In the Matter Of:

HAZLEHURST vs

HAYS, M.D., ET AL.

WILLIAM STEPP, M.D.

August 31, 2020

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REPORTING

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

WILLIAM STEPP, M.D.

AUGUST 31, 2020

** TAKEN VIA ZOOM VIDEOCONFERENCE **

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

The deposition of WILLIAM STEPP, M.D. is taken via Zoom videoconference on behalf of the Plaintiff, on this the 31st day of August, 2020, pursuant to notice and consent of counsel, beginning at approximately 9:00 a.m.

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

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

A P P E A R A N C E S

** ALL PARTIES APPEARED VIA ZOOM VIDEOCONFERENCE **

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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. William Stepp. This is August 31, 2020. We are on the record at 8:00 -- excuse me, at 9:36. Counsel, would each of you state your appearances for the record which will then be followed by the swearing in of the witness by the court reporter.

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

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

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

WILLIAM STEPP, M.D.,

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

EXAMINATION

BY MR. SIRI:

Q Good morning, Dr. Stepp.

A Good morning.

Q Can you please state your full name for the record?

A It's William Price Stepp, Jr.
Q Have you been deposed before?
A Yes, I have.
Q Okay. How many times have you been deposed?
A This will be the third time.
Q Okay. Okay. So two other times apart from today; correct?
A That's correct.
Q Okay. Can you tell me about the other two depositions, what those were about, context and so forth?
A One was -- I was asked by an attorney to give an opinion on a case of meningitis and I was giving a deposition on that. To be honest, I can't remember if it was for the defense or the plaintiff. And the other time was a lawsuit against myself.
Q You were the defendant in the second lawsuit?
A Yes.
Q And what was the issue?
A It was a hyperbilirubinemia case with kernicterus.
Q And what was the claim being made?
A That myself and the other doctor involved

were not following the standard of care and we caused the child to have a problem.

Q And what was the outcome of that case?

A Settlement.

Q Okay. When did that case occur?

A It was initiated in 1996, I believe.

Q Were you the treating physician?

A I was one of them.

Q Okay. And when they said you violated the standard -- they claimed that you violated the standard of care, in what way were they claiming you violated the standard of care?

A I saw the baby initially in the nursery when there was no jaundice present. The baby was discharged by another physician. They came back to me later, the baby was quite jaundiced, and I treated with phototherapy and they claimed that I should have used exchange transfusion instead.

Q What happened to the child?

A Gradually it appeared there was some neurological deficit and it was felt that that was due to kernicterus, which is brain damage due to high bilirubin.

Q I'm -- so -- and when did the case settle

approximately?
A I think it was 2004 or '05, right around there.
Q Do you recall what court it was pending in?
A No, I do not.
Q Did you have to -- did you ever have to go to court for it, for that case?
A No.
Q Were you deposed in that case?
A Yes.
Q Yeah, I apologize. I meant how many times were you deposed in that case?
A Oh, once.
Q Okay. And then you said you were an expert on meningitis, in a case regarding meningitis; correct?
A That's correct. I was asked to give an opinion.
Q And how long ago did that -- when did you -- were you deposed in that case?
A It was probably between 1990 and 2000. I don't remember specifically.
Q Okay. And what did that case involve? More specifically, what was the claim in that case?

A That the treating physician had improperly or failed to diagnose meningitis and the child suffered as a result.
Q And were you testifying regarding the standard of care in that case?
A Yes.
Q Now that you've answered two or three more questions about it, do you recall whether you were testifying for the defense or the plaintiff?
A To be honest, I really do not remember.
Q Okay. Do you recall -- where were you deposed for that case? Do you remember where?
A In a meeting room -- in a meeting room at The Jackson Clinic.
Q And were you deposed more than once in that case?
A No, just the one time.
Q Do you remember either the name of the plaintiff or the defendant in that case?
A No.
Q Do you remember the name of the attorney that hired you?
A No.
Q Do you remember any details about that case

beyond what we've already discussed?
A I remember that it was a bacterial meningitis and specifically due to pneumococcus.
Q Do you remember the child's name?
A No.
Q Do you have any of the documents related to that case still in your possession?
A No.
Q Did you write an actual report in that case?
A Nothing written.
Q You just showed up to testify?
A At the deposition.
Q Did you have an engagement letter with the attorneys that governed how they would pay you?
A On that particular case?
Q Yes.
A No.
Q All right. I'm going to go through a few rules with you, Dr. Stepp, regarding the deposition. Okay. You've done it twice, but it sounds like it's been a little bit of time.
A It has been.
Q So I'll review them for your benefit and the benefit of the record. The court reporter has

placed you under oath. That's the same as a court of law. You're testifying under penalty of perjury. Do you understand what I mean when I say perjury?

A Yes.

Q Now, the court reporter is making a record by typing up everything that you say; okay? The court reporter can't record nods, so nodding, you know, yes or no while obviously we're on a Zoom and we can see each other, I understand what it means, the record won't reflect that. Understood?

A Yes.

Q The other thing too is that when we see each other, you know, incantations such as uh-huh might have meaning when we hear them, but they don't -- they're not meaningful on paper. It's not clear whether that means yes or no, so I ask that when you respond to not use uh-huhs and things of that nature; okay?

A Okay.

Q Okay. If you don't understand a question, let me know; all right?

A Yes.

Q The other thing too is that you might very

well be able to predict the question I'm about to ask. Even though you're almost 100 percent certain you know what I'm going to ask, I'd kindly ask that you wait until I finish the question before you respond. This way there's a complete record; okay?

A Okay.

Q All right. Another thing too is that if you don't know the answer to something, you can say I don't know, that's fine. And also, you know, you're not being asked to speculate. However, you know, if you have a partial or memory of something or remember only a portion, then you should so state; okay?

A Okay.

Q I'm going to ask you a question that's not implying that -- doesn't intend to imply anything. It's just a standard question that we ask. Are you taking any medications or under the influence of any other substances that might affect your ability to testify today?

A No.

Q Okay. How did you prepare for this deposition?

A Mr. Sanders provided me with some materials and I read them.
Q Okay. What materials did he provide you with?
A Depositions of witnesses that have already, you know, given their testimony.
Q Okay.
A And he's given me a few excerpts from two different editions of the Red Book.
Q So which deposition transcripts did you have?
A It's easier if I just read them. Is that okay?
Q That's fine.
A I have the complaint that was filed in 2010; the complaint filed in 2019; plaintiff's expert disclosure of Dr. Zimmerman; plaintiff's second supplemental answers to defendant's first set of interrogatories; plaintiff's expert disclosure of Ramon Ramos, Dr. Ramos; plaintiff's expert disclosure of Dr. Mumper; defendants' expert disclosures; defendants' supplemental expert disclosures; medical records from The Jackson Clinic; medical records from Vanderbilt University Medical Center; Dr. Hays' deposition; Rolf

Hazlehurst's deposition; Angela Hazlehurst's deposition; LuAnn Upchurch's deposition; the deposition of Dr. Riikola; deposition of Dr. Ramos. I think that's it.

Q Okay. If there were any other materials, would they be somewhere other than what you just looked through?

A The only other thing I can remember looking at is I pulled up the VIS sheet for MMR, the current one, on the Internet.

Q When did you do that?

A A few days ago.

Q And why did you do that?

A I -- just to look at it. I mean, there was no special reason.

Q Did somebody prompt you to pull up the VIS for the MMR?

A No.

Q Okay. Was that in the context of reviewing any other materials?

A It was while I was reading the other material, yeah. I just took a moment, pulled it up, looked at it, and then went on.

Q Okay. Did you pull up anything else and look

at it as you were reading the deposition materials?

A No.

Q Okay. And when you say you pulled up the VIS for the MMR, do you mean the current VIS?

A The current one.

Q There's also a copy of that in your office, I presume; correct?

A I don't have an office anymore.

Q Ahh. Now, AAP, you said that you were provided some expert material from the AAP. Did you mean the AAP Red Book?

A Yes, sir.

Q Okay. And from what year was that Red Book?

A It was one from 2000, and the other is -- I'm not sure. It's probably on here, but it's not the whole book, so it's just Xerox copies, and -- but it's a later edition than 2000. I don't know the year.

Q Can you hold it up in front of you?

A I have it in my hand.

Q Okay. If you look at the bottom of the page, do you see a number, a year?

A There's several pages. So far I'm not seeing

that.
Q Can you hold up to the screen the first page of what you're looking at?
A It's not very helpful, I realize.
Q Yeah.
A Do you want the second page?
Q Sure. Okay. When were you provided these two editions of the excerpts of the Red Book?
A It was several weeks ago.
Q Okay. And you were provided those separately from the rest of the materials that you were asked to review?
A No. I got them at the same time.
Q Okay. Got it. What instructions were you provided upon receiving these materials, including the AAP Red Book excerpts?
A Well, I think the instructions, or certainly implied instructions, were that I should read them so I'm better able to form an opinion.
Q An opinion with regard to --
A This case.
Q As well as the standard of care applicable to the case?
A Yes.

Q Would you say that your opinions regarding the standard of care in this case were formed in the last few weeks?
A Well, I've been aware of this case for a long time, as Dr. Hays is one of my partners, or was one of my partners, but reviewing the case recently and in reading the depositions and looking at the medical record has helped more cement my thoughts for me.
Q And so the opinion that you had prior to reviewing these materials has been cemented, you're meaning that it hasn't changed after reviewing the materials?
A In the sense that I think Dr. Hays performed his duties within the standard of care, no, it hadn't changed.
Q Okay. Well, we'll come back to that later in the deposition. Is there something that has changed in terms of the way you -- what it is you thought about this case after reviewing these materials that was different than when you previously assumed?
A Nothing different.
Q Did you have any discussions with anybody

prior to today to prepare for this deposition?
A Mr. Sanders.
Q Okay. And when did you meet to do -- to talk with Mr. Sanders?
A Twice within the last couple weeks.
Q Okay. And how did you meet? Via Zoom or in person?
A In person.
Q Okay. And how long was each meeting?
A Well, the first one was a little over two hours and the second one was a little less than two hours.
Q Okay. And I presume you discussed the testimony you were going to be providing today?
A He wanted to know what -- what my opinions were --
Q Uh-huh.
A -- so in a sense, yes.
Q And did you also learn additional information about this lawsuit during those meetings?
A Most of the additional information has been from reading the material he provided because it's -- it's detail that I didn't know before.
Q Okay. Did you -- during those discussions,

did you discuss Amoxicillin?
A Yes.
Q Did you discuss standard of care?
A Yes.
Q Okay. Do you believe that the testimony you're going to provide today was influenced by those discussions?
MR. SANDERS: Object to the form of the question. You can answer, Doctor, if you have an answer.
A Not from the discussion with Mr. Sanders, no, but from the material he provided.
Q (By Mr. Siri) Other than Mr. Sanders, did you have a discussion with anybody else --
A No.
Q -- about -- anybody else relating to the deposition you were going to take today?
A No.
Q Okay. When is the last time you had any discussion with anybody regarding this case in any way that was other than Mr. -- with Mr. Sanders?
A Well, since I was asked to review the case, nobody.
Q Okay.

A And as some people know, I'm, you know, participating, but they don't know anything about it. Now, way back, because this started when Yates Hazlehurst was born, I'm a partner of Dr. Hays, and so some of us discussed the fact that this had been going on.

Q And you --

A And that's a long time and before I knew I was going to be involved.

Q Okay. So just to make sure that I understand. So you said since you were -- became involved, I guess, as an expert in this case, you have not had any discussions about this case with anybody other than Mr. Sanders. Is that correct?

A That's correct.

Q Okay. So when were -- just so I'm again clear, when did you, you know, in your mind become an expert in this case?

A They first asked me -- it was actually over a year ago.

Q Okay.

A And actually Mr. Phillips was present when I met with Mr. Sanders then, and I was given some of the material at that time. Then nothing happened

in the case for a long time, and I didn't think about it or talk about it until recently when I found out I was going to give this deposition, and that's when I met twice with Mr. Sanders in the last couple weeks.

Q Okay. So would it be accurate to state that for the past year you've spoken to nobody else about this case in any manner other than Mr. Sanders?

A That would be fair, yes.

Q Okay. Would it be accurate?

A Accurate.

Q Is that yes?

A Yes.

Q Okay. So but in the past you said that you have had discussions with other individuals about this case, you know, and it sounds like it might have even been a bit more temporally removed from today. Who were those discussions with?

A It's long enough ago where I don't remember specifically, but we had several partners there at The Jackson Clinic in the pediatric department, and it could have been any or all of them. I would suspect it was not Dr. Anderson, doc -- not

Dr. Shelby-Kennedy, not Dr. Hays for sure, more likely possibly Dr. Owens or Dr. Woods, but again, a long time ago, don't remember.

Q Okay. But it wouldn't have been with Dr. Hays?

A No.

Q Okay. So then how did you know about the case if it wasn't -- oh, because the clinic was also a defendant; right?

A Correct.

Q But you never had a discussion with Dr. Hays about the case?

A I have no recollection of ever talking to Dr. Hays about the case.

Q Is there a reason you wouldn't have spoken to Dr. Hays about the case?

A Well, after I was asked to participate, I knew I should not do that, and before that, I just felt like, you know, he didn't need to hear about it from me for -- so just being sensitive to his feelings, and but again, after I became involved, I knew I was not -- I was not supposed to do that, so I did not.

Q Okay. And then -- and but before you became

an expert, you didn't want to talk to Dr. -- you didn't talk -- bring up it up with Dr. Hays because you thought it might be a sore spot with him?

A Yes.

Q Did anybody else --

A Did anybody else what?

(Audio disruption.)

MR. SIRI: Does anybody else hear that noise or is it just me?

THE WITNESS: I do.

MR. RILEY: Oh, I hear it.

Q (By Mr. Siri) Okay. Dr. Stepp, do you hear a noise?

A I hear a noise. It sounds like it's in the background.

Q Okay. Well, let's keep going. Do you -- are you aware of anybody who did speak with Dr. Hays about this case?

A No.

Q When is the last time you had a conversation with Dr. Hays about anything?

A Earlier this year.

Q Okay. And what was it about?

A Dr. Hays is my son and my daughter's doctor, and my son had a checkup with Dr. Hays, and we mentioned what we needed to talk about as it relates to his care of my son, and then other than that, it was just about the weather or something. I don't remember. It was just casual conversation.

Q How -- how old are your son and daughter?

A My daughter is 34 and my son is 32.

Q Okay. Were you with them in the office when they saw Dr. Hays or is the conversation you had separately with Dr. Hays about your son and daughter?

A About my daughter, she lives in Memphis, and she will come -- she drives to Jackson to see Dr. Hays, and I do not attend when she is there. And she doesn't come very often. As far as my son's checkup earlier this year, I went with him to the visit, but I sat in the waiting room until he was finished and then asked him what he thought about a few medical issues that pertained to my son's health.

Q And then with regard to your daughter, was that discussion over the phone?

A Oh, I didn't talk to him about his visit -- where he had a visit with my daughter. She had an issue she wanted to discuss and I wasn't involved at all.
Q So have you had a discussion with Dr. Hays relating to your daughter in the past year?
A No.
Q Okay. So the discussion that you had with Dr. Hays in the past year that you recall was when you talked with him about your son after waiting in the waiting room while your son was getting a medical checkup?
A I don't understand the question.
Q No problem. You went in with your son for a medical visit that he had with Dr. Hays; correct?
A Correct.
Q You waited in the waiting room; right?
A Yes.
Q After the -- Dr. Hays met with your son, you then spoke with Dr. Hays; yes?
A Yes.
Q Okay. That -- did that conversation occur in the waiting room?
A No, back in his office --

Q Okay.
A -- down the hall.
Q How long was that conversation?
A A few minutes.
Q Okay. And --
A Less than five.
Q And besides -- and did it pertain to anything other than your son's medical situation or the weather?
A No.
Q Okay. Was there any other conversation you've had with Dr. Hays in the past year other than that one?
A I do not remember one.
Q Is it possible you've had one and don't recall?
A Not likely. The only time I see him is if I go to the clinic and visit, and you -- he's usually busy and I'm talking to some of the other pediatricians, so I don't remember talking to him other than that time in the last year.
Q And why would you -- how often have you been to The Jackson Clinic in the past year?
A Well, of course, I go there for my own

health, and needless to say I don't see the pediatricians, but to go and just visit my former colleagues, this calendar year probably just once, and once the coronavirus pandemic came, I've not done that.

Q Is that something you've done over the years, gone back and visited The Jackson Clinic to see your colleagues?

A Yes. It's usually if I have an appointment there for myself and then afterwards I'll drop up and say hi.

Q Uh-huh. So, you know, over the last ten years, excluding this year, how many times a year would you say on average you've gone down to The Jackson Clinic?

A Are you talking about visiting the pediatricians or for my own personal healthcare?

Q Both.

A Well, I probably have an office visit three or four times a year for myself, and in the last ten years to go visit and just talk to my former pediatric colleagues probably four, maybe five. Less than once a year.

Q You mean four or five when you add the

meeting to meet -- see your colleagues, two of the visits you have for yourself, your checkup? Let me strike that. So you would go down about four times a year for a checkup yourself; correct?

A To various different doctors, yes.

Q Okay. And then separate from that, you would go down approximately four or five times a year just to -- as a former colleague to visit with your former pediatric partners and colleagues?

A That would certainly be approximately correct.

Q Okay. So about ten times a year you'd visit The Jackson Clinic over the last ten years every year?

A Well, there's times when I would see a doctor for myself and then visit with the pediatricians on that one occasion, so they were not necessarily separate.

Q Were these routine visits that you would be going down for when you'd go four times a year?

A For the most part. I've been lucky enough to be fairly healthy. But, for example, I've had some kidney stones so I go see the urologist. I get my eyes checked every year so I see the

ophthalmologist. My general healthcare is taken care of by one of the internal medicine doctors, and I have one or two visits a year there. I had surgery recently, so I had to get approval by the cardiology department, so I had a cardiology visit for myself. They're located in a different campus than Dr. Hays is, so --

Q Now --

A -- I would not have visited on that occasion.

Q And how many pediatricians are in The Jackson Clinic's pediatric practice, on average during -- you know, over the last ten years?

A Seven or eight.

Q Seven or eight? And when you went down there to go and, you know, pay a social visit to the -- to the doctors in the pediatrician division, I -- would you talk to, you know, whoever happened to be there just collegially?

A Yes, because I don't want to interrupt their work for the day.

Q Absolutely. And so over the years, you've had, I assume, a number of conversations with -- with Dr. Hays during those visits?

A Not very many.

Q Okay.
A Not -- that's not what I would usually see.
Q Okay.
A Other than to say hi as I passed by in the hall.
Q Are there more doctors that you're more friendly with in the pediatric department?
A That's -- that would be correct.
Q Who is that?
A Dr. Woods and Dr. Owens and Dr. Pedigo, although she's no longer there.
Q Now, going back beyond 2010, so -- you know what, let's come back to that. You worked at The Jackson Clinic; correct?
A That is correct.
Q Okay. From when to when did you work at The Jackson Clinic?
A I was in the pediatric department, it -- I mean the pediatric group in Jackson between 1980 and 1982, and 1982 we had discussions with The Jackson Clinic administration and we decided to merge, and so in 1982 would be my start date with The Jackson Clinic.
Q What was your position when you started?

A General pediatrician.
Q And how long did you hold that position at The Jackson Clinic?
A Until the end of 2013.
Q Okay. Were you a partner in The Jackson Clinic?
A Yes.
Q And in terms of how the clinic was structured, what did being a partner mean in terms of ownership?
A In terms of ownership, you owned stock in the professional association, and then in addition, and this has changed, it's not that way now, but in addition, you had the opportunity to buy into the limited partnership that owned the property.
Q Okay. And did you own shares in the general partnership?
A Pardon?
Q Did you own shares in the general partnership?
A Yes.
Q Okay. And did you own shares in the limited partnership?
A Yes.

Q Okay. Until -- do you still own those shares in the general and limited partnership?
A No.
Q Okay. Do you still own shares in either the general or limited partnership?
A No, neither.
Q Okay. And when did you stop owning those shares?
A It was approximately 2011.
Q Okay. And in 2011 you stopped owning both the general and the limited shares that you had in The Jackson Clinic?
A Yes.
Q Okay. And what changed in 2011 such that you no longer -- that you no longer owned shares in -- the general or limited shares in The Jackson -- for The Jackson Clinic?
A The Jackson Clinic required the physicians that were owners in those two things to produce enough income so that they continued to qualify that -- for that. However, I was planning to retire in a few years and intentionally reduced my workload, and I hit the criteria for having to sell, so that's what happened.

Q And -- and who bought your shares?
A The Jackson Clinic.
Q Okay. From the period of 1980 to 2013, was the remuneration that you received from The Jackson Clinic -- Jackson Clinic the primary source of your income?
A Yes.
Q During -- between 1980 and 2013, was the remuneration that you received from The Jackson Clinic your only source of income?
A Well, going back one second, 1980 I was with the Jackson Pediatrician Clinic.
Q Yeah, but --
A And it was 1982 that we merged with The Jackson Clinic.
Q But other than -- let me rephrase the question.
A But I have -- would have bank accounts that would generate interest, other investments that might give dividends, but other than -- other than that, no, it was The Jackson Clinic.
Q And since leaving The Jackson Clinic in 2013 in your role as a general pediatrician, have you received any form of remuneration or compensation

or any type of financial benefit since 2013 from The Jackson Clinic?

A Only one. There is a committee that I am on at The Jackson Clinic, and I'm on it not as a physician, but as a Medicare patient. It's a Medicare accountable care organization and they have to have a Medicare patient on that committee, and I'm that one, and they do give me a small check for attending four meetings a year. And other than that, I have no association with The Jackson Clinic at all.

Q And how long have you held that position -- let me strike -- back up. What's the name of that committee at The Jackson Clinic that you've been sitting on --

A I believe it is called Jackson Integrated Medical Society.

Q And it's part of The Jackson Clinic; correct?

A That's correct.

Q Okay. And for how long have you sat on that committee?

A I believe I started in 2014.

Q And have you continuously been on that committee since 2014?

A Yes, I have.
Q Do you currently sit on that committee?
A Yes.
Q You said it was called the Jackson Integrated -- what was the full name?
A I hope I'm correct on this, but I believe it's the Jackson Integrated Medical Society, JIMS.
Q Got it. All right. So from 2014 until the present, you've been a member of the Jackson Integrated Medical Society, which is part of The Jackson Clinic; correct?
A I'm on -- I sit on that committee, yes.
Q Okay. And how much remuneration do you receive a year for sitting on that committee?
A $1,200.
Q Okay. And you're currently still on that committee; correct?
A Yes, I am.
Q Okay. Other than the -- the amount paid to you for being a member of that committee, is there any other benefit that you receive from The Jackson Clinic since 2013?
A None.
Q Okay. Any pension?

A I don't -- I do not receive a pension. We had a profit sharing plan.

MR. SANDERS: Hang on one second, if I could. I've been kicked off for the last ten minutes or so.

MR. SIRI: Oh.

MR. SANDERS: Have y'all kept -- have y'all been going?

THE WITNESS: Yes.

MR. SIRI: Yeah, yeah.

MR. SANDERS: Randy, could you not tell that I got kicked off?

THE VIDEOGRAPHER: No, I did not.

MR. SANDERS: Is there any way to tell that in the future if it happens again?

THE VIDEOGRAPHER: Yeah, I'll put a flag on your account.

MR. SANDERS: All right. If I do get kicked off, can --

THE VIDEOGRAPHER: Yeah, I --

MR. SANDERS: -- can you -- can you let everybody know so they don't keep going?

THE VIDEOGRAPHER: Okay.

MR. SIRI: And then, of course, if we

know you get kicked off, we'll, of course, Mr. Sanders, stop in the future.

MR. SANDERS: Thank you.

MR. RILEY: And, Craig, might I suggest that if something like that happens again and you're aware of it, just send me a -- send me a text or --

MR. SIRI: Yeah.

MR. RILEY: -- I have my phone near me so I can -- call me or text me.

MR. SANDERS: Okay.

THE VIDEOGRAPHER: I show you in twice, so -- and in the waiting room, so if we lose you again, I'll alert everyone as well.

MR. SANDERS: All right. Thank you.

THE VIDEOGRAPHER: You bet.

MR. SIRI: Okay.

MR. SANDERS: Hey, Aaron, do you mind if the court reporter reads to me what happened since I've been out before we --

MR. SIRI: Yeah, I -- I was just -- yeah, I wasn't going to do -- I was actually going to summarize for you. I don't think -- that's fine. And I can just tell you that, I mean, we've

just been going over Dr. Stepp's history with The Jackson Clinic. That's -- that's been -- we're still there.

MR. SANDERS: Okay. Samantha, can you read for me -- the last that I heard was when Dr. Stepp was talking about that he was a patient of The Jackson Clinic and will visit his colleagues every so often, you know, if he goes up there. How far back is that, Samantha?

THE COURT REPORTER: It's going to take me just a second to find it.

MR. SANDERS: Sure.

THE COURT REPORTER: Do you want to go off the record or do you want me to just --

MR. SANDERS: Yeah, that's the --

THE VIDEOGRAPHER: Okay. We are off the record at 10:18.

(Whereupon, a portion of the record was read back by the court reporter.)

THE VIDEOGRAPHER: We are now back on the record at 10:27.

MR. SIRI: So we just took a quick break so that the questions and answers -- the questions

that I asked and the answers that Dr. Stepp provided while Mr. Sanders was unable to access Zoom were just read back to him by the court reporter and -- and with that, Mr. Sanders, are we ready to continue?

