PLOTKIN DEPOSITION IN FULL TEXT

ARAVIND MOHANOOR

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Stanley Plotkin Deposition

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Videotaped deposition of Stanley A. Plotkin, M.D. New Hope, Pennsylvania. January 11, 2018. State of Michigan in the Circuit Court for the County of Oakland Family Division. Lori Matheson f/k/a Lori Ann Schmitt, Plaintiff vs. Michael Schmitt, Defendant. Case No. 2015-831539-DM.

[00:00:02]

[Tom Liebman] This is the start of media label number one of the video recording deposition of Dr. Stanley Plotkin in the matter of Lori Mathison, formerly known as Lori Ann Schmidt versus Michael Schmidt, filed in the state of Michigan, the circuit court for the county of Oakland family division. This deposition is being held at 5833 Lower York Road in New Hope, Pennsylvania on January 11, 2018. My name is Tom Liebman and I'm the legal video specialist for TSG Reporting Incorporated, headquartered at 747 Third Avenue in New York City. The court reporter is Maureen Broderick in association with TSG Reporting. Counsel, please introduce yourselves for the record.

[Aaron Siri] Aaron Seary, co-counsel on behalf of plaintiffs.

[Tom Liebman] Amy Ruby, co-counsel on behalf of plaintiffs.

[Laura Nusma] Laura Nusma, counsel for defendant, Michael Schmidt.

[Tom Liebman] The court reporter would now swear in the witness.

[00:01:02]

[Court Reporter] Raise your right hand please, sir. You swear or affirm the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God.

[Aaron Siri] Yes. Good morning, Dr. Plotkin.

[Court Reporter] Can we just make a recommendation? I would just like to clarify that this is being recorded by a video deposition on pursuant to MCR 2.315. Good morning.

[Aaron Siri] Can you please state your full name for the record? Stanley A. Plotkin.

[Stanley Plotkin] Dr. Plotkin, have you been deposed before? A long time ago, many years ago. And what matter was that? Oh, that had to do with an abortion done because of congenital rubella. What year approximately? The 1960s. And what was your testimony about?

[00:02:00] My testimony was about the abnormalities that occur in infants of women born, that is, infants of women who have congenital, who have rubella during pregnancy and whose fetuses are frequently affected with considerable congenital abnormalities. From rubella? From rubella. Did that involve a vaccine? At the time, I was developing a vaccine against rubella, yes. Have you been deposed in any other case?

[Aaron Siri] Not that I can recall, no. Have you ever been an expert witness in any lawsuit other than this one? Again, not for many years.

[00:03:00]

[Stanley Plotkin] I believe I did a couple of those cases in the 60s, but I have avoided deposition since then. Why is that? Because I consider that they seldom bring out all the facts, but I'm willing to help in this case.

[Aaron Siri] I'm going to go over a few rules with you for this deposition. The court reporter has placed you under oath. Same as a court of law, you're testifying under penalty of perjury.

The court reporter is making a record and will take down the questions that I ask and the answers that you provide.

If you don't understand a question, let me know before answering. The court reporter can't take down nods. That's another rule.

[00:04:00] Any time you want to vocalize. Please wait until I complete asking a given question, even if you think you know the answer, so that we have a complete record, please. Don't speculate. If you don't know the answer, then so state, but you should provide your best recollection, even if it's vague or partial. Are you taking any medications or are under the influence of any substance that might affect your ability to testify today? I don't think so, no. Is that no? No. Did you discuss this deposition with anyone? Actually, no.

[Stanley Plotkin] I've had some conversations with Laura Niezma, but not about the substance of my testimony.

[Aaron Siri]

Before today, did you have any discussions with anyone related to this deposition?

[00:05:03] No.

[Stanley Plotkin] Actually, I know very little about the issue here. I understand that there's a disagreement between parents, but that's all I really know.

[Aaron Siri] And you haven't discussed this lawsuit with anyone apart from opposing counsel?

[Stanley Plotkin] No.

[Aaron Siri] How did you first learn about this lawsuit?

[Stanley Plotkin] It was from a lady by the name of Karen Ernst, who was the head of an organization called Voices for Vaccines, which is a group of laypeople who are favorable to vaccination. And she had heard from the father, I believe, who was looking for experts to testify on his behalf.

[00:06:04] So you discussed this lawsuit with her? Not really discussed the lawsuit. She referred me to the father, and I sent an email saying that I would be willing to testify. I have not talked to the father. I've never met the father. So everything has happened secondhand, so to speak.

[Aaron Siri] And it was Karen Ernst who asked you to be an expert in this case? She asked me if I would be willing, yes. And how many discussions have you had with her? No discussions. About this case?

[Stanley Plotkin] About this case. I simply had an email exchange asking me to do it.

[Aaron Siri] Okay.

[00:07:03] I'm going to request a copy of that email chain, okay, Dr. Plotkin? If I can find it, I'll be glad to send it to you. Thank you. So before today, other than speaking with opposing counsel and an email communication with Karen Ernst, you have not discussed this lawsuit, this deposition, or the role that you'd be playing here today with anybody else. Is that right?

[Stanley Plotkin] I've had an email exchange with Paul Offit, Dr. Paul Offit, who is actually a former student of mine.

[Aaron Siri] And who's Dr. Offit?

[Stanley Plotkin] Dr. Offit is a pediatrician at the Children's Hospital of Philadelphia.

[00:08:03]

[Aaron Siri] And what did you discuss with Dr. Offit?

[Stanley Plotkin] I discussed with him the issues or the possible issues about refusal to vaccinate.

[Aaron Siri] Okay. And what was the substance of those discussions?

[Stanley Plotkin] The substance basically concerned what arguments are often used to oppose vaccination.

[Aaron Siri] And what are those arguments?

[Stanley Plotkin] The arguments generally are that vaccines can cause reactions and that the reactions are worse than the disease.

[Aaron Siri] And what did Dr. Offit have to say about that?

[Stanley Plotkin] Well, he pointed out, of course, and he's the author of a chapter in my vaccines book, that the opposite is true, that the disease is worse than the reactions to the vaccines.

[00:09:05]

[Aaron Siri] Do you have peer-reviewed science to support that statement? Do I have what? Peer-reviewed science to support that statement? Yes, of course. And would you be willing to provide that science?

[Stanley Plotkin] Well, the science is in the chapter in my textbook, but there are innumerable references, some of which I have. But I can certainly provide you with a list of references in the chapter.

[Aaron Siri] Have you reviewed any documents to prepare for this deposition? You know, I've looked at the web.

[Stanley Plotkin] I don't usually do that, but I've looked at the web, some of the anti-vaccination websites.

[00:10:07]

[Aaron Siri] Which of those sites did you look at?

[Stanley Plotkin] Oh, gosh. I can't give you the names. I've just sort of scanned through a number of them.

[Aaron Siri] Do you remember the names of any of them? Let's see.

[Laura Nusma] Dr. Plotkin, just to be clear, if you don't remember something, just say you don't remember, and you can move on from there.

[00:11:03]

[Aaron Siri] Yeah.

[Stanley Plotkin] Well, there's one called VaxTruth, everything you ever needed to know about medical exemptions to vaccination, but didn't know to ask. There were a couple of others that I looked at, many of which were appalling. And why do you believe they're appalling? Because they're ignorant of the facts, exaggerations, half-truths. Or even misconceptions.

[Aaron Siri] VaxTruth, is that a website that catalogs personal stories of families who believe their child was injured by vaccines?

[00:12:07]

[Stanley Plotkin] You know, I did not, what shall I say, read these word for word. I imagine that that's the case, but I couldn't tell you specifically about which website says what.

[Aaron Siri] But you found VaxTruth appalling? Yes. Okay. Other than reviewing what you refer to as anti-vaxxer websites, did you review any other documents to prepare for this deposition? Yes.

[Stanley Plotkin] I looked at a number of vaccine safety studies, which, again, are referenced in the vaccine safety chapter.

[Aaron Siri] And apart from that, anything else? No. Okay.

[00:13:00] Have you provided any documents related to this lawsuit? To whom? Have you, Dr. Plotkin, been provided any documents relating to this lawsuit specifically?

[Stanley Plotkin] No, I have not.

[Aaron Siri] Okay. Have you reviewed any medical records related to this case? Medical records? No. Have you done anything other than what we've already discussed to prepare for this deposition today? No, basically, no. Okay. Have you discussed the child at issue in this case? No. So you don't know anything specific about the child at issue in this case, correct? I do not.

[00:14:07] And you don't know anything about her medical history, correct? Correct. And you don't know anything about her family's medical history, correct? Correct. Have you been on any trips in the last year? How many? Where to? Oh, gosh.

[Stanley Plotkin] Well, several trips to Europe, to France, to Germany. Let's see. Have I been to Asia in the last year? Yes, I've been to Japan. Basically, I mean, of course, many trips in the United States, England, at least a dozen trips.

[00:15:11]

[Aaron Siri] At least a dozen. How many times were you in France in the last year? Oh, gosh. Twice, I think. Germany? Once. England? Once. These were all separate trips? Yes. In which you got on a plane from the United States, flew there, flew back. Okay. Japan, how many times? Once. How many times to other countries outside of the U.S.? Oh, gosh. I probably had about a dozen trips altogether.

[Stanley Plotkin] A dozen trips. Okay. If I had known you were interested, I would have brought my calendar.

[Aaron Siri] How about trips in the United States that required you to get on a plane? How many of those would you say in the last year? Ah.

[00:16:03]

[Stanley Plotkin] Mainly to California. A lot of trips to Washington.

[Aaron Siri] Boston. California, Washington. Same city in California each time or different?

[Stanley Plotkin] No. San Francisco, San Diego.

[Aaron Siri] What were the purpose of most of these trips? Attend meetings, scientific meetings. Were any of them related to companies developing vaccines? Oh, yes. Would you say most of them were?

[Stanley Plotkin] Most of them. Probably about half of them.

[Aaron Siri] Do you have any trips planned for 2018?

[00:17:01]

[Stanley Plotkin] Yes.

[Aaron Siri] Where to?

[Stanley Plotkin] I'll be going to India next month. However, I'm trying to cut down on foreign trips at the moment. I'll be going to Germany in June. Aside

from that, I'll be going to France in May. I think that's all I can recall at the moment.

[Aaron Siri] What's your trip to France for?

[Stanley Plotkin] I'll be teaching an advanced vaccinology course in Annecy.

[Aaron Siri] Where, I'm sorry?

[Stanley Plotkin] Annecy.

[Aaron Siri] What's that, I'm sorry?

[Stanley Plotkin] A-double-N-E-C-Y. It's a town in France.

[00:18:02]

[Aaron Siri] And who's sponsoring this course?

[Stanley Plotkin] Well, it's sponsored by the University of Geneva and the Gates Foundation. Anybody else? No, basically those are the funders.

[Aaron Siri] Okay. And your trip to Germany, what's that for?

[Stanley Plotkin] I'll be going to visit a biotechnology company that is trying to develop vaccines based on RNA.

[Aaron Siri] Do you have a position or affiliation with that company?

[Stanley Plotkin] Simply on their scientific board.

[Aaron Siri] And your trip to India, the purpose of that one?

[Stanley Plotkin] To discuss vaccination against chikungunya virus, which is epidemic in India and in South America.

[00:19:00]

[Aaron Siri] And who are those discussions with?

[Stanley Plotkin] Well, it's under the aegis of an organization called CEPI, which is a coalition to develop vaccines against epidemic diseases. So it's an organization that's received funding from various governments to meet the challenges of epidemic diseases like Ebola and chikungunya, et cetera.

[Aaron Siri] This trip also include meeting with vaccine developers?

[Stanley Plotkin] Well, they will be present at the meeting. They will come and present the results of their efforts to develop a vaccine against chikungunya.

[Aaron Siri] Any trips planned in the United States for 2018?

[Stanley Plotkin] I wish I had known to bring my calendar.

[00:20:01] I have no trips planned this month. Actually, next month. But I will be going to some NIH-sponsored meetings in March, as I recall. And there's a vaccine conference in Washington in April that I'll be going to.

[Laura Nusma] When you say Washington, do you mean Washington State or District of Columbia?

[Stanley Plotkin] District of Columbia. In May I'll be going back to France for the advanced vaccinology course. That's as much as I can remember at the moment.

[Aaron Siri] There might be others, you just don't have your calendar here today, right? Right. And the NIH meetings, where are those taking place?

[00:21:02] In Bethesda. Okay. How far is that from here? From here? Yeah. Do you drive there?

[Stanley Plotkin] Oh, no, no. I take the train to Washington and then the metro to Bethesda.

[Aaron Siri] How long does that trip take?

[Stanley Plotkin] The train is an hour and a half, the metro is maybe 20 minutes.

[Aaron Siri] What's the name of the plaintiff in this case?

[Stanley Plotkin] Well, from what was said before, the plaintiff, I think, is someone named Schmidt. I've not followed, as I said before, I have not been involved in the legal details. So I don't know the names except from what I've heard.

[Aaron Siri] What's the name of the defendant in this case?

[00:22:02]

[Stanley Plotkin] As I understand it, they're a married couple, but that's all I can tell you. So I presume that they're both named Schmidt.

[Aaron Siri] What's the name of their child?

[Stanley Plotkin] I do not know.

[Aaron Siri] How old is their child? I do not know. Do you know whether the child has received any vaccines? I do not know. The name of the child is Faith, and I'll refer to the child as Faith in this deposition, okay? Mm-hmm. Faith's father believes that Faith's mother was wrong to not have given Faith all CDC-recommended vaccines on time. Do you agree with the father?

[00:23:00]

[Stanley Plotkin] Yes.

[Aaron Siri] Is it your understanding that the father wants Faith to receive all vaccines she has missed and continue to receive all CDC-recommended vaccines? That is my understanding, yes. Do you agree with the father that Faith should receive these vaccines?

[Stanley Plotkin] Absent any contraindication, yes.

[Aaron Siri] Sitting here today, do you know whether Faith has any contraindication?

[Stanley Plotkin] I do not know.

[Aaron Siri] So sitting here today, you don't know whether Faith should or should not actually get these vaccines?

[Stanley Plotkin] In the absence of a contraindication, Faith should receive the vaccines.

[Aaron Siri] But you don't know whether she has a contraindication?

[Stanley Plotkin] I do not know the medical history of the child.

[00:24:06]

[Aaron Siri] What vaccines has Faith missed according to the CDC schedule that you believe she should get?

[Stanley Plotkin] Well, the CDC's schedule includes diphtheria, tetanus, pertussis, hepatitis B, haemophilus influenzae, polio, measles, mumps, rubella. I don't know how old she is, so I don't know where to stop. But there are vaccines recommended in pre-adolescence. So she should receive those when she reaches the appropriate age.

[Aaron Siri] So just so I got, just to make sure I understand, you believe she should get the hepatitis B vaccine? Yes. Rotavirus? Yes. DTaP?

[00:25:00] Yes. Hib? Yes. PCV13? Yes. IPV? Yes. The flu shot annually? Yes. IIV? Call it the flu shot? At the moment, yes. I'm sorry, at the moment? At the moment. What do you mean?

[Stanley Plotkin] I mean that there are two influenza vaccines, one of which is recommended for this year. The other is not recommended at the moment, but may be in the future.

[Aaron Siri] You think she should get the recommended one? Yes. And you think she should get the MMR, I believe you said?

[Stanley Plotkin] Yes, and varicella.

[Aaron Siri] And hepatitis A vaccine? I'm sorry? And the hep A vaccine?

[Stanley Plotkin] And the hep A vaccine, yes.

[Aaron Siri] Okay. How many doses of hep B as a child do you recommend they receive? Three. How many doses of rotavirus do you recommend?

[00:26:00] Two or three. And you recommend Faith receive those, right? Yes. And you recommend that she receive the three doses of hep B? Yes. And how many doses of DTaP do you recommend she receive?

[Stanley Plotkin] Well, currently at least three, then a booster, and eventually another booster.

[Aaron Siri] And how many doses of HIV do you recommend she receive? Well, three are usually sufficient. And how many doses of PCV13? Three. And how many doses of IPV or inactivated polio vaccine? Three. How many doses of the flu shot? Well, one per year. And how many doses of MMR?

[Stanley Plotkin] At least two, yes. How many doses of varicella? Two.

[Aaron Siri] And hep A?

[Stanley Plotkin] Two or three. Two is often sufficient.

[00:27:00]

[Aaron Siri] Okay. And those are the doses that you recommend that Faith receive, correct? Yes. Okay. For each of those vaccines we just went through? Yes. Okay.

[Stanley Plotkin] And then there are the adolescent vaccines as well. And what are those? Well, meningococcus is often recommended, and also human papillomavirus vaccine, especially if she is a girl.

[Aaron Siri] But it's also recommended for boys as well. And you recommend that Faith receive those as well, the meningococcus and HPV vaccine? Yes. Okay. Any others?

[Stanley Plotkin] Well, I could look up the vaccine schedule if you wish me to, but I am sure that I agree with all of the CDC recommendations.

[Aaron Siri] How about when she becomes an adult, would you recommend that she get all of the adult, the vaccines that are recommended by the CDC for adults?

[00:28:07]

[Stanley Plotkin] Well, certainly, yes.

[Aaron Siri] Okay.

What are the, can you please tell me the brand name and manufacturer for each of the Hep B vaccines?

[Stanley Plotkin] I do not try to memorize brand names. As I recall, Engerix is the most commonly used Hepatitis B vaccine. Which is manufactured by GlaxoSmithKline. There's also a vaccine manufactured by Merck. I don't remember the trade name at the moment. As I said, I don't try to memorize trade names.

[Aaron Siri] Okay. So for the Hepatitis B, there's a vaccine manufactured by GlaxoSmithKline.

[00:29:02] Can we refer to that either as Glaxo or GSK today? Yes. And there's one manufactured by Merck? Correct. Okay. Rotavirus, what are the brand names and companies that manufacture those?

[Stanley Plotkin]

Well, actually, one of the Rotavirus vaccines I developed, so I do know that the trade name is called Rotatech, and the other one is called Rotarix.

[Aaron Siri] Okay. And who manufactures those?

[Stanley Plotkin] I'm sorry?

[Aaron Siri] Who sells those, manufactures those?

[Stanley Plotkin] Merck manufactures Rotatech, and GSK manufactures Rotarix.

[Aaron Siri] Okay. How about DTaP? Who are the brand names and manufacturers for DTaP? Oh, boy.

[Stanley Plotkin] Sanofi Pasteur manufactures DTaP, and so does GSK.

[00:30:05]

[Aaron Siri] I do not remember the trade names. How about the Hepatitis B vaccine? Can you tell me what are the brand names for those products and the manufacturer? For Hepatitis B? For Hib. I'm sorry. For Hib. I apologize. Did I say Hib? I meant Hib. Which stands for what, by the way, Dr. Plotkin?

[Stanley Plotkin] Haemophilus influenzae type B. Thank you. Well, again, my recollection is that Sanofi and GSK, yes, both manufacture Hib.

[Aaron Siri] Okay. And what about PCV13?

What is the name of the product and the manufacturer of that vaccine?

[00:31:01] I don't remember the trade name, but Pfizer is the manufacturer. Okay. And what about the Flushot? Oh, well, there are multiple manufacturers. Yes, there are multiple manufacturers for Flushot. Let's, in terms of Flushot's – I strike that. We're going to come back to the Flushot and make it simpler. Well, let me ask you this, actually, about the Flushot. What Flushot's – are there any Flushot's recommended for children under one year of age? No.

[Stanley Plotkin] Six months usually is the time, the age at which influenza vaccines are recommended for children.

[Aaron Siri] Okay. And do you know who manufactures Flushot's recommended for children under one year?

[Stanley Plotkin] For children? Yes. I don't remember which of the manufacturers.

There are probably 10 different influenza vaccines, not all of which have been tested in children.

[00:32:04] So there are relatively few for children, all of them manufactured in a chick embryo. But anyway, I don't – I'm sure that the major manufacturers like Sanofi and GSK certainly manufacture influenza vaccines. There's an Australian manufacturer, CSL.

[Aaron Siri] But, I mean, just for – I'm sorry, Dr. Plotkin, just for – by age group, let me make this simpler. Do you know – do you have a recollection of which Flushot's are recommended for which age groups?

[Stanley Plotkin] You mean which manufacturers? Right. No, I don't recollect.

[Aaron Siri] In terms of the IPV, the inactivated polio vaccine, who – what is the product name manufacturer for that?

[00:33:15]

[Stanley Plotkin] I don't remember the trade name, but Sanofi and GSK both make IPV.

[Aaron Siri] Okay. And the MMR vaccine, what is the product name and manufacturer for that one?

[Stanley Plotkin] Merck is the manufacturer. GSK also makes one, but Merck is pretty much the American manufacturer for MMR. Okay.

[Aaron Siri]

And for varicella, the product name and the manufacturer?

[Stanley Plotkin] Well, Merck, again, manufactures varicella vaccine, and GSK also does.

[00:34:05]

[Aaron Siri] And then for the hepatitis A vaccine, who's the – what are the product names of manufacturers?

[Stanley Plotkin] Hepatitis A, GSK is the biggest manufacturer of hepatitis A. Okay.

[Aaron Siri] Is there any – got it. Okay. And then how about the meningococcal vaccine?

[00:35:09] What's the product name and manufacturer for that one?

[Stanley Plotkin] Meningococcal vaccines are manufactured at the present time by Sanofi, by GSK, by Pfizer.

[Aaron Siri] Those are the three. And how about the HPV vaccine manufacturer – product name and manufacturer, please?

[Stanley Plotkin] Merck and GSK both manufacture HPV vaccines.

[00:36:25]

[Aaron Siri] Okay. So every vaccine that you believe faiths to receive is produced by either Merck, Sanofi, GSK, or Pfizer, correct?

[Stanley Plotkin] Yeah, that's pretty much the case in this country at the present time. There are a limited number of vaccine manufacturers because a vaccine manufacturer is difficult and costly.

[Aaron Siri] Would it be correct to call these four companies the big four vaccine manufacturers?

[00:37:02]

[Stanley Plotkin] Yes, that's correct. Johnson & Johnson is attempting to come into the field, but they are not yet one of the major manufacturers.

[Aaron Siri] Have you received any payments from Sanofi or any of its related or predecessor entities?

[Stanley Plotkin] Yes, certainly.

[Aaron Siri] Okay. In what years did you receive payments?

[Stanley Plotkin] Well, first of all, as you should know, in the 1990s, I was medical and scientific director of Sanofi Pasteur, and so obviously I was paid by them. And since then, I've been consulting for manufacturers, for biotechs, for governments, for nonprofits, and essentially for anyone interested in vaccine development.

[00:38:07] And so I have been remunerated by companies, not by nonprofits, obviously, and that is essentially what I do.

[Aaron Siri] Is there a year since 1990 that you've not received any kind of payment or remuneration from Sanofi?

[Stanley Plotkin] Probably not, no. Okay.

[Aaron Siri] How much did you receive? What would you say is the approximate total amount of payments and remuneration you've received from Sanofi during your lifetime? Oh, my God.

[Stanley Plotkin] I have no idea.

I'm sure it's a sizable amount of money, but you'd have to ask my wife, who's essentially my accountant.

[00:39:10]

[Aaron Siri] Is your wife the person that would have the records to know that amount? Yeah, she probably would. Okay. Would you say it's more or less than $100,000? Oh, I'm sure it's more than that. Would you say it's more or less than $500,000?

[Stanley Plotkin] Probably, yes. Over the years, I imagine it is.

[Aaron Siri] Would you say it's more or less than a million dollars?

[Stanley Plotkin] Well, again, I'm not prepared to answer this question, but I am sure it's a considerable amount of money, and over the years, it could well be more than a million. Do you believe it could be a few million? You know, Counselor, I cannot give you a precise figure.

