about serious adverse
22 reactions. Let's -- let's -- let's take a quick
23 look here. Now, Yates received Prevnar, you said;
24 correct?

1 A Yes.

2 Q Now, he received Prevnar 7 or Prevnar 13?

3 A I would have to look at the record for that.

4 Q Well, he was vaccinated in 2001, so it would
5 be Prevnar 7; correct?

6 A I don't have the dates memorized, I'm sorry.

7 Q No problem. Let's just assume it's
8 Prevnar 7. You can confirm it later; okay? Now,
9 in the -- in the clinical trial used to license
10 Prevnar 7, all right, was there a Prevnar vaccine,
11 a pneumococcal vaccine that existed prior to
12 Prevnar 7?

13 A There's a pneumococcal polysaccharide vaccine
14 that covers 23 serotypes, and I don't -- I just
15 don't recall exactly when that one was approved
16 for use, but that one is given at a different age.

17 Q Right.

18 A And then we had Prevnar 7 and then we had
19 Prevnar pneumococcal 13.

20 Q Right.

21 A I would think that the pneumococcal 23-valent
22 vaccine preceded pneumococcal 7.

23 Q Right. But the pneumococcal 23 is only
24 licensed for two years of age and above; correct?

1 A I believe that's correct, yes. I only order
2 it for ages two and older.

3 Q All right. But Prevnar 13 is given -- and 7
4 were given at six weeks of age until two; correct?

5 A It may be licensed for age six weeks, yes,
6 I -- I routinely give it at two months of age, but
7 we can give it a little bit earlier.

8 Q Okay. And so when Prevnar 7 was licensed,
9 are you aware of any pneumococcal vaccine that
10 existed that -- that was licensed to be given to
11 children under two years of age?

12 A Not to my knowledge, no.

13 Q Okay. Are you aware -- are you aware of what
14 the control group received in the clinical trial
15 used to license Prevnar 7?

16 A I have not reviewed that study.

17 Q The information is also in the package
18 insert. Have you ever looked at that information
19 in the package insert?

20 A I -- I have not studied in depth the clinical
21 trials because these were licensed vaccines.

22 (Whereupon, Exhibit No. 9
23 was marked to the
24 testimony of the

1 witness.)

2 Q (By Mr. Siri) Understood. But this package
3 insert would have been in the boxes of hundreds of
4 Prevnar vaccines that you ordered to be
5 administered over the years; correct?

6 A Yes, correct.

7 Q Okay. So you've seen this package insert
8 before; correct?

9 A It is available to me if I have questions and
10 want to consult it.

11 Q Okay. You'll have a chance to review it then
12 as well, but if you go down to the adverse
13 reactions, you can see here that -- you know, you
14 can see the safety review, but let's -- duration
15 and -- but let's take a look at what the
16 placebo -- excuse me, what the control was because
17 I -- I think you might find that interesting.

18 Check this out. This is the clinical trial for
19 Prevnar, this -- that was relied upon. Here's one
20 that actually had a control. The others -- some
21 of them didn't. Do you see where it says control,
22 it's got a little cross next to it; correct?

23 A I see that.

24 Q And that would mean to look down, find the

1 little cross to see more information about what
2 the control is; correct?

3 A Correct. It would be a comment related to
4 control.

5 Q Right. And so what does the comment say?

6 A It says, investigational meningococcal group
7 C conjugate vaccine.

8 Q So the control used to license Prevnar 7 was
9 another investigational meningococcal group C
10 conjugate vaccine?

11 A That's what it looks like.

12 Q So the clinical trial used to license
13 Prevnar 7 compared it -- that then investigational
14 vaccine to another investigational vaccine;
15 correct?

16 A That's what that cross seems to imply to me,
17 but I haven't read the study, and I -- you know,
18 I -- I'm not an expert on this, and --

19 Q Fair enough. But you -- but -- you know,
20 you're proficient at reading package inserts
21 because you read them sometimes; correct?

22 A Yes.

23 Q Okay. And so -- and, you know, you've gone
24 through medical school and you've read lots of

1 studies; correct? So let's just scroll down and
2 see what other studies we can find. Here's
3 another one. And what was the control?

4 A Control group received concomitant vaccines
5 only in the same schedule as the Prevnar group.
6 So the control group was receiving the other
7 vaccines that I -- that were due to be given at
8 that same age, that they were comparing a group
9 who got all of their vaccines plus Prevnar and
10 just all of the, at that point, routine vaccines
11 is what it looks like to me.

12 Q And what is HbOC?

13 A That, I think, would be a -- so it's not
14 hepatitis B because hepatitis B is listed, so that
15 would be a HIB vaccine, haemophilus influenza type
16 B.

17 Q And removed from the market. Let me ask you
18 this. This investigational meningococcal group C
19 conjugate vaccine, right, the MnCC that was used
20 as the control in the main study here that they
21 did, was it ever licensed?

22 A I don't know the answer to that. I would
23 really need to look, you know, in more detail at
24 the study before I could give you, you know, a

1 well-informed comment about it.

2 Q Okay. Are you aware of any licensed
3 meningococcal group C conjugate vaccine?

4 A Not for group C alone, but there are vaccines
5 that are licensed outside the U.S., and I don't
6 know about that.

7 Q Okay.

8 A That -- the current vaccines in use here,
9 I -- my understanding are the ACWY and the newer
10 meningococcal B vaccine.

11 Q Now, after licensing Prevnar 7 by comparing
12 it to an investigational vaccine, here is -- this
13 is the package insert for Prevnar 13; correct?

14 A That's what it looks like.

15 Q Okay. Have you seen this before?

16 A I've looked at package inserts. I don't
17 recall reading any specifics of this one.

18 Q How many times would you say you've ordered
19 administration of Prevnar 13 in children and
20 babies?

21 A I've ordered thousands of doses of
22 Prevnar 13.

23 Q And there would be a package insert in every
24 one of the boxes of those vaccines; correct?

1 A There's a package insert, correct.

2 Q Okay. But you're not sure if this is the
3 package insert?

4 A No, I -- as I told you earlier, I don't read
5 the package insert. That's not where I go for my
6 information. I order vaccines. I go to the
7 American Academy of Pediatrics Red Book, UpToDate,
8 and other resources, continuing education
9 conferences to get my information. So only if I
10 have a specific question do I pull out the package
11 insert and go through that and try to find the
12 answer to the question at hand.

13 Q All right. Well, does the Red Book have
14 information about the clinical trials relied upon
15 to license these products given to Yates?

16 A It -- I -- it provides recommendations about
17 vaccinations. It doesn't give the -- this level
18 of detail about clinical trials.

19 Q Okay. Well, we're going to go through all
20 those other materials as well, but let's --
21 let's -- we're getting close to wrapping up the
22 pre-licensure stuff. So just taking a look at
23 Prevnar 13, just, you know -- so Prevnar 13, the
24 control uses Prevnar 7 in the clinical trials to

1 license Prevnar 13; correct?

2 A The control uses -- I don't know. I --

3 Q Okay. Let's go up. I mean -- so the safety
4 of Prevnar 13 was evaluated in 13 clinical trials
5 in 4,700 kids and toddlers receiving at least one
6 dose of Prevnar 13 and 2,700 approximately infants
7 and toddlers receiving at least one dose of --

8 A Prevnar active control.

9 Q Right. So Prevnar was the control.

10 A Right.

11 Q That means Prevnar 7; correct?

12 A Yes.

13 Q Okay. So let's scroll down now. And what
14 does it say it found in terms of serious adverse
15 events?

16 A You have highlighted serious adverse events
17 reported following vaccination in all infants and
18 toddlers occurred in 8.2 percent among Prevnar 13
19 recipients and 7.2 percent among Prevnar
20 recipients.

21 Q Now, serious adverse events means serious;
22 right? It's an FDA definition that means
23 hospitalization, it means death, it -- it's not --
24 you know, it wouldn't even include most autoimmune

1 and neurological issues; correct?

2 A No, I don't think so. I would want to know
3 exactly how they define serious adverse events.
4 They could mean fever over 102 or, you know -- I
5 mean -- no, I -- serious adverse events, certainly
6 I've been administering Prevnar. I haven't had
7 8.2 percent of my patients wind up hospitalized or
8 who died from Prevnar vaccine.

9 Q Well, you know, it could be because this
10 clinical trial actually looked at safety for six
11 months, right, instead of just 30 days. Check
12 this out. All right. What did they say?

13 A This reporting period is longer than the
14 30-day post-vaccination period. So -- so if
15 they --

16 Q Here's our explanation. You have one. Keep
17 reading. Go ahead. The longer --

18 A The longer reporting period may have resulted
19 in serious adverse events being reported in a
20 higher percentage of subjects than for other
21 vaccines. So -- you know, if a child is
22 hospitalized within a six-month period following a
23 vaccination, there are many explanations for
24 hospitalization.

1 Q Uh-huh.

2 A But a hospitalization is serious. But we
3 don't know that the vaccine caused that. That
4 child could have had, you know, a high fever or an
5 asthma attack or diarrhea and dehydration, and so
6 again, I need more information to know to be able
7 to give you an explanation for that.

8 Q Right. I mean, for example, if Prevnar 7 had
9 been licensed based on a clinical trial that
10 lasted six months and reviewed safety against the
11 placebo, then we could know what the serious
12 adverse event was from that clinical trial;
13 correct?

14 MR. SANDERS: Object to the form of the
15 question. You can answer, Dr. Mace, if you have
16 an answer.

17 A I just -- I -- I don't -- I don't know that
18 serious adverse event following vaccine
19 necessarily means causation, and I think that --

20 Q (By Mr. Siri) Well, yeah --

21 A I --

22 Q I'm sorry, please. Yes. It certainly
23 doesn't mean causation. Absolutely. Right. It's
24 just to risk. It doesn't mean causation. It

1 means you have -- and that's why you have clinical
2 trials. You have an experimental group and you
3 have a control group, and by having a placebo
4 control group, you can then compare the two to see
5 is there a difference, and that would give you an
6 answer on whether or not there was a causal
7 relationship; correct?

8 A That makes sense.

9 Q Okay. And so but since that wasn't -- that
10 wasn't done with Prevnar 7, right, because it
11 wasn't compared to a placebo control group;
12 correct?

13 A It was compared to a group of children who
14 received their routine vaccines without the
15 Prevnar. Is that -- is that right? Didn't we
16 look at that? One of the studies showed other
17 vaccines not including Prevnar, and it --
18 control kids -- compared kids receiving routine
19 vaccines and routine vaccines plus Prevnar.

20 Q And which categories of items did they look
21 at? Did they look for six months at serious
22 adverse events in this group? You probably want
23 to take a chance to look at it. I don't want you
24 to have to answer that. Why don't you read it and

1 you can see for yourself what it looked at; all
2 right? So coming back -- going back to the
3 Pevnar -- oops. You know what -- sorry. My only
4 point is this. Would you agree that Pevnar 13
5 was deemed safe even though 8.2 percent of
6 children had an adverse event following
7 vaccination, maybe causal, maybe not, because the
8 control group had a similar rate of serious
9 adverse events that were reported; correct?

10 A From this paragraph, that seems -- that seems
11 like a correct statement.

12 Q Okay. And here's the FDA website where it
13 defines what a serious adverse event is in
14 clinical trials. You now have an opportunity to
15 look at it so that you're aware of what it means.
16 It means death, life-threatening,
17 hospitalizations. Well, you can see for yourself.
18 I'll even mark this as an exhibit so that you have
19 it.

20 MS. CHEN: This will be Exhibit 11.

21 MR. SIRI: Thank you.

22 (Whereupon, Exhibit
23 No. 11 was marked to the
24 testimony of the

1 witness.)

2 Q (By Mr. Siri) Okay. So yes, you know,
3 serious adverse events do occur within clinical
4 trials, and it absolutely is important to
5 determine whether or not it's actually caused by
6 the vaccine; correct?

7 A I agree with that.

8 Q Yeah. But over here, do we know whether or
9 not Prevnar, the control, do we know what percent
10 of the 7.2 percent of serious adverse events that
11 happened in the control group were caused by
12 Prevnar?

13 A Please tell me that -- tell me that question
14 again.

15 Q No, no problem. I said, is there a way to
16 determine what percent of the 7.2 percent of
17 serious adverse events that happened in the
18 Prevnar group were actually caused by Prevnar?

19 A I think there are ways to try to get at that
20 piece of information. You know, again, people
21 who -- who devote their careers to doing research
22 into the -- of vaccines would be able to answer
23 that question more thoroughly than I can.

24 Q You're not able to determine that?

1 A I'm not able to tell you what percent of
2 those 7.2 were due to the Prevnar vaccine.

3 Q Okay. Can you take a look here at what is a
4 serious adverse event? And just tell me when
5 you're ready for me to scroll down.

6 (Whereupon, the witness
7 is reading the document.)

8 A Okay.

9 (Whereupon, the witness
10 is reading the document.)

11 A Okay.

12 Q Is it your opinion that somewhere between 7
13 and 8 percent of all infants and toddlers every
14 six months will develop a serious adverse event or
15 have a serious adverse event?

16 A No, that's --

17 Q Is that defined on this page?

18 A No, it's not.

19 Q Okay. Okay. All right. It would -- 6, 7 to
20 8 percent of -- when you say no, it's not, you
21 mean that 7 to 8 percent of infants and toddlers
22 every six months will not have a serious adverse
23 event in the United States in your experience?

24 A As defined by this, yes --

1 Q Okay.

2 A -- I do.

3 Q All right. The vaccine for DTaP, the DTaP
4 vaccine that Yates received was Infanrix; correct?

5 A I can look at the record, but it -- again, I
6 wrote down DTaP. I didn't write down the brand
7 name.

8 Q Oh. Any idea what the safety review period
9 was for Infanrix in its pre-licensure clinical
10 trial?

11 A I don't know that.

12 Q Okay. If it -- if its package -- if the --
13 if the safety review period in its pre-licensure
14 clinical trial was only 28 days, would you agree
15 that tracking safety for only 28 days after
16 administering this vaccine at 18 months of age
17 would not be long enough in the pre-licensure
18 clinical trial to determine whether or not that
19 product caused autism?

20 A I agree that that -- that 28 days is not
21 enough time to determine if something were to
22 cause autism.

23 Q And then, you know, let's -- so the -- the
24 last one is also for the MMR vaccine. Are you

1 aware that the pre-licensure clinical trial for
2 the MMR vaccine included less than a thousand
3 individuals receiving MMR vaccine?

4 A I don't know the numbers.

5 Q Okay. Are you aware that it only reviewed
6 safety for 42 days after licensure?

7 A I don't know those numbers.

8 Q Okay. But you would agree that if the MMR
9 vaccine only reviewed safety for 42 days after
10 licensure -- excuse me. If it only reviewed 42
11 days -- if it only reviewed safety for 42 days in
12 the clinical trial relied upon that product -- to
13 license that product, that clinical trial would
14 not have been able to determine whether or not MMR
15 caused or doesn't cause vaccine prior to
16 licensure; correct?

17 A Forty-two -- if -- one study with a period of
18 observation of 42 days wouldn't necessarily be
19 long enough to determine if something caused
20 autism. But again, these -- I think these studies
21 have to be looked in -- in the context of an --
22 additional studies and additional information.

23 Q Absolutely. Whole body -- okay. Let's
24 just -- I'm going to quickly pull up the clinical

1 trial if we have it. Just one second. I'm going
2 to ask you a question. All right. Okay. Have
3 you ever seen this document before?

4 A I don't believe I've ever seen this document.

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

9 Q (By Mr. Siri) Okay. The current -- are you
10 aware the current MMR vaccine was licensed in
11 1978?

12 A I don't know the date.

13 Q Do you know who Maurice Hilleman is?

14 A I do not.

15 Q Okay. Let me just ask you a question about
16 this. This is a summary of the clinical trials
17 that were relied upon to license the MMR vaccine.
18 You'll have an opportunity to review this because
19 you haven't. Do you see those number -- study
20 numbers in the first column?

21 A Yes, I see that.

22 Q And you see there's the number of vaccinees
23 where it lists the number of individuals that were
24 vaccinated in each of those studies?

1 A I see that.

2 Q Do you see that the total number of
3 individuals receiving it -- children receiving MMR
4 vaccine in the clinical trials relied upon in
5 licensing the MMR vaccine was 834 children?

6 A I see that number in that column. Again, I
7 don't know the whole context of all of the studies
8 and information, so I can't --

9 Q Yeah, that's entirely fair. You need an
10 opportunity to look at this. Let me ask you
11 something specific that doesn't require a lot
12 of -- require you to have preexisting knowledge;
13 okay? I apologize. All right. It's very
14 different doing a depo on Zoom, I'll tell you
15 that. Okay. Let me ask you a question. All
16 right. So over here it says Table 6; right? And
17 this doc -- and it represents that the maximum
18 temperatures reported among children who received
19 .5 ML dose of combined live measles, mumps,
20 rubella virus vaccine, do you see that?

21 A I do.

22 Q Okay. So based on what you're seeing on this
23 page, this would be a chart of the temperatures of
24 children in this particular study, 443, after

1 receiving MMR vaccine; correct?

2 A Yes.

3 Q Based on what you're seeing on this page.

4 A Yes.

5 Q Okay. And you see over here it says days
6 post vaccination?

7 A Yes.

8 Q Okay. Now, the first category is zero to
9 four days; right?

10 A Yes.

11 Q Okay. One child in this group of 102
12 children had a temperature between 103 and 104;
13 correct?

14 A Yes.

15 Q Similar number of children, at least in the
16 five to 12-day period, had a temperature of -- in
17 that range; right?

18 A Yes.

19 Q Okay. There were also seven children out of
20 102, that's around 7 percent; correct?

21 A Yes.

22 Q Had -- oh, 8 percent, it says. I -- I don't
23 know how that happened. I -- I didn't write this.
24 Had a temperature between 101 and 102.9; right?

1 A Yeah, I wonder if it's 7 percent and -- no,
2 you're right. It says percent above. At any
3 rate, yes, I see what you're pointing out.

4 Q Yeah. I -- well, in any event, you know, I
5 guess Merck is not infallible; huh? Okay. So
6 based on this, if you -- based on the results of
7 this study, do you believe children that developed
8 101 to 102.9 fever within zero to four days after
9 MMR vaccine, that fever could have triggered a
10 seizure in the same manner that maybe getting that
11 fever from something else could've triggered a
12 seizure?

13 A Sure. Fever can trigger seizures --

14 Q Okay.

15 A -- in children who are susceptible.

16 Q So do children who receive MMR develop fevers
17 in the first, you know, three days after
18 vaccination?

19 A Then really my understanding of the MMR
20 vaccine is that because it's a live virus and
21 replicates in the blood stream, that side effects
22 of the vaccine are typically going to show up
23 between eight and 21 days following vaccination,
24 though not typically within the first three days.

1 Q And so not typically within the first five to
2 12 days either?

3 A So five to 12 days you're getting into the --
4 into the eight, so five to 12 includes my -- my
5 cutoff of eight. I -- I explain to families that
6 they can expect fever and/or rash in between eight
7 to 21 days.

8 Q So in your experience, do some children spike
9 a fever in the first three days after getting MMR?

10 A Quite often we're giving MMR along with other
11 vaccinations, so I tell them, for instance, our
12 current practice is hepatitis A vaccine along with
13 MMR and chicken pox, I tell them that the
14 hepatitis A being a killed virus vaccine could
15 cause fever or rash within 48 hours and then the
16 MMR chicken pox vaccine could cause fever and rash
17 between eight and 21 days. And then there are
18 other things that can cause fever as well. A
19 child, you know, can pick up a viral illness
20 somewhere along the way or, you know, some other
21 infection or illness.

22 Q Let me ask you something. Do you think 834
23 children total at that -- to license a vaccine is
24 well powered to detect anything but maybe the

1 absolute most common adverse reactions?

2 MR. SANDERS: Object to the form. You
3 can answer, Dr. Mace, if you have an answer.

4 A Yeah, I'm not a statistics expert. I really
5 couldn't address how many it takes. It -- you
6 know, it depends -- it depends on the frequency of
7 the reaction that you're looking for. I think
8 your point is that if it's a very rare potential
9 side effect, it would take larger numbers of
10 patients that I would expect to determine
11 something like that.

12 Q (By Mr. Siri) Do you know what the control
13 was in these studies with the 834 kids total?

14 A I do not.

15 Q Okay. Do you see where -- do you see a
16 listing in a control group in this page where it
17 summarizes the trials?

18 A Well, I've got such a limited view here that
19 I -- I'm not seeing anything on this page.

20 Q All right. You'll have a chance to review
21 that before trial. So let me ask, and I -- do you
22 ever prescribe any type of drugs other than
23 vaccines?

24 A I do.

1 Q Okay. Do you ever -- have you ever
2 prescribed a drug, for example, Enbrel?

3 A I don't prescribe Enbrel.

4 Q Because that's a drug typically given to sick
5 adults; correct?

6 A Yes.

7 Q Sick adults with rheumatoid arthritis; right?

8 A I believe that -- that Enbrel is a drug for
9 rheumatoid arthritis.

10 Q All right. Typically not given to children?

11 A Unless they have a rheumatologic disorder,
12 and that would be managed by someone other than
13 me.

14 MR. SIRI: So I'm going to mark this as
15 Plaintiff's -- is it 9?

16 MS. CHEN: Exhibit 13.

17 MR. SIRI: Oh, 13. Thank you.

18 MS. CHEN: Yes.

19 (Whereupon, Exhibit
20 No. 13 was marked to the
21 testimony of the
22 witness.)