MR. SANDERS: Yes. Thank you for letting me hear that.

MR. SIRI: No problem, of course.

Q (By Mr. Siri) Okay. So Dr. Stepp, now, you said that in 2011, you had to sell your ownership in The Jackson Clinic because you were not producing enough income to meet the requirement for making a partner; correct?

A That is correct.

Q Okay. And what is it that you were doing less of -- strike that. How is the income requirement determined?

A Work is measured by RVUs, and there's a median RVU for pediatricians across the nation, and The Jackson Clinic board of directors decided that you needed to be at or above that median in order to get full reimbursement, and when my workload was reduced, my RVU generation was reduced, and I fell below their lower limit.

Q And what does -- what does RVU stand for?
A I should know this. Relative value units.
Q And how are RVUs calculated, meaning what generates RVUs?
A They're -- for each activity that a doctor may participate in, there is a set number of RVUs assigned to that procedure or activity. For example, for a surgeon that does an appendectomy, there may be a certain number of RVUs assigned to that procedure, and once he does an appendectomy, he gets credit for that number of RVUs. For an office visit, there's a number of RVUs assigned, and this is a national number, not a Jackson Clinic number, and so the clinic keeps track of how many circumcisions I did, how many office visits I did, or anything else I may have done, and they add them up and that's your RVU total for the year.
Q What percentage of the office visits that you had by your patients approximately would you say over the years were well-child visits?
A It's -- it's hard to say. 20 percent maybe. Could be slightly larger.
Q Okay. You're uncertain?

A I'm uncertain. I've never given that a thought before.
Q Okay. And what would the -- and what would the visits that weren't well-child visits typically be for?
A Sick-child visits.
Q Okay. So, for example, how many well-child visits would there typically be in the first year of life?
A Six, I believe, if I'm counting correctly.
Q Okay. And in the second year of life?
A Two.
Q And then in the years after that?
A Once per year.
Q Okay. And how often would a typical child come in for a sick office visit?
A Of course, that's extremely age dependent. The older children aren't sick near as much, particularly after they've entered the first grade. They don't have near so many illnesses. It depends on whether they're in daycare or not, if they're a smaller child or a toddler or an infant. Obviously it depends on the time of the year. We have a lot more sick visits in the

winter than the summer. Summer tends to be more injury-related visits. I guess those are still sick visits, so they're not infections, like, flu, colds, ear infections, strep throat as much in the summer. It depends on how old they are, and it's really hard to say. Some of them are healthier than others.

Q Okay. Do you think that there were more than three times as many sick-child visits than well-child visits on average per child in your practice?

A Probably.

Q Okay. And administering vaccines, I presume -- or ordering vaccines, I assume, would generate RVUs; correct?

A The vaccine itself does not. I think the act of giving a shot may give a little bit, but it was pretty minimal. I don't remember the RVU, but we didn't get credit for the actual vaccine in the vial.

Q But you would get paid for the administration of each vaccine?

A I'm sure The Jackson Clinic would because there's an administrative fee, but I just do not

remember whether the physician got that credit or it just went to the clinic in general.
Q Was there an RVU for a sick-child visit?
A Yes.
Q And was there an RVU for a well-child visit?
A Yes.
Q Okay. And was that RVU increased -- was there more RVU if the child also was administered vaccines during the well-child visit?
A It -- that did not change the RVU for the -- for a well-child visit, whether they got vaccines or not. The RVU would be the same.
Q Meaning the RVU for the well-child visit itself would be the same?
A Yes.
Q All right. But they're separately -- if the -- if there were vaccines administered, there would be a -- another RVU for the administration of vaccines; correct?
A That's correct. I just do not remember whether that RVU was credited to the physician or to the clinic as a whole.
Q Okay. So the RVU that was for the well-child visit itself, would that be credited to the clinic

or to the doctor?
A That's to the doctor.
Q Okay. And if there was a visit for a sick child, would that be credited to the doctor or to the clinic?
A That is to the doctor.
Q Okay. So and why would you suspect that the RVU for the administration of a vaccine might be credited to the clinic and not the doctor?
A Because the -- there was no activity that the doctor participated in that he should deserve to get that. And again, I do not remember whether that went to the doctor or the clinic.
Q You just don't know?
A I just don't know. I probably knew at one time.
Q Okay. Does the doctor, the one who orders the vaccines to be administered?
A Yes.
Q All right. And it's the doctor who would discuss the risks and benefits of vaccination with the parents; correct?
A That is correct.
Q During a well-child visit, the nurse, for

example, would typically weigh the baby; correct?
A Correct.
Q Okay. And so part of the well-child visit would be performed by a nurse or some other assistant in the office; right?
A That's correct.
Q Okay. But the full credit for the well-child visit would go to the doctor for the -- strike that. The full credit for the RVU for the well-child visit would go to the doctor; correct?
A That is correct.
Q Okay. In terms of ordering immunizations, it would be the doctor that ordered it; correct?
A Correct.
Q It would be the doctor that would obtain informed consent from the parent or guardian of the child before vaccines are administered; correct?
A Correct.
Q But it would be a nurse that would actually administer them; correct?
A That is correct.
Q And in your clinic, it would be the nurse that would provide the VIS before administering

the vaccine; correct?
A That's correct.
Q Okay. But the VIS -- but the -- strike that. But you're not sure whether the doctor gets credit for the RVUs from that -- for the ordering of the immunizations; correct?
A For the physical act of the injection, and that's correct, I do not remember who got credit for that.
Q Would the doctor get credit for the act of ordering immunizations?
A There is no RVU for that at all.
Q Okay. RVUs are there related to administering vaccines from, you know, beginning to end, anything and everything involved with administering vaccines in a pediatric -- in your pediatric office, in The Jackson Clinic pediatric office?
A There's a -- there's a charge for the vaccine itself. There's a charge for the act of performing the injection or that is -- and there's an RVU to the doctor for doing what would amount to the history, physical, discussion with the parent, the whole thing that involves a checkup,

and that would be it. You know, there -- there's no RVU for the lab work if there -- any was done.

Q So there would be an RVU for the vaccines itself?

A There's a --

Q I --

A Vaccines themselves are not an activity of work, and so there's a code for that that's used in the billing process, but the vial of vaccine, there's no -- there's no work there. It's a commodity and there's a charge, but there's no RVU.

Q So what -- when you say RVU, does -- does that -- would that be equivalent to an ICD-9 or ICD-10 code?

A No. Those are diagnostic codes.

Q Okay.

A This is a work RVU, a management of physician work.

Q Okay. And this is a standardized -- this is something that's standardized across the country in pediatric offices?

A All offices.

Q All offices?

A Yeah, surgeons, everybody.
Q Is there a -- you know, if you wanted to look up what the RVU was for a procedure, where would you have done that?
A I would -- I would probably have to ask somebody in the billing department at The Jackson Clinic. There's some we knew just because you do them all the time and you knew what it was, and I know there's got to be some reference somewhere, probably on the Internet, where you could look it up. The work RVU component for the physician is part of a bigger RVU because -- and I'm really trying to remember something I hadn't thought of in years, there's a total RVU and it's made up of the work RVU and two others that I'm having trouble to remembering, but those -- the only work RVU goes to the doctor. The other ones may go to the clinic, or if it's hospital related go to the hospital, but it's just a national system for everybody, neurosurgeons, pediatricians, dermatologists, et cetera, to use that RVU system. And there's a regional factor that -- factored in on some of that so that -- New York may have a different coefficient for part of it than

Tennessee or California or wherever.
Q Is there any synonyms to the term RVU that you're familiar with?
A Synonym? Not that I can think of.
Q Was the RVU for a sick-child visit more or less than the RVU for a well-child visit?
A Sick visits are divided into five categories, so level 1, level 2, level 3, level 4, level 5. A level 5 visit would be a very extensive visit, and that would get the maximum RVU. A level 1 visit would be basically a nurse visit, and it had a minimal RVU associated with it, and so level 2 had more than level 1, level 3 had more than level 2, and so forth. So if you had to come in and get your blood pressure taken and recorded and the nurse saw you and you did not see the doctor at all, that might be a level 1 visit. If it was something just horrendous and you spent hours and -- you know, dealing with whatever the problem was, that might be a level 5 visit, so they were not all the same.
Q Were there different levels for well-child visits?
A No, there was different age group-related,

but other than -- for a given age group, it was all the same.
Q And so the RVU that was provided for a well-child visit, would that be more or less than a level 3 RVU for a sick-child visit?
A They likely were slightly different, but they were probably close. I'm going to -- I hate to guess because I don't remember this, but probably it was just a little more than a level 3.
Q The well-child visit would be a little more than a level 3 sick-child visit?
A I believe that's correct. I --
Q Were most sick-child visits level 1 or level 2?
A No. Most of them were 2, 3, or 4. Again, the level 1, you wouldn't even need to see the doctor.
Q Uh-huh. So in 2011, your RVUs fell below the threshold that was the national average for pediatricians, and for that reason, you had to sell your shares in The Jackson Clinic back to The Jackson Clinic?
A That's correct, and that put me on a different pay formula.

Q And what specifically caused the reduction in your RVUs?
A I -- I did it on purpose.
Q Right.
A It was my decision. I didn't want to work as much. I knew what the consequences were going to be in terms of pay, and I just chose to do it.
Q Did you work less hours?
A Yes.
Q Okay. But during the hours you did work, were you seeing -- you know, were you working in the same manner as you had done prior to 2011?
A Yes.
Q So in 2011, was it that -- can you describe how your hours were reduced? Was it that you, you know, didn't work certain days anymore, did you still work five days and you --
A No, I --
Q Please.
A I took an extra day off and I quit working weekends.
Q So in 2011, you started working four days a week and no weekends; correct?
A Three days a week and no weekends.

Q Okay.
A The weekends went away in 2010.
Q When did the policy regarding minimal RVUs to remain in the partnership come into effect?
A I'm going to have to take a guess, but probably 2008 or '09. It had been a discussion with the board of directors for some time, and actually I was on the board of directors at that time --
Q Uh-huh.
A -- so a year or two before it happened for me.
Q What prompted that change in policy?
A It was a financial decision by The Jackson Clinic board at the recommendation of the administrator. They didn't feel like they could afford to pay that much and they weren't wanting to encourage more work, so part of it was financial, part of it was to incentivize the doctors to work hard.
Q And so prior to that change in policy, what incentives were provided to get pediatricians to work -- to increase their RVUs?
A Well, the more you work, the more you get

paid.
Q Okay.
A Simple as that.
Q So prior to 2000 -- to the policy change in 2008, '09 -- strike that. So prior to the policy change regarding minimal RVUs to remain a partner, the compensation was -- for each pediatrician was determined by their total RVUs for the year?
A Correct.
Q Okay. So a pediatrician in The Jackson Clinic in the period 1999 to 2002 that had higher RVUs for the year would make more money than if -- than a pediatrician that had lower RVUs. Is that correct?
A That's correct, and that would be correct for all the physicians in The Jackson Clinic.
Q Okay. Did that policy change when the minimal amount of RVUs for being a partner policy was adopted?
A I -- I didn't understand.
Q Yeah, let -- let me strike it. The -- so has it always been the case that compensation for doctors in The Jackson Clinic would change based on the total amount of RVUs produced by that

individual doctor for the year?
A That's basically true. The pay formula that the clinic used, which was applicable to all the physicians, would change every couple years. So the -- in my time there, it changed multiple times, so when we started in 1982, we were on a totally different pay formula than when I finished in 2013.
Q Okay. If a child came in -- if a child -- strike that. So if a child was being seen by the office for a well-child visit, there would be an RVU code for the well-child visit; correct?
A That is correct.
Q And if the child also during the well-child visit ended up being also diagnosed with having some kind of sickness and was, let's say, prescribed antibiotics, in addition to an RVU for the well-child visit, there would also be an RVU code that would be charged for a sick-child visit as well; correct?
A That would be at the discretion of the physician, but there was a provision that allowed you to do that.
Q Okay. And that -- has the ability to do

that -- has -- that's always existed at The Jackson Clinic for the entire duration that you were a pediatrician there?

A When I started with The Jackson Clinic in 1982, the concept of RVUs had not taken place, so not then.

Q Okay. So when did it start?

A And I couldn't tell you when we started using that, but since the RVUs came into existence, whenever that was, yes, you could charge the well-child visit and then add a modifier to the code, which would be, like, dash and then a numeral, so that the payee, the insurance company or whoever would know what was going on, and you -- but it didn't happen automatically in the billing department. It was at the discretion of the doctor.

Q And the R -- the total RVU for that visit would increase if there was that additional notation by the doctor that in addition to being a well-child visit there was also treatment for some illness; correct?

A That is correct.

Q Okay. Was the ability to charge an RVU for

the well-child visit and for the portion of the visit relating to the child being sick in existence during the period of 1991 to 2002?

A 1991 to 2002?

Q 1999.

A 1999? I do not remember.

Q What is your memory of when RVUs were first introduced into The Jackson Clinic?

A We started using them when the rest of the country started, and I really would have to completely speculate to come up with an answer. I --

Q Okay.

A I just don't know.

Q But from the very beginning when RVUs first became available in The Jackson Clinic, through your -- is it your memory that you could charge an additional fee if a child came in for a well-child visit and was also treated for an illness?

A Correct.

Q Okay. That would include, for example, prescribing penicillin; correct?

A It would be for the evaluation and work done to make the diagnosis, which then would lead to

the prescription, but there's no RVU for writing a prescription.

Q Was there any additional revenue at all that would come to the clinic, either the clinic or the doctor if a doctor did or -- if a doctor wrote a prescription for an antibiotic?

A Well, presume -- well, presumably you've done something to make you want to do that, which is typically the child comes in, is examined, a decision is made, and you write the prescription. There might be an instance where you knew the patient and there was a phone call and you -- and you felt comfortable writing that prescription based on the phone call, in which case there is no RVU at all. We didn't charge for phone calls.

Q But if the child was brought into the office, there would be a charge for seeing the child before writing a prescription to evaluate the child to determine whether there should be a prescription written; correct?

A Correct.

Q All right. Has Dr. Hays ever been at your home?

A Our department has a Christmas party every

year. One year it was held at my home and I have no recollection whether he attended that year or not, but if that was it, that would be the only time.

Q Are there any social functions that you attended that Dr. Hays attended outside of the office?

A The yearly Christmas party for the pediatric department and that's it.

Q Okay. Have you ever met with Dr. Hays outside of the office other than potentially at the yearly Christmas party?

A I can think of no time where I met with him outside the office other than a Christmas party.

Q Okay. Is your wife friendly with Dr. Hays' wife?

A It depends on what you mean by friendly. If we're there together, they know each other's name and will say hi, but other than that, they never see each other.

Q Do they ever speak --

A No.

Q -- on --

A I'm sorry. I apologize.

Q No, no problem. Are -- are any of your children friends with any of Dr. Hays' children?
A No.
Q I assume nothing personal is meant by that. Strike --
A Pardon me?
Q Strike the question. It was my bad attempt at levity. Okay. How were the nurses trained in pediatrics at The Jackson Clinic?
A Of course, they've had some education before they're being hired because they're usually either medical assistants or LPNs, and so they've gone to school. And once they're at The Jackson Clinic, the -- specifically the pediatric department, they're trained by the pediatric nursing supervisor and to some extent by the other nurses that have been there a while and have experience.
Q Okay. Can you please explain the difference between a -- you know, a medical assistant, an LPN, or a nurse?
A I think that we use the term nurse in the office as sort of a generic term to mean the people that help the doctors, see patients, bringing them in, weighing them, giving them

shots, et cetera. Probably people that are registered nurses are -- may not really approve of that way to use the word nurse, but for our purposes, it's the physician's primary assistant in the office, usually an LPN or a medical assistant. Anything -- the education level of the LPN is greater than the medical assistant, so we don't have too many of them helping us, and we do not have RNs in the pediatric department, RNs being registered nurse.

Q What does LPN stand for?

A Licensed practical nurse. And I think there's several levels, like a level 1 and a level 2.

Q A pediatric nurse supervisor, would that ever be a medical assistant?

A Could be. I believe ours has an EMT degree.

Q Who was the pediatric nurse supervisor during the period 2000 to 2001?

A Patricia French.

Q And during the period of 2000 to 2001, were there any LPNs in the -- in the pediatric practice at Jackson Clinic?

A Yes.

Q And who were they?
A Becky Austin is the only one I know of.
Q Okay. And were there -- during the period of 2000 to 2001, were there any medical assistants in The Jackson Clinic, the pediatric clinic?
A All the -- all the other nurses, I believe, were MAs, medical assistants.
Q And how many were there approximately in pediatric practice?
A Well, it would be the same number as there are doctors, and the number of doctors, of course, varies as people come and go.
Q Each doctor had either one MA or one LPN assigned to them?
A In the pediatric department, yes.
Q Okay. And the pedi -- and the pediatric nurse supervisor who you just mentioned before, was she an MA or an LPN?
A I believe she's an EMT.
Q Oh, okay. That's who you were referring to. What was her name again?
A Patricia French.
Q So were the -- were the MAs and the LPNs trained in the same way when they arrived to --

when they started to work at the -- in the pediatric division of Jackson Clinic?

A Yes.

Q Okay. What type of training did they receive?

A Since I did not participate, I just have to assume some of this, but they needed to know how to get patients from the waiting room, they needed to know how to take vital signs, which would include weight, height, head circumference, and they needed to know the other vital signs if that was also requested by the physician. They needed to know how to administer vaccinations or other shots because occasionally you might need to give an antibiotic injection. They're not trained to draw blood, although a few of them do that, have to do that, because we had a laboratory that did the venipunctures and whatnot. They were certainly trained to give out the VIS sheets. They were trained to give out the other handouts. And since I didn't participate in their training, that's it as far as I can think of right now.

Q But you believe that they were trained to provide VISs to a parent or guardian prior to

providing immunizations because that would have been the standard of care; correct?
A That is correct.
Q And that would have been the standard of care applicable in 2000, 2001; correct?
A That is correct.
Q Okay. And -- and it would -- and you would give a VIS for each particular vaccine to the parent or guardian?
A Yes, yes.
Q And you would do so, of course, even if you gave the same vaccine multiple times, you would give it before each office -- each -- before each administration of even the same vaccine; correct?
A That's correct. They received it each and every time.
Q Okay. Who provided the training that you -- who provided the MAs and the LPNs the training that you just described?
A That would primarily be the responsibility of Patricia French, the nursing supervisor.
Q Okay. Were there any written materials provided to the LPNs or the nurses in the -- excuse me, the MAs or LPNs as part of their

training?
A I believe they were given written materials on how to give shots. I'm not sure about anything else.
Q Okay. Would those materials have been prepared by the CDC?
A I don't know.
Q Okay. What was the length of time that the -- that the MAs or LPNs would have received training -- and LPNs would have received training before becoming assistants to a pediatrician?
A I don't know.
Q Okay. Were you involved in training any of the LPNs or MAs?
A No.
Q Okay. And just -- I think we talked about this already, but to confirm, do the LPNs have any different responsibilities than the MAs in the pediatrician division at Jackson Clinic?
A No. Same responsibility.
Q Did Dr. Hays have a -- an assistant assigned to him in 2000 and 2001?
A Yes.
Q Okay. Who was that?

A My understanding, it was LuAnn Upchurch at the time.
Q Okay. Are you familiar with LuAnn Upchurch?
A Yes.
Q Okay. How so?
A Well, they just worked the next hall over and she was there, so I knew who worked for everybody.
Q Did she ever work for you?
A No.
Q Okay.
A Well, I'd -- it's conceivable that on a weekend on call, you would not necessarily work with your own nurse, you would -- there was a schedule for them to take the weekends, just like it was for us, and so I can't tell you that she never helped me on an odd time like that, but during the course of Monday through Friday, no.
Q Okay. Do you have any -- do you have any specific recollection of LuAnn Upchurch working for you directly during --
A No. No.
Q Did you interview her before she was hired?
A No.
Q What is your understanding of what experience

she had in working with pediatrics before starting to work as a medical assistant to Dr. Hays?
A I don't know.
Q Okay. Do you know anything about how she was trained?
A Only in terms of what we've discussed earlier. She had to go through the same thing everybody else did, but other than that, I don't know.
Q Did you have any role in training LuAnn Upchurch?
A No.
Q Do you know who was responsible for training LuAnn Upchurch?
A Patricia French.
Q Did Jackson Clinic have a written policy about providing informed consent to the parents of a child when vaccinating a child?
A Not that I know of.
Q Okay. Did Jackson Clinic have a written policy about providing VISs to parents?
A Not that I know of.
Q Approximately how many pediatricians were working for The Jackson Clinic in 2001?

A I would think eight or nine.
Q Okay. And what specific training did The Jackson Clinic provide to new pediatricians that joined the pediatric practice, The Jackson Clinic?
A If we had a -- if we hired a new pediatrician, they really wouldn't have any additional training. I mean, they need to learn where things are and what the service sheet looked like and just simple logistics like that, but as far as academic pediatrician training, nothing. They were already trained.
Q When you say where things are, you mean, like, physically in the cabinets of the office?
A Yes. Like, where is the bathroom, where's the lab, et cetera.
Q Okay. And the sheet that you mentioned, what was that again?
A It's a service sheet.
Q And what's that?
A Every patient that comes in would have a service sheet. It's a sheet that has on it the variety of office visits that might occur, well check, level 1, 2, 3, 4, 5s. It will -- it will

have a sampling of typical diagnoses, and of course that's going to be specialty dependent, so the surgeons would have one set of diagnoses there, so it would be easy to come up with the ICD-9 code. And for practical purposes, we used it to order things on, so if I was going to give a flu shot, then I'd check flu shot and make it available to the nurse. She knows to give a flu shot. If I check hemoglobin, they know they need to get the lab to come and draw blood. So we use it for that, and then once we're finished with it, it goes to the billing department where they can see that we did this, that, and the other, and add up to make the charges.

Q Okay. So that sheet once filled out would be used to then -- for the billing department to determine what ICD-9 codes to charge; correct?

A Of course, the ICD-9 codes are the diagnosis codes.

Q Right.

A So, for example, there's a code for various types of pneumonia and you're not making the charge off that. You're making the charge off the type of office visit, well check, level 3,

et cetera.
Q Okay. But you'd use the sheet to determine what ICD-9 codes to charge; correct?
A My understanding is that the payors needed a diagnosis code in order to make the payment to the clinic or to any doctor.
Q Okay.
A And so if you charged a level 3 office visit, they'd at least want to see what you diagnosed that day, so if you charged a level 5 and the diagnosis was one pimple, they probably would object, as you can imagine.
Q Uh-huh.
A So you had to have the ICD-9 code, but that wasn't the charge.
Q So -- right. And then in terms of -- would the sheet be used to determine the BVUs for that office visit?
A The RVUs?
Q RVUs, thank you.
A Yes, yes.
Q Okay.
A Because you're going to circle or check or however you're going to make the determination,

circle a level 3 visit, for example, and when they see that, the RVU is a standard number no matter who you are, surgeon, EMT, dermatology, et cetera.

Q Were you involved in the decision to hire Dr. Carlton Hays?

A Yes.

Q Okay. Did you interview Dr. Hays before he was hired?

A Yes. We all did.

Q Okay. Tell me about the interview that you had with him.

A This is a long time ago, so I don't remember any detail. But what we would typically do is he would come to the office, he would meet everybody, we would show him around. Each of us would sit down and talk to him, and this is the same for Dr. Hays or any other doctor. Most of the time these people have come from out of town, so they're going to stay at a hotel. We would have dinner with them at night in a restaurant or somebody's home, perhaps, and then the next day they would probably come talk to us again and then that would be the interview.

Q Approximately how many people did Dr. Hays

interview with in this process of being hired at The Jackson Clinic?

A Outside the pediatric department, I would at least theorize that he talked to the clinic administrator, he probably talked to our medical directors, we have two. He may or may not talk to anybody else. Now, of course, Dr. Hays does pediatrics and internal medicine, so I'm sure he talked to the internal medicine doctors as well.

Q Okay. So how many people would you say that is approximately total that Dr. Hays would have interviewed with prior to being hired by The Jackson Clinic?

A I'd -- I would -- I'd guess at least 15.

Q Okay. Did anybody raise any concerns regarding Dr. Hays before he was hired?

A No.

Q If there were any concerns raised by any of the approximately 15 doctors at The Jackson Clinic that had interviewed him prior to him being hired, would you have been aware of those concerns?

A I think it highly likely that I would be, because chances are, if there's much concern, he wouldn't have gotten hired.

Q Uh-huh. You're familiar with the standard of care for a pediatrician or a medical doctor in administering childhood vaccines in Jackson, Madison County, Tennessee in the period 1999 to 2002; correct?
A That is correct.
Q Okay. And during the rest of this deposition, whenever I say -- use the term standard of care or ask any questions relating to that standard, I will be referring to the standard of care applicable in Jackson, Madison County, Tennessee in the period 1999 to 2002; okay?
A That is okay.
Q Okay. Any questions about that?
A No.
Q Okay. And when I use the term parent as used in this deposition, I'll also -- it will also mean guardian; okay?
A Okay.
Q Okay. Any questions about that?
A No.
Q Okay. Now, the standard of care is that before having a vaccine administered to a baby or toddler, the doctor should evaluate whether there

are any contraindications or precautions to administering the vaccines; correct?
A Correct.
Q Okay. And how do you determine whether the baby or toddler has a contraindication or precaution to a vaccine?
A You talk to the parents, you examine the child, basically the history and physical, if you will, and those things should come out --
Q Uh-huh. So the --
A -- and be aware of them.
Q So in determining whether or not there's a contraindication or precaution, the standard of care is prior to administering the vaccine to elicit information from the parents that would permit the pediatrician to be able to make that determination of whether there's a contraindication or precaution; correct?
A Correct.
Q Okay. And I assume as part of that, inquiring about any reactions the child might have had to a prior vaccine is part of the standard of care as well; correct?
A Correct.