[00:40:00] It is a considerable amount of money, I do not doubt, but I couldn't not give you a specific number because I've never looked at it.

[Aaron Siri] Okay. Well, I'm going to make a request for the documents to understand precisely how much you've received from Sanofi over the years.

[Laura Nusma] I mean, you guys can do any discovery requests that you want, but he doesn't have it with him today, he can't produce it right now.

[Aaron Siri] Your objection is noticed, Counselor. Thank you.

Has any entity in which you directly or indirectly have a greater than 1% ownership interest received any payment from Sanofi or any of its related or predecessor entities?

Could you repeat that question? Sure.

[00:41:00] Any entity. Do you understand what I mean by the term entity, Dr. Plotkin? Are you talking about me personally or? When I say, I'm asking if you understand what the term entity means in that question. No. Okay. Great. So, when I use the term entity, I mean it to include any business, sole proprietorship, company, LLC, LLP, limited liability company, organization, and so forth. Is that clear what entity

means? Yeah. Okay. So, what I'm asking is, any entity, so any business company that you've had directly or indirectly more than 1% ownership interest, okay, has any company like that received money from Sanofi?

[Stanley Plotkin] Well, again, I'm not sure I understand the question, but I am the principal of a company called VaxConsult, which essentially was organized to make things easier from the tax point of view.

[00:42:15]

And that entity, if that's what you mean, has received payments from companies for whom I consult.

So, it's a device, if you will, to make things simpler for the accountant.

[Aaron Siri] Okay. So, who owns VaxConsult? I do. My wife and I do. Okay. And what percent do you own? 100%. Okay. And is there any other company? And payments have been made to VaxConsult by Sanofi? Sure. Okay. And what's the total amount of payments that have been made to VaxConsult by Sanofi?

[00:43:01]

[Stanley Plotkin] Well, again, I do not have an exact number. I am sure that over the years it's a considerable amount, but I cannot tell you exactly how much.

[Aaron Siri] Is there any other company in which you have an ownership interest that's received money from Sanofi? No. Okay.

Do you anticipate to continue to receive payments or any kind of other remuneration from Sanofi in the future?

[Stanley Plotkin] As long as my health holds out, yes. Okay.

[Aaron Siri] And what are those payments for? For advice. Okay. Have you received any payments from Merck or any of its related or predecessor entities?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. And what year did you receive payments?

[Stanley Plotkin] All I can say is since I stopped working for Sanofi, which was in early 2000s, I have consulted for essentially all of the major manufacturers.

[00:44:18] I do not know how much I received, but I certainly received payments from Merck, from Glaxo, from Pfizer, and many other entities.

[Aaron Siri] So what was approximately the first year that you received payments from Merck? Sometime in the 2000s. Would you say that you've received more than $100,000 in payments remuneration from Merck since then? I have no idea. But you would have records that would be able to determine that amount, correct?

[00:45:04]

[Stanley Plotkin] Yes. Actually, I doubt that it's $100,000, but I don't recall. As I said, my wife does the accounting, and I pay no attention to it.

[Aaron Siri] Do you anticipate receiving any payments remuneration from Merck in the future? Sure. You said that you've received payments and other remuneration from GSK in the past. Yes. When did those payments start?

[Stanley Plotkin] Again, I cannot give you a precise year, but as I've tried to say repeatedly since 2000, I've been consulting for many different entities, including GSK and the others.

[Aaron Siri] Do you expect to continue to receive payments remuneration from GSK in the future?

[00:46:01] Yes. I'll ask you the same question about Pfizer. You indicated that you have received payments remuneration from Pfizer. Yes. Do you

remember when you first received any payments from them or any remuneration? No, I don't recall what year that would be. Do you have a sense of approximately how much you've received? No. Do you anticipate continuing to receive payments remuneration from Pfizer? Very likely. Now, all of the payments that you've received from the big four vaccine manufacturers, as we've defined it, they were either made to you directly or through VAX? I'm sorry, what was it? VAX Consul. Or VAX Consul?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay.

[00:47:02] Why don't we try this a little bit of a different way, since it appears your memory over longer periods of time is not as clear with regard to how much payment remuneration you received from the big four. Can you tell me what is the total amount of payments in dollars you received in 2017, last year, from anyone or any entity involved in the development or sale of vaccines? Of what? From any entity involved in the development or sale of vaccines. Oh.

[Stanley Plotkin] My recollection is in the neighborhood of $200,000.

[00:48:23]

[Aaron Siri] Okay. Sorry about that. My microphone wire got stuck. Let me just get this back on.

[00:49:07] Do you own any stock in Sanofi? Have you ever? No. Do you own any stock options in Sanofi? No. Have you ever? No. How about from Merck, Lax, or Pfizer? Do you own any stock in any of those companies? No. Any stock options? No. Okay. Has any educational or not-for-profit institution in which you have been involved received funding from Sanofi?

[Stanley Plotkin] That's a very difficult question to answer.

[00:50:01] I don't inquire about the finances of the organizations that I work for or that I advise. So I find that question very difficult to answer. I imagine that some of them do, but I have no knowledge of the matter.

Voices for Vaccines, for example, receives no funding from any of the pharmaceutical companies.

And that is in order to avoid any suggestion of a conflict of interest. And I think that's probably true for a number of the nonprofits I advise, but obviously it may not be true for companies.

[Aaron Siri] So you're saying Voices for Vaccines doesn't receive any funding from pharmaceutical companies?

[00:51:00] None. What's your affiliation with that group?

[Stanley Plotkin] Well, I was one of those who suggested that an organization of laypeople, as opposed to scientists, would be a good idea to oppose all of the nonsense that one sees on the web from anti-vaccination organizations.

[Aaron Siri] So it was your idea to create Voices for Vaccines?

[Stanley Plotkin] That wasn't my sole idea. It was a suggestion that I made at a certain point, and it turned out that there were laypeople who were interested in promoting vaccines. Since then, I've been on their advisory board.

[00:52:05] But other than that, I have no role in the organization.

[Aaron Siri] But you were, from what I'm understanding, tell me if I'm correct, but it sounds like you were a driving force in suggesting its creation, and at least initially getting it set up. Yes. Is that correct? Okay. I'm going to hand you what has been marked as Plaintiff's Exhibit 1.

[Laura Nusma] And, Amy, is that coming to my email?

[Court Reporter] It will be in just one moment.

[Aaron Siri] All right. I don't get it.

[00:53:05] The marked one? Yeah, that's fine. I'm going to hand you what's been marked as Plaintiff's Exhibit 1. Yeah, go ahead.

[00:55:03] It's been sent.

[Court Reporter] Hopefully it will come through.

[Laura Nusma] I'm sure it will. Got it?

[Aaron Siri] Okay, great. Dr. Plotkin, do you recognize this as a printout from the Voices for Vaccines website? Well, that's what it says.

[Stanley Plotkin] I don't read the website that often, but yes.

[Aaron Siri] Okay. And I see that it's got you listed on the scientific advisory board on the third page, correct? Yes. Yes. Now, you see at the very end on the last page, Dr. Plotkin, you see at the very bottom it says, Voices for Vaccines is an administrative project of the Task Force for Global Health?

[00:56:00] Yes. Okay. And it receives funding from that organization, correct? No.

[Stanley Plotkin] Okay. It does not receive funding. The task force was asked to do the, what shall I say, the financial stuff required for an organization like Voices for Vaccines. But it does not contribute financially to Voices for Vaccines.

[Aaron Siri] I'm going to, Dr. Plotkin, I'm going to hand you what's been marked as Exhibit 2. This is a Form 90 tax return for the Task Force for Global Health. Yeah. I'm just not going to ask him questions until he emailed it.

[00:57:29] So I've handed you what has been marked as Plaintiff's Exhibit 2. It is the tax return for, the 990 tax return for the Task Force for Global Health. If you turn to the second page, do you see Section 4C? Where there's expenses of $3,757,924?

[Stanley Plotkin] Yes. Okay.

[Aaron Siri] Do you see that one of the groups receiving part of that funding was on the last line, Voices for Vaccines?

[00:58:05]

[Stanley Plotkin] I don't see where it says.

[Aaron Siri] The last sentence in 4C.

[Stanley Plotkin] Voices for Vaccines has expanded its educational outreach through new media and parenting networks, increasing its membership and its on-the-ground reach.

[Aaron Siri] So? If you go up to Number 4, Dr. Plotkin, can you read what the items in that list are supposed to be describing?

[Stanley Plotkin] Expenses, including grants, revenues.

[Aaron Siri] I'll read it to you, Number 4. It says, Number 4 says, Describe the organization's program service accomplishments for each of its three largest program services as measured by expenses.

[Stanley Plotkin] Yeah.

[Aaron Siri] Okay. Are you claiming that this document does not represent that Voices for Vaccines received funding from the Task Force for Global Health?

[00:59:11]

[Stanley Plotkin] As far as I am aware, the Voices for Vaccines receives no funding from the Task Force. Under Dr. Alan Hinman has agreed to do the financial, whatever is required by the government to do the financial work for Voices for Vaccines. But as far as I'm aware, it receives no funding from the Task Force or any other governmental or semi-governmental entity.

[Aaron Siri] So the Task Force does provide some support for Voices for Vaccines, correct? It does, yes.

[Laura Nusma] He already answered. He said he doesn't know.

[Aaron Siri] Your objection is noted. Thank you. The Task Force for Global Health.

[01:00:02] Does the Task Force for Global Health receive funding from any of the Big Four pharmaceutical companies?

[Stanley Plotkin] I do not know for a fact, but I doubt it. The Task Force, I know secondhand, but I believe that they receive funding from CDC. But as far as I know, not from companies.

[Aaron Siri] Dr. Plotkin, I'm going to hand you what's in Marcus' plaintiffs. Let's give it three. Thank you.

[Stanley Plotkin] Yes, so?

[Aaron Siri] This is a fact.

[Stanley Plotkin] Oh, I see, yes, where it says funders. Well, I stand corrected.

[01:01:01] So the Task Force then does receive funding from companies. However, I don't see that it has any bearing on its work for Voices for Vaccines.

[Aaron Siri] Did she get the email?

[Laura Nusma] Where is that in this? Am I looking at the same exhibit you guys are? You should have received deposition exhibit three. And it's a page from The Lancet?

[Aaron Siri] No, number 80. No, that's the wrong one.

[Court Reporter] Give me one second, sorry. All right.

[Aaron Siri] No. Hold on.

[01:02:02] Just type Task Force, can you search? Search task. Open that one? No. No. Send to the webpage. Just search that webpage on the internet.

[01:03:02] About us. No. Counsel?

[Laura Nusma] Yes?

[Aaron Siri] What it is, it's a fact sheet printed out from the Task Force for Global Health. And on the left side, it just shows the donors. Dr. Plotkin's already, you know, he's already. I'm just going to ask him to read the donors and that's it. I assume.

[Laura Nusma] All right.

[Aaron Siri] Okay. So does this show that the Task Force for Global Health received funding from GSK?

[01:04:00]

[Stanley Plotkin] Yes, it does.

But I want to repeat that the Voices for Vaccines has studiously avoided receiving funding from any company.

And the fact that the Task Force is doing its finances was only a matter of convenience and an offer from Dr. Hinman that they would do that because they have experience with filing tax returns, etc. And I do not believe, and I strongly do not believe, that any of the funding to the Task Force passes to Voices for Vaccines.

[Aaron Siri] Does the Task Force for Global Health receive funding from Merck? Yes. And from Pfizer?

[Stanley Plotkin] Apparently, yes.

[Aaron Siri] Okay. So the Task Force for Global Health receives funding from pharmaceutical companies and at the least, I'm understanding from

you, provides some kind of administrative support services to the Voices for Vaccines, correct?

[01:05:03] Correct. And one of the founding voices to create that organization was yourself, correct?

[Stanley Plotkin] I was one of those who suggested it, yes.

[Aaron Siri] And you receive remuneration from pharmaceutical companies, correct? I do, yes. Does anybody that works for Voices for Vaccines strike that? Okay. Okay. Okay, so going back to what we were discussing, I had asked you earlier, has any educational or not-for-profit institution in which you have been involved received funding from Sanofi? And you indicated that would be difficult to answer. Can you tell me, but you did indicate to me, and correct me if I say anything, I don't want to misspeak, but you indicated there are some groups that don't receive any funding from pharmaceutical companies, correct?

[01:06:02] And you mentioned Voices for Vaccines as the main one.

Is there any other education or non-profit institution in which you've been affiliated that you're aware of that does not and has not received funding from any vaccine company?

[Stanley Plotkin] Well, I certainly advise the Gates Foundation. I advise the National Institutes of Health. I think those are the major institutions that are not in the business of developing vaccines. And they do not receive funding from companies.

[Aaron Siri] Does the NIH hold any patents on any vaccine-related technology?

[01:07:02] I believe they do, yes. Do they receive royalties from those patents? I imagine they do, yes. To your knowledge, you're not aware of whether any of the other educational non-for-profit institutions outside of

Voices for Vaccines as you've said, Gates Foundation or NIH, that don't receive any money from any of the pharmaceutical companies.

[Stanley Plotkin] I'm not sure I can answer that question categorically.

[Aaron Siri] Just based on your knowledge. I mean, if you don't know, then...

[Stanley Plotkin] I'm sure there are organizations that are not funded by industry, but whether... I'm trying to think of ones that I've advised over the years.

[01:08:05] Well, the Sabin Foundation. I'm not sure whether they receive funding from industry or not. But I don't normally inquire of the organizations that I advise where their funding comes from.

[Aaron Siri] Have you ever worked on developing a vaccine that was eventually used by the public?

[Stanley Plotkin] Yes.

[Aaron Siri] Which ones?

[Stanley Plotkin] Let's see. Well, rubella, rotavirus, rabies. And I've made contributions here and there to anthrax, cytomegalovirus, varicella.

[01:09:14] That's all I can remember at the moment.

[Aaron Siri] The varicella vaccine, you're talking about the Averivax?

[Stanley Plotkin] Yes.

[Aaron Siri] When you say you contributed to it, how did you contribute to the development of varicella?

[Stanley Plotkin] Essentially by showing how it could be used and demonstrating that it was safe and effective.

[Aaron Siri] Did you work directly with Merck on that?

[Stanley Plotkin] I don't recall whether it was directly with Merck or not. Certainly it was the vaccine produced by Merck.

[01:10:06] But I don't recall that they actually funded my studies of varicella vaccine. But they were the producers of the vaccine, certainly.

[Aaron Siri] Where were you working when you did this work?

[Stanley Plotkin] At Children's Hospital of Philadelphia.

[Aaron Siri] Did Children's Hospital ever acquire any intellectual property rights on what was developed?

[Stanley Plotkin] From varicella, no.

[Aaron Siri] No.

Have you developed or been part in any way in the development of any vaccine from which you have received any payment, revenue, or income related to the sale of that vaccine?

[Stanley Plotkin] Yes. Although I should stipulate that all of the patents on vaccines that I've developed have been taken out by the institutions for which I was working, and that they gave me, and I stress that it was not a requirement, but they gave me part of the profits deriving from the patents.

[01:11:27]

[Aaron Siri] Which are those?

[Stanley Plotkin] Sorry?

[Aaron Siri] Which vaccines are those?

[Stanley Plotkin] Mainly rubella, rotavirus, and rabies.

[Aaron Siri] And the rubella vaccine that you developed is currently used as part of the MMR vaccine? Correct. Okay. And this is one of the vaccines you

believe Faith's pediatrician should purchase and administer to her? Absolutely. What is the total amount of payments in any form you have directly or indirectly received from the sale of the rubella vaccine?

[01:12:08]

[Stanley Plotkin] I cannot give you a figure. I would say that I do not doubt, but again, I'd have to ask my wife. I do not doubt that they were substantial amounts of money, and similarly for rotavirus and rabies.

[Aaron Siri] Was it in the millions of dollars for rubella, just rubella? I don't think so. Well, that's all I can say. I don't think so. Okay.

Are you in the possession of documents that would illuminate how much you've received in payments from the sale of the rubella vaccine?

[Stanley Plotkin] Probably. I hope they have been retained. I don't know, but I imagine.

[01:13:01]

[Aaron Siri] Okay. And do you continue to receive any payments from the sale or royalties or any other remuneration from the sale of the rubella vaccine?

[Stanley Plotkin] Currently, I don't think so. When did it cease? Oh, Jesus. I couldn't tell you exactly. Sometime during this century, I don't know. You know, if I had thought that this was going to be about my finances, I would have had my wife come along, because I don't follow these things, and certainly what I've done has not been based on what remuneration I could receive from the work that I've done.

[01:14:01] So if you want financial details, I will have to collect them in some other form.

[Aaron Siri] But how do you think your wife would feel of you offering her up for a deposition?

[Stanley Plotkin] I don't think she would like it very much.

[Aaron Siri] Right. It wasn't a serious question. Okay. But I'll request those documents. Now, do you have – you said that you're not sure whether it was in the millions of dollars that you've received from the sale of rubella, correct? Correct. But it could have been?

[Stanley Plotkin] I doubt it, but it could have been. I don't think so.

[Aaron Siri] Who provided you those payments?

[Stanley Plotkin] The Wistar Institute.

[Aaron Siri] Did it come from any other source other than Wistar?

[01:15:07]

[Stanley Plotkin] I don't think so, because the Wistar holds the patent.

[Aaron Siri] Okay. Were you listed as one of the patent – One of the inventors?

[Stanley Plotkin] One of the inventors. I believe so, yes.

[Aaron Siri] But Wistar was the assignee, is that right? Yes. And so they received the – they're the ones who had the – gave the license to Merck? Yes, yes. So Merck would pay Wistar, and then Wistar would remit some of that to you. Is that correct?

[Stanley Plotkin] That's correct. I'm trying to recall whether Children's Hospital was involved. I don't think so at that point, because that was many years ago.

[01:16:06]

[Aaron Siri] And you indicated that you've also developed the rotavirus vaccine earlier. I believe you said it was Rotatech?

[Stanley Plotkin] Yes.

[Aaron Siri] And I think you said earlier that's currently one of two rotavirus vaccines currently on the market in the U.S.? And you obtained a patent for Rotatech?

[Stanley Plotkin] Wistar and Children's Hospital developed patents.

[Aaron Siri] Who was listed as the inventor or co-inventors?

[Stanley Plotkin] Myself, Paul Offit, and Fred Clark.

[Aaron Siri] Okay. And who were the assignees of the patent for Rotatech?

[Stanley Plotkin] The assignees, you mean who used the – ?

[01:17:00]

[Aaron Siri] Well, you know, when you file the patent, there's usually an inventor listed, and then there's who the patent's assigned to.

[Stanley Plotkin] Well, the patents were taken out by Wistar and Children's Hospital, if that's what you mean.

[Aaron Siri] Okay. And so they were the ones who had the rights to the patent? Yes. Okay. How much remuneration to date have you received from sales of Rotatech? I couldn't tell you exactly, but it's been a considerable amount.

[Stanley Plotkin] Okay. Has it been in the millions? I hesitate to say exactly. It could be, but I really do not know.

[Aaron Siri] You were entitled – so you indicated that Children's Hospital, Philadelphia, is that sometimes referred to as CHOP?

[01:18:05] Yes. Okay. CHOP was entitled to receive revenue from the sale of Rotatech? Yes. Okay. And what portion from the sale of Rotatech was CHOP entitled to? Well, as I understand it, 50 percent. And what percent of that 50 were you entitled to? I don't know. Do you know how much revenue CHOP received from the sale of Rotatech? I do not.

Did it ever come a time where CHOP sold its interest in the Rotatech virus vaccine?

I believe so, yes. Do you remember how much approximately it was sold for?

[01:19:02] No. Okay. Exhibit 10. I'm going to hand you what is being marked as Plaintiff's Exhibit 4. This is a press release from Royalty Pharma, and the title of the press release is Royalty Pharma Acquires Royalty Interest in Rotatech from the Children's Hospital Foundation for $182 million.

[01:20:17]

[Court Reporter] Ms. Newsom, I know you should have that in just one second.

[Aaron Siri] Okay. Looking at Exhibit 4, does that refresh your recollection? Of how much CHOP sold its interest in Rotatech for in 2008?

[Stanley Plotkin] Assuming it's correct, yes. Does that sound about right?

[Aaron Siri] I have no idea, but presumably it's correct. Do you have any reason to doubt the authenticity of this press release? No. Do you have any reason to doubt that CHOP sold its Rotatech interest in 2008 for $182 million? I have no reason to doubt it. Did you receive a portion of those proceeds?

[01:21:02]

[Stanley Plotkin] I believe so, yes.

[Aaron Siri] And what was that amount?

[Stanley Plotkin] I could not tell you precisely. I really can't. I don't do these things for the money, and although it's gratifying to receive monetary awards, I don't personally keep track of it. And again, if I had realized this was going to be the tone of this deposition, I would have asked my wife to come along.

[Aaron Siri] You're here today opining that faith should receive vaccines that are made by the Big Four pharmaceutical companies, correct? I am, yes. And you didn't anticipate that your financial dealings with those companies would be relevant to that issue?

[Stanley Plotkin] I guess, no. I did not perceive that that was relevant to my opinion as to whether a child should receive vaccines.

[01:22:02]

Vaccines have to be made by somebody, and of course in this world they're made by pharmaceutical companies who make profits on vaccines.

And the fact that they make profits on vaccines has no bearing on whether those vaccines are good for a child or not.

[Aaron Siri] So you think the fact that pharmaceutical companies make money on vaccines doesn't bias how they approach the promotion of their own products?

[Stanley Plotkin] I imagine it biases them in favor of vaccines, but so does most of the scientific world.

[Aaron Siri] Are you saying most of the scientific world is biased because of financial profits?

[Stanley Plotkin] No, I'm saying that most of the scientific world believes that vaccines protect children against serious diseases.

[Aaron Siri] Do you have a peer-reviewed study that actually supports what you just said?

[01:23:02] Absolutely, yes. Okay, good. We'll make a demand for that, too.

[Stanley Plotkin] Well, you can certainly buy a copy of the vaccines textbook which contains thousands of references showing that vaccines work and are safe.

[Aaron Siri] So from the $182 million sale to CHOP, that CHOP made to Royalty Pharma, do you believe that you received more or less than a million dollars?

[Stanley Plotkin] I could have received more than a million dollars. I don't have an exact figure.

[Aaron Siri] You stated earlier that your co-inventor on this patent was Paul Offit. Yes. Were you entitled to similar remuneration as he was? Yes. Are you aware that he has stated publicly how much he's received from that sale?

[01:24:00]

[Stanley Plotkin] I am not aware that he has.

[Aaron Siri] If I told you he said that he received approximately $6 million, would that help you recall how much you received?

[Stanley Plotkin] Not really, but I believe whatever Paul has said, I'm sure, is correct.

[Aaron Siri] Is $6 million a lot of money, in your opinion? Yes. If you received $6 million, do you think you'd remember?

[Stanley Plotkin] Actually, Counselor, no. I hesitate to say this because it sounds as if I'm some sort of idiot, but I really do not follow what income I get. I have no doubt that it was a lot of money, but I cannot give you an exact figure.

[01:25:04] I actually do not read my own tax returns. I say that in complete honesty.

[Aaron Siri] How about the Wistar Institute? I believe you stated earlier they also held intellectual property on RotaTek, correct? Yes. Did that ever come to time? And you receive a portion of the proceeds that Wistar receives, correct? Yes. And you continue to receive payments from Wistar for the sale of RotaTek?

[Stanley Plotkin] I don't think I've received anything in the last couple of years, but I have in the past. Okay.

[Aaron Siri] How much approximately have you received in the past?