23 Q (By Mr. Siri) And so this looks like most
24 package inserts you've seen; correct?

1 A Yes.

2 Q And this is Enbrel; correct?

3 A Yes.

4 Q Okay. And as is typical, we would go down to
5 Section 6.1 to see the clinical trial studies
6 experience; right?

7 A Yes.

8 Q Okay. So I want to go down there and take a
9 look at how long safety was reviewed. Probably
10 this drug was licensed to get to sick adults.
11 Here's one of the studies. What does it say?

12 A The data described below reflect exposure to
13 Enbrel in 2219 adult patients with RA followed for
14 up to 80 months.

15 Q Okay. So in this study, they followed
16 through the clinical trial experience for adverse
17 reactions, for safety, they followed them for 80
18 months; correct?

19 A That's what that says, yes.

20 Q Do you have any reason to doubt that that's
21 not accurate?

22 A No.

23 Q All right. Now, when you made -- I believe I
24 asked you earlier whether or not was your opinion

1 that none of the vaccines that Yates received
2 causes autism and you said yes, it's your opinion
3 that none of the vaccines Yates -- that Yates
4 received individually or collectively causes
5 autism. Is that correct?

6 A That's correct.

7 Q Okay. So just to make sure your testimony --
8 I'm clear on your testimony, so your testimony is
9 that the MMR vaccine cannot cause autism. Is that
10 correct?

11 A The MMR vaccine does not cause autism.

12 Q Okay. Is it true to say that the MMR vaccine
13 cannot cause autism?

14 A Yes.

15 Q Is it your testimony that the HepB vaccine
16 cannot or does not cause autism?

17 A Does not cause autism.

18 Q Well, what's the difference between cannot
19 and does not? I'm not trying to be tricky about
20 it. I'm not sure.

21 A I -- I -- cannot sort of implies is any --
22 you know, is there any -- any possibility, you
23 know, and I -- I don't believe that these
24 vaccines -- it is my opinion that these vaccines

1 do not cause autism, so -- so if that --

2 Q Okay. But it's possible they could, you're
3 saying?

4 A I don't think so.

5 Q But you're not 100 percent sure?

6 A I'm way -- you know, I mean, my degree of
7 medical certainty is that they do not cause
8 autism.

9 Q Okay. Are you familiar that the CDC, for
10 example, puts on its website vaccines do not cause
11 autism?

12 A You know, I look at lots of things on the CDC
13 website. I don't know that I -- you know, I --
14 I -- I don't know that I've seen that in big block
15 letters.

16 Q Have you ever heard vaccine experts on TV
17 saying definitively vaccines do not cause autism?

18 A Probably, yes.

19 Q Okay. So what you're saying is that -- your
20 opinion is that they probably don't cause autism,
21 but you're not sure?

22 MR. SANDERS: Object to the form.

23 A No, my opinion is that they do not cause
24 autism.

1 Q (By Mr. Siri) Okay. So your testimony is
2 that the MMR vaccine does not cause autism.

3 A Correct.

4 Q And your testimony is that the HepB vaccine
5 does not cause autism.

6 A Correct.

7 Q Okay. But your testimony is not that it
8 cannot cause autism; correct?

9 A I -- you know, I -- I think if I believe it
10 does not cause autism then I have to believe that
11 it cannot cause autism. It's -- you know, it's
12 semantics. It's how we are comfortable saying
13 things. I -- I -- I -- it is my opinion that
14 vaccines do not cause autism.

15 Q Is it your testimony that IPOL cannot cause
16 autism?

17 A Correct, yes.

18 Q Okay. Is it your testimony that HIB vaccine
19 cannot cause autism?

20 A Does not cause autism, yes. I would say does
21 not cause autism for all of these.

22 Q But are you saying it also can -- they --
23 none of them can cause autism as well?

24 A Yes, yes. I agree with that statement. They

1 cannot.

2 Q All right. Let me put it this way. Do you
3 think that maybe there are rare exceptions in
4 which they could cause autism?

5 A I don't think vaccines cause autism, no. I
6 think that the causes of autism are complex.

7 Q Okay. Do you -- do you think there are rare
8 exceptions in which vaccines could be a
9 contributing factor to causing autism?

10 MR. SANDERS: Object to the form of the
11 question. Asked and answered.

12 Q (By Mr. Siri) Go ahead, Dr. Mace. Please
13 answer.

14 MR. SIRI: And it was not asked and
15 answered.

16 Q (By Mr. Siri) Please go ahead, Dr. Mace.

17 A No, I don't think that vaccines -- so phrase
18 the question -- just tell me -- tell --

19 Q Sure, no problem. So no problem.

20 MR. SIRI: And, you know, I know that
21 that's a question that -- that -- that maybe the
22 other side doesn't like being asked, but your
23 objection is already on the record, so I ask, you
24 know, that it not be used again to coach the

1 witness.

2 Q (By Mr. Siri) I just -- I was asking you, do
3 you think there are potentially rare exceptions in
4 which vaccines, one or more, could be a
5 contributing factor --

6 MR. SANDERS: Same objection.

7 Q (By Mr. Siri) -- that --

8 MR. SIRI: You've got to let me finish
9 the question, and I know you don't like the
10 question, but, you know, you've got to let me
11 finish the question. And if you -- and if you
12 want to object, just object to the form. You
13 know, the asked and answered, I think, kind of
14 signals to the witness that she shouldn't answer
15 when she -- when, of course, she's required to.

16 Q (By Mr. Siri) Okay. With that said, what
17 I'm asking you is, is that could there be
18 exceptions in which any of the vaccines that Yates
19 received could have been a contributing factor to
20 causing his autism?

21 MR. SANDERS: Same objection.

22 A I don't think so, no.

23 Q (By Mr. Siri) But you're not completely
24 sure; correct?

1 A No, I -- I don't think that vaccines were --
2 could be a contributing factor to the cause of his
3 autism.

4 Q Do you think vaccines can ever be a
5 contributing factor to the cause -- to causing
6 autism in a child?

7 A No, I don't think vaccines are a contributing
8 factor to the development of autism in children.

9 Q Do you think it could be a contributing
10 factor in rare instances?

11 MR. SANDERS: Same objection. Asked and
12 answered.

13 A I -- I don't think so. I -- I -- I don't
14 think so. I think there are experts in the field
15 of vaccinations that -- and especially in rare
16 circumstances who have looked at this question and
17 have concluded that vaccines are not a
18 contributing cause to autism.

19 Q (By Mr. Siri) Okay. So you're basing your
20 conclusion on their opinion?

21 A My training, my experience, looking at the
22 literature, and the opinion of experts that I
23 think have good experience in this -- in
24 addressing this specific question.

1 Q All right. Now, we -- earlier, we talked
2 about hepatitis B vaccine, and -- and you
3 testified that there is no study that supports a
4 hepatitis B vaccine does not cause autism.

5 A No studies that I'm aware of. I haven't
6 looked at that specific question.

7 Q Are you aware of any study that supports that
8 IPOL does not cause autism?

9 A I am not.

10 Q Are you aware of any study that HIB vaccine
11 does not cause autism?

12 A I'm not, but -- you know, I haven't looked at
13 the typical resources I look at, but no, I'm not
14 aware of any studies.

15 Q Okay. Are you aware of any vaccine -- any
16 studies that support that the Prevnar vaccine does
17 not cause autism?

18 A I am not.

19 Q Are you aware of any test -- any studies that
20 DTaP vaccine does not cause autism?

21 A I am not off the top of my head, no.

22 Q All right. So you haven't seen -- reviewed
23 any such studies, but you've already reached your
24 conclusion that vaccines don't cause autism. Is

1 that correct?

2 A Based -- yes. Based on experience and based
3 on literature that's reviewed by the American
4 Academy of Pediatrics Committee on Infectious
5 Diseases, I look at the Children's Hospital of
6 Philadelphia website and other resources for
7 information about that.

8 Q Okay. So let's take that in pieces. So you
9 based your opinion on the Children's Hospital of
10 Philadelphia website. Is that right?

11 A That's one factor that I look at to help
12 understand, yes.

13 Q Okay. Okay. What would be -- is there any
14 other factor? You said other factors. I want to
15 make sure I take them in pieces. What other
16 factors?

17 A The continuing education conferences,
18 discussions with other pediatricians, review of
19 the information by the CDC, the pediatric
20 Red Book. There's the AAP website,
21 healthychildren.org has a review that lists a lot
22 of articles, studies about vaccine safety.

23 Q And you reviewed all these sources; correct?

24 A I -- I have looked at those resources, yes.

1 Q Okay. Because you're here as an expert
2 testifying that the vaccines Yates received did
3 not cause his autism; right?

4 A That's right.

5 Q All right. Okay. And so in reviewing all of
6 those, you didn't actually see any studies for any
7 of the vaccines Yates received other than the MMR;
8 right?

9 A Well, there are no studies that show that
10 they do cause autism. You know, not every
11 question can be looked at. We could think of
12 some, you know, something is -- doesn't -- isn't
13 proven that it doesn't cause something doesn't
14 mean that it does.

15 Q Okay. I mean, usually there has to be some
16 concern raised, right, that the product causes
17 that injury before, I guess, research is
18 conducted?

19 A Sure. There needs to be a scientific
20 plausibility to the question and there needs to be
21 concern raised about -- about an adverse event or
22 reaction.

23 Q What else? What if parents are coming and
24 stating they believe that, you know, based on

1 their parental experience, their intimate
2 knowledge of their child, their child changed
3 after getting certain vaccines and they believe
4 the vaccine was the cause, would that be a cause
5 to conduct studies to see if the vaccines were the
6 cause?

7 A I -- you know, I -- I'm not an expert on
8 those sorts of decisions. Again, I rely on the
9 consensus statements by the American Academy of
10 Pediatrics and others to come to my conclusion as
11 a primary care general pediatrician.

12 Q You just trust their conclusory -- their
13 conclusions regarding these things?

14 A When there's an overwhelming amount of
15 information and evidence, yes.

16 Q Do you review that information and evidence?

17 A I review summaries of the evidence. You
18 know, as a general pediatrician I look at
19 consensus statements and committee reports and
20 those sorts of things, but I don't -- I'm not a
21 researcher who digs into the details of all of the
22 studies.

23 Q Okay. Like, for example, when something
24 becomes a concern, you know, maybe the HHS or CDC

1 will conduct a study to see if there's a
2 relationship; correct?

3 A That seems like a reasonable process, yes.

4 Q Sometimes they'll ask the IOM to review
5 whether or not there's a connection between the --
6 you know, let's say the vaccine and the claimed
7 adverse events; correct?

8 A Well, I'm not sure of the process of the IOM
9 deciding to study a topic, but they -- yes.

10 Q What's your understanding of when parents
11 first started complaining about any vaccine
12 causing autism?

13 A Is this a general question?

14 Q Yeah, I'm asking about you -- your personal
15 understanding. I mean, you've been a pediatrician
16 for 30 years, and so, you know -- you know, in
17 your experience, when did the -- what's your
18 understanding of when parents began to complain
19 about when vaccines -- what -- what's your
20 understanding of when parents began complaining
21 about, you know, one or more vaccines causing
22 autism?

23 A My understanding is that some of the concern
24 was linked to the study published in Lancet by

1 Andrew Wakefield, that he did a study that was
2 later retracted that -- that tried to link the MMR
3 vaccine to autistic symptoms and gastrointestinal
4 symptoms in children who had been diagnosed with
5 autism.

6 Q What year was that study published? Do you
7 know?

8 A I don't have that on the top of my head.

9 Q Would 1998 sound about right to you?

10 A Yeah, late 1990s seems reasonable.

11 Q Okay. So that's -- you know, that --
12 that's -- do you think that if you asked more
13 pediatricians, that's the answer you'd get?

14 A In terms of when it was brought to light and
15 people started asking more questions, I would
16 think probably yes. I mean, vaccine safety has
17 been a topic that I've discussed with families
18 throughout my entire career. I, you know, would
19 talk to families before those studies about
20 vaccines and what they protected children from and
21 what -- you know, what was to be administered, and
22 I don't know how quickly the -- you know, that
23 study was publicized. I remember though that, you
24 know, we -- you know, our -- well, I can say we

1 are asked more questions, you know, in more recent
2 years since that study was published about the MMR
3 and autism.

4 Q Were concerns raised before Wakefield's study
5 regarding whether vaccines caused autism?

6 A I don't recall.

7 Q Okay. But you don't believe they were?

8 A Yeah, I -- I don't -- I don't know the answer
9 to that.

10 Q Are you aware that in the 1986 Act, Congress
11 required the federal health authorities to review
12 whether pertussis-containing vaccine caused
13 certain adverse events?

14 A I know that there were concerns back in the
15 1980s with the whole-cell pertussis vaccine,
16 and -- and my recollection would be that concerns
17 about adverse reactions, that that vaccine may
18 have contributed to the development of the
19 1986 Act because drug manufacturers were becoming
20 less willing to produce the vaccine.

21 Q Right.

22 A They wanted to try to -- to be able to
23 maintain a vaccine supply for children so they
24 could be protected.

1 Q All right. All vaccine manufacturers for
2 DTP, for example, had either withdrawn from the
3 market or gone bust because of liability from
4 injuries before the passage of the '86 Act except
5 for one; correct?

6 A My understanding is that there was only one
7 left producing the vaccine --

8 Q All right.

9 A -- in the passage of that act.

10 Q And there was only one company producing an
11 MMR vaccine before the passage of the '86 Act,
12 Merck; correct?

13 A I don't know the answer to that, but --

14 Q Yeah, and there was only one other vaccine
15 that was routinely recommended, and do you -- at
16 that time before -- right before '86. Do you know
17 what that was?

18 A I would assume it would be oral polio.

19 Q That's right, OPV, and then there was -- are
20 you aware there's only one company left producing
21 oral polio vaccine today?

22 A No, I wasn't.

23 Q The rest of them had all gone out of business
24 or withdrawn because of liability for injuries.

1 Are you aware of that?

2 A Because of concerns about liability and --
3 yes.

4 Q Weren't they being sued -- weren't there --

5 A I don't know the details.

6 Q Fair enough. But parents were demanding
7 studies because of injuries that they were
8 claiming were being -- were occurring from the
9 then whole-cell pertussis, tetanus, and diphtheria
10 vaccine; correct?

11 A That's my understanding, yes.

12 MR. SIRI: Okay. I'm going to mark this
13 as plaintiff's -- is it --

14 MS. CHEN: Exhibit 14.

15 MR. SIRI: Thank you.

16 (Whereupon, Exhibit
17 No. 14 was marked to the
18 testimony of the
19 witness.)

20 Q (By Mr. Siri) There's a section of -- this
21 is the -- this is the law called the National
22 Childhood Vaccine Injury Act of 1986; okay? And
23 what I've done is I've just excerpted the one page
24 where Congress directed certain studies be

1 conducted. Would you kindly read the yellow?

2 A The Secretary of Health and Human Services
3 shall complete a review of all relevant medical
4 and scientific information on the nature,
5 circumstances, and extent of the relationship, if
6 any, between vaccines containing pertussis,
7 including whole cell, extracts, and -- oh, sorry,
8 and the following illnesses and conditions, and
9 number 9 is autism.

10 Q Right. And so, you know, as we talked about,
11 parents were complaining that this vaccine caused
12 certain conditions, demanded studies, and one of
13 the conditions these parents were complaining this
14 vaccine was causing was autism; correct?

15 A That's what -- yes.

16 Q Okay. Are you aware then that in 1991 the
17 Institute of Medicine issued its report on whether
18 or not pertussis-containing vaccine causes autism?

19 A I have not seen that.

20 MR. SIRI: This is going to be
21 Plaintiff's 15. Oh, wait. Sorry. I'm going to
22 let you do it, Patricia. Thank you.

23 MS. CHEN: This is Plaintiff's
24 Exhibit 15.

1 (Whereupon, Exhibit
2 No. 15 was marked to the
3 testimony of the
4 witness.)

5 Q (By Mr. Siri) Okay. Have you seen this IOM
6 review before?

7 A If I -- it -- yeah. If I have seen it, I
8 have not studied the details of it.

9 Q Have you seen the Institute of Medicine
10 reviews before regarding vaccine safety?

11 A From 1991.

12 Q Right. Have you seen any Institute of
13 Medicine reviews regarding vaccine safety?

14 A I don't recall any specific.

15 Q So this is -- and, you know, I presume that
16 these types of studies, you're aware, typically
17 have a summary of the conclusions that are reached
18 in the study; correct? In the review; correct?

19 A Yes.

20 Q Okay. And -- and I -- what's on the page
21 would be the summary from the 1991 IOM report;
22 correct?

23 A As far as I can see, yes.

24 Q Fair enough. What was the causality

1 conclusion regarding whether or not DPT vaccine
2 causes autism?

3 A Conclusion, no evidence bearing on a causal
4 relation, and then there's a Footnote C.

5 Q Which reads, no category of evidence was
6 found on a judgment about causation, all
7 categories of evidence left blank in Table 1,
8 meaning they couldn't find any study whatsoever
9 whether or not this vaccine did or did not cause
10 autism; correct?

11 A I would have to read the report to -- to say
12 exactly what that means.

13 Q Okay. There is a Category 2; correct?

14 A I'm sorry?

15 Q Do you see there's a Category 2 for
16 conclusion?

17 A Yes.

18 Q What's that?

19 A Evidence insufficient to indicate a causal
20 relation.

21 Q What would that mean to you?

22 A That there wasn't enough evidence to
23 determine cause.

24 Q Meaning there was some evidence, but not

1 enough to reach a conclusion; right?

2 A Yes.

3 Q As opposed to maybe no evidence bearing on a
4 causal relation; right?

5 A That's what that appears to say.

6 Q Yeah, okay. So 1991, parents are claiming --
7 1986, 1991, parents are claiming
8 pertussis-containing vaccine, including diphtheria
9 and tetanus, are causing autism. No studies are
10 available. And nonetheless, are you aware that
11 20 years later the claim that pertussis, including
12 acellular pertussis vaccine, was causing autism
13 remained one of the most commonly claimed injuries
14 from vaccines?

15 A I don't know data on claims.

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

20 Q (By Mr. Siri) Have you seen this report from
21 the IOM from 2011?

22 A Is that the most recent report?

23 Q They have a number of reports. This is the
24 most -- this is the most recent report that was

1 comprehensive or reviewed over 150 potential
2 adverse events for certain vaccines, if that jogs
3 your memory.

4 A So I think I'm familiar with that, but I
5 haven't read the whole thing.

6 Q Okay. Do you recall that in this report the
7 IOM looked at whether autism was caused by
8 diphtheria tetanus, tetanus tetanus, and acellular
9 pertussis-containing vaccines?

10 A I see that here.

11 Q Do you know what they concluded?

12 A I do not.

13 Q What do you think they concluded?

14 A I can't speculate about that.

15 Q Well, why don't we just jump to the causality
16 conclusion? Why don't you take a look at it.

17 A Can you make it a little bit bigger?

18 Q Oh, yes. How is that?

19 A So the Institute of Medicine says the
20 evidence is inadequate to accept or reject a
21 causal relationship between diphtheria toxoid,
22 tetanus toxoid, or acellular pertussis-containing
23 vaccine in autism.

24 Q All right. So let's go back up. They look

1 at epidemiological evidence. Take a look at this.
2 They did find only one study; correct? Is
3 that fair?

4 A Yes.

5 Q Okay.

6 A They reviewed a lot.

7 Q Now, it -- well, that's because they could
8 only identify one study. That was the whole point
9 of this review, correct, was to identify relevant
10 studies?

11 A Sure.

12 Q Isn't that what you do in a review?

13 A You -- yes, you look for studies that are
14 relevant.

15 Q Okay. And so they identified one, Geier and
16 Geier. Do you know -- are you aware that what
17 Geier and Geier found was that there was an
18 association between DTaP vaccine and autism?

19 A So I -- I don't know a lot about Dr. Geier's
20 findings.

21 Q Okay. Was there any other study that they
22 found that beared on the epidemiological -- any
23 other epidemiological study that they found to
24 answer the question of whether or not DTaP vaccine

1 causes autism?

2 A This doesn't list any additional studies.

3 Q Okay. And similarly, they didn't find any
4 mechanistic evidence on whether or not vaccines --
5 DTaP vaccines one way or another causes autism;
6 correct?

7 A That's what it says, yes.

8 Q Okay. So and as -- as -- as you've -- you --
9 and as you've said, you know, and as you've
10 honestly said, you've also never seen, because as
11 the IOM has found, there's no study on whether or
12 not DTaP does or does not cause autism; correct?

13 A That's -- I agree with that.

14 Q Okay.

15 A I haven't seen any studies.

16 Q Okay. So don't you think that you should
17 wait until you actually have the science, at least
18 one study that supports that DTaP vaccine does not
19 cause autism before you say that DTaP vaccine does
20 not cause autism?

21 A These are incredibly important questions. My
22 opinion is based on the information that is
23 available to me.

24 Q So are -- do you have any study that supports

1 that DTaP vaccine does not cause autism?

2 A Do I have any study -- I do not have a study
3 that says DTaP doesn't cause autism.

4 Q So shouldn't you wait, as a matter of
5 integrity, science, and shouldn't you wait until
6 you do have a study, until you do have mechanistic
7 evidence, until you have some epidemiological
8 evidence, until you have support that DTaP does
9 not cause autism before you claim that DTaP
10 vaccine does not cause autism?

11 A You're asking a great question. I think that
12 there -- there are reasons that the ACIP and the
13 Red Book and others have -- and -- and the vaccine
14 experts have said, and so I'm basing my -- my
15 opinion on that of -- of other experts and my
16 review of -- of literature.