Q Okay. Now, during the -- during that discussion, did the stand -- the standard of care would also be to convey the benefits and the risks of the vaccine that are going to be administered to the parents' child; correct?
A Correct.
Q Okay. And -- and if after evaluating the information obtained from the parent you determine that there was a precaution or contraindication to vaccinating the child, the standard of care would be to advise the parent that there is a contraindication or precaution potentially to a vaccine to be administered; correct?
A Correct.
Q Okay. Now, when there's a -- when there is a contraindication present, the CDC and AAP guidance is to not vaccinate the child; correct?
A Correct.
Q And -- and when there is a contraindication, the standard of care is to not vaccinate the child; correct?
A If there is a contraindication, the standard would be not to vaccinate.
Q Okay. And if there was a condition, which

was a precaution to vaccination, right, which were present, the standard of care is to conduct a careful assessment of the individual child before determining whether the benefits of the vaccine outweigh the risks; correct?

A Correct.

Q Okay. And the case of an ill child, all right, the standard of care is that a parent has the right to know that a risk/benefit analysis is being made before informed consent can be given; correct? Strike that. I -- I made that -- let me ask it in a simpler manner. In the case of an ill child, a parent has the right to know that a risk/benefit analysis is being made before informed consent can be given; correct?

A Seems reasonable.

Q Is that a yes?

A Okay, I'll go with a yes.

Q Okay. In order for the parents to give effective informed consent, the parents have a right to know that some children should not be vaccinated, and specifically that moderately ill children should generally not be vaccinated; correct?

MR. SANDERS: Object to the form of the question. You can answer, Doctor.
A Well, you know, if you have a well child and none of those are applicable, I don't know that you would bring that up to say that a severely ill child shouldn't be vaccinated when their child is not ill and should be vaccinated, so the -- the typical parent that -- where it's appropriate to vaccinate, they don't need to know that maybe you shouldn't give the MMR to somebody with ITP. They don't need to know that.
Q (By Mr. Siri) But if the child is moderately ill, all right --
A Then that subject would come up and that would be discussed.
Q All right. So to give a -- if a child were moderately ill, to give effective informed consent, the doctor would need to discuss -- should discuss with the parents that --
MR. RILEY: Mr. Siri, I'm so sorry to cut you off. I believe we've lost Mr. Sanders.
THE VIDEOGRAPHER: Yes, sure enough, David. He's off again.
MR. SIRI: Oh, okay.

MR. RILEY: I'm sorry. It just looks like it happened about two questions ago --

MR. SIRI: Okay.

MR. RILEY: But we might want to just go off --

THE VIDEOGRAPHER: We'll go off the record then. We are off the record at 11:21.

(Brief recess.)

THE VIDEOGRAPHER: We are now back on the record at 11:35.

MR. SIRI: Just to place it on the record, Mr. Sanders unfortunately was -- had his connection to Zoom lost again for just a few questions. The court reporter, Ms. Cohen, just read those back to Mr. Sanders. Mr. Sanders, are we ready to continue?

MR. SANDERS: Yes, thank you.

Q (By Mr. Siri) Now, Dr. Stepp, sometimes it's a judgment call, correct, with regard to -- strike that. Dr. Stepp, sometimes it's a judgment call regarding whether a child is too ill to receive additional vaccines; correct?

A Correct.

Q Okay. And in the instance where a doctor

needs to exercise their judgment to determine whether or not a child is too ill to receive additional vaccines, the standard of care would be to discuss that decision with the parents prior to vaccinating the child; correct?

A Correct.

Q And we used the term VIS in this deposition. You know what that term stands for?

A The --

Q I -- oh, please.

A Vaccine information --

Q Information.

A -- something.

Q Right. It stands for vaccine information statement; correct?

A Yeah, statement.

Q Statement. You've used the term VIS in your practice over the years?

A Sure.

Q Okay. Is the term vaccine information statement, is VIS, would you consider that synonymous with the term vaccination information material or VIM?

A I would think so, yes.

Q Okay.
A I've never used VIM, but that's okay.
Q Okay. Now, if the parents had any questions regarding the vaccines to be administered to their child, the standard of care is that the pediatrician would answer those questions before the vaccines are administered; correct?
A Correct.
Q Okay. Answering the parents' questions is also required in order to obtain informed consent; correct?
A Correct.
Q Most VISs contain a section which explains that some children should not receive vaccination when moderately ill; correct?
A I believe that's what it says.
Q Okay.
A Or it says it's a precaution.
Q If there was a moderately ill child, how would you determine whether to give a vaccine?
A Really it's a case-by-case issue depending on how -- what the diagnosis is, how moderately ill he is, how the parents feel about it. It might even have to do with where they live in terms of

being able to come back and get the vaccine at a later date. So quite a few variables there to consider.

MR. SIRI: Ms. Cohen, can you read that answer back to me, please?

(Whereupon, the question was read by the court reporter.)

Q (By Mr. Siri) Now -- now, VISs also advise parents to tell their doctors certain information that would be relevant in deciding whether a child should be vaccinated; correct?

A Are you saying that's written on the VIS sheet?

Q Yeah, strike -- strike the question. Now, do you agree that physicians should be familiar with the information in the package insert for vaccines?

A Not necessarily.

Q Okay. Why is that?

A I don't think any of us read those.

Q Okay. Each packet -- each -- each vaccine that's administered to a child, it comes in a little box from the manufacturer; correct?

A That's correct.
Q And in each one of those boxes is a piece of paper; correct?
A Correct.
Q And that piece of paper is referred to as the package insert; correct?
A That's correct.
Q It's written by the manufacturer of the vaccine; correct?
A Correct.
Q It provides information that the manufacturer believes is relevant to the vaccine?
A I'm sure it is.
Q Okay. And why is it you think that information from the manufacturer regarding a vaccine is -- is not important for parent -- for the pediatrician to read?
A I think the same information is available elsewhere in a more relevant fashion for pediatricians or physicians as opposed to what the drug company is deciding.
Q And where is that information contained elsewhere?
A The primary source -- I'm getting an echo in

this thing. I don't know -- in my computer. The primary source that pediatricians use is the American Academy of Pediatrics Red Book.

Q And was that the source that would have been used in 2000 and 2001 at The Jackson Clinic by pediatricians?

A Yes.

Q Okay. Is there any other source that pediatricians in The Jackson Clinic would have referred to in 2000 to 2001 in -- in dispensing their pediatric care?

A If they chose to, the Center for Disease Control provides that information.

Q Okay. When you say the Center -- the CDC provides that information, are you referring to the information on -- in the package insert for each vaccine?

A No. I think if we were looking to see what the CDC had to say, we would go to the cdc.gov and look at it on the Internet.

Q Okay. When you were a practicing pediatrician during the period 2000 to 2001, did you go to the CDC website to ever obtain information regarding your -- providing

pediatrician care?
A Yes. Not about vaccines, but other things.
Q Okay. By the year 2000, 2001, since you had already been practicing for, you know, a good number of years, did you already know by heart which vaccines should be administered to children based on the CDC schedule?
A Once again, we looked to the Red Book for all that information, but yes, I pretty well had it memorized.
Q Okay. So you -- you looked to the Red Book to determine which vaccines to administer to babies and toddlers in 2000, 2001 when you practiced at The Jackson Clinic?
A That's correct.
Q Okay. And -- and in terms of contraindications and precautions, did you look to the CDC and the AAP with regards to what contraindications and -- you know -- strike the question. So do you know Dr. Kathryn Edwards?
A No.
Q Have you ever heard that name before?
A Not that I can remember. Is she involved in this case? I don't know her.

Q Okay. Do you know Dr. Rachel Mace?
A No.
Q Have you ever heard her name before?
A Yes.
Q Okay. In what context have you heard it?
A Mr. Sanders spoke of her deposition.
Q And what did he tell you about her deposition?
A That it was long.
Q Well, he would say that, wouldn't he? Okay. And any substance of the deposition itself, are you aware of anything that transpired during that deposition?
A Only generalities about questions of standard of care. I think she already knew who Dr. Hays was from her experience at Vanderbilt since he was trained there, but details, really not.
Q Okay. So and what is it about the standard of care in Dr. Mace's deposition did you learn?
A Nothing.
Q Okay. Is there anything else substantive regarding Dr. Mace's deposition that you're aware of sitting here today?
A No.

Q Okay. Other than hearing Dr. Rachel Mace's name from Mr. Sanders, were you aware in any way about -- did you know -- strike the question. Other than learning about Dr. Mace from Mr. Sanders, did you know who Dr. Mace was in any way prior to being told that name from Mr. Sanders?

A I had never heard of her.

Q Okay. After Mr. Sanders told you about Dr. Rachel Mace, did that jog your memory at all about any knowledge you would have -- have had -- had about with regard to Dr. Mace?

A I'd never heard of her before.

Q Okay. Can you please describe your academic and professional background?

A I went to medical school at the University of Tennessee in Memphis. I did pediatric training at City of Memphis Hospitals and the Le Bonheur Children's Hospitals. That's a three-year residency. Did you want back before medical school?

Q Oh, no, just -- just your relevant medical training, Doctor.

A Okay.

Q Did you --
A Yeah.
Q Yeah. Okay. And can you -- after medical school, where did you go to work?
A I -- well, after medical school, my first work was residency, and that was three years at Le Bonheur in Memphis.
Q Okay. And during your residency, did you have a focus?
A General pediatrics.
Q Okay. And you did that for all three years of your residency?
A Three years, yes.
Q Okay. So after your three years of residency regarding general pediatrics, what did you then do?
A For one year I worked in Memphis at a pediatric group, and then I moved to Jackson, Tennessee, so I finished my residency in '76, so that would have been the summer of '77 I moved to Jackson. My first position in Jackson was with the University of Tennessee faculty. I was in the department of pediatrics and in the department of family medicine. Family medicine department

activities were training the family practice residents there because they have a program here in Jackson, training them in pediatrics, and my responsibility in the pediatric department was to set up a neonatal intensive care unit at the Jackson-Madison County General Hospital.

Q How long did you do that for?

A Until the end of 1979, so two and a half years. After that, I joined the Jackson Pediatric Clinic with three other general pediatricians, and then as we mentioned before, that clinic then merged with The Jackson Clinic in 1982.

Q Okay. What was the name of the clinic that you worked at in Memphis for that one year after your residency?

A Mason, Stepp & Threlkeld Pediatrics.

Q And you practiced as a pediatrician in that -- in that --

A Yes.

Q -- pediatric practice?

A Yes. I was the fourth pediatrician. That practice eventually changed its name to Pediatrics East, which it is now, but that was after I was gone.

Q Okay. So in total, you have well over 34 years of practice as a pediatrician; correct?
A Yeah, and since my residency was exclusively pediatrics except for two months, I felt like I was a pediatrician during that time as well.
Q So would --
A So yes.
Q If we add those three years, we're over 37 years of pediatric practice; correct?
A That's correct.
Q And if we add the two and a half years at the hospital relating to where you -- were you also engaging pediatrics during that period as well?
A Are you talking about when I was on the faculty at the University of Tennessee?
Q Yep.
A Yes. It was in pediatrics, the -- I would certainly consider it -- neonatal work to be pediatrics, newborns, and exclusively I was teaching pediatrics to the residents. Now, I did not have a practice of my own, but it was constantly pediatric issues.
Q Have you consulted or received any money from any pharmaceutical company?

A I'm not sure how to answer that. The answer is no, with the exception that while I was at The Jackson Clinic, I was the head of The Jackson Clinic research department, and so we would undertake clinical studies from drug companies because they had a new drug they wanted to get on the market, and we would follow their protocols, and so that -- I did get reimbursement, but the reimbursement was through the clinic's pay formula, so the pharmacy -- or the -- I mean, the pharmaceutical company would pay the clinic and then the clinic would in turn pay me through the pay form, but it was for doing work for them, not for anything else.

Q Right. And how many of these clinical trials did you participate in where you received remuneration from a pharmaceutical company?

A I -- it's -- obviously I didn't keep count in terms of trying to keep track of the total, but I would say 12 to 15.

Q Okay. And for what duration of time typically for each of these clinical trials provide services for the pharmaceutical company regarding the clinical trial?

A I'm not sure I understand.
Q Yeah, that's because I didn't ask it very clearly. Let me try that again. So for each of these clinical trials where you were working, were -- strike that. For each of these clinical trials where you were providing services remunerated by the pharmaceutical company, how long were the services that you rendered for each clinical trial?
A Well, it would be different for every trial. Some trials went on a long time, some were very brief, some wanted just a few patients, some wanted a large number of patients.
Q Would you say that typically they lasted at least a few months?
A Yes.
Q Okay. Some of them for years?
A Maybe not years.
Q Okay.
A But maybe close to a year.
Q Okay. And your role in a clinical trial would be administering a, I presume, drug or vaccine that was being evaluated for potential licensure?

A That's correct.
Q Okay. In any of these clinic -- were -- did any of these clinical trials involve a yet unlicensed vaccine?
A Yes.
Q Okay. Out of the 12 to 15 clinical trials, how many would you estimate involved an unlicensed vaccine?
A We started to enroll in an influenza vaccine trial, but it never came to fruition. We participated in the Prevnar 13 trial when they were moving from Prevnar 7 to Prevnar 13. I can't think of any other vaccine trials. We wanted to do some but never got them.
Q Understood. So Prevnar 13 was the only clinical trial that you participated in that involved a vaccine; right?
A That's all I remember at this moment.
Q Okay. The rest of them were drugs for pediatric use?
A Correct.
Q And how much compensation did you receive for your participation in each of these clinical trials? Strike -- let me ask that a little more

clearly. How much compensation -- strike -- strike the last question. How much compensation did you receive from the pharmaceutical company conducting the trial for each of these clinical trials?

A Well, I did 12 or 15 of them, and for each and every one of them, I don't remember them in that way. You know, I might have gotten 5 or 10 percent of my total income from those trials, but to say the dollar figure for the Prevnar trial, for example, I -- I just don't know.

Q Okay. Understood. So in -- do you recall approximately from what year to what years while you were working at The Jackson Clinic you were receiving this remuneration for participating in clinical trials?

A Well, again, I was the director of the research department, so there was a small payment just for being the director, even if I did no trials.

Q Okay.

A And another doctor had been the director previously, and I'm thinking it was probably something like 2008 or -- give or take when he

left and I took over.
Q Okay. Did you participate in any of these clinical trials prior to 2008?
A No, because the whole project had not been going on very long, and I -- we didn't have any trials for me prior to that.
Q So after 2008, 5 to 10 percent of your income came from participating in these clinical trials?
A That's a guess, but yes.
Q Okay. And that ended presumably in 2013?
A It dramatically slowed down about 2011 or so. I didn't have many trials after that. It was just a matter of that there weren't very many pediatric trials to do, and we had other trials for other departments, for example, OB-GYN may have one, but there weren't very many pediatric trials available for me to participate in the last couple of years I was there.
Q So for the period 2008 to 2011, approximately, you know, what would be the amount of remuneration you received from pharmaceutical companies each year for participating in these clinical trials?
A There was one --

Q And a range -- please.
A Pardon?
Q I was going to say a range is fine. Please.
A Okay. A range would be from a low of maybe $2,000 in a year up to -- there was one in -- one year that was a lot bigger than the rest of them, but all the other years other than that one big year, it was probably in the range of 2 to $15,000. There was one big study that we had a lot of participation in, and it was about 40 or 50,000.
Q That you received?
A Yes.
Q Okay. Do you remember what -- was that the Prevnar 13 study?
A No.
Q Okay. Was that a -- was that a pediatric medicine?
A Yes.
Q Okay. What was the medicine?
A I'm trying to remember the drug company. I think it was Shire. They wanted to have a Ritalin product that was administered through a patch, that it would be applied to the skin. So it was a

methylphenidate patch for the treatment of attention deficit disorder.

Q Got it. So it would be a patch to administer Ritalin through a patch?

A Through a patch on the skin, yes.

Q Yeah. How many -- how many children from your -- from The Jackson Clinic participated in the Prevnar 13 trial approximately?

A Of course, we -- we would take people that weren't patients of the clinic, so there were a few that way.

Q Uh-huh.

A A good guess is we had 20 to 25.

Q Okay. Now, how -- how many vaccines would you estimate during the course of your career have you ordered to be administered or maybe directly administered into infants, toddlers, or children?

A Of course, I never did it myself. I ordered it and a nurse did it, but it's thousands. I don't know.

Q Okay. Would --

A Tens of thousands.

Q Have you ever injected a vaccine directly into a child?

A No.
Q So over the course of your career, you would estimate that you ordered the injection of tens of thousands of vaccine into children?
A Over almost 40 years, yeah, I would. Yes, I would.
Q And during that period of time of ordering the administration of those pharmaceutical products, I presume you became knowledgeable about those pharmaceutical products; correct?
A Knowledgeable in the clinical sense, yes. Not knowledgeable in the chemistry sense of it.
Q Parents would trust you -- strike that. Okay. You -- have you had -- have you reviewed Yates' vaccination record from the -- from The Jackson Clinic?
A Yes.
Q Okay. I guess I should have first asked, do you know the name of the child at issue in this case?
A Yes, sir. Yates Hazlehurst.
Q Okay. Thank you. And -- okay. Now, when you say you reviewed Yates' vaccination record, does that include reviewing the vaccination record

that had handwritten notations on it?
A Yes.
Q Okay. I'm going to pull it up on the screen so that we can take a look at it together.
MR. SIRI: Okay. Okay. I'm going to mark this as Plaintiff's Exhibit 1.
(Whereupon, Exhibit No. 1 was marked to the testimony of the witness.)
Q (By Mr. Siri) Now, Dr. Stepp, have you seen this record before?
A Yes.
Q Okay. Was it common in Jackson -- do you see that there's a sticker on the top left corner of the vaccine record?
A Yes.
Q Okay. And that -- that was a sticker that was placed over the preprinted form; correct?
A That's correct.
Q Okay. Was it typical in The Jackson Clinic to place the sticker in that location on the vaccine record?
A I think it would be, yes.

Q Is that what your practice was, Dr. Stepp?
A Those stickers came off the service sheet that we've discussed previously, and you just peel them off, and a nurse would apply that to the blank area where the patient's name is and therefore she would not have to handwrite it in there. Plus it's easier to read.
Q Right.
A And so I believe indeed all the nurses did that.
Q So if -- if we took a random sampling of these -- of let's just say 500 of these vaccine forms from the year 2000 at The Jackson Clinic for 500 random children in your -- in your practice at that time, would we find that the sticker was typically placed on the top left corner as it -- as it -- as it was placed on Yates' vaccine record?
A I believe we would.
Q Okay. And, Dr. Stepp, you've already -- please take a look at the column that says vaccine information material publication date.
A I see it, yes.
Q Okay. Did you come here today prepared to

address the information included or not included in that column?

A I did.

Q Okay. And how did -- how were you prepared -- how did -- how were you prepared to address the information in that column?

A That's LuAnn Upchurch's initials, so she's the one that put it there. In the top of each vaccine, so for DPT and Hib, et cetera, she's put given at the top, and it would appear to me that for expediency and to keep her from writing it again, although given is not a big word, she's put some ditto marks, meaning the exact same thing in the -- in the column down from the original given. In the same way where it says Connaught for the IPV, which is a longer word, she's got some ditto marks and then she put C-o-n-n rather than spelling it all the way out, and so I think she just wrote it that way for expediency, and in her mind, I would think, she has documented that the vaccine information materials were given.

Q Did you discuss the content of the column vaccine information material publication date with anybody prior to today's deposition?

A The only possible person would be Mr. Sanders. We discussed the issue of distributing vaccine information sheets prior to administering the vaccine, but no one else.
Q Okay. And I assume you already had a discussion regarding the -- the word given to the right in the -- in the row for administering Prevnar on June 6, 2000?
A Yes. She's put -- she didn't write out given, but for expediency, she just put those little quotation marks or ditto marks.
Q Do you see the row June 6, 2000 for administering Prevnar?
A Yes.
Q That would have been the first Prevnar dose administered to Yates; correct?
A I see a DPT -- oh, I see, yeah, she's written in Prevnar, yes.
Q Yeah. And so in 2000 and 2001 during that time period, you had vaccine information statements available for each vaccine in your office; correct?
A Incorrect. Sometimes the vaccine information sheet hadn't been finalized because it has to go

through quite an ordeal to get finalized by a whole lot of people, and I cannot tell you all of the names, so before we would have the official vaccine information sheets, we would have -- either have and -- what they called an interim vaccine information sheet, something that had been less rigorously approved but still okay, and that would have been the case for the Prevnar. We would have had some type of interim sheet. So although that sheet hadn't had its final approval on that date, we had a more -- rather than a VIS, some more general vaccine information material, either a V -- either an interim VIS or some printed material to give, and Ms. Upchurch probably didn't know the difference between an interim VIS and a real approved VIS, so she put given, she probably didn't know the difference, but we did have material to hand out even though we didn't have the finalized copy.

Q Do you specifically recall having an interim VIS for Prevnar --

A Yes.

Q -- at your office --

A Yes.

Q -- in 2000 --
A Yes, I don't -- I'm sorry. Yes, I remember us doing that, but I don't remember whether it was an interim VIS or some other material.
Q Okay. Do you recall having an interim VIS or some other substitute material for a VIS for any other vaccine prior to the availability of a VIS for that vaccine?
A Not offhand.
Q Okay. Do you recall anything about the -- in either the interim VIS or the alternative material to a VIS for Prevnar that your office, The Jackson Clinic, would have had in 2000?
A In a specific way, no. It's 20 years ago. I just don't remember.
Q If there were a copy of that material, where would it be located?
A It's unlikely that it could be located. It probably doesn't exist anymore. I have no idea where to go to get that.
Q And if that information -- now, the interim VIS or the other material, is -- as -- that would have been created as a substitute to the Prevnar VIS, who would have created the interim VIS or

that substitute material?
A Without knowing specifically, my -- the likelihood is it came from the CDC because it was the CDC that said it was okay to give interim VIS sheets prior to a finalized copy. We did not produce it ourselves.
Q Okay. And then when we take a look over there, we see that on April 7, 2000, there were three vaccines administered; correct?
A Correct.
Q And the word given was put in the vaccine information material publication date column across each one of those rows; correct?
A Correct.
Q Okay. So then on June 6, there were another three vaccines administered; correct?
A Correct.
Q And in that instance, there were the ellipses provided in each of those rows in the vaccine information material publication date column; correct?
A Correct.
Q Okay. Now, on August 16, 2000, the -- there were -- there were three vaccines administered --

four vaccines administered on that date; correct?
A Correct.
Q Now, LuAnn Upchurch provided an ellipses in the row for Prevnar that was administered on that day, in the -- she provided an ellipses, excuse me, in the vaccine information material for the row for the Prevnar administered on August 16, 2000; correct?
A Correct.
Q Okay. Now, a hepatitis B vaccine was also administered on that day; correct?
A Correct.
Q But the box for vaccine information material publication date was left blank; right?
A It is blank.
Q Would that indicate to you that the HepB vaccine -- the VIS for the HepB vaccine was not provided to Yates' parents on that day?
A No.
Q Okay. Why not?
A She gave VIS sheets for other vaccines on that day, and there's no reason for her to pick those and then eliminate the hepatitis B vaccine information sheet, and so I think it's just a

documentation oversight and that she likely gave them.

Q But you can't know for certain; correct?

A Well, I -- I was not there to see her do it.

Q Now, on November 22, 2000, LuAnn Upchurch provided Yates additional vaccines; correct?

A Which date again?

Q November 22, 2000.

A Yes, correct.

Q And on that date, she again -- she filled out another row for a second HepB vaccine she provided to Yates; correct?

A Correct.

Q And she would have filled in the date that vaccine was administered; right?

A November the 22nd, yes.

Q She has left his -- the age that Yates was on that date; right?

A By month.

Q She would -- she wrote out the site that the vaccine was administered?

A Yes.

Q She wrote the vaccine manufacturer's initials?

A Correct.
Q She carefully documented, I presume, the lot number for the vaccine that was administered?
A Correct.
Q Okay. But then she again left the box for whether vaccine information material publication date was provided blank; correct?
A It's blank.
Q It's blank. And so this was the second opportunity for her to fill in that a VIS was provided for the HepB vaccine; correct?
A Correct.
Q And she did not do that; right?
A She did not.
Q Is it possible that she hadn't provided the HepB VIS for some reason and left it blank?
A Can you repeat that, please?
Q Sure. Is it possible that LuAnn Upchurch left that -- the HepB -- strike that. Is it possible that LuAnn Upchurch purposefully did not write given or an ellipses to indicate that she provided a VIS for the HepB vaccine to Yates' parents?
A I doubt she omitted that purposefully.

Q So you believe that on November 22, 2000, she mistakenly forgot potentially to indicate she gave a VIS for HepB to Yates' parents?
A I was not there to watch her. I don't know why she left that blank. So I don't think she purposefully left it blank in the sense that she knowingly did not give the VIS sheet and therefore she could not honestly fill it in. The most likely scenario that I can only guess at is that she just made a documentation error.
Q If we -- if you were to take a look at -- if you were to take a look at a random sampling of a hundred vaccine sheets, such as this one from The Jackson Clinic for the year 2 -- in the year 2000, in the vaccine information material publication date column that was filled out by LuAnn Upchurch, would others also provide given only on the first row for each vaccine and then ellipses for the next row and then blank after that?
A Not knowing -- well, certainly, my presumption would be that you would find a lot of them like that.
Q But you don't know?