[01:26:00] I don't remember.

Do you recall Wistar selling a portion of its royalty interest to RotaTek?

I believe they have. Okay. Do you remember approximately how much? No. I'm going to hand you what's in Marcus Plaintiff's Exhibit 5. It's a PR Newswire article. Can you read the title, please?

[Stanley Plotkin] The Wistar Institute sells partial royalty interest in Merck's RotaTek to the Paul Royalty Fund.

[Aaron Siri] Does that refresh your recollection of how much they sold their royalty interest?

[01:27:03] No.

[Court Reporter] Ms. Nussbaum, did you receive Exhibit 5?

[Laura Nusma] I did. I believe it's Exhibit 5. Yep, just got it. Thank you.

[Aaron Siri] Can you please read the first sentence of the article, Dr. Falken?

[Stanley Plotkin] The Wistar Institute today announced that it sold a portion of its anticipated worldwide royalty revenues from RotaTek to an affiliate of the Paul Royalty Fund for $45 million.

[Aaron Siri] Does that refresh your recollection of how much they received for selling a portion of their interest in RotaTek?

[Stanley Plotkin] I know that they sold it. I don't have in my head how much they sold it for, but I presume this is correct.

[01:28:02]

[Aaron Siri] The Wistar Institute is entitled to what percentage of the sales from the RotaTek? I do not know. And do you, from this $45 million sale, any recollection of all of how much you received? No recollection.

[Stanley Plotkin] I'm sure I received some. Do you think it was sizable? I think it was probably sizable, yes. More than a few hundred thousand? I think so.

[Aaron Siri] I don't have a figure in my head. Do you have documents that would indicate how much you received? I would imagine so, yes. I'll make a request for those as well. Are you familiar with the Immunization Action Coalition? Yes. What is your understanding of what this group does?

[01:29:02] They promote vaccination through education and e-mails and meetings. Would you say it's one of the main advocacy groups for vaccines in this country?

[Stanley Plotkin] I think it's an important one, yes. Does it receive funding from pharmaceutical companies? I believe so. I think so. I'm not certain. I don't know exactly where their financing comes from, but I think they very well may.

[01:30:00]

[Aaron Siri] I'm going to hand you what's on Marcus Plaintiff's Exhibit 6. It's a printout from the Immunization Action Coalition webpage showing their funding for 2017. You can kindly take a look at that in the section that says, that lists the pharma company donors. Are any of the companies listed there vaccine manufacturers trying to develop vaccines? Which ones?

[Stanley Plotkin] AstraZeneca, Glaxo, Merck, Pfizer, Sanofi, Seqirus. So all of them?

[Aaron Siri] Yes.

[Court Reporter] Ms. Newsomak, can you confirm you received Exhibit 6?

[Laura Nusma] Haven't gotten it yet, but I should have it in just a second.

[01:31:00]

[Stanley Plotkin] Got it. Thank you. Okay.

[Aaron Siri] Do you know approximately what percent of Immunization Action Coalition's funding comes from those pharmaceutical companies? No idea. Can you name me a major medical group, such as the American Academy of Pediatrics or similar, that you know does not receive any funding from any pharmaceutical company?

[Stanley Plotkin]

Well, inasmuch as I do not know what organizations receive what funding, I really can't answer that question.

[01:32:06]

[Aaron Siri] Sitting here today, you don't know of one?

[Stanley Plotkin] I don't know what funding, for example, AAP receives from manufacturers, no.

[Aaron Siri] Okay. So sitting here today, you're not aware of any medical group that does not receive any support from pharmaceutical companies, correct?

[Stanley Plotkin] I am not aware of the funding of medical organizations and whether or not they receive funding from pharmaceutical companies.

[Aaron Siri] So just to recap, I think it would be correct to say that you've received in total from the companies that develop or manufacture vaccines payments or remuneration at least in the amount of a few million dollars, correct?

[01:33:12]

[Stanley Plotkin] I think it's correct to say that since I left Children's Hospital in the 1990s, I have received considerable funding for my work in

developing vaccines and in advising companies how to develop vaccines. And I have also given advice freely to organizations that could not pay me because I believe that vaccines are important to the health of children and adults.

[01:34:06] So the answer is yes? The answer is yes. But I wish to say very clearly that none of the things that I have done have been done with the objective of gaining money. It has been my fortune that I have been rewarded financially for the work that I've done, but none of the things that I've done have been done for financial gain. And I resent very much the line of questioning that suggests that what I believe and what I've done have been done for financial reasons.

[Aaron Siri] Nobody's suggesting that, Dr. Plotkin.

[01:35:00] I'm just asking you. Bologna, you are suggesting that. Well, you're suggesting that. Dr. Plotkin, so you indicated that a lot of the remuneration you received is from the 1990s. Have you received any funding from the big four pharma companies or their predecessors before 1990?

[Stanley Plotkin] I would say probably not. It's very hard to remember that far back, but certainly not any substantial funding. I may have received honoraria for attending meetings in those days, but certainly nothing considerable.

[01:36:03] At that point I was working at the University of Pennsylvania in the Children's Hospital and the Wistar Institute and was, of course, paid by those entities.

[Aaron Siri] Could you read the last answer back for me, please?

[Court Reporter] Answer, I would say probably not. You know, it's very hard to remember that far back, but certainly not any substantial funding. I may have received honoraria for attending meetings in those days, but certainly nothing considerable. At that point I was working at the University of Pennsylvania in the Children's Hospital and the Wistar Institute and was, of course, paid by those entities. Okay.

[Aaron Siri]

Did you receive any funding from any pharmaceutical company related to the development of vaccines before 1990?

[01:37:12]

[Stanley Plotkin] I don't recall receiving any funding for the development of Rubella vaccine before it was licensed and then funding passed through Wistar. As far as rotavirus is concerned, I did have grants, not personal money, but grants for rotavirus development from Sanofi.

[01:38:01] I had no funding for rabies.

[Aaron Siri] That's as much as I can recall. But you indicated that you didn't get funding for the work on the Rubella vaccine, right?

[Stanley Plotkin] I don't believe I had any funding until it was eventually licensed by Merck. And when was that? That was about 1970, early 70s. Okay.

[Aaron Siri] So from the early 70s you were receiving funding, you're saying, from Merck related to Rubella?

[Stanley Plotkin] No. Wistar was receiving funding.

[Aaron Siri] Wistar from Merck.

[Stanley Plotkin] Yes. Got it. But before that? Merck did not fund the development of Rubella vaccine until it was licensed.

[01:39:10]

[Aaron Siri] 73. It's got to be 77.

[Court Reporter] Ms. Newsome, you should have Exhibit 7.

[Aaron Siri] I'm going to hand you, Dr. Plotkin, once it's marked as Plaintiff's Exhibit 7.

[Laura Nusma] Just got it.

[Aaron Siri] Okay. Can you read the title of the article, please?

[Stanley Plotkin] Attenuation of RA-27.3 Rubella virus in WI-38 human diploid cells.

[Aaron Siri] And who's the first listed author? I am. Okay. And what is the year of this publication? 1969. And if you go to the summary?

[01:40:02] You know what, Dr. Plotkin, let me, may I? Oh, yes. Yes. And does it say there that Dr. Plotkin is a recipient of an award from SmithKline? Is that a predecessor to GSK? Yes, it is. Yes. And French Inc., Philadelphia, for research on Rubella vaccine, correct?

[Stanley Plotkin] Yes. Unfortunately, that was not the vaccine that eventuated. In other words, the RA-27.3 was not really the product of any GSK funding.

[Aaron Siri] So does that refresh your recollection now of maybe what was an earlier time that you received funding from pharmaceutical companies towards development related to a vaccine?

[01:41:11]

[Stanley Plotkin] Yes. I did have some funding from GSK, but they had their own candidate Rubella vaccine.

[Aaron Siri] Dr. Plotkin, I'm going to hand you, what does it mark? Is it Plaintiff's Exhibit 8?

[01:42:04]

[Court Reporter] Ms. Nussbaum, did you receive that Exhibit 8?

[Laura Nusma] I'm sure I will.

[Court Reporter] It might take a second. It's Dr. Plotkin's curriculum data.

[Laura Nusma] Oh, I've got a copy of that already. Thank you.

[Aaron Siri] This is your CV, correct, Dr. Plotkin? Yes. Did you update the CV recently?

[Stanley Plotkin] I think it was updated last year, but I'm not sure exactly. It probably doesn't have every last publication.

[Aaron Siri] On the first page in the top right corner, do you see the date? June 2017. Was that when it was last updated?

[Stanley Plotkin] Yes.

[Aaron Siri] If you go to the end, I saw that you went to its – there are some articles here that were published in 2017 in which you're an author.

[01:43:09] Yes. I think I count 1, 2, 3, 4, 5, 6, 7 articles, correct? I guess. Okay. Some of these were published within the last few months? Mm-hmm. I think some of them were published in December, November, correct?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. So this has been updated very recently, correct?

[Stanley Plotkin] Well, June 2017.

[Aaron Siri] The articles – if you go to Article 794, Rodriguez-Pinto – Do you know what month of the year that was published? No. Okay.

[Stanley Plotkin] If I told you it was published after June, would that – Well, I guess my secretary must have added it.

[Aaron Siri] Okay.

[Stanley Plotkin] When's the last time you reviewed this CV? Probably in June 2017.

[01:44:06]

[Aaron Siri] You provided this CV to the attorney for the defendant in this case? Yes. Okay. It's quite a hefty CV, Dr. Block. It's over 200 pages. I see there's 794 articles in it, which you were the author, correct? Yes. That's a lot of articles. I see a lot of honors, including a who's who in America since 1978. Mm-hmm. I've got a number of faculty appointments at a number of universities I see here.

[01:45:05] 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13. Any faculty appointments missing from this list? I don't think so. Okay. I also see that there's – you have a professor emeritus position at the University of Pennsylvania, Wistar. Do you teach any courses there? Yes. Do you continue to teach any courses? Yes. What do you teach there?

[Stanley Plotkin] Participate in the vaccine course at the university and essentially give advice to Wistar.

[Aaron Siri] And for the university, did you teach a course last semester?

[01:46:00] Yes. Have you been doing that every year for the last few years? Pretty much, yes. What's the name of the course?

[Stanley Plotkin] Vaccines. I don't remember the exact name, but it's essentially a course in vaccines.

[Aaron Siri] How many days a week does the class meet?

[Stanley Plotkin] Oh, two days a week.

[Aaron Siri] I see you have a number of hospital and administrative appointments, 1, 2, 3 – you have six of them, right? It looks like they're all at the Children's Hospital of Philadelphia and then Department of Pediatrics. Any of your hospital and administrative appointments missing from this list, Dr. Plotkin?

[Stanley Plotkin] No, I don't think so. I do have an appointment at Johns Hopkins, but, yeah.

[01:47:00] And what is that? I'm an adjunct professor. Since when? Gosh. I think sometime in the 2000s.

[Aaron Siri] I see you have positions in industry listed, correct? Yes. I see two of them. I see one is from 1991 to 1997, the medical and scientific director at Sanofi.

[Stanley Plotkin] Yes.

[Aaron Siri] And 1997-2009, executive advisor to the CEO of Sanofi, correct? Correct. Okay. But as discussed earlier, since 2009 you've also worked for Sanofi, correct? I have, yes. And you've worked for Merck? Yes. And Glaxo? Yes. And Pfizer? Yes. How come those aren't listed here, Dr. Plotkin?

[Stanley Plotkin] Well, they are consultancies. They're not official appointments.

[01:48:00] I don't have, let's say, a title at Merck. I'm simply a consultant to them. So it's not in my CV.

[Aaron Siri] So in providing this CV to Defendant's Counsel, you didn't think disclosing your affiliations with the very companies whose product you're saying Faith should receive who her pediatrician purchased and provide to her was necessary to disclose? The CV — Strike the question. Let me ask you this. Are you willing to update your CV to disclose all of the connections you have with the Big Four pharmaceutical companies? Yes, of course.

[Stanley Plotkin] The CV is created for, not for legal purposes. This is created to inform people who want to know about my papers and my appointments at various universities.

[01:49:09]

[Aaron Siri] You provided this to Defendant's Counsel, correct? Yes. To show your experience as relevant to being an expert witness in this case, correct?

[Stanley Plotkin] To show my experience as in the field of vaccines, yes. What is Dynavax Technologies? Dynavax is a company that is working on adjuvantation of vaccines and has recently licensed a hepatitis B

vaccine that is more immunogenic than the current vaccines. This is a for-profit company?

[Aaron Siri] Yes. And it's involved in the development of vaccines, right? Yes. You're on the board of directors of this company, correct?

[01:50:00] Correct. That affiliation is not disclosed on the CV, correct? It's not on the CV, no. What is VBI Vaccines?

[Stanley Plotkin] Variation Bio. And what is that? That's a biotech developing vaccines.

[Aaron Siri] And this is a for-profit company as well, correct? Yes. And you are also on the board of directors of this company, right? Yes. And that affiliation is not disclosed in your CV, correct? It is not in my CV, no. Okay. What is MyMedx?

[Stanley Plotkin] MyMedx is a biotech in Europe. I've actually, I haven't done anything for them in at least a year now. But I think I'm still officially on their board. You're chairman of their scientific advisory board, correct? As I said, I haven't done anything for them for at least a year or so.

[01:51:02]

[Aaron Siri] If that is correct, that's sort of an old thing. But they're a for-profit company? Yes. And how long were you on their board? A couple of years. I don't remember exactly. But that affiliation is not on your CV, correct? No. Dynavax Technologies, what have you done for them? Dynavax, I've been on their board. Do you attend the board meetings? Not recently, but yes, in the past. Have you advocated on their behalf? Yes. Have you done that in any government meetings, for example? Yes, yes. To seek licensure of the vaccine?

[Stanley Plotkin] Yes. It was just licensed.

[Aaron Siri]

And so you were advocating, as a board member of a technology company, to get licensure of a new vaccine, correct?

Yes.

[01:52:02] Inovio Biomedical Corp. What's that?

[Stanley Plotkin] That's a biotech that's developing vaccines based on DNA.

[Aaron Siri] And is this a for-profit company?

[Stanley Plotkin] Yes.

[Aaron Siri] And what is your affiliation with the company? I'm on their board. Okay. And was that affiliation disclosed in your CV? No. Okay. What's CureVac AG? It's also a biotech. Okay. Is it a for-profit company? Yes. Is it involved in the development of vaccines? Yes. What's your affiliation with that company? I'm on their board. Okay. Is that affiliation disclosed in your CV? No. Okay. What is Synvaccine?

[Stanley Plotkin] Actually, I'm not sure about that name, but as I recall, it's a company trying to develop synthetic vaccines.

[01:53:11] What's your affiliation with that company? Actually, I don't recall that. I've certainly helped them, but I don't recall that I have a board position, whether I'm officially on the board or not. I haven't had contact with them for some time.

[Aaron Siri] What is GeoVax Labs? It's also a biotech. Okay. Is it a for-profit company? Yes. Is it involved in the development of vaccines? Yes. What's your affiliation with that company?

[Stanley Plotkin] I've been an advisor, and I think I'm officially on their board. They're trying to develop a vaccine against HIV.

[01:54:03]

[Aaron Siri] Was this affiliation disclosed in your CV? No, right? No. I don't have my consultancies on my CV. You're on the board of these companies, correct? Yes. Okay. What is GlycoVaxin AG? That's G-L-Y-C-O, then capital V-A-X-Y-N-A-G. It was a biotech in Europe. Okay. Is it a for-profit company? It was. Okay. Was it involved in the development of vaccines? Yes. Were you on the board of this company as well? Okay. Is that disclosed in your CV? No. What is Adjuvance Technologies? That's A-D-J-U-V-A-N-C-E Technologies.

[Stanley Plotkin] It's a company trying to develop adjuvants for vaccines.

[Aaron Siri] Okay. Is it a for-profit company? Yes.

[01:55:00] Okay. You're on the board of this company as well, right? Yes. Okay. And that affiliation isn't disclosed in your CV either, right? No. What is Bionet Asia?

[Stanley Plotkin] A company developing a new pertussis vaccine.

[Aaron Siri] Okay. Is this a for-profit company as well? Yes. Okay. And you're on the board of this company as well?

[Stanley Plotkin] Yes.

[Aaron Siri] That affiliation also wasn't disclosed in your CV, correct?

[Stanley Plotkin] Correct.

[Aaron Siri] Okay. What's Abcombi? That's A-B-C-O-M-B-I. Biosciences.

[Stanley Plotkin] I haven't heard from them in a long time, and actually I'm not even sure. I mean, I had an interview with the founder once.

[01:56:01] Whether he listed me as a board member, I don't know. I haven't heard from him in a long time.

[Aaron Siri] It's a for-profit company?

[Stanley Plotkin] I really have no idea. I assume it is, but I don't know.

[Aaron Siri] And I should say that I'm spelling them out for the benefit of the core reporter. I assume you know the spelling. I'm just doing it for the benefit of the core reporter. What's Hoekipia Biotech?

[Stanley Plotkin] Oh, Hoekipa.

[Aaron Siri] Thank you. H-O-O-K-I-P-I-A.

[Stanley Plotkin] Biotech. Yes. It's a European biotech. Okay.

[Aaron Siri] Is it a for-profit company?

[Stanley Plotkin] Yes.

[Aaron Siri] All right. And it's involved in the development of vaccines?

[Stanley Plotkin] Yes, hopefully.

[Aaron Siri] And you're also on the board of this company? Yes. Okay. And that affiliation also wasn't disclosed in your CV, right?

[Stanley Plotkin] No.

[Aaron Siri] Okay.

[01:57:02]

You mentioned one of the companies was in the process developing a new, trying to develop a new pertussis vaccine.

Which company was that? Bionet. Thank you. Why are they trying to develop a new pertussis vaccine?

[Stanley Plotkin] Because a problem with current acellular vaccines is that although they are protective, the protection doesn't last as long as we would like. And Bionet has developed a component of pertussis vaccine that should give longer-lasting responses.

[Aaron Siri] And how long does the current immunity last from the current acellular pertussis vaccine?

[Stanley Plotkin] Well, it lasts for probably on the order of five years, but the efficacy diminishes after two years or so.

[01:58:00] And the result is that there have been more pertussis in adolescence than we would like.

[Aaron Siri] So when you say after five years immunity's gone and two years the efficacy, do you mean after the four or five-dose Tdap, DTaP series?

[Stanley Plotkin] Well, I should go into some detail. The first three doses are given.

[Aaron Siri] You know what, I apologize. It's about to run out, and I don't want to give the video for a hard time.

[Tom Liebman] This is one of the depositions of Dr. Stanley Plotkin. We're going off the record. The time is 10.32. I apologize for cutting off. This is the beginning of tape number two of the deposition of Dr. Stanley Plotkin. We are on the record. The time is 10.42. Okay.

[01:59:01]

[Aaron Siri] Thank you. Apologies again for cutting off your answer to the last question. The tape needed to be changed. If you could kindly read back the last question to give Dr. Plotkin an opportunity to respond.

[Court Reporter] Question. So when you say after five years immunity is gone and two years efficacy, do you mean after, dash, the four or five-dose DTaP series? Answer. I should go into some detail. The
first, dash, well, answer, the first three doses are given, dash, you know what, I apologize. It's about to run out.

[Stanley Plotkin]

So Pertussis vaccine is given in three doses in infancy and is quite protective during the childhood or infancy years.

[02:00:04] Then there's a booster dose given before school entry, and that results in pretty good protection for two, three years, but then begins to fade when the child reaches eight or nine years. And a dose is recommended in preadolescence, and there in particular what's been found is that with the so-called acellular vaccines that after two or three years that the efficacy diminishes considerably, and so there are efforts to try to improve that persistence of efficacy.

[02:01:03] And Bionet is one of the companies that is, in effect, trying to develop a longer-lasting acellular Pertussis vaccine. There are other companies also working to improve the vaccine for adolescence. Q.

[Aaron Siri] So the last vaccine recommended for adolescence is around what age of Tdap or typhtheria type of Pertussis-containing vaccine?

[Stanley Plotkin] A. About 13, 11, 13.

[Aaron Siri] Q. And did I understand correctly that a few years after that last dose, the most folks who have gotten that vaccine are no longer immune to Pertussis? A.

[Stanley Plotkin] Well, most folks is perhaps a bit of an exaggeration, but it depends on the study.

[02:02:00] But certainly I would say that the high effectiveness that's seen initially after the vaccine diminishes considerably by five years. Q. And what do you mean by considerably? A. Well, so it falls somewhere between 30 to 50 percent protection. So it's not nearly as good as after the vaccine dose is given.

[Aaron Siri] Q. So after the last vaccine dose in adolescence, five years later only 30 to 50 percent of people are receiving the CDC-recommended

childhood schedule are protected from Pertussis? A. Yes. Q. How about 10 years out? A.

[Stanley Plotkin] I'm not sure there are many studies that go that far out, but I would imagine that the protection is diminished considerably by that time.

[02:03:01] Q. So most adults aren't protected for Pertussis? A. Not unless they've received a booster dose. But that being said, it becomes complicated because if they are infected with the organism that causes Pertussis, even if they are not ill because of it, they will get a natural booster. And so they may not have symptomatic Pertussis. Pertussis is not uncommon in adults. So it's – but the epidemiology is not as well established as it is for children.

[Aaron Siri] Q. But in terms of protection from vaccination from Pertussis, most adults are not protected from the vaccination.

[02:04:05] You're saying if they're protected, they're protected from exposure to the actual Pertussis. A. Yes. Q. Is it bacteria? A. Yes.

[Stanley Plotkin] But, you know, you have to bear in mind that Pertussis as a disease is most important in the newborn and in children. And fortunately, we have very effective means of preventing Pertussis in those highly susceptible individuals. Adults will have a cough disease, but they won't die of Pertussis. So although we want to protect them as well, the main point of Pertussis vaccine is to protect the newborn and the young child.

[Aaron Siri] Q. So is it only really dangerous in the first, what, few months of life? A.

[02:05:00]

[Stanley Plotkin] Yes. Infants with Pertussis may frequently die of Pertussis, and that's why immunization in pregnancy is now practiced. In other words, to provide passive immunity to the infant during the first months of life before the infant is vaccinated. Q.

[Aaron Siri] And if the mother had been exposed to Pertussis bacteria itself and had immunity that way, that would also confirm immunity to the baby?

[Stanley Plotkin] A. Yes. But one can't depend on that, whereas if you give a dose of vaccine during pregnancy, you can depend on the antibodies passing to the infant. Q.

[Aaron Siri] Does the acellular Pertussis vaccine prevent the infection and transmission of Pertussis in the person vaccinated with acellular Pertussis vaccine?

[02:06:28]

[Stanley Plotkin] A. Well, that's an area of active research.

It appears that the acellular vaccines don't protect the individual from carrying the organism as much as the so-called whole-cell Pertussis vaccines did.

But those data are based largely on animal studies, and we don't really have a lot of human data to tell us whether the animal results are true in humans or not.

[02:07:06] But there is a concern that the acellular vaccines may not protect an individual from passing the organism to another individual, even if the vaccinated person doesn't get sick himself or herself. Q. What animals were used in those studies? A. Baboons. Q. Why were baboons used? A. Why were baboons used? Because they are susceptible to Pertussis, and obviously they are close to humans.

[Aaron Siri] Q. Would those experiments be ethical to do with people as opposed to baboons? A.

[Stanley Plotkin] Well, I'm not sure it would be ethical to infect someone with Pertussis.

[02:08:03] That would require an ethical committee to consider how the experiment would be done. For example, if someone were infected with Pertussis and then given antibiotics soon after administration of the organism, that could be ethical because the antibiotics would cure the individual before he or she becomes ill.