17 Q Have you ever seen an expert say that the
18 DTaP vaccine does not cause autism?

19 A I don't know -- I -- you know, a specific
20 quote of a time and an occasion, no.

21 Q Have you ever read anywhere that DTaP vaccine
22 does not cause autism in any of these
23 conclusory --

24 A I've never -- yeah, I've never read that DTaP

1 vaccine does cause autism or that there have been
2 studies that support that it does.

3 Q Okay. So there's -- and I'll show you two
4 more, but here's one study by Geier and Geier
5 supporting it does. There are no studies
6 supporting that it doesn't. This is the Institute
7 of Medicine conducting a comprehensive review of
8 the literature; correct?

9 A That's what this appears to be, yes.

10 Q Okay. That's what they're -- that's what
11 they're hired by the CDC and HRSA to do, is to
12 look comprehensively at the literature. Let me --
13 strike that. Look, when you say that vaccines
14 don't cause autism, what you really mean is that
15 MMR vaccine doesn't cause autism. Isn't that
16 right?

17 MR. SANDERS: Object to the form of the
18 question. You can answer, Dr. Mace.

19 A I don't believe any vaccines cause autism.

20 Q (By Mr. Siri) What is your proof that DTaP
21 vaccine does not cause autism? What is it that
22 you have found that the IOM could not find, that
23 the Agencies for Health Research and Quality a few
24 years after this report could not find, nor that

1 the HHS could find -- strike all of that. What
2 evidence do you have -- let me -- what evidence do
3 you have that DTaP vaccine does not cause autism
4 that the IOM wasn't able to identify?

5 A I don't have specific evidence.

6 Q All right. So you don't have any evidence
7 that DTaP vaccine does not cause autism?

8 A I -- I can't quote you specific evidence for
9 that.

10 Q Okay. You similarly don't have any evidence
11 that any of the other vaccines that Yates
12 received, let's leave MMR on the side for a
13 moment, you have no evidence that any of those
14 don't cause autism; right?

15 A And I don't have any evidence that they do
16 cause autism.

17 Q All right. But you're claiming they don't
18 cause autism; correct?

19 A I am saying that, yes.

20 Q Without evidence; correct?

21 A I can't quote you specific evidence.

22 Q Meaning you're just guessing there's
23 evidence?

24 A I'm not guessing. I'm basing it on

1 experience and training and -- and other experts.

2 Q Isn't evidence just evidence? How does
3 evidence materialize from -- I -- okay. Strike
4 that. You know, isn't that what parents of
5 injured children say, that's our experience, and
6 the medical community says, we can't trust that?

7 A Parents -- parents have -- have beliefs and
8 concerns, and those need to be taken seriously.
9 You know, we have lots of studies that have shown
10 that, you know, autism is not cause -- that --
11 that we -- we don't have any scientific studies
12 that say that autism is caused by vaccines.

13 Q Let's go there. But before we do that, I'm
14 going to say one other thing. We're going to do
15 this based on experience. Who spends more time
16 with the children that you treat, you or their
17 parents?

18 A A parent spends more time with an individual
19 child certainly, but I spend time with large
20 numbers of children.

21 Q But unless you do an actual study, correct,
22 that is -- let me finish -- that's properly
23 controlled, all right, and scientifically valid,
24 you're not supposed to draw an actual scientific

1 conclusion based on that, are you?

2 MR. SANDERS: Object to the form of the
3 question. You may answer, Dr. Mace.

4 A We try very hard to use evidence for every
5 decision that we make, and sometimes there is a
6 lack of evidence, and we use experience and get
7 input from others including our -- our experts to
8 help us make these decisions.

9 Q (By Mr. Siri) So are you saying that the
10 fact that you see many kids for a very short
11 duration of time is more valuable, more reliable
12 than, let's say, what 40 to 50 percent of parents
13 of autistic children are saying about their
14 experience with their children?

15 MR. SANDERS: Object to the form of the
16 question. You may answer, Dr. Mace, if you have
17 an answer.

18 A I think parents of autistic children have
19 really important insight into their own child and
20 their condition. In terms of causality, I don't
21 know that they are able to put it in context and
22 determine the actual -- I mean, they can -- they
23 can talk a lot about timing of the onset of
24 symptoms and what the symptoms are, but that

1 doesn't necessarily establish causality.

2 Q (By Mr. Siri) What they should do is look at
3 the science; right?

4 A Science is important.

5 Q Look at the studies; right?

6 A Science and studies are important.

7 Q Yeah. And so if they went out and they tried
8 to see what studies exist regarding all the
9 vaccines that Yates received, again, putting MMR
10 aside for a moment, we'll get to that too, let's
11 take a look at what they might find; okay? I'm
12 going to mark -- now, sorry. Typically the way
13 that studies are often done is they compare an
14 exposed to an unexposed group, right, and you see
15 the differential; yeah?

16 A Yes. Some studies are done that way, yes.

17 Q Okay. Well, now, this is -- I'm going to
18 tell you beforehand, this is a pilot study; all
19 right? And I will tell you readily that this
20 study is based on parental surveys, meaning it's
21 got recall bias, right, and so forth. But in
22 looking at this study, I'll want you to tell me so
23 you have an opportunity before I ask the question,
24 to let me know if there's any other study that

1 shows this study is not correct. So have you seen
2 this study before?

3 A I've not seen this study before.

4 Q Okay. So this is a pilot comparative study
5 of the health of vaccinated and unvaccinated
6 children 6 to 12 years old in the United States.
7 That's what the title says; right?

8 A Yes.

9 Q And it's out of the Department of
10 Epidemiology and Biostatistics School of Public
11 Health, Jackson State University; correct?

12 A Yes.

13 Q Epidemiologists and biostatisticians would be
14 the right people to conduct a study, a
15 retrospective study comparing health between
16 vaccinated and unvaccinated children; correct?

17 A They would be reasonable people to conduct a
18 study like that, yes.

19 Q Okay. Are you familiar with the School of
20 Public Health at the Jackson State University?

21 A I am not.

22 Q Okay. Now, there was a -- there was only,
23 you know, 600-something children, like I said,
24 parental surveys, you know, and you can have

1 all -- it's got a bunch of disclaimers about
2 those, right, as all epidemiological retrospective
3 studies do, right, there are always -- you have to
4 try and control for confounders; correct?

5 A Yes.

6 Q Okay. And I -- you know, you can read this
7 study, you'll have a chance now because it's been
8 marked, they tried to do that. Let's see what
9 they found, shall we? Okay. So taking a look at
10 this page, they compared the rate of chicken pox
11 between the vaccinated and unvaccinated; correct?

12 A Yes.

13 Q And they found that the vaccinated actually
14 had -- the unvaccinated had, what, about four
15 times the rate of chicken pox; correct?

16 A Yes.

17 Q And it was statistically significant; right?

18 A Yeah, I -- I'm -- I can't comment on the
19 power, all -- et cetera, but --

20 Q Well, but based on what's here, the .2 to .4,
21 it's both under one at a .2 -- I mean, I'm just
22 saying, based on what you see in front of you,
23 it's representing just those significant; correct?

24 A Yes.

1 Q And then in terms of whooping cough,
2 pertussis -- whooping cough, pertussis, again, it
3 found that the vacc -- the unvaccinated kids had,
4 what does it look like, about three times the rate
5 of pertussis; correct?

6 A Yeah, the odds -- yeah, the odds ratio of
7 .03.

8 Q Yeah, and that was statistically significant
9 too; right?

10 A Yeah. It has a significant P value.

11 Q Okay. It also looked at autism spectrum
12 disorder between the vaccinated and unvaccinated.
13 Do you see what it concluded?

14 A It has a report of autism spectrum disorder
15 that is higher in the vaccinated children compared
16 to the unvaccinated group.

17 Q All right. 4.2 times higher; correct?

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

19 Q Now, with -- you know, given whatever
20 limitations this study has, as a general matter, a
21 finding of four times risk is a huge difference in
22 these types of studies, isn't it?

23 A Well, you know, it -- I can't comment
24 specifically on whether this study, you know,

1 proves something without bigger context of the
2 situation.

3 Q Well, it's an epidemiological study, right,
4 so they generally can't prove causation, can they?

5 A Right.

6 Q I mean, if you want to prove causation, you
7 need to do a placebo controlled clinical trial
8 typically; correct?

9 A Correct.

10 Q I mean, you -- you know, like, if you want to
11 know, for example, is one thing causally related
12 to another, typically what you've got to do is
13 compare those receiving it to those not receiving
14 it blinded prospectively and then seeing the
15 outcome; correct?

16 A That's in an ideal situation, yes.

17 Q Ideal. Fair. Okay. So by the way, isn't it
18 true that every single stud -- MMR study relied
19 upon to claim that MMR can cause autism are all
20 epidemiological?

21 A I -- you know, I can't tell you that every
22 single study that looked at MMR and autism.

23 Q Well, we'll take a look at the IOM report;
24 right? It lists every one of them. It threw all

1 of them out except four; right? It found every
2 single study that was done on MMR causing autism,
3 they were all retrospective epidemiological;
4 right? They found no mechanistic evidence and it
5 only found four to be reliable and they were all
6 retrospective epidemiological. Are you aware of
7 that?

8 A I don't recall the details of that, no.

9 Q All right. We'll come back to that. So a
10 parent -- let's go back to this parent who's got,
11 you know, the -- all these parents who based on
12 their experience, you know, they're -- they're
13 with their kid every day, especially when they're
14 little, you know, I've got -- I have a little --
15 my kids are getting bigger, they don't want to
16 spend as much time with me, but when they were
17 little, I spent a lot more time with them. All
18 right. Based on their experience with them, so
19 they -- you're saying, well, you know, parents
20 experience, or whatever you said, it's on the
21 record, and I said to you, yeah, well, they should
22 look at the science, and you said, yes, but
23 there's no science, but here's a published study
24 actually that they went out, right, and this is

1 relatively recently that does show a -- that
2 children who have been vaccinated compared to
3 unvaccinated in a pilot study have four times the
4 risk of autism; correct?

5 A That's what this study says, yes.

6 Q Do you have any study comparing vaccinated
7 with unvaccinated children to dispute this study?

8 A Off the top of my head, I can't tell you
9 that.

10 Q Okay. Isn't it true that no study of
11 vaccinated and unvaccinated children that doesn't
12 show a difference in autism rates exist?

13 A I can't answer that question.

14 Q You never looked?

15 A Well, there's lots of -- I've looked at lots
16 of studies, but I don't have them memorized and
17 exactly how many patients were enrolled and all of
18 that.

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

20 (Whereupon, Exhibit

21 Nos. 17 and 18 were

22 marked to the testimony

23 of the witness.)

24 Q (By Mr. Siri) So this is out of the same

1 group. It's from the same, you know, parental
2 surveys, and this one looks specifically at
3 preterm birth and neurodevelopmental disorders.
4 Can you read what this -- what it found in the
5 abstract?

6 A This study says, no association was found
7 between preterm birth and neurodevelopmental
8 disorders in the absence of vaccination, but
9 vaccination was significantly associated with
10 neurodevelopmental disorders in children born at
11 term.

12 Q Right.

13 A Odds ratio 2.7, 95 percent confidence
14 interval 1.2 to 6.

15 Q All right. So that's okay. Read the next
16 sentence.

17 A However, vaccination coupled with preterm
18 birth was associated with increasing odds of
19 neurodevelopmental disorder ranging from 5.4
20 compared to vaccinated but non-preterm children at
21 14. -- to 14.5 compared to children who were
22 neither preterm nor vaccinated. Honestly, I need
23 to read this and --

24 Q Absolutely. You should. And you should have

1 an opportunity to look at it. I'm not asking you
2 to agree to it. You should have a chance to take
3 a look at it. But I'm just showing you this study
4 does exist in the literature and you'll have a
5 chance to read it. What it does claim though was
6 that children that were born preterm and
7 vaccinated have 14.5 times the rate of
8 neurodevelopmental disorders compared to children
9 who were neither preterm nor vaccinated; correct?
10 I mean, that's what it's saying.

11 A That's what it says.

12 Q Okay. But you've never seen this before;
13 right?

14 A Correct.

15 Q Okay. We also looked at the -- there was an
16 AHRQ report that we looked at before that's been
17 marked. There was a study of HepB vaccine that
18 found in kids that got HepB in the first month
19 of -- one had -- three months of life had three
20 times the rate of autism compared to those that
21 didn't; correct?

22 A I didn't write down any notes about that
23 study.

24 Q It's -- it's marked in one of the exhibits

1 from earlier. You'll have it for after the depo.
2 And then, of course, there's the Geier and Geier
3 study that found increased rates of autism in kids
4 that got DTaP vaccine; correct?

5 A I would need to review that study to comment
6 on it.

7 Q Okay. Now, you need to review it to
8 comment -- oh, right, because you hadn't seen it
9 at all. Do you believe it's accurate to say that
10 there's no studies out there that support that
11 certain vaccines can cause autism?

12 A State that one more time.

13 Q Sure. Isn't it true that there are studies
14 that have been published that do find a
15 correlation between vaccination and autism?

16 A I don't know that there are -- I don't know
17 that there are studies that withstand scrutiny
18 and -- and that show that there is a relationship
19 between vaccines and autism.

20 Q Okay. So what you're saying is, is that
21 there might be studies out there, but there may --
22 you may not find them to be valid; correct?

23 A Like the studies by Andrew Wakefield that
24 were discredited and withdrawn.

1 Q So the study that was in the AHRQ report
2 regarding HepB, so that was reviewed by the
3 Federal Government and included in a Federal
4 Government report in 2014, are you aware of that
5 study being withdrawn or -- by the journal?

6 A No, I'm not.

7 Q Okay.

8 A I'm not familiar one way or the other.

9 Q Okay. All right. Now, there are a number of
10 other studies and, you know, we'll save most of
11 them for trial. You can probably go on the
12 Internet and find them yourself. And, you know,
13 other than the -- the Wakefield study, you know,
14 are you aware of any other study that did find
15 a -- strike that. The Wakefield study in 1998
16 didn't actually find a correlation to the MMR
17 vaccine and autism. Isn't that true?

18 A I'd need to pull up the study to be able to
19 tell you exactly what it says and what the
20 conclusions are.

21 Q Okay. It's worth taking a read because I --
22 it doesn't actually say that. In fact, the
23 conclusion doesn't relate to vaccines at all, but
24 four studies that actually did say there's an

1 association to vaccines and autism, which the 1998
2 Lancet study was far -- if you read it, it doesn't
3 have that in its conclusion, for the studies that
4 do find the association between vaccines and
5 autism, are you aware of any of those being
6 withdrawn by the -- by the journals that published
7 them?

8 A I don't have knowledge one way or the other.

9 Q Why do you think you're not aware of this
10 Mawson study that I just showed you?

11 A The epidemiological study?

12 Q Yeah.

13 A That -- there could be criticisms of that
14 study in terms of exclusions, what the differences
15 are between the two groups. I -- you know, I
16 can't really comment on it without looking at it.

17 Q It would be a good idea though to -- wouldn't
18 you agree it would be a good idea for the health
19 authorities to maybe do at least one study
20 comparing children that have received no vaccines
21 with children that have received vaccines
22 retrospectively, right, so there's no ethical
23 issue to see the difference in the rate of autism
24 between the two groups?

1 A Yep, but it would be hard to do because we
2 want all of our patients to be vaccinated.

3 Q But the CDC already says 1.3 percent of
4 children by two years of age today are completely
5 unvaccinated. Isn't that correct?

6 A I don't know what the exact number is. I --
7 I also think there are some epidemiological
8 studies from -- you know, I -- I -- I think one in
9 Denmark that looked at large numbers of children
10 with -- who were vaccinated and not vaccinated. I
11 don't remember if it was specifically MMR vaccine.
12 I'd have to look at that again or did it include
13 other vaccines and looking at rates of autism.
14 And there have been a lot of epidemiologic studies
15 that do look at -- at -- at rates of autism in
16 children. I just was focusing most particularly
17 on the MMR vaccine in my most recent literature
18 review.

19 Q Yeah, right. Of course, are you familiar
20 with the -- with healthy user bias?

21 A That -- that phrase itself is not -- you
22 know, again, I'm not a statistician or a
23 researcher.

24 Q It's clearly by CDC scientists in studies

1 they published long ago. Have you ever heard of
2 the confounder whereby children who receive
3 vaccines, right, for example, in the first six
4 months of life and suffer an injury then don't go
5 on to receive more vaccines, and hence when you,
6 let's say, are only looking at, you know, receipt
7 of the MMR, you end up with an issue called
8 healthy user bias, which is the kids who got the
9 first six months vaccines had no issues, they went
10 on to get the MMR; the kids who did have issues in
11 the first six months of life, they didn't go on to
12 get the MMR. Have you ever heard of this concept,
13 which is -- it's called -- which is -- which was
14 identified by the CDC as -- and coined by them, by
15 CDC researchers, as healthy user bias?

16 A No, I'm not familiar with that concept.

17 Q Okay. In all the -- in the Danish study you
18 just mentioned and the few other MMR studies that
19 have not been thrown out as unreliable by the IOM,
20 and you should take a look at the most recent IOM
21 report again in the MMR section, are you aware
22 that what they compared was basically completely
23 vaccinated children with completely vaccinated
24 children except for just missing MMR?

1 A Yeah, I'd have to look at the details of the
2 report to -- to --

3 Q Okay. All right. All right. Let me -- so
4 the bottom line is this. Okay. Are you familiar
5 with Stanley Plotkin?

6 A I'm -- I'm aware of that name, Stanley
7 Plotkin, yes, but I don't know a lot about him.

8 Q Okay. Are you aware he's the inventor of the
9 rubella vaccine?

10 A That rings a bell.

11 Q Okay. And that he -- and his -- and he's
12 also contributed to developing the polio vaccine,
13 are you aware of that?

14 A That does not ring a bell.

15 Q Okay. And so -- for other vaccines -- have
16 you -- have you seen this medical textbook before
17 called Plotkin's Vaccines?

18 A Well, you held it up a little earlier.

19 Q Okay. Other than that. I apologize.

20 A You know, I may have seen it. It's not a
21 resource that I have used to go to.

22 Q Okay. You've never developed a vaccine
23 before; correct?

24 A That's correct.

1 Q If Stanley Plotkin stated that as a matter of
2 logic and as a matter of science, one could not
3 yet state that vaccines do not cause autism
4 because the science is lacking, would you disagree
5 with him?

6 A So I -- I don't know enough about Stanley
7 Plotkin to -- you know, again, I would want to see
8 that in the context of how it was said, what --
9 what was the context of that. I -- you know, I
10 need to know something more about Stanley Plotkin
11 and look at the -- the context of that -- that
12 comment. But I think that, you know, we want --
13 we -- we want -- we want to do what's right and
14 what's best for children and we want to base that
15 on good scientific knowledge.

16 Q On scientific evidence; correct?

17 A Yes, as much evidence is available. We have
18 to make the best decision we can at the time we do
19 with the evidence that we currently have.

20 Q Okay. And in the absence of evidence, one
21 doesn't draw a conclusion. For example, in the
22 absence of evidence, one doesn't say that MMR
23 vaccine causes leprosy; correct?

24 A I would agree with that.

1 Q And one doesn't say MMR vaccine causes
2 rheumatoid arthritis in the absence of evidence;
3 correct?

4 A I would agree with that.

5 Q And in the absence of evidence, one doesn't
6 say that DTaP vaccine does not cause autism
7 either; correct?

8 A There's -- it's -- if there's a complete
9 absence of evidence, you know, yes, if there's a
10 complete absence of evidence. But again, I think
11 we look at -- at long-term studies and the health
12 of children and do the best we can to make the
13 right decisions.

14 Q There's a long-term study that compares
15 vaccinated and unvaccinated children that -- with
16 regards to the rates of autism?

17 A We have to -- I -- I can't answer that off
18 the top of my head.

19 Q Sitting here today, you're not -- you've
20 already said you don't -- you're not aware of any
21 evidence that supports that any of the vaccines
22 that Yates received other than MMR does not cause
23 autism. Assuming that you're not able to find any
24 evidence --

1 A Wait. Back up. Back up. Say that again.

2 Q Sure. Let me ask -- let me ask it this way.

3 Okay. I don't want to characterize your

4 testimony. That sometimes gets messy. Strike

5 what I said. Let me -- let me put it this way.

6 In the absence -- if there is no evidence to

7 support that DTaP -- if there are no studies,

8 right -- let me back up. Science is --

9 MR. SIRI: David got kicked out. Okay.

10 THE VIDEOGRAPHER: We've got him back.

11 Q (By Mr. Siri) When we want to -- science and

12 the evolution of science is typically done by

13 conducting and publishing peer-reviewed studies;

14 correct?

15 A Yes.

16 Q Okay. That is how science develops. We

17 conduct peer-reviewed studies and then we

18 replicate the findings and by other scientists who

19 then publish their findings, and if we have enough

20 studies that find the same thing, we can say, oh,

21 well, we can start reaching a scientific

22 conclusion about the issue; correct?

23 A Yes.

24 Q Okay. And so if one were to try and

1 understand where the science stood on an issue,
2 they would go into the peer-reviewed literature;
3 correct?

4 A Yes.

5 Q Okay. If there's no peer-reviewed study to
6 support that HepB does not cause autism, then
7 scientifically, as a matter of science, you cannot
8 yet claim that HepB doesn't cause autism; right?

9 MR. SANDERS: Object to the form of the
10 question. This is going back over steps again,
11 Mr. Siri.

12 A So the lack of a study that says hepatitis B
13 doesn't cause autism doesn't mean that hepatitis B
14 does cause autism.