A Well, I do not know.
Q Do you think that there's -- strike that. Are you aware that Mr. Hazlehurst went down to The Jackson Clinic and asked Dr. Hays for a copy of this vaccine record?
A Are you referring to the time where he had filed the lawsuit?
Q No. Five days prior to filing in court to obtain a copy of this by compulsion of law, are you aware that Dr. -- that Mr. Hazlehurst was in The Jackson Clinic in a room with Dr. Hays while Dr. Hays was holding a copy of this vaccine record and Mr. Hazlehurst was demanding -- requesting that Dr. Hays make a copy for him of this vaccine record?
A I heard that he was there. I didn't hear the specifics of what he wanted, other than the medical record, so I had heard that that event had occurred, yes.
Q Okay. If a parent asked you for a copy of their child's vaccine record and you had it in your hand, would you make a copy of it for them?
A Yes.
Q Is there any reason why you believe Dr. Hays

wouldn't have made a copy of this record if he was holding it in his hand and Dr. -- and Mr. Hazlehurst was asking for a copy of it?

A I do not know what his thinking was at the time.

Q Okay. Are you --

A So I don't know.

Q Are you aware that in the -- the -- that day, as well as the next few days, Mr. Hazlehurst made a number of requests to get a copy of this vaccine record from Dr. Hays and The Jackson Clinic?

A I don't know the number, but I knew that he had wanted the record, yes.

Q And you're also aware that Mr. Hazlehurst was only finally able to obtain a copy of this record when he got a Court Order requiring The Jackson Clinic to turn it over; correct?

A I do know that he got a Court Order. My understanding, and this is just my understanding, because again, I was not involved, is that The Jackson Clinic could not produce it in the timely manner that he was hoping for. I think they would have produced it because they've always produced it for people that have wanted their

records in the past. No reason to withhold it for him. But my understanding was it was not able to be obtained as quickly as he wanted it.

Q Well, Dr. Hays had a copy in his hand while Mr. Hazlehurst was in the office with him, so why is it that it was not able to be produced during the five-day period that Mr. Hazlehurst was demanding it between first requesting it in the office with Dr. Hays and when Mr. Hazlehurst had to get a Court Order to get a copy of it?

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

A I'm not sure if you're referring to this just one page we're looking at now or the entire medical record, but if -- and I don't know why Dr. Hays would have the page we're looking at now with the immunizations on it in his hand and no other piece of information, so I can't tell you why if that was the case that he had just one piece of documentation of vaccines in his hand and he did not do that. I do not know. However, as far as the entire chart goes, you know, we were converting to an electronic medical record, and so

that would be easy to click -- to print, and print the electronic version off and he could have the copy.

Q (By Mr. Siri) But --

A The prior --

Q Please, I'm sorry.

A The prior record was a -- was a paper record, and we're in the north clinic, and the paper record is kept at the other campus, which is on West Forest Avenue, which is some, I don't know, 4 or 5 miles away.

Q So --

A And you just couldn't get it right away. Not to mention, it's going to have to be Xeroxed.

Q So in 2000 --

A They --

Q Please, I keep -- I apologize I keep cutting you off. Please.

A Well, I guess I pause too much, but I -- I've never heard of The Jackson Clinic not giving those records. But it does take some time. There is some procedure that's required. They're not trying to stall anybody. It just takes some time and the record is not physically where Dr. Hays

was practicing.
Q But in 2002, the records had already been converted into an electronic format; correct?
A Correct. Before that even.
Q And so if a parent wanted the records, it was really just a matter of clicking print to print out the child's records; correct?
A For the electronic component, that's correct.
Q Okay. And then in terms of the non-electronic component, such as this vaccine record, you're saying that it was at a location a few miles away from The Jackson Clinic; correct?
A Yes. The Jackson Clinic had several locations and the paper record was kept at what we would refer to as the main location.
Q All right.
A And the north clinic would be a satellite location. And -- so yes, that's where that would be kept, and you'd have to go there to get it.
Q Did -- okay. So when Mr. Hazlehurst walked in with a court-appointed officer, I think it would be a sheriff, and the Court Order requiring the paper records to be produced, did they have to go to some far off clinic to get it or was it

already in The Jackson Clinic and provided when they came in with that Court Order?

A I -- I don't know the answer to that. My -- the routine is that the paper record is at the main clinic, and we were at the north clinic. And whether they had already brought the paper record to the north clinic or had not, I just do not know the answer to that.

Q You never actually witnessed LuAnn Upchurch fill in the information on this vaccine record that's been marked as Plaintiff's Exhibit 1; correct?

A That's correct.

Q Okay. You don't know when she filled in the column that says vaccine information material publication date; correct?

A I don't know it, no, correct.

Q Meaning it -- it could be that she filled it out on the same day that each of the vaccines listed on this vaccine record were given or it's even possible that she filled it out at some later date; correct?

A I don't know when she filled it out.

Q So it's possible that she filled it out --

okay. Strike that. In 2000, 2001, what would you have prescribed to a child with otitis media?
A There's not one answer for that. It depends on the circumstances. Certainly if the child hadn't had a lot of recent antibiotic and, of course, certainly if they're not allergic to it, Amoxicillin is a first line drug of choice.
Q And how much -- strike that. What dose of Amoxicillin would you have prescribed to a child who had moderate otitis media in 2000, 2001?
A The way all of us think about antibiotic dosages is we think of how many milligrams per kilogram body weight per day we're going to give and how we're going to divide it. So a routine dose of Amoxicillin in 2001 would have been in the range of 80 to 90 milligrams per kilogram per day.
Q Divided how many times?
A For Amoxicillin, twice.
Q Okay.
A So it would be written BID.
Q And presumably for a -- the more mild the otitis media, the less the amount would be prescribed versus the amount prescribed for a severe form of otitis media; correct?

A No.
Q Okay. So even the most mild case of otitis media you would prescribe 80 milligrams per kilogram per day twice a day?
A That is correct, and the reason for that has nothing to do with mild, moderate, or severe. It has to do with the frequency of intermediate resistance to penicillin by pneumococcus, which is one of the more common bacteria to cause ear infection, so to cover that resistance, not the severity, that you choose that dose and then indeed that's recommended in the Red Book.
Q And the Red Book from what year?
A To my knowledge, every time it's been published.
Q So the Red Book --
A I --
Q Please.
A I'm sorry.
Q No, no, please.
A I wouldn't want to say that going back -- I don't know when they started publishing the Red Book. We've had it for a long time, but any reasonably recent version, let's just say from the

mid 1990s onward, because if you -- if there were a Red Book in 1950, the bacterial resistance patterns were entirely different, so the recommendations would've been different, and we didn't even have Amoxicillin in the 1950s, so I don't mean to imply, you know, indefinitely backwards in time, but certainly the recent ones because pneumococcal resistance has been a problem for quite a while.

Q So would the amount of Amoxicillin that's recommended by the AAP in a given year for otitis media be considered the standard of care for what dose of Amoxicillin to provide when a child has otitis media?

A I don't know that I would look at that as a -- as a standard of care issue because resistance patterns vary from place to place, so resistance in Tennessee may not be the same as it is in California, and you have to know of the resistance patterns. But certainly if you know you have frequent pneumococcal resistance, you give the larger dose, and -- and indeed, anywhere from 80 to 100 milligrams. The good thing about Amoxicillin, it is well-tolerated, and if you gave

them 200 milligrams, it wouldn't be a problem. Before roughly the late 1970s, we didn't have Amoxicillin. We had Ampicillin, which was -- didn't taste as good and it was more problematic from side effects, for specifically diarrhea, so we got Amoxicillin, I don't remember the year, but it's probably 1978 or -- or 1979, something like that. And Amoxicillin is the bubblegum medicine. It is much more tolerated and we were giving the lower dose when it first came out of 40 milligrams per kilogram per day, but it didn't take long before we all realized that we were not having the cure rate that was adequate, and the Red Book says give them 8 -- I forget what -- it's like 80 or 90 per kilogram per day, and that became pretty well the standard dose because we figured everybody has got pneum -- penicillin -- intermediate resistance to penicillin to -- by the pneumococcus, which is a common bacterial etiology of otitis media, so that's a routine dose.

Q So the change from 40 milligrams per kilogram per day to 80 milligrams per kilogram per day as the standard happened when the AAP published with regards to recommending that change?

A I'm not -- I'm not sure we changed because they published it. We changed in my mind because we could see that first of all a bigger dose was easily tolerated and the cure rate was insufficient. The presumption is bacterial resistance, and it didn't take a proclamation by the AAP to do that. I think everybody just did it, and I think it was of common practice -- it was certainly the practice at The Jackson Clinic, but I think it's a common practice for pediatricians everywhere.

Q Across the country?

A I -- I can only presume, but it's likely because it's a nationwide problem with resistance, and enough for the AAP to mention that in the Red Book under otitis media.

Q And when did the change happen from 40 milligrams per kilogram per day to 80 milligrams per kilogram per day as the standard treatment for otitis media, if you can --

A I can only hazard a guess. The 1980s probably, give or take five years.

Q And where did you -- from -- from whom did you first learn that you should be changing from

40 milligrams per kilogram per day to 80 milligrams per kilogram per day for treating otitis media?

A Again, that is so long ago that I'm not sure I can tell you --

Q Okay.

A -- and be feeling like I'm giving you an honest answer.

Q Okay.

A Certainly otitis media is one of the more common things we see and that we treat, and the pediatricians that you work with were talking about it all the time.

Q So Amoxicillin was a very common antibiotic in the 1980s; correct?

A Yes.

Q And the '90s?

A And still is, yes.

Q Still is. And otitis media is one of the most -- one of the more or maybe most common infections that pediatricians have to deal with in their practice including Tennessee and the rest of the country; correct?

A Yes.

Q Okay. So presumably given that the dosage appeared to double for one of the most common antibiotics used to treat one of the most common infections in the country for children, that change in practice would have been documented someplace; correct?
A It very likely was in journal articles or in some kind of article or given at conferences, so it seems likely, but do I remember a publication or a written statement, no.
Q But given how common Amoxicillin is and otitis media are, it would be extremely surprising, wouldn't you say, if the standard dosage for Amoxicillin for otitis media changed among pediatricians but wasn't documented someplace in some kind of official publication, journal article, AAP publication, and so forth?
A Yeah, it seems reasonable that somewhere it's written down. I just can't point you to where it is.
Q Okay. What is the current -- well, as of 2013 when you last practiced, what was the standard dose of Amoxicillin for otitis media for children when you were last practicing?

A 80 to 90 milligrams per kilogram per day in two divided doses, and to be honest, then rounded off generally, because if you do the arithmetic, it comes out that you needed to give .89 teaspoons, you're not going to do that. You're going to give them a teaspoon. Or if it's 1.13 that the arithmetic shows that you need to give, you're going to give one teaspoon because the parents are not going to be able to handle those tiny fractions. It's a liquid you can stick -- you pour it in hopefully some container that the pharmacy provides so that the family knows and we tell them that we're not talking about a teaspoon being out of their silverware, you know, with the knives and forks, but rather a pharmacy teaspoon, and so we round the dose off. So when we say 80 to 90 milligrams per kilogram per day, the dose may end up being a variance of that by a small amount because we tend to round it off. I would give it usually in CCs. That way, like, for example, 6 CCs twice a day I think that Yates was prescribed on a visit that I assume you're discussing in February of '01, a teaspoon BID, and I calculated that, and I think that's about

74 milligrams per kilogram per day. The reason they have 400 milligrams in a teaspoon is for convenience. This is a drug frequently given to children that are in the, you know, 10-month to 2-year range, and a teaspoon is just easy for the family. And so, look, if you're a 10-kilo child, you can take a teaspoon twice a day. It's an easy way to do it. They didn't want to put 10 milligrams of Amoxicillin in a teaspoon or a thousand because then you'd get these odd-size dosages.

Q Uh-huh. So if the -- what -- did it -- did you always round down or did they do -- did you ever round up?

A I would round up, sure.

Q So if it was 1.6, you would -- you would provide for 2 or 1?

A 1 and a half.

Q 1 and a half. I see. You would always round to the half -- like --

A To the nearest half.

Q To the nearest half. So if it was 1.9, you would round to --

A 2.

Q 2. Okay. And if it was 1., you know, 74, you would round to 1.5?
A Probably, yeah.
Q Okay. What -- did you have a copy of the Physician's Desk Reference in your office at The Jackson Clinic in 2001?
A Probably.
Q Did you ever refer to the Physician's Desk Reference when treating children when you were a pediatrician at The Jackson Clinic in 2001?
A Hardly ever.
Q Okay. What resources did you refer to?
A Well, there's so many. First of all, the common dosage of antibiotics, you don't need to refer to anything. You know what they are. You do it every day. But that aside, there's certainly the Red Book. There's textbooks of pediatrics, although they have a hard time staying up to date. You can buy textbooks of pediatric drug dosages, so it just -- it's a big thick book with nothing but drugs in it and it tells you the dose, and they're frequently edited and republished so that you can stay up to date. And most of us if we had a question would refer to a

book that is specifically for pediatric drugs. We wouldn't refer to the PDR. There's nothing -- there's no reason to even look in it.

Q And the -- can you recall the name of any textbooks that you used when you were a pediatrician?

A Textbooks?

Q You said that you would refer to textbooks in pediatrics, you know, that would provide --

A Well, I forget the name of it, but I had one that was -- I believe it was simply Pediatric Drug Dosage.

Q Okay.

A They're -- I mean, there's so many.

Q Do you remember the color of the book, Pediatric Drug Dosage?

A I think it was white with yellow and red and green lettering.

Q Do you remember anything else about that book?

A Well, it was exclusively about drugs, so it was a paperback.

Q Okay. Other than the Red Book, the Pediatric Drug Dosage textbook, which you believe is the

title, you remember, were there any other books specifically that you remember that you had in your office in 2001 that you might have referred to in the treatment of children?

A Well, I had a bookcase full, so that's going to be hard to sit here and tell you the name of all of them, but most everybody has got a Nelson's Textbook of Pediatrics. I had a Pediatric Physical Diagnosis Color Atlas, I had a pediatric dermatology textbook, I had a neonatology textbook, we had the Red Book. I --

Q And --

A I had a pediatric neurology textbook. I mean, I --

Q Let me ask you this. Let me ask you this. Okay. It sounds like you have a lot of books, which is great. What -- what other pediatric reference books did you have on your shelves that would have provided information about potential dosing of drugs for children other than the ones you've already listed?

A I had -- and it -- some of these you just rarely looked at. When I was in training, I had a Harriet Lane. Harriet Lane is a small little

textbook that fits in your pocket. Residents have big white coats with great big pockets, so you have a stethoscope in there as well as whatever else, and the Harriet Lane manual is something particularly younger pediatricians, I don't know if they do currently or not, but when I was training, we referred to, and I never got a new edition, but I kept that, so I had that, and I would look up things in that, but rarely drug dosages.

Q Okay. And so, you know, pediatricians in The Jackson Clinic in 2001 would have been unlikely to refer to the Harriet Lane manual for what dosage of a -- for example, Amoxicillin to provide to children?

A Correct. It's not likely we would look at that. And once again, most of these dosages you have memorized. You don't have to look anywhere.

Q Where would Dr. Hays have learned the dosage of Amoxicillin to provide for otitis media?

A He trained at Vanderbilt University, so I presume there.

Q Okay. And he would have brought that knowledge, you're saying, with him to The Jackson

Clinic?
A Correct.
Q Okay. And it's not something -- you're saying the dosage of Amoxicillin that he would be prescribing would not be some -- would that be something that he would discuss with any of the other pediatricians in The Jackson Clinic?
A Not likely.
Q Okay. Would the different doctors within The Jackson Clinic who were pediatricians have -- would there be, you know, opportunity where a child would come in, see a different doctor, and the doctor would be able to -- you know, would see the medical record and the amount of Amoxicillin that a different pediatrician in the practice was providing?
A That certainly could happen, yes.
Q Okay. And, you know, if -- if an amount of Amoxicillin was being provided by one pediatrician that differed from what the other -- a different pediatrician would prescribe, do you think they would discuss that?
A No.
Q They would each just accept what the other

one was prescribing even if it differed than what they understood was the amount to be prescribe -- of the amount of Amoxicillin to be prescribed for otitis media?

A I never knew of it to be a discrepancy that was anything other than insignificant, so I don't think it ever occurred.

Q So if the medical records were reviewed for children in The Jackson Clinic during the period of 2000 and 2001, who had otitis media, would you -- do you believe it would consistently show that those children were prescribed 80 milliliters per kilogram per day twice a day of Amoxicillin?

A 80 milligrams per kilogram per day, yes.

Q Okay. Thank you. Because it's your understanding that that is what all the pediatricians understood in 2000 and 2001 was the amount of Amoxicillin to prescribe for otitis media for a child; correct?

A Can you say that again? I -- I want to make sure I understood.

Q Sure. Sure. Is it your understanding that all the pediatricians in The Jackson Clinic in 2000 and 2001 understood that the amount of

Amoxicillin to provide for otitis media, whether it was mild, moderate, or severe, was 80 milligrams per kilogram per day?
A I would think that would be correct.
Q Okay. Are you familiar with the normal hemoglobin range in a 9-month-old baby?
A Yes.
Q What would that be?
A Shouldn't be under 10 and a half, not likely to be over 12.
Q Okay. So a normal range would be 10 and a half to 12?
A That would be a good range, yes.
Q Okay. And what would you be concerned about if it was over 12 or under 10 and a half?
A It would depend on the over. It would depend on how much over. If it was 12.3, I wouldn't think anything about it. In levels higher than that, short of situations like severe dehydration, which would concentrate the blood and make the hemoglobin high, I can't think of seeing a child with high -- a 9-month-old with a high hemoglobin. This diagnosis just doesn't often occur. Low brings in a whole list of diagnoses that are

associated with anemia because you're basically diagnosing anemia, and way and above the most likely thing is iron deficiency, but there are certainly a huge list of other possibilities.

Q So that would be for the -- if it was below the standard range that you provided, and if it was the standard range, what do you think it could potentially be indicative of?

A Dehydration would be the most likely thing. And just to be complete, we're excluding newborns from this?

Q Yes.

A They have a high hemoglobin because of intrauterine life.

Q Okay.

A Adults have things like polycythemia vera where they have a real high hematocrit or a hemoglobin, but children just don't have much that's going to do that. They would have to have been recently transfused and maybe gotten too much, and dehydration, as we mentioned, can make -- can hemoconcentrate the blood. Rehydration, of course, would immediately lower the hemoglobin or the hematocrit right back down

to where it should be. There are just not many diagnoses for a hemoglobin of 15 or 16 or something like that.

Q And so if a child did have a hemoglobin level above the 12 range, as you've indicated, you would be very concerned, I presume, if a 9-month-old infant had a hemoglobin level that was, you know, above 12, you'd be -- you'd be -- you'd be very concerned; correct?

A Well, not if it was 12-point something.

Q But --

A If it starts getting over 13, again you're going to begin to wonder why. The first thing I think is lab error and then repeat it.

Q And if you repeat -- okay. But putting aside a potential lab error, you would ask -- you would ask for it to be repeated because you would be concerned that there was some issue as to why the child had a hemoglobin range -- level that was well above -- that was above 13, for example?

A That would make me have to think about what's going on, yes.

Q Okay. It would be a -- it would be an outcome that would make you concerned as a

pediatrician to conduct further evaluation, either rerun the test or otherwise engage in some kind of evaluation as to what is potentially medically wrong with the child; correct?

A Yes. An excessively high hemoglobin would get your attention and you would undertake some kind of evaluation.

Q And Dr. Carlton Hays, he would have been the healthcare provider under whose authority Yates was vaccinated; correct?

A Correct.

Q Dr. Stepp, would you like a break?

A I would love one, please.

MR. SIRI: Okay. Well, why don't we -- why don't we do that. Why don't we take a --

MR. SANDERS: May I make a suggestion, Mr. Siri?

MR. SIRI: Sure.

MR. SANDERS: I know based on our prior depositions last week that we're likely to go late into the afternoon. It's -- it's about to be one o'clock here Central. Would anybody be opposed to taking about a 30-minute break and letting him get a quick sandwich or something like

that?

MR. RILEY: That sounds fine to me.

MR. SIRI: No problem. Absolutely.

MR. SANDERS: So if it's 12:52 or -- Central time, say 1:25 Central time, would that be fair?

MR. SIRI: That sounds -- that sounds great. Is that good for you, Dr. Stepp?

THE WITNESS: That is perfect for me.

MR. SIRI: Ms. Cohen?

THE COURT REPORTER: Perfect. Thank you.

MR. SIRI: She's doing the hardest work here. Okay. So 1:25 then. Mr. Lawson?

THE VIDEOGRAPHER: Okay. We are off the record at 12:53.

(Lunch recess.)

THE VIDEOGRAPHER: We are now back on the record at 1:37.

Q (By Mr. Siri) Okay. Dr. Stepp, we just took a short lunch break. During that break, did you discuss this deposition with anybody?

A No. Excuse me, no, sir, I did not.

Q Okay. And one of the ground rules I should

have discussed at the beginning, but I'll do it now, and this is because, you know, we're doing depositions in a bit of a different way than we've normally done them which is in person in the room, during the course of the deposition, one of the rules is that you're not supposed to consult with anybody regarding your testimony. Are you aware of that rule?

A Yes.

Q Okay. And during the course of the deposition thus far, have you received any information or consulted with anybody regarding any of the testimony that you've provided today?

A No.

Q And will you agree to continue to not consult or take any information from anybody with regards to the testimony you'll be providing today?

A I agree.

Q Okay. And you have not been prompted or been provided any help during this deposition up to this point; correct?

A That's correct.

Q Okay. During your time at The Jackson Clinic, you were -- you would have been senior to

Dr. Hays; correct?
A That's correct.
Q Okay. Did Dr. Hays ever ask you for advice?
A The chances of that happening are fairly good. I don't have any special memory of such.
Q You can't remember a specific instance where that occurred?
A I can't remember a specific instance where that occurred. I remember the reverse occurring where I went and asked him, but I don't remember him coming and asking me.
Q Okay. What did you ask him about?
A I don't remember the details, but it would -- it was an occasion of an older teenager with an adult-type of a problem, and of course, he does internal medicine as well as pediatrics, and so since it was an adult-type problem more than a pediatric problem, but nonetheless I'm the one seeing him, I asked him what he thought, and I can't remember what it was about.
Q Okay. But had Dr. Hays had any questions, you would have been available to discuss it with him; correct?
A Yes.

Q Would you say that pediatricians at The Jackson Clinic were encouraged to speak to their colleagues about questions concerning treatment of a patient, including children?
A Nobody had to come around and encourage us to do that, but we clearly enjoyed doing that and did it frequently, but the tendency was to discuss cases with the pediatricians that worked on the same hall that you did, and so -- because it was so much easier, you were right there, and you tended not necessarily to go to the next hall down, and Dr. Hays was on the next hall, but -- so everybody talked about cases.
Q And who was in the hall with Dr. Hays?
A All of the med peds doctors were all on the same hall, so Dr. Jim Payne, Dr. Lisa Anderson were there, and -- on his hall, and for a time there was a fourth med peds, and that was Dr. Hannah Shelby-Kennedy.
Q Okay. I now understand why you were -- everybody waited for me to start because my video was off. I just realized that. Okay. Now, the -- The Jackson Clinic did financially profit from administering vaccines to children; correct?

A I know they upped the charge. Your video just went out for me anyway. They charged more for them than paid for them.
Q Okay. And are you aware of how much more they charged for them than they paid for them?
A No.
Q Do you know what the routine charge for a well-baby visit was during your last years at The Jackson Clinic?
A No. Of course, and I don't remember the RVU, and the thing about the RVUs is it's different payors would pay a different amount to the same amount of RVU, so BlueCross® BlueShield® may pay one thing for one RVU, Medicare pay -- may pay a different amount for one RVU and so on and so on, but no, I don't remember what it was.
Q Do you remember approximately what a private insurance company would pay for a -- for a well-child -- well-baby visit?
A I know that they tended to pay 140 percent of Medicare per RVU because Medicare doesn't pay for well-child visits, but based on the RVU number, they tended to pay about 140 percent, but I don't know how much that is.

Q Was there any financial incentive provided either by Medicare or by private health insurance companies where a child -- for a child that was fully vaccinated versus having children that were not fully vaccinated in the practice?
A Do you mean was there a financial penalty, so to speak, if a child wasn't fully vaccinated? Is that what you're --
Q Yes.
A Not that I know of, no.
Q Okay. And was there a financial incentive payment provided by any of the payors if there was a higher proportion of children in the practice that were fully vaccinated?
A I'm not aware of any incentive pay for that.
Q So if The Jackson Clinic was able to achieve close to 100 percent of its pediatric patients being fully vaccinated, you're not aware of any additional payment above the standard payments that would be provided for maintaining that high level of immunization in the practice?
A I'm not aware of any extra pay for that. I mean, Tennessee's Medicaid is TennCare, and TennCare would come around and make sure we had a

high level of vaccination for TennCare patients, but as far as money, if it -- if it did, I was not aware of it.

Q And what would happen if the TennCare came around and the level of vaccination wasn't high? What was the repercussion, if any?

A I don't -- I don't know.

Q Do you know what level of vaccination they expected when they reviewed the records?