[Aaron Siri] Q. Wouldn't that mess up the study, though? A. Sorry? Q. But then wouldn't that mess up the study in terms of? A.

[Stanley Plotkin] It would certainly influence the study, but it could allow us to determine whether an individual who has been vaccinated with the A-cellular vaccine can pass the organism despite the vaccination to another individual. Q.

[Aaron Siri] Has that study been done?

[02:09:00] A. No. It has not yet been done. Q. In terms of the study that was done with baboons, that study? A. Yes. Q. Could that study be done with humans? Do you think any IRB approval could ever be obtained to do that study with humans? A.

[Stanley Plotkin] To allow an individual to develop symptomatic Pertussis? I don't think that would be approved. Q.

[Aaron Siri] So in terms of the baboon studies that were done, those are about as good as you're going to get for those studies because you can't do the human studies, correct, in terms of evidence about the transmissibility and infection of Pertussis from? A. Yes.

[Stanley Plotkin] Q.

[Aaron Siri] After A-cellular Pertussis vaccination?

[Stanley Plotkin] A. Yes. But I believe that workers are trying to determine whether vaccinated individuals are still colonized by the Pertussis organism.

[02:10:12] If they are colonized, then they probably could transmit to others. There's a lot of work going on in this field, including developing an attenuated Bordetella Pertussis, which could be given to boost immunity and, in particular, to prevent carriage.

[Aaron Siri] So as I said, this is a very active area of investigation. Q. What was Merck's total revenue from vaccine sales in 2016? A. No idea. Q. Do you think it was in the millions? A.

[Stanley Plotkin] I imagine so, but I certainly have no knowledge. Q. Do you think it was in the billions? A. I do not know. Q.

[02:11:08]

[Aaron Siri] Do you know what the global sales of vaccines were approximately last year? A.

[Stanley Plotkin] My vague recollection is something like $30 billion. Q.

[Aaron Siri] $30 billion. And do you know what percent approximately Merck's share of that
was? A. No. Q. Sanofi's? A. No. Q. Glaxo? A. No. Q. Or
Pfizer? A. No. Q. Combined, do you have a sense of what percent those four represent in terms of that $30 billion in vaccine sales?

[Stanley Plotkin] A. Probably, I would guess, but it's purely a guess, $20 billion.

[Court Reporter] Q.

[Aaron Siri] $20 billion.

[02:12:21] Q. The increase in the vaccine market has been due to the fact that new vaccines give higher profits, correct? A. Correct. Q. Are you familiar with the New England? Strike that. If I told you, in terms of the $30 billion and you said approximately, what percent did you say approximately you thought was in the big four vaccine makers?

[02:13:46]

[Stanley Plotkin] A. I said 20.

[Aaron Siri] I really don't have an accurate idea, but that's my
guess. Q. Twenty? A. Billion. Q. Oh, billion. Okay. And you said what percent of that was related to the four big vaccine manufacturers?

[02:14:00] A. No.

[Stanley Plotkin] What I said was that I thought the overall income was 30, but that the big four probably account for 20. But those are purely guesses.

[Aaron Siri] Q. When you say it's a guess, how off do you think you might be? A.

[Stanley Plotkin] If it's a guess, how do I know how off I am? Q.

[Aaron Siri] How did you come up with the $20 billion?

[Stanley Plotkin] A. Because I vaguely recall having seen a paper with those numbers, but my memory may be incorrect.

[Aaron Siri] Q. Are you familiar with the New England Journal of Medicine? A.

[02:15:00] Yes, of course. Q. What does an editor for this journal do? A. What does an editor for the journal do? Q. Yeah. A.

[Stanley Plotkin] I presume that he edits articles that are submitted to the journal. Q.

[Aaron Siri] And what does the editor-in-chief do? A. Selects articles to be published. Q. And what is your opinion about this, the New England Journal of Medicine?

[Stanley Plotkin] A. It is an influential medical journal.

[Aaron Siri] Q. I'm going to read you a quote from Dr. Edmund J. Safra, a professor at Harvard Medical School and a former editor-in-chief at the New England Journal of Medicine, and I'm going to ask you a question about it, okay? A. Yes. Q. So the quote says, Conflicts of interest and biases exist in virtually every field of medicine, particularly those that rely heavily on drugs or devices. It is no longer possible to believe much of the clinical research that is published or to rely on the judgment of trusted physicians or authoritative medical guidelines.

[02:16:06] I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as the editor of the New England Journal of Medicine. Are you familiar with that quote? A. No. Q. Then let me read you a different quote, again by Dr. Angell, in which she blames the issues that I just quoted, the issues with truth in medical publishing on individuals that use the legitimacy of academia to push pharmaceutical company agendas. Here's what she said about those individuals. She says, They serve as consultants to the same companies whose products they evaluate, join corporate advisory boards and speakers' bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten by interested companies,

[02:17:03] promote drugs and devices at company-sponsored symposia, and allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity interests in sponsoring companies. Are you familiar with that quote? A. Yes, I think I have read that. Q. You've consulted for the big four vaccine manufacturers, correct? A. Yes. Q. You're in the corporate advisory boards of numerous vaccine developers, correct? A. Yes. Q. You've received royalties from the sale of one or more vaccines, correct? A. Yes. Q. You're listed as an author — A. I'm so sorry. Q. I missed the next question completely. Q. You have received royalties from the sale of one or more vaccines, correct? A. Yes. Q. And you said yes. Q. You are listed as an author on at least one or more papers where individuals authoring the papers receive compensation from vaccine makers, correct?

[02:18:04] A. Would you repeat that question? Q. Sure. Q. Have any of your coauthors on any of the papers that you've published received compensation from pharmaceutical companies? A. Presumably, yes. Q. And you've taken numerous trips over the last 30 years to various parts of the world? A. Yes. Q. Okay. Q. I'm going to read you a list of acronyms, and for the record, could you please state what you understand each to be? This way we can have commonality in terms of language. HHS? A. Health and Human Services. Q. Okay. CDC? A. Centers for Disease Control. Q. I know that you know these. This is just so that when I use the term CDC later we have it defined. A. Centers for Disease Control. Q. Thank you. Thank you. Have you

ever been involved with the CDC? A. Yes, of course. Q. What's been your involvement? A.

[Stanley Plotkin] Well, actually, I was an epidemic intelligence service officer in the 1950s, and I have served on committees.

[02:19:11] I've attended numerous meetings at CDC. I've worked or, let's say, collaborated frequently with people from CDC. CDC is the world's most important epidemiology organization. Q. FDA? A. Yes, I've actually done consultation for FDA and interacted with people on FDA, yes. Q.

[Aaron Siri] And it stands for the Food and Drug Administration?

[Stanley Plotkin] A.

[Aaron Siri] And the FDA is an agency within HHS, correct? Q. Yes.

[02:20:00] A. And CDC is also an agency within HHS? Q. Yes. A. Okay. NIH? Q. Yes, of course. National Institutes of Health. A. Right. And you've been involved with the NIH?

[Stanley Plotkin] Q. Yes.

[Aaron Siri] A. And how have you been involved? Q.

[Stanley Plotkin] Served on committees, worked with people at NIH, scientific collaborations.

[Aaron Siri] A. NIH is an agency within HHS as well, correct? Q. Yes. A. Okay. HRSA? Q. I'm not sure. A. Health Resources Services Administration? Q. Okay. A. All right. They're also an agency within HHS, correct? Q. Yes. A. Any involvement with HRSA? Q. I don't think so.

[Stanley Plotkin] A. ACIP? Q. Well, yes. The Advisory Committee for Immunization Practices. I have attended their meetings since 1960s probably.

[02:21:03] A.

[Aaron Siri] Have you ever served on the board at ACIP?

[Stanley Plotkin] Q. On ACIP itself, no.

[Aaron Siri] A. Okay. Q. No. Q. Have you ever served on any board related to ACIP? A. ACIP?

[Stanley Plotkin] I've worked, I've participated in working groups, which they have organized on specific subjects. Q. What working groups were those? A. Let's see. MUMPS. Let's see. What else? MUMPS was the most recent one. I can't recall for the moment, but anyway, two or three working groups that they've organized from time to time. A yellow fever was one. Q. Ever work on a working group for rotavirus?

[02:22:01] A. Actually, no. Q. And measles? A. Measles? No. Q. Not measles, I'm sorry. Rubella? A. No. Not for ACIP, no.

[Aaron Siri] Q. A different government agency? A. No. Actually, that was for WHO. Q. Oh, for the Rubella? A. Yes. Q. And for rotavirus, did you serve on a committee for any other governmental entity?

[Court Reporter] A. No. No. Q.

[Aaron Siri] I hate to hear the whole question.

[Court Reporter] A. I'm sorry.

[Aaron Siri] Q.

[Court Reporter] You're answering while he's still questioning, and there's no question in the record. Q. And for rotavirus, did you serve in a?

[Aaron Siri] A. You could strike that. That's okay. Oh, and WHO stands for? A. World Health Organization. Q. Okay. Thank you. I don't know if I'm going to pronounce this acronym correct. You can correct me if I don't. Is it VRBPAC?

[Stanley Plotkin] How is it normally pronounced? A. VRBPAC. Vaccines and Related Biological Advisory Committee.

[02:23:03] Q.

[Aaron Siri] And that's V-R-B-P-A-C? A. Yeah. Q. Okay. Any involvement with that committee? A.

[Stanley Plotkin] I have testified, but I've not served on the committee. Q.

[Aaron Siri] What did you testify there for?

[Stanley Plotkin] A. On the, at least the last time concerned, the Dynavax vaccine.

[Aaron Siri] Q. Oh, the, for the company you're on the board for? A. Yes. Q. Okay. And this was to try to seek approval of that vaccine? A. Yes. Q. Okay. Which ended up getting approved? A. Yes. Q. The NVAC? A.

[Stanley Plotkin] National Vaccine Advisory Committee. I've given talks to the committee.

[02:24:05] Q. Okay. About what? A.

[Aaron Siri] About vaccines. Q. Fair enough. Anything in particular about vaccines or particular vaccines? A. No, actually, it was more or less general.

[Stanley Plotkin] I was not pushing any particular vaccine, but in relation to the administration and development of new vaccines. Q.

[Aaron Siri] Did you ever give a presentation about the vaccine market? A. About the vaccine market? No. Q. And so all of the agencies and committees we just listed, CDC, FDA, NIH, HRSA, ACIP, VRBAC, and NVAC, they're all under HHS?

[02:25:16] A. I believe so, yes. Q. And what's the, what about IOM? What does that stand for? A.

[Stanley Plotkin] The Institute of Medicine, now the National Academy of Medicine. Q.

[Aaron Siri] Have you ever been involved with IOM? A.

[Stanley Plotkin] Well, I'm a member of the National Academy. So, yes.

[Aaron Siri] Q. Since when have you been a member? A. Oh, gosh.

[Stanley Plotkin] Ten years, but that's just a guess.

[Aaron Siri] Q. Okay. Q. What is the National Childhood Vaccine Injury Act of 1986? A.

[Stanley Plotkin] Well, that's, in effect, it funds the organization that, what shall I say, receives requests from individuals who believe that they've been injured by vaccines and remunerates them if they decide that there was a possibility that the vaccine did cause injury.

[02:26:38]

[Aaron Siri] Q. So if somebody's injured by a vaccine, this law provides that they submit a claim to Health and Human Services? A. Yes. Q. And Health and Human Services then adjudicates? A. Yes. Q.

And those claims are filed in something called the Vaccine Injury Compensation Program, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Administered in D.C.? A. Yes.

[02:27:00] Q. And the respondent in those cases is HHS, the Secretary of HHS? Q. And the Secretary of HHS in those cases is represented by the Department of Justice? A. Yes. Q. To defend against claims that vaccines cause injury, right? A.

[Stanley Plotkin]

I would say that they determine whether there is a reasonable possibility that the vaccine caused injury.

They, I would say, are relatively open and will give an award if there is a reasonable possibility.

[Aaron Siri] When this was first organized ---- Q.

[02:28:06] Do you have any governmental report or any authoritative source, any kind of governmental report or similar that supports the assertion you just made? A. Well, I don't know.

[Stanley Plotkin] I'd have to look that up. Q. Okay. by the American Academy of Pediatrics. And their idea, which I now think was a good idea, was that rather than have an adversary situation, that they would set up an organization whereby if there was a reasonable possibility of injury, that they would offer remuneration as opposed to the situation

[02:29:04] where lawsuits were being filed against companies and having an impact on whether the company was continuing, would continue to make the vaccine. At a certain point, there were relatively few companies making vaccines. And so this is an idea which over the years I have realized was a good idea because it removed the, what shall I say, the oppositional part of the story and made it possible for people who thought that they had been injured to be remunerated, whether or not that was biologically the case.

[02:30:03]

[Aaron Siri] Q. So is it your testimony that the national, that the Vaccine Injury Compensation Program is not an adversarial system?

[Stanley Plotkin] A. It's an adversarial system in that people have to have some reasonable information base to say that a child, let's say, has been injured, whether it's because of the vaccine or whether it's a chance occurrence, fortunately does not have to be adjudicated under this kind of system.

[Aaron Siri] Q. That's only if it's a table injury, correct? A. Yes. Q. But if it's not a table injury, then the petitioner would need to show that it was the vaccine that caused the injury. A. Yes. Q. Okay.

[02:31:00] So this is, I'm going to refer to this as the 1986 Act. This is the Act that gave vaccine manufacturers immunity from liability.

[Tom Liebman] A. Yes. Q.

[Aaron Siri] For injuries caused by vaccines. A. Yes. Q.

[Stanley Plotkin] What is a bacteria? A. It's a microorganism which has certain properties. It has a cell wall, and it has DNA within the organism. And it can, depending on what bacteria it is, it can multiply in humans and sometimes cause disease. Q. Okay. How does it replicate? A. It divides. It has mechanisms for dividing and multiplying.

[02:32:04]

[Aaron Siri] Q. And what is a virus?

[Stanley Plotkin] A.

A virus is a DNA or RNA molecule with properties to produce proteins and to replicate in cells and make more of it, and is capable of causing disease under certain circumstances.

Q.

[Aaron Siri] When you say replicate in cells, do you mean in the host, the person that it affects? A. Yes. Q. So it takes over the person it affects' own cellular DNA material? A.

[Stanley Plotkin] Well, it doesn't take over the DNA necessarily, but it is able to replicate in cells which, of course, have DNA. Not all viruses require that they influence the DNA of the cell, but they all are able to replicate in the cytoplasm or in the nucleus of the cells of the host.

[02:33:15]

[Aaron Siri] Q. And in that fashion, they will spread from cell to cell? A. Yes. Q. By duplicating themselves into more and more cells in the body? A. Yes. Q. And the virus DNA will, you said it can be either DNA or RNA? A. Yes. Q. And those DNA and RNA pieces, they provide coding for protein structures?

[Stanley Plotkin] A.

[Aaron Siri] Yes. Q. Those protein structures are typically, DNA creates protein structures that are important for regulating bodily functions?

[Stanley Plotkin] A. Well, the virus is produced …

[Aaron Siri] Q. I meant DNA in general. I'm sorry.

[02:34:00]

[Stanley Plotkin] A. Oh, DNA in general, yes. DNA in general codes for RNA, which then codes for proteins. Q.

[Aaron Siri] Essential for human life? A. Yes. Q. And is DNA shared across humans? Meaning, is there similarity between the DNA sequence in different people? A.

[Stanley Plotkin] There are similarities, yes, and there are differences.

[Aaron Siri] Q.

What percent of the similarity is there between human DNA amongst individuals?

A.

[Stanley Plotkin] Well, there are mostly similarities, but there are, of course, differences.

[Aaron Siri] That's why we are each different from one another. Q. Tell me if this is not accurate, that human DNA is approximately, among individuals, 99.9 percent similar among different people.

[02:35:10] Is that correct?

[Stanley Plotkin] A. Yes. But that still allows for differences.

[Aaron Siri] Q. Right. Some of us have different eye color. A. Yes. Q. Yes? A. Sorry? Yes. Q. Do all humans and mammals strike that?

What is the percentage of similarity between human DNA and the DNA in mammals of different kinds?

Why don't we start with primates?

[02:36:02] A.

[Stanley Plotkin] Well, the similarities are in the upper 90s, no doubt, but one has to appreciate that the differences that occur are critical and result in critical differences. So the fact that we're, let's say, 99 percent similar to chimpanzees doesn't mean that the differences are, the 1 percent difference is unimportant because much of the DNA actually, the function of most of the DNA is unknown. Q.

[Aaron Siri] So humans have approximately, between humans, have about a 99.99 percent similarity in DNA, and between humans and, I think you said chimpanzees, about 99 percent similarity in terms of sequence.

[02:37:06] Q. What about for other mammals, such as, let's say, between humans and chickens or cows? Is there a similarity? A. Well, there are similarities, certainly, but there are key differences.

[Stanley Plotkin] That's what I was referring to. Even though much of the DNA is the same, most of the DNA that we have, the function of which is unknown.

[Aaron Siri] Q. And what percent would you say is similar? A. With chickens, I don't know offhand. Q. Cows? A.

[Stanley Plotkin] Again, I don't know the number. But the point is that it doesn't require a large percentage of the DNA to be different.

[Aaron Siri] Q. Sure. What about guinea pigs? If you don't know, that's fine.

[02:38:00]

[Tom Liebman] You can just say you don't know. A.

[Aaron Siri] I don't know.

[Tom Liebman] Q.

[Aaron Siri] Okay. Are you familiar with how the CDC makes changes to its pediatric vaccine schedule? A. Yes. Q. Okay. Have you ever been part of that process? A. Not part of the process, but certainly part of the discussion. Q. Okay. In addition and changes to the CDC pediatric schedules voted upon by ACIP, correct? A. Yes. Q. Okay. What happens when ACIP votes for a pediatric vaccine to be added to the CDC's pediatric vaccine schedule for universal use?

[Stanley Plotkin] A. It is adopted by various medical organizations and recommended to the physicians.

[Aaron Siri] And so the pediatricians around the country rely on those recommendations to decide whether or not to administer a vaccine? A. Absolutely. Q. Okay.

[02:39:00] And what about children in the United States that can't afford the vaccines recommended by ACIP? A.

[Stanley Plotkin] Well, until the present time, it remains to be seen whether that will still be the case. The government pays for those children to receive vaccines.

[Aaron Siri] Q. Is that called the Vaccine for Children Program? Q. And ACIP votes on whether or not to add a vaccine to that program, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q.

And when a vaccine is added to that program, the manufacturer is paid for the vaccine even if the child can't pay, correct?

A. Correct. Q. Do you know what percentage of vaccines, pediatric vaccines administered in the United States, are purchased from pharmaceutical companies using federal money through the Vaccine for Children Program? A. Fifty to sixty percent.

[02:40:00] Q. So when ACIP recommends a vaccine for universal use, it will essentially create a liability-free market of millions of children for the pharmaceutical company manufacturing that vaccine, right? A. Correct.

[Stanley Plotkin] The Act provides payment to the pharmaceutical company to manufacture the vaccine.

[Aaron Siri] That is correct. Q. Are you talking about the 1986 Act? A. Yes. Q. And they're not liable for injuries from the vaccines, right? A. Right, unless it is the result of a bad manufacturer. Q. But not for, if it wasn't, not for design defect claims?

[02:41:00] A. Right. Q. Meaning you can't sue a vaccine manufacturer claiming that they could have made the vaccine safer? A. Correct. Q. Who comprises the voting members of ACIP? A. ACIP? Strike that. I didn't want the names. Let me ask it a different way. Are the individuals that serve on ACIP government employee? A. No. Q. Where do these individuals come from?

[Stanley Plotkin] A. They come from all over the United States, and they are chosen because they have no conflict of interest. That is to say, they receive no funding from vaccine companies but are thought to know something about vaccines nevertheless, with the exception of a community representative who is a layperson.

[02:42:08]

[Aaron Siri] Q. So none of the members of ACIP have any conflict with regards to the manufacture, development, or vaccination? A. Right. Q. When was the first rotavirus approved by ACIP for universal pediatric use?

[Stanley Plotkin] A. That was, I don't remember the year, but my recollection is that was in the 1990s.

[Aaron Siri] Q. If I tell you June 25, 1998, does that jog your memory? A. Yeah, that could be right.

[02:43:09] Q. On that date, June 25, 1998, you and your co-inventors, Paul Offit and Fred Clark, had already had a patent on the rotavirus vaccine, correct? A. Yes. Q.

Were you at ACIP at the meeting that they first approved the first-ever rotavirus vaccine for universal pediatric use?

A. I believe I was. Q. Was Fred Clark at that meeting? A. I think he was. I'm not certain. Q. Was Paul Offit at that meeting? A. Yes. Q. What was Paul Offit's role at that meeting? A. His role.

[Stanley Plotkin] I don't remember whether he was still on the committee or not.

[02:44:03] I don't remember. Q. He was on ACIP? A. He was on ACIP, yes. Q. He was a voting member of ACIP? A. But I am confident that he was not allowed to vote on the licensure of Rothertech or on the administration of Rothertech.

[Aaron Siri] Q. For the first, what was the first rotavirus vaccine that was approved for universal use in this country? A. Rothertech. Q. Okay. Well, is that the rotavirus vaccine that you worked on? A. Yes. Q. There wasn't a rotavirus vaccine that was approved before that?

[02:45:00]

[Stanley Plotkin] A. I don't believe so. Well, yes, there was a vaccine that had been developed at the National Institutes of Health that had been licensed but was found to cause intussusception, and the manufacturer took it off the market.

[Aaron Siri] Q. Polofit was on the committee and voted to approve that vaccine for universal use, correct? A. Very likely, yes. Q. At the time that he voted to approve that rotavirus vaccine for universal use, he was a patent holder with you and Fred Clark on a rotavirus vaccine, correct? Q. He didn't accuse himself from voting on recommending the rotavirus vaccine for universal use at that meeting, correct? A.

[Stanley Plotkin] That's correct, which in a sense was voting against himself since obviously he was in favor of the vaccine that we were trying to develop.

[02:46:11] So in effect, he was voting for a competitor.

[Aaron Siri] Q. When you have one vaccine for a given disease approved for universal use, wouldn't that make it easier to then have another vaccine for that same disease approved for universal use? A.

[Stanley Plotkin] Assuming that the properties of the second vaccine were equal to or better than the first, yes.

[Aaron Siri] Q. So approval of the first one paves the way for the second one, doesn't it?

[Stanley Plotkin] A. It paves the way in the sense that if people believe that rotavirus disease is worth preventing, they will want more than one vaccine licensed so that in case there's a shortage of supply of one vaccine, there's an alternative.

[02:47:07]

[Aaron Siri] Q. So there's, once you have one approved, it's a good idea to have a second one approved then, isn't it? A. It is, yes. Q. Are you aware of the many other conflicts of interest regarding the vote to approve the

rotavirus vaccine for universal use that we've just been discussing that's been reported in a U.S. House of Representatives Committee on Government Reform report? Q. Are you aware that this report found that, quote, the overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry, end quote? A.

[Stanley Plotkin] Well, I can't go back to 1998, but at the moment my criticism of the ACIP Committee is that many of the people on the committee do not have a very large knowledge about vaccines because they are eliminated from participating on the committee if they have any connections with industry.

[02:48:26] And I understand why that is the case, but it does result in a group of people who aren't necessarily the best informed.

That being said, I agree with the idea that people who are on the ACIP should have no conflict of interest.

[Tom Liebman] Q. Pardon?

[Aaron Siri] A. The videographer was kindly advising me not to keep smacking my mic.

