In the Matter Of:

HAZLEHURST vs

HAYS, M.D., ET AL.

RACHEL MACE, M.D.

August 26, 2020

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

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 **

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

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

VIDEOGRAPHER: RANDY LAWSON, Law Media Productions

ALSO PRESENT: ROLF HAZLEHURST
PATRICIA CHEN

I N D E X

E X H I B I T S

EXHIBITS - CONTINUED

P R O C E E D I N G S

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

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

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

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

RACHEL MACE, M.D.,

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

EXAMINATION

BY MR. SIRI:

Q Good morning, Dr. Mace.

A Hi.

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

your full name for the record?
A Rachel Lenox Mace.
Q Have you ever been deposed before?
A I have.
Q Okay. How many times have you been deposed?
A I've given a deposition just once.
Q Okay. And what was your role in that case?
A That was many years ago in the early 1990s. My recollection is it was a custody dispute between parents. I had provided care for their child and they wanted some explanation of the medical records.
Q Did it involve a vaccine issue?
A It did not.
Q Okay. Thank you. I'm going to go over a few rules since it's been a while since you've been deposed, which is a good thing, and, you know, if you don't understand any of the rules, please let me know.
A Okay.
Q Now, the court reporter has placed you under oath, same as a court of law, meaning you're testifying here today under penalty of perjury. Do you understand what I mean when I say perjury?

A I do.
Q Okay. The court reporter is making a record by typing up all the questions and your answers.
MR. SIRI: So I'll try not to go too fast, Ms. Cohen.
Q (By Mr. Siri) And to do that though, when you answer, kindly do so audibly. If you nod your head, she can't take that down.
A Okay.
Q Okay. And also, uh-huhs, you know, are -- we don't know if that means yes or no --
A Right.
Q -- when you read it, only when you hear it. So if you could say yes or no instead of uh-huhs, I'd appreciate it.
A I'll do my best.
Q Thank you. If you don't understand the question, please let me know before answering; okay?
A Okay.
Q All right. And please wait until I complete asking the question before you answer. There will definitely be times where you know what I'm about to ask, but if I don't complete the question

before you answer, there's no complete record.
A Okay.
Q Okay. If you don't know an answer to a question, you can say I don't know. That's entirely fine. There will be probably questions you don't know the answer to. You don't have to guess or speculate. But if you don't know the answer, you know, you could state -- but you should provide your best recollection, you know, even if it's partial or vague; okay?
A Okay.
Q All right. Now, as I mentioned yesterday, this is now my second Zoom deposition, so under normal conditions, I would be handing you exhibits.
A Okay.
Q Instead, I'm going to put them on the screen, and so you won't be able to manipulate them on your end. If you want me to move up or down or show you something, just let me know; okay?
A Yes.
Q Or if you can't see anything, you need me to zoom in, or what have you. Okay. So I'm going to start with a standard question, and it's -- are

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

A I am not.

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

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

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

A We did.

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

A Not in any specific terms. Just, you know, prepare the office, close the door, people don't talk outside the room, that sort of thing.
Q Oh, so people just in your general vicinity, in your office about not dropping in.
A Right. I'm at work and in my office in the back and wanted to make sure that I don't have interruptions for this.
Q Okay. Did you -- have you spoken to anyone other than Mr. Sanders about this case at all?
A No. I -- I -- before agreeing to review the case, I -- I notified our hospital risk management office just to make sure that they thought that that was okay.
Q Okay. Have you had any conversations with Dr. Kathryn Edwards about this deposition?
A I have not.
Q Or about this case?
A I have not.
Q Okay. And well, you said you reviewed a number of depositions. Were one of those that of Dr. Kathryn Edwards?
A No, it wasn't.
Q Okay. And which depositions have you

reviewed?
A I have reviewed depositions from Carlton Hays on September 12 and 13, a deposition of -- I'm sorry, September 12 and 13 of 2006; LuAnn Upchurch from June 29 of 2016; Robert Riikola, September 21, 2015; Angela Hazlehurst, September 12, 2006; Angela Hazlehurst, July 1, 2015; Rolf Hazlehurst, July 1, 2015 and May 13, 2016 -- 2016; Andrew Zimmerman from June 22, 2018; Ramon Ramos, I don't have that date right -- right handy; Elizabeth Munford, those are all the -- and I'm sorry, Richard Kelley from November 7 of 2016.
Q And you reviewed all of those depositions?
A Yes.
Q Wow, okay. And besides those depositions, you reviewed Yates' medical records?
A I reviewed medical records beginning from his birth until -- the last record I have is an evaluation from July 3, 2002.
Q Okay. Have -- so other than the deposition transcripts and the medical records, were there any other documents that you reviewed?
A Yes.
Q Okay.

A Let me get the correct notebook. I also reviewed the complaint for damages and the answer of the defendants.
Q Okay. You might be more prepared today than me. Anything else?
A I reviewed medical literature that I thought was pertinent to support my -- my beliefs with regard to standard of care, just -- you know, to -- to see where that -- where the information came from that I base my practice on, so I -- I reviewed specifically the 2000 Red Book because that's a document that was in place at the time of the -- of the vaccinations of Yates. I also reviewed through the 2015 and the most current Red Book, which is 2018 to 2021, because this is a resource that I use regularly. I also looked at some information about vaccinations and potential complications like the question of whether autism is caused by MMR vaccine. I looked a little bit at the resources I typically use to get medical information and information about mitochondrial disorders as well.
Q Okay. Did you -- so you looked at the 2000 Red Book. Did you also look at any of the --

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

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

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

A Yes.

Q Okay.

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

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

care in 2000?
A Yes.
Q Okay. So and do you -- did anybody discuss with you the topics that would be covered today during the deposition?
A In general terms we talked about the standard of care and questions about, you know, the -- what -- what is standard of care for a pediatric patient with regard to immunizations, care for otitis media, standard procedures in the office with regard to vaccine information sheets and information provided to families. We also talked a little bit about -- a little bit about his diagnosis of autism and the -- I'm aware that there is -- there are some records or some information about him possibly having a mitochondrial disorder, which is why I looked at that information.
Q Okay. Do you feel like you were -- you were coached to give certain answers or do you -- are you -- are you going to give your -- the testimony that -- well, do you believe -- do you feel like you were coached to give certain answers here today during this deposition?

A No.

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

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

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

A Okay.

Q Okay. HHS.

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

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

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

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

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

A That's the Center for Disease Control.

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

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

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

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

A Yes.

Q Okay. CDC is part of HHS; correct?

A I don't know.

Q Okay. FDA?

A The Food and Drug Administration.
Q Do you consider the FDA to be a reliable source -- authority and source of information for regard to vaccines?
MR. SANDERS: Same objection. You can answer, Doctor.
A I -- I look at this -- the FDA as a -- I believe they license drugs, so they decide what -- what medications or vaccines can be used and are licensed in the United States, but I don't look at them for information with regard to what vaccinations should be administered.
Q (By Mr. Siri) Okay. Fair enough. So you would consider them a reliable authority with regards to the licensure of vaccines?
A Yes.
Q Okay. And NIH.
A National Institutes of Health.
Q Okay. And would you consider the NIH to be a reliable authority of information regarding vaccines?
MR. SANDERS: Same objection.
A I would make the same comment as well about -- about this as well -- as with all of

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

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

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

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

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

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

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

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

A I've heard of it, yes.

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

A I don't know what HRSA does.

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

A ACIP?

Q Yes.

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

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

A Uh-huh.

Q Is that correct?
A Yes, that's what I understand. They -- they make -- they don't decide. They -- they produce guidelines for us as practicing physicians to help us make decisions about what to do for our patients.
Q Understood. And when -- and the CDC publishes the recommended childhood immunization schedule; correct?
A That's -- that's correct.
Q All right. And the pediatricians such as yourself look to that schedule in deciding what vaccines should be administered to children?
A We do use that schedule as a resource for making decisions.
Q Okay. In deciding what vaccines to administer, if -- is there anything else you would look at other than the CDC's childhood immunization schedule?
A I -- I look at the CDC schedule. I think about the individual patients and -- and talk with the family and consider multiple factors. Every time I write orders for vaccines I think about what's recommended, what -- if -- does that child

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

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

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

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

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

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

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

A That's correct.

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

A That's correct.

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

to the child?
A As long as they ask me beforehand, yes.
Q Of course. Now, the members of ACIP, they're supposed to be independent of the pharmaceutical companies whose products are being voted upon; correct?
A I would imagine that's correct. I don't know for a fact.
Q All right. Okay. Going back to the process that you described in terms of, you know, before you administer a vaccine, that's the process, I presume, that you've been using for most of your career?
A Yeah, yes.
Q Okay. And one you would consider the standard of care?
A The -- the -- so you're referring to the process of considering the individual child and what's recommended and making a decision after seeing if the parents have questions or concerns, making a decision and then ordering vaccines.
Q Right. Providing them with the VIS and answering any questions they have before you administer the vaccines, that entire process,

would you consider that to be the standard of care?

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

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

A Yes.

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

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

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

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

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

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

A Providing the VISs at the time of giving vaccines.

Q Are you -- before giving the vaccines?

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

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

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

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

Q Before --

A So sometimes it's simultaneous.

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

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

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

A I don't think so.

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

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

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

important information sheet, families need to have that.

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

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

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

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

Q And one of the ways you help inform parents

is providing them a vaccine information statement; correct?
A That is one of the ways we inform them, yes.
Q Right. And the AAP Red Book provides that you should provide it prior to vaccination; correct?
A As I said, I haven't looked at that specific information. I can imagine that's correct. Again, AAP I view as guidelines and ideals, things that we should be aiming for.
Q And the CDC guidelines applicable when Yates was vaccinated and today on their website clearly state that the VIS materials need to be provided prior to vaccination. Isn't that true?
A Well, I'll take your word for that. I haven't looked at the CDC website for exactly how they state that.
Q Okay. If the CDC guidance is to provide it before vaccination and the AAP Red Book's guidance is to provide the VISs before vaccination and that's what's provided in the federal law, would you consider providing VIS prior to vaccination to be the standard of care that would be applicable with regards to when the VIS needs to be provided?

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

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

A In --

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

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

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

Q So the nurse puts the VIS on the table?

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

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

A I've not had a discussion with my nurses about exactly what order they do things. We've said these -- these sheets are important, the parents need to receive them.
Q So do you believe the VIS provides important information for the parents to receive?
A I do.
Q And, you know, they're prepared through the limited process at the CDC; correct?
A I don't know what the process is. I know it's an -- it's an extensive process. It takes a lot of time to come up with the document. I know there's -- in the past, the documents that were produced were kind of lengthy and, you know, may have contained too much information and it had to be kind of reduced to provide just the most important information, so I think the VIS sheets are a good piece of information for families to have.
Q Okay. And they explain the benefits of the vaccine; correct?
A They do explain the benefits. I don't know that they explain it in the same way as I can, as a pediatrician who's actually cared for children

with some of these life-threatening infections.
Q And they explain risks of vaccinations as well of the vaccine; correct?
A Yes.
Q Okay. And so if the VIS is not received by the parent before vaccination, what you're saying is you're providing even better information to the parents orally before vaccination. Is that right?
A Sometimes I'm providing more extensive information, sometimes I'm providing less information. It depends on that family's needs. If it's the very first set of vaccines, then I spend more time. At the two-month visit I spend a little more time explaining the diseases because I think it's important. If it's a repeat of vaccines they've had before, then I spend less time, but parents are always given opportunities to ask questions throughout the visit, including when we tell them what vaccines we're ordering.
Q Have you ever had a parent ask you a question about information on a VIS?
A Not -- you know, I can't -- I can't recall a specific time that a parent looked at the VIS and asked me a question about it.

Q Do you --
A Parents ask me lots of questions about vaccines. It's a common topic. We talk about it a lot, but I haven't had a parent who pulled out the VIS and said tell me about this.
Q Uh-huh. Is it -- is it possible that the questions were being asked because they did review a VIS, they just didn't reference it?
A Is it possible? Sure.
Q So the VISs provide information of benefits and risks, and you've indicated that, you know, informing parents about the benefits and risks of vaccinations and before vaccinating is important. So then wouldn't it be important to give the VIS prior to vaccinating?
A I view it as an additional document. I think the information on there about the -- about the National Child Injury Acts and the -- you know, that information is that -- there's some phone numbers in there, there's information that families have. I would love for them to keep the VISs. I sometimes tell families, particularly for our live virus vaccines with delayed reactions, I'll say, make sure you hang on to those

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

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

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

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

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

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

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

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

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

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

A Yes, for sure.

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

A Because --

Q Correct?

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

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

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

while the nurse is doing her job.
Q And so in the few instances you've been in the room, did the nurse provide the VIS to the parents before or after vaccinating the child?
A I didn't pay any attention to that, except that I'll say the nurse has to set the information sheets down somewhere before she administers the vaccines. She's not holding them, so I'm imagining that she, you know, puts them on the table, sometimes we, you know, hand people things so they can stick it in their stroller or diaper bag, and then she administers the vaccines.
Q So she puts it someplace the parents are, you know, aware that this is for them; correct?
A I think, yes.
Q She doesn't shove it in some drawer somewhere, I assume.
A No.
Q Right. She will set it someplace where they will know this information is for them; correct?
A In general. But I'm -- I'm, again, always surprised by the number of times there are handouts that are left on the table or on a chair in the room.

Q Well, just because a handout is left in the room doesn't mean it wasn't provided prior to the administration of vaccines; correct?
A That's correct.
Q Okay. So the nurse walks in the room, she puts down the vaccine information statements someplace where the parents are, you know, in -- with an intention that the parents are aware that these are for them; correct?
A Yes.
Q Okay. And then the nurse will proceed to inject the vaccines; correct?
A Yes.
Q Okay. And that -- and -- okay. Let's come back to this topic because we -- we're, like, halfway -- we'll talk about standard of care later. We -- we've gotten on a tangent. Let's keep going. So VRBPAC.
A I'm -- VRBPAC?
Q Yep.
A Can you spell that out for me?
Q Sure. V-R-B-P-H-C, Vaccines and Related Biologics --
A I don't know what that is.

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

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

A Yeah, repeat the question.

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

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

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

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

Q Fair enough. Okay. IOM.

A Institute of Medicine.

Q Okay. And what is your understanding of the

Institute of Medicine?
A I think the Institute of Medicine is a highly regarded organization of leaders within the field of medicine who -- I -- I think they will consider important topics and review topics and provide guidance for healthcare professionals.
Q Okay. And the IOM issues a number of reports regarding vaccinations; correct?
A I don't know that off the top of my head.
Q Okay. For the -- for reports that the IOM would issue regarding vaccination, would you consider those to be a generally reliable source for information regarding vaccines?
A I would consider the Institute of Medicine generally reliable with the understanding that I would have to consider it in context of other sources of information.
Q Sure. So generally you consider it a reliable authority for information on vaccines?
MR. SANDERS: Object to the form of the question. She just answered that.
MR. SIRI: Nope, it's different.
Q (By Mr. Siri) Please, Doctor.
A I view the Institute of Medicine as a

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

Q All right. Great, thank you. DSMB.

A Spell that again.

Q DSMB.

A DSMB? Okay.

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

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

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

A Right. Right. So I --

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

A Yeah, so I'm not familiar with the data safety monitoring board.
Q Okay.
A I --
Q No problem.
A I'm familiar with -- data safety monitoring would be some information sheets that are kept in a notebook in our office.
Q Okay. Have you heard of the National Childhood Vaccine Injury Act of 1986?
A Yes, I have.
Q Okay. And that's the law that gave vaccine manufacturers immunity from economic liability for injuries caused by vaccines; correct?
A Say that again.
Q Sure. I'll say that's the law that provided immunity for economic injury, liability if one of their vaccine products injures somebody.
A I think that sounds like a reasonable explanation of that, yes.
Q Okay.
A I mean, I -- I -- I'm not an expert, you know, I haven't studied that act in detail to be able to tell you exactly the description of what

it is.
Q Fair enough. During the deposition, I'll refer to the National Childhood Vaccine Injury Act of 1986 as the 1986 Act; okay?
A Okay.
Q All right. Okay. Can you please describe your academic background?
A I graduated from Purdue University with a degree in chemical engineering. I graduated from Vanderbilt University School of Medicine with an M.D. degree. I completed three years of residency training in pediatrics. The first was in Memphis at the University of Tennessee Center for Health Sciences, and then the second and third years were at Vanderbilt University Medical Center. I'm board certified in general pediatrics. I've been a member of the faculty at Vanderbilt University Medical Center since 1989 starting as an instructor, then assistant professor, and now associate professor of clinical pediatrics. I was director of the residency training program in pediatrics from 1990 to 1996. I was co-director of the combined internal medicine and pediatrics residency program during that same time frame.

Q Okay. Did you have any other academic appointments that involved vaccines or vaccination that you didn't just describe?
A Any other academic appointments, no.
Q Okay. And you're certified with the American Board of Pediatrics; correct?
A Correct.
Q And you've held that certification since 1989?
A That's correct.
Q Are there any professional organizations in which you're involved that encourage or support vaccination?
A Well, I'm a member of the American Academy of Pediatrics, I'm a member of the Tennessee chapter of the -- in addition to the AAP, the Tennessee chapter of the American Academy of Pediatrics, and then I'm a member at -- here in Nashville of the Cumberland Pediatrics Foundation, which is an organization of both community pediatricians and academic specialty pediatricians, and that organization provides continuing education conferences for pediatricians that sometimes cover the topic of immunizations.

Q Okay. Can you please describe the professional activities in which you've been engaged which relate or -- to vaccination?
A So I was -- as director of the resident continuity clinic in the early '90s, I was responsible for helping with the education of residents in primary care, which would include providing immunizations to children during that time. I was also involved with the Nashville Immunization Coalition at that time which was a group of community members, as well as members from the health department and Vanderbilt, to promote better immunization coverage in the community. I attended a conference in Washington DC in the early to mid '90s where we gave a presentation about building a coalition, building a group to support immunizing children to try to improve vaccine rates, particularly for children under the age of two.
Q Uh-huh. Are there any committees in which you've been a member that are involved in supporting or encouraging vaccinations?
A Everything that -- everything that we do is -- is -- you know, vaccinating is one of the

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

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

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

Q Right, right.

A -- and therefore supportive of vaccinations.

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

A Yes. I -- I -- providing vaccinations is one of the most important things about my work.
Q Do you know what a speakers' bureau is?
A In general terms, yes.
Q Okay. What is it?
A A speakers' bureau, I would think, would be a resource of people who are experts or have some -- have experience on a variety of topics and could be provided to community groups perhaps that need someone to come in and talk with them.
Q Okay. And speakers' bureaus are typically funded by a specific pharmaceutical company; correct?
A I don't know. I don't know about any pharmaceutical-supported speakers' bureaus.
Q Oh, okay. Understood. You're talking about a different form of speakers' bureau?
A Yes.
Q Yeah, okay. Are you familiar with pharmaceutical-funded speakers' bureaus?
A No, I'm not.
Q Okay.
A I know that pharmaceutical companies will provide information to groups and that they will

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

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

A Yes.

Q All right.

A That would be my understanding, yes.

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

A They --

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

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

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

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

A That's correct.

Q Why not?

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

Q And why is that?

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

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

do the kind of work you do?
A Having never been in the position of making that decision, I can't really say that it would be a conflict. I think that anybody who makes a decision to do that type of work is going to consider very carefully whether it's a conflict with their current work or not.
Q What's the name of the plaintiff in this case?
A The plaintiff would be Yates Hazlehurst. I don't know whether that would also include his parents.
Q That's okay. And the name of the child at issue in this case is -- you just said is Yates; correct?
A Yes.
Q We went over that earlier. All right. Have you ever physically examined Yates?
A No, I have not.
Q Have you ever met Yates?
A I have not.
Q Okay. Approximately how long would you estimate you spent reviewing Yates' medical records?

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

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

A Okay.

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

A Yes, that is my opinion.

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

A Can you repeat --

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

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

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

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

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

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

A Correct.

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

A Correct.

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

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

Q Nope.

A Pneumococcus.

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

A Two months.

Q Okay. And, again, without looking at

anything, at approximately what age did Yates receive his last set of vaccines?
A It would be either 18 months or 24 months.
Q Okay. And finally without looking at any documents, can you please describe any adverse events that you are aware of that occurred after Yates received any of his vaccines?
A Adverse events related to the vaccinations specifically?
Q Well, adverse events following vaccinations, yes.
A From the deposition of Rolf and Angela Hazlehurst, they described some period of crying following his six-month vaccination.
Q Uh-huh. Anything else?
A And after his 12-month MMR vaccine, approximately two weeks later he developed a rash.
Q Anything else that you recall?
A That's all that I think of as adverse events related within a time period of having been vaccinated.
Q All right. Those are the only adverse events that occurred that you can recall that occurred, let's say, so we're on the same page, within two

weeks of any of the vaccines that he received?
A In terms of the timing that was reported, yes.
Q Okay. Do you know Dr. Kathryn Edwards?
A I do.
Q Okay. How do you know her?
A She was a member of the faculty at Vanderbilt School of Medicine from the time I was a medical student through residency training and is a -- is currently a faculty colleague.
Q Okay. So how long ago would that -- so when did you first meet Dr. Edwards, how long ago would that have been?
A 1984 or '85.
Q Okay. So when you first met her, what was your respective roles vis-à-vis each other?
A I was a medical student, and she probably doesn't remember but I asked her for advice as I was considering a career in pediatrics. I remember going into her office and asking her sort of via faculty advisor in an informal way, so she and I talked about residency training and programs to apply to, that sort of thing.
Q What did she -- what advice did she give you?

A She gave me great advice, to definitely go into pediatrics.
Q Okay. And so she was your -- you were a medical student and she was one of your professors?
A Correct.
Q Okay. And then as you continued through your career, has it typically been that she has been in a -- you know, a role where -- a role where she was, you know, somebody who was either your supervisor or mentor?
A Not supervisor. During my residency training period she would have been a supervisor, so for the -- as a student, and then two years of residency were done at Vanderbilt.
Q Okay.
A And then --
Q Oh, please.
A Yeah, after that, we were faculty colleagues, although certainly she was, you know, much more advanced. She -- she's someone who is a very respected -- an incredibly respected infectious disease expert at Vanderbilt.
Q Okay. Is she also an incredibly respected

expert in vaccinology?
A I would say yes. When we -- when we want to know about a new vaccine or changes, you know, there's a change in the vaccine schedule, we have a question about things, she would absolutely be a colleague that we would turn to and be very happy to receive information from her about her thoughts about something.
Q Would she be, like, the main go-to expert at Vanderbilt on, you know, any, like, difficult vaccine question?
A One of a number. Vanderbilt has a really strong pediatric infectious disease division, and we have a number of colleagues that we can turn to for that, but certainly she is, you know, one of the -- the very most respected.
Q Have you ever considered her a mentor?
A In an informal way I would say yes. As a -- as a pediatrician, she -- and also as a -- a professional mom, she, you know, has a family and we've had brief conversations about raising children.
Q It's tough on dads too, I promise.
A I'm sorry?

Q It's tough on dads too, I promise.
A Okay.
Q So have you -- my wife is an attorney as well. Have you -- so, you know, so you were a medical student, and I assume, you know, she'd be somebody who you learned -- she's one of the people who educated you about vaccines. Is that correct?
A I would think, yes.
Q Okay.
A You know, I don't ever recall a specific lecture or setting, but certainly she's provided continuing education. Even in my -- in my role as a faculty member, I try to attend continuing education conferences and lectures and she's been involved in that for sure.
Q And what are the lectures that she typically gives? What are the -- what's the topic of those lectures?
A I -- you know, I can't give you a -- I -- I've attended lectures on -- let me think. When she -- there -- there may have been a Cumberland Pediatrics -- Cumberland Pediatrics Foundation meeting a year or so ago about there was a measles

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

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

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

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

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

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

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

Q Okay.

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

Q Understood. Would it be fair to say that Dr. Edwards has helped train, you know, a number of generations of pediatricians that have come through Vanderbilt with regards to vaccines?
A Yes.
Q Okay. And that would include vaccine safety; correct?
A Yes.
Q And part of her influence is her extensive experience in the area of vaccines; correct?
A Yes.
Q Are you aware, for example, that she receives funding from federal health agencies relating to some of her vaccine work?
A I'm not aware of the details, but certainly research needs to be funded and research is funded I'm -- I know from both federal grants as well as by pharmaceutical companies.
Q And were you aware that she was a member of a federal committee related to vaccines?
A I'm not aware of any of those sorts of details.
Q Uh-huh. Are you familiar with CIS -- CISA?
A C-E-S-A?