A Other than say they expected it to be high. To put a number on it, I don't know that they had a threshold if you fell below that they would start reprimanding you in some way. Obviously they wanted them immunized.

Q Did you ever dismiss a child or parent from The Jackson Clinic because they refused a vaccine?

A I did not.

Q Did other pediatricians in The Jackson Clinic do that?

A I don't think they did, so if they did, I'm not aware of it.

Q Okay. Was there a policy at The Jackson Clinic concerning how to deal with parents that refused one or more vaccines?

A Not a Jackson Clinic policy, no.
Q Okay. Did you have many patients -- excuse me. Did you have many parents who refused to vaccinate their children?
A There were very few.
Q Okay. When parents asked you if vaccines were safe, what would you tell them?
A Well, by and large I'd say that they are safe, but nothing is perfect. There are certain circumstances where there could be precautions or contraindications, but by and large, yes, they're safe.
Q Okay. And that would be what you would tell them?
A Yes.
Q Okay. And if they asked you how you know they're safe, what would you tell them?
A I would say you would have to look at their track record of the -- of the vaccinations and see that almost every child is vaccinated and problems are very, very small.
Q So you're saying you would point to the overall health of children in society? Is that right?

A That would be one thing, yes.
Q And so, for example, in -- there were far less vaccines in the 1990s as there, for example, are in the 2010s; correct?
A Correct.
Q Okay. And so what you're saying is to -- well, an indicator that vaccines are safe is that during that time period, you would look at the overall health of children in society; correct?
A Overall health of the children in society, plus the infrequency of having a major problem with vaccine administration in terms of some kind of adverse event.
Q And if they said to you, well, what about long-term chronic health issues, how do we know vaccines don't cause those?
A Well, of course, some vaccines can. I have a friend who has a child who has permanent vaccine-related injury, so they can, but those are infrequent and we know what they are, and in -- the vaccine schedule has been amended to eliminate that or minimize that.
Q What was the injury that your friend's child had?

A He was given the oral polio vaccine and developed polio.
Q Okay. And you said that we know -- when you said we, I presume you mean the medical profession?
A Yes.
Q When you said we know what they are. Okay. And so how is it that you know what adverse events vaccines cause and don't cause?
A There's a tracking mechanism, and so once it's reported and looked into, then that be -- adds to the body of knowledge about vaccines, and if it's a big enough problem, of course, then the people that develop the vaccine schedules will make some amendment like they did with the oral polio vaccine.
Q And what is the tracking system called?
A I think it's VAERS, is it not?
Q And what -- what does that stand for?
A I may struggle to tell you every word of it. Vaccine Adverse Event Reporting System. I think it's close.
Q Have you ever filed a VAERS report?
A No.

Q Have you ever had a child that has within a -- that's developed a health condition, you know, within a -- let's say a month of receiving vaccinations?
A That's related to the vaccine I assume you mean, and no.
Q Okay. So you only report adverse events following vaccination that you believe are related or caused by the vaccine?
A Correct.
Q And but what you're saying is that VAERS would pick up if there were a new -- if there were an issue that were caused by the vaccine; correct?
A I would like to think so.
Q Okay. But you and I presume -- and, you know, most pediatricians, they'll only report conditions to VAERS that they believe are already caused by vaccines; correct?
A I think that would be correct.
Q And how do you know what conditions are caused by vaccines?
A I don't know that there's a simple answer to that. Certainly you know that what conditions have in the past been associated, and so if it's

something like that. On the other hand, if they get their vaccine and three weeks later they have some minor unrelated medical condition, like if they get poison ivy or have pneumonia or strep throat, we know that's not related.

Q And what about, you know, before vaccines were licensed, how were they safety tested?

A Clinical trials.

Q Yeah. Are -- you know, are they -- can you -- can you describe what those clinical trials typically look like and how well they'll -- are able to assess safety?

A You know, clinical trials have to go through Phase 1, Phase 2, and Phase 3 trials. Phase 1 trials, they'll give vaccine to a small number of people just to make sure, you know, there's nothing real obvious, and then they'll get a larger cohort, and then in a -- and then an even bigger one in Phase 3 when they're getting ready to put it on the market. You have -- you figure that's what they're doing with the coronavirus as we speak. During those trials, the patient is being seen by some healthcare provider, and again as I mentioned, I participated in some of this,

and when they come in for their scheduled visit within the context of the protocol, you pretty much ask them everything that has happened to them and you have to record all those things, whether you -- whether they're related or whether you think they're related or not. So, for example, during the Prevnar study, if they'd had diaper rash and you figure that's probably not related, but nonetheless you would have to record diaper rash, and then when you turned your data over to the -- to the drug company for evaluation, it would be on there.

Q And it's the Phase 3 clinical trial that's the one that's large and, you know --

A Correct.

Q -- long term that would actually assess if they were to rely upon to them, decide whether or not to license the vaccine?

A Correct. Of course, the FDA now is involved and it's not the drug companies licensing it themselves, of course, but rather they have to get FDA approval, and the FDA can be pretty tough.

Q Okay. So for the vaccines that Yates received, you know, can you describe those Phase 3

clinical trials, you know, how long were they, how long did they review safety, and how many participants, you know, what the --

A No.

Q Do you know anything about them?

A Don't know anything about them.

Q What would you expect the safety review period to be in those Phase 3 clinical trials prior to licensure?

A I don't have any way to ascertain the answer. I mean, fairly long, but not indefinitely long.

Q What would you believe the reasonable period of time to review safety after administering those experimental vaccines before they were licensed?

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

A Well, I hate to answer when it's a guess, so I just don't know.

Q (By Mr. Siri) Do you think a year sounds at least reasonable enough?

MR. SANDERS: Same objection. Go ahead, Doctor, if you have an answer.

A Whatever period the FDA requires to get the

license, that wouldn't not necessarily stop the review, so if they're licensed this year and something happened the next year, that's what the VAERS is all about, and so it would still be reported. It just wouldn't be part of the data accumulated during the clinical trial.

Q (By Mr. Siri) Right. So it would get licensed, but after it was licensed, you're saying pediatricians would then report any adverse events they knew were caused by the vaccine; correct?

A Correct.

Q Based on the adverse events that have already been established to be caused by the vaccine; correct?

A Correct.

Q Okay. So in that regard, it seems very important to figure out before they were licensed what adverse events are actually caused by the vaccine; correct?

A Sure, yes.

Q Okay. So let's pick something that seems ridiculous. For example, would you believe that a vaccine -- do you think the vaccines that Yates received would have been licensed based on only

one week of safety review prior to -- in the clinical trials?
A No.
Q Okay. How about, like, only 60 days, do you think they would have been licensed on the safety that only lasted 60 days?
A No.
Q I mean, you would expect them, let me guess, they would at least last a year of safety review before -- in the clinical trials before they were licensed to make sure that they were safe?
A Possibly. I just don't know what the FDA requirement is or was for -- if you're talking about MMR, I don't -- I don't know.
Q Well, as a pediatrician who's administered tens of thousands of these, I assume you'd want to -- you'd want to know that they were -- they were properly studied before they were licensed to make sure they were safe; correct?
A Yes.
Q I mean, as -- you know, I assume on a personal, moral, ethical level, you'd want to feel good that you're administering pharmaceutical products that have been properly safety tested

before they were licensed; correct?
A That's correct.
Q Especially where after the license the only adverse events that are going to be reported are those that have already been shown to be caused by the -- by the vaccines; correct?
A I don't know that those are the only ones. If it was not on the list and some pediatrician or physician thought there was some other adverse event that they deemed likely to be associated but it wasn't on the list, they might report that too.
Q But without actually having science to support that, they'd be unlikely to do that; correct?
A Well, it's hard to say what they would do.
Q Fair enough. We know what -- so -- okay. So, you know, what else about vaccine safety can you tell me that you would be able to tell a parent to assure them that vaccines are safe?
A The general pediatrician is seeing sick kids and well kids, and he can't proceed to personally do studies, tests, investigations as to whether they're safe or not, so there's some reliance on others to form a consensus about whether they're

safe or not, and because the American Academy of Pediatrics is the one we look to for that very thing, and when they say it's fine, it's passed the FDA, then we trust that there's -- that all things have been looked into and that therefore they are safe.

Q So what you're saying is that you rely on the AAP to tell you that vaccines are safe. Is that correct?

A Yes.

Q You never independently verified by looking at any primary source that vaccines are safe?

A I wouldn't have the time or the expertise to be the one to do that, so no.

Q All right. Who would have the expertise to do that?

A Well, they -- they have to get past the FDA, so that's one, and then the members of the infectious disease committee at the AAP do have the wherewithal to make those evaluations, and the CDC as well.

Q And the CDC and the AAP rely on VAERS to make their conclusion about safety for the post-licensure period; correct?

A I doubt that that's the only thing, but yes.
Q What else do they rely upon?
A I -- I don't know. I've never asked them.
Q Are you aware of whether or not the AAP receives funding from pharmaceutical companies that sell vaccines?
A I don't know where they get their money other than dues, so I don't know.
Q Do you know what ACIP is?
A Advisory Committee of Immunization Practices at the CDC.
Q Okay. And what do they do?
A I think they do essentially the same as the infectious disease committee at the AAP in that they advise on immunization practices, as the name suggests.
Q And they're the ones that develop the CDC's recommended childhood schedule?
A My understanding is that they're the ones.
Q And would you assume that the individuals who sit on the ACIP committee do not have conflicts of interest with the pharmaceutical companies who sell vaccines?
A I would assume that to be true.

Q Okay. Would you also assume that to be true of the infectious disease committee at AAP?
A I would assume that to be true.
Q Okay. Would you be concerned if you learned that individuals who sit on ACIP while voting to add a vaccine to the CDC's recommended schedule are receiving funding from pharmaceutical companies that sell vaccines?
A I would be very surprised.
Q Because that would be an incredible conflict of interest, wouldn't it?
A I would think so, yes.
MR. SANDERS: Object to the form of the question.
Q (By Mr. Siri) And the same, I assume, would be true of individuals sitting on the infectious disease committee at AAP; correct?
A Correct.
Q You would be extremely surprised to learn that any of them while voting on the AAP's -- that -- recommended vaccine schedule receive money from pharmaceutical companies were otherwise involved with pharmaceutical companies that sell vaccines; correct?

A Correct.
Q Because that would be an incredible conflict of interest; correct?
A Correct.
Q Are you familiar with what VRBPAC is?
A No.
Q Okay. Are you familiar -- are you aware that there's a committee within the FDA that votes to recommend whether or not to license -- whether or not the FDA should license vaccines?
A Well, I assume they had some kind of mechanism. I didn't know the name of it.
Q Would you find it very troubling if the individuals who sat on that committee at the FDA were voting on whether or not to recommend a vaccine while they were either a consultant or receiving funding from pharmaceutical companies that sell vaccines?
MR. SANDERS: Object to the form of the question. Go ahead, Doctor.
A In the same manner, I would be extraordinarily surprised to find that out.
Q (By Mr. Siri) And if that were true, you would be -- you would find that very concerning;

correct?
A Correct.
Q What is the Institute of Medicine?
A I only know that it exists. It doesn't involve pediatrics, so I don't know much about it.
Q Are you aware of any reports issued by the Institute of Medicine with regards to vaccines or vaccine safety?
A No.
Q Can you tell me, what are the contrary -- well, can you tell me during the period 2000 to 2001, what are the contraindications of receiving one or more childhood vaccines?
A The first one would be if they've had an immediate anaphylactic allergic reaction to a previous dose of that vaccine.
Q Okay.
A And there's some others, and I'm probably going to omit some because I'm sitting here without notes, but, for example, you wouldn't give a live virus vaccine to a child who is currently on chemotherapy for leukemia, and you can just -- and there's a bunch of examples like that. I think there's an issue with ITP and the MMR,

previous intussusception in rotavirus, those are a few examples.
Q Any others that you can recall?
A I probably would remember it if I was looking at the -- at -- at the book, but right this minute --
Q Uh-huh. Yeah. It's been a -- it's been a few years since you've been practicing.
A It has.
Q When you were practicing, did you know all the contraindications and precautions to vaccination by heart?
A Probably not by heart.
Q Okay. So you would -- if you thought that one might exist, you would refer to the CDC contraindication and precaution list?
A If I thought that I had a patient that needed to be vaccinated and they might have a contraindication, I would go to the Red Book and look it up, and if it said that, then I would act accordingly, which is, of course, not to vaccinate.
Q Okay. So if the Red Book provided that in a certain situation you shouldn't vaccinate, you

would not have vaccinated the child; correct?
A Correct.
Q That would be the applicable standard of care; correct?
A Correct.
Q Do you consider yourself -- strike that. Do you have any training in the area of vaccinology?
A No.
Q Okay. Do you consider yourself an expert in any regard with regards to vaccinology?
A No.
Q Okay. Do you have any training with regards to mitochondrial disorder?
A No.
Q Do you consider yourself an expert in any regard with regard to mitochondrial disorders?
A No.
Q Do you -- do you conduct any -- have you conducted any science or been involved in researching the causes of autism?
A Personally, no.
Q Have you been involved in any research with regards to the causes of autism?
A No.

Q Okay. Have you been involved in any studies regarding vaccines and autism?
A No.
Q Are you familiar with the underlying pathological differences between children with autism and children who are considered neurotypical?
A You mean like brain biopsy?
Q I --
A No.
Q Like -- like difference in, for example, autoantibodies that might be in their blood.
A I don't know any reason that they would have autoantibodies in their blood. I haven't been involved in any research about that.
Q Have you ever read any articles about that?
A No.
Q Okay. Are you familiar with any literature that describes differences in underlying physiology of children with autism versus those who are neurotypical?
A Over the years, yes, I've seen some things.
Q Okay. And what differences have you read in the literature are there physiologically that have

been found between children with autism and those that are neurotypical?

A I don't remember any that have been completely verified by the scientific community. That is to say there may be some disagreement amongst people.

Q Is it -- okay. So give me -- can you please provide me just one example of a physiological difference that some studies say exist between neurotypical and children with autism that you say are not -- for which there isn't agreement in the medical community?

A I'm struggling a little bit with what you mean by physiologic difference.

Q I mean --

A I mean --

Q I'm with you.

A Their heart beats the same, their lungs are the same, et cetera, et cetera. So I'm not sure exactly what you're referring to. Obviously the gigantic problem with the autistic children is not so much their physiology as it is their behaviors, social interactions, learning, et cetera.

Q All right. Sure. There's some kind of

neurological pathology that results in autistic children being different than neurotypical children; correct?

A Clearly something is going on and it's obviously in the brain.

Q And so there is some neurological pathology that would result in a child being autistic; correct?

A Just to -- so I'm clear and that I understand what you say, when you say pathology, my thought is that if you did a biopsy and you looked at it under the microscope, you would see some difference in the same way that cancerous lung tissue looks different under the microscope than normal lung tissue, and I don't know that I know where the -- where at autopsy the brains appear different so that likely this is on a cellular or intracellular level instead of gross pathology.

Q The controversy -- strike that. Okay. Now, you indicated that your first -- strike that. The first, you know, argument that you put forth for why vaccines are safe is that looking at the overall health of children over time given the vaccines that they had received; correct?

A I hope I expressed myself correctly. I think it's the overall safety record that makes it seem safe.
Q Uh-huh.
A Whether the child is generally healthy or not may or may not be related to vaccines, but it would likely mean that they won't get the diseases that the vaccines are designed to prevent.
Q In 1985, how many were vaccine -- how many vaccines were on the CDC childhood schedule?
A I don't know the number, and we used the AAP vaccine schedule.
Q Okay. And which vaccines were on the AAP schedule in 1985?
A It's highly likely that they were exactly the same as the ones on the CDC's because I think those organizations try to correlate well with each other so as to not create a lot of confusion.
Q Right. The --
A And I --
Q Please.
A I can't tell you in '85 what the list was.
Q And AAP has a non-voting committee at ACIP; correct?

A I don't know.
Q Okay. Does it sound right that in '85, the recommended schedule included OPV, MMR, and DTP?
A That sounds right.
Q Okay. Can you recall maybe -- are there any other vaccines that were licensed and recommended at that point that you can potentially recall?
A This is 1985; correct?
Q Yeah.
A We didn't have rotavirus, we didn't have HPV, we didn't have chicken pox, we -- we -- I can't remember when we switched to -- from DTwP to DTaP. That is the whole cell versus the acellular. I don't think we had hepatitis A or B.
Q All right.
A But to pin it down to a specific year, and I had no reason to try to remember it, I --
Q No, and I -- and there wasn't haemophilus influenza vaccine yet; right? There was no Hib vaccine yet?
A I think that's correct, yes.
Q All right. And so all those other vaccines we -- you just mentioned, those all for the most part came out -- were added to the AAP and the CDC

schedule in the '90s; correct?
A I don't know the year, but correct, later.
Q As well as others that we didn't list; right?
A Yes.
Q Okay. And pretty much all of them -- do you recall any vaccine that was added to the schedule after the year 2000? It's okay if you don't recall.
A It seems like HPV was added after that. Rotavirus was probably after that, but as far as -- I could be overlooking something.
Q Yeah. Well, you're not incorrect. The first rotavirus, right, was RotaShield in the '90s, but then it was taken off, but the other rotavirus vaccine -- strike that. So -- okay. Now, according to the CDC, do you know what the chronic -- what percent of children in the United States were considered to have a chronic health condition in the mid '80s?
A No.
Q Would it surprise you if it's 12 -- that it's been published that 12 percent of children had a chronic health condition in the mid '80s?
A I don't know if it would surprise me.

Q Are you aware that the most recent data provides that chronic health conditions among children are now somewhere between 40 to 50 percent depending on, you know, whether you're looking at the CDC or some other major health authority's statistics?
A Seems a little high. It depends on -- it depends a lot on what they decide to include as a chronic health condition.
Q Sure. You've got to compare apples to apples; right?
A Right.
Q You've got --
A You know --
Q Please.
A Oh, I was going to say, you know --
Q You have --
A -- you have --
Q You have the same conditions and they -- and have 12 percent configuration as you do in the later figure; right?
A Yeah, and no additional ones, so right.
Q Of course. But assuming that they are looking at the same health conditions, do you find

it surprising that there has been a three-fold increase, at least, among chronic health condition among children from the mid '80s --

A Yes.

Q -- until -- okay. Let's just assume that that is the case, and we can go through the studies in a bit. Do you think it's possible that vaccines have been a contributor to that increase in what are mostly immune and neurological disorders that have increased precipitously during that time period?

A No.

Q Okay. And how would you know that?

A This kind of information is not something that one general pediatrician is going to spend his time studying and investigating, so you have to depend on some other source, and I -- and -- for example, we keep referring to the C -- to the American Academy of Pediatrics, and for pediatricians, that's going to be the prime source. And so we depend on them to discover those things and tell us about them, but -- certainly in my practice, I didn't see any indication that that would be the case.

Q Right. Well, isn't it true that most -- many neurological disorders and autoimmune disorders would not be diagnosed until a child is at least a few years old; correct?
A No. That applies to autism, but not necessarily anything else. We see a lot of neurologic conditions in the newborn nursery and some others have a later onset.
Q What about asthma, what's the average age for diagnosing asthma?
A Asthma is a tough one because of the way babies under 12 to 15 months respond in their pulmonary system, and it's also some overlap with respiratory syncytial virus infections, which is referred to as bronchiolitis, and so many of those that -- are going to have some reactive airway in the first year or so of life, but not have it later, have that reactive airway disease because of a viral infection they had early on, specifically RSV.
Q All right. But --
A Ones that have true asthma usually are 15 -- 12 to 15 months or older where they have asthma and it's going to continue to be a problem, and

yet there's another subset who have other allergic manifestations early on, like, eczema and then later will develop asthma.

Q Well, learning disabilities, for example, those aren't diagnosed until typically when children start school; correct?

A Some of them are earlier than that, and it depends on the learning disability, but -- but yes, it's hard to diagnose until they start learning.

Q Right. Aren't there many conditions that require having some -- you know, the individual you're trying to diagnose and -- needs to be able to speak and explain their neurological reactions, symptoms that they're having?

A I'm not sure I understand what you're asking.

Q All right.

A Children --

Q Well --

A -- that are small --

Q Go ahead. I don't want to interrupt you. Were you going to say something? I'm sorry.

A Well, I was going to say, small children aren't the ones that come to us saying what they

have. It's the parents that come to us and say.
Q All right. And so, you know, a typical 2, 4, 6-month-old baby's primary way of expressing themselves is through crying; correct?
A No.
Q Okay. Tell me.
A Well, they may cry, and they do, but the primary way is the way they interact, and this is with the parents, of course, in a social way, so 2 months old start smiling and they start -- you know, get them a little older than that and they can start rolling over and they'll reach for things and they'll interact with the mother or the father's face because they recognize it, and they smile and laugh and coo and talk, and you know what I mean by talk, it's not -- baby talk.
Q Right.
A Not -- not language. And so it's their -- the development of their social interaction that they express themselves, and they might cry, certainly if they had an earache they might cry, or if they got their -- just got their vaccinations they might cry or if they were injured or hurt in some way or if they were sick,

but -- but the primary important way is the social interaction.

Q To determine whether or not getting all of these pharmaceutical products during the first year of life does have an impact long term on the chronic rates of, for example, one in six kids having asthma today and -- and the other neuro -- and the neurological disorders that have also gone up -- it's like -- what line of study do you think would need to be conducted to determine whether vaccines cause -- are causing those increases in autoimmune and neurological disorders?

A I don't know.

Q Do you think that the study that would be necessary would be what science typically does is you compare an exposed group to an unexposed group when evaluating whether a product or a substance causes something?

A If one were to decide to undertake that, that would be one way.

Q Well, isn't it true that there are large health databases that already exist, for example, insurance companies or HMOs that have lots of children who are completely unvaccinated, for

example?
A The immunization rates are pretty good, so I don't think they have lots.
Q Okay. Are you aware that according to the most recent CDC data, 1.3 percent of all 2-year-olds are completely unimmunized in the United States?
A I could believe that. I don't know that -- I don't know that data, but I could believe that.
Q So if 1.3 percent of all 2-year-olds are completely unvaccinated, wouldn't that amount to a significant number of children in the United States who are completely unvaccinated?
A Well, since the population is large, that makes for a large number.
Q So wouldn't you expect that our health authorities would compare the health outcomes between those children who have never received any vaccines and those who have received vaccines to see what the difference is?
A I wouldn't necessarily expect them to do that. There may be someone who decides they want to do that.
Q And why not? Why would you not expect them

to conduct that basic study that's done to confirm, you know, scientifically whether any product causes an issue?

A The -- if we're talking about should we study the number of vaccines given to vaccinated people and the ones that are unvaccinated and the hypothesis is that the number of antigens presented to the child is somehow injurious, then -- then I don't think we need that study. The number of antigens people process is in the hundreds of thousands, if not millions, and so the number of antigens in the immunizations in the -- from birth to kindergarten pales in comparison to that number and the immune system handles it with no problem, so I don't see any reason to even wonder about that.

Q All right. So do vaccines only contain antigens in their formulation?

A No. You have to have something that you can pull up into the syringe.

Q Okay.

A So there's undoubtedly water and other things in there.

Q So, for example, if all you did was inject

pertussis -- the antigens in the pertussis vaccine with nothing else, just the antigens, what do you think would happen? Do you think that the body would generate an immune response to those antigens to those pieces of protein particles?

A I think they likely would. I don't think it's possible to do that, but I think in a hypothetical situation of if it was possible and you did that, I think your immune system would respond.

Q So you think that if it was just saline and just -- do you know how many antigens are in the DTaP vaccine?

A Well, other than what's obvious, that -- I'm not sure there's any other antigens. I know there's other things. They have to put some kind of -- and they may have an adjuvant or a -- or a preservative, and I don't know what's in there, so I don't know.

Q Okay. But --

A But as far as protein antigens, I don't think there's, you know, cow's milk in there or anything else like that. I mean, what else would they put in there?

Q You don't think there's any casein in any vaccine's final formulation, you're saying?
A Not -- I don't know. I would be surprised to find that out, but --
Q Right, because you would sensitize the child to casein; right?
A Yeah, I can't believe it would be in there.
Q All right. And they would develop antibodies to casein, so you --
A Sure.
Q -- remove --
A You're immunizing against that, so -- so -- but as far as me being an expert in the chemistry of putting together the vaccine in the vial, I don't know that.
Q All right. So just -- all right. So I mean -- right. The viruses and bacteria used in vaccines have to be grown in some substrate; correct?
A Sure. They have to develop it somewhere. There's a -- yes.
Q And that substrate would be removed from the final formulation to avoid the body developing antibodies to those additional biological

material; correct?
A My supposition would be that the production activity involved in making these vaccines is such that they eliminate as much as they can that they don't want and make sure they have in there what they do want.
Q So, for example, if the rubella component of the MMR vaccine were grown on the culture cells strained of aborted fetal tissue, they would remove all human cellular components from the final formulation so that antibodies aren't going to develop to human components that might be in the vaccine, even protein particles that might be in the vaccine; correct?
A Well, I don't know what they grow rubella on, or any of the others for that matter, and I have to suppose without knowing because I don't -- I'm not involved with the production process, that they make it as clean and -- and good and safe, et cetera, that -- as they can, so in some kind of a vague way, yeah, I'm sure they try to --
Q Would --
A -- get rid of what they don't want in there.
Q And would you be concerned if, I don't know,

for example, there were millions of pieces of human DNA in each dose of MMR that's injected into babies?

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

A I have no knowledge of there being human DNA in the MMR vaccine.