[02:49:04] That's pinned to my tie. Q. Gotcha. Q. Last question on this. Are you aware that this report by the U.S. House of Representatives Committee on Government Reform concluded that ACIP, quote, reflects, quote, a system where the government officials make crucial decisions affecting American children without the advice and consent of the governed?

[Stanley Plotkin] A. I'm not aware of that report. I do not agree with it.

[Aaron Siri] Q.

[02:50:02] I'm going to hand you what's being marked as Plaintiff's Exhibit 9. Thank you. I'm happy to provide you a copy as well after the deposition that you can take home with you.

[Stanley Plotkin] A. No, I will be interested in reading this, but I would say two things. One is that CDC certainly recently has leant over backwards to try to avoid people with conflicts of interest being on ACIP. And second, that ACIP meets under public conditions.

[02:51:05] That is to say, the meeting is open to the public, the meeting is on the web, so that thousands of people literally can observe what goes on at the meeting and decide for themselves whether or not there is any hanky-panky. So although, as I said before, I might wish that people with more knowledge about vaccines be on the ACIP, by and large, I think that they do a hell of a good job under public scrutiny. Q. Are the working groups, are those also public? A. They are not public in the sense that the public does not attend the working group. The working group does report back to the full ACIP, and the working group's presentations are presented publicly.

[02:52:09]

[Aaron Siri] Q. But the discussions that the working groups have in conference calls leading up to ACIP meetings, those are not transcribed, are they? A. They are not, no. Q. And the members and individuals who participate in those working groups, right, which often lead to what ACIP then rubber-stamps, are permitted to have all forms and do have all forms of conflicts with industry, don't they? A. They may, but I would contest the word rubber-stamp.

[Stanley Plotkin]

I've never seen the ACIP rubber-stamp a working group recommendation.

Often it's just the opposite. Q.

[Aaron Siri] You've also said that the meetings are available to the public. You've attended, you said, almost every ACIP meeting, correct?

[02:53:01] A. Correct. Q. Since, was it the
60s? A. Yeah, roughly, yes. Q. And you attended the most recent one as well? A.

[Stanley Plotkin] The most recent one being, let's see, that would have been last October.

[Aaron Siri] Yes, I did. A. Yes. Q. Were you presented anything at that meeting?

[Stanley Plotkin] A. I presented the fact that I will no longer attend the meetings.

[Aaron Siri] Q. Were you presented anything by the ACIP committee?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. What were you presented?

[Stanley Plotkin] A. I was told that there is a gavel with my name on it that will be used henceforth at the meetings.

[Aaron Siri] Q. So going forward, from this point forward, the gavel that's used at ACIP will have your name on it? A. Correct. Q.

[02:54:00] You gave a speech at that meeting, correct? A. Yes. Q.

When they posted the video of that meeting on the Internet, did they include your speech, Dr. Plotkin?

[Stanley Plotkin] A. I don't know, but I suppose they did.

[Aaron Siri] Q. Well, you can check after this deposition on the website and see if your speech is there. We have not been able to find it. A. Really?

[Tom Liebman] Q.

[Aaron Siri] Now, regularly at ACIP meetings you get up and speak, correct? A. I often do, yes. Q. So you're given free, you're able to get up pretty much at any time and speak, aren't you? A. Yes.

[Stanley Plotkin] Q.

[Aaron Siri] You don't have to wait for the public comment period, correct? A. Correct. Q. And that's also true of vaccine manufacturers. They also are permitted to get up and come to the mic and speak, even not when there isn't public? A. Yes. They are often asked to answer questions that are being discussed.

[02:55:01] Q. Isn't it true that they also get up and come to the front to speak, even when not asked a question?

[Stanley Plotkin] A. They may do so if they have, if it's a discussion about one of their products. Q.

[Aaron Siri] But if members of the public want to speak, they have to wait until the public speaking period, correct? A. Normally, yes. Q. And when the videos are released, a lot of the conversations that occur between the pharmaceutical representatives and ACIP, do those also make it to the video that's released publicly?

[Stanley Plotkin] A. As far as I know, the video contains all of the public hearings. In other words, if somebody comes to the mic, they are photographed, and as far as I know, they appear on the web. I must say that since I've been attending the meetings, I haven't really watched them, but I will in February when they meet again.

[02:56:09]

[Aaron Siri] Q. So apart from the working groups that occur out of public sight, what other meetings or goings about does ACIP engage in that's outside of the scrutiny of the public? A.

[Stanley Plotkin] Aside from working groups, I'm not aware that they do have anything that's not public. I suppose they meet at lunchtime, and I don't attend those discussions, but that's all I know.

[Aaron Siri] Q. Billions of dollars' worth of rotavirus vaccine have been sold to date, correct? A. I believe so.

[Stanley Plotkin] I'm not acquainted with the sales figures.

[02:57:01] Q.

[Aaron Siri]

Does vaccination create a systemic change in the body?

A.

[Stanley Plotkin] Vaccination creates a change in the immune system of the body.

[Aaron Siri] Q. Is that supposed to be system-wide? Meaning, if I get vaccinated in my arm, but I'm infected in my toe, am I supposed to still be immune? A. Yes. Q. So would you say, is it correct to say that vaccination is intended to create a systemic change in the body, throughout the body? A.

[Stanley Plotkin] It's intended to create a systemic change in the immune system of the body. Q.

[Aaron Siri] The immune system everywhere in the body?

[02:58:00] A.

[Stanley Plotkin] The immune system is expressed everywhere in the body, yes.

The immune system consists of antibody-producing cells and cells that are able to influence other cells.

[Aaron Siri] Can you read back the last answer?

[Court Reporter] Q. The immune system is expressed everywhere in the body, yes. The immune system consists of antibody-producing cells and cells that are able to influence other cells.

[Aaron Siri] A. Does the immune system comprise of more than antibody-producing cells?

[Stanley Plotkin] It also includes what are called T-cells that are able to kill infected cells, for example, and to secrete substances that also have an effect on immunity.

[02:59:12]

[Aaron Siri] Q. And is that referred to typically as cellular immunity? A. Yes. Q. And the immunity conferred by vaccines that you were talking about earlier is called?

[Stanley Plotkin] A.

[Aaron Siri] Humoral immunity, yes.

[Stanley Plotkin] Q. Thank you.

[Aaron Siri] I appreciate that.

[Stanley Plotkin] Q.

[Aaron Siri] Humoral immunity? A. Yes. Q. Okay. So humoral immunity creates antibodies, and it's called humoral because it originates from the bones? Is that kind of where the name derives from? A.

[Stanley Plotkin] Well, the name derives from the ancient term humors, but in effect it means antibodies that circulate throughout the body and can impact against infecting organisms.

[Aaron Siri] Q. And the systemic change that you've described is supposed to last years, if not a lifetime, correct, from vaccination?

[03:00:04] A. Yes. Q.

When you say interact with other cells, when you say that the immunity created by vaccines creates antibodies which then interact with other cells, can you describe that a bit more?

What do you mean by interact with other cells?

[Stanley Plotkin] A. Well, the T cells, as I said, are able to attack infected cells in the body by a variety of mechanisms. They may actually directly kill those infected cells by direct action, as it were, or by secreting substances that can kill the cells. And they also influence cells to respond to the infection so that the infection doesn't continue to spread and impact on the individual's health.

[03:01:19]

[Aaron Siri] Q. And how do the cells respond to the infection? Can you describe that? A.

[Stanley Plotkin] You mean the patient's own cells? Q.

[Aaron Siri] I thought that's what you were referring to in your explanation.

[Stanley Plotkin] A. Yeah. Do you mean the infected cells or the T cells that are acting on the infected cells? Q.

[Aaron Siri] Let's start with the T cells.

[Stanley Plotkin] A. Well, the T cells, as I've said, have a variety of functions. They can secrete substances that will kill an infected cell, or they can influence actually the antibody-producing system.

[03:02:07] They have impacts on a variety of ways in which the body protects itself against infection.

There are cells called natural killer cells, for example, that can help protect an individual against an infection.

And the T cells can influence the natural killer cells. So it's a complicated system by which the body responds to an infection or to a vaccine which allows the individual's cells to be ready for infection if it occurs. Q.

[Aaron Siri] Modern immunology, though, doesn't fully understand that full cascade, correct?

[Stanley Plotkin] A.

[Aaron Siri] I'm sorry? Q. I said modern medicine, modern immunology does not fully understand the complete sequence of events in terms of going from vaccination to immunity, correct?

[03:03:13] A.

[Stanley Plotkin] Well, science never completely understands anything, but we know a great deal about how the body responds to vaccines or to infection. And that knowledge is growing every day. So, of course, we don't completely understand anything, including how the sun works, but that doesn't prevent us from using knowledge.

[Aaron Siri] Q. What about its effects on other body systems? Q. Can creating this immune response also have effects not only on creating antibodies to target cells that have been infected, but can it also have other bodily changes, other effects that are either known or unknown?

[03:04:11] A.

[Stanley Plotkin] Well, that's such a hypothetical question, I'm not sure how to answer it. Is an immunized individual any different than an unimmunized individual? Yes. Does the fact that the individual is immune have an effect on his or her general health? I'm not aware that that's the case. Remember that vaccines are, in effect, mimicking what happens after natural infections in many cases, but without causing the complete range of disease that the organism causes.

[03:05:14]

[Aaron Siri] So vaccines are just nothing more than a piece of the virus or bacteria? Is that it? Is that all they contain?

[Stanley Plotkin] It depends on the vaccine. That is to say, whether it's a live vaccine or a killed vaccine. The killed vaccines may only have small parts of the organism that they're protecting against. The live vaccines contain the whole organisms but altered so that they don't cause disease.

[Aaron Siri] Before vaccines are licensed, they go through clinical trials to confirm their safety, right? Correct. Okay.

[03:06:00] These clinical trials assess if there are any harms caused by the vaccine, correct? Yes. Was the DTP vaccine withdrawn from the U.S. market?

[Stanley Plotkin] The wholesale protested vaccines have been withdrawn, yes. Because of safety concerns, right? Because they cause significant fever and convulsions, febrile seizures, and it was decided that it would be better to have a pertussis vaccine that didn't cause that type of reaction. So they were taken off the market not because they were not working, quite the opposite, but because of safety concerns.

[03:07:05] Now, I do have to point out that aside from the U.S. and Europe, wholesale pertussis vaccines are still used in the vast majority of countries in the world, and they are getting along just fine with those vaccines.

[Aaron Siri] Are you familiar with Peter Abe, Dr. Peter Abe? Yes, of course. Didn't he recently publish a paper in which he looked at children who received DTP vaccine in the first six months of life versus children who received no vaccines in the first six months of life and found that those that received DTP died at a rate of 10 times that of the unvaccinated?

[Stanley Plotkin] I don't remember the exact figures, but you have to take into account that Peter Abe's – I have had many discussions with Peter Abe. Peter Abe's work is done in non-placebo-controlled ways.

[03:08:06] That is, his studies are observational. Second point is that those studies have been examined more than once by World Health Organization committees, and their judgment has been that the effects of the pertussis vaccine in particular are not sufficiently documented to be acceptable or to change vaccination practice. So WHO does not recommend against the use of whole-cell pertussis vaccines. Quite the opposite, they do recommend them. You said non-placebo-controlled. What do you mean? I mean that essentially what Peter does, and I'm not criticizing him because obviously it

is very difficult to do, but he doesn't have randomly vaccinated – or children who randomly receive pertussis vaccine or don't receive pertussis vaccine.

[03:09:13] What he has is he follows children who have received this or that or the other vaccine, and tries to draw conclusions from what he sees. But in the absence of random administration, you don't know for sure whether it's the vaccine or other factors that are operating.

[Aaron Siri] So in the study that I mentioned to you, if the children either that were exposed to DTP and unexposed were randomized, that would make the study valid. Yes.

[Stanley Plotkin] And again, the WHO has at least twice gone over Peter's studies and has decided that they are not of sufficient proof to change their recommendations.

[03:10:15]

[Aaron Siri] Do you have a copy of those reports from the WHO? Oh, gosh. Because I'm going to make a demand for those WHO reports. Do you remember when those reports came out? Oh, within recent years.

[Stanley Plotkin] I don't remember the year. More than a year ago? Probably, yes. Okay. Peter Abe's study just came out last year. Well, I imagine WHO will reconsider them.

But his studies suggesting that pertussis vaccine may increase mortality have been around for a while.

[03:11:08] It's not the first study that he's done. And also, one has to appreciate the context. By that I mean that he's also shown or attempted to show that live vaccines like measles vaccine has a very positive effect on mortality. In other words, that in his observations, those who receive measles vaccine suffer from fewer diseases in general and have a lower mortality. And that effect has actually been confirmed immunologically.

[03:12:02] So one has to look at the whole context of things. That is to say, his data are not anti-vaccine data. His data relate to the possibility that vaccines have effects beyond the specific disease that they're designed for. So you agree with his findings regarding live vaccines? I agree because, as I've said and as I advised him years ago, that he has to find some immunological correlate to his findings, or otherwise they're not believable. And what's happened is that scientists not working with Peter have looked at measles vaccination and have shown that the vaccine has effects on what I referred to as natural killer cells before, and that they do seem to reduce mortality against other diseases.

[03:13:15] So, you know, science works that way. One scientist does not gain acceptance for his findings unless they're repeated elsewhere and unless they're consistent with the entire range of facts, not just single ones. Peter Abbe is a respected researcher, correct?

[Aaron Siri] I'm sorry? Is a respected researcher.

[Stanley Plotkin] He's a respected researcher. I respect him just as I respect many other scientists who are attempting to find out things that we don't know yet.

[03:14:02]

[Aaron Siri]

In conducting pre-licensure clinical trials for vaccines, what is the difference between solicited and unsolicited reactions?

[Stanley Plotkin] Well, solicited reactions means that you ask the vaccinee whether he's had X, Y, or Z. Unsolicited are reactions that the patient reports to the investigator without being specifically questioned about them.

[Aaron Siri] And who decides what gets put on the solicited list and what's not? Who decides what symptoms get put on the solicited list of reactions?

[Stanley Plotkin] Well, generally the investigator. However, one has to take into account that the companies meet with FDA during the development of vaccines and that FDA basically has to approve the protocols.

[03:15:14] And so if FDA thinks that a particular reaction should be measured, they will tell the investigators to include them.

[Aaron Siri] But the list is created by the pharmaceutical company developing the vaccine?

[Stanley Plotkin] In the first instance, yes. And then approved by the FDA.

[Aaron Siri] Let's take a two-minute break. Does that sound good?

[Tom Liebman] We are going off the record. The time is 11.50. I just have to use the restroom. In the position of Stanley Plotkin, we are on the record. The time is 12.37. Okay.

[03:16:03]

[Aaron Siri] Dr. Plotkin, earlier you testified that there are two hep B vaccines on the market, one by Glaxo, GSK, that's Engerix B, and the other one is by Merck, Recombivax HB, right? Yes. Okay. For Recombivax HB, how long was the safety review period in the pre-licensure clinical trial for this vaccine? I don't know. Okay.

[Tom Liebman] 17.

[03:17:06]

[Aaron Siri] Dr. Plotkin, I'm going to hand you what's been labeled Plaintiff's Exhibit 10. Is that it? That's it. Okay. This is the product, the manufacturer insert for Recombivax HB, correct? Yes. And the clinical trial experience would be found in Section 6.1, correct? Correct? Dr. Plotkin?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. In Section 6.1, when you look at the clinical trials that were done pre-licensure for Recombivax HB, how long does it say that safety was monitored after each dose?

[Stanley Plotkin] Let's see.

[03:18:02]

[Aaron Siri] Five days. Okay. Is five days long enough to detect adverse reactions that occur after five days?

[Stanley Plotkin] No. Is it? They would be reported separately as observed in the clinic.

[Aaron Siri] In Section 6.1 of the manufacturer insert, which under the Code of Federation they're supposed to describe the clinical trial, does it provide for anything other than five days of monitoring after each dose for adverse events?

[Stanley Plotkin] It does not specifically say that, no.

[Aaron Siri] Okay. Is five days long enough to detect an autoimmune issue that arises after five days?

[Stanley Plotkin] No.

[Aaron Siri] Is five days long enough to detect a seizure that arises after five days?

[Stanley Plotkin] It would be unlikely to have a seizure occur after five days.

[03:19:00]

[Aaron Siri] Is five days long enough to detect any neurological disorder that arose from the vaccine after five days?

[Stanley Plotkin] No.

[Aaron Siri] Okay. Was there any control group in this trial? Let me rephrase that. There is no control group, correct?

[Stanley Plotkin] Not, let's see. Well, they mention 3,258 doses were administered to 1,252 healthy adults.

[Aaron Siri] That's right. But does it mention any control group, Dr. Plotkin?

[Stanley Plotkin] It does not mention any control group, no.

[Aaron Siri] If you turn to Section 6.2, what is the list of adverse reactions listed in this section?

[03:20:06]

[Stanley Plotkin]

These are reports of adverse reactions that likely were reported to the VAERS system.

[Aaron Siri] Under immune system disorders, does it say that there were reports of hypersensitive reactions, including anaphylactic, anaphylactoid reactions, bronchospasms, and uticaria, having been reported within the first few hours after vaccination?

[Stanley Plotkin] Yes.

[Aaron Siri] Have there been reports of hypersensitivity syndrome?

[Stanley Plotkin] Yes, that's what it states.

[Aaron Siri] Does it, reports of arthritis?

[Stanley Plotkin] It is mentioned.

[Aaron Siri] It also reports autoimmune diseases, including systemic lupus, arythmatosis, lupus-like syndrome, vasculitis, and polytereitis, nodosa as well, correct?

[03:21:11]

[Stanley Plotkin] Yes, that's what it states.

[Aaron Siri] And also it states that, under the nervous system disorders, it states that there have been reports of Guillain-Barre syndrome, correct?

[Stanley Plotkin] Yes.

[Aaron Siri] As well as multiple sclerosis, exacerbation of multiple sclerosis, myelitis, including transverse myelitis, seizure, febrile seizure, peripheral neuropathy, including Bell's palsy, radiculopathy.

[Stanley Plotkin] Radiculopathy.

[Aaron Siri] Thank you very much. Muscle weakness, hypothesia, and encephalitis, correct?

[Stanley Plotkin] Correct. Before you go on, these reports are required to be included because they have been reported to the authorities as happening after vaccination.

[03:22:10] That is not proof that the vaccine caused those reactions because things happen to people all the time, whether or not they've been vaccinated. And as I said, the company is required to report these. Now, I mention that specifically because multiple sclerosis, for example, is mentioned here.

Multiple sclerosis has been studied in relation to hepatitis B vaccine, and there's no relationship, no causal relationship.

So the fact that these things are in the package circular does not mean that the vaccine necessarily caused the stated phenomenon.

[03:23:33]

[Aaron Siri] When you say that multiple sclerosis has been studied and is determined to not have been caused, you're talking about the 2011 IOM report, I assume?

[Stanley Plotkin] I'm talking about studies mostly done in France where the situation arose where there was a concern about that.

[Aaron Siri] You're aware of the 2011 IOM report that looked at certain vaccines in relation to whether they can cause certain adverse reactions?

[03:24:04] Okay. Are you aware that one of the conditions they looked at was multiple sclerosis?

[Stanley Plotkin] Among others, yes.

[Aaron Siri] Among others, and that they specifically looked at it with regards to hepatitis B? Yes. And do you know what their finding was?

[Stanley Plotkin] I don't remember the exact wording, no.

[Aaron Siri] Maybe this will remind you. Inadequate to accept or reject a causal relationship.

[Stanley Plotkin] Yes, but you have to understand, first of all, that science continues and so studies continue. And secondly, that the IOM specifically decided that they would not draw a conclusion if they weren't sure of the conclusion. So what that statement means is that they don't have data that confirm that multiple sclerosis is caused by the hepatitis B vaccine, but they don't regard that they have enough data to positively exclude it.

[03:25:10]

So you cannot read that as saying that multiple sclerosis is caused by hepatitis B vaccine.

[Aaron Siri] I never said that. The IOM did, for some of the vaccines and adverse reactions, did conclude that it favors rejection of a causal relationship, correct?

[Stanley Plotkin] Yes, that's correct.

[Aaron Siri] But it didn't reach, sorry, it didn't reach that conclusion for hepatitis B and multiple sclerosis, correct?

[Stanley Plotkin] It did not reach that conclusion, but other data suggests that that conclusion is warranted, that there is no relationship. Okay.

[Aaron Siri] Well, I'll make a remand for that. You can produce that after this deposition.

[03:26:01] So what would need to be done to, in order to know whether or not any of these reported conditions are caused by the vaccine, what you would need is a properly randomized, as you said earlier, placebo-controlled study, correct?

[Stanley Plotkin] Correct.

[Aaron Siri] Okay.

[Stanley Plotkin] And also, I would point out that multiple sclerosis is a disorder of adults, and the issue that arose in France was related to vaccination of adults.

[Aaron Siri] Okay.

[Stanley Plotkin] That does not mean that it would be an issue, even if it were an issue, for children.

[Aaron Siri] Dr. Plotkin, I was just asking what it says on there. There's lots of conditions listed. I'm not saying that multiple sclerosis is caused by this. I'm just asking if it's listed on Section 6.2. In fact, we can even read the top of Section 6.2, which says, the following additional adverse reactions have been reported with the use of the marketed vaccine.

[03:27:12] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure. Right? Okay. So that's what it says right at the top of 6.2. But these are events that are reported after vaccination, and as we've just discussed, in order to establish whether it's causal between the vaccine and the condition, you need a randomized placebo-controlled study. But that was not done for this hepatitis B vaccine before licensure, was it? No. Okay. Okay. And given that the vaccine now

appears on the CDC's recommended list, isn't it true that it would now be considered unethical to conduct such a study today?

[03:28:10]

[Stanley Plotkin] It would be, yes, it would be ethically difficult.

[Aaron Siri] Okay. So let's take a look at Engirex B. That's the other hepatitis B vaccine that you testified you recommend Faith receive.

Do you know how long adverse reactions were reviewed after each dose of that vaccine in the pre-licensure clinical trial?

[Stanley Plotkin] Not offhand, no.

[03:29:05]

[Aaron Siri] I'm going to hand you what has been marked Plaintiff's Exhibit 11. This is the manufacturer insert for the Engirex B, correct? Yes. Okay. If you turn to Section 6.1, which is Clinical Trials Experience, can you please tell me how long the safety review period was in the pre-licensure clinical trials after each dose?

[Stanley Plotkin] All subjects were monitored for four days post-administration. That does not necessarily mean that they didn't collect reactions after four days.

[03:30:05]

[Aaron Siri] Are you claiming they collected reactions after four days, but didn't disclose it here in violation of the Code of Federal Regulations?

[Stanley Plotkin] I dare say that they collected putative reactions for a longer period. I feel quite positive about that. When they say they were monitored for four days, that means active monitoring as opposed to collecting reports later on. That is not uncommon in clinical trials.

[Aaron Siri] Is four days long enough to detect an autoimmune issue that arises after four days? No. Or a neurological disorder that arises after four days?

[Stanley Plotkin] No. That would be reported later.

[Aaron Siri] And can you provide any proof that there was any reports or follow-up after those four days?

[03:31:07]

[Stanley Plotkin] Well, it doesn't say that here, but I am willing to bet that they did collect reactions after four days. And I imagine that the FDA would not have allowed them not to do that.

[Aaron Siri] But as you sit here today, that's just speculation, correct?

[Stanley Plotkin] Yes. That's speculation based on experience.

[Aaron Siri] I'm going to make a request for you to provide proof of what you're claiming, that there was actually, for both hepatitis B vaccines, any safety review that occurred after four days of administration of any dose of these vaccines.