15 Q (By Mr. Siri) Absolutely correct, Doctor. I
16 completely agree. The absence of evidence does
17 not prove that it's causally related, but the
18 absence of evidence doesn't permit drawing the
19 conclusion at all, does it?

20 A The -- there's an absence of evidence that
21 hepatitis B causes car accidents. I can conclude
22 that hepatitis B doesn't -- vaccine doesn't cause
23 car accidents, so I think you're asking a
24 really -- I mean, I -- I think it's -- it's --

1 Q Have parents been claiming for 30 years
2 that -- that pertussis-containing vaccines are
3 causing car accidents or have they been claiming
4 that they're causing autism?

5 A Parents have raised concerns about autism,
6 but autism also develops at a time when children
7 are receiving vaccines, and I have plenty of kids
8 who have signs of autism and there's data to
9 support that autism develops before the MMR and,
10 you know, early in childhood, and it is
11 contributed to by genetic factors and other
12 things.

13 Q There's a lot of science to support that, in
14 fact, it develops during the first six months of
15 life; correct?

16 A I think there is data that shows there are
17 signs in children even younger than six months of
18 age.

19 Q All right. Babies receive a HepB dose at
20 birth, correct, according to the CDC schedule?

21 A Yes. Not 100 percent, but it's recommended
22 that they receive it.

23 Q And then they receive a number of vaccines at
24 two months; correct?

- 1 A Yes.
- 2 Q And then four months?
- 3 A Yes.
- 4 Q Then six months?
- 5 A Correct.
- 6 Q Couldn't it be that those -- injecting all of
7 those products during critical phases of neuro
8 development could potentially cause autism in some
9 children?
- 10 A I don't believe that's the case.
- 11 Q But you don't have any studies to support
12 that; correct?
- 13 A I don't have any studies that prove the
14 negative, that vaccines -- I can't quote you
15 studies that -- that prove that those vaccines
16 don't contribute to the development of autism.
- 17 Q But you do believe there are studies that
18 prove the negative, that MMR doesn't cause autism;
19 correct?
- 20 A Yes.
- 21 Q So studies can be conducted to show that --
22 to prove a negative regarding whether or not a
23 vaccine causes autism; right?
- 24 A They -- they -- they need to be big studies,

1 and I'm not an expert in designing studies.

2 Q But they're possible; right?

3 A I would think possible, yes.

4 Q Okay. Could it be that the question of
5 whether vaccines causes autism is so unbelievably
6 controversial that pediatricians, vaccinologists
7 just are so -- they're even scared to look at the
8 question or maybe it is that large databases such
9 as insurance companies and the VSD, which have
10 thousands of unvaccinated kids, maybe the question
11 has been looked at? Strike that. That's not a
12 question really, I guess, and you don't have to
13 speculate. How do you know? Right? Look, I get
14 it, you -- you're a pediatrician, you -- I believe
15 that you mean the best for your patients, and you
16 trust what health authorities are telling you,
17 generally speaking. Let me ask you this.

18 Correlation doesn't equal causation; correct?

19 A Correct.

20 Q But there is a significant correlation in the
21 rise of autism along with the rise in the number
22 of vaccines on the CDC's childhood recommended
23 schedule; correct?

24 A The rise of the diagnosis of autism has

1 increased in recent years, and the number of
2 vaccines that are given have increased in recent
3 years. I think that's our explanations for why we
4 believe that is happening.

5 Q Okay. There are the same number of
6 60-year-old autistic folks around right now as
7 there are children with autism; correct? Is that
8 what you're saying? No, I -- strike that. There
9 are far more children with autism, multiple-fold
10 more than there are people who are 60 years old
11 that have autism; correct?

12 A There are more children who've been diagnosed
13 with autism. The definition of autism has been
14 brought in and expanded over the years. Autism is
15 much better recognized because we're screening and
16 looking for it, and so -- so autism is -- is
17 diagnosed more, but I can't state yes or no that
18 there are more four year olds with autism than
19 there are 60 year olds with autism.

20 Q Yes, there's a better autism diagnosis;
21 right?

22 A Correct.

23 Q But the scientific community is in general
24 agreement that the rise in autism cannot be fully

1 explained by better diagnosis. Isn't that true?

2 A I -- I -- I think that's a large part of it.
3 I can't tell you exactly what the whole medical
4 community believes about the rising rates of
5 autism. We make the -- we have more diagnosed
6 children with autism now.

7 Q What about what the CDC says? Does the CDC
8 say that there's been a rise in actual cases, you
9 know, beyond just -- that would exceed just better
10 diagnosis?

11 A Yeah, I would have to look at exactly what
12 the CDC says. At this moment, it's hard for me
13 to --

14 Q I don't -- yeah, let's -- you can look at
15 that. It's -- it's -- I don't want to get into a
16 tangent that's not directly relevant to our case.
17 Okay. The human immune system is typically
18 used -- used to dealing with pathogens which first
19 come into contact with mucosal surfaces such as
20 the lungs, the intestinal tract, the eyes,
21 scratches or open wounds; correct?

22 A Yes.

23 Q Okay. How are viruses grown or replicated
24 for use in manufacturing vaccines?

1 A I'm not an expert in that. I can't answer
2 it.

3 Q Okay. Are you not -- are you aware -- are
4 you aware that viruses and bacteria do need to be
5 grown though on some type of substrate in the
6 manufacturing process of vaccines?

7 A Yes.

8 Q Okay. Is it true that the growth mediums
9 that -- that the bacteria viruses used in vaccines
10 are grown on are removed from the final
11 formulation of the vaccines?

12 A I'm not an expert in the manufacture of the
13 vaccine itself.

14 Q Are you aware of what ingredients are in
15 vaccines?

16 A I can look up the list of all the
17 ingredients, yes, I have it readily available.

18 Q Okay. At any point in the 30 years that
19 you've been a pediatrician administering all of
20 these vaccines, was there a time when you knew the
21 ingredients in the vaccines?

22 A Have them memorized, no. But having reviewed
23 the list, yes.

24 Q What is serum?

1 A Serum as in, like, human blood serum?

2 Q (Nodding head affirmatively.)

3 A It is -- it's blood with the cellular
4 components removed.

5 Q Okay. And it could also refer to animal
6 serum as well; correct?

7 A Yes.

8 Q It's just any blood of either an animal or
9 human or -- so -- where the cell components are
10 removed; right?

11 A Yes.

12 Q Okay. But there are still some biological
13 material in the serum even after they remove the
14 cellular components; correct?

15 A Yes.

16 Q Okay. And are you aware that some vaccines
17 are grown on blood serums from calves?

18 A I'm not an expert on how vaccines are
19 produced.

20 Q Okay. I'm asking you if you're aware that
21 some vaccines are grown on the blood serum of
22 calves.

23 A No, I'm not.

24 Q Okay. So I assume that also means you're not

1 aware of whether or not all the blood calf serum
2 is removed from the final formulation of the
3 vaccine?

4 A That's correct.

5 Q Okay. But understanding, I assume, enough
6 about vaccines, that certainly would be something
7 that would be -- would be removed from the final
8 formulation; correct? Because you don't want the
9 body to then develop antibodies to -- to --
10 basically cow blood serum; correct?

11 A Correct.

12 Q Okay. Are you aware, for example, that some
13 vaccines are -- are grown in -- on cow's milk
14 medium, casein?

15 A I am not.

16 Q Okay. And again, you'd want to have that --
17 that would be entirely removed from the final
18 product because otherwise the body and the babies
19 would then develop antibodies to casein; correct?

20 A That makes sense, although, you know, babies
21 are exposed to casein through the --

22 Q But I assume you agree that ingestion is
23 different than injecting along with aluminum
24 adjuvants, right, where the biological material in

1 the vaccine is bound to the aluminum adjuvant such
2 that it can create a sustained immune response to
3 the biological material into the vaccine; correct?

4 A Yes.

5 Q Okay. Do you -- for example, do you know if
6 Yates received any vaccines that were grown on
7 monkey kidney cells?

8 A No, I don't.

9 Q Do you know what vero cells are that are used
10 to grow the -- for example, the polio vaccine
11 that's more recently used and sold by Sanofi?

12 A I do not.

13 Q You're not aware that they are abnormal cells
14 and that they have extra chromosomes and like
15 tumors can grow forever?

16 A I am not aware of what they're grown on.

17 Q Okay. Do you think it would be -- and -- and
18 so you also don't know whether or not the final
19 formulation of those vaccines include any vero
20 cell components?

21 A That would be correct.

22 Q Okay. How about yeast, are you aware of
23 whether any vaccines can -- are grown on yeast?

24 A Not specifically, no.

1 Q Okay. And if it were grown on yeast, I --
2 you know, yeast is a pretty common product. I
3 assume you'd want to remove the yeast from the
4 final formulation before you inject it into the
5 baby; correct?

6 A I don't -- I don't know the answer to that.

7 Q Okay. Were any of the vaccines injected into
8 Yates grown on any cells -- cell strains from
9 aborted fetal tissue?

10 A I don't know the answer to that.

11 Q You're -- you're not aware that MMR vaccine
12 is grown on the cultured cell strains of aborted
13 fetal tissue?

14 A So you -- you ring a bell with -- I -- I know
15 that there -- there are some vaccines where that
16 has been a concern that has -- has been raised,
17 and I've looked through that study and -- and, you
18 know, tried to address parents' concerns about
19 that. I don't remember all the details of what I
20 learned about that.

21 Q You testified today the MMR vaccine doesn't
22 cause autism; right?

23 A That's my -- my belief. That's my opinion.

24 Q And that varicella vaccine doesn't cause

1 autism; right?

2 A Yes.

3 Q But you're not aware that both of those
4 products contain millions of pieces of human DNA
5 below 500 base pairs?

6 A I don't know the details of all of the
7 components that are in vaccines.

8 Q I mean, are you surprised to find out that
9 there's human material inside the MMR and
10 varicella vaccine?

11 A No, I'm not.

12 Q Okay. Why not?

13 A Because I know the manufacturer of vaccines
14 is an incredibly complex process, and the details
15 of which are -- you know, I'm not an expert in.
16 I'm not involved in the development of vaccines,
17 so I look at the FDA licensure and again at our --
18 at our experts who are involved in vaccines and
19 the development to help us decide what's safe for
20 children.

21 Q Do you -- do you look at the package inserts
22 which will often describe the ingredients of the
23 vaccine?

24 A As I said earlier, I look at the package

1 insert when I have a specific question, but I
2 don't just sit down and read it from beginning to
3 end.

4 Q Okay. I'm just going to mark this so you
5 have it.

6 (Whereupon, Exhibit
7 No. 19 was marked to the
8 testimony of the
9 witness.)

10 Q (By Mr. Siri) Okay. So -- so does this page
11 of vaccine ingredients published by the CDC look
12 familiar at all?

13 A That doesn't look like a page that I have
14 studied.

15 Q So if -- how is it you've ever looked at what
16 ingredients are in vaccines?

17 A So I've looked at -- I -- you know, I -- I --
18 as I said, I've looked at in general terms a long
19 time ago what -- but not something that I studied
20 every single line of. I've looked up on the
21 Children's Hospital of Philadelphia website
22 specific information about the adjuvant and
23 about -- and, you know, I've looked at questions
24 about thimerosal and aluminum and other --

1 other -- and when a question comes up, I can look
2 for information, like the aborted fetal cells. I
3 had a family that we, you know, addressed that
4 question with a couple of years ago.

5 Q Only a few pages long; correct? It's four
6 pages long. It's a list of vaccine ingredients.

7 A Yes, I see that.

8 Q Okay. Do you see this MRC-5 human diploid
9 cells --

10 A Yes.

11 Q -- including DNA and protein?

12 A Yes.

13 Q In fact, it's the first listed ingredient,
14 isn't it?

15 A It is.

16 Q Do you know why it's the first listed
17 ingredient?

18 A I do not. Well, generally I would think the
19 first listed ingredient would be that contained in
20 the -- like -- like, you know, through the -- the
21 things of the highest concentration.

22 Q If you're growing a virus on cell substrate,
23 isn't it extraordinarily difficult to actually
24 separate the virus that you're growing from the

1 cell substrate?

2 A I can't answer that.

3 Q You're not aware that, in fact, most of
4 what's in, for example, the varicella vaccine is
5 this stuff, is -- I -- I just broke one of my
6 rules -- is MRC-5 human diploid cells including
7 DNA and protein?

8 A That's what it says on this site.

9 Q And this is according to the document
10 published by the --

11 A By the Centers for Disease Control and
12 Prevention.

13 Q And Epidemiology and Prevention of Vaccine
14 Prevention, the 13th edition, which is commonly
15 known as the Pink Book; correct?

16 A I don't look at the Pink Book. That's
17 probably why that page is unfamiliar to me.

18 Q Have you ever heard of the Pink Book?

19 A I have heard of the Pink Book.

20 Q That's the CDC's kind of -- it doesn't
21 matter. Okay. Strike that. So it's reasonable,
22 you know, for example, somebody, a doctor
23 administers a product, let's say, you know, once
24 every two years, I would say, you know, that they

1 don't have the time to know everything about it,
2 but you've been administering vaccines for
3 30 years thousands and thousands of times. Do
4 you -- don't you think parents expect that you
5 would know far more about vaccines, including
6 their ingredients, including the studies used to
7 license -- you know, I'll -- strike that. Let me
8 move on. What is a vaccine information statement?

9 A A vaccine information statement is a --
10 generally a two-page document that -- that is
11 required to be provided to families at the time
12 vaccines are administered.

13 Q And they're often referred to as VISs;
14 correct?

15 A Correct.

16 Q Okay. And the CDC develops a VIS for each
17 vaccine; correct?

18 A Yes, that's my understanding.

19 Q Okay. And are you aware that, you know,
20 federal law requires that each VIS explain the
21 risks of the vaccine; correct?

22 A I'm not aware what the federal law says, but
23 that's what is listed on those forms.

24 Q Okay. Are you aware of a VIS that doesn't

1 include the risks -- a risk section in the form?

2 A Not that I'm aware of.

3 Q Okay. Are you -- are you aware that the
4 federal law requires that only risks that are
5 supported by available data information would
6 be -- are included?

7 A I haven't reviewed what the federal law says.

8 Q Are you aware that the CDC denies petitions
9 to add risks to the VIS for various vaccines?

10 A I'm not aware of what the process is, no.

11 Q Okay. Okay. Now I'm -- so that we hopefully
12 don't have to go through all the law, are you --
13 is it your understanding though that -- that only
14 risks where there is evidence of a causal
15 relationship between the vaccine and the listed
16 reaction are listed on the VIS?

17 A No, that's not my understanding. My
18 understanding is that it lists reactions that
19 are -- are common or serious or are important, but
20 I don't -- I don't know that it is all necessarily
21 causation, but that's because I haven't read the
22 law to --

23 Q So you're not -- you're not sure?

24 A That's a fair statement.

1 Q All right. So you're not sure whether or not
2 the only risks listed on a VIS are those for which
3 the CDC was able to identify, you know, evidence
4 that they're supporting a causal relationship?

5 A That's correct, I'm not aware.

6 Q Okay. Now, I -- I assume you're familiar
7 with how doctors record in a patient's record that
8 a vaccine was administered?

9 A Yes.

10 Q And -- and a doctor is required to record
11 whether a parent or guardian received a VIS for
12 each vaccine administered; correct?

13 A So the vaccine administration is generally
14 recorded by the person who administers the
15 vaccine, so it's not actually the doctor that
16 enters the record and writes down the lot number
17 and the date and the --

18 Q Oh, fair enough. But -- but you are aware
19 that one of the required pieces of recordkeeping
20 in a pediatric practice is for somebody,
21 presumably the person that administered the
22 vaccine, to record that a VIS was provided;
23 correct?

24 A Yes.

1 Q And that it was provided to the parent and
2 the guardian of the child that's been vaccinated;
3 correct.

4 A The -- yes.

5 Q Okay. Now, have you reviewed Yates' vaccine
6 record?

7 A I have.

8 Q Including the handwritten one?

9 A Yes.

10 Q And you've already gone over the -- you know,
11 the column with regards to whether a VIS was or
12 wasn't given with somebody before today; correct?

13 A We've looked at that, yes.

14 Q Right. And -- and I assume that a particular
15 entry was already identified for you of interest;
16 correct?

17 A We looked at the column in general. So I
18 don't know what you're -- I don't want to
19 presuppose what you're asking me.

20 Q Was there -- was there anything in particular
21 about that column, that, you know, was of interest
22 in discussing?

23 A That -- that hashmarks were made below. You
24 know, it was said given and then hashmarks were

1 made was something that we talked about.

2 Q Did you talk about anything else regarding
3 that column?

4 A There were not hashmarks made beside the
5 hepatitis B vaccine and there were hashmarks --
6 or -- it was either written given or hashmarks
7 made at the Prevnar vaccine, the first dose.

8 Q Okay. And what was the explanation discussed
9 for why, you know, it said given next to the
10 Prevnar vaccine?

11 A Looking -- well, looking -- I read LuAnn
12 Upchurch's deposition, and I understand that she
13 had a protocol for picking up the VISs and picking
14 up the vaccines and going into the room, so her
15 protocol would have been to pick up whatever
16 information sheet she had available at that time
17 and provide that to the family, and I know there
18 were information sheets in general that were
19 developed before the official VISs, there was some
20 preliminary VISs, there were vaccine information
21 pamphlets on some of our vaccines, so my
22 understanding would be that it was her routine to
23 pick up whatever she had available and bring those
24 into the room and document that.

1 Q And where did you obtain that knowledge from?

2 A Well, from her deposition. She said it was
3 her routine to pick up the -- she said it was, I
4 think, on the right-hand side of her desk and that
5 she picked those up and she would give them when
6 she went in the room to administer the vaccines.

7 Q And then with regards to the blanks for the
8 hepatitis B vaccines, what was the explanation for
9 why those were left blank?

10 A I didn't see any explanation for why the VISs
11 weren't given for hepatitis B. I'm not aware.

12 Q And so, you know, those two HepB vaccines
13 were given on different dates; correct?

14 A Yes.

15 Q So the first time it was given, the row would
16 have been filled out and the blocks -- the box for
17 whether a VIS was given was left blank; correct?

18 A That's -- yes.

19 Q And then on another date at another time,
20 another HepB was given, and that row right below
21 that one was then filled out; correct?

22 A The row below that one was left blank where
23 it said -- I believe where it said -- I think both
24 hepatitis B vaccines, my recollection is both

1 vaccines had nothing written in the VIS column.

2 I -- I might be wrong about that.

3 Q Let's pull it up. It would probably be
4 easier for both of us. How is that? So here's
5 the --

6 A Go ahead.

7 Q Here's the form; right?

8 A Right.

9 Q So on August 16, 2000, it states a HepB
10 vaccine was given; correct?

11 A Yes.

12 MR. SIRI: And this -- this is going to
13 be Plaintiff's --

14 MS. CHEN: Exhibit 20.

15 MR. SIRI: Thank you.

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

20 Q (By Mr. Siri) Okay. And so, you know, a VIS
21 was given; correct? Or excuse me. Strike that.
22 On August 16, 2000, presumably a HepB vaccine was
23 administered; correct?

24 A That is documented.

1 Q Yes. And then whose ever initials this is,
2 right, then filled out this row; correct?

3 A Yes.

4 Q This row being the row that documents
5 administering HepB vaccine on August 16, 2000;
6 correct?

7 A Yes.

8 Q And when that row was filled out, it did not
9 say -- no given was added to that box; correct?

10 A That's correct.

11 Q Okay. Now, on August 16, were any other
12 vaccines administered, like, for example, was
13 Prevnar administered?

14 A On August 16, yes.

15 Q Okay. And so if you look at the row for
16 August 16, is there any notation in the VIS
17 column -- row? Excuse me.

18 A Under Prevnar for the VIS materials, yes,
19 there are hashmarks.

20 Q Okay. And so whoever filled this out on that
21 same date did put some notation that a VIS was
22 given; correct?

23 A Yes.

24 Q Okay. What do those hashmarks mean to you?

1 A To me it means it -- it means ditto to given
2 that was written above that.

3 Q So the person who filled out this -- the
4 vaccines given on August 16, they were --
5 consciously remembered to put the ditto mark that
6 a VIS or some other material, as you've stated,
7 was provided regarding Prevnar on that date;
8 correct?

9 A Yes.

10 Q But they put those hashmarks in, right, and
11 then they filled out the row for HIB 3, correct,
12 on August 16?

13 A Yes.

14 Q And then they would have gone down and they
15 would have added a row on August 16, 2000 for
16 giving HepB; right?

17 A Yes.

18 Q Is there any reason to believe that they
19 didn't consciously leave that blank?

20 A I -- I don't know why those spots beside
21 hepatitis B were left blank. I didn't see any
22 comments specific in my recollection of
23 Ms. Upchurch's deposition about why it wasn't --
24 it wasn't written there.

1 Q So by reviewing this record, it's possible
2 that the HepB VIS or some other materials for HepB
3 were not provided to Yates' parents or guardian on
4 August 16, 2000 regarding HepB; correct?

5 A Possible.

6 Q Okay. All right. Now, Yates was vaccinated
7 again on November 22; correct?

8 A Yes.

9 Q Okay. Now, on November 22, Yates received
10 three vaccines; right?

11 A Yes.

12 Q And when he received -- he also received a
13 HepB vaccine; right?

14 A Yes.

15 Q So the person who filled out the vaccines
16 given on November 22 would have gotten to the HepB
17 column -- HepB row, filled it out, and would have
18 had another opportunity to see that the box for
19 whether or not a VIS or some other material was
20 provided on August 16, 2000 was left blank;
21 correct?