Q (By Mr. Siri) But if there were, would you be concerned?

MR. SANDERS: Same objection. Go ahead, Doctor.

A Well, in a -- in an if world, I guess you could have some stuff in there that doesn't sound very appropriate.

Q (By Mr. Siri) Would you be concerned, Doctor?

A That sounds like it could be a concern if it was true.

Q It sounds like something that -- floating around the Internet is -- one of those pieces of propaganda about vaccines that floats around the Internet; correct?

A That's what it sounds like.

Q Now, the other -- the other thing that could

float around the Internet as propaganda is that the vaccines are not safety tested for more than a few days or even a month, you know, not longer than a month before they're a licensed -- you know, that the amount of safety review after inoculation is only for a few weeks in the pre-clinical trials of a lot of licensed vaccines. Have you seen that floated around?

A I don't believe I've ever looked at any anti-vaccine propaganda on the Internet, so therefore, I would not have seen that floating around.

Q Are there any other -- are there any other false claims about vaccines that you've heard over the years that you, you know, know to be false?

A I mean, the answer is yes. I'm just trying to decide which one to say.

Q Okay. All right.

A I think the most glaring one is the one that concerns this case, that it's alleged that MMR vaccine causes autism, and I think that's false.

Q The allegation in this case, Doctor, is that the vaccines that Yates received caused autism, right, not just the MMR; correct?

A I think they've tried to pin it on a couple of things. There was the thimerosal issue and pinning it on that, but to my knowledge, the main thing is the MMR vaccine is alleged to cause autism.
Q But in this case, the allegation is that the vaccines, which included, as we looked at in his vaccine chart, numerous vaccines cause autism, correct, caused Yates' autism.
A If -- if that's the allegation this lawsuit is making, then I accept for whatever you say it is. If that's what you're saying, then yes.
Q Because he didn't just receive MMR, right, on -- on February 8, 2001. He received on that date three other vaccines as well; correct?
A Correct.
Q He received the Prevnar vaccine on that day?
A Correct.
Q Okay. A Hib vaccine?
A I don't have it in front of me, but I trust you're saying what you -- you're reading it right from the thing, so --
Q Okay.
A I'd have to look at it to know.

Q Okay.
A But assuming you're reading it right off the sheet, yes.
Q Okay. And a HepB vaccine; correct?
A Yes.
Q All right. So those are just the other three he received on the date that he got MMR; correct?
A Correct.
Q Okay. And he -- and Yates also received vaccinations at 2, 4, and 6 months of age; correct?
A Correct.
Q Okay. And those were a number of vaccines none of which were MMR; right?
A Correct.
Q Okay. How did you reach your conclusion that -- now, when you say the MMR vaccine doesn't cause autism, I assume that you're relying upon what to say -- well, I shouldn't assume. What are you relying upon to say that?
A Over the years of being exposed to this issue as is discussed in the literature, the organizations that we look to for advice, and again, the American Academy of Pediatrics have

noted that there's multiple studies that have all concluded that there's no relationship between the two, and these have been multiple and from different countries as well.

Q Well --

A So we trust what they're saying, not to mention there's -- you know, anything that we would have seen ourselves in practice would simply be anecdotal and therefore not valid, but that said, we've never seen it.

Q All right. You've never seen what, Doctor?

A Oh, I'm sorry, a case where we thought that MMR resulted in autism or any of the other vaccines.

Q All right.

A But again, that's anecdotal data and it really doesn't figure in to -- even though it would be supporting these other studies, it can't be used, but the other studies have been peer reviewed and published and it allows the scientific community to come to a consensus that there's no relationship.

Q And that's how science is conducted, studies, well-designed studies are conducted and then

published in peer-reviewed literature?
A I believe that describes it, yes.
Q And then based on those peer-reviewed studies, the medical community draws conclusions regarding whether something is or isn't causally related to a product; correct?
A Correct.
Q Okay. In the absence of studies though, I assume the medical community would not draw a conclusion one way or another of whether a product caused an issue; correct?
A Well, not necessarily. It depends on what's out alleged caused what, because if it doesn't seem rational to begin with, then they may not be interested in conducting that study. You know, a certain example might be somebody that claimed introducing carrots into the baby's diet before 6 months of age causes dyslexia, but there's no reason to study that.
Q Is there anybody claiming that introducing carrots into the baby --
A No.
Q I --
A I'm sorry, I didn't mean to interrupt you.

No.
Q But there are -- but 40 to 50 percent of parents whose children have autism do claim that vaccines, not just MMR vaccines, based on their experience with their children, that vaccines were a causal factor in causing their child's autism. Isn't that true?
A That's what they believe, but as far as the science goes, that's anecdotal data and it's not useful to draw scientific conclusions.
Q All right. So similarly, you know, when -- based on just observation, you're saying -- of children is anecdotal. What you need is a well-designed study; correct?
A Yes.
Q And what those parents should do is go and look at the science to see has there been a study conducted that shows that vaccines do not cause autism; correct?
A That would be a reasonable thing for them to do, yes.
Q And they would want to see, presumably they would be able to find studies that show that vaccines do not cause autism?

A I think they could very easily find that.
Q Have you ever seen a study that showed that vaccines, not just MMR, do not cause autism?
A Yes.
Q Okay. What's the name of the study?
A I don't know.
Q When did you see the study approximately?
A They've come out over time, and I couldn't tell you because I practiced for 37 years, and if I picked up a journal and there was an article and I say here's another one that shows there's no relationship, I would make no attempt to try to memorize the date of that article, the page number, the name of that article, and so I just don't know. I think it's something that could be obtained, but I can't tell you that off the top of my head.
Q But do you -- do you have an approximate sense, three years ago, five years ago, ten years ago?
A Well, all of the above multiple times.
Q Oh, okay. Involving vaccines other than MMR?
A I think most of the attention has been placed on MMR.

Q Okay. For example, have you ever seen a study that showed that DTaP doesn't cause autism?
A No, but I hadn't really seen any scientific data that would claim that it does. It's not mentioned anywhere. Now, you know, if -- if you are speaking to a group of anti-vaxxers, then you may hear that, but if you're listening to the American Academy of Pediatrics, the CDC, or anything like that, I mean, you'll never hear that allegation.
Q How about parents of autistic children, do their -- does their opinion count or are they just lumped in with the anti-vaxxers too?
MR. SANDERS: Object to the form of the question. Go ahead, Doctor.
A Can you repeat that?
Q (By Mr. Siri) Sure. What about the --
A I'm -- I want to make sure I understood.
Q What about the opinion of parents whose children have autism? Do their opinions count?
A Their opinions count in the sense that they're parents of a child with a serious disability and your heart goes out to them, but their opinion doesn't count in terms of some

controlled scientific study to show vaccines do this, that, or the other.

Q Okay. So they should look at -- they should look at the science, you're saying?

A They should look at the science. It's fine to listen to the parents, and I think it's appropriate, and I mentioned that I have a friend who has a child that's been damaged by a vaccine, and I know he spoke out, and he should have been listened to, and he was, but he didn't have the science. He had the emotions of a father.

Q Are you aware of any injury from a vaccine that doesn't occur in let's say the 30 days after vaccination that has been carefully studied?

A No.

Q Okay. Up -- to assess whether it's caused by the vaccine. Is that what you were going to say no to?

A Yes. I thought you were finished with the question.

Q No problem. Because the assumption is, is that if there's going to be an adverse effect from a vaccine, it would happen relatively quickly; correct?

A Yes.
Q Okay. Now, when you say anti-vaxxers, can you define what that means?
A Well, my understanding is it's the -- anti-vaxxers are people who are just what it says, they're against vaccinations.
Q Okay. Is it socially unacceptable to be an anti-vaxxer?
MR. SANDERS: Object to the form of the question. You can answer, Doctor, if you have an answer.
A I don't know that it's socially unacceptable.
Q (By Mr. Siri) Do you think that most anti-vaxxers are looked up to or down to by an average person in society?
MR. SANDERS: Same objection. Go ahead, Doctor, if you have an answer.
A I think the average person in society might think that they are incorrect. Now, looking down on them is a -- is a different kind of interaction.
Q (By Mr. Siri) Do you think that there's a whole lot to gain for the parents who choose not to vaccinate their child?

A I don't think there's anything to be gained by not vaccinating their child.
Q I mean, their child could potentially be kicked out of school; correct?
A Well, that's one problem.
Q Some parents might choose to not have their children interact with -- play dates, for example, with their children; correct?
A That's correct.
Q Some doctors might even -- might kick them out of their pediatric practice; correct?
A There are doctors that do that.
Q Okay. So, you know, and -- and it could, you know -- some folks might socially ostracize a family that chooses not to vaccinate; correct?
A Some people would do that.
Q Okay. So there's a lot of downsides to not vaccinating; right?
A I would think so.
Q It must take a powerful personal experience or similar for parents to choose to not vaccinate then, don't you think?
A How powerful it is, you'd have to ask them, but it's -- it's a significant decision.

Q Probably one that they don't make -- that most folks wouldn't make lightly, I would assume?
A I assume they don't make that lightly.
Q There's been a lot of discussion, probably can't -- couldn't miss it, about folks who are labeled anti-vaxxers spreading what they call vaccine misinformation. Have you seen all of the scuttlebutt around that?
A I've seen some scuttlebutt around that.
Q Yeah. Do you believe that vaccine -- do you believe that information about vaccines that's incorrect is dangerous?
A Yes.
Q And so if one were to share information about a vaccine, it's really to make sure it's accurate; correct?
A That sounds like it should be correct, yes.
Q And if information is not correct, that person is spreading misinformation about vaccines; right?
A Correct.
Q The kind of thing that basically folks are saying anti-vaxxers are doing; correct?
A Correct.

Q All right. Let's go over some of the things that you've told -- told me about vaccines, Doctor. Now, you're familiar with the CDC Pink Book?
A No.
Q No?
A No.
Q Okay. Are you aware that the CDC publishes the ingredients of each vaccine?
A I'm not surprised.
Q Okay. Let me show you something.
MR. SIRI: Okay. 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) Have you ever seen this document before, Dr. Stepp?
A No.
Q Are you familiar with the Centers for Disease Control and Prevention?
A Yes.
Q Okay. And have you ever heard of the

Epidemiological and Prevention of Vaccine-Preventable Diseases book that they published and they're in the 13th edition?

A No.

Q Okay. So you're not aware that it's available on the CDC website?

A I've been to the CDC website. I have not seen that, but I have not looked for it.

Q So this is one of the nice things about Zoom. We can -- I can just pull it up. Pull it up. I've never been able to do this before in a deposition, but here it is. This is the Centers for Disease Control; correct?

A Correct.

Q This is the Pink Book, this is the -- you know, the colloquial term for their Epidemiology and Prevention of Vaccine-Preventable Diseases handbook, they're in the 13th edition right now, as you can see here, and it provides a lot of information about vaccines. In any event, let's put this away. So if we go down, for example, to -- let's just take a look at the varicella VARIVAX vaccine. That's the vaccine for chicken pox; correct?

A Correct.
Q Okay. Can you read the first ingredient, please?
A MRC-5 human diploid cells.
Q Including?
A Oh, sorry. Including DNA and protein.
Q Okay. Do you know what MRC-5 human diploid cells are?
A I know in a very basic way what they are.
Q And what are they?
A They're human cells that have been propagated to grow -- to serve as a medium in which to grow the virus.
Q Okay. And the virus -- when you say the virus, you mean the virus used in the vaccine; correct?
A The vaccine virus, yes.
Q All right. And in this case, it would be the chicken pox virus; correct?
A Correct.
Q Otherwise known as varicella.
A Correct.
Q Okay. So they grow chicken pox virus inside of these human diploid cells; correct?

A Correct.
Q Okay. And where did the MRC-5 human diploid cells originate?
A I don't know.
Q Okay. Are you aware that it originated from the lung fibroblasts of an aborted fetus, human fetus?
A No. Is that where they came from?
Q Usually depositions are one way.
A Sorry.
Q But you can certainly -- the answer is yes, but I'm not testifying here today. You can look that up after the deposition.
A Well, thank you. Thank you.
Q Now, the MRC-5 human diploid cells, they're cells -- all right. They're cell strains, all right, because -- first they're -- strike that. Now, okay, but you are aware that they're human cells. Now, when you grow a virus in a cell, a human cell, when you're -- one of then -- isn't it true that it's incredibly expensive to -- if you were going to try to isolate just the virus from the human cell and only have that in the final formulation?

A I don't know.
Q Okay.
A I don't do that. I would guess it might be.
Q Okay. Well, but it is true that at the end of the -- the end product for varicella, its first listed ingredient is the human diploid cells, including the DNA and protein from those cells; correct?
A Correct.
Q Okay. And that DNA is human DNA; correct?
A Yes.
Q Are you aware that it's purposefully fragmented down to below 500 base pairs per piece?
A No.
Q Do you have any knowledge of what snippets of DNA below 500 base pair, what their ability to insert into human DNA is?
A No.
Q And, of course, human protein structures that are in the vaccine that then get injected could potentially be taken up by macrophages; correct?
A I suppose.
Q I mean, what else would happen to that -- protein structures into the vaccine -- in the

vaccine that are injected, which is --
A They could just be degraded in some way and eliminated.
Q Well, the -- the -- those DNA and protein structures are -- all right, they're -- they -- the virus has been growing in them; correct?
A Okay, yes.
Q Okay. So when they're injected -- when the viral material is injected, along with the human protein and DNA material, and the viral material is replicating, right, because it's an attenuated vaccine; correct?
A Correct. It's a live attenuated vaccine.
Q What you're saying is you're not -- you don't know what happens then to the human cellular material that's in the vaccine?
A No, and I don't know how much is in there.
Q Well, isn't it true that most of the vaccine is actually the human diploid cellular material protein and DNA because it is -- cells are massive and giant compared to tiny viruses?
A They're very large compared to the virus, yes.
Q And hence -- well, do you think there's a

reason it's the first listed ingredient?
A There might be. I don't know.
Q Now, you mentioned earlier, for example, that you'd be concerned if there were, let's say, you know, cow's milk in there. Well, what about if there were cow's blood in the -- portions of cow blood in the final formulation of the vaccine? Would that be concerning to you?
A It says fetal bovine serum, and serum is only a portion of the blood.
Q That's right.
A But I know nothing of the chemistry involved in making these vaccines. Somebody does, and somebody that does that feels the need to use that in some way to produce the vaccine, and the mechanism by which they produce it is not something I know anything about.
Q Let's look specifically at casein. Do you see here that Infanrix and Kinrix, in fact, in the final formulation include bovine casein?
A I see that.
Q And these are adjuvant in vaccines; correct?
A I don't know.
Q Do you see here in the ingredients where it

says aluminum hydroxide for Infanrix?
A Yes.
Q Okay. And it says aluminum hydroxide for Kinrix?
A Yes.
Q Do you have any reason to doubt that they don't contain aluminum hydroxide?
A No.
Q Okay. And aluminum hydroxide is the adjuvant that you were referring to earlier; correct?
A That's correct.
Q Aluminum hydroxide is the -- the antigen in the vaccines that bind to those aluminum particles; correct?
A At a basic level, that would be my understanding.
Q Because this way they're able to actually sustain an immune response if the aluminum is not biodegradable; correct?
A Yes. My understanding is they enhance the immune response.
Q So if the aluminum adjuvant also -- is there any reason that it can't bind to casein, another piece of protein biological substance in the

vaccine formulation?
A I don't know whether it would or whether it would not.
Q Fair enough. Do you know what vero cells are, for example?
A No.
Q You're not aware that they're monk -- irregular monkey kidney cells that have extra chromosomes such that would replicate indefinitely like a cancer cell?
A I -- I -- before seeing this, I'd never heard of vero cells.
Q You're not familiar that that's how starting in 1988 IPOL was produced?
A No.
Q Do you believe that your patients over the last 30 years assumed that you were knowledgeable regarding the ingredients in the various vaccines that were being injected into their children?
A I assume that they knew that the MMR vaccine contained measles, rubeola, and rubella, but I don't think they assumed I knew whether there was phenol red indicator or yeast extract or protamine sulphate, et cetera, et cetera. I don't think

they assumed that. I didn't know about it and they didn't know to ask me.

Q You were unaware that there was yeast in certain vaccines' final formulation?

A I don't know the chemistry of vaccine formulation.

Q Okay. Before today, were you aware that there was yeast in certain vaccines' final formulation?

A Not that I can remember.

Q Okay. Are you aware that there is a precaution and contraindication for yeast sensitivity for certain vaccines?

A I think that's part of the propaganda on the Internet that we discussed earlier. I've never seen an admonition against that come from our main source, which is the AAP.

Q Okay. Sorry. Let me set here -- my screen is not looking right. Dr. Steep -- Stepp, sorry.

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

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

witness.)

Q (By Mr. Siri) This is the CDC website; correct?

A Correct.

Q And this is the ACIP's contraindication precautions guide?

A Yes.

Q This is the contraindications and precautions to commonly used vaccines; right?

A Yes.

Q This column over here is the contraindications?

A Correct.

Q Okay. So let's scroll down. Do you see that for hepatitis B, okay, that hypersensitivity to yeast is a contraindication?

A Yes.

Q Okay. But you believe that claims that hypersensitivity to yeast is a contraindication to certain vaccines is one of those conspiracy theories on the Internet?

A No.

Q That is what you just said a minute ago; correct?

A We've gone back and forth. I don't remember saying that.
Q Do you believe that the CDC is engaging in conspiracy theories regarding vaccines?
A No.
Q Could it be that some of the information that's viewed as conspiracy theories on the Internet about vaccines are a fact, just factual information about vaccines?
A I think if they were factual that the scientific consensus would have taken that into account already, and I have not seen that happen.
Q Okay. Let's -- let's move away from vaccine ingredients. Let's talk about the clinical trials, and let's take a -- now we're on -- now we're -- in the tens of thousands of vaccines that you've administered, you indicated that you are aware that each box that a vaccine is administered in contains a package insert; correct?
A That's correct.
Q It's basically one big sheet of paper; right?
A Correct.
Q Okay. And it's broken up into standardized sections; correct?

A It's broken up into sections.
Q Okay. So that information can be easily found in those package inserts; correct?
A If you read the package inserts, you will have access to the information.
Q Okay. Fair enough. Now, are you aware what Section 6 in pretty much every package insert provides?
A No.
Q Okay. Are you aware that it provides the adverse reaction profile for the vaccine?
A I -- I don't know since I'm not aware of Section 6.
Q Fair enough. And that means you're also not aware that Section 6.1 of probably pretty much all the vaccines you've administered also required under federal law to describe the clinical trial experience that the vaccine was relied upon to gain licensure; correct?
A I don't know that. I don't -- I believe you. I don't know what it says.
MR. SIRI: So I'm going to mark this as Plaintiff's --
MS. CHEN: Exhibit 6.

MR. SIRI: Thank you.

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

Q (By Mr. Siri) Dr. Stepp, what is this document?

A I don't know.

Q I --

A Highlights of prescribing information.

Q This is the package insert for Engerix-B; correct?

A Apparently so.

Q You've ordered the administration of hepatitis B to newborn babies on the first day of life; correct?

A Correct.

Q And you've done so many times; correct?

A Correct.

Q Okay. What are the hepatitis B products that have been available to do that over the last 30 years?

A Engerix comes to mind since it's right in front of me. There are other brands. Right this

second I can't think of the brand name.
Q Are you aware the only other brand is Recombivax HB?
A Recombivax rings a bell, so yeah, there's another one, but I don't -- if there's yet another one, I don't know.
Q And did you ever once look at the package insert for any of the vaccines that you administered, you ordered administered in all the years that you've been a pediatrician?
A I don't use the package insert as a source of information, so if I want to read about that, I would go to the Red Book and see what the AAP says about it.
Q Okay. Well, we can take a look at that as well. Well, do you see here Section 6 of the package insert provides for adverse event -- excuse me, adverse events -- adverse reactions?
A Yes.
Q And 6.1 provides for clinical trials experience that are relied upon to license the vaccine?
A Yes.
Q Okay. Why don't we take a look down at

Section 6.1. Now, you can see that there's an introduction that explains the clinical trial, and then they go through the incidents that they found, and they go to the post marketing. Can you take a moment to just read this section from Line 140 to Line 151?

A Sure.

(Whereupon, the witness is reading the document.)

A There's something that's obscuring Lines 148 through 151 and I can't see them.

MR. RILEY: Mr. Siri, did you hear him?

MR. SANDERS: I think we'll have to wait a minute. I think Mr. Siri got up from his desk. He'll have to move his mouse. Mr. Siri, can you move your mouse so that he can read those last three lines?

MR. SIRI: Absolutely. Sorry about that.

A Thank you.

(Whereupon, the witness is reading the document.)

A Okay.

Q (By Mr. Siri) So here are the FDA approved

package insert that was written by the manufacturer for Engerix-B describing the clinical trial experience relied upon to license this product. And how long did they review safety in the clinical trial relied upon to license Engerix-B?

A Four days.

Q All right. So that's not a conspiracy theory either that the HepB vaccine, for example, was only -- where the safety was only reviewed for four days prior to being licensed; correct?

A That's correct.

Q Are you aware that the FDA also issues a summary basis of approval for each vaccine that it licenses?

A I believe that is correct.

Q And that would also describe the -- the period that safety was reviewed; correct?

A Presumably so.

Q And there would also typically be a peer-reviewed study that would be published describing in more detail the clinical trial relied upon for -- that was conducted for each vaccine; correct?

A I don't know if that's correct or not. I don't remember seeing vaccines come out from a drug company and then some researcher somewhere did that study for every time they did that. Now, there's -- the -- the clinical trials involve a study, but an -- but an unrelated study by somebody else about that vaccine, every time that it's approved, I -- I'm not aware that that always happens.

Q What I meant is there's a principal investigator typically for each clinical trial; correct?

A That's correct.

Q And then there are individuals who actually undertake the clinical trial, right, underneath the principal investigator; correct?

A You don't mean --

Q Like, for instance --

A You mean the doctor.

Q The doctors, for example. For example --

A Yeah.

Q -- for some clinical trials, in fact, you were -- for the Prevnar vaccine, you participated in that clinical trial; correct?

A I did that myself, yes.
Q Right. You did that yourself. And, you know, the -- and then there will be, you know, some of the -- the -- there will be often a -- an article written about the clinical trial describing it in a bit more detail that will be published in the peer-reviewed literature; correct?
A I guess there could be.
Q Okay. You're just not aware?
A I'm just not aware of it. And with -- I'm assuming that you're not talking about the drug company themselves publishing an article in Pediatrics, for example. I don't know that I've seen articles written by drug companies in the medical journals that I would see. I guess they publish something.
Q Yeah, well, it's another opportunity to publish, you know, a peer-reviewed study; right? So, for example, here is a peer-reviewed study that described that clinical trial that we just looked at, right, for hepatitis B?
A Uh-huh, yes.
Q And -- and you can see here it confirms the

reactogenicity of the vaccine was assessed on the day of vaccination for three days afterwards using individual checklists completed either by the vaccine or in the case of children by their parents; correct?

A Correct.

Q I just wanted to ask you if you were aware that -- you know, that the summary for basis of approval from the FDA and the peer-reviewed study also confirmed that, in fact, it only reviewed safety for four days, but you've already established you don't -- you're not aware of either of those. Okay. So that's the first time that you've ever learned that safety of this product that you've been giving to newborns for years was only -- had safety review for four days prior to licensure; correct?

A From what you've shown me, that's what it says, and so I don't have any reason to believe anything else. I don't have any other data that says anything different, so --

Q Okay. Well, if you're at all unsure, let's take a look also at the summary for basis of approval from the FDA. Okay. Have you ever seen

this document before?
A No.
Q Okay. And this is entitled Summary for Basis for Approval -- of Approval; correct?
A Correct.
Q And this is for Engerix-B; correct?
A Correct.
Q Let's scroll down to the clinical studies. Can you please read the yellow portion?
A Out loud?
Q Sure.
A Adverse reactions were solicited using a symptom checklist by recording clinical signs and symptoms reported by all of the vaccinees both immediately post vaccination and for four days thereafter.
Q And you now have this marked as an exhibit so you'll have an opportunity to read the entire thing, and you can see if it says anything else, which it does. Okay. So the claim that -- you know, assuming the FDA is correct, the package insert is correct, and the peer-reviewed study are correct, is it also a conspiracy theory to claim that the HepB vaccine given to newborns was

licensed based on only a few days of safety review prior to licensure?
A In the documents you've shown me, that's what that says.
Q Are you aware of any documents that show anything different?
A No.
Q If you're only assessing safety for four days prior to licensure, before licensure, do you know whether the adverse -- an -- the vaccine can cause an adverse event on day seven?
A If you're talking about me alone and you're just looking at what that says, I guess not.
Q Well, let me ask you this. And is reviewing safety for four days long enough to assess whether that vaccine did or did not cause autism prior to its licensure?
A I'm not in a position to make that judgment, but others apparently have.
Q Meaning you -- you don't -- you don't know whether or not the clinical trials relied upon to license the vaccines that Yates received were designed to determine whether or not they caused autism before the products were licensed; correct?

A I don't know if the studies were designed to see if Engerix caused autism. I think nobody suspected that it might. There probably was no reason to look for autism after hepatitis B vaccine. I'm not in a position to say whether the study that got that approved was adequate or not regardless of the number of days, but somebody was, and it got approved, and then it got put into the recommended vaccine schedule, and although the CDC showed all those ingredients, nonetheless, their basic statement is vaccines are safe and you should get immunized against hepatitis B.

Q We should also be concerned though about the children who could potentially be injured by that product; correct?