Q C-I-S-A, Clinical Immunization Safety Assessment Network.
A No.
Q Okay. Are you familiar with the medical textbook Plotkin's Vaccines?
A I have some -- vague, but I don't have a copy of it. I don't know that I've ever consulted it.
Q What would you consider the -- you know, the -- the authority -- if you have an opinion on this, you know, if -- if -- what would you consider to be authoritative, a medical textbook with regards to vaccines?
MR. SANDERS: I'm going to object to the form of the question. You can answer, Doctor, if you have an answer.
A Well, I look at -- I mean, I use the Red Book as -- as my resource, but I think you're asking a different question.
Q (By Mr. Siri) Yeah, that's okay. You're talking about practice. I just meant about, you know, medical knowledge. That's okay. Let's -- we can move on. But I presume, is it your understanding that Dr. Edwards has published hundreds of articles relating to vaccines?

A I would imagine, yes, but I don't have -- you know, I don't -- I've not reviewed her CV.
Q Would it be fair to say that she has a substantial influence in the field of vaccinology?
A Yes.
Q Okay. To your knowledge, has Dr. Edwards been an advisor to Merck?
A I don't know.
Q To your knowledge, has Dr. Edwards received payments or personal fees from Merck?
A I don't know.
Q To your knowledge, has Dr. Edwards been a consultant to Merck?
A I don't know.
Q To your knowledge, has Dr. Edwards received research funding from Merck?
A I don't know.
Q To your knowledge, has Dr. Edwards been on the speakers' bureau of any pharmaceutical company that sells vaccines?
A I don't know.
Q To your knowledge, has Dr. Edwards been a consultant for Sanofi?
A I don't know.

Q To your knowledge, has Dr. Edwards been a consultant for Connaught?
A I don't know.
Q To your knowledge, has Dr. Edwards ever received payment from Sanofi for giving lectures?
A I don't know.
Q To your knowledge, has Dr. Edwards ever received research funding from Sanofi?
A It's possible that there was a live intranasal flu vaccine study looking -- comparing the live attenuated influenza vaccine to the standard killed virus vaccine, and I'm not certain at all, but you told me to tell you what I -- to do my best, and I think that --
Q That's correct.
A -- Sanofi may have had -- played a role in the funding for that particular study.
Q All right. Thank you. To your knowledge, has Dr. Edwards traveled to numerous foreign destinations that were paid for by Sanofi?
A I have no knowledge of that.
Q To your knowledge, has Dr. Edwards received personal fees from Sanofi?
A I have no knowledge of that.

Q To your knowledge, has Dr. Edwards been a consultant for SmithKline Beecham?
A I don't know.
Q To your knowledge, was Dr. Edwards a consultant for GSK?
A I don't know.
Q When I say GSK, do you know what that means?
A GlaxoSmithKline Beecham or just GlaxoSmithKline.
Q Perfect. To your knowledge, was Dr. Edwards receiving payments from GSK for giving lectures?
A I don't know.
Q To your knowledge, was -- has Dr. Edwards been a member of the speakers' bureau for GSK?
A I don't know.
Q To your knowledge, has Dr. Edwards been on an advisory board within GSK?
A I don't know.
Q To your knowledge, has Dr. Edwards received research funding from GSK?
A I don't know.
Q To your knowledge, has Dr. Edwards been a member of the speakers' bureau for Wyeth Lederle?
A I don't know.

Q To your knowledge, was Dr. Edwards a consultant for Wyeth Lederle?
A I don't know.
Q To your knowledge, was Dr. Edwards an advisor to Pfizer?
A I don't know.
Q Were you aware that Dr. Edwards was on the speakers' bureau of Connaught and Lederle at the same time that she was on the FDA's advisory committee that voted in favor of licensing one or more of their products?
A No, I was not.
Q If that were true, what would you think about that?
A Well, I think that when we have advisory committees, the good thing is that they are committees, and, you know, that it considers many people's opinions, and I think that most of the time physicians are -- and researchers are required to disclose any conflict of interest that they have, so I think Dr. Edwards is a very reliable physician and I would trust her to disclose her potential conflict of interest to the group and that that would be taken into

consideration with decisions that are made.
Q And what would you say if those conflicts were not disclosed when she was sitting on that FDA committee and voted?
A Well, I don't know what the procedures are in those types of committees when that type of information is asked for and -- and released, but in general, in medical literature and -- and in giving lectures and other things, people are always asked to reveal conflict -- potential conflicts of interest.
Q It's a very important thing to do; correct?
A Yes, that's important.
Q Were you aware that Dr. Edwards was a consultant for SmithKline Beecham while she was a member of the FDA's federal advisory committee regarding vaccines?
A No, I was not.
Q Were you aware that Dr. Edwards was a consultant for SmithKline Beecham while she was a member of the FDA's federal advisory committee on vaccines?
A No.
Q Were you aware that Dr. Edwards was

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

A No.

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

A Yes.

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

A It is.

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

A No.

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

A No.

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

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

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

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

A Okay.

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

A I have not.

Q Have you ever read that before?

A I have not.

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

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

A I have not.

Q Have you ever read that quote any place?

A I have not.

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

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

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

Q Right. Children should certainly be protected; correct?

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

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

A Yes, I --

Q All right. She's --

A That --

Q She's saying -- oh, please.

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

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

reliability of the studies that are published by those individuals; correct?
A Yes. She's saying it creates a potential problem, yes.
Q Okay. And she -- and, you know, this is from somebody who was the editor in chief of the New England Medical Journal for 20 years. Would that -- would that give her opinion about the reliability of medical literature published by such individuals more weight in your eyes?
A It's a very important statement. I don't think that it can necessarily be applied just in general terms to -- to all published studies and all individuals.
Q Are you aware of the number of doctors that have written books which present evidence for why the risks of vaccination outweigh the benefits for some or all people?
A I'm aware that there -- there are publications that -- read the statement again.
Q Sure. Are you aware that there are a number -- that there are numerous doctors that have written books which present evidence for why the risks of vaccination outweigh the benefits for

some or all people?
A So I would say no. I'm -- I'm not aware of books that present evidence that would meet the standards of -- of -- of -- that we expect of research studies that we rely upon to make our decisions about vaccines. I think there's a lot of anecdotal information out there about the risks of vaccinations that -- in -- in some cases is incorrect and not backed by evidence.
Q Have you ever read the book by Dr. Richard Moskowitz, M.D., entitled Vaccines: And Re -- A Reappraisal, who's been practicing medicine for 50 years, and wrote, quote, I cannot keep silent about the major epidemic of vaccine-related suffering and disability, sufficient to break any heart, that continues unabated, remains -- and remains largely unacknowledged, end quote?
A I have not read that book.
Q Okay. Have you read the book, for example, by Dr. Thomas Cowan, M.D., called Vaccine Autoimmunity and the Changing Nature of Childhood Illness?
A I have not read that book.
Q Okay. Are you certain that the evidence

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

A Having --

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

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

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

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

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

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

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

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

A I would think possibly so.

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

A Yes.

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

A Yes.

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

apologize. How many times approximately have you ordered the administration of the MMR vaccine?
A Certainly hundreds. Possibly -- possibly in the thousands. Just thinking about the number of patients for whom I've provided primary care over -- over my 30-year career as a pediatrician.
Q Uh-huh. And so you've ordered hundreds and potentially thousands of MMR -- the administration of MM -- strike that. So over the last 30 years, you've ordered hundreds and potentially thousands of administrations of MMR vaccine during that period?
A Yes.
Q I think you said that the first time. Okay. And -- and have doctors who you've been supervising also ordered the administration of MMR vaccines?
A In that time period when I was supervising doctors up until 1996, yes. Since 1996, I have been doing patient care directly, so not generally supervising resident doctors.
Q Okay. So how many doses of MMR vaccine would you say were administered under your supervision?
A Certainly thousands.

Q Okay. So in total, between MMR vaccines that you ordered to be administered directly or that were ordered by other doctors who you've supervised, it's been thousands of administrations of the MMR vaccine; correct?
A Yes.
Q Okay. Have you ever administered the MMR vaccine yourself?
A I've not administered an MMR.
Q You're familiar with the varicella chicken pox vaccine Varivax; correct?
A Yes.
Q Okay. And have you ever ordered the administration of the Varivax vaccine?
A Yes.
Q Okay. How many times approximately have you ordered the administration of this vaccine?
A Thousands.
Q Okay. And over what period of time did that occur?
A Over -- let's see. Twenty-five years in my own practice at Vanderbilt and then six years -- yeah, so 24 and six as a supervising physician, so 30 years.

Q And how many doses of Varivax have been administered by other doctors who were under your supervision?
A Ordered by other doctors, I included all of that in the thousands.
Q Understood. So and are you familiar with the hepatitis B vaccine Engerix-B?
A Yes.
Q Are you familiar with the polio vaccine IPOL?
A Yes.
Q Are you familiar with the pneumococcal vaccine Prevnar?
A Yes.
Q Are you familiar with the DTaP vaccine Infanrix?
A Yes.
Q And are you familiar with the HIB vaccine HibTITER?
A Yes.
Q Is it also true that you either ordered directly or -- or supervised doctors -- other doctors who've ordered the administration of a few thousand doses of each one of these vaccines over the course of your career?

A Yes, that's correct.
Q Okay. Vaccines come in packages; correct?
A Yes.
Q Okay. In fact, each one of those packages will have a package insert; correct?
A Yes.
Q The package insert provides information with regards to the vaccine; correct?
A Yes.
Q Including providing information regarding its clinical trial experience; correct?
A Yes.
Q Okay. Now, the FDA decides whether to license a vaccine based on a review of the pivotal clinical trial conducted for the vaccine; correct?
A Yes, I believe that's correct.
Q Okay. And the clinical trial will compare a group receiving the vaccine with a group not receiving the vaccine; correct?
A Generally speaking, yes.
Q But not always?
A Well, I -- I don't go back to all of the original studies and read all of them, but I would think that -- I mean, vaccines go through many,

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

Q Right.

A -- vaccinated to not vaccinated individuals.

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

A That sounds correct.

Q Okay. Not your area?

A Not my area, right.

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

A Yes.

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

A Correct.

Q And what does placebo control mean?
A Placebo control means that a patient is administered something that does not contain material being tested so that we can compare whether -- for example, with a vaccine, it might be an injection that doesn't contain the vaccine so that we can determine if there are any side effects that are due to just receiving the vaccine -- receiving an injection itself, did the needle or the -- the liquid that it's contained in cause any type of problem.
Q So and for that reason, a placebo is an inert substance, like a saline injection; correct?
A In most cases, yes.
Q Okay. I mean, the definition of the -- of a placebo by the CDC and FDA means a substance that has no effect on the human body; correct? Or, you know --
A I -- yeah, I haven't looked at how they define it. We certainly do know that in some things placebos can have effects as well.
Q Ahh. The placebo effect, true. The psycho -- which is viewed as the psychological effect; right? But the -- but in terms of the

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

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

Q Right.

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

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

A Right.

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

A Right.

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

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

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

A Statistically significant, that's what I was looking for.
Q Okay.
A Yes.
Q Right. But -- but, you know, having an appropriate control and being properly powered isn't enough. You also need to have review safety for sufficient duration during a trial; correct?
A That makes sense, yes.
Q Okay. And so, like, for example, if you wanted to determine whether a product causes asthma, which is typically diagnosed at five years of age, the clinic trial would typically need to track children until at least around that age; correct?
A If you're giving me an example of something that's diagnosed at age five and we're trying to determine if something prevents it, then yes, you would need to follow until at least age five.
Q All right. So if you were going to try -- if you were going to conduct a clinical trial to try to determine whether a vaccine, for example, does or doesn't cause autism, you would need any vaccinated children, let's say, up to 18 months,

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

A That makes sense, yes.

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

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

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

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

Q So how much later was the diagnosis

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

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

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

MR. SANDERS: Yes.

MR. SIRI: I can.

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

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

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

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

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

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

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

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

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

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

A I have not read this specific article.

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

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

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

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

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

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

detect whether a vaccine causes the autism?
A I can't answer that. I don't know.
Q Okay. Probably a statistician is a lot smarter than us and can figure that out; right? Okay. And based -- now, based on the duration of the trials, the control use and the size of trials, is it accurate to state that the clinical trials relied upon to license the vaccines given to Yates were not designed to determine whether these products caused autism when given to an infant or toddler at or below the age of 18 months?
A I can't comment on the trials that were used to license the MMR vaccine because I haven't studied those.
Q Okay. What about the rest of the vaccines that Yates received?
A I haven't studied -- I -- you know, as we talked about earlier with the package insert, I don't go back to the original research studies and look at those. I rely on -- on -- on the FDA's approval of -- and licensing of drugs and the AAP and ACIP vaccine schedules. I have those package inserts available so that I can consult with them

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

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

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

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

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

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

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

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

MR. SANDERS: Object to the form of the

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

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

Q (By Mr. Siri) Uh-huh.

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

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

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

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

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

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

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

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

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

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

A Read that -- say that --

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

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

Q Okay.

A Yes.

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

A I'm -- I can tell you just from a common sense standpoint that -- what safety review period would mean, but I don't have any specific technical knowledge of that terminology.
Q And so in common sense parlance, what would it mean to you?
A It means that we need to allow some time to make sure that -- that a treatment is safe and that there aren't unexpected consequences, adverse consequences of a treatment. The period means a period of time.
Q A period of time in which safety is reviewed. Would that be fair?
A Yeah.
Q Okay. Now, the package inserts for each of the vaccines that are provided with -- strike that. With each of the, you know, pack -- you know, packets of vaccines that -- that are distributed by manufacturers, we discussed earlier there -- they each include a package insert; correct?
A Yes.
Q Okay. And the package inserts will each describe the clinical trial experience relied upon

by the FDA to license the vaccine; correct?
A I don't know if it's an exhaustive list of all the clinical trials, but there is certainly trial information in the package insert.
Q Are you aware that the Code of Federal Regulations require that the -- the full database of safety from those clinical trials be represented within Section 6 of those package inserts?
A I'm not an expert on federal regulations.
Q Fair enough. I'm just going to share this for a moment just because that's -- it's worth taking a quick look at.
MR. SIRI: I'm going to mark this as Plaintiff's 2.
(Whereupon, Exhibit No. 2 was marked to the testimony of the witness.)
Q (By Mr. Siri) Okay. You'll have a chance to look at it, Dr. Mace. Have you ever seen this section of the Code of Federal Regulations before, Section 201.57 entitled specific requirements on content and format of labeling for human

prescription drug and biological products?
A I have not ever seen this.
Q Okay. And biological products means --
includes vaccines; correct?
A I would think, yes.
Q Okay. And labeling would -- would include --
is it -- do you -- are you aware that labeling
would include package inserts?
A You know, I don't study these types of
regulations, so I don't know -- I can't comment on
the specific meanings of the terminology of this.
Q That's entirely fair, absolutely. If you
don't know, it's -- just say -- it's totally fine.
You could probably show me medical stuff and I
would be a deer in the headlights, so -- okay. So
here it is, Section 6, adverse reactions, these
are the requirements of what needs to be on the
package insert, Section 6. I'm going to read it
out loud and then we'll just move on and you'll
have a copy of it for trial. It says, this
section must describe the overall adverse reaction
profile of the drug based on the entire safety
database. All right. For purposes of
prescription drug labeling, an adverse reaction is

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

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

Q What has been your understanding?

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

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

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

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

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

MR. SANDERS: Object. Object to the

form of the question. You can answer, Dr. Mace, if you have an answer.
A I don't really have an answer to that question.
Q (By Mr. Siri) Okay. Are you aware that under the 1986 Act vaccine manufacturers actually can be held liable for a vaccine injury if they knew that the vaccine caused that injury and didn't disclose it to the public?
A I haven't studied the details of that act, so I can't comment specifically on that.
Q Fair enough. And do you think that vaccine manufacturers would violate this federal legal provision by not only listing only those adverse reactions for which there is some basis to believe there's a causal relationship, but, in fact, just listing adverse reactions for which they have no basis to believe there's a causal relationship?
A I haven't studied the topic enough to be able to answer that question.
Q Not in a position to make -- draw any, you know, opinion based on your experience about -- to reach a conclusion or opinion about that question?
A I -- yes, I agree with that. I agree with

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

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

A I don't know the answer to that.

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

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

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

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

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

A That's what it looks like to me.

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

this format for a table of contents for a package insert before?
A Yes. In general terms, I have.
Q You've administered or supervised administration of this product thousands of times; correct?
A Engerix-B?
Q Yes.
A I don't order vaccines by brand name, so I've ordered the hepatitis B vaccine thousands of times.
Q Okay. And so -- and it's -- how many HepB vaccines are there on the market?
A I don't know. I really don't study brand names. I order a vaccine by its generic term, so I don't know the answer to that.
Q So when you're looking at a package insert of a product that you have ordered for a patient, if you don't know the brand name, how do you look up the package insert?
A Well, I have the brand name on the vaccine in our refrigerator, so I know that if I order -- if I want to look at the rotavirus vaccine package insert, that's the one that we buy and that's the

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

Q You order hepatitis B?

A Correct.

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

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

Q Or a -- a -- at birth?

A Right.

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

A Correct.

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

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

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

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

A They certainly sound familiar.

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

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

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

A I'm not aware of that.

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

A Yes.

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

A Normally I unfold the package insert and scroll through to find what I'm looking for, so I'm sure I've seen it.
Q So in all the times that you've done that for HepB vaccine, have you ever looked at the section, the Section 6.1, the clinical trial experience, the clinical trials that were relied upon to license the Engerix-B vaccine?
A I have not read that section on Engerix-B.
Q Okay. What would you think would be the period of time that safety was reviewed after injecting Engerix-B in the clinical trials relied upon to license that product?
A I'm not an expert on clinical trials for licensing, so I can't really give you an opinion about that.
Q What would you guess?
MR. SANDERS: Object to the form of the question. You can answer, Dr. Mace, if you have an answer.
A I think it depends on what type of adverse reaction we're looking at.
Q (By Mr. Siri) How about any and all adverse reactions.

MR. SANDERS: Object to the form of the question.
A I really am not an expert in vaccine research and how long one should be extending the safety review period.
Q (By Mr. Siri) Well, would you say that, you know, two years sounds like a reasonable period of time?
MR. SANDERS: Object to the form of the question. It's been asked and answered.
A I -- I really -- I don't know whether shorter than that is appropriate or longer than that is appropriate.
Q (By Mr. Siri) Okay. Would it sound like a conspiracy theory if I told you it was only four days?
MR. SANDERS: Object to the form of the question.
A Would it sound like a conspiracy theory? No, because I don't believe in conspiracy theories.
Q (By Mr. Siri) Fair enough. Would it sound like some kind of, you know, one of the -- I forgot the exact wording you used, but, you know, one of these ad hominem attacks that are made on

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

A I --

MR. SANDERS: Same objection.

A I can't really comment on that.

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

A Uh-huh, yes.

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

(Whereupon, the witness is reading the document.)

A Okay.

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

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

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

administration?
A No.
Q Okay. Is four days long enough to assess whether this vaccine could cause autism?
A No, but this is why we have post-marketing studies and we have systems for reporting. We have great systems for reporting adverse events, and while I can't explain all of the details of it, we all know about the rotavirus vaccine and that there were adverse events reported after that that changed -- that resulted in the changes in policies about the safety of that -- that particular vaccination.
Q Well, we'll certainly get to the post-licensure safety --
A Yes.
Q -- as well, Dr. Mace, for sure. That's critically important to it, and we will get there. First I want to go through the pre-licensure clinical trial, and you've brought up rotavirus, which I assume you're talking about RotaShield; correct?
A Correct.
Q And intussepsis is the issue that arose after

licensure. That's what you're referring to?
A Intussusception.
Q Thank you. See? Now, intussusception -- that's what happens when you're only reading things and you don't say them. Intussusception is something that happens within 21 days of receiving typically a rotavirus vaccine; right?
A Intussusception can occur in settings that are unrelated to vaccines, and probably more of the children I've seen with intussusception had it occur not in relationship to vaccination.
Q Okay.
A So I -- I can't tell you the exact, but it -- maybe that they attribute one happening within 21 days following the vaccine as --
Q I didn't mean to say that at all that intussusception occurs from vaccination. I just said that if intussusception were to occur, if it were to occur from a rotavirus vaccine, it would usually happen within the first 21 days after getting that vaccine; correct?
A I would want to look at what the guidelines say about that.
Q Okay. That's fair. You'll -- and I think

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

A It's a specific event, yes.

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

A I see that, yes.

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

it's the principal investigator who's paid by the sponsor that makes that determination typically?
A I don't know who is responsible for making that statement.
Q No problem. Fair enough. Okay. Just to -- okay. Are you aware that the FDA also issues a summary basis of approval separate from this document when it approves each new vaccine?
A No, I'm not.
Q Okay. So you're not aware that the FDA summary basis of approval for Engerix-B also makes clear that the safety was only reviewed for four days?
A I'm not aware of that.
Q Are you aware that there's also typically a peer-reviewed study that would be published that the -- you know, summarizes and describes clinical trials, not always, but typically, after they're concluded?
A That seems like a reasonable process.
Q Okay. And -- and I assume then you're also not aware when you read that the peer-reviewed study summarizing clinical trials for hepatitis B, for Engerix-B, it also again reconfirms that

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

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

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

A I don't know.

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

Okay.

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

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

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

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

Q Okay.

A -- to get information.

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

A Yes.

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

A Yes, that's what it says.

Q And so you said, well, maybe there was a HepB vaccine licensed before that. Well, there was, you were right, there is, and that's Recombivax HB which we mentioned earlier; correct?
A Yes.
Q Okay. Well, you know, it could be, you're right. Maybe the safety review period for Recombivax HB was, you know, three years, and so -- and it's -- maybe it's just a -- like a knockoff of Engerix-B and so they figured they didn't need to do three years for that one too; right? Well, let's -- why don't we take a look. Okay. And so here is the FDA website, vaccines licensed in United States; correct?
A Yes.
Q Okay. So let's take a look. Here we go. There was two HepB vaccines, right, Engerix-B and Recombivax HB, and there's more recently the HEPLISAV-B, but that's only licensed for individuals 18 years and over; correct?
A I don't know about that one. I can't tell you about it.
Q Fair enough. You're a pediatrician. You're not normally vaccinating adults; correct?

A Correct.
Q Okay. So -- and let's take a look at Recombivax HB. Click on it, and we can go to the package insert; right? And again, it's going to have a section, all right, so here it is, Recombivax HB; right? You would agree this is the package insert for Recombivax HB?
A That's what it looks like, yes.
Q And Section 6.1 is going to be the clinical trial experience; right?
A Yes.
Q Okay. So let's scroll down. And why don't you take a moment to read the summary of the clinical trials that were relied upon to license Engerix-B -- Recombivax HB. Excuse me on that. Sorry. I'm going to save it as an exhibit so we can mark it.
MS. CHEN: Aaron, this will be marked as Exhibit Number 5.
MR. SIRI: Thank you.
(Whereupon, Exhibit No. 5 was marked to the testimony of the witness.)

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

(Whereupon, the witness is reading the document.)

Q Dr. Mace?

A Yes.

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

A Okay. I've generally reviewed it.

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

A I do.

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

A I'm not aware of the literature.
Q So, you know, you brought up a good point, maybe the vaccine for HepB before Engerix-B had a longer safety review period, but, in fact, it only reviewed safety for five days; correct?
A For this Recombivax HB, yes.
Q Okay. And going back to the -- do you have any reason to doubt that Table 1 in the CDC Pink Book is not accurate with regards to which hepatitis B vaccines are currently licensed for pediatric use in the United States?
A No, but my question is was there another hepatitis B vaccine that preceded the recombinant vaccines.
Q You might be aware that there was a plasma vaccine, were you aware of that, which is a completely different type of technology?
A Right. Right. There was a -- there was a hepatitis B vaccine that preceded these two vaccines.
Q And it was made using actual human blood; correct?
A I don't have a strong recollection of it, but that sounds correct.

Q Right. And those were withdrawn from the market, weren't they?
A I don't know the details. I think my recollection would be that these vaccines were felt to be safer and better and that's why they were developed instead of the human product vaccine.
Q And they determined they were safer by studying them for four or five days respectively?
MR. SANDERS: Object to the form of the question. You can answer, Dr. Mace, if you have an answer.
A Well, they probably already knew a lot about hepatitis B vaccination, and in this case we were removing some of the risks by using a recombinant vaccine rather than a human blood product. That would be my understanding of the development of these vaccines.
Q (By Mr. Siri) Uh-huh. And so you're saying they just assumed they were safe maybe because the completely different HepB vaccines that, you know, had a -- that were -- based on using human blood were withdrawn from the market let them have an assumption such that they only reviewed safety for

four or five days?

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

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

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

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

Q Okay.

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

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

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

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

Q But that's just your belief; correct?

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

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

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

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

A That's a --

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

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

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

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

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

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

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

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

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

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

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

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

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

Q Okay. Are you aware that many parents also

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

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

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

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

A I can agree with that, yes.

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

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

Q Okay.

A -- to find out.

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

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

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

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

A I --

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

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

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

A Yes.