22 A Yes.

23 Q But on November 22, no notation was added
24 that a VIS was given; correct?

1 A That's correct.

2 Q Okay. Did Yates receive additional vaccines
3 after November 22?

4 A He did.

5 Q Okay. Now, do you notice -- do you find it
6 strange that the given -- that the -- that there's
7 a blank on the third row below each given?

8 A From Ms. Upchurch's deposition, she indicated
9 that she put given in the top row and then she put
10 the hashmarks below that and then that it was
11 implied that it was given at the additional -- you
12 know, when you get to that third row, you can see
13 as she goes down, there aren't any instances where
14 she put hashmarks in the third row, but she talked
15 a lot about her procedures and protocols about
16 picking up the VISs and walking in the room with
17 those along with the vaccines.

18 Q Hold on for one second. I'm -- I apologize.
19 Just 10 seconds.

20 (Brief pause in the
21 proceedings.)

22 Q (By Mr. Siri) My apologies. Okay. So what
23 you're saying though is --

24 (Brief interruption in

1 the proceedings.)

2 MR. SIRI: What's that?

3 MR. SANDERS: Sorry. Somebody just
4 opened my door. They didn't realize I was still
5 here.

6 MR. SIRI: Not a problem.

7 Q (By Mr. Siri) Okay. So what you're saying
8 though is that you don't know whether or not the
9 VIS in the boxes that were left blank were given
10 or not given. Is that right?

11 A She indicated that it was her routine and
12 that this is how she documented, so her deposition
13 says that she gave the vaccines at the time that
14 she had protocols and procedures for giving those
15 at the time of administering the vaccines, so I --
16 I don't know about her documentation habit, but
17 that's what she said.

18 Q So it's possible that she didn't give them on
19 those dates; correct?

20 A I think it's possible. I don't know that
21 it's -- it's likely if she has a protocol and
22 procedure in place.

23 Q Okay. Are you aware that Mr. Hazlehurst went
24 down to the medical -- Dr. Hays' medical office

1 and demanded a copy of this document at some point
2 when Yates was around two years of age?

3 A I did see notes in the record about a visit
4 when he came and was asking for records and
5 videotaping a conversation with Dr. Hays.

6 Q So you're aware then that Dr. Hays was
7 holding this document in his hand as
8 Mr. Hazlehurst was demanding a copy of it;
9 correct?

10 A I don't --

11 MR. SANDERS: Object to the form of the
12 question. Go ahead, Dr. Mace.

13 A Yeah, I don't know what he was holding in his
14 hand.

15 Q (By Mr. Siri) Okay. Do you -- do you have a
16 reason to doubt that Mr. Hazlehurst is being
17 anything but accurate and honest when he says that
18 Dr. Hays was holding a copy of this document in
19 his hand as he was demanding it from him?

20 A I -- I don't know Mr. Hazlehurst. I don't
21 know of any reason to -- you know, to doubt yes or
22 no. I think, you know, memory is difficult, but I
23 don't have any -- any reason to doubt one way or
24 the other.

1 Q Okay. And are you aware that despite
2 numerous demands over five days, Mr. Hazlehurst
3 wasn't able to get a copy of this document until
4 he finally got a Court Order to get a copy of it?

5 MR. SANDERS: Object to the form of the
6 question. Go ahead, Dr. Mace.

7 A I don't know what all the details were about
8 that, about the interactions related to the --
9 obtaining the medical records. I know if someone
10 comes to our office and asks instantaneously for a
11 record, we have to pull things together and get
12 copies and we can't necessarily hand it over
13 instantly, but we would do our very best to make
14 copies and get -- get families anything that they
15 requested, including involving our medical records
16 department so we could be sure that we complied
17 with their request.

18 Q (By Mr. Siri) Did this -- did this small
19 pediatric practice have a medical records office?

20 A I imagine they did. I -- I'm aware that they
21 have more than one location and that not all the
22 records -- my impression from reading it was that
23 not all the records were in one location.

24 Q But if Dr. Hays was holding this record in

1 his hand, couldn't he have just gone to a
2 photocopy machine and made a copy of it?

3 A But I -- I don't know what he was holding in
4 his hand.

5 Q Okay. I mean, in the same way that you don't
6 know that, isn't it true that you don't really
7 know whether or not the givens that were written
8 in this column, you don't know whether they were
9 added during the period of time between
10 Mr. Hazlehurst demanding a copy of this and the
11 time that he was receiving it -- and the time he
12 received it from their medical office; correct?

13 A What I have based my impression on is
14 Ms. Upchurch's deposition that she had a protocol
15 in place for picking up the VISs and bringing them
16 into the room and giving them to the family at the
17 same time that vaccines were brought in.

18 Q Isn't it possible that they -- that the given
19 and the ellipses were added after the fact even
20 though no VIS and no materials were provided to
21 Yates' parents or guardians?

22 A I think that would be highly unlikely. I
23 don't think that physicians and staff members are
24 ever in the practice of altering medical records

1 before they give copies to individuals.

2 Q But in a situation where a father is saying
3 he urgently needs a copy of this document and the
4 doctor is holding it and refusing to provide it,
5 don't you find that to be the atypical situation?

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

8 A Can you phrase that question again?

9 Q (By Mr. Siri) Sure. Don't you find it to be
10 an atypical situation where a father is saying he
11 urgently needs a vaccine record for the treatment
12 of his child and is asking that a photocopy of
13 that medical record be made for the -- and for the
14 record to -- with regard to your last comment,
15 that it would be unusual for a medical office to
16 modify a medical record after the fact?

17 A So I -- I don't -- first of all, again, I
18 don't know what he was holding in his hands or
19 whether this form was readily available at that
20 moment. If a parent asked for a copy of a
21 vaccination record and it was readily available, I
22 think offices would provide that, and I don't see
23 motivation to going in and -- and altering the
24 record. At that moment, we have a parent who is

1 asking for a vaccine record, which is part of his
2 child's medical record. We have parents every day
3 who ask for vaccine records, and we provide what
4 we can in the most timely way that we can.

5 Q Right. So right. So a parent comes in and
6 asks for a vaccine record, the normal course would
7 be to just in a -- you know, to make a copy and
8 provide a parent a copy of it; correct?

9 A If -- if I -- if we have access to that. I
10 mean, there are, you know, Tennessee state forms
11 and all sorts of other things, but if someone asks
12 for a copy of the record and we have it readily
13 available, we would provide that record, and we
14 certainly, you know, wouldn't be motivated or, you
15 know, do anything to alter the record.

16 Q All right. So if, you know, you were
17 standing with a parent and you had a copy of the
18 record and the parent asked for a copy of -- you
19 know, of let's say their child's vaccine record,
20 you would have no issue making a copy and
21 providing it to the parent; correct?

22 A Yeah, in general terms I would provide the
23 record to the parent.

24 Q Okay. Now, I'm assuming before today you've

1 also discussed the issue regarding the Amoxicillin
2 that was prescribed to Yates?

3 A Yes. I -- well, I've seen that in the --
4 yes, and I've seen it in the depositions.

5 Q Okay. And what is your understanding of what
6 dosage of Amoxicillin was prescribed for a child
7 that has severe otitis media versus a child that
8 has moderate to mild otitis media?

9 A So if a child has severe otitis media, I
10 would really be inclined to consider skipping
11 Amoxicillin and using Augmentin, which is
12 Amoxicillin and Clavulanate.

13 Q Is that what you would have done in 2001?

14 A So in -- so in -- in -- first of all, most --
15 most children -- when most children have otitis
16 media, it is -- we consider it a mild illness. We
17 would consider it severe if they had high fever
18 and they were toxic appearing, if we were
19 considering other complications like occult
20 bacteremia or pneumonia, and in that setting, I
21 would -- I would have to individually evaluate
22 that child. My starting dose of Amoxicillin in --
23 in an uncomplicated case is 80 milligrams per kilo
24 per day.

1 Q Okay.

2 A Divide them twice daily.

3 Q Okay. And then in a moderate situation, how
4 much Amoxicillin would you prescribe for a -- in a
5 moderate case of otitis media?

6 A If I'm prescribing Amoxicillin, I would use
7 the same dose, 80 per kilo per day. That's the
8 standard dosage even for a first-time otitis
9 media, in a mild infection in a child in this age
10 range.

11 Q And if it was severe otitis media?

12 A If it was severe, I might choose a different
13 antibiotic because I'm worried about other
14 potential complications.

15 Q That includes in 2001?

16 A I -- I think probably, yes.

17 Q You're not sure?

18 A Well, what I've got are some practice
19 guidelines published by the American Academy --
20 you know, trying to put it all in historical
21 context, like, you know, when I trained, we used a
22 lower dose of Amoxicillin. During the 1990s, it
23 was recommended that we use higher doses. So I'm
24 trying to put it into historical context. I have

1 a set of practice guidelines that were published
2 in 2004, but by the time a guideline gets
3 published, we've probably been -- you know, we --
4 I mean, we're at Vanderbilt, we're ahead of things
5 a little bit, just in terms of -- of trying to
6 stay up to date on what's -- what makes the most
7 sense. So we were using the dose of 80 per kilo
8 per day earlier than when those guidelines were
9 published, and in those guidelines, it says severe
10 otitis media, use Augmentin.

11 Q And what -- and what was the guidelines that
12 were published before 2004? What did those say?

13 A I had trouble finding a published guideline,
14 so my -- my -- my -- what I -- what I tell you
15 about a dosage that I use would be based on my
16 recollection of the timing of my own career. When
17 I -- when I stopped being residency director, I
18 moved to this practice of university pediatrics,
19 and early in the first couple of years, in '96 and
20 '97, I was using 40 milligrams per kilo per dose,
21 but trying to stay up to date with current
22 guidelines, working together with residents and
23 others, it became apparent during that phase of my
24 recollection would be late 1990s that we switched

1 to using 80 per kilo. It was a hard change. I
2 didn't want to change. I wanted to stick with 40.
3 I -- but -- but the -- but our experts were
4 telling us that we should use a higher dose
5 because of bacterial resistance patterns, so I
6 moved to 80 per kilo per day.

7 Q All right. So you said you moved to
8 80 milligrams per kilo per day twice a day?

9 A Yes.

10 Q Okay. And so you would give that for a mild
11 and for moderate. But let's say you were going to
12 give Amoxil in 2001 for severe. What would you
13 give?

14 A Eighty per kilo per day. Eighty to 90. For
15 the --

16 Q Was that --

17 A The recommended dose was 80 to 90 milligrams
18 per kilo per day.

19 Q So you would have given -- for severe you
20 would have done 90?

21 A I --

22 Q No?

23 A What I do is I calculate 80 and then round
24 off to -- you know, to get a -- to get a near by

1 kind of round number. I like to prescribe
2 5 milliliters or 6 milliliters, not
3 6.3 milliliters. So I try to prescribe in the
4 range of 80 to 90 milligrams per kilo per day
5 divided twice daily.

6 Q And your testimony today is that even though
7 there was a severe case of otitis media, you're
8 saying you'd be concerned such that you would want
9 to go to Augmentin, but if you had to use Amoxil,
10 your testimony today is you'd give the same dose
11 that you would as if it were mild otitis media?

12 A That's the recommended dose, yes.

13 Q Okay. And where is that recommendation?

14 A So the recommended dose that -- what -- what
15 I -- what I have printed is the -- the guidelines
16 from 2004.

17 Q Can you hold those up a second so we can take
18 a look at them?

19 A Yeah. So this is just the cover.

20 Q Okay.

21 A I can move to the -- to the first page.

22 Q I've got it. I appreciate it.

23 A Okay. And then do you want to see the --

24 Q Hold on. I'll take the second page too.

1 A Okay. The second page?

2 Q That's the second -- yeah, let me just grab
3 that and take a second. Thank you.

4 A Okay.

5 Q Okay. I appreciate that.

6 A Where -- that would specify his dose. Would
7 you like me to hold that table up for you?

8 Q It's only fair. I've been doing it to you
9 all day.

10 A Okay. So this is Table 6 and it's on
11 Page 1459 of this document, and so in this table,
12 it's a long -- it -- it's a long document.
13 There's a lot of detail there.

14 Q Understood. Okay. Understood. So do you
15 ever use the Physician's Desk Reference?

16 A Long ago I used the PDR before there were
17 other resources available, so long ago.

18 Q So from what period -- from what -- during
19 what period of time did you use the PDR to decide,
20 you know, what level of dosage to give for
21 medications?

22 A Well, the -- the -- so my training was in the
23 late 1980s and then in the early part of the
24 1990s. You know, we were sent an updated version

1 every year and would look at the PDR, but that was
2 a guideline, and there were times when -- when our
3 practice in pediatrics might vary from those
4 guidelines.

5 Q I -- okay. But you would use the PDR as like
6 the base and then maybe there would be a
7 modification for pediatrics?

8 A Early on, yeah. Early on, yes.

9 Q Were you using the PDR in 2001?

10 A No, I don't -- I probably wasn't. The other
11 thing I used quite a bit was a book called the
12 Harriet Lane Handbook. That was a nice pocket
13 reference that I probably used even more --
14 certainly more often than the PDR.

15 Q Okay. In 2001, you were using both of those
16 as a reference?

17 A I had other smaller books than the PDR that
18 were more pediatric friendly that I think were
19 published by the PDR, whoever publishes the PDR
20 that were smaller handbooks that I might use, and
21 again, I -- a lot of my decision was made from
22 attending things like pediatric grand rounds at
23 Vanderbilt and other conferences where we -- we
24 would talk about, you know, the change from 40.

1 As I said, I didn't want to move. I learned 40.

2 I didn't want to move from 40. But because
3 additional studies showed that 80 to 90 was
4 better, we moved on to that.

5 Q Uh-huh. And the guidance has changed again,
6 right, to try and to avoid prescribing antibiotics
7 for otitis media now?

8 A Sure, yeah, and that's been for a while. I
9 mean, we -- you know, we -- that -- and this --
10 this practice guidelines that -- that I have from
11 2004 even addresses that. They included non
12 treatment with antibiotics as an option in -- in
13 that -- they included that as one of the options
14 on the --

15 Q And those -- and those changes happened
16 because studies were conducted to show which
17 treatment was better; right?

18 A To show that the higher dose was more
19 effective.

20 Q And then later there were other studies that
21 showed actually potentially not using the
22 antibiotics at all for otitis media might have
23 better outcomes.

24 A All along we recognized that viruses play a

1 big component in the development of otitis media
2 and that while it was our practice to prescribe
3 antibiotics, they -- they may not have always been
4 necessary.

5 Q Okay. So let me make sure I -- so in 2001,
6 you're saying you did use these smaller versions
7 of the PDR as well as the Harriet Lane Handbook?

8 A If I were looking -- if I needed to look up a
9 dose of a medicine. I didn't look up the dose of
10 Amoxicillin. I knew the dose of Amoxicillin, so I
11 would only look at the PDR if I was prescribing
12 something I was less familiar with.

13 Q Okay. And so when did you start -- did you
14 change the amount of Amoxicillin that you would
15 give for otitis media, when did that change
16 happen?

17 A Probably in the late 1990s. I moved to my
18 practice in -- again, it's just a move within
19 Vanderbilt, but I changed how I was spending most
20 of my time in 1996, and it was shortly after that
21 that we started making changes in the dosage of
22 Amoxicillin.

23 Q Okay. So late 1990s you changed to
24 80 kilograms?

1 A Milligrams per kilogram.

2 Q Milligrams, thank you, per kilogram, per day
3 for -- okay. And -- and you're saying from the
4 late 1990s on, you didn't need to consult neither
5 the PDR nor Harriet Lane Handbook or any other
6 source to know that?

7 A For -- for the dosage of Amoxicillin,
8 certainly. We use it a lot and everybody has
9 those doses memorized.

10 Q What would be the normal hemoglutin range in
11 a nine-month-old baby?

12 A Hemoglobin?

13 Q Yes, right, thank you. What would be the
14 normal hemoglobin range in a nine-month-old baby?

15 A 10.5 or higher. We -- we actually look for
16 11.0, but have some debate. 10.5 or higher is
17 normal for a child in that age range.

18 Q Any number above that?

19 A Any number above that. Well, yeah, I mean,
20 you know, something way up in the 20s, you know --

21 Q Okay. And -- well, I'm sorry, say -- in the
22 20s --

23 A Oh, something way up in the 20s would make me
24 think that it was, you know, either a lab error or

1 I would be concerned about heart disease,
2 polycythemia. In a child this age, you know,
3 we're looking for 10.5 or higher.

4 Q Okay. Now, going back just for a second to
5 Amoxicillin, you said you started -- you moved to
6 the, you know, 80 milli per kilo per day two times
7 a day in the early 19 -- early 1990s or --

8 A Late --

9 Q -- late 1990s. How did you learn about that
10 change?

11 A From, well, part of an academic medical
12 center, being part of a work group, perhaps from
13 attending pediatric -- I attended pediatric grand
14 rounds at Vanderbilt pretty regularly during that
15 time. Conversations with colleagues. You know,
16 we -- we talked with one another about, like, even
17 though I wasn't teaching, I was still talking with
18 and interacting with part of the group of people
19 who were primarily teaching, so we do try to stay
20 up to date on things.

21 Q Right. But that guidance had to have
22 originated from some type of scientific review;
23 correct?

24 A Right. Probably from our infectious disease

1 colleagues.

2 Q And it would have -- before it became widely
3 adopted, it would have been published somewhere;
4 correct?

5 A Not necessarily so. Our infectious disease
6 colleagues will do studies within Vanderbilt, they
7 look at -- we -- we know which bacteria tend to
8 cause otitis media. You know, streptococcus
9 pneumoniae, haemophilus influenza, non-typical
10 Moraxella catarrhalis, so they might have had data
11 from the microbiology lab that in our region this
12 is the resistance pattern that we see, these are
13 the drug levels that are required and the -- a
14 dose of 80 per kilo per day is going to give
15 better coverage than a dose of 40 per kilo per day
16 in children with otitis media.

17 Q So your infectious disease experts engaged in
18 some kind of review there and then made this
19 determination, and you're saying that they didn't
20 publish it someplace in the medical literature?

21 A So we get that sort -- we -- we have ongoing
22 relationships with our infectious disease
23 colleagues. They sit down and review practice
24 guidelines with us from time to time and we talk

1 about urinary tract infection and antibiotic
2 choices. That's not necessarily a published
3 report. It is based on -- on data from Vanderbilt
4 Hospital. So I'm -- I'm at this point guessing
5 about what sorts of things went into the
6 recommendation and who provided that, but that --
7 that change was made from 40 per kilo per day to
8 80 per kilo per day in terms of routine dose of
9 Amoxicillin.

10 Q What -- what year did you learn about that
11 change?

12 A I don't know the exact answer to that.

13 Q Okay. Who told you about the change?

14 A I don't know exactly where that information
15 came from.

16 Q What did they base it on?

17 A On resistance patterns of the common bacteria
18 that are known to cause otitis media, and studying
19 minimum inhibitory concentrations of bacteria to
20 certain drugs.

21 Q And that would need to be a -- a -- a
22 well-designed study, I presume; correct?

23 A Not necessarily. So they may be going to our
24 lab and just looking at these are the -- these are

1 the pneumococcus that grew and this is what
2 their -- you know, there's data collected that's
3 not necessarily in a double-blind placebo
4 controlled study. This is --

5 Q Sure.

6 A Yeah.

7 Q And there are case controlled studies,
8 correct, that just are about one specific case,
9 for example; right?

10 A Sure. There are case controlled studies.

11 Q And there's publications about, you know,
12 giving guidelines for best practices that are
13 published all the time by various medical
14 societies; correct?

15 A Yes.

16 Q And Amoxicillin is a pretty commonly used
17 antibiotic; correct?

18 A It is.

19 Q Including the 1990s; correct?

20 A Yes.

21 Q And doctors around the country were using it;
22 correct?

23 A Yes.

24 Q A change in the amount of otitis -- of

1 Amoxicillin for otitis -- scratch that. Otitis
2 media also is a very common issue, I believe you
3 said earlier; correct?

4 A Yes.

5 Q Among infants and children; correct?

6 A Yes.

7 Q So a change in the amount of Amoxicillin
8 that's recommended to be prescribed would affect
9 doctors all across the country, wouldn't it?

10 A That's why the practice guidelines were
11 published in 2004. But it takes time. Changes
12 happen, changes in clinical practice happen before
13 practice guidelines are published.

14 Q So you're saying it took multiple years
15 before anybody anywhere in this whole country
16 wrote in any place about this change in what
17 amount of Amoxicillin should be given for otitis
18 media, what you're saying is a very common issue
19 that's been treat -- being treated by doctors
20 around the country.

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

24 A So that's not what I'm saying. I think

1 that --

2 Q (By Mr. Siri) Oh, oh, I apologize.

3 A The practice guidelines were published in
4 2004. If you look at the practice guidelines,
5 there are dozens of publications that went into
6 the development of a practice guideline, so I did
7 not review the literature to see what studies were
8 exactly published when about making that change in
9 dose, but that was a change in dose that was made
10 and it was a good change and it stands to this
11 day.

12 Q And do doctors across the country know about
13 this change in the early '90s, late -- late '90s?
14 Sorry.

15 A I have no idea. I practice locally. I know
16 what we were doing here. I think that's the
17 purpose of -- of developing and publishing
18 practice guidelines. We look at local data all
19 the time in terms of what's happening in middle
20 Tennessee for what antibiotics we should be
21 choosing for -- to treat our patients with certain
22 conditions.

23 Q But the change in the recommended dose of
24 Amoxicillin for otitis media in the early -- in

1 the late '90s was one that you said earlier
2 happened nationally; correct?