A You're -- in the general sense that you're concerned about children, yes.

Q And that vaccine was made with recombinant technology; correct?

A I don't remember from the slide you showed me earlier the ingredients of that vaccine.

Q Are you aware that -- are you aware that prior to Engerix-B and Recombivax HB, there had never been a vaccine that was created using

recombinant technology?
A No.
Q Okay. Do you know what recombinant -- do you know what -- when I say recombinant technology to develop a vaccine, do you know what that means?
A I probably did at one time, but right this minute, I would have -- I would be hard pressed to explain it.
Q Okay. Do you know what a HepB -- the HepB antigens as it were that are created using recombinant technology, do you know what they're grown in?
A No.
Q Well, they're grown in yeast, which is hence the yeast sensitivity contraindication. All right. Let's move on to Prevnar. So with regards to -- you said you participated in the Prevnar 13 clinical trial; right?
A That's correct.
Q So you -- yeah, sorry. You had an opportunity to review that clinical trial firsthand; correct?
A Correct.
Q Okay. Now, in that clinical trial, some

children received Prevnar 13; correct?
A Correct.
Q And that was the experimental group; right?
A Correct. I'm trying hard to remember the protocol, but certainly, yes, there was a group that got Prevnar 13 and they were looking to draw blood to see how -- what the antibody response was.
Q And the -- and the -- what did the control group receive in that clinical trial?
A I'm confident they didn't receive nothing. It might have been the Prevnar 7, but I just do not remember the details of that study.
Q Right. Well, let's pull it up.
MR. SIRI: So we're going to mark this as Plaintiff's --
MS. CHEN: Exhibit 7.
(Whereupon, Exhibit No. 7 was marked to the testimony of the witness.)
Q (By Mr. Siri) Okay. And this is Prevnar 13's package insert; correct?
A Correct.

Q So as we did before, we're going to go down -- sorry, we're going to go down to Section 6.1, to the clinical trials experience. Okay. If you want to take a moment to just read that first sentence.

A I will.

(Whereupon, the witness is reading the document.)

A I have. I assume Prevnar active control is the Prevnar 7 vaccine.

Q That's correct. When it was licensed, it was the only Prevnar, so they just called it Prevnar; right?

A Right.

Q And -- well, yeah. It's also referred to as Prevnar 7. I believe that's what you would have -- what you would have called the prior Prevnar vaccine versus the Prevnar 13 vaccine.

A Like you said, before there was a Prevnar 13, we just called it Prevnar.

Q Okay.

A And then afterwards --

Q All right.

A -- we put the numbers so it would be clear on

what we were talking about.
Q Okay. Now, when I say the term serious adverse event, what does that mean to you?
A The simplistic answer, it's a serious adverse event. It would be something like something happened that required hospitalizations, or certainly death would be there, but it's something that's very serious.
Q Right. It's -- it's the term used in clinical trials typically. You know, it's a defined term that you engage in a certain number of clinical trials, and so there's often a review of serious adverse events in these trials that are longer than just adverse events; correct?
A Correct.
Q Okay.
A They frequently just stop the trial if one was reported.
Q Correct. So typically it would mean death, permanent disability, hospitalization, or some other equivalent very serious condition; correct?
A That category of event, yes.
Q Would that be your understanding of serious adverse event?

A Yes.
Q Okay. And in your experience within a, you know, typical six-month period of children from birth to 18 years of age, which would also include many periods of time where kids aren't vaccinated, what percentage of kids do you think -- otherwise healthy children would experience a serious adverse event in a six-month period of time?
A Can you repeat that to make sure I'm clear?
Q Sure. In your, you know, almost 40 years as a pediatrician treating children of all ages, including children, you know, beyond the first year of life when they're getting relatively fewer vaccines, you know, in many years none, my question is, what percentage of children that you treat in your practice in a six-month period who are otherwise previously healthy would typically -- would develop a serious -- would experience a serious adverse event?
A During the period that they were not being vaccinated?
Q Yes, during the period they were not being vaccinated. Why not?
A I would expect zero.

Q Okay. And has that been your experience, that close to zero percent of children in your practice had a serious adverse event in most six-month periods of time?
A Yes. I don't see children having serious adverse events within a six-month period during the time which -- in which they have not been vaccinated.
Q I'd like to show you --
MR. SIRI: I'm going to mark this as Plaintiff's --
MS. CHEN: Exhibit 8.
(Whereupon, Exhibit No. 8 was marked to the testimony of the witness.)
Q (By Mr. Siri) And this is the FDA's definition of what is a serious adverse event. Just to make sure that we're on the same page, I'd like to give you an opportunity to just read through this.
(Whereupon, the witness is reading the document.)
A Okay.

Q Let me know when you're ready for me to scroll down.
A You can scroll down.
Q Okay.
(Whereupon, the witness is reading the document.)
A Okay. I'm finished.
Q Okay. So the -- I just want to make sure that the definition of serious adverse event that we discussed earlier that you said you had, is this the same definition of serious adverse event?
A Yes, it includes the things that we both discussed a few minutes ago.
Q Okay. So here is the serious adverse event profile for the study that compared Prevnar 13 to Prevnar 7. Take a moment to take a look at that.
(Whereupon, the witness is reading the document.)
A Okay.
Q Okay. So now first it explains that most clinical trials for vaccines only reviewed serious adverse events for up to 30 days; correct?
A It said 30-day post-vaccination period used in some clinical trials.

Q Yes.
A Okay.
Q Fair enough. In this one though, unlike the other vaccine clinical trials that it's referring to for other vaccines, serious adverse events weren't reviewed for only 30 days, they were reviewed for a six-month period after vaccination; correct?
A If that's what it says. I don't see the six months, but yes.
Q I apologize.
A Oh, it's up there, yeah. Sure.
Q Okay. So and then what percentage of the infants and toddlers had a serious adverse event who received Prevnar 13?
A 8.2.
Q And what percent of children received Prevnar had a serious adverse event in that six-month period?
A 7.2.
Q Okay. Now, because the experimental group and the subject group had a similar serious adverse event profile, the license was, as a technical matter, deemed safe for licensure by the

FDA; correct?
A I'm sorry, say that again.
Q Sure. In these clinical trials, as long as the experimental group and the control group have similar profiles, they're considered safe and acceptable for licensure; correct?
A I'm not involved in the licensure and so it -- I guess that's what they look at.
Q Okay. As a matter of just -- I understand that you're not involved in clinical trials, but as -- you know, as a matter of just basic logic, right, in order to say that Prevnar 13 -- that the outcome for Prevnar 13 has an 8.2 percent serious adverse event rate and Prevnar has a 7.2 adverse -- Prevnar has a 7.2 percent adverse event rate, presumably Prevnar should have been licensed -- well, the -- presumably would have been licensed based on the clinical trial in which it was compared let's say to a placebo and, in fact, had its safety profile confirmed before it was licensed; correct?
A That would be --
MR. SANDERS: Object to the form of the question.

A That would be presumably correct.
Q (By Mr. Siri) Because you'd need to -- in order to say that -- because if you could have -- as long as you had confirmed in a clinical trial that Prevnar was, in fact, safe before it was licensed, you could then use it as a control and at least as some degree of confidence that these numbers aren't highly concerning; correct?
MR. SANDERS: Object to the form of the question. You can answer, Doctor, if you have an answer.
A I don't know how to answer that. I -- presumably.
Q (By Mr. Siri) Okay. Do you know what the control group received in the clinical trial relied upon to license the Prevnar 7 vaccine?
A No. I haven't seen that study. It's possible they just measured antibody levels, but I just don't know anything about that study.
Q You've administered the Prevnar 7 vaccine -- you've -- you have -- you have prescribed to be injected the Prevnar 7 vaccine numerous times during your time as a pediatrician; correct?
A Yes.

Q Okay. So here is the Prevnar 7 vaccine's package insert; correct?
A Correct.
MR. SIRI: And this is going to be marked as Plaintiff's Exhibit --
MS. CHEN: 9.
(Whereupon, Exhibit No. 9 was marked to the testimony of the witness.)
Q (By Mr. Siri) So let's scroll down to the clinical trial experience, and you'll have an opportunity, Doctor, to review this before trial because it doesn't sound like you've seen -- you've really looked at these before, all right, so you'll have an opportunity to carefully study these before trial. But with that said, let me focus you on -- in on the -- oh, the first time we encounter a -- the term control in one of these studies, it provides a little cross next to the word control; correct?
A Yes.
Q And what was the vaccine licensed -- what was the vac -- excuse me. What was the control used

in the primary clinical trial relied upon to license the Prevnar 7 vaccine?
A Meningococcal C.
Q And it was an investigational meningococcal C conjugate vaccine; correct?
A That's what it says.
Q Meaning it was also an experimental vaccine; correct?
A That would be my assumption, yes.
Q There was no pneumococcal vaccine, which is what Prevnar is, that was licensed for children under 2 when the clinical trials of Prevnar 7 were occurring; correct?
A I'm not sure that's correct because I seem like I remember there was an unconjugated vaccine. For children under 2 -- it's polysaccharide vaccine. In children under 2, their immune system doesn't respond to polysaccharide vaccine well. For example, the Pneumovax that adults get is a 23-valent polysaccharide vaccine, and I -- I just -- it's been so long, I can't remember whether we used some unconjugated vaccine before that or not, but they did have a polysaccharide non-conjugated vaccine that was in existence. I

just don't remember whether we gave it to children or not.

Q All right. That's --

A Children don't respond to that type vaccine.

Q All right. That's a 23-valent vaccine; correct?

A Correct.

Q And that was licensed before Prevnar 7?

A I believe so.

Q But it would -- it's only license -- have you -- for children 2 and above. Have you ever given that vaccine to a child under 2 years of age?

A I don't think we did that.

Q Okay.

A It's been so long, I don't remember what our practice was.

Q But -- but --

A We might give it to someone older than that.

Q But even that vaccine wasn't used as a control in this study; correct?

A Correct.

Q Another experimental vaccine was used as a control; correct?

A Apparently it was the investigational meningococcal group C vaccine.
Q Okay. It wasn't a placebo; right?
A No.
Q All right. You'll have an opportunity to look at this, but there was also another smaller study that looked at -- followed for three days that included a control where the control group received comp and Hib vaccines. Do you see that?
A What vaccine did -- take it?
Q Oh, you -- it's all right here highlighted in yellow.
A Okay, yes. I see what it says.
Q But there was no placebo control trial for Prevnar 7 upon which it was licensed. As far as you -- as far as the package insert for Prevnar 7.
A As far as I can see from what I'm seeing, that's the case.
Q I'm scrolling through here so that, you know, you can see the controls. You'll have again, you know -- here's the post-marketing experience. You'll have a chance to review this before trial as well.
MR. SANDERS: Mr. Siri, whenever you get

a chance to take a short break, we've been going a little over two hours. I just need to go to the rest room. There's no rush, but at some point maybe in the not too distant future.

MR. SIRI: Let's take a ten-minute break right now.

MR. SANDERS: Okay. Thank you.

THE VIDEOGRAPHER: We are off the record at 3:34.

(Brief recess.)

THE VIDEOGRAPHER: We're now back on the record at 3:51.

Q (By Mr. Siri) Okay. Well, my co-counsel, Mr. Riley, has asked me to see if we can abridge the rest of this deposition, and I will attempt to oblige him and everybody else on the call. Dr. Stepp, how many conversations have you had with Carol Rudd with regards to anything -- this case or anything to do with this case?

A I do not know Carol Rudd.

Q Does that name sound familiar at all?

A No.

Q Excuse me. Carl Rudd. How many conversations have you had with Carl Rudd with

regards to this case or anything to do with this case?

A I've had zero conversations with him about this case.

Q All right. At any point to -- including today, at any time prior to today?

A Never.

Q How many licensed polio vaccines, stand-alone polio vaccines are there, have there been in the United States since -- that are injectable since 1988?

A I don't know the number of brands of IPV.

Q Okay. Does the brand IPOL sound familiar?

A I think so.

Q Are you aware that that's the only brand of stand-alone I -- inactivated polio vaccine that's been available in the United States since 1988?

A No.

Q Okay. Are you aware that it is very different than the polio vaccine developed by Jonas Salk?

A Is the Salk vaccine the OPV?

Q No, that would have been the Sabin vaccine. The Salk --

A Okay.
Q -- vaccine, I --
A I get Sabin and Salk mixed up.
Q No problem. And so let me ask you again. Are you aware that IPOL is a very different product than the IPV vaccine developed by Jonas Salk?
A I would assume so because of the number of years in between.
Q Okay.
A But I don't know the details of what would make them different, other than if it was an inactivated polio years ago and it still is that the essence of it would be the same, but specific differences I do not know.
Q For example, are you aware that the substrate on which it is grown, for example, has changed from the primary monkey kidney cells, which those are kidneys taken out of a monkey while they're alive, to the vero cells that we looked at earlier, which were the monkey cells that are converted -- they're basically -- they live -- they're -- they don't -- they don't die, they -- they're kind of like cancer cells, they live

forever as the substrate on which the IPOL vaccine -- the polio virus that is used in the IPOL vaccine is grown?

A I don't know anything about the development or the production of these vaccines in that sense.

Q Okay.

A No, so I do not know that.

Q Okay. But some of the ingredients -- being aware of some of the ingredients, of course, is important to know what contraindications or precautions to these products exist as published by the AAP and CDC; correct?

A It's important to know the AAP's list. I don't know if there's any easy way for me to know that any of those contraindications have to do with some monkey cell, nor if it is important for me to know that.

Q But for some of the ingredients, for example, yeast are specifically provided on precaution and contraindication lists, and sensitivity to yeast, for example, is included on the precaution and contraindication list published by the CDC and AAP; correct?

A Yes.

Q Okay. Or for example, sensitivity to some egg components is also listed as a contraindication or precaution to -- for some vaccines that are grown using that material on the AAP and CDC contraindication and precaution list; correct?
A I believe they've lessened the one that involves the influenza vaccine. If that were to come up, I'd refer to the Red Book, see what it said, and act accordingly.
Q Okay. Are you aware that IPOL was licensed based on a clinical trial that only reviewed safety for 48 hours?
A I'm not aware of anything relating to the investigation of IPOL.
Q Okay. Are you aware of anything relating to the clinical trials relied upon to license the MMR vaccine?
A No.
Q And when I say the MMR vaccine, I mean the MMR vaccine that was licensed in 1978 and has been used continuously in the United States since then; okay? Does that change your answer by me giving you that clarification?

A No, but I think they changed the MMR at some point in time.
Q Why did they change it?
A It was so long ago, I don't remember.
Q Okay. Are you aware that the current licensed MMR vaccine called MMR2 was licensed in 1978 after they changed out the rubella components?
A I knew they changed some things. I couldn't have told you the date.
Q They changed it out to add the rubella component because it used to be grown on a different substrate and wasn't as efficacious, but then Dr. Stanley Plotkin developed the current rubella vaccine grown on the human diploid cells, in which he spent a lot of time developing, and he, you know -- which was shown to be more efficacious in the clinical trials conducted for that product. Does that ring a bell at all?
A No.
Q Okay. How many varicella vaccines are there -- have ever been licensed in the United States?
A Don't know.

Q Okay. How many stand-alone varicella vaccines, chicken pox vaccines are currently licensed in the United States?
A My assumption would be one, but I don't know for sure.
Q Okay. Have you ever injected neomycin or -- or ordered its injection into any of your patients?
A Not as a stand-alone. If -- if I discovered that -- by what you're telling me that it's in some of these vaccines, then I -- then I have in that way, but in no other way.
Q Are you familiar with the vaccine HibTITER?
A Yes.
Q Do you know how long safety was reviewed prior to licensing that product?
A No.
Q Okay. How about the DTaP vaccines that you've administered over time, are you familiar with anything about the clinical trials relied upon to license those vaccines?
A No.
Q Are you aware that many drugs like -- drugs licensed by the FDA for adults have safety review

periods that last multiple years prior -- before they're licensed?
A I don't really know anything about studies for drugs for adults.
Q Are you familiar with the drug, for example, Enbrel?
A I've heard of it.
Q It's given to adults typically; correct?
A Correct.
Q And it's given to sick adults; correct?
A Correct.
Q Vaccines are typically given to healthy newborns and babies; correct?
A For the most part. Adults get vaccines too, but -- but yes, certainly the children get a lot of vaccines.
MR. SIRI: Okay. I'm marking this as Plaintiff's Exhibit --
MS. CHEN: 10.
(Whereupon, Exhibit No. 10 was marked to the testimony of the witness.)
Q (By Mr. Siri) And this is a package insert

for Enbrel; correct?
A Yes.
Q Okay. So we'll scroll down to Section 6.1. Can you read the first sentence which describes one of the clinical trials and how long the safety review period was?
A The data described below reflect exposure to Enbrel in 2,219 adult patients with rheumatoid arthritis followed for up to 80 months.
Q And this is in -- and this is in the adverse reaction section of its package insert describing clinical studies experienced with regard to adverse reactions; correct?
A It's under the adverse reactions heading.
Q Okay. Don't you think it would have been a good idea to review the safety of products given to babies for a similar duration prior to licensing them and injecting them into millions of babies around this country?
A I don't know how Enbrel is given. I assume it's given chronically. I think if you're going to take a medicine every day or once a week, I have no idea how it's administered, but presumably over a longer period of time, that would indicate

the need for a longer period of observation because of the continuous taking of the medicine.

Q If --

A Shots are given one at a time.

Q How many doses of DTaP are provided to a child in the first few years of life?

A Five, up to going to kindergarten.

Q So it's given at 2 months of age; correct?

A Yes.

Q It's given at 4 months of age; correct?

A 4.

Q It's given at 6 months of age; correct?

A 2, 4, and 6, yes.

Q And then it's given at --

A About 15.

Q Months of age? And then it's given at around 4 years of age; correct?

A 4 or 5, depending on when they start kindergarten.

Q So there's multiple exposures to DTaP vaccine over a four-year period; correct?

A Yes.

Q That's true for a number of the other vaccines too as well; correct?

A Yes. They get several of them several times.
Q Now, are you aware that there has -- oops. Now, in this case, as we mentioned earlier, you know, Dr. Edwards was -- Kathryn Edwards was deposed in this case, you said you've never heard of her, but she claims that she's a vaccinologist, and have you ever seen -- this is the medical textbooks -- the standard medical textbook for vaccines called Plotkin's Vaccines?
A I have not.
Q You've never seen this before?
A I have not seen that before.
Q Do you see that Dr. Kathryn Edwards is one of the four --
A She is indeed one of the four.
Q And do you see the first listed individual, Dr. Stanley Plotkin?
A I see him.
Q Do you know who he is?
A No.
Q Do you know who Dr. Walter Orenstein is?
A I've heard the name.
Q Okay. In what context?
A It seems like I've heard the name in the

context of infectious diseases.
Q Do you know who Dr. Paul Offit is?
A I know who Dr. Paul Offit is.
Q Okay. How do you know who he is?
A Because he's also an author.
Q Author of what?
A Of books that have medical orientation. He's in a pediatric -- I think he's pediatric, a pediatric infectious disease specialist.
Q Have you been told that Dr. Edwards and Dr. Mace -- well, before we do that, that -- Dr. Mace is a professor of pediatrics at Vanderbilt; correct?
A Correct.
Q She's been training pediatricians for 30 -- or on and off for 30 years there; correct?
A That's what I'm told, so --
Q Okay. Are you aware that both of them have testified in this case that there isn't a single study to support that any of the vaccines given to children do not cause autism other than MMR?
MR. SANDERS: Object to the form of the question. You can answer, Doctor.
A No, I didn't read their depositions.

Q (By Mr. Siri) Okay. If they testified to that, do you have any reason to doubt that their testimony was accurate?
A No, I have no reason to doubt.
Q When did the controversy regarding vaccines causing autism first arise?
A My understanding is it arose when Andrew Wakefield published an article in the Lancet, but I don't know the date of that publication. I'm sure I've read it. I just don't remember it.
Q And what did that study say?
A It said that there was an association. I think in essence that's what it said.
Q And -- and I presume it was in AAP and similar publications where this notion of this whole controversy started with Andy Wakefield. Is that where you learned -- gain -- you know, you -- you came to believe this whole controversy of vaccines and autism started?
A That's what I've been led to believe.
Q Is this the paper that you're talking about that was published by Andy Wakefield in 1998?
A I don't see anything.
Q Oh, I apologize. I have to share my screen.

Okay. There we go.

MR. SIRI: I'm going to mark this as Plaintiff's Exhibit 11?

MS. CHEN: 11, yes.

MR. SIRI: Thank you.

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

Q (By Mr. Siri) So when you say Andy Wakefield's report -- study, which has been retracted, you're talking about this one published in 1998; correct? In the Lancet?

A I guess that's it. I don't know.

Q Well, let's just assume it is, and you can, you know, confirm it later; okay?

A The Lancet, yeah.

Q Yep. Okay. I mean, was the -- there was only one study regarding MMR that they said related to vaccination and autism that was studied -- published in Lancet by Wakefield that you're aware of; correct?

A Correct.

Q Okay. Just -- just look at the -- now,

you're saying that he concluded in here that there was an association between MMR and autism?
A I'm led to believe that's what he said.
Q If he didn't say that, what would be -- would you find that surprising?
A I don't know that I'd be surprised.
Q Okay. Isn't that the roundly-made claim that Dr. Wakefield published a study in the Lancet which claimed an association between MMR and autism and now that has been debunked because this study has been withdrawn -- has been retracted? Excuse me.
A I would think that's what most people's understanding is.
Q Well, you'll have the chance to read this. I mean, it -- you know, on your own and you can see whether or not he actually says that in here, Doctor, for trial. So -- so what you're saying though is that -- this is the study that gave rise to the whole vaccine autism controversy; correct?
A That's what I understand --
Q Okay.
A -- the case to be.
Q What is the National Childhood Vaccine --

National -- I don't want to misstate it. The -- strike that. Let me just go to something else. You know, let's start there. What is the National Childhood Vaccine Injury Act of 1986?

A I think -- I can't answer that the way an attorney would, but it was an act that allowed for compensation to patients or people that are injured by vaccines.

Q And it provided that the companies that made vaccines, the pharmaceutical companies, cannot be sued for the injuries caused by the vaccines; correct?

A That's my understanding, that if you go through them, you can't sue the -- the company.

Q Okay. And in the 1986 Act, all right, which was -- you -- you were around during that period; right? There were parents of children injured by vaccines and they were complaining loudly about the injuries their children -- about their injured children saying that it was the vaccines that caused those injuries; correct?

A That sounds correct, yes.

Q And -- and it was that public outcry by parents that in part, you know, led to the passage

of the National Childhood Injury Act of 1986; correct?

A I guess it is. I didn't keep up with it at the time or try to study how it came to be.

Q Fair enough.

A So --

Q Are you --

A So I don't really know.

Q Are you aware that the 1986 Act based on parental complaints mandated that the Department of Health and Human Services conduct a review of whether or not pertussis-containing vaccine caused certain adverse events?

A I don't know what it required in that regard.

Q Okay. You're not aware that the 1986 Act, the National Childhood Vaccine Injury Act of 1986 mandated that HHS review whether or not pertussis-containing vaccine caused autism?

A I'm learning that just now.

MR. SIRI: Mark this as Plaintiff's Exhibit 12?

MS. CHEN: Yes.

(Whereupon, Exhibit No. 12 was marked to the

testimony of the witness.)

Q (By Mr. Siri) And so you're not a lawyer and you'll have a chance to look at this later, but this is the -- this is the act that enacted the National Childhood Vaccine Injury Act of 1986; okay? And this is a page excerpted in which Congress required studies to be conducted for certain things. Can you please read that, the portion highlighted in yellow? Can you read it out loud?

A Oh, I'm sorry. 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 and the following illnesses and conditions, and number 9 on that list of conditions is autism.

Q So were concerns about whether or not certain vaccines, in this instance pertussis, causing autism, were those raised -- were there concerns raised about vaccines causing autism before Andy Wakefield's article in 1998?

A Apparently they were in this particular instance here because autism is on the list.

MR. SIRI: All right. Mark this as Plaintiff's Exhibit 12? And --

MS. CHEN: 13.

MR. SIRI: 13, thank you.

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

Q (By Mr. Siri) Now, the Institute of Medicine was a creation of Congress; correct?

A I don't know. I guess.

Q And when Congress required the Department of Health -- the Secretary of Health and Human Services to conduct this review of whether or not pertussis-containing vaccine caused autism, are you aware that the Secretary of Health and Human Services then contracted with the Institute of Medicine to conduct that review?

A No.

Q Are you aware that the Institute of Medicine published a report in 1991 that actually reviewed whether there's any science or whether

pertussis-containing vaccine causes autism?
A I am now.
Q Okay. And from -- based on what's in front of you on the screen, can you see what the IOM concluded?
A They concluded that there's no evidence bearing on causal relationship with autism.
Q Meaning there is no study one way or another with regard to whether pertussis-containing vaccine causes autism; correct?
A I don't know what it means in terms of them leading -- leading them to draw that conclusion. All I know is that's their conclusion.
Q Well, you see the second category is evidence insufficient to indicate a causal relation?
A Yes.
Q So that means there's some evidence, but not enough to reach a conclusion; correct?
A I don't know that it implies some evidence. It just says that evidence is insufficient.
Q Okay. What do you think no, no evidence bearing on a causal relation means?
A Well, it means that there's not any.
Q So the concern that pertussis-containing

vaccines was causing autism was well and alive well before Andy Wakefield's study published in 1998; correct?

A Yes.