Q Including conclusions about safety?
A Yes.
Q Not based on beliefs or anecdotal stories?
A I agree with you.
Q Okay. Because human beings have biases; right?
A Yes.
Q For example, if somebody engaged -- devoted their career to helping children, which is an honorable thing to do, part of their self-schema is that they want to help children; correct?
A Part of --
Q A big part of their self-schema is that they've been helping children; correct?
A That's something that's very important to them, yes.
Q All right. And obviously, if there's evidence that either may exist or could exist that would undermine that the bevy of pharmaceutical products they've been injecting into babies and children maybe cause harm, do you think they might be a bit biased in how they absorb that information potentially? Like, for example, if they just learned that there's only four or five

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

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

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

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

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

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

Q Fair enough. Fair enough, yeah.

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

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

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

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

MR. SIRI: Okay. Fair enough.

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

A Okay.

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

A That concern is raised by parents.

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

A The issue has been studied.

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

vaccine doesn't cause autism?
A I have not.
Q Okay. Because no such study exists, does it? Isn't that true?
A I am not aware.
Q Are you familiar with the Agency for Health Research and Quality?
A Not exactly, no.
Q Are you familiar with the report that they issued in 2014 regarding vaccine safety that HHS has said is the most comprehensive report on vaccine safety issue to date?
A I'm not aware of that. I might have seen it, but --
Q Okay. And you're -- and you're -- so you've never seen that study?
A I don't know whether I've seen it or not. I've looked at a lot of studies.
Q Okay. We can pull it up. And that they looked at whether Hep -- they looked at HepB and autism. Why don't we pull it up.
MR. SIRI: And then we'll take a break, counsel.
MR. SANDERS: Thank you.

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

MS. CHEN: 6.

MR. SIRI: Thank you, Patricia.

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

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

A I have not.

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

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

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

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

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

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

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

MR. SANDERS: Yes.
MR. SIRI: Yes. Is that okay with you, Dr. Mace?
THE WITNESS: That's fine, yes, thank you.
MR. SIRI: Okay. Well, thank you.
THE VIDEOGRAPHER: Okay. We are off the record at 4:40.
(Brief recess.)
THE VIDEOGRAPHER: We are now back on the record at 4:51.
Q (By Mr. Siri) Okay. All right. So Dr. Mace, well, let's move on to -- we were talking about clinical trials relied upon to license the vaccines that Yates received, and we'll move on to another vaccine. Now, why don't we talk about varicella. Okay. So varicella vaccine, VARIVAX, sold by Merck, that's the -- that's the first and only vaccine licensed for chicken pox in the United States; correct?
A As far as I know, yes, that's correct.
Q Okay. There was never a chicken pox vaccine before VARIVAX; correct?
A You know, I order my vaccines by generic

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

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

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

Q Okay.

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

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

A Yes.

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

A I have no idea what the number is.

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

A I don't know --

Q Okay.

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

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

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

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

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

MR. SIRI: Not a problem.

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

MR. SIRI: Thank you.

THE VIDEOGRAPHER: You bet.

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

A Yes, I see that.

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

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

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

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

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

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

A Yes.

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

A Yes.

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

not the vaccines Yates received causes autism. Would you agree with that?

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

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

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

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

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

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

Q Do you ever inject neomycin into children or babies?

A Neomycin?

Q Yes.

A I believe there's neomycin in some vaccines.

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

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

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

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

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

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

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

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

A Yes.

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

A Sure, that's helpful.

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

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

Q Are you aware that the polio vaccine that Yates received, IPOL, is a very different product than the polio vaccine that was developed by Jonas Salk many years prior?
A It -- it wouldn't surprise me because vaccines are -- as all medicines, are researched and hopefully improved over time.
Q All right. Are you aware that the -- that the polio vaccine IPOL that Yates received was licensed in 1988?
A I don't know the year of licensure.
Q Okay. Are you aware that IPOL is -- that the poliovirus used in the IPOL vaccine is grown on substrate monkey kidney cells known as vero?
A I don't know the details of how that vaccine is developed.
Q So you're not aware that Jonas Salk used a different substrate?
A That's correct.
Q Okay. And I presume you're not aware that the culturing techniques as well as the amount of the different types of antigen are different in the two products?
A That's correct.

Q Okay. Are you aware that the safety review period in the clinical trials relied to license IPOL was only 48 hours after injection?
A I'm not aware of that.
MR. SIRI: I'm going to mark this as Plaintiff's 7.
(Whereupon, Exhibit No. 7 was marked to the testimony of the witness.)
Q (By Mr. Siri) Now, the only IPV, inactivated polio vaccine, used in the United States is IPOL, this product, since 2 -- since the '90s; correct?
A That seems correct to me.
Q Okay. And it even notes over here, for example, it describes that with regards to this product, it says, this culture technique and improvements in purification, concentration, and standardization of poliovirus antigen produce a more potent and consistent immunogenic vaccine than the inactivated polio vaccine available in the U.S. prior to 1988. Do you see that?
A I do see that.
Q Do you have any reason to doubt that that's

not accurate?
A No, I don't.
Q Okay. So, you know, why don't we scroll down to the section that discusses the adverse reactions and the clinical trials that were relied upon, and you can see here how long the safety was reviewed. Do you see that?
A I do see what you've highlighted in yellow.
Q Okay. But you've never looked at this portion of this package insert before?
A That's correct.
Q Okay. In the 30 years that you've been administering polio vaccines, this would have been the only package -- this would have been the package insert that would have been contained in all of those products -- okay. Strike that. Now you have it, you'll have a chance to review the entire adverse reaction section before trial. It's -- you know, it's got a few clinical trials and you'll see the safety review duration in all of them, so -- all right. That's -- do you believe that reviewing the safety of IPOL for 48 hours after giving this product to a nine-month-old would have been long enough to

determine whether or not it caused autism?
A A 48-hour period of observation would not be enough to determine whether or not something caused autism.
Q Do you know the duration safety was reviewed after injection of HibTITER in a pre-licensure clinical trial relied upon to license that product?
A Are you asking me a question?
Q Yeah, I'm sorry. I said are you -- are you aware of the -- how long safety was reviewed in the clinical trials relied upon to license HibTITER?
A I do not know the duration of safety monitoring.
Q Okay. This is the package insert for HibTITER. Is that correct?
A It looks like a package insert for HibTITER.
MR. SIRI: And I'm going to mark it as Plaintiff's Exhibit 8.
(Whereupon, Exhibit No. 8 was marked to the testimony of the witness.)

Q (By Mr. Siri) You'll -- have you seen this package insert before?
A I haven't -- I haven't looked at specifically this -- I -- you know, I've looked at package inserts, but I -- I don't recall the specifics of seeing this.
Q Okay. Well, you'll have a chance to review it. If it provides that safety was only reviewed for 30 days in the clinical trials relied upon to license this product, would you agree that the clinical trials to license HibTITER would not have determined whether giving this product to an 11-month-old --
A So -- so again, I'll say I'm not an expert on what the requirements are to -- to be printed in this information. My understanding is that these -- they come pre and post-licensure safety monitoring that -- that adequate amounts of time are -- are provided for determining serious and significant adverse events.
Q You're saying pre licensure or post licensure? I apologize.
A The combination of studies. And I, you know, don't -- again, I don't know about other studies

that -- that were done in the preliminary stages of these vaccines in terms of the -- you know, but maybe this is reporting, I don't know, Phase 3 studies only, but we've had Phase 1 and Phase 2 and other types of studies that are not reported in the package insert. Again, this is beyond my area of expertise in terms of the steps that are taken and the studies that are done for licensure.

Q Are you aware that Phase 1 and Phase 2 types of studies are almost always shorter than Phase 3 studies, the pivotal trials actually relied upon to license the vaccine?

A I don't know what the duration are, the requirements are for those phases.

Q Are you aware that the Phase 1 and Phase 2 studies have far less people in them typically than a Phase 3 study because they want to first make sure there isn't an immediate reaction to the product?

A Yes, I am.

Q Okay. You talked about serious adverse reactions. Let's -- let's -- let's take a quick look here. Now, Yates received Prevnar, you said; correct?

A Yes.
Q Now, he received Prevnar 7 or Prevnar 13?
A I would have to look at the record for that.
Q Well, he was vaccinated in 2001, so it would be Prevnar 7; correct?
A I don't have the dates memorized, I'm sorry.
Q No problem. Let's just assume it's Prevnar 7. You can confirm it later; okay? Now, in the -- in the clinical trial used to license Prevnar 7, all right, was there a Prevnar vaccine, a pneumococcal vaccine that existed prior to Prevnar 7?
A There's a pneumococcal polysaccharide vaccine that covers 23 serotypes, and I don't -- I just don't recall exactly when that one was approved for use, but that one is given at a different age.
Q Right.
A And then we had Prevnar 7 and then we had Prevnar pneumococcal 13.
Q Right.
A I would think that the pneumococcal 23-valent vaccine preceded pneumococcal 7.
Q Right. But the pneumococcal 23 is only licensed for two years of age and above; correct?

A I believe that's correct, yes. I only order it for ages two and older.
Q All right. But Prevnar 13 is given -- and 7 were given at six weeks of age until two; correct?
A It may be licensed for age six weeks, yes, I -- I routinely give it at two months of age, but we can give it a little bit earlier.
Q Okay. And so when Prevnar 7 was licensed, are you aware of any pneumococcal vaccine that existed that -- that was licensed to be given to children under two years of age?
A Not to my knowledge, no.
Q Okay. Are you aware -- are you aware of what the control group received in the clinical trial used to license Prevnar 7?
A I have not reviewed that study.
Q The information is also in the package insert. Have you ever looked at that information in the package insert?
A I -- I have not studied in depth the clinical trials because these were licensed vaccines.

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

witness.)

Q (By Mr. Siri) Understood. But this package insert would have been in the boxes of hundreds of Prevnar vaccines that you ordered to be administered over the years; correct?

A Yes, correct.

Q Okay. So you've seen this package insert before; correct?

A It is available to me if I have questions and want to consult it.

Q Okay. You'll have a chance to review it then as well, but if you go down to the adverse reactions, you can see here that -- you know, you can see the safety review, but let's -- duration and -- but let's take a look at what the placebo -- excuse me, what the control was because I -- I think you might find that interesting. Check this out. This is the clinical trial for Prevnar, this -- that was relied upon. Here's one that actually had a control. The others -- some of them didn't. Do you see where it says control, it's got a little cross next to it; correct?

A I see that.

Q And that would mean to look down, find the

little cross to see more information about what the control is; correct?
A Correct. It would be a comment related to control.
Q Right. And so what does the comment say?
A It says, investigational meningococcal group C conjugate vaccine.
Q So the control used to license Prevnar 7 was another investigational meningococcal group C conjugate vaccine?
A That's what it looks like.
Q So the clinical trial used to license Prevnar 7 compared it -- that then investigational vaccine to another investigational vaccine; correct?
A That's what that cross seems to imply to me, but I haven't read the study, and I -- you know, I -- I'm not an expert on this, and --
Q Fair enough. But you -- but -- you know, you're proficient at reading package inserts because you read them sometimes; correct?
A Yes.
Q Okay. And so -- and, you know, you've gone through medical school and you've read lots of

studies; correct? So let's just scroll down and see what other studies we can find. Here's another one. And what was the control?

A Control group received concomitant vaccines only in the same schedule as the Prevnar group. So the control group was receiving the other vaccines that I -- that were due to be given at that same age, that they were comparing a group who got all of their vaccines plus Prevnar and just all of the, at that point, routine vaccines is what it looks like to me.

Q And what is HbOC?

A That, I think, would be a -- so it's not hepatitis B because hepatitis B is listed, so that would be a HIB vaccine, haemophilus influenza type B.

Q And removed from the market. Let me ask you this. This investigational meningococcal group C conjugate vaccine, right, the MnCC that was used as the control in the main study here that they did, was it ever licensed?

A I don't know the answer to that. I would really need to look, you know, in more detail at the study before I could give you, you know, a

well-informed comment about it.
Q Okay. Are you aware of any licensed meningococcal group C conjugate vaccine?
A Not for group C alone, but there are vaccines that are licensed outside the U.S., and I don't know about that.
Q Okay.
A That -- the current vaccines in use here, I -- my understanding are the ACWY and the newer meningococcal B vaccine.
Q Now, after licensing Prevnar 7 by comparing it to an investigational vaccine, here is -- this is the package insert for Prevnar 13; correct?
A That's what it looks like.
Q Okay. Have you seen this before?
A I've looked at package inserts. I don't recall reading any specifics of this one.
Q How many times would you say you've ordered administration of Prevnar 13 in children and babies?
A I've ordered thousands of doses of Prevnar 13.
Q And there would be a package insert in every one of the boxes of those vaccines; correct?

A There's a package insert, correct.
Q Okay. But you're not sure if this is the package insert?
A No, I -- as I told you earlier, I don't read the package insert. That's not where I go for my information. I order vaccines. I go to the American Academy of Pediatrics Red Book, UpToDate, and other resources, continuing education conferences to get my information. So only if I have a specific question do I pull out the package insert and go through that and try to find the answer to the question at hand.
Q All right. Well, does the Red Book have information about the clinical trials relied upon to license these products given to Yates?
A It -- I -- it provides recommendations about vaccinations. It doesn't give the -- this level of detail about clinical trials.
Q Okay. Well, we're going to go through all those other materials as well, but let's -- let's -- we're getting close to wrapping up the pre-licensure stuff. So just taking a look at Prevnar 13, just, you know -- so Prevnar 13, the control uses Prevnar 7 in the clinical trials to

license Prevnar 13; correct?
A The control uses -- I don't know. I --
Q Okay. Let's go up. I mean -- so the safety of Prevnar 13 was evaluated in 13 clinical trials in 4,700 kids and toddlers receiving at least one dose of Prevnar 13 and 2,700 approximately infants and toddlers receiving at least one dose of --
A Prevnar active control.
Q Right. So Prevnar was the control.
A Right.
Q That means Prevnar 7; correct?
A Yes.
Q Okay. So let's scroll down now. And what does it say it found in terms of serious adverse events?
A You have highlighted serious adverse events reported following vaccination in all infants and toddlers occurred in 8.2 percent among Prevnar 13 recipients and 7.2 percent among Prevnar recipients.
Q Now, serious adverse events means serious; right? It's an FDA definition that means hospitalization, it means death, it -- it's not -- you know, it wouldn't even include most autoimmune

and neurological issues; correct?
A No, I don't think so. I would want to know exactly how they define serious adverse events. They could mean fever over 102 or, you know -- I mean -- no, I -- serious adverse events, certainly I've been administering Prevnar. I haven't had 8.2 percent of my patients wind up hospitalized or who died from Prevnar vaccine.
Q Well, you know, it could be because this clinical trial actually looked at safety for six months, right, instead of just 30 days. Check this out. All right. What did they say?
A This reporting period is longer than the 30-day post-vaccination period. So -- so if they --
Q Here's our explanation. You have one. Keep reading. Go ahead. The longer --
A The longer reporting period may have resulted in serious adverse events being reported in a higher percentage of subjects than for other vaccines. So -- you know, if a child is hospitalized within a six-month period following a vaccination, there are many explanations for hospitalization.

Q Uh-huh.
A But a hospitalization is serious. But we don't know that the vaccine caused that. That child could have had, you know, a high fever or an asthma attack or diarrhea and dehydration, and so again, I need more information to know to be able to give you an explanation for that.
Q Right. I mean, for example, if Prevnar 7 had been licensed based on a clinical trial that lasted six months and reviewed safety against the placebo, then we could know what the serious adverse event was from that clinical trial; correct?
MR. SANDERS: Object to the form of the question. You can answer, Dr. Mace, if you have an answer.
A I just -- I -- I don't -- I don't know that serious adverse event following vaccine necessarily means causation, and I think that --
Q (By Mr. Siri) Well, yeah --
A I --
Q I'm sorry, please. Yes. It certainly doesn't mean causation. Absolutely. Right. It's just to risk. It doesn't mean causation. It

means you have -- and that's why you have clinical trials. You have an experimental group and you have a control group, and by having a placebo control group, you can then compare the two to see is there a difference, and that would give you an answer on whether or not there was a causal relationship; correct?

A That makes sense.

Q Okay. And so but since that wasn't -- that wasn't done with Prevnar 7, right, because it wasn't compared to a placebo control group; correct?

A It was compared to a group of children who received their routine vaccines without the Prevnar. Is that -- is that right? Didn't we look at that? One of the studies showed other vaccines not including Prevnar, and it -- control kids -- compared kids receiving routine vaccines and routine vaccines plus Prevnar.

Q And which categories of items did they look at? Did they look for six months at serious adverse events in this group? You probably want to take a chance to look at it. I don't want you to have to answer that. Why don't you read it and

you can see for yourself what it looked at; all right? So coming back -- going back to the Prevnar -- oops. You know what -- sorry. My only point is this. Would you agree that Prevnar 13 was deemed safe even though 8.2 percent of children had an adverse event following vaccination, maybe causal, maybe not, because the control group had a similar rate of serious adverse events that were reported; correct?

A From this paragraph, that seems -- that seems like a correct statement.

Q Okay. And here's the FDA website where it defines what a serious adverse event is in clinical trials. You now have an opportunity to look at it so that you're aware of what it means. It means death, life-threatening, hospitalizations. Well, you can see for yourself. I'll even mark this as an exhibit so that you have it.

MS. CHEN: This will be Exhibit 11.

MR. SIRI: Thank you.

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

witness.)

Q (By Mr. Siri) Okay. So yes, you know, serious adverse events do occur within clinical trials, and it absolutely is important to determine whether or not it's actually caused by the vaccine; correct?

A I agree with that.

Q Yeah. But over here, do we know whether or not Prevnar, the control, do we know what percent of the 7.2 percent of serious adverse events that happened in the control group were caused by Prevnar?

A Please tell me that -- tell me that question again.

Q No, no problem. I said, is there a way to determine what percent of the 7.2 percent of serious adverse events that happened in the Prevnar group were actually caused by Prevnar?

A I think there are ways to try to get at that piece of information. You know, again, people who -- who devote their careers to doing research into the -- of vaccines would be able to answer that question more thoroughly than I can.

Q You're not able to determine that?

A I'm not able to tell you what percent of those 7.2 were due to the Prevnar vaccine.
Q Okay. Can you take a look here at what is a serious adverse event? And just tell me when you're ready for me to scroll down.
(Whereupon, the witness is reading the document.)
A Okay.
(Whereupon, the witness is reading the document.)
A Okay.
Q Is it your opinion that somewhere between 7 and 8 percent of all infants and toddlers every six months will develop a serious adverse event or have a serious adverse event?
A No, that's --
Q Is that defined on this page?
A No, it's not.
Q Okay. Okay. All right. It would -- 6, 7 to 8 percent of -- when you say no, it's not, you mean that 7 to 8 percent of infants and toddlers every six months will not have a serious adverse event in the United States in your experience?
A As defined by this, yes --

Q Okay.
A -- I do.
Q All right. The vaccine for DTaP, the DTaP vaccine that Yates received was Infanrix; correct?
A I can look at the record, but it -- again, I wrote down DTaP. I didn't write down the brand name.
Q Oh. Any idea what the safety review period was for Infanrix in its pre-licensure clinical trial?
A I don't know that.
Q Okay. If it -- if its package -- if the -- if the safety review period in its pre-licensure clinical trial was only 28 days, would you agree that tracking safety for only 28 days after administering this vaccine at 18 months of age would not be long enough in the pre-licensure clinical trial to determine whether or not that product caused autism?
A I agree that that -- that 28 days is not enough time to determine if something were to cause autism.
Q And then, you know, let's -- so the -- the last one is also for the MMR vaccine. Are you

aware that the pre-licensure clinical trial for the MMR vaccine included less than a thousand individuals receiving MMR vaccine?

A I don't know the numbers.

Q Okay. Are you aware that it only reviewed safety for 42 days after licensure?

A I don't know those numbers.

Q Okay. But you would agree that if the MMR vaccine only reviewed safety for 42 days after licensure -- excuse me. If it only reviewed 42 days -- if it only reviewed safety for 42 days in the clinical trial relied upon that product -- to license that product, that clinical trial would not have been able to determine whether or not MMR caused or doesn't cause vaccine prior to licensure; correct?

A Forty-two -- if -- one study with a period of observation of 42 days wouldn't necessarily be long enough to determine if something caused autism. But again, these -- I think these studies have to be looked in -- in the context of an -- additional studies and additional information.

Q Absolutely. Whole body -- okay. Let's just -- I'm going to quickly pull up the clinical

trial if we have it. Just one second. I'm going to ask you a question. All right. Okay. Have you ever seen this document before?

A I don't believe I've ever seen this document.

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

Q (By Mr. Siri) Okay. The current -- are you aware the current MMR vaccine was licensed in 1978?

A I don't know the date.

Q Do you know who Maurice Hilleman is?

A I do not.

Q Okay. Let me just ask you a question about this. This is a summary of the clinical trials that were relied upon to license the MMR vaccine. You'll have an opportunity to review this because you haven't. Do you see those number -- study numbers in the first column?

A Yes, I see that.

Q And you see there's the number of vaccinees where it lists the number of individuals that were vaccinated in each of those studies?

A I see that.
Q Do you see that the total number of individuals receiving it -- children receiving MMR vaccine in the clinical trials relied upon in licensing the MMR vaccine was 834 children?
A I see that number in that column. Again, I don't know the whole context of all of the studies and information, so I can't --
Q Yeah, that's entirely fair. You need an opportunity to look at this. Let me ask you something specific that doesn't require a lot of -- require you to have preexisting knowledge; okay? I apologize. All right. It's very different doing a depo on Zoom, I'll tell you that. Okay. Let me ask you a question. All right. So over here it says Table 6; right? And this doc -- and it represents that the maximum temperatures reported among children who received .5 ML dose of combined live measles, mumps, rubella virus vaccine, do you see that?
A I do.
Q Okay. So based on what you're seeing on this page, this would be a chart of the temperatures of children in this particular study, 443, after

receiving MMR vaccine; correct?
A Yes.
Q Based on what you're seeing on this page.
A Yes.
Q Okay. And you see over here it says days post vaccination?
A Yes.
Q Okay. Now, the first category is zero to four days; right?
A Yes.
Q Okay. One child in this group of 102 children had a temperature between 103 and 104; correct?
A Yes.
Q Similar number of children, at least in the five to 12-day period, had a temperature of -- in that range; right?
A Yes.
Q Okay. There were also seven children out of 102, that's around 7 percent; correct?
A Yes.
Q Had -- oh, 8 percent, it says. I -- I don't know how that happened. I -- I didn't write this. Had a temperature between 101 and 102.9; right?

A Yeah, I wonder if it's 7 percent and -- no, you're right. It says percent above. At any rate, yes, I see what you're pointing out.
Q Yeah. I -- well, in any event, you know, I guess Merck is not infallible; huh? Okay. So based on this, if you -- based on the results of this study, do you believe children that developed 101 to 102.9 fever within zero to four days after MMR vaccine, that fever could have triggered a seizure in the same manner that maybe getting that fever from something else could've triggered a seizure?
A Sure. Fever can trigger seizures --
Q Okay.
A -- in children who are susceptible.
Q So do children who receive MMR develop fevers in the first, you know, three days after vaccination?
A Then really my understanding of the MMR vaccine is that because it's a live virus and replicates in the blood stream, that side effects of the vaccine are typically going to show up between eight and 21 days following vaccination, though not typically within the first three days.

Q And so not typically within the first five to 12 days either?
A So five to 12 days you're getting into the -- into the eight, so five to 12 includes my -- my cutoff of eight. I -- I explain to families that they can expect fever and/or rash in between eight to 21 days.
Q So in your experience, do some children spike a fever in the first three days after getting MMR?
A Quite often we're giving MMR along with other vaccinations, so I tell them, for instance, our current practice is hepatitis A vaccine along with MMR and chicken pox, I tell them that the hepatitis A being a killed virus vaccine could cause fever or rash within 48 hours and then the MMR chicken pox vaccine could cause fever and rash between eight and 21 days. And then there are other things that can cause fever as well. A child, you know, can pick up a viral illness somewhere along the way or, you know, some other infection or illness.
Q Let me ask you something. Do you think 834 children total at that -- to license a vaccine is well powered to detect anything but maybe the

absolute most common adverse reactions?

MR. SANDERS: Object to the form. You can answer, Dr. Mace, if you have an answer.

A Yeah, I'm not a statistics expert. I really couldn't address how many it takes. It -- you know, it depends -- it depends on the frequency of the reaction that you're looking for. I think your point is that if it's a very rare potential side effect, it would take larger numbers of patients that I would expect to determine something like that.

Q (By Mr. Siri) Do you know what the control was in these studies with the 834 kids total?

A I do not.

Q Okay. Do you see where -- do you see a listing in a control group in this page where it summarizes the trials?

A Well, I've got such a limited view here that I -- I'm not seeing anything on this page.

Q All right. You'll have a chance to review that before trial. So let me ask, and I -- do you ever prescribe any type of drugs other than vaccines?

A I do.