3 A No. That happened locally. That was
4 something that we started doing at Vanderbilt, and
5 I can't comment on what was going on nationally at
6 that time.

7 Q Was -- do you know of any other place in the
8 country that changed their guideline about the
9 amount of Amoxicillin for otitis media in the late
10 '90s?

11 A I don't have knowledge about what other
12 institutions were doing with their guidelines.

13 Q So how far outside of -- so -- do you know
14 what -- anything in the surrounding -- any --
15 any -- with the -- what anybody, hospitals in the
16 surrounding states changed the prescribing
17 guidelines for Amoxicillin for otitis media in the
18 late 1990s?

19 A Oh, A lot of the -- you know, our region is
20 fairly large. A lot of -- are referred to
21 Vanderbilt. We have people from southern
22 Kentucky, we have people from northern Alabama,
23 from pretty far reaches within the state of
24 Tennessee being very broad, so, you know, it --

1 it -- changes in dosages are not instantaneous
2 where, boom, one day it's this is done and the
3 very next day everybody in the country knows and
4 changes their practice. These things take time to
5 happen, so I would imagine as the infectious
6 disease folks were or our own, you know, our --
7 our own general pediatrics division looked and
8 would review a lot of literature and sit down and
9 have discussions about things as well. As those
10 discussions were being held here, I'm imagining
11 there were similar discussions in the region, and
12 that -- you know, I -- I can't tell you when other
13 people adopted those changes, but I can tell you
14 it takes a long time to get a practice guideline
15 agreed upon and published.

16 Q So it's possible, you're saying, maybe that
17 change even happened in your hospital, but it may
18 not have spread outside of your hospital until
19 2003; right?

20 A I don't -- yeah, I don't know when it went to
21 other places.

22 Q Right. So it could be something you did in
23 your hospital, but you have no idea if maybe -- if
24 anybody else adopted it outside of your hospital

1 until maybe even 2004 when the guideline was
2 issued; correct?

3 A Right. I -- yes, but I can say that Dr. Hays
4 was training within that time in the late 1990s,
5 so --

6 Q Dr. Hays was what? I'm sorry?

7 A Training at Vanderbilt at that time, so he
8 would have been exposed to that same information.
9 He might have made the change to 80 per kilo per
10 day before I did because he was -- you know, he
11 might have heard the word before I did.

12 Q Do you find this explanation to be a little
13 bit convenient, Doctor, for the --

14 MR. SANDERS: Object to the form of the
15 question. Go ahead.

16 MR. SIRI: Well, I've got to finish the
17 question.

18 MR. SANDERS: Sure.

19 Q (By Mr. Siri) Do you -- yeah. Do you -- put
20 yourselves in -- put yourself in my shoes. You're
21 telling me that there was a change in medical
22 practice, you don't know what year it was, you
23 don't know who told you, you just know it
24 happened, and you don't even know if it's

1 something that happened anywhere outside your
2 hospital, and you're not aware of a single shred
3 of documentation that supports it until 2004, but
4 yet you're saying it happened in the late 1990s at
5 your hospital.

6 MR. SANDERS: Object to the form of the
7 question. Argumentative and compound. Go ahead,
8 Dr. Mace, if you have an answer.

9 A So I remember changing from 40 per kilo to 80
10 per kilo. There is -- it doesn't -- I don't know
11 what phrase -- I don't know what word you said,
12 but -- convenient. It just is what happened.
13 That's how medicine happens. We learn things and
14 we adapt to new information, and the -- the -- the
15 academic community tries to get things published
16 and tries to make practice guidelines, but
17 practice guidelines probably lag behind what's
18 actually being done in many situations.

19 Q (By Mr. Siri) Is it possible you're not
20 remembering when you switched over the amount of
21 Amoxicillin to 80 milligrams per kilogram per day?

22 A I told you I don't remember the exact date
23 when I made that change.

24 Q Right. But is it possible that the change

1 actually occurred in 2002, you just don't
2 remember?

3 A I don't think that's very likely.

4 Q I'm sorry?

5 A I don't think that's very likely. And if you
6 would -- I can give you an explanation from the
7 medical chart that I -- I think supports the idea
8 that we made this change in the 1990s. When Yates
9 was diagnosed with his very first ear infection --

10 Q Okay.

11 A -- he was diagnosed with early otitis media
12 on 9/27 of 2000. So this was not the date that --
13 that he was vaccinated. It -- the visit that day
14 was check ears, he was fussy, had a low grade
15 fever, and was diagnosed with early otitis media.
16 Dr. Hays that day prescribed 80 milligrams per
17 kilo per day for that very first early otitis
18 media, which was, you know, clearly a mild
19 infection.

20 Q When you say clearly, how do you know that?

21 A Because it was documented in the record and I
22 calculated based on his weight and the dosage that
23 was documented.

24 Q So based on the weight and the dosage,

1 you're -- you're saying that it was mild otitis
2 media, but if the dosage was more than that, you
3 would have -- that it was --

4 A No, I'm sorry.

5 Q I'm sorry. I misunderstood.

6 A I know that the dose was 80 milligrams per
7 kilo per day by doing the math. I know that it
8 was mild because he described it as early otitis
9 media, so not a moderate or severe infection.

10 Q Early otitis media is a term of art that you
11 would use?

12 A Early otitis media, sure. It means that it
13 is the beginnings of an infection, certainly a
14 phrase that we would not use to describe a
15 moderate or severe. We would use different words.

16 Q And what words would those be?

17 A I think we would use words like
18 toxic-appearing child, you know, fussy child,
19 ill-appearing, that's what severe would mean to
20 me.

21 Q And what words would you use to describe
22 moderate otitis media?

23 A I don't know that I -- I -- you know, really,
24 I -- I describe -- I think otitis media in terms

1 of -- is the child mildly ill or severely ill.
2 Moderate otitis media might be one that hasn't
3 resolved from prior treatment. You know, we've
4 already tried one antibiotic and it hasn't gotten
5 better, so we're thinking about changing to
6 another one. A child who's in a lot of pain,
7 crying, you know, can't be consoled during the
8 visit, I think that might be a moderate otitis
9 media. But again, those are, you know,
10 distinct -- those are not exact written in stone
11 types of distinctions.

12 Q So if it's, like, repetitive, it happens at
13 certain -- you know, a repeat of otitis media, it
14 would fall into the moderate category?

15 A Not --

16 MR. SANDERS: Object to the form of the
17 question. Go ahead, Dr. Mace.

18 A Not necessarily so. If it's an ear infection
19 that's -- if it's -- I start an ear infection and
20 they're back three days later, you know, three
21 days, and the child is still running fever and
22 still ill-appearing, then -- you know, then that
23 would be -- that would more fall into a moderate
24 infection because now it's -- it doesn't appear to

1 be responding to the initial antibiotic that was
2 chosen, so that might be a -- more of a moderate
3 infection.

4 Q (By Mr. Siri) What other symptoms would you
5 normally, you know, be exhibiting when a child has
6 moderate otitis media?

7 A So are we talking about moderate illness or
8 moderate otitis media?

9 Q Moderate otitis media, what other, you know,
10 symptoms typically accompany moderate otitis
11 media?

12 A Pain, fever, and then I look for, you know,
13 bulging eardrums, I look for an opaque, red
14 eardrum, so it's a -- it's a combination of all
15 of -- red alone, bulging alone doesn't make it
16 moderate, but it's more that bulging, red,
17 painful-appearing eardrum in a child who's crying
18 and uncomfortable and most likely running a fever.

19 Q Not to be -- I mean, that sounds like the
20 severe that you described earlier.

21 A Yeah, severe infection would be a child who's
22 really toxic-looking, like they look like they
23 might have a complication, like, bacteria in the
24 blood stream are called bacteremia, you know,

1 other complications, mastoiditis, we're worried
2 that they might have pneumonia, other things that
3 would be severe.

4 Q Now, Dr. Hays was the healthcare provider
5 under whose authority Yates was vaccinated;
6 correct?

7 A Yes.

8 Q Okay. Now, we discussed this earlier, but
9 just to make sure we've covered the bases here,
10 are you aware that there is a federal law that
11 requires providing a VIS prior to administering a
12 vaccine?

13 A Yes.

14 Q Let me rephrase that. Is there -- and when I
15 say provide the VIS, I mean to the parent or
16 guardian; correct?

17 A Yes.

18 Q Okay. And -- and one of the purposes of the
19 VIS, as we discussed earlier, is to inform the
20 parents of some of the benefits and risks of the
21 vaccine to assist the parent in making a decision
22 on whether to consent to administration of the
23 vaccine to their child; correct?

24 A I don't agree with the VIS routinely being

1 used to assist parents in making decisions. Our
2 discussion about the vaccine assists the parents
3 in making the decision. The VIS is for them to
4 have some written materials to take home about
5 that, that vaccine.

6 Q So what's the purpose of the VIS?

7 A The purpose of the VIS is so that they can
8 have some written materials from -- to -- to refer
9 back to, it has information about the child injury
10 that -- the 1986 Act and contact information about
11 that, so these are reference sheets for parents to
12 look at after they've left the clinic, but
13 generally it's not used as something for
14 parents -- it's just generally not used for
15 parents to make a decision about consenting or not
16 consenting to a vaccination.

17 Q Okay. So the -- make sure I understand this.
18 The VIS provides information about potential
19 precautions and contraindications for the vaccine
20 the VIS discusses; correct?

21 A Yes.

22 Q And that would be information a parent -- for
23 it to be useful would be information a parent
24 would need to have before the vaccine is

1 administered; correct?

2 A It's useful information, yes.

3 Q But to be useful for, you know, a VIS
4 provided on a particular -- for a vaccine given,
5 it would need to be provided -- a parent would
6 need to review that prior to the vaccine being
7 administered; correct?

8 A If -- if -- if they're going to use that
9 piece of information, then they need to review it
10 prior to the immunization being given.

11 Q Okay. And, you know, similarly a VIS will
12 discuss the reactions that can occur from
13 receiving a -- a vaccine.

14 A Right.

15 Q This way they're aware of the potential risks
16 of the vaccine; correct?

17 A Yes.

18 Q Okay. And it also provides explanations for,
19 you know, why the child should get the vaccine in
20 terms of, you know, preventing certain disease;
21 correct?

22 A That's correct.

23 Q And that's information that's intended for
24 the parent to review before they get the vaccine

1 to assist the parent in deciding presumably to get
2 the vaccine; correct?

3 A It's supplementary to the discussion that's
4 held between the pediatrician and the family about
5 what vaccines are being ordered, so I view that as
6 supplementary material. It's important, they need
7 it, but -- but again, generally our families have
8 the opportunity to look at it. You know, our
9 current procedure is that it's given at the
10 beginning of the visit, but most of the time they
11 don't look at it.

12 Q Sure. Parents may choose to, you know, look
13 at the VIS or not look at the VIS; correct?

14 A Right.

15 Q Just like parents may choose to not ask you
16 any questions when you provide them information
17 about the benefits and risks of vaccination;
18 correct?

19 A That's right.

20 Q But those -- but those -- but information
21 about the benefits and risks of vaccination and
22 potential contraindications as provided in the VIS
23 is the type of information that a parent to be
24 useful would need to get before the vaccine is

1 administered; correct?

2 A That information sheet is only useful if
3 someone reads it.

4 Q Okay. But -- okay. But it -- it -- sure.
5 But to be useful, if they do read it, they would
6 need to receive it before the child is vaccinated;
7 correct?

8 A It depends on what the use is. If they're
9 using it to make a decision about the vaccine,
10 then they should read it before the vaccine is
11 administered. If they're using it for reference
12 material particularly about adverse reactions and
13 having it at home so they can look back at it
14 after the vaccine has been given and they can --
15 they can look back, then reading it after the
16 vaccine is then -- is also useful in that way.

17 Q Right. Sure. But it's the parent who's
18 going to decide whether they're going to read it
19 or not read it when it's given to them to decide
20 and it's the parent that also decides whether or
21 not they're going to consent or not consent to the
22 vaccination; correct?

23 A Yes.

24 Q So the parent may choose to read it before

1 the child is vaccinated; correct?

2 A Yes.

3 Q And a parent may rely on information there to
4 make the decision to vaccinate or not to
5 vaccinate; correct?

6 A They may. I find that very uncommon.

7 Q Okay. But a highly educated parent that
8 maybe already has some concerns about prior
9 vaccines, you think that they might be more
10 attuned and likely to read the VIS if given to
11 them?

12 A I think a highly educated parent who might
13 have some concerns about vaccines would express
14 those concerns to the doctor when the vaccines are
15 being discussed or say, wait, I have a question.

16 Q Okay. Are you aware that Mr. Hazlehurst has
17 testified that he has -- he, as well as surrogates
18 who brought Yates, did express concerns about
19 vaccines that Yates was going to receive?

20 A I am aware of concerns that were raised later
21 about whether the vaccines had anything to do with
22 his condition later. I didn't see documentation
23 in the record about specific questions that were
24 addressed with vaccines, and I don't recall the

1 specific details of Mr. Hazlehurst's deposition.
2 I -- I don't -- I -- I remember that they
3 discussed symptoms, but I don't remember anything
4 in his testimony that said I didn't want them or
5 asked them about this vaccine or that vaccine. I
6 just don't remember the specific details of
7 exactly what he said about that. If he asked
8 questions though, Dr. Hays would, I believe,
9 answer those questions.

10 Q Are there reactions to vaccines that are
11 caused by vaccines that could arise more than 15
12 minutes after getting a vaccine?

13 A Yes.

14 Q Okay. And is -- and the risk of anaphylactic
15 reaction is considered one in a million from a
16 vaccine typically; correct?

17 A Very rare, yes.

18 Q Okay. But there are other risks that
19 vaccines can potentially -- there are other
20 injuries that vaccines can cause beyond an
21 anaphylactic reaction; correct?

22 A There are other adverse reactions following
23 vaccines, yes.

24 Q So if Mr. Hazlehurst expressed that he has

1 concerns about vaccines because his child
2 exhibited some reaction to a prior dose and he was
3 reassured by Dr. Hays that the only adverse
4 reaction would happen within 15 minutes and it's
5 one in a million and that's the only risk he
6 informed Mr. Hazlehurst of, do you believe that
7 that would meet the standard of care of advising
8 Mr. Hazlehurst of the risks of receiving --

9 MR. SANDERS: Object to the form of the
10 question. Go ahead.

11 A If Dr. Hazlehurst said that, the only
12 question --

13 Q (By Mr. Siri) Dr. Hays. Sorry. If Mr. --
14 Dr. Hays.

15 A Thank you.

16 Q No problem.

17 A If Dr. Hays said the only possible reaction
18 was anaphylaxis, then -- then that isn't informing
19 him of all the possible reactions to the
20 vaccination.

21 Q And that would have violated the applicable
22 standard of care that Dr. Hays owed to
23 Mr. Hazlehurst and Yates; correct?

24 A So if that's the only thing that was said, if

1 that's the only thing that was said about
2 vaccinations. I do recall some discussion about
3 the Prevnar vaccine, the first time -- I believe
4 it was the first time it was administered that
5 doctor -- that Mr. Hazlehurst had questions
6 about -- because it was a new vaccine had
7 questions about whether it was appropriate to give
8 that vaccine, and my recollection is there was
9 a -- a -- more of a discussion about that vaccine.
10 At that time there was some comment in one of the
11 Hazlehurst depositions about that I believe he
12 listened to the information and he might have used
13 the word overruled Angela, that he thought it was
14 appropriate to go ahead and give that vaccination,
15 so it sounds like they -- they -- at least on that
16 occasion there was some very specific recollection
17 of more than just a discussion about anaphylaxis.
18 Q But if Dr. Hays had said the only risk to be
19 concerned about is a one in a million chance of an
20 event, and that -- and it would occur within 15
21 minutes, isn't it true that that would not meet
22 the standard of care that was required of Dr. Hays
23 to inform Mr. Hazlehurst, or whoever was there
24 to -- on behalf of Yates, applicable to

1 vaccinating Yates?

2 A If he said that was the only possible
3 reaction, then that is not typical of what we tell
4 families.

5 Q Right. So if he said -- he said the only
6 reaction is a one in a million chance of a
7 reaction within 15 minutes of vaccination, and
8 that's the only risk he said could have happened,
9 you would agree that that would not meet the
10 standard of care for vaccinating Yates; correct?

11 A I think it depends on if he was talking about
12 life-threatening risks or any risks whatsoever,
13 you know. I mean, we talk about fever and
14 soreness at the injection site and those sorts of
15 things which are not generally life-threatening or
16 serious, and we generally mentioned those others.
17 I think if he's talking about life-threatening
18 immediate reactions and, you know, mentioned that
19 one, then, you know, he was doing an appropriate
20 thing by mentioning that. If that's the only
21 thing he ever said about vaccines, that that's the
22 only thing that could ever possibly happen or go
23 wrong or be a side effect of administration of a
24 vaccine, that's not typical of what pediatricians

1 do. We include more information.

2 Q And that would not meet the applicable
3 standard of care for vaccinating Yates when he was
4 vaccinated; correct?

5 A If that was the only thing that was said, I
6 think that's not typical standard of care.

7 Q It would not meet the standard of care;
8 correct?

9 A If that was the only thing, yes, that
10 would -- that -- if that was the only thing that
11 was ever said about that -- about vaccination,
12 that would not meet the standard of care.

13 Q Since there was a lot of questions, I just
14 want to make sure we're on the same page. So if
15 the only thing that Dr. Hays -- so if -- strike
16 that. So if -- when Mr. Hazlehurst asked what are
17 the risks, if Dr. Hays said the only risk of
18 giving Yates one or more vaccines would be a
19 reaction that would happen immediately within 15
20 minutes and it's a one in a million chance and
21 that's the only risk that he advised
22 Mr. Hazlehurst of, that wouldn't meet the standard
23 of care for informing Mr. Hazlehurst of the
24 potential risks and benefits of vaccination;

1 correct?

2 A If that was the only risk he ever discussed,
3 that there was not any discussion at other times
4 about vaccines, that -- and that was the only
5 thing that was ever said, that --

6 Q That was -- as of that date and the -- and
7 those -- and the administration of those vaccines,
8 if that was the only risk that was -- that was --
9 that was told to Mr. Hazlehurst, that would not
10 meet the standard of care; correct?

11 A So I would say that pediatricians have short
12 discussions and long discussions with families,
13 and -- and our goal is to answer their questions
14 fully, and sometimes someone might say that's
15 the -- that's the risk that you need to be most
16 worried about, so I don't know exactly what his
17 words were, I don't know exactly how it was
18 phrased. He said there's only one risk ever and
19 it happens within 15 minutes, that's not the
20 standard of care of the discussion that most
21 pediatricians have with their patients prior to
22 administering vaccinations.

23 Q So I want to make sure I understand you,
24 that's all. I'm not trying to be difficult, so

1 let me boil it down. If the -- as of a particular
2 date that Yates was vaccinated, all right, if as
3 of that date the only information provided to
4 Mr. Hazlehurst about the risks of vaccination was
5 being told by Dr. Hays that there is a one in a
6 million chance of a -- you know, of real reaction,
7 and it would occur within 15 minutes, that would
8 not meet the standard of care applicable for
9 vaccinating Yates; correct?

10 A And you're saying as of that date, like all
11 discussions leading up until that date or all
12 discussions up until that date.

13 Q Yes.

14 A I think we have to --

15 Q Yes, that's why I said all discussions up
16 until that date.

17 A All discussions. If there was never any --

18 Q Let me -- I'll do it again. If from the day
19 that Yates was born up until the day that Yates
20 was vaccinated, okay, right, on that date that he
21 was -- received a vaccine, whether it was two
22 months or four months, I counted for all
23 discussions that occurred between Dr. Hays and
24 Mr. Hazlehurst, if the only thing that Dr. Hays

1 had told Mr. Hazlehurst about risks of
2 vaccination, serious risk of vaccination, as of
3 that date when Yates was vaccinated, was that
4 there was only a one in a million chance of a
5 serious reaction and it -- and if it would happen,
6 it would happen within 15 minutes, if that is what
7 occurred, would that have violated the minimum
8 standard of care that Dr. Hays owed to
9 Mr. Hazlehurst or any of Yates' guardians or his
10 mother?

11 A Well, you've added the word serious into that
12 sentence that you weren't saying earlier, the only
13 discussion about serious reactions. I think you
14 also have to take into context whether or not he
15 gave him vaccine information sheets at prior
16 visits and that they had had that information
17 previously. If he said the only possible
18 reaction -- the only possible reaction is
19 anaphylaxis and it happens within 15 minutes, then
20 that's not the standard of care. If he said the
21 only serious reaction, then that -- you know, I
22 mean, we believe vaccines are safe, and so we --
23 we -- we tell families, like, anaphylaxis is a
24 serious and life-threatening reaction. There's

1 other things that we talk about; fever, soreness
2 at the injection site are not serious or
3 life-threatening reactions, so if he's talking
4 about a life-threatening reaction, the only thing
5 you have to worry about is anaphylaxis, and that
6 does meet the standard of care.

7 Q Are you aware that the IOM has confirmed that
8 various vaccines can cause very serious reactions
9 that are not anaphylactic in nature?

10 A What we generally talk to families about
11 our -- I -- you know --

12 Q I know. I asked you are you aware that the
13 IOM has reached causality conclusions and found
14 that vaccines, various vaccines can cause very
15 serious reactions causally related to them beyond
16 anaphylaxis?

17 A Generally, yes. I can't quote you exact
18 information from that.

19 Q So anaphylaxis is not the only serious
20 reaction that vaccines can cause; correct?

21 A It's the serious reaction that we probably
22 most often -- as pediatricians we most often would
23 discuss with families.