Q Okay. Now, 20 years later, are you aware that the IOM was again commissioned, this time by an agency within the Department of Health and Human Services called the Agency for Health -- excuse me, Health Research Services Administration, HRSA, and paid for by them and the CDC, are you familiar -- are you aware of that?

A No, I don't know any of this history.

Q Well, they looked at a whole host, about over 150 conditions, and whether or not there's any evidence whether those -- each of those conditions are caused by the vaccine under review. Here they're looking at autism and whether or not pertussis, diphtheria, or tetanus-containing vaccines cause autism. Can you read the causality conclusion?

A The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid, tetanus toxoid, or acellular pertussis-containing vaccine and autism.

Q You'll have an opportunity to look at the rest of this, and what you'll find is that when you review the epidemiological evidence and mechanistic evidence, what you'll see is that they couldn't identify any signs to support that pertussis-containing vaccines, as well as the tetanus and diphtheria vaccine, do not cause autism. Twenty years after the 1991 IOM report saying there's no evidence -- well, I guess we should start with 25 years after the Congress required a review of whether pertussis-containing vaccine caused autism, 20 years after the Institute of Medicine reviewed that question in 1991, in 2011 there still had never been a study conducted of whether pertussis-containing vaccine caused autism. Is that true?

A I don't know.

Q You've -- you've never seen a study -- I mean, the Institute of Medicine's report is 800 pages long and had a giant panel of scientists looking for a study of whether DTaP vaccine did not cause autism. They only found one by Geier and Geier, which did show an association between DTaP and autism. Have you ever seen a study that

showed that DTaP vaccine does not cause autism?
A I've never seen a study that says it does.
Q And Dr. Stepp, have you ever seen this study?
A No.
Q As the title states, it's a pilot study of health -- of the health of vaccinated and unvaccinated 6 to 12-year-old children in the United States.
A Okay.
Q Do you see that?
A Yes.
Q Do you see that it's out of the Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University?
A Yes.
Q Okay. Now, it's a pilot study, right, meaning it's not going to be a large study, and like all the MMR studies you relied upon, it's retrospective. Let's just take a quick look at some of the conclusions in this study when they compared vaccinated to unvaccinated children. Do you see that in unvaccinated children they had about four times the rate of chicken pox?
A Yes.

Q Okay. And it's statistically significant, right, the confidence interval of .2 to .4?
A Yes.
Q And do you see that the children who are unvaccinated have about three times the rate of whooping cough?
A Yes.
Q And it's statistically significant as well; correct?
A That's correct.
Q Do you see that the study when in -- comparing it to the autism spectrum disorder rate, do you see that it found that the vaccinated children are 4.2 times the rate to have autism versus the unvaccinated children?
A I see those numbers, yes.
Q Okay. Was it also statistically significant since it didn't cross the 1 value?
A Not being an epidemiologist, these odds rate shows -- I struggle with them, but the numbers are right there.
Q Okay. So have you now seen a study in which children who received vaccines, including DTaP, did have higher rates of autism compared to those

who haven't?
A You're showing me this study. I don't know anything about that journal. I don't know anything about what others think of this study, and so it's -- it's just not within my --
Q Okay.
A -- expertise to be able to evaluate the results of this study.
Q Well, it's a pilot study of about 600-and-something kids. It was -- had some parental interviews, so there's some recall bias in it and it was also a retrospective, but it was what the person who did it could do on the budget that they had. But you said you'd never seen a study, all right, that supported that DTaP can cause autism, but now you've seen one study; correct?
MR. SANDERS: Object to the form of the question.
A I'm looking at this study, but I don't have the expertise to evaluate the study.
Q (By Mr. Siri) Fair enough.
A And I don't know anything about the journal.
Q All right.

A If I had heard of the journal, I might have more confidence.
Q Okay. I mean, it might be that the study, as I said, based on parental surveys and with the small sample size, it's a pilot study, would certainly be good to have a larger study with more kids; right?
A Sure.
Q And it would be good to look directly at medical records, not parental surveys; correct?
A If -- that would sound good.
Q Yeah, and but that study has never been done, has it?
A I don't know. Not that I know of.
Q All right. Well, that's true. How would you know? But here's the other -- I shouldn't have asked you if it's ever been done. I should ask you has it ever been published, because that's something you could know.
A I could know, but I do not know.
Q Okay. The -- you know, the clinic, The Jackson Clinic has got this video about autism that I'd like to play for you for a moment. It's just going to take me a second to pull it up.

Let's see if I can pull this off, so to speak.

THE VIDEOGRAPHER: If you're going to share, be sure to take -- click off those little boxes on the bottom about computer audio.

MR. SIRI: Yes. Absolutely. So let's see. Oops. Sorry. Just a second. And -- I apologize. Hopefully I'll have this in a minute. Okay. Here we go. Sorry about that. Okay. Sorry. I apologize. I think I've got it. I was trying to get it to -- all right. I'm just going to play it from the -- from The Jackson Clinic website. I was trying to do it a different way, but so be it. Okay. I'm going to mark this video right here from The Jackson Clinic website as Plaintiff's --

MS. CHEN: Exhibit 16.

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

Q (By Mr. Siri) Okay. All right. Actually, to make sure that my -- you can hear the audio, let me make sure that I've clicked the right button. Okay. Here we go, and --

(Whereupon, a video clip was shown.)

THE VIDEOGRAPHER: Only audio is playing.

MR. SIRI: I'm sorry. You couldn't see the video?

THE VIDEOGRAPHER: No, it's just audio. We're seeing a Word document displayed.

MR. SIRI: I showed the wrong screen.

THE VIDEOGRAPHER: I --

MR. SIRI: That's weird. Really --

Q (By Mr. Siri) Well, could you hear what she said? Well, you couldn't see that it's from The Jackson Clinic. So much for --

A I could see that it was from The Jackson Clinic.

Q You could see the video?

A I -- there was video in the first couple of seconds and then it went to something else but the audio continued.

Q Okay. I want to see if I can fix that.

MR. SIRI: To the extent that any document was being shown on the screen, that's obviously work product or privileged. Please make

sure to delete any captures of that document.
Okay, Mr. Sanders?
MR. SANDERS: Yes.
MR. SIRI: Thank you.
MR. SANDERS: I don't have it captured.
MR. SIRI: Okay. All right. So let's -- we'll try it one more time and then we'll just move on. Okay. Last try. Can everybody see the video?
MR. SANDERS: Yes.
THE VIDEOGRAPHER: Yes, and the website.
(Whereupon, a video clip was shown.)
Q (By Mr. Siri) Okay. So that was a video from The Jackson Clinic; correct?
A Correct.
Q Do you recognize the individual in the video?
A I recognize an individual, but not the one that was just speaking. She was hired after I left.
Q Okay. And she identified a number of risk factors for an increase in autism; correct?
A Correct.
Q One of those was being born premature;

correct?
A Correct.
Q Okay. Now, I showed you in one of the studies that was done by that group out of Jackson State -- well, I'm going to show you one more. Have you ever seen this study? Preterm Birth, Vaccination, and Neurodevelopmental Disorders?
A No.
Q Okay. Take a moment to read the yellow portion to yourself.
(Whereupon, the witness is reading the document.)
A Okay.
Q Okay. Now, without asking you about the validity of this study or whether its results are correct, this study does though claim that what it found was that children who were born preterm and vaccinated have 14.5 times the rate of children that were born that were not preterm and not vaccinated, that the vaccinated children have 14.5 times the rate of NDD, which was defined as ADHD and autism spectrum disorder and learning disability.
A That's what it says.

Q Okay. But you've never seen this study; correct?
A I've never seen that study.
Q Okay. Are you aware that -- that there have been studies that -- that found a three-time risk among children that got HepB vaccine in the first month of life compared to those that didn't get HepB vaccine, three times the risk of autism?
A No.
Q Okay. I want to make sure you've never seen this study. Have you ever seen this study, Doctor?
A No.

MR. SIRI: Okay. This is going to be Plaintiff's Exhibit --

MS. CHEN: 18.

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

Q (By Mr. Siri) And take a moment to read the yellow.

(Whereupon, the witness is reading the document.)

A Okay. I've read it.
Q Okay. And this study, without casting any conclusion about its, you know, validity or -- or anything else about it, this study though found that children who received HepB in the first month of life, compared to those that don't, have three times the rate of autism spectrum disorder; correct?
A That's what this states at the yellow.
Q Okay. Let me ask you this. Okay. Assume -- let's assume the Institute of Medicine is correct, as well as subsequent reviews by an agency within HHS called the Agency for Healthcare Research and Quality, who neither of which was able to find any study that showed that DTaP vaccine doesn't cause autism, and let's further assume that just as the AHRQ found, they couldn't find -- there was no -- they didn't find a study that HepB vaccine causes autism. And as far as, you know -- as far as -- apparently I'm aware and Dr. Edwards is aware and Dr. Mace is aware, there are no studies that showed that any of the other vaccines that Yates received other than MMR have a study which showed it doesn't cause autism.

A Okay.
Q Shouldn't you wait until you do have a study that supports that DTaP vaccine does not cause autism to then claim that DTaP vaccine does not cause autism?
A You're asking that to a person who has no influence with the committee on infectious disease at the Red Book, and that's not a decision for me to make. It would be a decision for them to make before they recommend it, and so I -- and I -- so I don't have a good answer. I know when you're trying to do a study that proves the negative that there could be a philosophical debate about trying to prove any negative.
Q Well, aren't --
A Generally the philos -- I'm sorry.
Q Yeah, didn't you claim that there are -- well -- well, then -- then, you know, it appears that the CDC and everybody else are philosophers or something. Is that correct?
A It --
Q Strike that. Strike that. Isn't it -- didn't you claim earlier that studies have been done to show that MMR vaccine does not cause

autism?
A I think I said that there's studies that show no association with autism.
Q Okay. Are there any studies which show no association between DTaP vaccines and autism?
A I do not know.
Q Okay. Assuming there are none, as a practicing pediatrician for almost 40 years, if a parent asked you, Doc, does DTaP vaccine cause or does it not cause autism, and assuming you were not aware of a single study that showed no association between DTaP and autism, wouldn't it be premature to tell that parent that DTaP vaccine does not cause autism?
A I wouldn't go about thinking about it in that way. I think that I have to depend on the consensus of the experts who make the recommendations, and they certainly recommend pertussis vaccine, so I would tell them that -- that it's the recommended vaccine. I also know that if you stop giving pertussis vaccine, you'll have an outbreak of pertussis, so I would still recommend it based on the consensus of the people I depend on.

Q But I'm asking you, if there's no study to support that DTaP vaccine does not cause autism, isn't it as a matter of logic, as a matter of science improper, invalid to state that DTaP vaccine does not cause autism?

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

A No.

Q (By Mr. Siri) So even in the absence of science to support that DTaP vaccine does not cause autism, you would still tell a parent that DTaP vaccine does not cause autism?

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

A I don't try to keep current in these vaccine studies that you're referring to. However, if you're trying to do a study that proves a negative, like this does not cause that, and you have evidence over a period of time that there's no evidence that it does, then after a while, you have to be satisfied with that data instead of doing one test after another test, trial, trying

to prove the negative. I -- I think there's just a point in time you just go this doesn't cause that.

Q (By Mr. Siri) Okay. Meaning --

A But --

Q Right. Meaning parents are widely complaining that pertussis vaccine causes autism, so you go out and you test the hypothesis and the number of studies, and if you can't find an association, then you say, that vaccine doesn't cause autism; correct?

A Okay, yeah.

Q But if you don't do the studies, despite parents complaining that that vaccine causes autism all the way back before 1986, and you haven't done any studies at all regarding whether DTaP -- to see whether there's an association between DTaP and autism, and the only study out there that the parent could find is that Mawson study we looked at that did show an association, isn't it premature to tell that parent DTaP vaccine doesn't cause autism?

MR. SANDERS: Object to the form of the question. He's asked -- been asked and has

answered that question.
A The burden of that decision was not on my shoulders. It was on other people's shoulders, so I didn't make that decision. Other people came to the conclusions they did on their basis, whatever that may have been, so if the Red Book recommends that you do be immunized against pertussis, I rely on their consensus and advice and I don't --
Q (By Mr. Siri) But --
A -- try to reinvent the wheel by doing some study on my own.
Q I didn't mean to cut you off. Are you finished? I'm sorry.
A I -- that's enough, yeah.
Q Okay. Does the Red Book state anywhere in it that DTaP vaccine does not cause autism?
A I'd have to look at it to see, but I suspect that it doesn't. I think it probably addresses the controversy, but again, I'd have to have it in front of me.
Q But you're certain that DTaP vaccine does not cause autism?
A I am personally satisfied that it does not.
Q And you base that on?

A There's no evidence that it does.
Q And you're okay with the fact that parents have been complaining that pertussis vaccine is a cause of their child's autism for at this point over 24 -- 34 years, but yet, no study has been done to see if there's an association between pertussis vaccine and autism?
A In my personal --
Q You're okay with that?
A In my personal experience, I never had a patient complain about there being a possible association between DTaP and autism. Now, I have had them with the MMR and autism, but I never experienced that, so if they're complaining, they're not complaining to me, and I have to be okay with the consensus of the medical community as to what to do about vaccinations, and the consensus is that they should be administered.
Q All right. That's -- that's a different question though. I'm not asking you what -- the consensus about administering vaccines. I'm just -- I'm asking you a different question, and I understand that it's a difficult question to answer and you don't want to answer it. I'm just

asking you something quite far more basic than that. I'm asking you if there are no studies to support that a certain vaccine doesn't cause autism, shouldn't you wait until there is? Shouldn't you wait until there's -- the science has been conducted one way or another before you reach a conclusion about whether the vaccine causes autism?

MR. SANDERS: Same objection.

A I think no. I think you go ahead and vaccinate. No, I don't think you need to wait for that study because that study is very difficult to come by. You're trying to prove a negative. And if you do do a study and it, quote, proves a negative, unquote, and somebody doesn't like that, then you have to do another one and then another one, and at some point, you have to just act and trust what you want. It's just difficult to prove a negative --

Q (By Mr. Siri) But again --

A -- in a study.

Q Right. But again, the -- for the MMR vaccine, it does, but yet, nonetheless the CDC states, right, categorically vaccines do not cause

autism; correct?
A That's my understanding of what they say, as well as the AAP.
Q They don't say no association has been found or not found. They say vaccines do not cause autism; correct?
A Correct.
Q And the AAP says that; right?
A Correct.
Q Okay. So you think it's okay to ignore parental complaints regarding pertussis vaccines and autism because -- let me just finish the question -- and conduct no studies regarding whether pertussis-containing vaccine causes autism, even though it's given at 2, 4, and 6 months of life, well before any MMR vaccine, because you don't think -- because you just are going to rely on what the AAP and CDC say.
MR. SANDERS: Object to the form.
A I'm going to rely on what the AAP says.
Q (By Mr. Siri) Okay. And you're not -- and -- and you are okay with those parental concerns going uncalled and unresponded to in the scientific literature regarding where parents

complain that pertussis-containing vaccines are causing their children's autism?

MR. SANDERS: Same --

A I have never had a patient complain that they think DPT causes autism.

Q (By Mr. Siri) It --

A So I'm not hearing that complaint.

Q And that -- your experience would be anecdotal though; correct?

A Well, yes, it's just me.

Q Yeah, and your experience is similar to the parents who claim a vaccine caused an injury and they're told, hey, that's anecdotal, you're just --

A Sure.

Q Right?

A Right.

Q We like to rely on properly controlled studies; right?

A Okay.

Q Would you agree that to reach a determination of whether there's a causal relationship, you should have properly designed studies?

A Studies are great, and so whatever study is

fine, but again, studies to prove a negative are difficult, and if I were to call up the AAP and say I'm not satisfied with your studies, you need to do more, I don't think they would talk very long to me.

Q So you don't --

A I don't know what influence I could have if I agreed with you.

Q So you're saying that because it might be difficult, despite parental complaints for 34 years that pertussis-containing vaccines don't [sic] cause autism, we shouldn't even -- the scientific community shouldn't even publish one study, not even one, one looking for an association between pertussis and autism, they should just not do any science on that question; correct?

A I'm not saying what they should or shouldn't do.

Q Uh-huh. Isn't it true that studies have been done regarding MMR vaccine and autism?

A I know studies have been done. The exact nature of those I couldn't tell you.

Q You had no issue earlier in this deposition

saying that those studies have concluded that there's no association between MMR vaccine and autism; correct?

A Apparently the CDC and the AAP have had no problem and therefore they made their conclusions and I'm following their advice.

Q And you'll follow their advice irrespective of how substantiated or unsubstantiated it is; correct?

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

A Yes.

Q (By Mr. Siri) Okay. So what serious adverse events are you aware of that vaccines can cause?

A I think we went over this earlier and they're written in the Red Book. Certainly you can have an immediate allergic reaction, and if you want me to list them, it would be easier if I read them out of the book.

Q Sure.

A I don't have the book.

Q Oh, okay. But the serious adverse events that you're saying vaccines can cause, you're saying the ones listed in the Red Book are serious

adverse events that vaccines can cause; correct?
A I think the Red Book's list of those is correct.
Q Have you ever conduct -- do you consider yourself an expert in any regard with -- when it comes to aluminum adjuvants?
A No.
Q Have you read any studies regarding aluminum adjuvants?
A No.
Q Do you have any knowledge whatsoever about the mechanism of action that aluminum adjuvants have in the body?
A I have no idea.
Q You're not aware that -- that there's a long series of studies that shows that aluminum adjuvants are taken up by macrophages and then after going to lymph nodes are deposited in various organs including the brain?
A I'm not aware of it being deposited in the brain, but that's the usual mechanism for foreign material in the body, for the --
Q But if --
A -- lymph nodes it goes -- it's eliminated

other ways. I don't think it goes to the brain, but no, I'm not aware of these studies.

Q But if animal studies shows that after injecting animals with aluminum adjuvant and then sacrificing them, the aluminum adjuvant was found in the brain in those studies, would that change your opinion?

A For those animals.

Q Well, we don't typically sacrifice children after they're vaccinated, do we?

A I hope not.

Q Yes. Is there a better-designed study you could think of other than doing it in animals to see where it goes?

A I have no expertise in designing studies, so I have no idea.

Q You are aware that encephalopathy after a prior pertussis-containing vaccine is a contraindication to further pertussis-containing vaccine; correct?

A Correct.

Q Okay. So that means that if a child had a pertussis-containing vaccine and had encephalopathy within seven days, you would not

give that child more pertussis-containing vaccine; correct?

A That's correct.

Q Okay. Are you aware that the various package inserts for a number of vaccines disclose encephalitis or encephalopathy as an adverse event following those products -- the administration of those products?

A I don't read the package inserts.

Q Okay. Let's see one more.

MR. SIRI: Mr. Lawson, I'm -- I'm -- I mean, Mr. Riley, I'm almost done. I'm going to try to honor your request. I just want to see one other thing.

MR. RILEY: You make it sound like we're a good cop and bad cop. I don't intend to make it like that.

MR. SIRI: Well, I mean, you know, as we talked about it already, you're from Tennessee, I'm from New York. You can be the bad cop.

(Laughter.)

MR. SIRI: You know what, I -- I think I'm almost done. Let's go off the record for just five minutes and we'll come back and I'll wrap it

up very quickly and we can put this one to bed. Sound good, everybody?

MR. SANDERS: Yes.

MR. RILEY: Sounds good.

MR. SIRI: Okay.

THE VIDEOGRAPHER: We are off the record at 4:53.

(Brief recess.)

THE VIDEOGRAPHER: We are now back on the record at 5:01.

Q (By Mr. Siri) Okay. Dr. Stepp, I've got just a few more questions and we'll -- we'll wrap this up. Are you a member of any organization in your community?

A What type of organization are you referring to?

Q Well, let's start more specifically and we can broaden out. Are you a member of any country club?

A Yes.

Q Okay. What country club?

A Jackson Country Club.

Q Are you a member of any other country club?

A No.

Q How long have you been a member of the Jackson Country Club?
A Since 1977.
Q Okay. And are you a part of any civic association or committees in your community?
A No.
Q Okay. Are you a member of any religious organization?
A Church.
Q Okay. What church is that?
A Fellowship Bible Church here in Jackson.
Q Okay. Do you attend there regularly?
A Well, the COVID business has --
Q Gotcha.
A -- interrupted that, but yes.
Q Okay. Any other church that you attend?
A No, just the one.
Q Okay. And so more broadly, are there any other types of community groups, gatherings, formal or informal, that you participate in in your community?
A No.
Q Okay. So any social clubs?
A Not that's a -- not that's a formal club, no.

Q Is there an informal kind of club that you participate in?
A Well, within the Jackson Country Club there's an informal group of golfers that I play with, if that's what you mean.
Q Okay. Let me -- as you -- I'm not -- I'm not trying to pry. It's a jury trial, and obviously your connection to the community are -- you know, as doc -- and Mr. Sanders understands why I'm asking these questions, so that's why, you know, I'm asking the questions. Not -- I'm not trying to get into what you're doing day to day otherwise. Okay. It's only because it's relevant to the case. So and then -- and your wife, is she a member of any community -- you know, community organizations or country clubs or -- or any other social, formal or informal, group other than the ones you've already listed that you're a part of?
A Other than the ones that I've listed, no.
Q Okay. All right. Do you -- have -- have you ever had your patients sign any consent form before they are vaccinated?
A No.
Q Okay. And do you know who Dr. Ed Hazlehurst

is?
A Yes.
Q Do you consider him to be a person who is by the book?
MR. SANDERS: Object to the form of the question.
A I don't know him well enough to categorize him in that way.
Q (By Mr. Siri) Do you consider -- to the extent that you do know him, do you consider him to be somebody who has integrity?
A Yes.
Q Okay. How long have you known Dr. Ed Hazlehurst?
A He was doing general surgery, I'm pretty sure, when I moved to town, and you would occasionally run into each other in the hall of the hospital or something like that, so there may be some mutual patients in the hospital.
Q And over the years you've had conversations with him in those contexts?
A Some, not a lot.
Q Okay. Have you ever had conversations with him outside of the hospital?

A Once.
Q What was that about?
A He did not like the rules associated with the swimming pool at the country club, and I was president of the country club at the time, and so the general manager and I had to discuss with Dr. Hazlehurst his preferences for the swimming pool.
Q Was it --
A I'm being serious.
Q Was it a civil discussion?
A It was pretty good, yeah.
Q Okay. What was the outcome?
A He understood that we weren't going to change the rules for him. He wanted to swim at night by himself and we -- we turned the lights out, and he wanted them on so he could swim late at night.
Q And he respected your decision?
A Yes. There was no lifeguard. We were worried that something would happen to him.
Q Fair enough.
A So we -- it -- I think he just -- we resolved that amicably, I believe.
Q And then in terms of your discussions in the

hallways at the hospital, I presume those are typically about patients?

A They'd be about patients. We knew each other enough to say hi as we passed each other. Otherwise it was just about specific patient care, and The Jackson Clinic has surgeons of their own, and so most of my patients were seen by them. It would just be the occasional patient. And later he started doing gastroenterology, and of course, that didn't pertain to pediatrics at all.

Q Understood. I'd like to just show you one last exhibit, and I promise that -- Mr. Riley, that will be it. Let me just share my screen.

MR. SIRI: Mr. Lawson --

THE VIDEOGRAPHER: Yeah, stand by. You have the power.

MR. SIRI: Thank you.

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

Q (By Mr. Siri) Okay. Dr. Stepp, have you ever seen this page on the American Academy of Pediatrics website?

A I may have. I don't remember.
Q Okay. Do you see that it's in -- at the top left is the logo of the American Academy of Pediatrics; correct?
A That's correct.
Q And that is the logo of the American Academy of Pediatrics; correct?
A That is correct.
Q Okay. And have you ever seen the -- this page titled Corporate Friends of Children Fund Members?
A It seems like I've seen Friends of Children, but I don't remember it being corporate.
Q Excuse me. I apologize. Well, it says right above it corporate -- I was reading it from right here.
A Right. I see that. But in the past I've never seen the corporate.
Q Understood. This is www.aap.org is the AAP website; correct?
A Correct.
Q And these are companies that have donated more than $50,000. This is provided on an annual basis to the AAP; correct?

A That appears to be correct.
Q Merck is the manufacturer and seller of vaccines; correct?
A Correct.
Q Sanofi Pasteur is a manufacturer and sells vaccines; correct?
A That's correct.
Q Between the two of them, they would -- they would actually comprise the majority of the vaccines on the CDC and AAP's childhood immunization schedule; correct?
A They -- they would comprise a large percent. I wouldn't know what the percentage is, but yes, they make a lot of vaccines.
MR. SIRI: Okay. Well, Mr. Sanders, would you like to end the deposition now?
MR. SANDERS: I have no further questions, so if you don't have any more, yes, I'd like to.
Q (By Mr. Siri) And Dr. Stepp, thank you for taking the time to answer some questions today. We -- I've got -- we could probably spend a lot more time together, but I think that was probably sufficient.

A Thank you.

MR. SIRI: Thank you.

THE VIDEOGRAPHER: Okay. Anything further?

MR. SIRI: Nothing further.

MR. RILEY: Nothing further.

THE VIDEOGRAPHER: All right. This is the end of the video deposition of Dr. William Stepp. Counsel did waive the formal reading of the caption. We are now off the record at 5:11.

(Whereupon, the deposition of William Stepp, 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 4, 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:

_____
WILLIAM STEPP, M.D.

Subscribed and sworn to by me on this the _____ day of _____, 2020.

_____
Notary Public

My Commission Expires:

_____

B

J

Z