Q Okay. Do you ever -- have you ever prescribed a drug, for example, Enbrel?
A I don't prescribe Enbrel.
Q Because that's a drug typically given to sick adults; correct?
A Yes.
Q Sick adults with rheumatoid arthritis; right?
A I believe that -- that Enbrel is a drug for rheumatoid arthritis.
Q All right. Typically not given to children?
A Unless they have a rheumatologic disorder, and that would be managed by someone other than me.

MR. SIRI: So I'm going to mark this as Plaintiff's -- is it 9?

MS. CHEN: Exhibit 13.

MR. SIRI: Oh, 13. Thank you.

MS. CHEN: Yes.

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

Q (By Mr. Siri) And so this looks like most package inserts you've seen; correct?

A Yes.
Q And this is Enbrel; correct?
A Yes.
Q Okay. And as is typical, we would go down to Section 6.1 to see the clinical trial studies experience; right?
A Yes.
Q Okay. So I want to go down there and take a look at how long safety was reviewed. Probably this drug was licensed to get to sick adults. Here's one of the studies. What does it say?
A The data described below reflect exposure to Enbrel in 2219 adult patients with RA followed for up to 80 months.
Q Okay. So in this study, they followed through the clinical trial experience for adverse reactions, for safety, they followed them for 80 months; correct?
A That's what that says, yes.
Q Do you have any reason to doubt that that's not accurate?
A No.
Q All right. Now, when you made -- I believe I asked you earlier whether or not was your opinion

that none of the vaccines that Yates received causes autism and you said yes, it's your opinion that none of the vaccines Yates -- that Yates received individually or collectively causes autism. Is that correct?

A That's correct.

Q Okay. So just to make sure your testimony -- I'm clear on your testimony, so your testimony is that the MMR vaccine cannot cause autism. Is that correct?

A The MMR vaccine does not cause autism.

Q Okay. Is it true to say that the MMR vaccine cannot cause autism?

A Yes.

Q Is it your testimony that the HepB vaccine cannot or does not cause autism?

A Does not cause autism.

Q Well, what's the difference between cannot and does not? I'm not trying to be tricky about it. I'm not sure.

A I -- I -- cannot sort of implies is any -- you know, is there any -- any possibility, you know, and I -- I don't believe that these vaccines -- it is my opinion that these vaccines

do not cause autism, so -- so if that --
Q Okay. But it's possible they could, you're saying?
A I don't think so.
Q But you're not 100 percent sure?
A I'm way -- you know, I mean, my degree of medical certainty is that they do not cause autism.
Q Okay. Are you familiar that the CDC, for example, puts on its website vaccines do not cause autism?
A You know, I look at lots of things on the CDC website. I don't know that I -- you know, I -- I -- I don't know that I've seen that in big block letters.
Q Have you ever heard vaccine experts on TV saying definitively vaccines do not cause autism?
A Probably, yes.
Q Okay. So what you're saying is that -- your opinion is that they probably don't cause autism, but you're not sure?
MR. SANDERS: Object to the form.
A No, my opinion is that they do not cause autism.

Q (By Mr. Siri) Okay. So your testimony is that the MMR vaccine does not cause autism.
A Correct.
Q And your testimony is that the HepB vaccine does not cause autism.
A Correct.
Q Okay. But your testimony is not that it cannot cause autism; correct?
A I -- you know, I -- I think if I believe it does not cause autism then I have to believe that it cannot cause autism. It's -- you know, it's semantics. It's how we are comfortable saying things. I -- I -- I -- it is my opinion that vaccines do not cause autism.
Q Is it your testimony that IPOL cannot cause autism?
A Correct, yes.
Q Okay. Is it your testimony that HIB vaccine cannot cause autism?
A Does not cause autism, yes. I would say does not cause autism for all of these.
Q But are you saying it also can -- they -- none of them can cause autism as well?
A Yes, yes. I agree with that statement. They

cannot.
Q All right. Let me put it this way. Do you think that maybe there are rare exceptions in which they could cause autism?
A I don't think vaccines cause autism, no. I think that the causes of autism are complex.
Q Okay. Do you -- do you think there are rare exceptions in which vaccines could be a contributing factor to causing autism?
MR. SANDERS: Object to the form of the question. Asked and answered.
Q (By Mr. Siri) Go ahead, Dr. Mace. Please answer.
MR. SIRI: And it was not asked and answered.
Q (By Mr. Siri) Please go ahead, Dr. Mace.
A No, I don't think that vaccines -- so phrase the question -- just tell me -- tell --
Q Sure, no problem. So no problem.
MR. SIRI: And, you know, I know that that's a question that -- that -- that maybe the other side doesn't like being asked, but your objection is already on the record, so I ask, you know, that it not be used again to coach the

witness.
Q (By Mr. Siri) I just -- I was asking you, do you think there are potentially rare exceptions in which vaccines, one or more, could be a contributing factor --
MR. SANDERS: Same objection.
Q (By Mr. Siri) -- that --
MR. SIRI: You've got to let me finish the question, and I know you don't like the question, but, you know, you've got to let me finish the question. And if you -- and if you want to object, just object to the form. You know, the asked and answered, I think, kind of signals to the witness that she shouldn't answer when she -- when, of course, she's required to.
Q (By Mr. Siri) Okay. With that said, what I'm asking you is, is that could there be exceptions in which any of the vaccines that Yates received could have been a contributing factor to causing his autism?
MR. SANDERS: Same objection.
A I don't think so, no.
Q (By Mr. Siri) But you're not completely sure; correct?

A No, I -- I don't think that vaccines were -- could be a contributing factor to the cause of his autism.
Q Do you think vaccines can ever be a contributing factor to the cause -- to causing autism in a child?
A No, I don't think vaccines are a contributing factor to the development of autism in children.
Q Do you think it could be a contributing factor in rare instances?
MR. SANDERS: Same objection. Asked and answered.
A I -- I don't think so. I -- I -- I don't think so. I think there are experts in the field of vaccinations that -- and especially in rare circumstances who have looked at this question and have concluded that vaccines are not a contributing cause to autism.
Q (By Mr. Siri) Okay. So you're basing your conclusion on their opinion?
A My training, my experience, looking at the literature, and the opinion of experts that I think have good experience in this -- in addressing this specific question.

Q All right. Now, we -- earlier, we talked about hepatitis B vaccine, and -- and you testified that there is no study that supports a hepatitis B vaccine does not cause autism.
A No studies that I'm aware of. I haven't looked at that specific question.
Q Are you aware of any study that supports that IPOL does not cause autism?
A I am not.
Q Are you aware of any study that HIB vaccine does not cause autism?
A I'm not, but -- you know, I haven't looked at the typical resources I look at, but no, I'm not aware of any studies.
Q Okay. Are you aware of any vaccine -- any studies that support that the Prevnar vaccine does not cause autism?
A I am not.
Q Are you aware of any test -- any studies that DTaP vaccine does not cause autism?
A I am not off the top of my head, no.
Q All right. So you haven't seen -- reviewed any such studies, but you've already reached your conclusion that vaccines don't cause autism. Is

that correct?
A Based -- yes. Based on experience and based on literature that's reviewed by the American Academy of Pediatrics Committee on Infectious Diseases, I look at the Children's Hospital of Philadelphia website and other resources for information about that.
Q Okay. So let's take that in pieces. So you based your opinion on the Children's Hospital of Philadelphia website. Is that right?
A That's one factor that I look at to help understand, yes.
Q Okay. Okay. What would be -- is there any other factor? You said other factors. I want to make sure I take them in pieces. What other factors?
A The continuing education conferences, discussions with other pediatricians, review of the information by the CDC, the pediatric Red Book. There's the AAP website, healthychildren.org has a review that lists a lot of articles, studies about vaccine safety.
Q And you reviewed all these sources; correct?
A I -- I have looked at those resources, yes.

Q Okay. Because you're here as an expert testifying that the vaccines Yates received did not cause his autism; right?
A That's right.
Q All right. Okay. And so in reviewing all of those, you didn't actually see any studies for any of the vaccines Yates received other than the MMR; right?
A Well, there are no studies that show that they do cause autism. You know, not every question can be looked at. We could think of some, you know, something is -- doesn't -- isn't proven that it doesn't cause something doesn't mean that it does.
Q Okay. I mean, usually there has to be some concern raised, right, that the product causes that injury before, I guess, research is conducted?
A Sure. There needs to be a scientific plausibility to the question and there needs to be concern raised about -- about an adverse event or reaction.
Q What else? What if parents are coming and stating they believe that, you know, based on

their parental experience, their intimate knowledge of their child, their child changed after getting certain vaccines and they believe the vaccine was the cause, would that be a cause to conduct studies to see if the vaccines were the cause?

A I -- you know, I -- I'm not an expert on those sorts of decisions. Again, I rely on the consensus statements by the American Academy of Pediatrics and others to come to my conclusion as a primary care general pediatrician.

Q You just trust their conclusory -- their conclusions regarding these things?

A When there's an overwhelming amount of information and evidence, yes.

Q Do you review that information and evidence?

A I review summaries of the evidence. You know, as a general pediatrician I look at consensus statements and committee reports and those sorts of things, but I don't -- I'm not a researcher who digs into the details of all of the studies.

Q Okay. Like, for example, when something becomes a concern, you know, maybe the HHS or CDC

will conduct a study to see if there's a relationship; correct?
A That seems like a reasonable process, yes.
Q Sometimes they'll ask the IOM to review whether or not there's a connection between the -- you know, let's say the vaccine and the claimed adverse events; correct?
A Well, I'm not sure of the process of the IOM deciding to study a topic, but they -- yes.
Q What's your understanding of when parents first started complaining about any vaccine causing autism?
A Is this a general question?
Q Yeah, I'm asking about you -- your personal understanding. I mean, you've been a pediatrician for 30 years, and so, you know -- you know, in your experience, when did the -- what's your understanding of when parents began to complain about when vaccines -- what -- what's your understanding of when parents began complaining about, you know, one or more vaccines causing autism?
A My understanding is that some of the concern was linked to the study published in Lancet by

Andrew Wakefield, that he did a study that was later retracted that -- that tried to link the MMR vaccine to autistic symptoms and gastrointestinal symptoms in children who had been diagnosed with autism.

Q What year was that study published? Do you know?

A I don't have that on the top of my head.

Q Would 1998 sound about right to you?

A Yeah, late 1990s seems reasonable.

Q Okay. So that's -- you know, that -- that's -- do you think that if you asked more pediatricians, that's the answer you'd get?

A In terms of when it was brought to light and people started asking more questions, I would think probably yes. I mean, vaccine safety has been a topic that I've discussed with families throughout my entire career. I, you know, would talk to families before those studies about vaccines and what they protected children from and what -- you know, what was to be administered, and I don't know how quickly the -- you know, that study was publicized. I remember though that, you know, we -- you know, our -- well, I can say we

are asked more questions, you know, in more recent years since that study was published about the MMR and autism.

Q Were concerns raised before Wakefield's study regarding whether vaccines caused autism?

A I don't recall.

Q Okay. But you don't believe they were?

A Yeah, I -- I don't -- I don't know the answer to that.

Q Are you aware that in the 1986 Act, Congress required the federal health authorities to review whether pertussis-containing vaccine caused certain adverse events?

A I know that there were concerns back in the 1980s with the whole-cell pertussis vaccine, and -- and my recollection would be that concerns about adverse reactions, that that vaccine may have contributed to the development of the 1986 Act because drug manufacturers were becoming less willing to produce the vaccine.

Q Right.

A They wanted to try to -- to be able to maintain a vaccine supply for children so they could be protected.

Q All right. All vaccine manufacturers for DTP, for example, had either withdrawn from the market or gone bust because of liability from injuries before the passage of the '86 Act except for one; correct?
A My understanding is that there was only one left producing the vaccine --
Q All right.
A -- in the passage of that act.
Q And there was only one company producing an MMR vaccine before the passage of the '86 Act, Merck; correct?
A I don't know the answer to that, but --
Q Yeah, and there was only one other vaccine that was routinely recommended, and do you -- at that time before -- right before '86. Do you know what that was?
A I would assume it would be oral polio.
Q That's right, OPV, and then there was -- are you aware there's only one company left producing oral polio vaccine today?
A No, I wasn't.
Q The rest of them had all gone out of business or withdrawn because of liability for injuries.

Are you aware of that?
A Because of concerns about liability and -- yes.
Q Weren't they being sued -- weren't there --
A I don't know the details.
Q Fair enough. But parents were demanding studies because of injuries that they were claiming were being -- were occurring from the then whole-cell pertussis, tetanus, and diphtheria vaccine; correct?
A That's my understanding, yes.
MR. SIRI: Okay. I'm going to mark this as plaintiff's -- is it --
MS. CHEN: Exhibit 14.
MR. SIRI: Thank you.
(Whereupon, Exhibit No. 14 was marked to the testimony of the witness.)
Q (By Mr. Siri) There's a section of -- this is the -- this is the law called the National Childhood Vaccine Injury Act of 1986; okay? And what I've done is I've just excerpted the one page where Congress directed certain studies be

conducted. Would you kindly read the yellow?
A The Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis, including whole cell, extracts, and -- oh, sorry, and the following illnesses and conditions, and number 9 is autism.
Q Right. And so, you know, as we talked about, parents were complaining that this vaccine caused certain conditions, demanded studies, and one of the conditions these parents were complaining this vaccine was causing was autism; correct?
A That's what -- yes.
Q Okay. Are you aware then that in 1991 the Institute of Medicine issued its report on whether or not pertussis-containing vaccine causes autism?
A I have not seen that.
MR. SIRI: This is going to be Plaintiff's 15. Oh, wait. Sorry. I'm going to let you do it, Patricia. Thank you.
MS. CHEN: This is Plaintiff's Exhibit 15.

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

Q (By Mr. Siri) Okay. Have you seen this IOM review before?

A If I -- it -- yeah. If I have seen it, I have not studied the details of it.

Q Have you seen the Institute of Medicine reviews before regarding vaccine safety?

A From 1991.

Q Right. Have you seen any Institute of Medicine reviews regarding vaccine safety?

A I don't recall any specific.

Q So this is -- and, you know, I presume that these types of studies, you're aware, typically have a summary of the conclusions that are reached in the study; correct? In the review; correct?

A Yes.

Q Okay. And -- and I -- what's on the page would be the summary from the 1991 IOM report; correct?

A As far as I can see, yes.

Q Fair enough. What was the causality

conclusion regarding whether or not DPT vaccine causes autism?

A Conclusion, no evidence bearing on a causal relation, and then there's a Footnote C.

Q Which reads, no category of evidence was found on a judgment about causation, all categories of evidence left blank in Table 1, meaning they couldn't find any study whatsoever whether or not this vaccine did or did not cause autism; correct?

A I would have to read the report to -- to say exactly what that means.

Q Okay. There is a Category 2; correct?

A I'm sorry?

Q Do you see there's a Category 2 for conclusion?

A Yes.

Q What's that?

A Evidence insufficient to indicate a causal relation.

Q What would that mean to you?

A That there wasn't enough evidence to determine cause.

Q Meaning there was some evidence, but not

enough to reach a conclusion; right?
A Yes.
Q As opposed to maybe no evidence bearing on a causal relation; right?
A That's what that appears to say.
Q Yeah, okay. So 1991, parents are claiming -- 1986, 1991, parents are claiming pertussis-containing vaccine, including diphtheria and tetanus, are causing autism. No studies are available. And nonetheless, are you aware that 20 years later the claim that pertussis, including acellular pertussis vaccine, was causing autism remained one of the most commonly claimed injuries from vaccines?
A I don't know data on claims.
(Whereupon, Exhibit No. 16 was marked to the testimony of the witness.)
Q (By Mr. Siri) Have you seen this report from the IOM from 2011?
A Is that the most recent report?
Q They have a number of reports. This is the most -- this is the most recent report that was

comprehensive or reviewed over 150 potential adverse events for certain vaccines, if that jogs your memory.

A So I think I'm familiar with that, but I haven't read the whole thing.

Q Okay. Do you recall that in this report the IOM looked at whether autism was caused by diphtheria tetanus, tetanus tetanus, and acellular pertussis-containing vaccines?

A I see that here.

Q Do you know what they concluded?

A I do not.

Q What do you think they concluded?

A I can't speculate about that.

Q Well, why don't we just jump to the causality conclusion? Why don't you take a look at it.

A Can you make it a little bit bigger?

Q Oh, yes. How is that?

A So the Institute of Medicine says the evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid, tetanus toxoid, or acellular pertussis-containing vaccine in autism.

Q All right. So let's go back up. They look

at epidemiological evidence. Take a look at this. They did find only one study; correct? Is that fair?

A Yes.

Q Okay.

A They reviewed a lot.

Q Now, it -- well, that's because they could only identify one study. That was the whole point of this review, correct, was to identify relevant studies?

A Sure.

Q Isn't that what you do in a review?

A You -- yes, you look for studies that are relevant.

Q Okay. And so they identified one, Geier and Geier. Do you know -- are you aware that what Geier and Geier found was that there was an association between DTaP vaccine and autism?

A So I -- I don't know a lot about Dr. Geier's findings.

Q Okay. Was there any other study that they found that beared on the epidemiological -- any other epidemiological study that they found to answer the question of whether or not DTaP vaccine

causes autism?
A This doesn't list any additional studies.
Q Okay. And similarly, they didn't find any mechanistic evidence on whether or not vaccines -- DTaP vaccines one way or another causes autism; correct?
A That's what it says, yes.
Q Okay. So and as -- as -- as you've -- you -- and as you've said, you know, and as you've honestly said, you've also never seen, because as the IOM has found, there's no study on whether or not DTaP does or does not cause autism; correct?
A That's -- I agree with that.
Q Okay.
A I haven't seen any studies.
Q Okay. So don't you think that you should wait until you actually have the science, at least one study that supports that DTaP vaccine does not cause autism before you say that DTaP vaccine does not cause autism?
A These are incredibly important questions. My opinion is based on the information that is available to me.
Q So are -- do you have any study that supports

that DTaP vaccine does not cause autism?
A Do I have any study -- I do not have a study that says DTaP doesn't cause autism.
Q So shouldn't you wait, as a matter of integrity, science, and shouldn't you wait until you do have a study, until you do have mechanistic evidence, until you have some epidemiological evidence, until you have support that DTaP does not cause autism before you claim that DTaP vaccine does not cause autism?
A You're asking a great question. I think that there -- there are reasons that the ACIP and the Red Book and others have -- and -- and the vaccine experts have said, and so I'm basing my -- my opinion on that of -- of other experts and my review of -- of literature.
Q Have you ever seen an expert say that the DTaP vaccine does not cause autism?
A I don't know -- I -- you know, a specific quote of a time and an occasion, no.
Q Have you ever read anywhere that DTaP vaccine does not cause autism in any of these conclusory --
A I've never -- yeah, I've never read that DTaP

vaccine does cause autism or that there have been studies that support that it does.

Q Okay. So there's -- and I'll show you two more, but here's one study by Geier and Geier supporting it does. There are no studies supporting that it doesn't. This is the Institute of Medicine conducting a comprehensive review of the literature; correct?

A That's what this appears to be, yes.

Q Okay. That's what they're -- that's what they're hired by the CDC and HRSA to do, is to look comprehensively at the literature. Let me -- strike that. Look, when you say that vaccines don't cause autism, what you really mean is that MMR vaccine doesn't cause autism. Isn't that right?

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

A I don't believe any vaccines cause autism.

Q (By Mr. Siri) What is your proof that DTaP vaccine does not cause autism? What is it that you have found that the IOM could not find, that the Agencies for Health Research and Quality a few years after this report could not find, nor that

the HHS could find -- strike all of that. What evidence do you have -- let me -- what evidence do you have that DTaP vaccine does not cause autism that the IOM wasn't able to identify?

A I don't have specific evidence.

Q All right. So you don't have any evidence that DTaP vaccine does not cause autism?

A I -- I can't quote you specific evidence for that.

Q Okay. You similarly don't have any evidence that any of the other vaccines that Yates received, let's leave MMR on the side for a moment, you have no evidence that any of those don't cause autism; right?

A And I don't have any evidence that they do cause autism.

Q All right. But you're claiming they don't cause autism; correct?

A I am saying that, yes.

Q Without evidence; correct?

A I can't quote you specific evidence.

Q Meaning you're just guessing there's evidence?

A I'm not guessing. I'm basing it on

experience and training and -- and other experts.
Q Isn't evidence just evidence? How does evidence materialize from -- I -- okay. Strike that. You know, isn't that what parents of injured children say, that's our experience, and the medical community says, we can't trust that?
A Parents -- parents have -- have beliefs and concerns, and those need to be taken seriously. You know, we have lots of studies that have shown that, you know, autism is not cause -- that -- that we -- we don't have any scientific studies that say that autism is caused by vaccines.
Q Let's go there. But before we do that, I'm going to say one other thing. We're going to do this based on experience. Who spends more time with the children that you treat, you or their parents?
A A parent spends more time with an individual child certainly, but I spend time with large numbers of children.
Q But unless you do an actual study, correct, that is -- let me finish -- that's properly controlled, all right, and scientifically valid, you're not supposed to draw an actual scientific

conclusion based on that, are you?

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

A We try very hard to use evidence for every decision that we make, and sometimes there is a lack of evidence, and we use experience and get input from others including our -- our experts to help us make these decisions.

Q (By Mr. Siri) So are you saying that the fact that you see many kids for a very short duration of time is more valuable, more reliable than, let's say, what 40 to 50 percent of parents of autistic children are saying about their experience with their children?

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

A I think parents of autistic children have really important insight into their own child and their condition. In terms of causality, I don't know that they are able to put it in context and determine the actual -- I mean, they can -- they can talk a lot about timing of the onset of symptoms and what the symptoms are, but that

doesn't necessarily establish causality.
Q (By Mr. Siri) What they should do is look at the science; right?
A Science is important.
Q Look at the studies; right?
A Science and studies are important.
Q Yeah. And so if they went out and they tried to see what studies exist regarding all the vaccines that Yates received, again, putting MMR aside for a moment, we'll get to that too, let's take a look at what they might find; okay? I'm going to mark -- now, sorry. Typically the way that studies are often done is they compare an exposed to an unexposed group, right, and you see the differential; yeah?
A Yes. Some studies are done that way, yes.
Q Okay. Well, now, this is -- I'm going to tell you beforehand, this is a pilot study; all right? And I will tell you readily that this study is based on parental surveys, meaning it's got recall bias, right, and so forth. But in looking at this study, I'll want you to tell me so you have an opportunity before I ask the question, to let me know if there's any other study that

shows this study is not correct. So have you seen this study before?

A I've not seen this study before.

Q Okay. So this is a pilot comparative study of the health of vaccinated and unvaccinated children 6 to 12 years old in the United States. That's what the title says; right?

A Yes.

Q And it's out of the Department of Epidemiology and Biostatistics School of Public Health, Jackson State University; correct?

A Yes.

Q Epidemiologists and biostatisticians would be the right people to conduct a study, a retrospective study comparing health between vaccinated and unvaccinated children; correct?

A They would be reasonable people to conduct a study like that, yes.

Q Okay. Are you familiar with the School of Public Health at the Jackson State University?

A I am not.

Q Okay. Now, there was a -- there was only, you know, 600-something children, like I said, parental surveys, you know, and you can have

all -- it's got a bunch of disclaimers about those, right, as all epidemiological retrospective studies do, right, there are always -- you have to try and control for confounders; correct?

A Yes.

Q Okay. And I -- you know, you can read this study, you'll have a chance now because it's been marked, they tried to do that. Let's see what they found, shall we? Okay. So taking a look at this page, they compared the rate of chicken pox between the vaccinated and unvaccinated; correct?

A Yes.

Q And they found that the vaccinated actually had -- the unvaccinated had, what, about four times the rate of chicken pox; correct?

A Yes.

Q And it was statistically significant; right?

A Yeah, I -- I'm -- I can't comment on the power, all -- et cetera, but --

Q Well, but based on what's here, the .2 to .4, it's both under one at a .2 -- I mean, I'm just saying, based on what you see in front of you, it's representing just those significant; correct?

A Yes.

Q And then in terms of whooping cough, pertussis -- whooping cough, pertussis, again, it found that the vacc -- the unvaccinated kids had, what does it look like, about three times the rate of pertussis; correct?
A Yeah, the odds -- yeah, the odds ratio of .03.
Q Yeah, and that was statistically significant too; right?
A Yeah. It has a significant P value.
Q Okay. It also looked at autism spectrum disorder between the vaccinated and unvaccinated. Do you see what it concluded?
A It has a report of autism spectrum disorder that is higher in the vaccinated children compared to the unvaccinated group.
Q All right. 4.2 times higher; correct?
A That's what it says there, yes.
Q Now, with -- you know, given whatever limitations this study has, as a general matter, a finding of four times risk is a huge difference in these types of studies, isn't it?
A Well, you know, it -- I can't comment specifically on whether this study, you know,

proves something without bigger context of the situation.