24 Q Okay. You like talking about it because you

1 believe it's one in a million, but there are
2 serious adverse reactions that occur at a more
3 frequent rate than one in a million as confirmed
4 by the Institute of Medicine. Isn't that true?

5 A I'd have to review the Institute of Medicine
6 report to tell you.

7 Q Isn't the purpose of the VIS to actually
8 inform the parents of serious risks for which
9 there has been science -- for which there is
10 science to support that there is a causal
11 relationship?

12 A The VIS is to inform parents of risks. The
13 part about the causal relationship, I'm not an
14 expert on -- on all of that.

15 Q Okay. So, for example, isn't it true that
16 encephalopathy after a prior dose of DTaP vaccine
17 is a contraindication to further DTaP vaccine;
18 correct?

19 A Correct.

20 Q Okay. Meaning DTaP can cause encephalopathy;
21 correct?

22 A That's implied. I can't say for sure that it
23 causes it, but I know that we shouldn't give
24 subsequent doses in the setting of a

1 contraindication.

2 Q If a child got DTaP and had -- you know, and
3 then develops encephalopathy within seven days, if
4 you don't think it's related to the vaccine, why
5 not just keep giving the kid DTaP?

6 A Well, you'd want to figure out what the cause
7 of the encephalopathy was to the very best of your
8 ability.

9 Q Are you aware that there have been numerous
10 cases in which parents and families are
11 compensated for encephalopathy following DTaP
12 vaccination, serious brain injuries?

13 A I haven't reviewed compensation studies or
14 reports.

15 Q Are you aware of the Institute of Medicine's
16 discussion regarding pertussis-containing vaccines
17 and encephalopathy?

18 A I haven't reviewed the -- that specific
19 document.

20 Q If it is the case that there are serious
21 adverse reactions beyond anaphylaxis, would it
22 have violated the standard of care applicable if
23 Mr. Hazlehurst is asking what are the risks of
24 vaccines to not inform Mr. Hazlehurst of those

1 other serious adverse reactions?

2 A So I -- I can tell you what we do on a
3 practical level, and that is address the parents'
4 questions and do the best we can to provide them
5 with information.

6 Q If a vaccine can cause a serious adverse
7 reaction and the parent is asking the doctor here,
8 Dr. Hays, if Mr. Hazlehurst had asked Dr. Hays
9 what are the serious adverse reactions that can be
10 caused by this vaccine, if Dr. Hays doesn't tell
11 him what they are, isn't that a violation of the
12 minimum standard of care applicable for Dr. Hays
13 to vaccinate Yates?

14 MR. SANDERS: Object to the form of the
15 question as overbroad. You can answer, Dr. Mace.

16 A Pediatricians focus on telling parents about
17 the more common side effects of the vaccinations.
18 We don't list every possible, even -- even serious
19 ones. For example, when I administer the MMR
20 vaccine, I know that thrombocytopenia can occur
21 after an MMR vaccine is given. I do not tell all
22 families that their child could experience
23 thrombocytopenia. I can't list every possible --
24 and that's a serious reaction because they're very

1 rare.

2 Q (By Mr. Siri) Thrombocytopenia --

3 A I'm sorry, was that a question?

4 Q Yeah, sorry. How -- how often -- one in how
5 many million -- one in how many doses does
6 thrombocytopenia occur after an MMR vaccine?

7 A I'd have to look that up to give you an exact
8 number.

9 Q But you're sure that it's rare?

10 A It's -- it's rare. I've had patients who've
11 had thrombocytopenia following MMR. I have not
12 had patients who have had encephalopathy following
13 their DTaP.

14 Q Is -- isn't it -- well, they're far -- one is
15 far easier to diagnose; right? Two-month-old
16 babies typically can't talk; correct?

17 A Correct.

18 Q Okay. They can't express issues that they
19 have with cognitive processing, can they?

20 A That's correct.

21 Q I mean, at most, what babies can often do is
22 just cry; right?

23 A Right.

24 Q So if there is encephalopathy to a

1 two-month-old baby, the best -- I mean, at most,
2 what they can really do is cry; right?

3 A Encephalopathy is bad. Encephalopathy is
4 altered level of consciousness.

5 Q Right.

6 A But coma, it lasts longer than 24 hours, and
7 I -- I -- I cannot imagine a child with
8 encephalopathy that does not present to medical
9 care during the time period when they're affected
10 by their encephalopathy.

11 Q Encephalopathy is just a term -- general term
12 for basically damage to the brain; correct?

13 A That's a general term, yes.

14 Q Right. Meaning -- encephalopathy can mean
15 many -- it can have many different types of
16 effects on cognition. It doesn't necessarily have
17 to result in a coma; correct?

18 A Correct. But there are specific guidelines
19 for encephalopathy following vaccination that
20 describe what we're looking for.

21 Q I'm talking about encephalopathy in the real
22 world, not, you know, not -- you know,
23 encephalopathy is not -- the term -- medical term
24 encephalopathy is some lowered level of

1 consciousness; correct? It's some impact on
2 cognition, cognitive abilities; right?

3 A It -- it's a decreased level of alertness,
4 could be other -- affecting other cognitive
5 capacities as well, confusion, et cetera. But
6 decreased level of alertness, bizarre behavior,
7 that sort of thing is part of -- bizarre isn't a
8 word I -- that's a word I would use in my own
9 terminology.

10 Q If a two-month-old baby suffered, you know,
11 some form of encephalopathy, became sleepier after
12 those vaccines, just generally was a sleepier,
13 less aware baby, you wouldn't necessarily
14 recognize it, would you?

15 A I wouldn't consider just being slightly
16 sleepier an encephalopathy. I, in fact, tell
17 parents that one of the side effects of vaccines
18 is their -- that their child might sleep more than
19 usual in the first 24 or 48 hours following
20 vaccination, and that -- I consider that a routine
21 side effect or -- of being vaccinated.

22 Q But how do you know that they don't have a
23 reduced level of -- I mean, they're two months
24 old. How do you know that their cognitive

1 functioning hasn't been impacted by the
2 vaccination? How do you know that there isn't
3 some encephalopathy that's affecting, you know,
4 portions of their brain that you're not -- they're
5 not -- they don't have a major impact on a
6 two-month-old, like the ability to speak, the
7 ability to run, the ability to do all kinds of
8 things that a two-month-old cannot do yet?

9 A Well, two-month-olds feed. They have -- they
10 awaken, they feed, they make eye contact with
11 parents. If they're sleepier than usual following
12 a vaccination, you know, that -- that happens
13 commonly, but I don't expect a baby to be so
14 sleepy that they're not eating, that they're not
15 waking up, that they're -- they're, you know, not
16 making some eye contact with their parents.

17 Q There are even a -- there are -- there are
18 children and adults who get serious significant
19 neurological deficits that are still able to eat;
20 correct?

21 A It depends on the type of neurological
22 deficit.

23 Q We're going on a tangent. Let's go back.

24 Now, so --

1 MR. SANDERS: Mr. Siri, can I interrupt
2 for just a second? If -- we've now been going for
3 over six hours on this one.

4 MR. SIRI: Yep.

5 MR. SANDERS: And we've only had one
6 short break. If we get to a break at some point,
7 and I also want to note that myself and the court
8 reporter also had an over five-hour deposition
9 before. She's been going for over eleven straight
10 hours, so I just want you to take that into
11 account and just let us know if -- if we're
12 getting close or if we need to take a longer break
13 and --

14 MR. RILEY: I would -- I would like to
15 let everybody know I've been a part of it too.
16 This is David.

17 MR. SANDERS: Yeah, sorry, David. I --
18 Mr. Riley has also been --

19 MR. RILEY: And we're off. That's all
20 right. But go ahead, Mr. Siri.

21 MR. SIRI: How are you doing, Ms. Cohen?
22 Are you okay?

23 THE COURT REPORTER: I'm doing okay.

24 MR. SIRI: Okay. Would you -- well, let

1 me get to a good breaking point and we'll both
2 take a break. Is that all right?

3 THE COURT REPORTER: Perfect.

4 Q (By Mr. Siri) Okay. All right. So for MMR,
5 for example, you know, like you said,
6 thrombocytopenia is a serious reaction, and
7 thrombocytopenia is one of the reactions listed on
8 the VIS, correct, for MMR?

9 A Yes, it is listed. Temporary low platelet
10 count is listed.

11 Q All right. And it's there because there is
12 evidence to support that it's causally related to
13 the vaccine; correct?

14 A Yes.

15 Q Okay. And there -- also, as you could -- all
16 right. Did you just pull up the VIS?

17 A I have a copy of the MMR VIS, yeah.

18 Q Also, for example, rash all over the body has
19 also been known to be causally related to
20 receiving MMR vaccine; correct?

21 A Yes.

22 Q Okay. So that's also listed on the VIS;
23 right? And -- because -- and temporary pain and
24 stiffness in the joints, mostly in teenage and

1 adult women, has been confirmed by the IOM to be
2 causally related to the rubella component of the
3 MMR vaccine. That's why it's listed on the VIS;
4 correct?

5 A I see that, yes.

6 Q And it's there because it was -- there's
7 evidence to support that it's causally related to
8 the vaccine; correct?

9 A Yes.

10 Q Okay. As -- as -- similarly, there's
11 evidence to support that seizures, jerking and
12 staring often associated with fever, febrile
13 seizures basically, can be caused by the vaccine
14 which is confirmed by studies that show an
15 increased risk beyond just what would be expected
16 in the certain time period after getting MMR
17 vaccine for getting febrile seizures, even though
18 it -- this literature does appear to indicate that
19 many febrile seizures after MMR could be caused by
20 other things, there is an increased amount of
21 febrile seizures that do occur that is explained
22 by getting MMR; correct?

23 A That makes sense. I would agree with that.

24 Q Okay. And similarly, there has been

1 documented cases of MMR vaccine causing deafness;
2 correct?

3 A I'm not aware of that.

4 Q Okay. Similarly long-term seizures, coma,
5 and lowered consciousness, there is proof of those
6 being causally related to the MMR in rare, rare
7 cases.

8 A I have not reviewed information about that.

9 Q And also similarly, brain damage, there's
10 dozens of cases in vaccine court, for example, in
11 which brain damage was compensated, encephalopathy
12 after receipt of an MMR vaccine, there's even a
13 study published by the Vaccine Injury Compensation
14 Program by the doctors and scientists in HRSA, a
15 part of HHS, in which they've confirmed many cases
16 in which MMR has resulted in encephalopathy and
17 what they describe here as brain damage; correct?

18 A I have not reviewed that specifically. I
19 think we talked about that earlier.

20 Q Okay. You don't know that, okay. So, you
21 know, isn't the reason that they give the VIS so
22 parents will know what are the risks and, of
23 course, which is where they start, Section 1, the
24 benefits of vaccines; correct?

1 A Correct.

2 Q What use is this information for a parent to
3 decide on vaccinating or not vaccinating in a
4 given section if they don't get this thing before
5 the child is vaccinated?

6 A The discussion with the pediatrician, which
7 is limited in its scope, supplemented with this
8 material is what parents typically use to make the
9 decisions about vaccinating or not vaccinating
10 their children.

11 Q Got it. So if a parent didn't get any VISs
12 and the only thing they were told by their doctor
13 before getting vaccines on that day or in a prior
14 day was that when asked by the parent, and we'll
15 use a specific case, when asked of Dr. Hays by
16 Mr. Hazlehurst, what are the risks of the vaccines
17 that my child Yates is going to receive, if the --
18 Dr. Hays said the only risk of a serious adverse
19 event is one that would happen in the first 15
20 minutes and it happens only one in a million
21 doses, isn't it true that would not meet the
22 standard of care for vaccinating Yates?

23 MR. SANDERS: Object to the form of the
24 question. This has been asked and answered

1 several times. Go ahead, Dr. Mace.

2 A So you're asking me the theoretical question
3 if he was never given any VISs, if he was never
4 given VISs and this was the only piece of
5 information. I mean, I will say that
6 pediatricians would focus on anaphylaxis if we're
7 talking about the most serious reaction, and
8 again, we -- we do not list every possible serious
9 adverse event. It is -- we -- we don't -- in the
10 setting of a busy practice, the standard of care
11 is not that we list every single or numerous side
12 effects. We tell them the one that seems most
13 important at that time or the -- you know, the
14 more than one, but we have the discussion that we
15 think is most appropriate at that time and try to
16 give them good information.

17 Q (By Mr. Siri) Isn't that why you give the
18 VIS beforehand, so the parents can get all that
19 information?

20 A In general, parents are given VISs at the
21 time vaccines are administered and -- in -- in our
22 standard practice.

23 Q Okay. So, you know, so there are, you know,
24 contraindications and precautions to vaccines,

1 right, and so if the only thing a parent is told
2 that is, hey, the only reaction you're going to
3 have -- that could happen is in 15 minutes, it's
4 one in a million, if that -- if they don't -- if
5 their child doesn't have a reaction within
6 15 minutes, serious adverse reaction in
7 15 minutes, the parent would be just left assuming
8 that anything that happened to their kid after
9 their 15 minutes wasn't caused by the vaccine;
10 correct?

11 A That's -- seems speculative. I think parents
12 have more knowledge in general than that, but if
13 that's the only thing they were told, you could
14 draw that conclusion, yes.

15 Q And then they wouldn't -- they wouldn't be
16 able to -- they would then not be in a position to
17 really give real consent because they're not
18 really being told the real risks and benefits of
19 the products that their child is being injected
20 with; correct?

21 A Well, you know, we're talking about what's
22 done on a practical level day-to-day standard
23 care. We give them the VISs, we have a brief
24 discussion about the benefits and risks of

1 vaccines, and parents on a day-to-day basis make
2 that decision to consent to vaccines. If they
3 have additional concerns, they typically raise
4 those concerns and ask questions about it. And
5 families are also told at every single visit to
6 call our office if you have questions or concerns
7 or, you know, if something comes up that worries
8 you.

9 Q Okay. And that -- that all happen -- so the
10 process you just described is, you know, a parent
11 comes in and you provide the VIS, the doctor has a
12 discussion, discusses the potential risks and
13 benefits, answers any questions the parents have,
14 and then the parents -- and then the child is
15 administered the vaccines; correct?

16 A Yeah, the VIS is provided at some point along
17 that phase. You said that first. That's not
18 always the case. In many practices it's provided
19 after the discussion with the pediatrician.

20 Q All right. But -- but it's given to the
21 parents, whether it's placed in front of them on a
22 table and so forth or in some other manner before
23 the nurse injects the vaccines; correct?

24 A It's given -- it's brought in the room and,

1 yes, laid down on the table for the parents or
2 given, you know, that -- that's between the nurse
3 and the -- and -- exactly how that piece of paper
4 exchanges hands, but it's brought in at the time
5 the vaccines are administered.

6 Q But you -- you've never seen a VIS given
7 after a vaccination was administered by a nurse;
8 correct?

9 A Oh, I suspect there are occasions when that
10 comes up.

11 Q I'm asking if you've ever witnessed that.

12 A I can't think of a specific occasion, but,
13 you know, sometimes the -- the -- you know,
14 somebody forgets to hand people their handouts on
15 their way in into the office.

16 Q So I'll ask you this and let's take a break.
17 Is it -- is it your testimony that a parent who is
18 not provided any VISs and is only -- and is told
19 when the parent asks what are the risks of
20 vaccination, that there is a one in a million
21 chance of a serious adverse event and it would
22 happen within 15 minutes of vaccination, is it
23 your testimony that that would meet the standard
24 of care for informing the parents of the risks and

1 benefits of vaccination before administering
2 vaccines?

3 A A parent who has never been given any
4 other --

5 Q Exactly what I said, Doctor.

6 A Okay. So I -- I think that probably does not
7 meet what's typical standard of care.

8 Q So if Mr. Hazlehurst had never received a VIS
9 and upon inquiring from Dr. Hays what are the
10 serious risks of giving a vaccine to my child, if
11 Dr. Hays then told him, there's only a one in a
12 million chance of a serious adverse reaction and
13 it would happen within 15 minutes of vaccinating
14 Yates, and if that's the only information about
15 risks that was conveyed to Mr. Hazlehurst about
16 the risks, serious risks of vaccinating Yates,
17 that would not meet the standard of care
18 applicable for vaccinating Yates; right?

19 MR. SANDERS: Object to the form of the
20 question. You may answer, Dr. Mace.

21 A If all of that exactly as you said --

22 Q (By Mr. Siri) Exactly as I said it, Doctor.

23 A Right.

24 MR. SIRI: Okay. Let's take a break.

1 (Brief recess.)

2 THE VIDEOGRAPHER: We are now back on
3 the record at 8:36.

4 Q (By Mr. Siri) Dr. Mace, how much are you
5 being compensated for being an expert in this case
6 on behalf of the defendants?

7 A I am charging an hourly rate, \$400 per hour.

8 Q How many hours have you spent on this case
9 approximately so far?

10 A I -- it's in the ballpark of 40 or 45, not --
11 40 to 45 hours reviewing records, not counting
12 today's deposition.

13 Q I suspect reviewing the records was more
14 pleasant. Okay. I am -- you know, I am -- let's
15 see if I can wrap this up fairly quickly. Just a
16 few. Would you consider encephalopathy,
17 irrespective of whether caused by a vaccine,
18 right, just encephalopathy, to be a serious event,
19 a medical event?

20 A Yes.

21 Q Okay. Would you consider meningitis to be a
22 serious adverse event?

23 A Yes.

24 Q Would you consider long-term seizures to be a

1 serious adverse event?

2 A Yes.

3 Q Would you consider coma to be a serious
4 adverse event?

5 A Yes.

6 Q Would you consider lowered consciousness to
7 be a serious adverse event?

8 A It depends on the circumstances.

9 Q Okay. Would you consider permanent brain
10 damage to be a serious adverse event?

11 A Yes.

12 Q Would you consider chronic arthritis to be a
13 serious adverse event?

14 A Yes.

15 Q I will skip that. Would you consider deaf --
16 deafness to be a serious adverse event?

17 A Deafness, yes.

18 Q Would you consider long-term seizures to be a
19 serious adverse event?

20 A Yes.

21 Q Okay. Dr. Mace, do you consider yourself to
22 be an expert with regard to mitochondrial
23 disorders?

24 A No, I don't.

1 Q Okay. Do you have any training with regard
2 to mitochondrial disorders?

3 A No specific training, no.

4 Q Okay. Do you specifically treat kids with
5 mitochondrial disorders?

6 A I have treated one patient with a diagnosis
7 of mitochondrial disorder that I'm aware of.

8 Q Okay. And --

9 A I mean, one who was diagnosed with
10 mitochondrial disorder.

11 Q But what you treated them for wasn't the
12 mitochondrial disorder?

13 A I provided general pediatrics primary care to
14 that patient.

15 Q All right. But with regard to their
16 mitochondrial disorder, they went and saw a
17 specialist, I assume?

18 A They did.

19 Q Okay. A specialist with regard to
20 mitochondrial disorders?

21 A A neurologist.

22 Q A neurologist. Thank you. Right. You're
23 not a neurologist; correct?

24 A That's correct.

1 Q Okay. Do you have any experience diagnosing
2 mitochondrial disorders?

3 A No.

4 Q Okay. You're not aware that CISA, the
5 Clinical Immunization Safety Assessment Network
6 has a hub -- has a center within Vanderbilt?

7 A I am not aware of that.

8 Q Okay. You're -- you are aware that large
9 managed healthcare organizations have the health
10 records as well as the ICD-9/10 codes of the
11 patients millions -- often of patients within
12 their health systems?

13 A Yes. I don't know the details of that, but
14 as a general statement, yes.

15 Q All right. And -- and those medical records,
16 as well as how -- ICD-9 and 10 codes, are used by
17 researchers frequently to conduct all forms of
18 studies; correct?

19 A Yes.

20 Q I'm sorry?

21 A Yes.

22 Q All right.

23 A I'm aware that some studies are done. I
24 don't know to the extent that that's done.

1 Q Sure. But you review studies in the medical
2 literature; correct?

3 A Yes.

4 Q And you're aware that studies, for example,
5 comparing outcomes of different populations within
6 managed healthcare organizations are conducted to
7 advance the medical sciences; correct?

8 A Yes.

9 Q There are children who are more susceptible
10 to a vaccine injury than others; correct? Let --
11 strike that. Let me ask you this; okay? Are you
12 aware that in 1994 the Institute of Medicine
13 stated, quote, the committee was able to identify
14 little information pertaining to why some
15 individuals react adversely to vaccines when most
16 do not. Are you aware of that quote?

17 A I haven't seen that specific quote. I --
18 I've reviewed lots of materials and may have seen
19 that, but I don't recall specifically.

20 Q Okay. Then let me -- you said you have seen
21 the 2011 IOM report; correct?

22 A I -- I have looked at it but not studied it
23 in detail.

24 Q Okay. Let's just quickly take a look at

1 this.

2 MR. SIRI: Oh, Mr. Lawson, if you could
3 kindly give me screen sharing capabilities.

4 THE VIDEOGRAPHER: You should have it
5 now.

6 MR. SIRI: Thank you. I appreciate
7 that.

8 (Whereupon, Exhibit
9 No. 21 was marked to the
10 testimony of the
11 witness.)

12 Q (By Mr. Siri) Okay. So this is an excerpt
13 from the 2011 IOM report Adverse Effects of
14 Vaccines, Evidence and Causality, and a section
15 entitled Increased Susceptibility. Have you seen
16 this portion of the 2011 IOM report before?