[Laura Nusma] Again, I'm going to continue the objection I got from last time since we took a longer break. There's a proper procedure to request documents and discovery. He doesn't have to come back and produce it.

[Aaron Siri] The objection is noted.

[03:32:00] Thank you. Okay. And there was no placebo group, correct? No. In the trial at the top where it talks about 13,000 doses being administered?

[Stanley Plotkin] It does not say that there was a control group. I don't know. I'd have to go back and look at the study.

[Aaron Siri] And do you believe, so you think there, but you're just speculating that there might have been a control group?

[Stanley Plotkin] There well might have been. It is not unusual for controls to be included, especially if you're looking at reactions. But I don't know specifically for this study.

[Aaron Siri] All right. Well, if you're claiming there might have been a control group, then please do provide support for that, because as far as I understand, the manufacturer, and this was, who makes EngerXP?

[03:33:03] Glaxo?

[Tom Liebman] Glaxo.

[Aaron Siri] One of your clients. If there was a control group, they needed to have disclosed that. And I assume they're not disclosing it because there was none. Well.

[Stanley Plotkin] Go ahead. Yeah. All right, go ahead. All right.

[Laura Nusma] Ms. Newsom, are you still there? Yeah, my headset died, but I called back in, so I don't think I missed much. We're still going over the inserts.

[Aaron Siri] So let's go back to section, now section 6.2 on this manufacturer insert for EngerXP. It talks about the postmarketing experience for this vaccine. This one lists for immune disorders, immune system disorders that were reported, a whole number of them, correct? And it also lists a number of nervous system disorders, including
encephalitis, encephalopathy, migraine, multiple
sclerosis, neuritis, neuropathy, parathesia.

[03:34:10] I'll ask the question all the way at the end. Guillain-Barre syndrome, Bell's palsy, optic
neuritis, paralysis, paresis, seizures, syncope, and transverse
myelitis, correct? It lists all of those?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. But to know whether or not these are actually caused by EngerXP, again, you would need a properly randomized placebo-controlled study, correct? Okay.

But this study wasn't done pre-licensure for this vaccine, right?

[Stanley Plotkin] I'd have to go back and look at the original studies. But these data undoubtedly refer not only to the study that was done before licensure, but also to phenomena reported after licensure.

[03:35:14]

[Aaron Siri] That's 6.2, right. Okay. And again, given that this vaccine now appears on the CDC's recommended list, it would be unethical to do a randomized placebo-controlled study of this vaccine, right?

[Stanley Plotkin] In children it would be unethical. It could be done in adults.

[Aaron Siri] Okay. Now, please go to page 11 of this same manufacturer insert for the hepatitis B.

[03:36:04] If you take a look over there, I think you'll find that it provides that there was a follow-up with regard to efficacy, not safety, efficacy, that was beyond the four days. Do you see there that there was a 12-month and an 18-month follow-up?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. So just to be clear, efficacy of the vaccine was followed up for at least 12 months, for 18 months, but safety was only done for four or five days. I do not agree with that statement.

[Stanley Plotkin] I do believe that GSK, like any other company, would have followed their patients much longer than four days and would have collected reaction data.

[Aaron Siri] And if they didn't do that, you would agree that that is completely inadequate in terms of assessing safety pre-licensure?

[Stanley Plotkin] I would say that would be inadequate, yes.

[03:37:05]

[Aaron Siri] Do you agree with the CDC's recommendation that babies receive a hepatitis B on the first day of life? Yes. And these are the Endrix B and Recombivax HB are the only two hepatitis B vaccines approved for one-day-old babies, correct?

[Stanley Plotkin] Correct.

[Aaron Siri] Okay.

[Stanley Plotkin] And why is that, you may ask. It is because if the baby is not vaccinated, well, I'm telling you, that if a baby is not vaccinated at one day of age, transmission may occur from an infected mother, and hepatitis B occurring in babies is likely to become chronic and to cause serious disease later in life. That's why the dose is given at one day of age.

[Aaron Siri] I wasn't asking you any questions about efficacy or why it's done.

[Stanley Plotkin] But I'm telling you why it's given.

[03:38:00]

[Aaron Siri] Thank you, but obviously I'm just trying, like any product, obviously, you want to have informed consent, understand the risks and the benefits, and I'm just trying to understand what was done pre-licensure for these vaccines, and I think you've explained that to me. One of the things you've said in the past, I believe, is that without a control group in a clinical trial, you're in la-la land, right? You said that one time, do you recall?

[Stanley Plotkin] Without a control group, if you're looking for a phenomenon occurring in the vaccine group, you cannot judge that phenomenon without having a control group.

[Aaron Siri] There's only one standalone polio vaccine currently licensed in the United States, correct?

[Stanley Plotkin] Well, as far as licensure, I think both oral and inactivated vaccines are licensed, but the only one that is used in the U.S. currently is the inactivated one.

[03:39:00]

[Aaron Siri] IPV?

[Stanley Plotkin] Yes.

[Aaron Siri] And there's only one Sanofi? There's only one iPol-iSanofi?

[Stanley Plotkin] Yes.

[Aaron Siri] A vaccine, you strike that. Q.

How long was the safety review for each dose of iPol in the preclinical trials for that vaccine?

[Stanley Plotkin] A. I do not know offhand, but, Counselor, IPV has been used throughout the world for years in millions of people, and safety data have been collected on many such studies, and essentially serious reactions to IPV are extremely rare. So IPV is a very safe vaccine.

[03:40:00] Q.

[Aaron Siri] I'm asking you, in the prelicensure clinical trial for? A.

[Stanley Plotkin] That goes back to Jonas Salk, where he, where millions of children actually were vaccinated with IPV back in the 50s. Q.

[Aaron Siri] And is there clinical trial data on safety?

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] And is that the same vaccine that's used today?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Are you prepared to produce that clinical data? A.

[Stanley Plotkin] Those data are in this book, and I'll be glad to provide you with the references if you really insist. But IPV, as I've said, has been used in millions and millions of people. Q.

[Aaron Siri] If it's so safe, then how come the safety review period for the prelicensure clinical trial, as provided in the manufacturer insert for IPOL, only reviewed safety for 48 hours?

[03:41:07] A.

[Stanley Plotkin] Once again, I have no doubt that safety observations were made after 48 hours, but they expected that immediate reactions, such as a sore arm or fainting or something like that, would have happened within 48 hours. And also, I'm sure that they're talking about their own specific production of IPV and not relying on the millions of other people who have been vaccinated with IPV. Q.

[Aaron Siri] I'm going to hand you what's been marked as Exhibit 12. This is the manufacturer insert for the IPOL poliovirus vaccine inactivated. If you could please turn to Section 6.1, Dr. Plotkin.

[03:42:09] Well, this is an older one. If you could turn to the adverse reactions, which is on page 12.

[Laura Nusma] 14.

[Aaron Siri] Q.

[Laura Nusma] This preserves the objection. To my understanding, Dr. Plotkin had no role in the study design. You're asking to speculate as to the reasoning of other people that he had no contact with.

[Aaron Siri] Okay. He's testifying that my client should receive this vaccine. I can certainly ask him about the pre-licensure clinical trials that were done to assess its safety. And you put him up as an expert in vaccinology. But your objection is noted and preserved for the record. Thank you, Counselor.

[03:43:02] Okay, so if you go to page 14, Dr. Plotkin, how long does it say that adverse reactions were observed after vaccination? 48 hours. Okay. And did the subject group that received IPV only receive IPV, or did they receive another vaccine along with it?

[Stanley Plotkin] Concurrently with DTP. Uh-huh.

[Aaron Siri] And what did the control group receive? I don't see that stated. If DTP is given along with IPV, how could you know whether a reaction was caused by DTP or IPV?

[Stanley Plotkin] You could not.

[Aaron Siri] Okay.

[Stanley Plotkin] However, they do say these systemic reactions were comparable in frequency and severity to that reported for DTP given alone without IPV.

[03:44:10]

[Aaron Siri] And DTP was the vaccine we talked about earlier that was withdrawn from the market, correct? Yes. For safety issues. Okay. The only MMR vaccine available in the United States are made by Merck, correct?

[Stanley Plotkin] Correct. Okay.

[Aaron Siri] How long was the safety review?

Do you know how long the safety review period for each dose of MMR in the pre-licensure clinical trials for this vaccine?

I'm so sorry. No problem. Do you know how long the safety review period for each dose of MMR in the pre-licensure clinical trial was for this vaccine?

[Stanley Plotkin] Not offhand. The vaccine has only been used now for about 50 years.

[Aaron Siri] So it's more recent, right?

[03:45:18] Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 13. This is the manufacturer insert for MMR-2, correct? Yes. Okay. If you go to the precaution section. I'm sorry, the adverse reaction section. I apologize. On page 6, what you'll find is that there was no clinical trial prior to licensure for MMR, correct?

[03:46:01]

[Stanley Plotkin] I doubt very much that's the case.

[Aaron Siri] You're not aware that it's a, is it, are you aware that it is a grandfather product?

[Stanley Plotkin] I am not aware that it is grandfathered. I was alive and well when the product was first licensed, and it was tested extensively before it was licensed. So to say that it hasn't been tested is absolute nonsense.

[Aaron Siri] How come there is no clinical trial data in the manufacturer insert?

[Stanley Plotkin] That is something that the FDA would have decided isn't necessary. Are you willing to prove it? We're talking about a vaccine that's been given to millions of children. And just, I insist on this point, that measles is now a relatively rare disease in the United States because most children receive measles MMR vaccine.

[03:47:06] That, however, in the last, since 2000, because of children who have not been vaccinated, there have been five cases of measles, I'm sorry, 24 cases of measles encephalitis and three deaths caused by measles itself.

[Aaron Siri] Dr. Plotkin, we'll get to that piece of this, but right now I'm trying to talk to you about the pre-licensure clinical safety.

[Stanley Plotkin] And what I'm telling you is that millions of doses have been used of this vaccine and that there was pre-licensure trials, which I am absolutely confident about. And you're talking about stuff that's in a package circular that the FDA has approved in full knowledge that safety and efficacy have been demonstrated.

[03:48:01]

[Aaron Siri] Q. So you're saying there were clinical trials before the MMR was licensed?

[Stanley Plotkin] A. Absolutely. Q.

[Aaron Siri] Okay. And you can provide those? A.

[Stanley Plotkin] You can find them in this book, if you wish. Q. So you're saying you won't provide them? A. Well, yes, I guess I am saying I won't provide them. If you want to take the trouble, read the book. Q.

[Aaron Siri] Okay. So sitting here today, can you tell me what year these clinical trials occurred?

[Stanley Plotkin] A. Yes. Yes. They were done in the 1960s, yes, mainly in the 1960s.

[Aaron Siri] Q. So you're claiming something happened, but you're not willing to provide any proof that it happened?

[Stanley Plotkin] A. The proof is in the publications, which you can read. Q. Okay.

[Aaron Siri] Can you please turn to the page where it's in there? I'd like to note for the record that Dr. Plotkin has been reading from his notes as well as looking through a book entitled Plotkin's Vaccines, 7th Edition.

[03:49:30]

[Stanley Plotkin] So on pages, let's see, between pages 592 and 600, including tables that show the antibody responses, proportion of children with fever and rash after measles vaccine, et cetera, and the numerous references which go with this chapter.

[03:50:09]

[Aaron Siri] Q. So are you saying that that was a prelicensure clinical trial that you just read from?

[Stanley Plotkin] A. Yes. Yes.

But again, I insist that prelicensure or postlicensure, the fact remains that the vaccine has been studied extensively over a period of 50 years.

[Aaron Siri] Q. I know, I understand you want us to just take your word for it, but I prefer to rely on science, peer-reviewed publications and clinical trials.

[Stanley Plotkin] A.

[Aaron Siri] That's what you'll find in there. Q. And so I understand that you're getting a little upset about me trying to ask for the data, but I'm just trying to get to the substance. The FDA requires that clinical trials be on the insert. They're not here. So you're saying that this table, and let me take a look at it, this would have been postlicensure, not prelicensure, and it doesn't indicate a placebo group, nor that it was.

[03:51:19] So this is not a clinical trial as far as I can tell. Can you point me to something that had a placebo group and was prelicensure, please, sir?

[Stanley Plotkin] A. I'm not sure of the placebo group. I would have to go back and look at the individual studies.

But in terms of prelicensure studies, I am absolutely certain that they were done when the measles, the

rubella vaccine that I developed was incorporated into MMR.

Obviously, clinical trials were done before licensure, and I'm absolutely certain about that.

[03:52:05]

[Aaron Siri] Q. Well, maybe they're not included because they didn't include a placebo group.

[Stanley Plotkin] A.

[Aaron Siri] They may not have included placebo groups, yes.

[Stanley Plotkin] Q.

[Aaron Siri] So maybe they weren't deemed valid enough to consider a clinical trial. A.

[Stanley Plotkin] That's absolutely false because you can certainly collect reactions in individuals who receive the vaccine, for example, fever and seizures and that sort of thing, that happen immediately, and whether there's an effect on blood cells, et cetera. Those things were definitely done. I'm absolutely certain about that because I was there. Q. But there was no control group? A.

I don't remember there being a control group for the studies that I'm recalling.

[Aaron Siri] Q. So you're not aware of any trial that assessed safety in MMR with a control group, correct?

[03:53:03]

[Stanley Plotkin] A. I cannot cite such a study offhand. I'd have to go back and look to see whether control groups were included. Q.

[Aaron Siri] We talked earlier that to assess safety you need a randomized placebo-controlled study, and my understanding from looking at this insert is that no such study exists. You told me that it's in this chapter, and you assured me it's in there, but you're not citing anything in there right now. So I'm happy to get a copy from you if you'd like to provide it after this deposition. Would you like to do that?

[Stanley Plotkin] A. I will look.

[Aaron Siri] Q. Okay. Going back to page 6, of the manufacturer insert for MMR, there is an extensive list of adverse reactions that have been reported after licensure of this vaccine by individuals receiving the vaccine, correct?

[03:54:20] A. Yes. Q. Okay. I'm not going to read through all the ones because it's a page and a half long, but they're extensive. And of course we won't know whether or not MMR actually causes any of these unless we have a randomized placebo-controlled study, correct?

[Stanley Plotkin] A. Correct.

[Aaron Siri] Q.

And when I say these, I mean all the adverse reactions listed in the manufacturer insert for MMR on pages 6, 7, and 8, right?

[03:55:02] You understood that's what I meant?

[Stanley Plotkin] A. Yes. Q. Okay.

[Aaron Siri] Let me ask you this.

[Stanley Plotkin] A. Yeah.

[Aaron Siri] Q. Listen. Let me ask you this. Maybe you can help clarify, okay? Oh, I'm sorry. You know what? I'll leave that alone. You also testified that faiths should be vaccinated for Hib, correct? A. Yes. Q. Okay. Do you know how long the safety review

period was for each dose of Act-Hib in the prelicensure clinical trials for this vaccine?

[Stanley Plotkin] A. Not offhand, no.

[03:56:00] Q. Okay.

[Aaron Siri] I'm going to hand you what's been marked as Plaintiff's Exhibit 14, Dr. Plotkin. This is the manufacturer insert for Act-Hib, correct?

[Stanley Plotkin] A. Yes. Q. Okay.

[Aaron Siri] If we go to Section 6.1, which is the clinical trials experience, I believe you'll see it addresses a number of clinical trials that were performed, correct?

[03:57:04] A. Yes. Q. Okay. And what were the safety review periods in these trials? A. Forty-eight hours of force, yes. Q. Actually, you know, if you turn to page 8, Dr. Plotkin, they did one that actually was 30 days long, correct? A. Say again? Q. I said if you turn to page 8 of the insert, one of the clinical trials they did actually did look at, did do a 30-day follow-up, correct? A. Yes. Q. Okay. Now, I'm going to read you a sentence from the paragraph at the bottom of that page.

[03:58:02] It says, A. Yes. Q. Okay. Q.

Now, one way to establish whether or not those adverse events were related to the vaccine was to have a placebo group, a control group, receiving an inert substance, correct?

A. That's one way. Q. That's right. But there wasn't a control group here receiving an inert substance, correct? A. As far as it says, no. Q. All right. And the control group here received other vaccines, correct?

[03:59:00] A. Yes. Q. Okay. A.

[Stanley Plotkin] Well, actually, there does appear to be, well, for dose 4 anyway. Oh, no. I'm sorry. Excuse me.

[Aaron Siri] Q. Yeah.

[Stanley Plotkin] It's all right.

[Aaron Siri] Q. Anyway, so since there is no placebo group receiving an inert substance, then it's left to the vaccine manufacturer seeking licensure to determine whether or not the 50 adverse events that arose are or are not related to the vaccine, correct? A.

[Stanley Plotkin] In fact, generally speaking, studies organized by manufacturers or anybody else, for that matter, of vaccines has a safety board attached to the study, and they evaluate whether they think the reaction was due to the vaccine or not. As it says here, only one of the serious adverse events was attributed to the vaccine, which was a seizure with apnea occurring on the day of vaccination after the first dose, which is, you know, in 7,000 infants and a vaccine that prevents meningitis and other serious diseases is not too bad.

[04:00:24]

[Aaron Siri] Q. Right. So let's look at that more carefully. This is out of 1,455, correct? A. Yes. Q. And it was 50 children that had a serious adverse event within 30 days, correct?

[Stanley Plotkin] A. They had – where is that?

[Aaron Siri] Q. That's the bottom of page 8.

[Stanley Plotkin] A. Yes, but you have to understand what is meant by a serious adverse event. They try to accumulate all things that happen to children in a trial, and when they say it's serious, they mean it's not something like pain in the arm or something that's relatively trivial.

[04:01:12] And then they evaluate whether or not the serious adverse event could be related to the vaccine or not. And what this says is that only one of those events was attributed to the vaccine. Q. That's right.

[Aaron Siri] That's exactly what this says. A. Yes. Q. And you told me that the people that evaluate that is a board set up by the company, the pharmaceutical company, seeking approval, correct?

[Stanley Plotkin] A. Yes. They set up the board, and they choose individuals who are not employees of the company. Q.

[Aaron Siri] But they choose the individuals, correct?

[Stanley Plotkin] A. They choose the individuals, yes.

[Aaron Siri] Q.

In your experience, Dr. Plotkin, in any given 30-day period, do 3.4 percent of children in this country experience a serious adverse event?

[Stanley Plotkin] A. Yes, that's quite possible.

[04:02:01]

[Aaron Siri] Q. In your experience, would you expect 3.4 percent of children receiving a saline injection to experience a serious adverse event within 30 days of receiving the injection? A.

[Stanley Plotkin] That's what that means, yes.

[Aaron Siri] Q. Okay. So 3.4 percent every month, that would mean within three years, every child in this country would experience a serious adverse event, correct? A.

[Stanley Plotkin] Yes, correct. But you have to understand that serious adverse events mean, for example, that a child develops a respiratory infection during the period of the trial. And then the question is, could that respiratory infection be attributed to the vaccine? And the board decides whether or not it's likely that a vaccine could cause a respiratory infection two or three weeks after the vaccination, for example. Q.

[Aaron Siri] Wasn't there recently a study out of Hong Kong in which it was actually one of the few randomized placebo-controlled studies in which some children were randomly got flu vaccine and others didn't get the flu shot?

[04:03:06] And those that got the flu shot and those who didn't had the same rate of flu, but those who got the flu shot were four times more likely to get certain other respiratory infections? A. I have not read that particular study.

[Stanley Plotkin] Q.

[Aaron Siri] We can get to it later.

[Stanley Plotkin] A. But influenza vaccine is a whole story in itself.

[Aaron Siri] Q. Okay. That's fine. If you haven't read it, we can get to it. I have it. We'll come back to it. Now, there's another Hib vaccine called Hibirex, right? And then, which was licensed after Act-Hib, correct? A. Yes. Q. And in that clinical trial, they used Act-Hib as the placebo to assess safety, correct?

[04:04:03] A.

[Stanley Plotkin] If you say so. Q. Okay.

[Aaron Siri] The CDC's pediatric schedule you testified earlier also includes vaccination for HPV, correct? A. Yes. Q. Okay. I'm going to hand you what's been marked as Plaintiff's Exhibit 15. Vaccine.

[04:05:11] This is the manufacturer insert for Gardasil, correct? A. Uh-huh. Q. Which is a vaccine against HPV. A. Yes. Q. Gardasil is currently the only HPV vaccine used in the United States. A. I'm sorry. Gardasil. I'm going to ask you a question unrelated to what I just handed you for a moment while my co-counsel here sends a copy to opposing counsel. Q. You can keep on typing Gardasil insert. A. Okay. Thank you. So Gardasil is currently the only HPV used in the United States, correct? A.

[Stanley Plotkin] I'm not sure whether the GSK vaccine is still being used or not, but Gardasil is the one that is used mostly in any case.

[04:06:04]

[Aaron Siri] Q. Can you please turn to page 8, table 9 of this insert? A. Uh-huh. Q. This table reflects girls and women 9 through 29 years of age who reported an incident condition potentially indicative of a systemic autoimmune disorder during the clinical trial, correct?

[Stanley Plotkin] A. Yes. Q. Okay.

[Aaron Siri] The subjects receiving Gardasil show a rate of 2.3 percent, right? So that means 2.3 percent of the girls and women in the clinical trial during a six-month period had an incident that indicated a systemic autoimmune disorder, correct?

[04:07:12] A. Yes. Q.

And in the AAHS control or saline placebo group, it shows the same rate, correct?

A. Yes. Q. Do you know how many individuals were in the saline placebo group versus the AAHS control group?

[Stanley Plotkin] A. Well, it says 9,412. Q.

[Aaron Siri] That would be the total number for both groups, correct?

[Stanley Plotkin] A. No, for the placebo group.

[Aaron Siri] Q. For the placebo group, correct. But some of them received AAHS and some of them received a saline injection, correct?

[Stanley Plotkin] A. Correct.

[Aaron Siri] Q. Do you know how many received a saline injection over an AAHS injection?

[04:08:03] A. Don't know. Q. Okay. Let's go to page 4. Table 1 is for girls and table 2 is for boys. I'm assuming all participants were either girls or boys.

If we add up the saline placebo group for the girls and the saline placebo group for the boys, do we get 594?

A.

[Stanley Plotkin] Well, I'd have to do the arithmetic. It appears that there were about 5,000, more than 5,000 in the AAHS control.

[04:09:02]

[Aaron Siri] And about 600 in the saline placebo. Q. Right. It's about 594. It's about 600. That's right, right? A. Uh-huh. Q. Okay. So if we go back to page 8, the saline placebo group had about 600 and the rest of them were AAH control, correct?

[Stanley Plotkin] A. Apparently, yes. Q. All right.

[Aaron Siri] What does AAHS stand for? A. The Aluminum Adjuvant. Q. Okay. And I see it's defined here as amorphous aluminum hydro- A. Hydroxyphosphate sulfate. Q. Right? A. Yes. Q. All right. Thank you. Which we'll refer to as AAHS or the Aluminum Adjuvant.

[04:10:01] A. Yes. Q. Okay. AAHS is not an inert substance, correct?

[Stanley Plotkin] A. Well, it's not saline, if that's what you mean. But they use it as a control because they're trying to make, to determine what the reactions are to the HPV vaccine that contains the aluminum and separating the reactions to vaccine from reactions to the aluminum.

[Aaron Siri] Q. Just to make sure I understand that, are you saying they're trying to determine what the rate of reactions is between the group that gets Gardasil with the group that gets the aluminum, with the group that gets saline? Q. So they want to compare between those three distinct groups, correct? A. Yes. Q. Okay. And they did do that in Table 1 and 2 that we just looked at on page 2.

[04:11:00]

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] Page 4, correct? A. Yes. Q. Okay. Why is aluminum added to the Gardasil vaccine or any vaccine?