Q Well, it's an epidemiological study, right, so they generally can't prove causation, can they?

A Right.

Q I mean, if you want to prove causation, you need to do a placebo controlled clinical trial typically; correct?

A Correct.

Q I mean, you -- you know, like, if you want to know, for example, is one thing causally related to another, typically what you've got to do is compare those receiving it to those not receiving it blinded prospectively and then seeing the outcome; correct?

A That's in an ideal situation, yes.

Q Ideal. Fair. Okay. So by the way, isn't it true that every single stud -- MMR study relied upon to claim that MMR can cause autism are all epidemiological?

A I -- you know, I can't tell you that every single study that looked at MMR and autism.

Q Well, we'll take a look at the IOM report; right? It lists every one of them. It threw all

of them out except four; right? It found every single study that was done on MMR causing autism, they were all retrospective epidemiological; right? They found no mechanistic evidence and it only found four to be reliable and they were all retrospective epidemiological. Are you aware of that?

A I don't recall the details of that, no.

Q All right. We'll come back to that. So a parent -- let's go back to this parent who's got, you know, the -- all these parents who based on their experience, you know, they're -- they're with their kid every day, especially when they're little, you know, I've got -- I have a little -- my kids are getting bigger, they don't want to spend as much time with me, but when they were little, I spent a lot more time with them. All right. Based on their experience with them, so they -- you're saying, well, you know, parents experience, or whatever you said, it's on the record, and I said to you, yeah, well, they should look at the science, and you said, yes, but there's no science, but here's a published study actually that they went out, right, and this is

relatively recently that does show a -- that children who have been vaccinated compared to unvaccinated in a pilot study have four times the risk of autism; correct?

A That's what this study says, yes.

Q Do you have any study comparing vaccinated with unvaccinated children to dispute this study?

A Off the top of my head, I can't tell you that.

Q Okay. Isn't it true that no study of vaccinated and unvaccinated children that doesn't show a difference in autism rates exist?

A I can't answer that question.

Q You never looked?

A Well, there's lots of -- I've looked at lots of studies, but I don't have them memorized and exactly how many patients were enrolled and all of that.

MR. SIRI: Let's mark this one as well.

(Whereupon, Exhibit Nos. 17 and 18 were marked to the testimony of the witness.)

Q (By Mr. Siri) So this is out of the same

group. It's from the same, you know, parental surveys, and this one looks specifically at preterm birth and neurodevelopmental disorders. Can you read what this -- what it found in the abstract?

A This study says, no association was found between preterm birth and neurodevelopmental disorders in the absence of vaccination, but vaccination was significantly associated with neurodevelopmental disorders in children born at term.

Q Right.

A Odds ratio 2.7, 95 percent confidence interval 1.2 to 6.

Q All right. So that's okay. Read the next sentence.

A However, vaccination coupled with preterm birth was associated with increasing odds of neurodevelopmental disorder ranging from 5.4 compared to vaccinated but non-preterm children at 14. -- to 14.5 compared to children who were neither preterm nor vaccinated. Honestly, I need to read this and --

Q Absolutely. You should. And you should have

an opportunity to look at it. I'm not asking you to agree to it. You should have a chance to take a look at it. But I'm just showing you this study does exist in the literature and you'll have a chance to read it. What it does claim though was that children that were born preterm and vaccinated have 14.5 times the rate of neurodevelopmental disorders compared to children who were neither preterm nor vaccinated; correct? I mean, that's what it's saying.

A That's what it says.

Q Okay. But you've never seen this before; right?

A Correct.

Q Okay. We also looked at the -- there was an AHRQ report that we looked at before that's been marked. There was a study of HepB vaccine that found in kids that got HepB in the first month of -- one had -- three months of life had three times the rate of autism compared to those that didn't; correct?

A I didn't write down any notes about that study.

Q It's -- it's marked in one of the exhibits

from earlier. You'll have it for after the depo. And then, of course, there's the Geier and Geier study that found increased rates of autism in kids that got DTaP vaccine; correct?

A I would need to review that study to comment on it.

Q Okay. Now, you need to review it to comment -- oh, right, because you hadn't seen it at all. Do you believe it's accurate to say that there's no studies out there that support that certain vaccines can cause autism?

A State that one more time.

Q Sure. Isn't it true that there are studies that have been published that do find a correlation between vaccination and autism?

A I don't know that there are -- I don't know that there are studies that withstand scrutiny and -- and that show that there is a relationship between vaccines and autism.

Q Okay. So what you're saying is, is that there might be studies out there, but there may -- you may not find them to be valid; correct?

A Like the studies by Andrew Wakefield that were discredited and withdrawn.

Q So the study that was in the AHRQ report regarding HepB, so that was reviewed by the Federal Government and included in a Federal Government report in 2014, are you aware of that study being withdrawn or -- by the journal?
A No, I'm not.
Q Okay.
A I'm not familiar one way or the other.
Q Okay. All right. Now, there are a number of other studies and, you know, we'll save most of them for trial. You can probably go on the Internet and find them yourself. And, you know, other than the -- the Wakefield study, you know, are you aware of any other study that did find a -- strike that. The Wakefield study in 1998 didn't actually find a correlation to the MMR vaccine and autism. Isn't that true?
A I'd need to pull up the study to be able to tell you exactly what it says and what the conclusions are.
Q Okay. It's worth taking a read because I -- it doesn't actually say that. In fact, the conclusion doesn't relate to vaccines at all, but four studies that actually did say there's an

association to vaccines and autism, which the 1998 Lancet study was far -- if you read it, it doesn't have that in its conclusion, for the studies that do find the association between vaccines and autism, are you aware of any of those being withdrawn by the -- by the journals that published them?

A I don't have knowledge one way or the other.

Q Why do you think you're not aware of this Mawson study that I just showed you?

A The epidemiological study?

Q Yeah.

A That -- there could be criticisms of that study in terms of exclusions, what the differences are between the two groups. I -- you know, I can't really comment on it without looking at it.

Q It would be a good idea though to -- wouldn't you agree it would be a good idea for the health authorities to maybe do at least one study comparing children that have received no vaccines with children that have received vaccines retrospectively, right, so there's no ethical issue to see the difference in the rate of autism between the two groups?

A Yep, but it would be hard to do because we want all of our patients to be vaccinated.
Q But the CDC already says 1.3 percent of children by two years of age today are completely unvaccinated. Isn't that correct?
A I don't know what the exact number is. I -- I also think there are some epidemiological studies from -- you know, I -- I -- I think one in Denmark that looked at large numbers of children with -- who were vaccinated and not vaccinated. I don't remember if it was specifically MMR vaccine. I'd have to look at that again or did it include other vaccines and looking at rates of autism. And there have been a lot of epidemiologic studies that do look at -- at -- at rates of autism in children. I just was focusing most particularly on the MMR vaccine in my most recent literature review.
Q Yeah, right. Of course, are you familiar with the -- with healthy user bias?
A That -- that phrase itself is not -- you know, again, I'm not a statistician or a researcher.
Q It's clearly by CDC scientists in studies

they published long ago. Have you ever heard of the confounder whereby children who receive vaccines, right, for example, in the first six months of life and suffer an injury then don't go on to receive more vaccines, and hence when you, let's say, are only looking at, you know, receipt of the MMR, you end up with an issue called healthy user bias, which is the kids who got the first six months vaccines had no issues, they went on to get the MMR; the kids who did have issues in the first six months of life, they didn't go on to get the MMR. Have you ever heard of this concept, which is -- it's called -- which is -- which was identified by the CDC as -- and coined by them, by CDC researchers, as healthy user bias?

A No, I'm not familiar with that concept.

Q Okay. In all the -- in the Danish study you just mentioned and the few other MMR studies that have not been thrown out as unreliable by the IOM, and you should take a look at the most recent IOM report again in the MMR section, are you aware that what they compared was basically completely vaccinated children with completely vaccinated children except for just missing MMR?

A Yeah, I'd have to look at the details of the report to -- to --
Q Okay. All right. All right. Let me -- so the bottom line is this. Okay. Are you familiar with Stanley Plotkin?
A I'm -- I'm aware of that name, Stanley Plotkin, yes, but I don't know a lot about him.
Q Okay. Are you aware he's the inventor of the rubella vaccine?
A That rings a bell.
Q Okay. And that he -- and his -- and he's also contributed to developing the polio vaccine, are you aware of that?
A That does not ring a bell.
Q Okay. And so -- for other vaccines -- have you -- have you seen this medical textbook before called Plotkin's Vaccines?
A Well, you held it up a little earlier.
Q Okay. Other than that. I apologize.
A You know, I may have seen it. It's not a resource that I have used to go to.
Q Okay. You've never developed a vaccine before; correct?
A That's correct.

Q If Stanley Plotkin stated that as a matter of logic and as a matter of science, one could not yet state that vaccines do not cause autism because the science is lacking, would you disagree with him?
A So I -- I don't know enough about Stanley Plotkin to -- you know, again, I would want to see that in the context of how it was said, what -- what was the context of that. I -- you know, I need to know something more about Stanley Plotkin and look at the -- the context of that -- that comment. But I think that, you know, we want -- we -- we want -- we want to do what's right and what's best for children and we want to base that on good scientific knowledge.
Q On scientific evidence; correct?
A Yes, as much evidence is available. We have to make the best decision we can at the time we do with the evidence that we currently have.
Q Okay. And in the absence of evidence, one doesn't draw a conclusion. For example, in the absence of evidence, one doesn't say that MMR vaccine causes leprosy; correct?
A I would agree with that.

Q And one doesn't say MMR vaccine causes rheumatoid arthritis in the absence of evidence; correct?
A I would agree with that.
Q And in the absence of evidence, one doesn't say that DTaP vaccine does not cause autism either; correct?
A There's -- it's -- if there's a complete absence of evidence, you know, yes, if there's a complete absence of evidence. But again, I think we look at -- at long-term studies and the health of children and do the best we can to make the right decisions.
Q There's a long-term study that compares vaccinated and unvaccinated children that -- with regards to the rates of autism?
A We have to -- I -- I can't answer that off the top of my head.
Q Sitting here today, you're not -- you've already said you don't -- you're not aware of any evidence that supports that any of the vaccines that Yates received other than MMR does not cause autism. Assuming that you're not able to find any evidence --

A Wait. Back up. Back up. Say that again.
Q Sure. Let me ask -- let me ask it this way. Okay. I don't want to characterize your testimony. That sometimes gets messy. Strike what I said. Let me -- let me put it this way. In the absence -- if there is no evidence to support that DTaP -- if there are no studies, right -- let me back up. Science is --
MR. SIRI: David got kicked out. Okay.
THE VIDEOGRAPHER: We've got him back.
Q (By Mr. Siri) When we want to -- science and the evolution of science is typically done by conducting and publishing peer-reviewed studies; correct?
A Yes.
Q Okay. That is how science develops. We conduct peer-reviewed studies and then we replicate the findings and by other scientists who then publish their findings, and if we have enough studies that find the same thing, we can say, oh, well, we can start reaching a scientific conclusion about the issue; correct?
A Yes.
Q Okay. And so if one were to try and

understand where the science stood on an issue, they would go into the peer-reviewed literature; correct?

A Yes.

Q Okay. If there's no peer-reviewed study to support that HepB does not cause autism, then scientifically, as a matter of science, you cannot yet claim that HepB doesn't cause autism; right?

MR. SANDERS: Object to the form of the question. This is going back over steps again, Mr. Siri.

A So the lack of a study that says hepatitis B doesn't cause autism doesn't mean that hepatitis B does cause autism.

Q (By Mr. Siri) Absolutely correct, Doctor. I completely agree. The absence of evidence does not prove that it's causally related, but the absence of evidence doesn't permit drawing the conclusion at all, does it?

A The -- there's an absence of evidence that hepatitis B causes car accidents. I can conclude that hepatitis B doesn't -- vaccine doesn't cause car accidents, so I think you're asking a really -- I mean, I -- I think it's -- it's --

Q Have parents been claiming for 30 years that -- that pertussis-containing vaccines are causing car accidents or have they been claiming that they're causing autism?
A Parents have raised concerns about autism, but autism also develops at a time when children are receiving vaccines, and I have plenty of kids who have signs of autism and there's data to support that autism develops before the MMR and, you know, early in childhood, and it is contributed to by genetic factors and other things.
Q There's a lot of science to support that, in fact, it develops during the first six months of life; correct?
A I think there is data that shows there are signs in children even younger than six months of age.
Q All right. Babies receive a HepB dose at birth, correct, according to the CDC schedule?
A Yes. Not 100 percent, but it's recommended that they receive it.
Q And then they receive a number of vaccines at two months; correct?

A Yes.
Q And then four months?
A Yes.
Q Then six months?
A Correct.
Q Couldn't it be that those -- injecting all of those products during critical phases of neuro development could potentially cause autism in some children?
A I don't believe that's the case.
Q But you don't have any studies to support that; correct?
A I don't have any studies that prove the negative, that vaccines -- I can't quote you studies that -- that prove that those vaccines don't contribute to the development of autism.
Q But you do believe there are studies that prove the negative, that MMR doesn't cause autism; correct?
A Yes.
Q So studies can be conducted to show that -- to prove a negative regarding whether or not a vaccine causes autism; right?
A They -- they -- they need to be big studies,

and I'm not an expert in designing studies.
Q But they're possible; right?
A I would think possible, yes.
Q Okay. Could it be that the question of whether vaccines causes autism is so unbelievably controversial that pediatricians, vaccinologists just are so -- they're even scared to look at the question or maybe it is that large databases such as insurance companies and the VSD, which have thousands of unvaccinated kids, maybe the question has been looked at? Strike that. That's not a question really, I guess, and you don't have to speculate. How do you know? Right? Look, I get it, you -- you're a pediatrician, you -- I believe that you mean the best for your patients, and you trust what health authorities are telling you, generally speaking. Let me ask you this. Correlation doesn't equal causation; correct?
A Correct.
Q But there is a significant correlation in the rise of autism along with the rise in the number of vaccines on the CDC's childhood recommended schedule; correct?
A The rise of the diagnosis of autism has

increased in recent years, and the number of vaccines that are given have increased in recent years. I think that's our explanations for why we believe that is happening.

Q Okay. There are the same number of 60-year-old autistic folks around right now as there are children with autism; correct? Is that what you're saying? No, I -- strike that. There are far more children with autism, multiple-fold more than there are people who are 60 years old that have autism; correct?

A There are more children who've been diagnosed with autism. The definition of autism has been brought in and expanded over the years. Autism is much better recognized because we're screening and looking for it, and so -- so autism is -- is diagnosed more, but I can't state yes or no that there are more four year olds with autism than there are 60 year olds with autism.

Q Yes, there's a better autism diagnosis; right?

A Correct.

Q But the scientific community is in general agreement that the rise in autism cannot be fully

explained by better diagnosis. Isn't that true?
A I -- I -- I think that's a large part of it. I can't tell you exactly what the whole medical community believes about the rising rates of autism. We make the -- we have more diagnosed children with autism now.
Q What about what the CDC says? Does the CDC say that there's been a rise in actual cases, you know, beyond just -- that would exceed just better diagnosis?
A Yeah, I would have to look at exactly what the CDC says. At this moment, it's hard for me to --
Q I don't -- yeah, let's -- you can look at that. It's -- it's -- I don't want to get into a tangent that's not directly relevant to our case. Okay. The human immune system is typically used -- used to dealing with pathogens which first come into contact with mucosal surfaces such as the lungs, the intestinal tract, the eyes, scratches or open wounds; correct?
A Yes.
Q Okay. How are viruses grown or replicated for use in manufacturing vaccines?

A I'm not an expert in that. I can't answer it.
Q Okay. Are you not -- are you aware -- are you aware that viruses and bacteria do need to be grown though on some type of substrate in the manufacturing process of vaccines?
A Yes.
Q Okay. Is it true that the growth mediums that -- that the bacteria viruses used in vaccines are grown on are removed from the final formulation of the vaccines?
A I'm not an expert in the manufacture of the vaccine itself.
Q Are you aware of what ingredients are in vaccines?
A I can look up the list of all the ingredients, yes, I have it readily available.
Q Okay. At any point in the 30 years that you've been a pediatrician administering all of these vaccines, was there a time when you knew the ingredients in the vaccines?
A Have them memorized, no. But having reviewed the list, yes.
Q What is serum?

A Serum as in, like, human blood serum?
Q (Nodding head affirmatively.)
A It is -- it's blood with the cellular components removed.
Q Okay. And it could also refer to animal serum as well; correct?
A Yes.
Q It's just any blood of either an animal or human or -- so -- where the cell components are removed; right?
A Yes.
Q Okay. But there are still some biological material in the serum even after they remove the cellular components; correct?
A Yes.
Q Okay. And are you aware that some vaccines are grown on blood serums from calves?
A I'm not an expert on how vaccines are produced.
Q Okay. I'm asking you if you're aware that some vaccines are grown on the blood serum of calves.
A No, I'm not.
Q Okay. So I assume that also means you're not

aware of whether or not all the blood calf serum is removed from the final formulation of the vaccine?

A That's correct.

Q Okay. But understanding, I assume, enough about vaccines, that certainly would be something that would be -- would be removed from the final formulation; correct? Because you don't want the body to then develop antibodies to -- to -- basically cow blood serum; correct?

A Correct.

Q Okay. Are you aware, for example, that some vaccines are -- are grown in -- on cow's milk medium, casein?

A I am not.

Q Okay. And again, you'd want to have that -- that would be entirely removed from the final product because otherwise the body and the babies would then develop antibodies to casein; correct?

A That makes sense, although, you know, babies are exposed to casein through the --

Q But I assume you agree that ingestion is different than injecting along with aluminum adjuvants, right, where the biological material in

the vaccine is bound to the aluminum adjuvant such that it can create a sustained immune response to the biological material into the vaccine; correct?
A Yes.
Q Okay. Do you -- for example, do you know if Yates received any vaccines that were grown on monkey kidney cells?
A No, I don't.
Q Do you know what vero cells are that are used to grow the -- for example, the polio vaccine that's more recently used and sold by Sanofi?
A I do not.
Q You're not aware that they are abnormal cells and that they have extra chromosomes and like tumors can grow forever?
A I am not aware of what they're grown on.
Q Okay. Do you think it would be -- and -- and so you also don't know whether or not the final formulation of those vaccines include any vero cell components?
A That would be correct.
Q Okay. How about yeast, are you aware of whether any vaccines can -- are grown on yeast?
A Not specifically, no.

Q Okay. And if it were grown on yeast, I -- you know, yeast is a pretty common product. I assume you'd want to remove the yeast from the final formulation before you inject it into the baby; correct?
A I don't -- I don't know the answer to that.
Q Okay. Were any of the vaccines injected into Yates grown on any cells -- cell strains from aborted fetal tissue?
A I don't know the answer to that.
Q You're -- you're not aware that MMR vaccine is grown on the cultured cell strains of aborted fetal tissue?
A So you -- you ring a bell with -- I -- I know that there -- there are some vaccines where that has been a concern that has -- has been raised, and I've looked through that study and -- and, you know, tried to address parents' concerns about that. I don't remember all the details of what I learned about that.
Q You testified today the MMR vaccine doesn't cause autism; right?
A That's my -- my belief. That's my opinion.
Q And that varicella vaccine doesn't cause

autism; right?
A Yes.
Q But you're not aware that both of those products contain millions of pieces of human DNA below 500 base pairs?
A I don't know the details of all of the components that are in vaccines.
Q I mean, are you surprised to find out that there's human material inside the MMR and varicella vaccine?
A No, I'm not.
Q Okay. Why not?
A Because I know the manufacturer of vaccines is an incredibly complex process, and the details of which are -- you know, I'm not an expert in. I'm not involved in the development of vaccines, so I look at the FDA licensure and again at our -- at our experts who are involved in vaccines and the development to help us decide what's safe for children.
Q Do you -- do you look at the package inserts which will often describe the ingredients of the vaccine?
A As I said earlier, I look at the package

insert when I have a specific question, but I don't just sit down and read it from beginning to end.

Q Okay. I'm just going to mark this so you have it.

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

Q (By Mr. Siri) Okay. So -- so does this page of vaccine ingredients published by the CDC look familiar at all?

A That doesn't look like a page that I have studied.

Q So if -- how is it you've ever looked at what ingredients are in vaccines?

A So I've looked at -- I -- you know, I -- I -- as I said, I've looked at in general terms a long time ago what -- but not something that I studied every single line of. I've looked up on the Children's Hospital of Philadelphia website specific information about the adjuvant and about -- and, you know, I've looked at questions about thimerosal and aluminum and other --

other -- and when a question comes up, I can look for information, like the aborted fetal cells. I had a family that we, you know, addressed that question with a couple of years ago.

Q Only a few pages long; correct? It's four pages long. It's a list of vaccine ingredients.

A Yes, I see that.

Q Okay. Do you see this MRC-5 human diploid cells --

A Yes.

Q -- including DNA and protein?

A Yes.

Q In fact, it's the first listed ingredient, isn't it?

A It is.

Q Do you know why it's the first listed ingredient?

A I do not. Well, generally I would think the first listed ingredient would be that contained in the -- like -- like, you know, through the -- the things of the highest concentration.

Q If you're growing a virus on cell substrate, isn't it extraordinarily difficult to actually separate the virus that you're growing from the

cell substrate?
A I can't answer that.
Q You're not aware that, in fact, most of what's in, for example, the varicella vaccine is this stuff, is -- I -- I just broke one of my rules -- is MRC-5 human diploid cells including DNA and protein?
A That's what it says on this site.
Q And this is according to the document published by the --
A By the Centers for Disease Control and Prevention.
Q And Epidemiology and Prevention of Vaccine Prevention, the 13th edition, which is commonly known as the Pink Book; correct?
A I don't look at the Pink Book. That's probably why that page is unfamiliar to me.
Q Have you ever heard of the Pink Book?
A I have heard of the Pink Book.
Q That's the CDC's kind of -- it doesn't matter. Okay. Strike that. So it's reasonable, you know, for example, somebody, a doctor administers a product, let's say, you know, once every two years, I would say, you know, that they

don't have the time to know everything about it, but you've been administering vaccines for 30 years thousands and thousands of times. Do you -- don't you think parents expect that you would know far more about vaccines, including their ingredients, including the studies used to license -- you know, I'll -- strike that. Let me move on. What is a vaccine information statement?

A A vaccine information statement is a -- generally a two-page document that -- that is required to be provided to families at the time vaccines are administered.

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

A Correct.

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

A Yes, that's my understanding.

Q Okay. And are you aware that, you know, federal law requires that each VIS explain the risks of the vaccine; correct?

A I'm not aware what the federal law says, but that's what is listed on those forms.

Q Okay. Are you aware of a VIS that doesn't

include the risks -- a risk section in the form?
A Not that I'm aware of.
Q Okay. Are you -- are you aware that the federal law requires that only risks that are supported by available data information would be -- are included?
A I haven't reviewed what the federal law says.
Q Are you aware that the CDC denies petitions to add risks to the VIS for various vaccines?
A I'm not aware of what the process is, no.
Q Okay. Okay. Now I'm -- so that we hopefully don't have to go through all the law, are you -- is it your understanding though that -- that only risks where there is evidence of a causal relationship between the vaccine and the listed reaction are listed on the VIS?
A No, that's not my understanding. My understanding is that it lists reactions that are -- are common or serious or are important, but I don't -- I don't know that it is all necessarily causation, but that's because I haven't read the law to --
Q So you're not -- you're not sure?
A That's a fair statement.

Q All right. So you're not sure whether or not the only risks listed on a VIS are those for which the CDC was able to identify, you know, evidence that they're supporting a causal relationship?
A That's correct, I'm not aware.
Q Okay. Now, I -- I assume you're familiar with how doctors record in a patient's record that a vaccine was administered?
A Yes.
Q And -- and a doctor is required to record whether a parent or guardian received a VIS for each vaccine administered; correct?
A So the vaccine administration is generally recorded by the person who administers the vaccine, so it's not actually the doctor that enters the record and writes down the lot number and the date and the --
Q Oh, fair enough. But -- but you are aware that one of the required pieces of recordkeeping in a pediatric practice is for somebody, presumably the person that administered the vaccine, to record that a VIS was provided; correct?
A Yes.

Q And that it was provided to the parent and the guardian of the child that's been vaccinated; correct.
A The -- yes.
Q Okay. Now, have you reviewed Yates' vaccine record?
A I have.
Q Including the handwritten one?
A Yes.
Q And you've already gone over the -- you know, the column with regards to whether a VIS was or wasn't given with somebody before today; correct?
A We've looked at that, yes.
Q Right. And -- and I assume that a particular entry was already identified for you of interest; correct?
A We looked at the column in general. So I don't know what you're -- I don't want to presuppose what you're asking me.
Q Was there -- was there anything in particular about that column, that, you know, was of interest in discussing?
A That -- that hashmarks were made below. You know, it was said given and then hashmarks were

made was something that we talked about.
Q Did you talk about anything else regarding that column?
A There were not hashmarks made beside the hepatitis B vaccine and there were hashmarks -- or -- it was either written given or hashmarks made at the Prevnar vaccine, the first dose.
Q Okay. And what was the explanation discussed for why, you know, it said given next to the Prevnar vaccine?
A Looking -- well, looking -- I read LuAnn Upchurch's deposition, and I understand that she had a protocol for picking up the VISs and picking up the vaccines and going into the room, so her protocol would have been to pick up whatever information sheet she had available at that time and provide that to the family, and I know there were information sheets in general that were developed before the official VISs, there was some preliminary VISs, there were vaccine information pamphlets on some of our vaccines, so my understanding would be that it was her routine to pick up whatever she had available and bring those into the room and document that.