17 A No, I don't recall reading this.

18 Q Okay. Can you kindly read the portion in
19 yellow?

20 A Both epidemiologic and mechanistic research
21 suggest that most individuals who experience an
22 adverse reaction to vaccines have a preexisting
23 susceptibility. These predispositions can exist
24 for a number of reasons, genetic variants (in

1 human or microbiome DNA), environmental exposures,
2 behaviors, intervening illness, or developmental
3 stage, to name a few, all of which can interact as
4 suggested graphically in Figure 3-1. Some of
5 these adverse reactions are specific to the
6 particular vaccine, while others may not be. Some
7 of these predispositions may be detectable prior
8 to the administration of vaccine; others, at least
9 with current technology and practice, are not.
10 Moreover, the occurrence of the adverse event is
11 often the first sign of the underlying condition
12 that confers susceptibility.

13 Q Okay. Do you agree with what you've just
14 read, Dr. Mace?

15 A I -- you know, I would need to interpret that
16 in the context of other information to see is
17 there a subsequent report, you know, what
18 criticisms are there about this particular thing,
19 so I can't tell you whether I agree or disagree
20 about a statement that I've not ever read before.

21 Q All right. Well, I'm not asking about -- I'm
22 asking about the substance of the statement. Do
23 you agree with the substance of what's provided in
24 the statement?

1 A I'm not sure what you mean by do I agree with
2 the substance.

3 Q All right. Let me ask it to you this way
4 quickly. Do you agree that there are some
5 children who are more likely to be injured by a
6 vaccine than others?

7 A I -- I -- I think that's a possibility. I
8 don't have enough data to say yes or no.

9 Q So do you disagree with the Institute of
10 Medicine when it says that both epidemiologic and
11 mechanistic research suggests that most
12 individuals who experience an adverse reaction to
13 vaccines have a preexisting susceptibility?

14 A That seems like a very reasonable statement
15 to me.

16 Q So do you agree with that statement?

17 A It seems reasonable to me. Certainly I can
18 think of examples of things that -- that make me
19 agree with that statement.

20 Q Okay. So what would an example be?

21 A An individual who is immune suppressed being
22 given a live virus vaccine, that's -- that's an
23 environmental or, you know, a factor that could
24 cause them to be susceptible to reaction from that

1 vaccine.

2 Q So some children can have a preexisting
3 susceptibility to have an injury from a
4 vaccination; correct?

5 A Yes.

6 Q Can you kindly read the portions highlighted
7 in yellow from the 2011 IOM report?

8 A Much work remains to be done to elucidate and
9 to develop strategies to document the immunologic
10 mechanisms that lead to adverse effects in
11 individual patients. In some metabolically
12 vulnerable children, receiving vaccines may be the
13 largely nonspecific last straw that leads these
14 children to reveal their underlying genotype.

15 Q Do you disagree with the IOM when it says
16 that in some metabolically vulnerable children,
17 receiving vaccines may be the largely nonspecific
18 last straw that leads these children to reveal
19 their underlying genotype?

20 A You know, I'm not in a position to agree or
21 disagree with the Institute of Medicine. I view
22 it as a source of information.

23 Q Do you have -- are you -- do you have any
24 evidence that would indicate that that statement

1 is not accurate?

2 A I don't have evidence for that, no.

3 Q Okay. So you -- absent any additional
4 evidence, you believe, if I'm understanding
5 correctly, that it's a reasonable statement and
6 you would agree to it subject to learning
7 additional contrary evidence?

8 MR. SANDERS: Object to the form of the
9 question. That mischaracterizes her testimony.

10 A I would want to know more and put this into
11 context before I could say I agree or disagree
12 with this statement.

13 Q (By Mr. Siri) Okay. But you find it
14 reasonable?

15 A I find it possible.

16 Q Okay. Do you think the IOM got it wrong when
17 they wrote this?

18 A I can't answer that question. I -- I
19 don't -- I just don't know. I would need more
20 information.

21 Q Do you think it's -- do you think that it's
22 more likely than not that when they wrote this,
23 they had -- it was a well-supported statement and
24 hence that's the reason they put it in here?

1 A You know, I just don't have information about
2 how this document was developed.

3 Q So you're saying you just don't know one way
4 or another whether or not the statement is
5 correct?

6 A Yes, that's fair to say.

7 Q But you find it to be a reasonable statement?

8 A It -- I -- I think it's possible that -- yes.

9 Q It's -- it's possible that some metabolically
10 vulnerable children, receiving vaccines may be the
11 largely nonspecific last straw that leads these
12 children to reveal their underlying genotype;
13 right?

14 A You're asking me to speculate about that --
15 do I speculate that it's possible, I don't have
16 any evidence for that one way or the other.

17 Q Okay. Fair enough. What is the -- what is
18 VAERS?

19 A It's the adverse event reporting system.

20 Q Okay. Have you ever submitted a report to
21 VAERS?

22 A I have not submitted a report to VAERS. I
23 have though discussed an event with some
24 infectious disease specialists at Vanderbilt about

1 whether or not a vaccine reaction was likely, and
2 they were on a -- that person was on a committee
3 at the CDC who discussed it, and we did not report
4 that because it was found not to be likely due to
5 the vaccine.

6 Q So unless you -- unless -- unless you believe
7 that it was -- that the event was, you know,
8 caused by the vaccine, you don't report the event
9 to VAERS?

10 A My understanding is I should report serious
11 life-threatening events, things that are a
12 contraindication to future vaccinations, though I
13 would report under those circumstances.

14 Q Meaning you would report one of the
15 conditions that -- on that list that's -- of
16 conditions that are required to be reported is
17 what you're saying?

18 A Yes.

19 Q Okay. But otherwise, you don't report
20 adverse events to VAERS?

21 A I don't report routine adverse events, like
22 fever, soreness at the injection site, those sorts
23 of things.

24 Q All right. Or if it's a serious event, but

1 it's not within the scope of one of the reportable
2 adverse -- serious adverse events that's issued by
3 the CDC?

4 A I would not report if it's not listed as a
5 serious adverse event.

6 Q That's reportable.

7 A That's reportable.

8 Q Okay. Okay. Is your understanding of VAERS
9 that it's a passive surveillance system?

10 A Yes.

11 Q Okay. And that it's there to pick up
12 potential adverse events that are occurring that
13 are unknown to the CDC?

14 A Yes.

15 Q Okay. And are you aware that an agency
16 within HHS funded a study with Harvard Pilgrim
17 Health Care which stated that fewer than 1 percent
18 of vaccine adverse events are reported to VAERS?

19 A I'm not aware of that study.

20 Q Does that statistic surprise you?

21 A No, it doesn't, because so many of what
22 you -- what I would consider adverse events would
23 include things like fever, soreness at the
24 injection site, swelling at the site of

1 administration.

2 Q Would it surprise you that -- that, you know,
3 fewer than 1 percent of serious adverse events are
4 reported to VAERS?

5 A I think it -- it depends on if the -- if the
6 serious adverse event is thought to be related to
7 the vaccination or if it's some, you know, unknown
8 thing.

9 Q Right. Meaning it -- as long as it's
10 something that's already -- as long as it's a -- a
11 mandatory reported serious adverse event, then
12 you're saying you would be surprised if it was
13 less than 1 percent?

14 A Yes.

15 Q But if it was something that wasn't on the
16 list of items for which doctors are required to
17 report to VAERS, those serious adverse events you
18 wouldn't be surprised if it was less than
19 1 percent?

20 A Yes.

21 Q All right. Many vaccines contain aluminum
22 adjuvant; correct?

23 A Yes.

24 Q Okay. Isn't it -- are you -- have you

1 conducted any studies regarding aluminum adjuvant?

2 A I have not.

3 Q Okay. Do you have any experience doing any
4 science related to aluminum adjuvants?

5 A I do not.

6 Q Would you -- would you be able to identify
7 which vaccines have aluminum adjuvant and which
8 don't?

9 A I couldn't off the top of my head, but I can
10 access that information and can have my assistant
11 look it up.

12 Q Okay. All right. Are you aware that
13 aluminum adjuvant in vaccines can bind not only to
14 a target antigen, but to, you know, any other
15 biological material, by-products, impurities that
16 are contained in the vaccine?

17 A I'm not aware of the exact mechanism of
18 action or what it binds to other than it is an
19 adjuvant that increases the effectiveness of the
20 vaccine.

21 Q Okay. Can you name the types of aluminum
22 adjuvant used in vaccines?

23 A Not -- not the name of it, no.

24 Q Okay. Do you know which vaccines Yates

1 received had aluminum adjuvant in them off the top
2 of your head?

3 A I would need to look that up --

4 Q Okay.

5 A -- and to see which vaccines contain the
6 aluminum adjuvant.

7 Q I assume then you're also not familiar with
8 the particle size of the -- each piece of aluminum
9 adjuvant typically that are in vaccines?

10 A That's correct.

11 Q Okay. And you're not familiar with how many
12 pieces of aluminum adjuvant are contained in
13 vaccines typically?

14 A That's correct.

15 Q Okay.

16 A I think that information is easily available
17 though. I -- I mean, I've looked at sites about
18 aluminum with explanations for why aluminum is
19 helpful and not a risk to patients.

20 Q Have any of those studies ever involved
21 injecting aluminum into animals or humans?

22 A I don't -- I can't quote you the specific
23 studies. I look at summaries and recommendations
24 and -- of things.

1 Q Uh-huh. And the -- okay. And -- and those
2 summaries and recommendations will cite to
3 supporting studies; correct?

4 A Yeah. I mean, what I -- you know, one thing
5 that I've looked at again is that Children's
6 Hospital of Philadelphia website that gives
7 explanations that are useful to pediatricians and
8 to family members, answering common questions
9 including the question about the aluminum
10 adjuvant.

11 Q A hospital that's famously known for where
12 Paul Offit practices; correct?

13 A Correct.

14 Q All right. And Dr. Paul Offit has made
15 millions of dollars selling -- for inventing and
16 selling a RotaShield vacc -- a rotavirus vaccine;
17 correct?

18 A I understand that he was involved in the
19 development of that vaccine. I don't know his
20 financial -- finances.

21 Q Are you aware that he's disclosing making at
22 least \$6 million from selling that vaccine in one
23 disclosure alone?

24 A I don't --

1 MR. SANDERS: Object to the form of the
2 question. She -- asked and answered. Go ahead,
3 Dr. Mace.

4 A I don't know his finances.

5 Q (By Mr. Siri) Okay. So you looked at the
6 children's hospital for information about
7 safety -- Children's Hospital of Philadelphia for
8 safety of aluminum adjuvant, but you didn't look
9 at any of the studies that might or might not have
10 been cited on the web page of the Children's
11 Hospital of Philadelphia; correct?

12 A Correct.

13 Q Did you look anywhere else about the safety
14 of aluminum adjuvant any time in 30 years of being
15 a pediatrician?

16 A When I looked at that topic, I imagine that I
17 looked through UpToDate, which is an online
18 resource that provides information to read about
19 that, but I can't quote you specific studies or
20 articles.

21 Q Does the -- does the name Mitkus sound
22 familiar, the Mitkus study?

23 A No.

24 Q That's the study that the FDA and CDC rely on

1 to say that aluminum adjuvant is safe. You're not
2 familiar with that?

3 A I -- I don't have that.

4 Q You're not aware that that involves orally
5 ingesting aluminum adjuvant in animals?

6 A I've not looked at that study.

7 Q Okay. And aluminum adjuvant is in many ways
8 for the vaccines in which contains an active
9 ingredient; right? Without that aluminum
10 adjuvant, the immune response in the body to the
11 antigens in the vaccine would not be sufficient to
12 actually develop immunity, right, to the target
13 disease; correct?

14 A I can't tell you about whether it just
15 increases its -- whether we're at, you know, an
16 unacceptable response or just a better response,
17 but with the aluminum adjuvant, you have a better
18 response.

19 Q Are you aware that aluminum adjuvants can
20 increase production of all kinds of cytokines, for
21 example, IL-1, IL-2, IL-6, and IL-17?

22 A I haven't looked at the different studies
23 about that.

24 Q All right. Are you aware that there are

1 studies that have demonstrated aluminum adjuvant
2 injected into the body can cause an increase in
3 IL-6 in the brain?

4 A I'm not aware of that study. I haven't
5 looked at it.

6 Q Okay. Dr. Edwards has copies of those
7 studies, and you should -- you know, they
8 were already marked in her deposition. You can
9 take a look at them. Are you aware that there are
10 studies that have demonstrated that an increase in
11 IL-6 has been shown to introduce autism-like
12 features in lab animals?

13 A I am not.

14 Q Okay. Well, Dr. Edwards, again, has copies
15 of those studies from her deposition, and you can
16 look at those. Are you aware that antigen that is
17 absorbed by aluminum adjuvants are taken up by
18 microphages and dendritic cells and then travel to
19 other parts of the body?

20 A I -- I haven't studied the mechanism of the
21 aluminum.

22 Q Okay. When you inject a vaccine, right, the
23 antigen needs to go to the lymph nodes in order to
24 generate antibodies; correct?

1 A I don't know the -- if it happens in the
2 lymph node or in the blood system.

3 Q Well, the antigen needs to meet with a
4 matching T or B cell, correct, that's naive so it
5 can then proliferate; right?

6 A Yes.

7 Q So and that matching happens typically in the
8 lymph nodes; right?

9 A I finished medical school 30 years ago.

10 Q Okay.

11 A I -- so you're asking me questions of things
12 that are more detailed than what I can handle.

13 Q Well, we're talking about, you know, vaccines
14 causing autism, and aluminum adjuvant has been
15 widely implicated in causing autism by many of the
16 world-renowned scientists on aluminum adjuvant,
17 and so I -- I -- I assume it's something you've
18 looked at before you reached your conclusion about
19 whether vaccines cause autism. So let me -- I can
20 wrap this up pretty quickly then. Are you aware
21 that -- that antigens in the vaccine are bound to
22 the aluminum adjuvant?

23 A Yes.

24 Q Okay. And that they then are taken up by

1 macrophages to phagocytosis, which means they're
2 eaten up by the macrophages and dendritic cells?

3 A I understand what that means, yes.

4 Q Okay. And then they go someplace in the body
5 in order to create antibodies to the antigen;
6 correct?

7 A Makes sense, yes.

8 Q Okay. Now, after that happens, where do
9 these aluminum-loaded macrophages go in the --

10 A I don't -- I don't know the answer to that.

11 Q Okay. Are you aware that every study that
12 has looked -- injected aluminum adjuvant in
13 animals, including rabbits, mice, monkeys, and
14 then dissected them has found that after injecting
15 aluminum adjuvant into those animals, it was found
16 in many organs, but -- but prominently in the
17 brain of those animals?

18 A I'm not aware of that study.

19 Q Okay. It's not a study. It's a whole series
20 of studies starting in 1997, a few of which were
21 provided to Dr. Edwards. I -- I believe you
22 should take a look at those studies. I
23 provided her with -- I provided her with seven
24 studies, there are way more, but they consistently

1 find out, the first one being a rabbit in 1997 by
2 the CDC. Okay. So in any event, are you aware of
3 whether or not aluminum adjuvants in vaccines can
4 cause autism?

5 A My understanding is that aluminum adjuvants
6 in vaccines do not cause autism.

7 Q And what are you basing that on?

8 A On the same discussion that we had earlier
9 about the American Academy of Pediatrics,
10 information about autism and vaccines, along with,
11 you know, attending conferences and expert
12 opinions.

13 Q But today is the first time you've ever even
14 discussed the potential of aluminum adjuvants
15 causing autism; correct?

16 A I've looked at aluminum adjuvant in terms of
17 general reactions, but not specifically with
18 regard to autism.

19 Q When you say general reactions, you mean
20 local injection site reactions?

21 A Just in general. I looked at the safety of
22 aluminum adjuvant and we looked at the -- at --
23 looked at these -- at the level that a general
24 pediatrician does to understand about with regard

1 to the safety of administering of a vaccine to a
2 patient or not.

3 Q And would that be you going on to PubMed and
4 finding a study or two about injecting aluminum
5 adjuvants to see its safety?

6 A So I -- you know, I looked through UpToDate
7 and looked at references that were in UpToDate and
8 looked at the Children's Hospital of Philadelphia
9 website.

10 Q I just want to share my screen for a second
11 to make sure I'm looking at the same thing. Is
12 this the website -- web page you're talking about,
13 vaccine ingredients, aluminum?

14 A That -- that, yes, is part of the website.

15 Q Okay. And then so you looked at this page
16 and then you looked at the UpToDate page. Can you
17 show me that UpToDate page that you looked at?

18 A UpToDate is an online resource. I didn't
19 print anything from UpToDate about aluminum and --
20 and my looking at that question of aluminum
21 adjuvant was a while back. That's not something
22 that I've looked at in the last few months.

23 Q So the last time you looked at it was a few
24 months ago?

1 A With referring to aluminum, it was more than
2 that.

3 Q Okay. UpToDate, is there a web address for
4 that?

5 A No, it's a subscription, so the -- the
6 hospital has a subscription to UpToDate.

7 Q Would you be -- would you be willing to
8 provide me, you know, the aluminum -- the page on
9 there that describes aluminum adjuvant?

10 A I can -- I can look. Again, I don't know --
11 I -- my recall of what I specifically looked at
12 about that is not at the front of my mind because
13 that was a long time ago. UpToDate is a resource
14 that I commonly look at for information and
15 advice.

16 Q Okay.

17 A So I -- I can look and see what I can find.

18 Q Will you print out the page about aluminum
19 adjuvants, you know, provide it to Mr. Sanders
20 and --

21 A I'll see what I can find.

22 Q So you're not sure if there's a page on
23 UpToDate about aluminum adjuvant?

24 A Right, right. My -- my -- you know, what I'm

1 telling you are resources that I typically go to
2 that I would have sat down at my computer and
3 looked, and so UpToDate is a resource, I go to the
4 Children's Hospital of Philadelphia. I can't
5 quote specifically where -- exactly what I read
6 about aluminum adjuvants.

7 Q So you may or may not have read something
8 about aluminum adjuvants on UpToDate?

9 A Correct.

10 Q When is the last time you looked at the CHOP
11 website aluminum page?

12 A The -- specifically that page was probably a
13 year and a half ago.

14 Q And since you're in the business of
15 administering vaccines day in and day out, do you
16 think that the parents that trust you with the
17 safety of their children would appreciate if you
18 did read all those studies regarding aluminum
19 adjuvants, including all the ones that were
20 provided to Dr. Edwards, so that you could see
21 what the peer-reviewed literature, in fact, shows
22 about it? As you've said, sometimes clinical
23 practice takes many, many, many years to catch up
24 with science; right?

1 A Sometimes it takes time for things to get
2 published in terms of clinical practice
3 guidelines.

4 Q Especially, right, when it goes against what
5 the medical profession has been doing, and it
6 might even implicate the medical profession and
7 potentially cause harm, that can really end up
8 taking a lot longer for that practice change to
9 happen; true?

10 MR. SANDERS: Object to the form of the
11 question. You can answer, Dr. Mace.

12 A That's a -- question to me.

13 Q (By Mr. Siri) That's okay. I'll strike the
14 question. It's -- okay. So in line with David's
15 request, you know, he's from Tennessee, I'm from
16 New York, he's far more courteous than I am, that
17 I end this deposition sooner rather than later,
18 and despite the fact that I do have more material,
19 I think that -- I think that we can put this to
20 bed now. As long as we're going to, you know, end
21 it now, I'll stop now.

22 MR. SIRI: Are we going to -- would you
23 like to conclude, Mr. Sanders?

24 MR. SANDERS: Yes, I would.

1 MR. SIRI: Okay. Well, and I know
2 you've had a long day too. And thank you, you
3 know, Mr. Lawson for -- I know you've had a long
4 day, and Ms. Cohen as well. And, Dr. Mace, thank
5 you for spending the afternoon answering
6 questions.

7 MR. SANDERS: Dr. Mace, they'll take us
8 off the record and then you can click out. Thank
9 you.

10 THE WITNESS: Okay. Thanks.

11 MR. RILEY: Thanks to everybody.
12 Thanks, Samantha. Thanks, Randy.

13 THE COURT REPORTER: No problem.

14 MR. RILEY: All right.

15 THE WITNESS: Is it okay to click out?

16 THE VIDEOGRAPHER: Sorry. I was on
17 mute. I was giving the announcement and nobody
18 heard. Let's do this again. This is the end of
19 the video deposition of Dr. Rachel Mace. Counsel
20 did waive the formal reading of the caption. We
21 are now off the record at 9:10 p.m.

22 (Whereupon, the
23 deposition of Rachel
24 Mace, M.D., concluded.)

C E R T I F I C A T E

STATE OF TENNESSEE:

COUNTY OF SHELBY:

I, SAMANTHA COHEN, Registered Professional Reporter, Certified Realtime Reporter, and Notary Public for the State of Tennessee at Large, do hereby certify that I reported in machine shorthand the above-captioned proceedings.

I HEREBY CERTIFY that the foregoing pages contain a full, true, and correct transcript of my said Stenotype notes then and there taken.

I FURTHER CERTIFY that I am not an attorney or counsel of any of the parties, nor a relative or employee of any of the parties, nor am I a relative or employee of any attorney or counsel connected with the action, nor am I financially interested in the action.

I FURTHER CERTIFY that in order for this document to be authentic and genuine, it must bear my original signature and my embossed notarial seal and that any reproduction in whole or in part of this document is not allowed or condoned and that such reproductions should be deemed a forgery.

THEREFORE, witness my hand and my official seal in the State of Tennessee on October 17, 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:

RACHEL MACE, M.D.

Subscribed and sworn to by me on this the
_____ day of _____, 2020.

Notary Public

My Commission Expires:

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