[Stanley Plotkin] A. To increase the immunogenicity of the active part of the vaccine.

[Aaron Siri] Q. If I may, what you mean is that, if I could use a little more layman terms, are you saying it's intended to stimulate the immune system to create antibodies? A. Yes. Q. Would that be correct? A.

[Stanley Plotkin] Yes. Not by itself, but by enhancing the response to the vaccine antigens. Q.

[Aaron Siri] The antigens bind to the aluminum?

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] And the aluminum is persistent?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. And it remains in the body such that it continues to present the antigen such that antibodies can be created to it, correct?

[04:12:00]

[Stanley Plotkin] A. Well, at least during the immediate period of vaccination, yes.

[Aaron Siri] Q. There is, in fact, a syndrome called autoimmune, autoinflammatory syndrome induced by adjuvants, correct?

[Stanley Plotkin] A. That is a debatable point. There is a fellow named Yehuda Schoenfeld, an Israeli who has pushed this idea for many years. I think it's fair to say that he has never had acceptance by the larger community of immunologists or rheumatologists.

[Aaron Siri] Q. I am going to hand you what is being marked as Exhibit 16.

[04:13:34] Are you familiar with this book?

[Stanley Plotkin] A. Generally speaking, yes. I can't say I've read it all, no.

[Aaron Siri] Q. Okay. And it's entitled Vaccines and Autoimmunity, correct?

[Stanley Plotkin] A. Yes, correct. Q.

[Aaron Siri]

And it extensively discusses many autoimmune conditions that the authors believe can be caused by vaccines, and in particular by aluminum adjuvants, correct?

[04:14:10] A. Well, I know about it. Q. Aluminum adjuvants. A.

[Stanley Plotkin] I know about particularly aluminum adjuvants, but that's one of their arguments.

[Aaron Siri] Q. Can you please turn to the Contributors, which starts on little Roman numeral 9? Okay. Keep going. Two more pages. There are, I think, somewhere around 77 contributors listed here. You said that Yehuda Schoenfeld was kind of alone, I think, or something like that, with regard to the claim that autoimmune, autoinflammatory syndrome induced by adjuvants A.

[04:15:06] Yes. Q. Can you just flip through and look at the universities that are listed here, where these over 70 professors hail from? Are these respected institutions of medicine around the world? A.

[Stanley Plotkin] Well, first of all, Counselor, I'd have to go over the CVs of each of the people here. I don't know what their role is at the universities. As I said before, Schoenfeld, first of all, Schoenfeld himself is not anti-vaccination. I know that for a fact. On the other hand, at least one of his co-authors, Tom Lijanovich, is a well-known anti-vaccination person who's written a lot about how terrible vaccines are.

[04:16:06] And as far as the articles are concerned, you know, I have to read each one. But, for example, vaccination in patients with autoimmune inflammatory rheumatic diseases, in other words, patients who themselves already have autoimmune diseases, that's certainly a legitimate field of study. In other words, how do you vaccinate people who already have autoimmune disease? Could their vaccinations make things worse? But that doesn't necessarily mean that the vaccines themselves cause disease. Now, here we have a chapter called Measles, Mumps, and Rubella Vaccine, a Triad to Autoimmunity, of which Schoenfeld himself is one of the authors.

[04:17:06] I am, what shall I say, I do not believe there is any solid evidence that measles, mumps, and rubella vaccines cause autoimmune responses.

So, you know, lots of books are published, and a lot of them are absolute bull.

Q Are you saying that this book is bull? A I haven't read the whole thing, but I am almost certain that there's a lot of bull in it, judging from the editors. Q Without reading it, right? A Without reading all of it, yes.

[Aaron Siri] Q Okay. Are you familiar with the Tel Aviv Sorosky Medical Center? A No. Q Okay.

[04:18:01] Are you familiar with the University of Paris?

[Stanley Plotkin] A University of Paris. Paris has many different universities, and they are sort of numbered.

[Aaron Siri] Q Are you familiar with the University of Pisa?

[Stanley Plotkin] A No. I'm sure there is a University of Pisa.

[Aaron Siri] Q Okay. Are you familiar with the Technion, the Israel Institute of Technology? A Yes. Q The Rappaport School of Medicine?

[Stanley Plotkin] A I can't tell you one thing, because I've talked to Israelis about Schoenfeld, and Schoenfeld's opinions are not majority opinions, even in Israel.

[Aaron Siri] Q But, for better or worse, there is a syndrome out there that is called autoimmune, autoinflammatory syndrome induced by adjuvants, and there are apparently professors at universities who disagree about the syndrome, but it is out there, right?

[04:19:12]

[Stanley Plotkin] A There is. Schoenfeld has postulated this syndrome, yes.

[Aaron Siri] Q And there's at least 70 professors at universities around the world that are in agreement with that syndrome in this book?

[Stanley Plotkin] A No. Absolutely not. I'll bet if you go through that book and talk to them, you would find that most of them probably do not agree, because all of the articles in this book don't say that vaccines cause autoimmunity. Some of them do. Q Okay.

[Aaron Siri]

There has been concern raised that aluminum adjuvants in vaccines can cause autoimmunity.

[Stanley Plotkin] A There has been concerns raised, yes.

[Aaron Siri] Q So if there's been concerns raised that aluminum in vaccines can cause autoimmunity, and there's this medical textbook, which I understand your opinion on, why combine the autoimmunity rate in the aluminum adjuvant control with the autoimmunity rate in the saline placebo?

[04:20:16] Why not break those out to show them separately?

[Stanley Plotkin] A Well, they did to some extent, but I think the reasoning was that they wanted to be sure that the reactions that were seen, and let me parenthetically say that HPV vaccine is painful, and they wanted to be sure

that the reactions that they were seeing were not caused by the adjuvant, or that they were specific to the HPV antigens themselves and not to the adjuvant. So I could judge that's why they did that.

[04:21:02]

[Aaron Siri] Q Well, under that logic, then they certainly should have broken out the aluminum control from the saline placebo control and showed them in two separate columns on page 8, correct? A They probably should have, yes. Q So that you could see the difference in autoimmune rate between the individuals receiving the aluminum and the saline placebo, correct? A Yes. Q Okay. In your experience, would you expect 2.3 percent of girls and women in this country between the ages of 9 and 26 to develop a systemic autoimmune condition in a six-month period?

[Stanley Plotkin] A Well, that's a hard question for me to answer. I am not a rheumatologist, but when they say autoimmune conditions, I'd have to read exactly what they mean.

[Aaron Siri] If you go to page 8, they've got a long list, right?

[04:22:01] They have the conditions. It starts with arthralgia.

[Stanley Plotkin] So they have included just about everything that you could consider an autoimmune disorder. And all I can say is that they have, well, as I just said, they've attempted to include everything. And those are the data. What can I say?

As far as 2.3 percent autoimmune disorders in six months, these are women 9 through 26 years of age, so they're not just girls.

And I don't think it's impossible that that's the case, especially when you have a list of disorders that is so comprehensive as this.

[04:23:02]

[Aaron Siri] Q Okay. So 2.3 percent in six months, 4.6 percent in a year. In 10 years, half the women in this country would have autoimmunity. In your experience, would that be accurate?

[Stanley Plotkin] A Well, again, I am not a rheumatologist, so I cannot answer that question specifically. All that I can say is that they attempted to do a comprehensive study of autoimmune phenomena or putative autoimmune phenomena in this study, and that's what they found.

[Aaron Siri] Q Do you know the percentage of girls in the saline placebo group that developed a systemic autoimmune condition during this clinical trial versus the AAH control, APHS?

[Stanley Plotkin] A No, I do not, without going back to the original study.

[04:24:01]

[Aaron Siri] And Dr. Plotkin, I'm going to hand you what's been marked. Exhibit 6, Plaintiff's Exhibit 17. This is the clinical trial data for the saline placebo control group in the Gardasil trial. You can go to page 2, Dr. Plotkin. You can see that the number of vaccinated in the placebo is 596.

[04:25:00] Well, you can see at the top. On the first page, I'm sorry. On the first page, Dr. Plotkin, it says a study of Gardasil in preadolescent and adolescence, correct? A study of Gardasil in preadolescent and adolescence. Okay?

And page 2, you can see that it has the 596 saline placebo recipients.

Can you please turn to the Serious Adverse Events section, which is 1, 2, 3, 4, 5, 6, 7. The seventh page. They don't print with page numbers, unfortunately.

[04:26:01] Serious Adverse Events. Okay. Now, if you go to the next page, run right after that. Just take a look at that. You can see that the second column is the placebo, the results for the placebo group, correct? Uh-

huh. Okay. Can you please take a minute and go through each page and tell me if there was any value that wasn't zero in terms of finding a Serious Adverse Event? No, I don't see any. Okay. So in the saline placebo group during the trial, there was not a single systemic autoimmune disorder that was reported, but yet there was 218, 2.3 percent, or maybe more, actually, in the AAH control when you pull out the saline placebo group.

[04:27:02]

[Stanley Plotkin] Well, again, that has to do with the arithmetic, but if you subtract the 600 or so from the total, you could easily figure out the percentage in the aluminum group.

[Aaron Siri] So let's do that. Let's do that.

So there's 900,412 in the aluminum group, excuse me, in the total in both groups combined.

Yeah. If we pull out the saline placebo group of 594 from the 9,412, would that make the 2.3 percent number go up or down?

[Stanley Plotkin] It would go up slightly. That would be, I'd have to go back and look at the numbers, but that would be reducing the total to about 8,800.

[04:28:00] So I guess that would be in here, right?

[Aaron Siri] Go to page 8. Right.

[Stanley Plotkin] So the point is, is that if they would have broken out the 200 over 8,800, and I doubt if that would show a significant difference between the Gardasil and the AAHS group.

[Aaron Siri] So the Gardasil group would show 2.3, it shows 2.3 percent. Yes. If we took out the saline placebo group from the second column, it would show 2.3 or above, around 2.3 still, correct?

[Stanley Plotkin] Maybe.

[Aaron Siri] A little higher, 2.4, 2.5, 2.5. And then if we had a third column that was just the saline placebo, it would show zero percent.

[04:29:06] Yeah. Okay. Wouldn't that have been a significant finding to report?

[Stanley Plotkin] I don't think you'd have to ask a statistician, but I doubt that the statistical difference would be significant.

[Aaron Siri] Doesn't it at least caution having a larger saline placebo group if your concern is statistics in terms of statistical power, which I assume?

[Stanley Plotkin] Yeah. They might have done that.

[Aaron Siri] But they didn't do that.

[Stanley Plotkin] Yes. I don't know what that decision was based on. But if you're talking about implication of aluminum, at this point there's really no reason to suspect that aluminum by itself can cause autoimmune disease.

[04:30:09]

[Aaron Siri] Here is the pre-licensure clinical study in which 2.3 percent of participants in the Gardasil group and in the control group had a systemic autoimmune disorder, and it was deemed safe because they were around the same rate, right? Yes.

But the saline placebo group that didn't get the aluminum adjuvant had a zero percent, right?

A small group, yes. Of 594. Yeah. And so the vaccine apparently, if you turn back, Dr. Plotkin, to page 4, please, of the Gardasil insert. Are you there?

[04:31:05] Yeah. Do you see that they break out Gardasil in one column, those who received AAHS control in another, and those that had saline placebo in a third column? Right. And that's with only 320 participants in the saline group in Table 1, correct?

[Stanley Plotkin] Yes.

[Aaron Siri] And in Table 2 they break it out as well, correct? The saline group from the AAHS control group?

[Stanley Plotkin] Yes.

[Aaron Siri] If you turn to page 5, they again break out the Gardasil AAH control and saline placebo groups in Tables 3 and 4, correct? Yes. But they chose to conveniently combine it when it came to systemic autoimmune disorders, right?

[Stanley Plotkin] Well, in the case of page 4 and 5, they were looking at local reactions, and of course aluminum does give local reactions.

[04:32:11] On page 8, where they were looking at systemic autoimmunity, I guess they believed that aluminum in itself is reasonable control and would not cause autoimmunity.

[Aaron Siri] So going into this study, they just assumed aluminum wouldn't cause autoimmunity, and so that's how they proceed in designing it. I got it. All right. All right. Dr. Plotkin, I'm going to hand you what's— yes, I'm going to hand you what's been marked as Plaintiff's Exhibit 18.

[04:33:13] This is a—oh, did you send it? Okay. This is the manufacturer insert for a drug called Enbrel, correct? Mm-hmm. What is Enbrel a drug for?

[04:34:05]

[Stanley Plotkin] Well, it's essentially an immunosuppressive, and I think it's used a lot in autoimmune diseases and cancers.

[Aaron Siri] This is a drug given to sick people, not healthy people, correct? Right. Unlike vaccines, which are typically given to healthy children and babies, right? Right. Okay. If you turn to page 10, Dr. Plotkin, all the way to the bottom, the 6.1, Section 6.1, Clinical Studies Experience, the very first line under 6.1 says, The data described below reflect exposure to Enbrel in 2,219 adult patients with RA followed for up to 80 months.

[04:35:03] Mm-hmm. So in studying this drug given to sick people, they reviewed safety for up to six and a half years, correct? Mm-hmm. And they also used— Sorry. There's no answer to the question. Oh. Oh, sorry. You're right. I'm on. Okay. Was that a yes, Dr. Plotkin? Yes. Do we miss any others? No. It's gradually happening more and more. Okay, I'm sorry. Thank you. I appreciate that. Thank you.

And the placebo group here was, in this study, was a saline placebo for all controls, correct?

Yes.

[04:36:02]

[Stanley Plotkin] So what is your point?

[Aaron Siri] I think the point speaks for itself, Dr. Plotkin.

[Stanley Plotkin] Well, it doesn't, because Enbrel is given over long periods of time, and one has to, since it's immunosuppressive, one has to look for things that may happen because of immunosuppression. Vaccines are given at particular times and are generally not continuously given over long periods of time. But because, aside from that, you're basing this on the package circulars, not on the combined experience with the vaccines that, in many cases, has taken place over 50 or 60 years.

[Aaron Siri] I'm basing this, Dr. Plotkin, I'm not basing anything on anything.

[04:37:01] I'm just asking you questions, and my questions are geared towards being able for my client to be able to pick up what is supposed to be a document that includes the clinical trial experience of the particular biologic or drug and understand what the adverse events rate was for that product. And that's all I'm trying to ask you questions about, to understand. That's it. And in terms of what you've just said about Enbrel, let's just, we'll just have one quick vaccine, and then we've really got to move on because it's got a lot of, a little more material to cover. DTaP vaccine is given at 2 months of age, correct?

[04:38:00] Yes. And at 4 months of age? Yes. And at 6 months of age? Yes. 18 months? Yes. At 3 to 4 years of age? Yes. Then again at 11 years of age? Yes. In the slightly DTaP version? Mm-hmm. Okay, so here you have just one vaccine, put aside the other one, that is given over an extended period of time, but yet as we saw, you know, as the manufacturer interest will show, there is no clinical trial that I'm aware of, and I'm happy for you to show me or produce one that actually does what the study in Enbrel does, which is has a saline placebo-controlled group and reviews safety over anything more than, you know, typically a few days or a 30-day period. I dispute that.

[Stanley Plotkin] I think it is almost certain or certain in my mind that they observed the patients over a longer period of time, but that they looked specifically for acute reactions during the first few days after immunization.

[04:39:07] And also I add to that, and I insist on repeating, that one has to look at the total experience with a drug or a vaccine over a period of time, not simply what is in the FDA package circular.

[Aaron Siri]

So are you saying that instead of relying on clinical data, placebo saline, inert placebo-controlled studies, we should just rely on the experience?

Well, isn't it true that there's a lot of people out there? In fact, you've said a lot of, used a lot of adjectives to them today so far, who are out there and say that their experience is that vaccines have caused all kinds of serious adverse reactions. Isn't that precisely what is on Section 6.2 of each of those inserts?

[04:40:00] If your approach is used, why are they not given equal weight? I mean, if that's the way we're going to do science.

[Stanley Plotkin] I'm asking for the clinical data. Science depends on a body of work. It does not depend on any single studies. It depends on repetition, on data that confirm other data. And so you cannot take any single study and

rely on that and say that is the truth. The truth comes out of repetition and experience.

[Aaron Siri] So is your point just to trust you versus actually have the actual data to support? No, it's the accumulation of data. And you can provide the data to support everything you're saying here today, correct?

[Stanley Plotkin] Everything that I'm saying is in this book.

[Aaron Siri] You wrote that book?

[04:41:01] Sorry? You're the editor of that book, correct? Yes. It's called Plotkin's Vaccines? Yes. Dr. Plotkin, what is thrombocytopenia? Decreased platelets. Okay. Can it be caused by an autoimmune reaction? Isn't that what it's known to be caused by, the body attacking its own platelets? That's one of the reasons, yes. Okay. Can the MMR vaccine cause thrombocytopenia? Yes. Okay. What is brachial neuritis? Brachial neuritis is basically a reaction to a local injection where you have pain in the arm. Okay. I'm going to read you a definition of brachial neuritis from John Hopkins Medicine, and you can tell me if you agree or disagree with it. Quote, Brachial neuritis is a form of peripheral neuropathy that affects the chest, shoulder, arm, and hand.

[04:42:04] Peripheral neuropathy is a disease characterized by pain or loss of function in the nerves that carry signals to and from the brain and spinal cord, the central nervous system, to other parts of the body. End quote. Yes. Okay. Can DTAP or TDAP cause brachial neuritis? If it's administered in the incorrect way, yes. Can the MMR cause febrile seizures? Yes.

Can the flu shot cause Guillain-Barre syndrome?

Uncertain, but possible. Can the DTAP or TDAP cause Guillain-Barre syndrome? Not that I'm aware of. Hepatitis B cause Guillain-Barre syndrome?

[04:43:01] Again, I don't think the evidence supports that.

[Stanley Plotkin] Guillain-Barre syndrome is an uncommon event, particularly in adults.

[Aaron Siri] After vaccination, is that what you mean? No, I mean in general. In general, okay. Can the hepatitis B vaccine cause encephalitis? No, I would say definitely not. Okay. Can the MMR vaccine cause acute or chronic arthritis?

[Stanley Plotkin] It can cause, in adults, it can cause acute arthralgia, I would say, pains in the joints, but that does not seem to be a permanent phenomenon, and it's unusual in children.

[Aaron Siri] So yes for the acute in adults, but otherwise uncertain?

[04:44:05]

[Stanley Plotkin] In children, it must be quite rare if it occurs at all. But it does occur in adult women.

[Aaron Siri]

Can the flu shot, DTAP, or hep B cause transverse myelitis?

[Stanley Plotkin] I would say that's unlikely. You said influenza, what did you say, hepatitis B? Or DTAP. Or DTAP. I think that's the most unlikely. More likely that it would be the flu shot or hep B? Well, it's difficult with influenza because it's such a widely used vaccine, but I don't see any medical reason why any one of those vaccines should cause transverse myelitis.

[04:45:19] But it has been reported? It has been reported. Influenza, I suppose, maybe, but I'm not aware of any proof.

[Aaron Siri] Are you aware? Okay. Can hepatitis B or the flu shot cause fibromyalgia?

[Stanley Plotkin] Fibromyalgia, that's such a vague syndrome. It's, again, difficult to know, but influenza is, there are some differences between influenza vaccine and other vaccines.

[04:46:02] But with hepatitis B, I don't see any reason why it should cause fibromyalgia.

[Aaron Siri] So no on the hep B and maybe on the flu? Yeah, I guess it boils down to that. Can the DTaP or Tdap cause acute disseminated encephalomyelitis?

[Stanley Plotkin] I would say no.

[Aaron Siri] Can the hepatitis A vaccine cause autoimmune hepatitis? Oh, dear, no. No. Can hepatitis B cause lupus? I see no reason why it could. That's a no? No. Can influenza cause lupus, influenza vaccine?

[04:47:05]

[Stanley Plotkin] I can see no mechanistic reason why it would, and so I would say no.

[Aaron Siri] Can the hepatitis B vaccine cause rheumatoid arthritis?

[Stanley Plotkin]

There have been studies along those lines, and I would say that they're unconvincing as far as the vaccine causing rheumatoid arthritis.

The difficulty is that rheumatoid arthritis is a common disease, and it, of course, occurs frequently in adults. So it's very difficult to know whether some precipitating event could have caused it.

[Aaron Siri] But at this point, I would say no. Vaccines are also commonly given to most people in the country, correct?

[04:48:00] They're often given, yes. So determining causality really requires a double-blind placebo-controlled study, correct?

[Stanley Plotkin] It does if you want to be certain, or at least a statistically strong relationship.

[Aaron Siri] What do you mean by statistically strong relationship?

[Stanley Plotkin] I mean a situation where you have a comparative group, and you can say that compared to the comparative group, that the association you're looking at is statistically different than the control group. And from that, you believe you can determine causation? Well, you can determine association. Then you have to look and see whether there is some kind of biological explanation.

[04:49:02]

[Aaron Siri] Isn't it difficult to determine association when it comes to vaccines and an alleged injury because everybody, for the most part, gets vaccinated?

[Stanley Plotkin] That is true. That is precisely why there are so many false associations between vaccines and disease.

[Aaron Siri] Isn't it also the reason, then, that careful preclinical studies using an inert placebo should be conducted before licensure?

[Stanley Plotkin] It would be ideal to do so, but one would also have to be very large studies and covering different age groups. And by and large, those data come out much later after experience with a vaccine used in thousands or millions of people.

[04:50:10]

[Aaron Siri] Well, that, of course, presumes that the adverse events are—long-term adverse events are rare, doesn't it? Yes. Okay. Do you know whether faith is susceptible to any—I'm going to strike that. There's a lot of conditions, so I'm going to try this a little bit of a different way so we can get through this a bit quicker. Is faith susceptible to suffer any of the conditions we have reviewed thus far?

[Stanley Plotkin] You mean the infectious diseases or the non-infectious diseases?

[Aaron Siri] I'm talking about the adverse event. I'm talking about the conditions that we just reviewed, starting with thrombocytopenia and ending with rheumatoid arthritis.

[04:51:04] I know nothing about the child, and therefore I'm unable to answer. Do you know whether faith has a genetic variant that renders her predisposed to suffer any of these conditions and vaccinations? I do not. Do you know whether faith has a genetic variant in her microbiome DNA that renders her predisposed to suffer any of the conditions we reviewed? I am not aware of that. Do you know whether faith has any environmental exposure that would render her predisposed to suffer any of the conditions that we've just reviewed? In 1991, the IOM issued a report regarding vaccine safety. Are you familiar—correct? Yes. Are you familiar with that report? Yes. That report looked at 22 serious injuries associated with DTaP vaccines and rubella vaccines, correct?

[04:52:06] Did you provide information to the—was that a yes? Yes. Did you provide information to the IOM committee conducting this review? I believe I sent them papers.

[Stanley Plotkin] I was not involved with the committee in any direct way.

[Aaron Siri] Are you aware of whether they thanked you in the introduction?

[Stanley Plotkin] They may have. I mean, I obviously was a source of information about rubella vaccine, for example.

[Aaron Siri] The IOM searched for evidence regarding whether DPT can cause autism, correct? Yes. And they could not find any evidence that would help them to make any determination one way or another with regard to whether DPT causes autism, correct?

[04:53:08]

[Stanley Plotkin] Well, if you mean that they used their statement of not having enough information to make a decision, probably yes.

[Aaron Siri] Do you recall that they had five categories of conclusions, Dr. Plotkin, in that report?

[Stanley Plotkin] Yes, something like that.

[Aaron Siri] The first category—strike that.

[04:54:02]

Do you recall that the first category was no evidence bearing on a causal relation?