Q And where did you obtain that knowledge from?
A Well, from her deposition. She said it was her routine to pick up the -- she said it was, I think, on the right-hand side of her desk and that she picked those up and she would give them when she went in the room to administer the vaccines.
Q And then with regards to the blanks for the hepatitis B vaccines, what was the explanation for why those were left blank?
A I didn't see any explanation for why the VISs weren't given for hepatitis B. I'm not aware.
Q And so, you know, those two HepB vaccines were given on different dates; correct?
A Yes.
Q So the first time it was given, the row would have been filled out and the blocks -- the box for whether a VIS was given was left blank; correct?
A That's -- yes.
Q And then on another date at another time, another HepB was given, and that row right below that one was then filled out; correct?
A The row below that one was left blank where it said -- I believe where it said -- I think both hepatitis B vaccines, my recollection is both

vaccines had nothing written in the VIS column. I -- I might be wrong about that.

Q Let's pull it up. It would probably be easier for both of us. How is that? So here's the --

A Go ahead.

Q Here's the form; right?

A Right.

Q So on August 16, 2000, it states a HepB vaccine was given; correct?

A Yes.

MR. SIRI: And this -- this is going to be Plaintiff's --

MS. CHEN: Exhibit 20.

MR. SIRI: Thank you.

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

Q (By Mr. Siri) Okay. And so, you know, a VIS was given; correct? Or excuse me. Strike that. On August 16, 2000, presumably a HepB vaccine was administered; correct?

A That is documented.

Q Yes. And then whose ever initials this is, right, then filled out this row; correct?
A Yes.
Q This row being the row that documents administering HepB vaccine on August 16, 2000; correct?
A Yes.
Q And when that row was filled out, it did not say -- no given was added to that box; correct?
A That's correct.
Q Okay. Now, on August 16, were any other vaccines administered, like, for example, was Prevnar administered?
A On August 16, yes.
Q Okay. And so if you look at the row for August 16, is there any notation in the VIS column -- row? Excuse me.
A Under Prevnar for the VIS materials, yes, there are hashmarks.
Q Okay. And so whoever filled this out on that same date did put some notation that a VIS was given; correct?
A Yes.
Q Okay. What do those hashmarks mean to you?

A To me it means it -- it means ditto to given that was written above that.
Q So the person who filled out this -- the vaccines given on August 16, they were -- consciously remembered to put the ditto mark that a VIS or some other material, as you've stated, was provided regarding Prevnar on that date; correct?
A Yes.
Q But they put those hashmarks in, right, and then they filled out the row for HIB 3, correct, on August 16?
A Yes.
Q And then they would have gone down and they would have added a row on August 16, 2000 for giving HepB; right?
A Yes.
Q Is there any reason to believe that they didn't consciously leave that blank?
A I -- I don't know why those spots beside hepatitis B were left blank. I didn't see any comments specific in my recollection of Ms. Upchurch's deposition about why it wasn't -- it wasn't written there.

Q So by reviewing this record, it's possible that the HepB VIS or some other materials for HepB were not provided to Yates' parents or guardian on August 16, 2000 regarding HepB; correct?
A Possible.
Q Okay. All right. Now, Yates was vaccinated again on November 22; correct?
A Yes.
Q Okay. Now, on November 22, Yates received three vaccines; right?
A Yes.
Q And when he received -- he also received a HepB vaccine; right?
A Yes.
Q So the person who filled out the vaccines given on November 22 would have gotten to the HepB column -- HepB row, filled it out, and would have had another opportunity to see that the box for whether or not a VIS or some other material was provided on August 16, 2000 was left blank; correct?
A Yes.
Q But on November 22, no notation was added that a VIS was given; correct?

A That's correct.
Q Okay. Did Yates receive additional vaccines after November 22?
A He did.
Q Okay. Now, do you notice -- do you find it strange that the given -- that the -- that there's a blank on the third row below each given?
A From Ms. Upchurch's deposition, she indicated that she put given in the top row and then she put the hashmarks below that and then that it was implied that it was given at the additional -- you know, when you get to that third row, you can see as she goes down, there aren't any instances where she put hashmarks in the third row, but she talked a lot about her procedures and protocols about picking up the VISs and walking in the room with those along with the vaccines.
Q Hold on for one second. I'm -- I apologize. Just 10 seconds.
(Brief pause in the proceedings.)
Q (By Mr. Siri) My apologies. Okay. So what you're saying though is --
(Brief interruption in

the proceedings.)

MR. SIRI: What's that?

MR. SANDERS: Sorry. Somebody just opened my door. They didn't realize I was still here.

MR. SIRI: Not a problem.

Q (By Mr. Siri) Okay. So what you're saying though is that you don't know whether or not the VIS in the boxes that were left blank were given or not given. Is that right?

A She indicated that it was her routine and that this is how she documented, so her deposition says that she gave the vaccines at the time that she had protocols and procedures for giving those at the time of administering the vaccines, so I -- I don't know about her documentation habit, but that's what she said.

Q So it's possible that she didn't give them on those dates; correct?

A I think it's possible. I don't know that it's -- it's likely if she has a protocol and procedure in place.

Q Okay. Are you aware that Mr. Hazlehurst went down to the medical -- Dr. Hays' medical office

and demanded a copy of this document at some point when Yates was around two years of age?
A I did see notes in the record about a visit when he came and was asking for records and videotaping a conversation with Dr. Hays.
Q So you're aware then that Dr. Hays was holding this document in his hand as Mr. Hazlehurst was demanding a copy of it; correct?
A I don't --
MR. SANDERS: Object to the form of the question. Go ahead, Dr. Mace.
A Yeah, I don't know what he was holding in his hand.
Q (By Mr. Siri) Okay. Do you -- do you have a reason to doubt that Mr. Hazlehurst is being anything but accurate and honest when he says that Dr. Hays was holding a copy of this document in his hand as he was demanding it from him?
A I -- I don't know Mr. Hazlehurst. I don't know of any reason to -- you know, to doubt yes or no. I think, you know, memory is difficult, but I don't have any -- any reason to doubt one way or the other.

Q Okay. And are you aware that despite numerous demands over five days, Mr. Hazlehurst wasn't able to get a copy of this document until he finally got a Court Order to get a copy of it?

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

A I don't know what all the details were about that, about the interactions related to the -- obtaining the medical records. I know if someone comes to our office and asks instantaneously for a record, we have to pull things together and get copies and we can't necessarily hand it over instantly, but we would do our very best to make copies and get -- get families anything that they requested, including involving our medical records department so we could be sure that we complied with their request.

Q (By Mr. Siri) Did this -- did this small pediatric practice have a medical records office?

A I imagine they did. I -- I'm aware that they have more than one location and that not all the records -- my impression from reading it was that not all the records were in one location.

Q But if Dr. Hays was holding this record in

his hand, couldn't he have just gone to a photocopy machine and made a copy of it?
A But I -- I don't know what he was holding in his hand.
Q Okay. I mean, in the same way that you don't know that, isn't it true that you don't really know whether or not the givens that were written in this column, you don't know whether they were added during the period of time between Mr. Hazlehurst demanding a copy of this and the time that he was receiving it -- and the time he received it from their medical office; correct?
A What I have based my impression on is Ms. Upchurch's deposition that she had a protocol in place for picking up the VISs and bringing them into the room and giving them to the family at the same time that vaccines were brought in.
Q Isn't it possible that they -- that the given and the ellipses were added after the fact even though no VIS and no materials were provided to Yates' parents or guardians?
A I think that would be highly unlikely. I don't think that physicians and staff members are ever in the practice of altering medical records

before they give copies to individuals.
Q But in a situation where a father is saying he urgently needs a copy of this document and the doctor is holding it and refusing to provide it, don't you find that to be the atypical situation?
MR. SANDERS: Object to the form of the question.
A Can you phrase that question again?
Q (By Mr. Siri) Sure. Don't you find it to be an atypical situation where a father is saying he urgently needs a vaccine record for the treatment of his child and is asking that a photocopy of that medical record be made for the -- and for the record to -- with regard to your last comment, that it would be unusual for a medical office to modify a medical record after the fact?
A So I -- I don't -- first of all, again, I don't know what he was holding in his hands or whether this form was readily available at that moment. If a parent asked for a copy of a vaccination record and it was readily available, I think offices would provide that, and I don't see motivation to going in and -- and altering the record. At that moment, we have a parent who is

asking for a vaccine record, which is part of his child's medical record. We have parents every day who ask for vaccine records, and we provide what we can in the most timely way that we can.

Q Right. So right. So a parent comes in and asks for a vaccine record, the normal course would be to just in a -- you know, to make a copy and provide a parent a copy of it; correct?

A If -- if I -- if we have access to that. I mean, there are, you know, Tennessee state forms and all sorts of other things, but if someone asks for a copy of the record and we have it readily available, we would provide that record, and we certainly, you know, wouldn't be motivated or, you know, do anything to alter the record.

Q All right. So if, you know, you were standing with a parent and you had a copy of the record and the parent asked for a copy of -- you know, of let's say their child's vaccine record, you would have no issue making a copy and providing it to the parent; correct?

A Yeah, in general terms I would provide the record to the parent.

Q Okay. Now, I'm assuming before today you've

also discussed the issue regarding the Amoxicillin that was prescribed to Yates?
A Yes. I -- well, I've seen that in the -- yes, and I've seen it in the depositions.
Q Okay. And what is your understanding of what dosage of Amoxicillin was prescribed for a child that has severe otitis media versus a child that has moderate to mild otitis media?
A So if a child has severe otitis media, I would really be inclined to consider skipping Amoxicillin and using Augmentin, which is Amoxicillin and Clavulanate.
Q Is that what you would have done in 2001?
A So in -- so in -- in -- first of all, most -- most children -- when most children have otitis media, it is -- we consider it a mild illness. We would consider it severe if they had high fever and they were toxic appearing, if we were considering other complications like occult bacteremia or pneumonia, and in that setting, I would -- I would have to individually evaluate that child. My starting dose of Amoxicillin in -- in an uncomplicated case is 80 milligrams per kilo per day.

Q Okay.
A Divide them twice daily.
Q Okay. And then in a moderate situation, how much Amoxicillin would you prescribe for a -- in a moderate case of otitis media?
A If I'm prescribing Amoxicillin, I would use the same dose, 80 per kilo per day. That's the standard dosage even for a first-time otitis media, in a mild infection in a child in this age range.
Q And if it was severe otitis media?
A If it was severe, I might choose a different antibiotic because I'm worried about other potential complications.
Q That includes in 2001?
A I -- I think probably, yes.
Q You're not sure?
A Well, what I've got are some practice guidelines published by the American Academy -- you know, trying to put it all in historical context, like, you know, when I trained, we used a lower dose of Amoxicillin. During the 1990s, it was recommended that we use higher doses. So I'm trying to put it into historical context. I have

a set of practice guidelines that were published in 2004, but by the time a guideline gets published, we've probably been -- you know, we -- I mean, we're at Vanderbilt, we're ahead of things a little bit, just in terms of -- of trying to stay up to date on what's -- what makes the most sense. So we were using the dose of 80 per kilo per day earlier than when those guidelines were published, and in those guidelines, it says severe otitis media, use Augmentin.

Q And what -- and what was the guidelines that were published before 2004? What did those say?

A I had trouble finding a published guideline, so my -- my -- my -- what I -- what I tell you about a dosage that I use would be based on my recollection of the timing of my own career. When I -- when I stopped being residency director, I moved to this practice of university pediatrics, and early in the first couple of years, in '96 and '97, I was using 40 milligrams per kilo per dose, but trying to stay up to date with current guidelines, working together with residents and others, it became apparent during that phase of my recollection would be late 1990s that we switched

to using 80 per kilo. It was a hard change. I didn't want to change. I wanted to stick with 40. I -- but -- but the -- but our experts were telling us that we should use a higher dose because of bacterial resistance patterns, so I moved to 80 per kilo per day.

Q All right. So you said you moved to 80 milligrams per kilo per day twice a day?

A Yes.

Q Okay. And so you would give that for a mild and for moderate. But let's say you were going to give Amoxil in 2001 for severe. What would you give?

A Eighty per kilo per day. Eighty to 90. For the --

Q Was that --

A The recommended dose was 80 to 90 milligrams per kilo per day.

Q So you would have given -- for severe you would have done 90?

A I --

Q No?

A What I do is I calculate 80 and then round off to -- you know, to get a -- to get a near by

kind of round number. I like to prescribe 5 milliliters or 6 milliliters, not 6.3 milliliters. So I try to prescribe in the range of 80 to 90 milligrams per kilo per day divided twice daily.

Q And your testimony today is that even though there was a severe case of otitis media, you're saying you'd be concerned such that you would want to go to Augmentin, but if you had to use Amoxil, your testimony today is you'd give the same dose that you would as if it were mild otitis media?

A That's the recommended dose, yes.

Q Okay. And where is that recommendation?

A So the recommended dose that -- what -- what I -- what I have printed is the -- the guidelines from 2004.

Q Can you hold those up a second so we can take a look at them?

A Yeah. So this is just the cover.

Q Okay.

A I can move to the -- to the first page.

Q I've got it. I appreciate it.

A Okay. And then do you want to see the --

Q Hold on. I'll take the second page too.

A Okay. The second page?
Q That's the second -- yeah, let me just grab that and take a second. Thank you.
A Okay.
Q Okay. I appreciate that.
A Where -- that would specify his dose. Would you like me to hold that table up for you?
Q It's only fair. I've been doing it to you all day.
A Okay. So this is Table 6 and it's on Page 1459 of this document, and so in this table, it's a long -- it -- it's a long document. There's a lot of detail there.
Q Understood. Okay. Understood. So do you ever use the Physician's Desk Reference?
A Long ago I used the PDR before there were other resources available, so long ago.
Q So from what period -- from what -- during what period of time did you use the PDR to decide, you know, what level of dosage to give for medications?
A Well, the -- the -- so my training was in the late 1980s and then in the early part of the 1990s. You know, we were sent an updated version

every year and would look at the PDR, but that was a guideline, and there were times when -- when our practice in pediatrics might vary from those guidelines.

Q I -- okay. But you would use the PDR as like the base and then maybe there would be a modification for pediatrics?

A Early on, yeah. Early on, yes.

Q Were you using the PDR in 2001?

A No, I don't -- I probably wasn't. The other thing I used quite a bit was a book called the Harriet Lane Handbook. That was a nice pocket reference that I probably used even more -- certainly more often than the PDR.

Q Okay. In 2001, you were using both of those as a reference?

A I had other smaller books than the PDR that were more pediatric friendly that I think were published by the PDR, whoever publishes the PDR that were smaller handbooks that I might use, and again, I -- a lot of my decision was made from attending things like pediatric grand rounds at Vanderbilt and other conferences where we -- we would talk about, you know, the change from 40.

As I said, I didn't want to move. I learned 40. I didn't want to move from 40. But because additional studies showed that 80 to 90 was better, we moved on to that.

Q Uh-huh. And the guidance has changed again, right, to try and to avoid prescribing antibiotics for otitis media now?

A Sure, yeah, and that's been for a while. I mean, we -- you know, we -- that -- and this -- this practice guidelines that -- that I have from 2004 even addresses that. They included non treatment with antibiotics as an option in -- in that -- they included that as one of the options on the --

Q And those -- and those changes happened because studies were conducted to show which treatment was better; right?

A To show that the higher dose was more effective.

Q And then later there were other studies that showed actually potentially not using the antibiotics at all for otitis media might have better outcomes.

A All along we recognized that viruses play a

big component in the development of otitis media and that while it was our practice to prescribe antibiotics, they -- they may not have always been necessary.

Q Okay. So let me make sure I -- so in 2001, you're saying you did use these smaller versions of the PDR as well as the Harriet Lane Handbook?

A If I were looking -- if I needed to look up a dose of a medicine. I didn't look up the dose of Amoxicillin. I knew the dose of Amoxicillin, so I would only look at the PDR if I was prescribing something I was less familiar with.

Q Okay. And so when did you start -- did you change the amount of Amoxicillin that you would give for otitis media, when did that change happen?

A Probably in the late 1990s. I moved to my practice in -- again, it's just a move within Vanderbilt, but I changed how I was spending most of my time in 1996, and it was shortly after that that we started making changes in the dosage of Amoxicillin.

Q Okay. So late 1990s you changed to 80 kilograms?

A Milligrams per kilogram.
Q Milligrams, thank you, per kilogram, per day for -- okay. And -- and you're saying from the late 1990s on, you didn't need to consult neither the PDR nor Harriet Lane Handbook or any other source to know that?
A For -- for the dosage of Amoxicillin, certainly. We use it a lot and everybody has those doses memorized.
Q What would be the normal hemoglutin range in a nine-month-old baby?
A Hemoglobin?
Q Yes, right, thank you. What would be the normal hemoglobin range in a nine-month-old baby?
A 10.5 or higher. We -- we actually look for 11.0, but have some debate. 10.5 or higher is normal for a child in that age range.
Q Any number above that?
A Any number above that. Well, yeah, I mean, you know, something way up in the 20s, you know --
Q Okay. And -- well, I'm sorry, say -- in the 20s --
A Oh, something way up in the 20s would make me think that it was, you know, either a lab error or

I would be concerned about heart disease, polycythemia. In a child this age, you know, we're looking for 10.5 or higher.

Q Okay. Now, going back just for a second to Amoxicillin, you said you started -- you moved to the, you know, 80 milli per kilo per day two times a day in the early 19 -- early 1990s or --

A Late --

Q -- late 1990s. How did you learn about that change?

A From, well, part of an academic medical center, being part of a work group, perhaps from attending pediatric -- I attended pediatric grand rounds at Vanderbilt pretty regularly during that time. Conversations with colleagues. You know, we -- we talked with one another about, like, even though I wasn't teaching, I was still talking with and interacting with part of the group of people who were primarily teaching, so we do try to stay up to date on things.

Q Right. But that guidance had to have originated from some type of scientific review; correct?

A Right. Probably from our infectious disease

colleagues.
Q And it would have -- before it became widely adopted, it would have been published somewhere; correct?
A Not necessarily so. Our infectious disease colleagues will do studies within Vanderbilt, they look at -- we -- we know which bacteria tend to cause otitis media. You know, streptococcus pneumoniae, haemophilus influenza, non-typical Moraxella catarrhalis, so they might have had data from the microbiology lab that in our region this is the resistance pattern that we see, these are the drug levels that are required and the -- a dose of 80 per kilo per day is going to give better coverage than a dose of 40 per kilo per day in children with otitis media.
Q So your infectious disease experts engaged in some kind of review there and then made this determination, and you're saying that they didn't publish it someplace in the medical literature?
A So we get that sort -- we -- we have ongoing relationships with our infectious disease colleagues. They sit down and review practice guidelines with us from time to time and we talk

about urinary tract infection and antibiotic choices. That's not necessarily a published report. It is based on -- on data from Vanderbilt Hospital. So I'm -- I'm at this point guessing about what sorts of things went into the recommendation and who provided that, but that -- that change was made from 40 per kilo per day to 80 per kilo per day in terms of routine dose of Amoxicillin.

Q What -- what year did you learn about that change?

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

Q Okay. Who told you about the change?

A I don't know exactly where that information came from.

Q What did they base it on?

A On resistance patterns of the common bacteria that are known to cause otitis media, and studying minimum inhibitory concentrations of bacteria to certain drugs.

Q And that would need to be a -- a -- a well-designed study, I presume; correct?

A Not necessarily. So they may be going to our lab and just looking at these are the -- these are

the pneumococcus that grew and this is what their -- you know, there's data collected that's not necessarily in a double-blind placebo controlled study. This is --

Q Sure.

A Yeah.

Q And there are case controlled studies, correct, that just are about one specific case, for example; right?

A Sure. There are case controlled studies.

Q And there's publications about, you know, giving guidelines for best practices that are published all the time by various medical societies; correct?

A Yes.

Q And Amoxicillin is a pretty commonly used antibiotic; correct?

A It is.

Q Including the 1990s; correct?

A Yes.

Q And doctors around the country were using it; correct?

A Yes.

Q A change in the amount of otitis -- of

Amoxicillin for otitis -- scratch that. Otitis media also is a very common issue, I believe you said earlier; correct?

A Yes.

Q Among infants and children; correct?

A Yes.

Q So a change in the amount of Amoxicillin that's recommended to be prescribed would affect doctors all across the country, wouldn't it?

A That's why the practice guidelines were published in 2004. But it takes time. Changes happen, changes in clinical practice happen before practice guidelines are published.

Q So you're saying it took multiple years before anybody anywhere in this whole country wrote in any place about this change in what amount of Amoxicillin should be given for otitis media, what you're saying is a very common issue that's been treat -- being treated by doctors around the country.

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

A So that's not what I'm saying. I think

that --
Q (By Mr. Siri) Oh, oh, I apologize.
A The practice guidelines were published in 2004. If you look at the practice guidelines, there are dozens of publications that went into the development of a practice guideline, so I did not review the literature to see what studies were exactly published when about making that change in dose, but that was a change in dose that was made and it was a good change and it stands to this day.
Q And do doctors across the country know about this change in the early '90s, late -- late '90s? Sorry.
A I have no idea. I practice locally. I know what we were doing here. I think that's the purpose of -- of developing and publishing practice guidelines. We look at local data all the time in terms of what's happening in middle Tennessee for what antibiotics we should be choosing for -- to treat our patients with certain conditions.
Q But the change in the recommended dose of Amoxicillin for otitis media in the early -- in

the late '90s was one that you said earlier happened nationally; correct?
A No. That happened locally. That was something that we started doing at Vanderbilt, and I can't comment on what was going on nationally at that time.
Q Was -- do you know of any other place in the country that changed their guideline about the amount of Amoxicillin for otitis media in the late '90s?
A I don't have knowledge about what other institutions were doing with their guidelines.
Q So how far outside of -- so -- do you know what -- anything in the surrounding -- any -- any -- with the -- what anybody, hospitals in the surrounding states changed the prescribing guidelines for Amoxicillin for otitis media in the late 1990s?
A Oh, A lot of the -- you know, our region is fairly large. A lot of -- are referred to Vanderbilt. We have people from southern Kentucky, we have people from northern Alabama, from pretty far reaches within the state of Tennessee being very broad, so, you know, it --

it -- changes in dosages are not instantaneous where, boom, one day it's this is done and the very next day everybody in the country knows and changes their practice. These things take time to happen, so I would imagine as the infectious disease folks were or our own, you know, our -- our own general pediatrics division looked and would review a lot of literature and sit down and have discussions about things as well. As those discussions were being held here, I'm imagining there were similar discussions in the region, and that -- you know, I -- I can't tell you when other people adopted those changes, but I can tell you it takes a long time to get a practice guideline agreed upon and published.

Q So it's possible, you're saying, maybe that change even happened in your hospital, but it may not have spread outside of your hospital until 2003; right?

A I don't -- yeah, I don't know when it went to other places.

Q Right. So it could be something you did in your hospital, but you have no idea if maybe -- if anybody else adopted it outside of your hospital

until maybe even 2004 when the guideline was issued; correct?
A Right. I -- yes, but I can say that Dr. Hays was training within that time in the late 1990s, so --
Q Dr. Hays was what? I'm sorry?
A Training at Vanderbilt at that time, so he would have been exposed to that same information. He might have made the change to 80 per kilo per day before I did because he was -- you know, he might have heard the word before I did.
Q Do you find this explanation to be a little bit convenient, Doctor, for the --
MR. SANDERS: Object to the form of the question. Go ahead.
MR. SIRI: Well, I've got to finish the question.
MR. SANDERS: Sure.
Q (By Mr. Siri) Do you -- yeah. Do you -- put yourselves in -- put yourself in my shoes. You're telling me that there was a change in medical practice, you don't know what year it was, you don't know who told you, you just know it happened, and you don't even know if it's

something that happened anywhere outside your hospital, and you're not aware of a single shred of documentation that supports it until 2004, but yet you're saying it happened in the late 1990s at your hospital.

MR. SANDERS: Object to the form of the question. Argumentative and compound. Go ahead, Dr. Mace, if you have an answer.

A So I remember changing from 40 per kilo to 80 per kilo. There is -- it doesn't -- I don't know what phrase -- I don't know what word you said, but -- convenient. It just is what happened. That's how medicine happens. We learn things and we adapt to new information, and the -- the -- the academic community tries to get things published and tries to make practice guidelines, but practice guidelines probably lag behind what's actually being done in many situations.

Q (By Mr. Siri) Is it possible you're not remembering when you switched over the amount of Amoxicillin to 80 milligrams per kilogram per day?

A I told you I don't remember the exact date when I made that change.

Q Right. But is it possible that the change

actually occurred in 2002, you just don't remember?

A I don't think that's very likely.

Q I'm sorry?

A I don't think that's very likely. And if you would -- I can give you an explanation from the medical chart that I -- I think supports the idea that we made this change in the 1990s. When Yates was diagnosed with his very first ear infection --

Q Okay.

A -- he was diagnosed with early otitis media on 9/27 of 2000. So this was not the date that -- that he was vaccinated. It -- the visit that day was check ears, he was fussy, had a low grade fever, and was diagnosed with early otitis media. Dr. Hays that day prescribed 80 milligrams per kilo per day for that very first early otitis media, which was, you know, clearly a mild infection.

Q When you say clearly, how do you know that?

A Because it was documented in the record and I calculated based on his weight and the dosage that was documented.

Q So based on the weight and the dosage,

you're -- you're saying that it was mild otitis media, but if the dosage was more than that, you would have -- that it was --

A No, I'm sorry.

Q I'm sorry. I misunderstood.

A I know that the dose was 80 milligrams per kilo per day by doing the math. I know that it was mild because he described it as early otitis media, so not a moderate or severe infection.

Q Early otitis media is a term of art that you would use?

A Early otitis media, sure. It means that it is the beginnings of an infection, certainly a phrase that we would not use to describe a moderate or severe. We would use different words.

Q And what words would those be?

A I think we would use words like toxic-appearing child, you know, fussy child, ill-appearing, that's what severe would mean to me.

Q And what words would you use to describe moderate otitis media?

A I don't know that I -- I -- you know, really, I -- I describe -- I think otitis media in terms

of -- is the child mildly ill or severely ill. Moderate otitis media might be one that hasn't resolved from prior treatment. You know, we've already tried one antibiotic and it hasn't gotten better, so we're thinking about changing to another one. A child who's in a lot of pain, crying, you know, can't be consoled during the visit, I think that might be a moderate otitis media. But again, those are, you know, distinct -- those are not exact written in stone types of distinctions.

Q So if it's, like, repetitive, it happens at certain -- you know, a repeat of otitis media, it would fall into the moderate category?

A Not --

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

A Not necessarily so. If it's an ear infection that's -- if it's -- I start an ear infection and they're back three days later, you know, three days, and the child is still running fever and still ill-appearing, then -- you know, then that would be -- that would more fall into a moderate infection because now it's -- it doesn't appear to

be responding to the initial antibiotic that was chosen, so that might be a -- more of a moderate infection.

Q (By Mr. Siri) What other symptoms would you normally, you know, be exhibiting when a child has moderate otitis media?

A So are we talking about moderate illness or moderate otitis media?

Q Moderate otitis media, what other, you know, symptoms typically accompany moderate otitis media?

A Pain, fever, and then I look for, you know, bulging eardrums, I look for an opaque, red eardrum, so it's a -- it's a combination of all of -- red alone, bulging alone doesn't make it moderate, but it's more that bulging, red, painful-appearing eardrum in a child who's crying and uncomfortable and most likely running a fever.

Q Not to be -- I mean, that sounds like the severe that you described earlier.

A Yeah, severe infection would be a child who's really toxic-looking, like they look like they might have a complication, like, bacteria in the blood stream are called bacteremia, you know,

other complications, mastoiditis, we're worried that they might have pneumonia, other things that would be severe.

Q Now, Dr. Hays was the healthcare provider under whose authority Yates was vaccinated; correct?

A Yes.

Q Okay. Now, we discussed this earlier, but just to make sure we've covered the bases here, are you aware that there is a federal law that requires providing a VIS prior to administering a vaccine?

A Yes.

Q Let me rephrase that. Is there -- and when I say provide the VIS, I mean to the parent or guardian; correct?

A Yes.

Q Okay. And -- and one of the purposes of the VIS, as we discussed earlier, is to inform the parents of some of the benefits and risks of the vaccine to assist the parent in making a decision on whether to consent to administration of the vaccine to their child; correct?

A I don't agree with the VIS routinely being

used to assist parents in making decisions. Our discussion about the vaccine assists the parents in making the decision. The VIS is for them to have some written materials to take home about that, that vaccine.

Q So what's the purpose of the VIS?

A The purpose of the VIS is so that they can have some written materials from -- to -- to refer back to, it has information about the child injury that -- the 1986 Act and contact information about that, so these are reference sheets for parents to look at after they've left the clinic, but generally it's not used as something for parents -- it's just generally not used for parents to make a decision about consenting or not consenting to a vaccination.

Q Okay. So the -- make sure I understand this. The VIS provides information about potential precautions and contraindications for the vaccine the VIS discusses; correct?

A Yes.

Q And that would be information a parent -- for it to be useful would be information a parent would need to have before the vaccine is

administered; correct?
A It's useful information, yes.
Q But to be useful for, you know, a VIS provided on a particular -- for a vaccine given, it would need to be provided -- a parent would need to review that prior to the vaccine being administered; correct?
A If -- if -- if they're going to use that piece of information, then they need to review it prior to the immunization being given.
Q Okay. And, you know, similarly a VIS will discuss the reactions that can occur from receiving a -- a vaccine.
A Right.
Q This way they're aware of the potential risks of the vaccine; correct?
A Yes.
Q Okay. And it also provides explanations for, you know, why the child should get the vaccine in terms of, you know, preventing certain disease; correct?
A That's correct.
Q And that's information that's intended for the parent to review before they get the vaccine

to assist the parent in deciding presumably to get the vaccine; correct?

A It's supplementary to the discussion that's held between the pediatrician and the family about what vaccines are being ordered, so I view that as supplementary material. It's important, they need it, but -- but again, generally our families have the opportunity to look at it. You know, our current procedure is that it's given at the beginning of the visit, but most of the time they don't look at it.

Q Sure. Parents may choose to, you know, look at the VIS or not look at the VIS; correct?

A Right.

Q Just like parents may choose to not ask you any questions when you provide them information about the benefits and risks of vaccination; correct?

A That's right.

Q But those -- but those -- but information about the benefits and risks of vaccination and potential contraindications as provided in the VIS is the type of information that a parent to be useful would need to get before the vaccine is

administered; correct?
A That information sheet is only useful if someone reads it.
Q Okay. But -- okay. But it -- it -- sure. But to be useful, if they do read it, they would need to receive it before the child is vaccinated; correct?
A It depends on what the use is. If they're using it to make a decision about the vaccine, then they should read it before the vaccine is administered. If they're using it for reference material particularly about adverse reactions and having it at home so they can look back at it after the vaccine has been given and they can -- they can look back, then reading it after the vaccine is then -- is also useful in that way.
Q Right. Sure. But it's the parent who's going to decide whether they're going to read it or not read it when it's given to them to decide and it's the parent that also decides whether or not they're going to consent or not consent to the vaccination; correct?
A Yes.
Q So the parent may choose to read it before

the child is vaccinated; correct?
A Yes.
Q And a parent may rely on information there to make the decision to vaccinate or not to vaccinate; correct?
A They may. I find that very uncommon.
Q Okay. But a highly educated parent that maybe already has some concerns about prior vaccines, you think that they might be more attuned and likely to read the VIS if given to them?
A I think a highly educated parent who might have some concerns about vaccines would express those concerns to the doctor when the vaccines are being discussed or say, wait, I have a question.
Q Okay. Are you aware that Mr. Hazlehurst has testified that he has -- he, as well as surrogates who brought Yates, did express concerns about vaccines that Yates was going to receive?
A I am aware of concerns that were raised later about whether the vaccines had anything to do with his condition later. I didn't see documentation in the record about specific questions that were addressed with vaccines, and I don't recall the

specific details of Mr. Hazlehurst's deposition. I -- I don't -- I -- I remember that they discussed symptoms, but I don't remember anything in his testimony that said I didn't want them or asked them about this vaccine or that vaccine. I just don't remember the specific details of exactly what he said about that. If he asked questions though, Dr. Hays would, I believe, answer those questions.

Q Are there reactions to vaccines that are caused by vaccines that could arise more than 15 minutes after getting a vaccine?

A Yes.

Q Okay. And is -- and the risk of anaphylactic reaction is considered one in a million from a vaccine typically; correct?

A Very rare, yes.

Q Okay. But there are other risks that vaccines can potentially -- there are other injuries that vaccines can cause beyond an anaphylactic reaction; correct?

A There are other adverse reactions following vaccines, yes.

Q So if Mr. Hazlehurst expressed that he has

concerns about vaccines because his child exhibited some reaction to a prior dose and he was reassured by Dr. Hays that the only adverse reaction would happen within 15 minutes and it's one in a million and that's the only risk he informed Mr. Hazlehurst of, do you believe that that would meet the standard of care of advising Mr. Hazlehurst of the risks of receiving --

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

A If Dr. Hazlehurst said that, the only question --

Q (By Mr. Siri) Dr. Hays. Sorry. If Mr. -- Dr. Hays.

A Thank you.

Q No problem.

A If Dr. Hays said the only possible reaction was anaphylaxis, then -- then that isn't informing him of all the possible reactions to the vaccination.

Q And that would have violated the applicable standard of care that Dr. Hays owed to Mr. Hazlehurst and Yates; correct?

A So if that's the only thing that was said, if

that's the only thing that was said about vaccinations. I do recall some discussion about the Prevnar vaccine, the first time -- I believe it was the first time it was administered that doctor -- that Mr. Hazlehurst had questions about -- because it was a new vaccine had questions about whether it was appropriate to give that vaccine, and my recollection is there was a -- a -- more of a discussion about that vaccine. At that time there was some comment in one of the Hazlehurst depositions about that I believe he listened to the information and he might have used the word overruled Angela, that he thought it was appropriate to go ahead and give that vaccination, so it sounds like they -- they -- at least on that occasion there was some very specific recollection of more than just a discussion about anaphylaxis.

Q But if Dr. Hays had said the only risk to be concerned about is a one in a million chance of an event, and that -- and it would occur within 15 minutes, isn't it true that that would not meet the standard of care that was required of Dr. Hays to inform Mr. Hazlehurst, or whoever was there to -- on behalf of Yates, applicable to

vaccinating Yates?
A If he said that was the only possible reaction, then that is not typical of what we tell families.
Q Right. So if he said -- he said the only reaction is a one in a million chance of a reaction within 15 minutes of vaccination, and that's the only risk he said could have happened, you would agree that that would not meet the standard of care for vaccinating Yates; correct?
A I think it depends on if he was talking about life-threatening risks or any risks whatsoever, you know. I mean, we talk about fever and soreness at the injection site and those sorts of things which are not generally life-threatening or serious, and we generally mentioned those others. I think if he's talking about life-threatening immediate reactions and, you know, mentioned that one, then, you know, he was doing an appropriate thing by mentioning that. If that's the only thing he ever said about vaccines, that that's the only thing that could ever possibly happen or go wrong or be a side effect of administration of a vaccine, that's not typical of what pediatricians

do. We include more information.
Q And that would not meet the applicable standard of care for vaccinating Yates when he was vaccinated; correct?
A If that was the only thing that was said, I think that's not typical standard of care.
Q It would not meet the standard of care; correct?
A If that was the only thing, yes, that would -- that -- if that was the only thing that was ever said about that -- about vaccination, that would not meet the standard of care.
Q Since there was a lot of questions, I just want to make sure we're on the same page. So if the only thing that Dr. Hays -- so if -- strike that. So if -- when Mr. Hazlehurst asked what are the risks, if Dr. Hays said the only risk of giving Yates one or more vaccines would be a reaction that would happen immediately within 15 minutes and it's a one in a million chance and that's the only risk that he advised Mr. Hazlehurst of, that wouldn't meet the standard of care for informing Mr. Hazlehurst of the potential risks and benefits of vaccination;

correct?
A If that was the only risk he ever discussed, that there was not any discussion at other times about vaccines, that -- and that was the only thing that was ever said, that --
Q That was -- as of that date and the -- and those -- and the administration of those vaccines, if that was the only risk that was -- that was -- that was told to Mr. Hazlehurst, that would not meet the standard of care; correct?
A So I would say that pediatricians have short discussions and long discussions with families, and -- and our goal is to answer their questions fully, and sometimes someone might say that's the -- that's the risk that you need to be most worried about, so I don't know exactly what his words were, I don't know exactly how it was phrased. He said there's only one risk ever and it happens within 15 minutes, that's not the standard of care of the discussion that most pediatricians have with their patients prior to administering vaccinations.
Q So I want to make sure I understand you, that's all. I'm not trying to be difficult, so

let me boil it down. If the -- as of a particular date that Yates was vaccinated, all right, if as of that date the only information provided to Mr. Hazlehurst about the risks of vaccination was being told by Dr. Hays that there is a one in a million chance of a -- you know, of real reaction, and it would occur within 15 minutes, that would not meet the standard of care applicable for vaccinating Yates; correct?

A And you're saying as of that date, like all discussions leading up until that date or all discussions up until that date.

Q Yes.

A I think we have to --

Q Yes, that's why I said all discussions up until that date.

A All discussions. If there was never any --

Q Let me -- I'll do it again. If from the day that Yates was born up until the day that Yates was vaccinated, okay, right, on that date that he was -- received a vaccine, whether it was two months or four months, I counted for all discussions that occurred between Dr. Hays and Mr. Hazlehurst, if the only thing that Dr. Hays

had told Mr. Hazlehurst about risks of vaccination, serious risk of vaccination, as of that date when Yates was vaccinated, was that there was only a one in a million chance of a serious reaction and it -- and if it would happen, it would happen within 15 minutes, if that is what occurred, would that have violated the minimum standard of care that Dr. Hays owed to Mr. Hazlehurst or any of Yates' guardians or his mother?

A Well, you've added the word serious into that sentence that you weren't saying earlier, the only discussion about serious reactions. I think you also have to take into context whether or not he gave him vaccine information sheets at prior visits and that they had had that information previously. If he said the only possible reaction -- the only possible reaction is anaphylaxis and it happens within 15 minutes, then that's not the standard of care. If he said the only serious reaction, then that -- you know, I mean, we believe vaccines are safe, and so we -- we -- we tell families, like, anaphylaxis is a serious and life-threatening reaction. There's

other things that we talk about; fever, soreness at the injection site are not serious or life-threatening reactions, so if he's talking about a life-threatening reaction, the only thing you have to worry about is anaphylaxis, and that does meet the standard of care.

Q Are you aware that the IOM has confirmed that various vaccines can cause very serious reactions that are not anaphylactic in nature?

A What we generally talk to families about our -- I -- you know --

Q I know. I asked you are you aware that the IOM has reached causality conclusions and found that vaccines, various vaccines can cause very serious reactions causally related to them beyond anaphylaxis?

A Generally, yes. I can't quote you exact information from that.

Q So anaphylaxis is not the only serious reaction that vaccines can cause; correct?

A It's the serious reaction that we probably most often -- as pediatricians we most often would discuss with families.

Q Okay. You like talking about it because you

believe it's one in a million, but there are serious adverse reactions that occur at a more frequent rate than one in a million as confirmed by the Institute of Medicine. Isn't that true?

A I'd have to review the Institute of Medicine report to tell you.

Q Isn't the purpose of the VIS to actually inform the parents of serious risks for which there has been science -- for which there is science to support that there is a causal relationship?

A The VIS is to inform parents of risks. The part about the causal relationship, I'm not an expert on -- on all of that.

Q Okay. So, for example, isn't it true that encephalopathy after a prior dose of DTaP vaccine is a contraindication to further DTaP vaccine; correct?

A Correct.

Q Okay. Meaning DTaP can cause encephalopathy; correct?

A That's implied. I can't say for sure that it causes it, but I know that we shouldn't give subsequent doses in the setting of a

contraindication.
Q If a child got DTaP and had -- you know, and then develops encephalopathy within seven days, if you don't think it's related to the vaccine, why not just keep giving the kid DTaP?
A Well, you'd want to figure out what the cause of the encephalopathy was to the very best of your ability.
Q Are you aware that there have been numerous cases in which parents and families are compensated for encephalopathy following DTaP vaccination, serious brain injuries?
A I haven't reviewed compensation studies or reports.
Q Are you aware of the Institute of Medicine's discussion regarding pertussis-containing vaccines and encephalopathy?
A I haven't reviewed the -- that specific document.
Q If it is the case that there are serious adverse reactions beyond anaphylaxis, would it have violated the standard of care applicable if Mr. Hazlehurst is asking what are the risks of vaccines to not inform Mr. Hazlehurst of those

other serious adverse reactions?
A So I -- I can tell you what we do on a practical level, and that is address the parents' questions and do the best we can to provide them with information.
Q If a vaccine can cause a serious adverse reaction and the parent is asking the doctor here, Dr. Hays, if Mr. Hazlehurst had asked Dr. Hays what are the serious adverse reactions that can be caused by this vaccine, if Dr. Hays doesn't tell him what they are, isn't that a violation of the minimum standard of care applicable for Dr. Hays to vaccinate Yates?
MR. SANDERS: Object to the form of the question as overbroad. You can answer, Dr. Mace.
A Pediatricians focus on telling parents about the more common side effects of the vaccinations. We don't list every possible, even -- even serious ones. For example, when I administer the MMR vaccine, I know that thrombocytopenia can occur after an MMR vaccine is given. I do not tell all families that their child could experience thrombocytopenia. I can't list every possible -- and that's a serious reaction because they're very

rare.
Q (By Mr. Siri) Thrombocytopenia --
A I'm sorry, was that a question?
Q Yeah, sorry. How -- how often -- one in how many million -- one in how many doses does thrombocytopenia occur after an MMR vaccine?
A I'd have to look that up to give you an exact number.
Q But you're sure that it's rare?
A It's -- it's rare. I've had patients who've had thrombocytopenia following MMR. I have not had patients who have had encephalopathy following their DTaP.
Q Is -- isn't it -- well, they're far -- one is far easier to diagnose; right? Two-month-old babies typically can't talk; correct?
A Correct.
Q Okay. They can't express issues that they have with cognitive processing, can they?
A That's correct.
Q I mean, at most, what babies can often do is just cry; right?
A Right.
Q So if there is encephalopathy to a

two-month-old baby, the best -- I mean, at most, what they can really do is cry; right?
A Encephalopathy is bad. Encephalopathy is altered level of consciousness.
Q Right.
A But coma, it lasts longer than 24 hours, and I -- I -- I cannot imagine a child with encephalopathy that does not present to medical care during the time period when they're affected by their encephalopathy.
Q Encephalopathy is just a term -- general term for basically damage to the brain; correct?
A That's a general term, yes.
Q Right. Meaning -- encephalopathy can mean many -- it can have many different types of effects on cognition. It doesn't necessarily have to result in a coma; correct?
A Correct. But there are specific guidelines for encephalopathy following vaccination that describe what we're looking for.
Q I'm talking about encephalopathy in the real world, not, you know, not -- you know, encephalopathy is not -- the term -- medical term encephalopathy is some lowered level of

consciousness; correct? It's some impact on cognition, cognitive abilities; right?

A It -- it's a decreased level of alertness, could be other -- affecting other cognitive capacities as well, confusion, et cetera. But decreased level of alertness, bizarre behavior, that sort of thing is part of -- bizarre isn't a word I -- that's a word I would use in my own terminology.

Q If a two-month-old baby suffered, you know, some form of encephalopathy, became sleepier after those vaccines, just generally was a sleepier, less aware baby, you wouldn't necessarily recognize it, would you?

A I wouldn't consider just being slightly sleepier an encephalopathy. I, in fact, tell parents that one of the side effects of vaccines is their -- that their child might sleep more than usual in the first 24 or 48 hours following vaccination, and that -- I consider that a routine side effect or -- of being vaccinated.

Q But how do you know that they don't have a reduced level of -- I mean, they're two months old. How do you know that their cognitive

functioning hasn't been impacted by the vaccination? How do you know that there isn't some encephalopathy that's affecting, you know, portions of their brain that you're not -- they're not -- they don't have a major impact on a two-month-old, like the ability to speak, the ability to run, the ability to do all kinds of things that a two-month-old cannot do yet?

A Well, two-month-olds feed. They have -- they awaken, they feed, they make eye contact with parents. If they're sleepier than usual following a vaccination, you know, that -- that happens commonly, but I don't expect a baby to be so sleepy that they're not eating, that they're not waking up, that they're -- they're, you know, not making some eye contact with their parents.

Q There are even a -- there are -- there are children and adults who get serious significant neurological deficits that are still able to eat; correct?

A It depends on the type of neurological deficit.

Q We're going on a tangent. Let's go back. Now, so --

MR. SANDERS: Mr. Siri, can I interrupt for just a second? If -- we've now been going for over six hours on this one.

MR. SIRI: Yep.

MR. SANDERS: And we've only had one short break. If we get to a break at some point, and I also want to note that myself and the court reporter also had an over five-hour deposition before. She's been going for over eleven straight hours, so I just want you to take that into account and just let us know if -- if we're getting close or if we need to take a longer break and --

MR. RILEY: I would -- I would like to let everybody know I've been a part of it too. This is David.

MR. SANDERS: Yeah, sorry, David. I -- Mr. Riley has also been --

MR. RILEY: And we're off. That's all right. But go ahead, Mr. Siri.

MR. SIRI: How are you doing, Ms. Cohen? Are you okay?

THE COURT REPORTER: I'm doing okay.

MR. SIRI: Okay. Would you -- well, let

me get to a good breaking point and we'll both take a break. Is that all right?

THE COURT REPORTER: Perfect.

Q (By Mr. Siri) Okay. All right. So for MMR, for example, you know, like you said, thrombocytopenia is a serious reaction, and thrombocytopenia is one of the reactions listed on the VIS, correct, for MMR?

A Yes, it is listed. Temporary low platelet count is listed.

Q All right. And it's there because there is evidence to support that it's causally related to the vaccine; correct?

A Yes.

Q Okay. And there -- also, as you could -- all right. Did you just pull up the VIS?

A I have a copy of the MMR VIS, yeah.

Q Also, for example, rash all over the body has also been known to be causally related to receiving MMR vaccine; correct?

A Yes.

Q Okay. So that's also listed on the VIS; right? And -- because -- and temporary pain and stiffness in the joints, mostly in teenage and

adult women, has been confirmed by the IOM to be causally related to the rubella component of the MMR vaccine. That's why it's listed on the VIS; correct?

A I see that, yes.

Q And it's there because it was -- there's evidence to support that it's causally related to the vaccine; correct?

A Yes.

Q Okay. As -- as -- similarly, there's evidence to support that seizures, jerking and staring often associated with fever, febrile seizures basically, can be caused by the vaccine which is confirmed by studies that show an increased risk beyond just what would be expected in the certain time period after getting MMR vaccine for getting febrile seizures, even though it -- this literature does appear to indicate that many febrile seizures after MMR could be caused by other things, there is an increased amount of febrile seizures that do occur that is explained by getting MMR; correct?

A That makes sense. I would agree with that.

Q Okay. And similarly, there has been

documented cases of MMR vaccine causing deafness; correct?
A I'm not aware of that.
Q Okay. Similarly long-term seizures, coma, and lowered consciousness, there is proof of those being causally related to the MMR in rare, rare cases.
A I have not reviewed information about that.
Q And also similarly, brain damage, there's dozens of cases in vaccine court, for example, in which brain damage was compensated, encephalopathy after receipt of an MMR vaccine, there's even a study published by the Vaccine Injury Compensation Program by the doctors and scientists in HRSA, a part of HHS, in which they've confirmed many cases in which MMR has resulted in encephalopathy and what they describe here as brain damage; correct?
A I have not reviewed that specifically. I think we talked about that earlier.
Q Okay. You don't know that, okay. So, you know, isn't the reason that they give the VIS so parents will know what are the risks and, of course, which is where they start, Section 1, the benefits of vaccines; correct?

A Correct.
Q What use is this information for a parent to decide on vaccinating or not vaccinating in a given section if they don't get this thing before the child is vaccinated?
A The discussion with the pediatrician, which is limited in its scope, supplemented with this material is what parents typically use to make the decisions about vaccinating or not vaccinating their children.
Q Got it. So if a parent didn't get any VISs and the only thing they were told by their doctor before getting vaccines on that day or in a prior day was that when asked by the parent, and we'll use a specific case, when asked of Dr. Hays by Mr. Hazlehurst, what are the risks of the vaccines that my child Yates is going to receive, if the -- Dr. Hays said the only risk of a serious adverse event is one that would happen in the first 15 minutes and it happens only one in a million doses, isn't it true that would not meet the standard of care for vaccinating Yates?
MR. SANDERS: Object to the form of the question. This has been asked and answered

several times. Go ahead, Dr. Mace.
A So you're asking me the theoretical question if he was never given any VISs, if he was never given VISs and this was the only piece of information. I mean, I will say that pediatricians would focus on anaphylaxis if we're talking about the most serious reaction, and again, we -- we do not list every possible serious adverse event. It is -- we -- we don't -- in the setting of a busy practice, the standard of care is not that we list every single or numerous side effects. We tell them the one that seems most important at that time or the -- you know, the more than one, but we have the discussion that we think is most appropriate at that time and try to give them good information.
Q (By Mr. Siri) Isn't that why you give the VIS beforehand, so the parents can get all that information?
A In general, parents are given VISs at the time vaccines are administered and -- in -- in our standard practice.
Q Okay. So, you know, so there are, you know, contraindications and precautions to vaccines,

right, and so if the only thing a parent is told that is, hey, the only reaction you're going to have -- that could happen is in 15 minutes, it's one in a million, if that -- if they don't -- if their child doesn't have a reaction within 15 minutes, serious adverse reaction in 15 minutes, the parent would be just left assuming that anything that happened to their kid after their 15 minutes wasn't caused by the vaccine; correct?

A That's -- seems speculative. I think parents have more knowledge in general than that, but if that's the only thing they were told, you could draw that conclusion, yes.

Q And then they wouldn't -- they wouldn't be able to -- they would then not be in a position to really give real consent because they're not really being told the real risks and benefits of the products that their child is being injected with; correct?

A Well, you know, we're talking about what's done on a practical level day-to-day standard care. We give them the VISs, we have a brief discussion about the benefits and risks of

vaccines, and parents on a day-to-day basis make that decision to consent to vaccines. If they have additional concerns, they typically raise those concerns and ask questions about it. And families are also told at every single visit to call our office if you have questions or concerns or, you know, if something comes up that worries you.

Q Okay. And that -- that all happen -- so the process you just described is, you know, a parent comes in and you provide the VIS, the doctor has a discussion, discusses the potential risks and benefits, answers any questions the parents have, and then the parents -- and then the child is administered the vaccines; correct?

A Yeah, the VIS is provided at some point along that phase. You said that first. That's not always the case. In many practices it's provided after the discussion with the pediatrician.

Q All right. But -- but it's given to the parents, whether it's placed in front of them on a table and so forth or in some other manner before the nurse injects the vaccines; correct?

A It's given -- it's brought in the room and,

yes, laid down on the table for the parents or given, you know, that -- that's between the nurse and the -- and -- exactly how that piece of paper exchanges hands, but it's brought in at the time the vaccines are administered.

Q But you -- you've never seen a VIS given after a vaccination was administered by a nurse; correct?

A Oh, I suspect there are occasions when that comes up.

Q I'm asking if you've ever witnessed that.

A I can't think of a specific occasion, but, you know, sometimes the -- the -- you know, somebody forgets to hand people their handouts on their way in into the office.

Q So I'll ask you this and let's take a break. Is it -- is it your testimony that a parent who is not provided any VISs and is only -- and is told when the parent asks what are the risks of vaccination, that there is a one in a million chance of a serious adverse event and it would happen within 15 minutes of vaccination, is it your testimony that that would meet the standard of care for informing the parents of the risks and

benefits of vaccination before administering vaccines?

A A parent who has never been given any other --

Q Exactly what I said, Doctor.

A Okay. So I -- I think that probably does not meet what's typical standard of care.

Q So if Mr. Hazlehurst had never received a VIS and upon inquiring from Dr. Hays what are the serious risks of giving a vaccine to my child, if Dr. Hays then told him, there's only a one in a million chance of a serious adverse reaction and it would happen within 15 minutes of vaccinating Yates, and if that's the only information about risks that was conveyed to Mr. Hazlehurst about the risks, serious risks of vaccinating Yates, that would not meet the standard of care applicable for vaccinating Yates; right?

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

A If all of that exactly as you said --

Q (By Mr. Siri) Exactly as I said it, Doctor.

A Right.

MR. SIRI: Okay. Let's take a break.

(Brief recess.)

THE VIDEOGRAPHER: We are now back on the record at 8:36.

Q (By Mr. Siri) Dr. Mace, how much are you being compensated for being an expert in this case on behalf of the defendants?

A I am charging an hourly rate, $400 per hour.

Q How many hours have you spent on this case approximately so far?

A I -- it's in the ballpark of 40 or 45, not -- 40 to 45 hours reviewing records, not counting today's deposition.

Q I suspect reviewing the records was more pleasant. Okay. I am -- you know, I am -- let's see if I can wrap this up fairly quickly. Just a few. Would you consider encephalopathy, irrespective of whether caused by a vaccine, right, just encephalopathy, to be a serious event, a medical event?

A Yes.

Q Okay. Would you consider meningitis to be a serious adverse event?

A Yes.

Q Would you consider long-term seizures to be a

serious adverse event?
A Yes.
Q Would you consider coma to be a serious adverse event?
A Yes.
Q Would you consider lowered consciousness to be a serious adverse event?
A It depends on the circumstances.
Q Okay. Would you consider permanent brain damage to be a serious adverse event?
A Yes.
Q Would you consider chronic arthritis to be a serious adverse event?
A Yes.
Q I will skip that. Would you consider deaf -- deafness to be a serious adverse event?
A Deafness, yes.
Q Would you consider long-term seizures to be a serious adverse event?
A Yes.
Q Okay. Dr. Mace, do you consider yourself to be an expert with regard to mitochondrial disorders?
A No, I don't.

Q Okay. Do you have any training with regard to mitochondrial disorders?
A No specific training, no.
Q Okay. Do you specifically treat kids with mitochondrial disorders?
A I have treated one patient with a diagnosis of mitochondrial disorder that I'm aware of.
Q Okay. And --
A I mean, one who was diagnosed with mitochondrial disorder.
Q But what you treated them for wasn't the mitochondrial disorder?
A I provided general pediatrics primary care to that patient.
Q All right. But with regard to their mitochondrial disorder, they went and saw a specialist, I assume?
A They did.
Q Okay. A specialist with regard to mitochondrial disorders?
A A neurologist.
Q A neurologist. Thank you. Right. You're not a neurologist; correct?
A That's correct.

Q Okay. Do you have any experience diagnosing mitochondrial disorders?
A No.
Q Okay. You're not aware that CISA, the Clinical Immunization Safety Assessment Network has a hub -- has a center within Vanderbilt?
A I am not aware of that.
Q Okay. You're -- you are aware that large managed healthcare organizations have the health records as well as the ICD-9/10 codes of the patients millions -- often of patients within their health systems?
A Yes. I don't know the details of that, but as a general statement, yes.
Q All right. And -- and those medical records, as well as how -- ICD-9 and 10 codes, are used by researchers frequently to conduct all forms of studies; correct?
A Yes.
Q I'm sorry?
A Yes.
Q All right.
A I'm aware that some studies are done. I don't know to the extent that that's done.

Q Sure. But you review studies in the medical literature; correct?
A Yes.
Q And you're aware that studies, for example, comparing outcomes of different populations within managed healthcare organizations are conducted to advance the medical sciences; correct?
A Yes.
Q There are children who are more susceptible to a vaccine injury than others; correct? Let -- strike that. Let me ask you this; okay? Are you aware that in 1994 the Institute of Medicine stated, quote, the committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not. Are you aware of that quote?
A I haven't seen that specific quote. I -- I've reviewed lots of materials and may have seen that, but I don't recall specifically.
Q Okay. Then let me -- you said you have seen the 2011 IOM report; correct?
A I -- I have looked at it but not studied it in detail.
Q Okay. Let's just quickly take a look at

this.

MR. SIRI: Oh, Mr. Lawson, if you could kindly give me screen sharing capabilities.

THE VIDEOGRAPHER: You should have it now.

MR. SIRI: Thank you. I appreciate that.

(Whereupon, Exhibit No. 21 was marked to the testimony of the witness.)

Q (By Mr. Siri) Okay. So this is an excerpt from the 2011 IOM report Adverse Effects of Vaccines, Evidence and Causality, and a section entitled Increased Susceptibility. Have you seen this portion of the 2011 IOM report before?

A No, I don't recall reading this.

Q Okay. Can you kindly read the portion in yellow?

A Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons, genetic variants (in

human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name a few, all of which can interact as suggested graphically in Figure 3-1. Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not. Moreover, the occurrence of the adverse event is often the first sign of the underlying condition that confers susceptibility.

Q Okay. Do you agree with what you've just read, Dr. Mace?

A I -- you know, I would need to interpret that in the context of other information to see is there a subsequent report, you know, what criticisms are there about this particular thing, so I can't tell you whether I agree or disagree about a statement that I've not ever read before.

Q All right. Well, I'm not asking about -- I'm asking about the substance of the statement. Do you agree with the substance of what's provided in the statement?

A I'm not sure what you mean by do I agree with the substance.
Q All right. Let me ask it to you this way quickly. Do you agree that there are some children who are more likely to be injured by a vaccine than others?
A I -- I -- I think that's a possibility. I don't have enough data to say yes or no.
Q So do you disagree with the Institute of Medicine when it says that both epidemiologic and mechanistic research suggests that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility?
A That seems like a very reasonable statement to me.
Q So do you agree with that statement?
A It seems reasonable to me. Certainly I can think of examples of things that -- that make me agree with that statement.
Q Okay. So what would an example be?
A An individual who is immune suppressed being given a live virus vaccine, that's -- that's an environmental or, you know, a factor that could cause them to be susceptible to reaction from that

vaccine.
Q So some children can have a preexisting susceptibility to have an injury from a vaccination; correct?
A Yes.
Q Can you kindly read the portions highlighted in yellow from the 2011 IOM report?
A Much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients. In some metabolically vulnerable children, receiving vaccines may be the largely nonspecific last straw that leads these children to reveal their underlying genotype.
Q Do you disagree with the IOM when it says that in some metabolically vulnerable children, receiving vaccines may be the largely nonspecific last straw that leads these children to reveal their underlying genotype?
A You know, I'm not in a position to agree or disagree with the Institute of Medicine. I view it as a source of information.
Q Do you have -- are you -- do you have any evidence that would indicate that that statement

is not accurate?
A I don't have evidence for that, no.
Q Okay. So you -- absent any additional evidence, you believe, if I'm understanding correctly, that it's a reasonable statement and you would agree to it subject to learning additional contrary evidence?
MR. SANDERS: Object to the form of the question. That mischaracterizes her testimony.
A I would want to know more and put this into context before I could say I agree or disagree with this statement.
Q (By Mr. Siri) Okay. But you find it reasonable?
A I find it possible.
Q Okay. Do you think the IOM got it wrong when they wrote this?
A I can't answer that question. I -- I don't -- I just don't know. I would need more information.
Q Do you think it's -- do you think that it's more likely than not that when they wrote this, they had -- it was a well-supported statement and hence that's the reason they put it in here?

A You know, I just don't have information about how this document was developed.
Q So you're saying you just don't know one way or another whether or not the statement is correct?
A Yes, that's fair to say.
Q But you find it to be a reasonable statement?
A It -- I -- I think it's possible that -- yes.
Q It's -- it's possible that some metabolically vulnerable children, receiving vaccines may be the largely nonspecific last straw that leads these children to reveal their underlying genotype; right?
A You're asking me to speculate about that -- do I speculate that it's possible, I don't have any evidence for that one way or the other.
Q Okay. Fair enough. What is the -- what is VAERS?
A It's the adverse event reporting system.
Q Okay. Have you ever submitted a report to VAERS?
A I have not submitted a report to VAERS. I have though discussed an event with some infectious disease specialists at Vanderbilt about

whether or not a vaccine reaction was likely, and they were on a -- that person was on a committee at the CDC who discussed it, and we did not report that because it was found not to be likely due to the vaccine.

Q So unless you -- unless -- unless you believe that it was -- that the event was, you know, caused by the vaccine, you don't report the event to VAERS?

A My understanding is I should report serious life-threatening events, things that are a contraindication to future vaccinations, though I would report under those circumstances.

Q Meaning you would report one of the conditions that -- on that list that's -- of conditions that are required to be reported is what you're saying?

A Yes.

Q Okay. But otherwise, you don't report adverse events to VAERS?

A I don't report routine adverse events, like fever, soreness at the injection site, those sorts of things.

Q All right. Or if it's a serious event, but

it's not within the scope of one of the reportable adverse -- serious adverse events that's issued by the CDC?

A I would not report if it's not listed as a serious adverse event.

Q That's reportable.

A That's reportable.

Q Okay. Okay. Is your understanding of VAERS that it's a passive surveillance system?

A Yes.

Q Okay. And that it's there to pick up potential adverse events that are occurring that are unknown to the CDC?

A Yes.

Q Okay. And are you aware that an agency within HHS funded a study with Harvard Pilgrim Health Care which stated that fewer than 1 percent of vaccine adverse events are reported to VAERS?

A I'm not aware of that study.

Q Does that statistic surprise you?

A No, it doesn't, because so many of what you -- what I would consider adverse events would include things like fever, soreness at the injection site, swelling at the site of

administration.
Q Would it surprise you that -- that, you know, fewer than 1 percent of serious adverse events are reported to VAERS?
A I think it -- it depends on if the -- if the serious adverse event is thought to be related to the vaccination or if it's some, you know, unknown thing.
Q Right. Meaning it -- as long as it's something that's already -- as long as it's a -- a mandatory reported serious adverse event, then you're saying you would be surprised if it was less than 1 percent?
A Yes.
Q But if it was something that wasn't on the list of items for which doctors are required to report to VAERS, those serious adverse events you wouldn't be surprised if it was less than 1 percent?
A Yes.
Q All right. Many vaccines contain aluminum adjuvant; correct?
A Yes.
Q Okay. Isn't it -- are you -- have you

conducted any studies regarding aluminum adjuvant?
A I have not.
Q Okay. Do you have any experience doing any science related to aluminum adjuvants?
A I do not.
Q Would you -- would you be able to identify which vaccines have aluminum adjuvant and which don't?
A I couldn't off the top of my head, but I can access that information and can have my assistant look it up.
Q Okay. All right. Are you aware that aluminum adjuvant in vaccines can bind not only to a target antigen, but to, you know, any other biological material, by-products, impurities that are contained in the vaccine?
A I'm not aware of the exact mechanism of action or what it binds to other than it is an adjuvant that increases the effectiveness of the vaccine.
Q Okay. Can you name the types of aluminum adjuvant used in vaccines?
A Not -- not the name of it, no.
Q Okay. Do you know which vaccines Yates

received had aluminum adjuvant in them off the top of your head?
A I would need to look that up --
Q Okay.
A -- and to see which vaccines contain the aluminum adjuvant.
Q I assume then you're also not familiar with the particle size of the -- each piece of aluminum adjuvant typically that are in vaccines?
A That's correct.
Q Okay. And you're not familiar with how many pieces of aluminum adjuvant are contained in vaccines typically?
A That's correct.
Q Okay.
A I think that information is easily available though. I -- I mean, I've looked at sites about aluminum with explanations for why aluminum is helpful and not a risk to patients.
Q Have any of those studies ever involved injecting aluminum into animals or humans?
A I don't -- I can't quote you the specific studies. I look at summaries and recommendations and -- of things.

Q Uh-huh. And the -- okay. And -- and those summaries and recommendations will cite to supporting studies; correct?
A Yeah. I mean, what I -- you know, one thing that I've looked at again is that Children's Hospital of Philadelphia website that gives explanations that are useful to pediatricians and to family members, answering common questions including the question about the aluminum adjuvant.
Q A hospital that's famously known for where Paul Offit practices; correct?
A Correct.
Q All right. And Dr. Paul Offit has made millions of dollars selling -- for inventing and selling a RotaShield vacc -- a rotavirus vaccine; correct?
A I understand that he was involved in the development of that vaccine. I don't know his financial -- finances.
Q Are you aware that he's disclosing making at least $6 million from selling that vaccine in one disclosure alone?
A I don't --

MR. SANDERS: Object to the form of the question. She -- asked and answered. Go ahead, Dr. Mace.

A I don't know his finances.

Q (By Mr. Siri) Okay. So you looked at the children's hospital for information about safety -- Children's Hospital of Philadelphia for safety of aluminum adjuvant, but you didn't look at any of the studies that might or might not have been cited on the web page of the Children's Hospital of Philadelphia; correct?

A Correct.

Q Did you look anywhere else about the safety of aluminum adjuvant any time in 30 years of being a pediatrician?

A When I looked at that topic, I imagine that I looked through UpToDate, which is an online resource that provides information to read about that, but I can't quote you specific studies or articles.

Q Does the -- does the name Mitkus sound familiar, the Mitkus study?

A No.

Q That's the study that the FDA and CDC rely on

to say that aluminum adjuvant is safe. You're not familiar with that?
A I -- I don't have that.
Q You're not aware that that involves orally ingesting aluminum adjuvant in animals?
A I've not looked at that study.
Q Okay. And aluminum adjuvant is in many ways for the vaccines in which contains an active ingredient; right? Without that aluminum adjuvant, the immune response in the body to the antigens in the vaccine would not be sufficient to actually develop immunity, right, to the target disease; correct?
A I can't tell you about whether it just increases its -- whether we're at, you know, an unacceptable response or just a better response, but with the aluminum adjuvant, you have a better response.
Q Are you aware that aluminum adjuvants can increase production of all kinds of cytokines, for example, IL-1, IL-2, IL-6, and IL-17?
A I haven't looked at the different studies about that.
Q All right. Are you aware that there are

studies that have demonstrated aluminum adjuvant injected into the body can cause an increase in IL-6 in the brain?

A I'm not aware of that study. I haven't looked at it.

Q Okay. Dr. Edwards has copies of those studies, and you should -- you know, they were already marked in her deposition. You can take a look at them. Are you aware that there are studies that have demonstrated that an increase in IL-6 has been shown to introduce autism-like features in lab animals?

A I am not.

Q Okay. Well, Dr. Edwards, again, has copies of those studies from her deposition, and you can look at those. Are you aware that antigen that is absorbed by aluminum adjuvants are taken up by microphages and dendritic cells and then travel to other parts of the body?

A I -- I haven't studied the mechanism of the aluminum.

Q Okay. When you inject a vaccine, right, the antigen needs to go to the lymph nodes in order to generate antibodies; correct?

A I don't know the -- if it happens in the lymph node or in the blood system.
Q Well, the antigen needs to meet with a matching T or B cell, correct, that's naive so it can then proliferate; right?
A Yes.
Q So and that matching happens typically in the lymph nodes; right?
A I finished medical school 30 years ago.
Q Okay.
A I -- so you're asking me questions of things that are more detailed than what I can handle.
Q Well, we're talking about, you know, vaccines causing autism, and aluminum adjuvant has been widely implicated in causing autism by many of the world-renowned scientists on aluminum adjuvant, and so I -- I -- I assume it's something you've looked at before you reached your conclusion about whether vaccines cause autism. So let me -- I can wrap this up pretty quickly then. Are you aware that -- that antigens in the vaccine are bound to the aluminum adjuvant?
A Yes.
Q Okay. And that they then are taken up by

macrophages to phagocytosis, which means they're eaten up by the macrophages and dendritic cells?
A I understand what that means, yes.
Q Okay. And then they go someplace in the body in order to create antibodies to the antigen; correct?
A Makes sense, yes.
Q Okay. Now, after that happens, where do these aluminum-loaded macrophages go in the --
A I don't -- I don't know the answer to that.
Q Okay. Are you aware that every study that has looked -- injected aluminum adjuvant in animals, including rabbits, mice, monkeys, and then dissected them has found that after injecting aluminum adjuvant into those animals, it was found in many organs, but -- but prominently in the brain of those animals?
A I'm not aware of that study.
Q Okay. It's not a study. It's a whole series of studies starting in 1997, a few of which were provided to Dr. Edwards. I -- I believe you should take a look at those studies. I provided her with -- I provided her with seven studies, there are way more, but they consistently

find out, the first one being a rabbit in 1997 by the CDC. Okay. So in any event, are you aware of whether or not aluminum adjuvants in vaccines can cause autism?

A My understanding is that aluminum adjuvants in vaccines do not cause autism.

Q And what are you basing that on?

A On the same discussion that we had earlier about the American Academy of Pediatrics, information about autism and vaccines, along with, you know, attending conferences and expert opinions.

Q But today is the first time you've ever even discussed the potential of aluminum adjuvants causing autism; correct?

A I've looked at aluminum adjuvant in terms of general reactions, but not specifically with regard to autism.

Q When you say general reactions, you mean local injection site reactions?

A Just in general. I looked at the safety of aluminum adjuvant and we looked at the -- at -- looked at these -- at the level that a general pediatrician does to understand about with regard

to the safety of administering of a vaccine to a patient or not.

Q And would that be you going on to PubMed and finding a study or two about injecting aluminum adjuvants to see its safety?

A So I -- you know, I looked through UpToDate and looked at references that were in UpToDate and looked at the Children's Hospital of Philadelphia website.

Q I just want to share my screen for a second to make sure I'm looking at the same thing. Is this the website -- web page you're talking about, vaccine ingredients, aluminum?

A That -- that, yes, is part of the website.

Q Okay. And then so you looked at this page and then you looked at the UpToDate page. Can you show me that UpToDate page that you looked at?

A UpToDate is an online resource. I didn't print anything from UpToDate about aluminum and -- and my looking at that question of aluminum adjuvant was a while back. That's not something that I've looked at in the last few months.

Q So the last time you looked at it was a few months ago?

A With referring to aluminum, it was more than that.
Q Okay. UpToDate, is there a web address for that?
A No, it's a subscription, so the -- the hospital has a subscription to UpToDate.
Q Would you be -- would you be willing to provide me, you know, the aluminum -- the page on there that describes aluminum adjuvant?
A I can -- I can look. Again, I don't know -- I -- my recall of what I specifically looked at about that is not at the front of my mind because that was a long time ago. UpToDate is a resource that I commonly look at for information and advice.
Q Okay.
A So I -- I can look and see what I can find.
Q Will you print out the page about aluminum adjuvants, you know, provide it to Mr. Sanders and --
A I'll see what I can find.
Q So you're not sure if there's a page on UpToDate about aluminum adjuvant?
A Right, right. My -- my -- you know, what I'm

telling you are resources that I typically go to that I would have sat down at my computer and looked, and so UpToDate is a resource, I go to the Children's Hospital of Philadelphia. I can't quote specifically where -- exactly what I read about aluminum adjuvants.

Q So you may or may not have read something about aluminum adjuvants on UpToDate?

A Correct.

Q When is the last time you looked at the CHOP website aluminum page?

A The -- specifically that page was probably a year and a half ago.

Q And since you're in the business of administering vaccines day in and day out, do you think that the parents that trust you with the safety of their children would appreciate if you did read all those studies regarding aluminum adjuvants, including all the ones that were provided to Dr. Edwards, so that you could see what the peer-reviewed literature, in fact, shows about it? As you've said, sometimes clinical practice takes many, many, many years to catch up with science; right?

A Sometimes it takes time for things to get published in terms of clinical practice guidelines.
Q Especially, right, when it goes against what the medical profession has been doing, and it might even implicate the medical profession and potentially cause harm, that can really end up taking a lot longer for that practice change to happen; true?
MR. SANDERS: Object to the form of the question. You can answer, Dr. Mace.
A That's a -- question to me.
Q (By Mr. Siri) That's okay. I'll strike the question. It's -- okay. So in line with David's request, you know, he's from Tennessee, I'm from New York, he's far more courteous than I am, that I end this deposition sooner rather than later, and despite the fact that I do have more material, I think that -- I think that we can put this to bed now. As long as we're going to, you know, end it now, I'll stop now.
MR. SIRI: Are we going to -- would you like to conclude, Mr. Sanders?
MR. SANDERS: Yes, I would.

MR. SIRI: Okay. Well, and I know you've had a long day too. And thank you, you know, Mr. Lawson for -- I know you've had a long day, and Ms. Cohen as well. And, Dr. Mace, thank you for spending the afternoon answering questions.

MR. SANDERS: Dr. Mace, they'll take us off the record and then you can click out. Thank you.

THE WITNESS: Okay. Thanks.

MR. RILEY: Thanks to everybody. Thanks, Samantha. Thanks, Randy.

THE COURT REPORTER: No problem.

MR. RILEY: All right.

THE WITNESS: Is it okay to click out?

THE VIDEOGRAPHER: Sorry. I was on mute. I was giving the announcement and nobody heard. Let's do this again. This is the end of the video deposition of Dr. Rachel Mace. Counsel did waive the formal reading of the caption. We are now off the record at 9:10 p.m.

(Whereupon, the deposition of Rachel 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

SAMANTHA COHEN
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY

My Commission Expires:
June 4, 2022

SIGNATURE OF THE WITNESS

STATE OF TENNESSEE:

COUNTY OF SHELBY:

_____
RACHEL MACE, M.D.

Subscribed and sworn to by me on this the _____ day of _____, 2020.

_____
Notary Public

My Commission Expires:

_____