[Stanley Plotkin] I don't recall specifically, but I believe you're correct.

[Aaron Siri] Okay, well, I'll give you a copy. Let's get you a copy. I'm going to hand you, Dr. Plotkin, what's being marked as Exhibit 19. Yeah, you send it?

[04:55:05] Dr. Plotkin, the title of this is The Adverse Effects of Pertussis and Rubella Vaccines, correct? Yes. This was by the Institute of Medicine in 1991? Uh-huh. Okay, so if we go to all the way—if you go to the second-to-last page, Dr. Plotkin, I suspect that's what you're looking for. All right. This is a table of the summary of conclusions by adverse event for DPT and MMR, correct? Okay. So there are five conclusion categories, correct? Uh-huh. The first one is no evidence bearing on a causal relation, correct? Uh-huh. And what that means, if you see the—was that a yes? Yes. Okay. If you go to footnote C, which defines what no evidence bearing on a causal relation means, isn't it true that it says, no category of evidence was found bearing on a judgment about causation.

[04:56:12] All categories of evidence left blank in Table 1-1, correct? Yes. Okay. There's only one condition for which they literally—they couldn't find any evidence one way or another on whether it caused—whether the vaccine causes that condition, correct? Right. And that was—what was that condition?

[Stanley Plotkin] Autism. Okay.

[Aaron Siri] Now, the IOM reviewed whether DPT can cause 17 other serious conditions, and on this chart it found that evidence supported a causation for four of them for DPT, rejected causation for four of them, but that the evidence was insufficient to determine causation for nine of them.

[04:57:05] Is that correct? Okay.

As for the MMR vaccine, the IOM reviewed four conditions, right?

Mm-hmm. For the first two it—was that a yes, Dr. Plotkin? Yes. I hate to trouble you, but if you could say yes instead of mm-hmm, it would speed things along a bit. Appreciate it. For two of them, it found that the evidence was insufficient to make a causation determination, correct? Yes. Okay. But for chronic arthritis, it found that the evidence is consistent with a causal relationship. Yes. That would be—there's evidence consistent with a causal relationship between the MMR vaccine and chronic arthritis, correct? Yes. And it also found that the evidence indicates a causal relationship between the MMR vaccine and acute arthritis, correct?

[04:58:08] Yes. Do you dispute these findings?

[Stanley Plotkin] Well, first of all, the IOM's later report was not as definitive as far as chronic arthritis is concerned. And the evidence for the consistency, first of all, it must be stressed.

We're talking about adult women receiving the vaccine, not children.

And the other point is that the data really came from one center in British Columbia, and was not generally seen. As far as acute arthritis is concerned, it really should be arthralgia, not arthritis, because there's a difference between those two things.

[04:59:08] But anyway, there's no doubt that the vaccine does cause pains in the joints. But again, particularly in adult women, it is not a big problem in children.

[Aaron Siri] On the next page, Dr. Plotkin, where it says of the report, it's under research needs, does the first sentence say, in the course of its review, the committee encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines?

[Stanley Plotkin] Yep.

[Aaron Siri] And then the last sentence of that paragraph says, clearly if research capacity and accomplishment in these areas are not improved, future reviews of vaccine safety will be similarly handicapped, correct? Right. Correct. Okay.

[05:00:04]

[Stanley Plotkin] So I think it's worth pointing out that the vaccine community did respond to those conclusions, and that in particular, CDC set up a situation with centers like Kaiser Permanente in California, where they do very elaborate safety studies, because they have large populations receiving vaccines or not receiving vaccines, and they can do comparative studies. And in addition, WHO has set up safety reviews on vaccines. And, of course, CDC has a safety department, and there are funded sort of safety centers throughout the country.

[05:01:04] So it's not as if the vaccine community has ignored the issue of vaccine safety.

[Aaron Siri] Well, wonderful. We'll go through all of that, I can assure you. But I've got to take it piece by piece, okay? So one step at a time, and we will get to Kaiser and the various things that you just talked about, and we'll address all of them. Hopefully we get to everything. All right. You know what? Why don't we take just a two-minute quick break?

[Tom Liebman] I'm going to end it this way.

[Aaron Siri] Perfect.

[Tom Liebman] This ends disc number three of the deposition of Dr. Stanley Plotkin. We are going off the record. The time is 14.23. This is the beginning of disc number four of the deposition of Dr. Stanley Plotkin.

[05:02:02] We are on the record.

[Aaron Siri] The time is 14.33.

Dr. Plotkin, you earlier said that it would be ethical, you believe, to conduct a randomized double-blind placebo-controlled study of the childhood immunization schedule using adults.

Is that correct?

[Stanley Plotkin] Well, I suppose you could test the childhood schedule in adults, but it wouldn't make a lot of sense, if that's what you mean. You could test individual vaccines, I suppose, although the adults in all likelihood will have been either previously vaccinated or previously infected. So it wouldn't be a very easy study to do.

[05:03:00] But I suppose it's conceivable.

[Aaron Siri] And you think, and it is something that could be done to assess the, certainly adults are not children, but it would at least give a sense of the safety profile of people who have, on the one hand, gotten the childhood schedule versus those who haven't. And I would think it's something that you would welcome, given that it should hopefully, I presume, show that both groups will have similar rates of any total health outcomes.

[Stanley Plotkin] Well, it's difficult to imagine how one would do it. Now, for example, for haemophilus influenza, disease is rare in adults of the type B anyway. And so I'm not sure what one would learn by doing such a study.

[05:04:06]

[Aaron Siri] For hepatitis B, of course — The adverse events, not the efficacy, Dr. Plotkin.

[Stanley Plotkin] Yeah, well, I suppose. But whether it would be translatable from adults to children is uncertain in itself. So I don't think it's a very practical way of studying the safety of vaccines. Fortunately, for hepatitis B, it's indicated for adults as well as children. So that's something that can be done. And papillomavirus vaccine, of course, can be given to adults. So we have data from that type of study.

But in terms of systematic studies of childhood vaccines in adults, I don't think that's very feasible or useful.

[Aaron Siri] If the group that receives, the adults that receive the full schedule versus those that didn't, had significantly higher rates of autoimmune or neurological or other adverse events, you don't think that could provide useful information for potentially making, addressing potential safety concerns and making the schedule safer?

[05:05:22]

[Stanley Plotkin] So for that, you need a group of adults who have never received vaccines. Why is that? Well, what are you comparing? If you're comparing those who were vaccinated as children with those who weren't, so you need a group that was not vaccinated.

[Aaron Siri] Well, most adults today have not received anywhere near the number of vaccines that children are being exposed to today. So, for example, Dr. Plotkin, when you were a child, as an example, what vaccines did you receive?

[Stanley Plotkin] Diphtheria, well, in childhood, I think it was probably only diphtheria in those days.

[05:06:11]

[Aaron Siri] So if such a study were constructed, would you be willing to participate? You mean as someone who did not receive? Would you be willing to be part of the study in which you would either, you know, you would be randomized, so you'd either get the saline injections or the full childhood vaccine schedule? Would you be willing to do that? I'm sorry, I didn't hear the answer. Would you be willing to do that?

[Stanley Plotkin]

Yes, but then you'd have to have a group of 80-year-olds who have received all of the childhood vaccines that are now given, which would be pretty difficult to do.

So I think this kind of study you're talking about is either difficult or useless because you don't have the right groups to compare. You could do it perhaps in 20-year-olds, if you could find 20-year-olds who haven't been vaccinated.

[05:07:06]

[Aaron Siri] Well, if it was, if they did age controls and so they had a range of ages, including 80s and 20-year-olds, would you be willing to participate?

[Stanley Plotkin] Oh, I'd be willing to participate in any reasonable study, but I don't think it would be very useful.

[Aaron Siri] In 1994, the IOM issued another report regarding vaccine safety. Are you familiar with that report? In 1994? Yes.

[Stanley Plotkin] The last one was in 2000, as I recall. 2011 was the last one. Well, okay, there was a large one in about 2000 as well.

[Aaron Siri] Anyway, so. In 1994, let me give you, sounds like you don't remember, let's just give this to you.

[05:08:07] I'm handing you, Dr. Plotkin, what's been marked as Plaintiff's Exhibit 20. The title of this report is Adverse Events Associated with Childhood Vaccines, correct?

[Tom Liebman] Yes.

[Aaron Siri] This is also by the Institute of Medicine. In this report, the IOM looked at 54 serious injuries associated with a number of different vaccines, correct? Okay. Did you provide information to the IOM committee conducting this review?

[Stanley Plotkin] I don't recall doing that.

[Aaron Siri] So you see on, and there are the acknowledgements on the second page. Your name is in the middle there, Stanley A. Plotkin, Pastor Murek. I can't pronounce.

[Stanley Plotkin] Murek. Yeah.

[05:09:01]

[Aaron Siri] I don't speak French, I apologize. And can you pronounce that? That's M-E-R-K-U-E-X-C-O-N-N-A-U-G-H-T company. Okay. Now, if you go to, out of these 54 conditions pairs, the IOM found sufficient evidence to support a causal relationship for 14 of them and rejected a causal relationship for 4 of them. Do you see that? Where are you referring? So if you go, Dr. Plotkin, to the fifth to last page, it has the causality table.

[05:10:00] You see category 3 is the evidence favors rejection of a causal relationship. Okay, and you see they rejected it for 4 of the associated adverse events, correct? Mm-hmm. You see, is that a yes? Yes. You see in category 4 it says the evidence favors acceptance of a causal relation? Okay. Do you see that there's, 2, 3, there are 5 conditions listed there, including Guillain-Barre, brachial neuritis, anaphylaxis. Do you see that?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay.

And on the next page for category 5, which is the evidence establishes a causal relation, do you see that it lists 1, 2, 3, 4, 5, 6, 7 conditions, correct?

[05:11:05] Okay. However, for the remaining conditions, so they looked at 54, if we subtract out the 3 categories we just looked at, 38 of those conditions, the 38 remaining conditions, the IOM couldn't make a causality determination because the science hadn't been conducted yet, right? Yes. Okay. The IOM stated at the end of this report, quote, the lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern. Do you see the last page of the report that you're holding, of the excerpt? Do you see that it says that?

[05:12:00] The first two lines, under need for research and surveillance? Dr. Plotkin, in 2011 the IOM then issued another report on vaccine safety, and this time it looked at 158 of the most commonly claimed serious injuries after vaccination, right?

[Stanley Plotkin] Yes. Okay.

[Aaron Siri] The title of that report is Adverse Effects of Vaccines, Evidence of Causality. You're familiar with that report?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. Do you know who commissioned and paid for that report, by the way?

[Stanley Plotkin] Which commission?

[Aaron Siri] Sorry, who commissioned and paid for that report?

[Stanley Plotkin] No. Okay.

[Aaron Siri] Would it be surprising to you if I told you that HRSA, the agency within the HHS that defends against vaccine injury, claims that commissioned that report?

[05:13:11] Wouldn't surprise me. Okay. Did you provide information to the IOM committee conducting this review?

[Stanley Plotkin] I don't recall specifically whether I did or not. A lot of people ask for my opinions, and when asked, I give my opinions.

[Aaron Siri] Dr. Plotkin, I'm going to hand you what's been marked as Exhibit 21. Is this the 2011 IOM report we were just talking about? Yes.

[05:14:01] Do you see there's Roman numeral, little Roman numeral 7, page little Roman numeral 7? I see a section entitled Reviewers. Oh, yes. On the list. Okay. Do you see, I'm going to read the first two sentences, and you can tell me if that's what this report says. It says, This report has been reviewed in draft form by individuals chosen for their diverse perspective and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institutions in making its published report as sound as possible, and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge.

[05:15:02] Is that what it says? Yes. And you're one of the people that gave the report to you to review? Yes. And next to your name, it says University of Pennsylvania.

[Stanley Plotkin] Yes.

[Aaron Siri] It doesn't disclose that at that time you were working for all four of the major vaccine makers, correct? What do you mean by working for them? I mean, at that point, I was no longer at Pasteur Medio Canut. In 2011, were you receiving compensation or remuneration from Sanofi?

[Stanley Plotkin] I was, yes, as I've said before. I was consulting for Sanofi as well as others.

[Aaron Siri] Were you consulting for Merck? Yes, probably at that time, yes. And GSK? Yes. Okay. And as well as a whole host of other for-profit companies seeking to develop vaccines, correct? Yes. But I'm just saying that's not mentioned here, correct?

[05:16:01] No. Okay. So do you know how many other individuals who were involved in reviewing or compiling this report were receiving money from pharmaceutical companies making vaccines that's not disclosed in this report? I have no knowledge of that. You provided handwritten comments to the IOM for this report?

[Stanley Plotkin] If I reviewed the report, which apparently I did, I am sure I made comments. I don't know if they were handwritten. Probably not, since my hand reading is illegible.

[Aaron Siri]

In this report, the IOM found that 14 of the 158 serious injuries most commonly reported after certain vaccines were that the evidence supported a causal relationship, correct?

[05:17:11]

[Stanley Plotkin] Where is that stated?

[Aaron Siri] Well, if you go to page 3 of the report, it's a numeral here. Let me ask you the question a different way, Dr. Plotkin. If you look at that chart, you can see that there's little symbols. Do you see those, Dr. Plotkin? Yes. Okay. So an I represents inadequate to accept or reject a causal relationship, correct?

[05:18:04] Yes. And an F-A, F-R, means favors rejection of a causal relationship, correct? Yes, apparently, yes.

[Stanley Plotkin] If you look through this — No, F-A favors acceptance.

[Aaron Siri] I meant to — I said F-R, I'm sorry. F-R favors rejection. F-A favors acceptance. And C-S is convincingly supports a causal relationship, right? So I think that — I think what you'll note when you look through this chart is that most of the conditions have an I, correct?

[Stanley Plotkin] Yes.

[Aaron Siri] Any reason — the report indicates that for 135 out of the 158 reviewed, it found that it could not locate sufficient evidence to make a causality determination, right?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. So the IOM concluded that of the 135 most commonly claimed injuries from vaccination, it didn't know whether or not the vaccines caused that.

[05:19:09] Let me ask you something. You know, you earlier stated that — you stated that hepatitis B doesn't cause encephalitis, right? That's my opinion, yes. But the IOM, after doing its review, determined it couldn't find science to support a causal determination one way or another, correct? Yes.

[Stanley Plotkin] But that means that they don't have evidence for the supposition.

[Aaron Siri] That it either causes or doesn't cause.

[Stanley Plotkin] Right. They don't know.

[05:20:00] They don't know because there aren't enough data. But you have — But in the absence of data, my conclusion is that there are no — there's no proof that causation exists.

[Aaron Siri] So if there's no data to show that it causes or it doesn't cause — Yes. — your supposition, is that what I understand correctly? Yes. Is that it doesn't cause it? That there's no proof that it does. Okay. That's different than saying it doesn't cause it, correct? Correct. So when you were saying earlier that — when I asked you at the beginning of this whether certain vaccines cause certain

conditions, and you said, no, they don't, did you just mean that, no, there's not enough evidence to make a decision one way or another?

[Stanley Plotkin] I mean that there is no knowledge known to me that they do certain things that some may have alleged happen after vaccination.

[05:21:05]

[Aaron Siri] Like, for example, you know, they — the IOM reviewed whether hepatitis B can cause lupus because of lots of reports, or influenza can cause lupus. They concluded that there's insufficient evidence one way or another to make a determination. Right. But you indicated earlier that those vaccines don't cause lupus. Your testimony — you're saying that you said no because you weren't aware of a mechanism by which it could cause it. Is that right?

[Stanley Plotkin] Yes, that's correct.

[Aaron Siri] Okay. But the science really isn't available to make a determination on causation yet, right?

[Stanley Plotkin] The science doesn't show that there is a relationship. And it is, unfortunately, to prove a negative requires a lot more data than to prove a positive.

[Aaron Siri] If there was a study that had a placebo and a control group, then we could know whether or not these conditions are caused by these vaccines, correct?

[05:22:12]

[Stanley Plotkin] Yes. It would have to be an enormous study, and it would have to be randomized, ideally, which is unlikely to be the case since …

[Aaron Siri] It needs to be enormous because you're assuming these conditions are rare, correct? Correct. Okay. And this study that you're saying needs to be done before vaccines are licensed, they do do the clinical trials we've seen, right? Yes. And they have thousands of people typically in them, correct?

[Stanley Plotkin] Yes. And therefore, they can study common conditions. But uncommon conditions are very difficult to study because they are uncommon. And therefore, one would need a very, very large study, and one would have to have randomization, which is, of course, inherently difficult.

[05:23:01] Q.

[Aaron Siri] If you actually had a placebo-controlled study, an inert placebo-controlled study of 7,000, 8,000 people, you could at least determine that in a population of that size whether or not there is detectable adverse event rate for any of these conditions, correct?

[Stanley Plotkin] For some of those conditions, yes.

[Aaron Siri] All right. I'd like to show you an excerpt from that report, okay? Before I do that, actually, a few quick little questions. Tdap is one of the vaccines on the childhood schedule, right? Yes. It's administered to babies during the first year of life? Yes. We already talked about this at 2, 4, and 6 months, right?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. Did I say Tdap or DTaP?

[05:24:01] DTaP is the one that's used. I meant DTaP in that question.

[Court Reporter] I had Tdap.

[Aaron Siri] Okay. Same answer if it was DTaP, correct? Yes. Okay. So let's correct that, please. Now, as for Tdap, T-D-A-P, little d, little a, little p, with a capital T, that's given to pregnant women, correct? Yes. Okay. And DTaP and Tdap refer to vaccines which contain diphtheria toxoid, tetanus toxoid, and acellular pertussis, correct? Yes. Okay.

What was the IOM's conclusion in 2011 about whether these vaccines can cause autism?

[Stanley Plotkin] I'd have to look that up, but I feel confident that they do not cause autism.

[05:25:01]

[Aaron Siri] You feel confident that that's what the IOM concluded?

[Stanley Plotkin] I don't remember what the IOM concluded, but I don't believe there's any evidence that that's the case.

[Aaron Siri] Is there any evidence that that's not the case? Why don't I show you this, Dr. Plotkin? I'm going to hand you what's being marked as Exhibit 22. Oh, Dr. Plotkin, may I actually have that back for a moment? I'm sorry. I gave you the right one. There you go. Thank you. This is an excerpt from the IOM's report, right? Yes. Okay.

And this is where the IOM discusses the evidence with regard to whether DTaP or Tdap cause autism, correct?

[05:26:05] Correct. Okay. If you turn to the second page, can you read the causality conclusion with regard to whether DTaP and Tdap cause autism?

[Stanley Plotkin] The committee did not identify literature reporting clinical diagnostic or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens.

[Aaron Siri] Okay. Dr. Plotkin, I'm sorry, can you please
read, Dr. Plotkin, can you please read the causality conclusion with regard to that the IOM reads for three, one second. Dr. Plotkin, I'm sorry. The core report has got to be able to take down the full question or there won't be a clear record. Can you please read the causality conclusion in the IOM report with regard to whether DTaP and Tdap can cause autism?

[05:27:04]

[Stanley Plotkin] The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid, tetanus toxoid, or acellular pertussis containing vaccine in autism.

[Aaron Siri] So the IOM reviewed the available evidence with regard to whether Tdap or DTaP can cause autism, and their conclusion was the evidence doesn't exist to show whether DTaP or Tdap do or do not cause autism, correct?

[Stanley Plotkin] Yes, but the point is that there are no studies showing that it does cause autism except one study by two well-known anti-vaccination figures, Geyer and Geyer, who have no legitimacy whatsoever. So what they're saying is that there's no evidence, and the important point from my point of view is that there is no positive evidence to do a proper study, as we've been discussing, which would disprove it, would involve the controlled administration of vaccines and withholding vaccines from children who should have them.

[05:28:27] Q.

[Aaron Siri] Dr. Plotkin, was the IOM able to identify a single study that supported your claim? If you take a look at that section, please. Was the IOM able to identify a single study supporting that DTaP or Tdap do not cause autism?

[Stanley Plotkin] A. No, they did not identify a study. But the point is, and I have to repeat myself, that absence of evidence does not allow you to conclude that the two phenomena are related.

[05:29:07]

[Aaron Siri] Q. You're making assumptions, Dr. Plotkin, about, I think, what's built in. I understand that. I mean, I only interrupt because, you know, it's 3 o'clock, and I don't mind letting you, you know, give a lot of discussion about things that aren't relevant, but to the question.

[Stanley Plotkin] A. I think it's relevant in the reports issued by the IOM that their conclusion about evidence not being available does not allow you to conclude that the phenomena, that there is a causal relationship.

[Aaron Siri] Q. I'm not sure. I never said that. And I'm not sure anybody in this room said that, Dr. Plotkin.

[Stanley Plotkin] A. Good. I'm glad to hear that.

[Aaron Siri] Q. But it does allow you to conclude that the evidence doesn't exist to say that DTaP and Tdap do not cause autism, correct?

[05:30:01]

[Stanley Plotkin] A. There is not evidence to say a million different things. Q. Okay. A. You have to prove. Q.

[Aaron Siri] Did the IOM report look at whether the MMR vaccine can cause autism?

[Stanley Plotkin] A. I'd have to look and see.

[Aaron Siri] I believe that they did. Q. And what did it find? Found? I'm sorry. It said it did. A.

[Stanley Plotkin] I'm looking to see. Q.

[Aaron Siri] It said it favors rejection because it did find studies. A. Yes. Q. Correct? A. Yes. Q. That's right.

So studies are possible to determine whether or not a vaccine does or does not cause autism, correct?

A. They are possible, yes. Q. Okay. But the study to determine whether DTaP or Tdap does not cause autism has not been done, right?

[05:31:06] A.

[Stanley Plotkin] A study that would definitively show that it doesn't has not been done, but there's no evidence that it does.

[Aaron Siri] Q. Okay. But since, Dr. Plotkin, we don't know whether DTaP or Tdap cause autism, right, it would be a bit premature to make the unequivocal sweeping statement that vaccines do not cause autism, correct? A.

[Stanley Plotkin] In the absence of evidence, one should not draw any conclusions except that there is no evidence. And so I don't infer from the absence of evidence about a million different things that they're necessarily true. One has to do studies to determine whether or not a phenomenon exists, and usually those studies are done because there is some suspicion of a relationship.

[05:32:14] But we have no suspicions, at least I don't, that autism is caused by DTaP. Q.

[Aaron Siri] Well, you may not have that suspicion, but it is one of the most commonly reported conditions, adverse events, which is why it was reviewed in this IOM report from DTaP, Tdap, which we discussed earlier. So I'm not asking you to say that vaccines do cause autism. I'm not asking that at all.

I'm asking you as a scientist, can you make the statement that vaccines do not cause autism if you don't know whether DTaP or Tdap cause autism?

[05:33:07]

[Stanley Plotkin] A. As a scientist, I would say that I do not have evidence one way or the other. As a practicing physician, I have to weigh all kinds of things in making a decision about a patient, whether to do something or not to do something. And I make those decisions based on the body of knowledge, even in the absence of definitive information for every case. This has been true for medicine ever since its inception.

[Aaron Siri] Q. I'm asking you a simple question. I'm asking you, since the science has not yet been done regarding whether DTaP or Tdap cause autism, isn't it true that you cannot make the sweeping statement that vaccines do not cause autism?

[05:34:07] A.

[Stanley Plotkin] I could make the statement that there is no evidence that vaccines cause autism.

[Aaron Siri] Q. I'm not asking you that question.

[Stanley Plotkin] A. And therefore, vaccines should be given to protect against serious diseases.

[Aaron Siri] Q. Dr. Plotkin, we've already reviewed the IOM report. The IOM could not find evidence that DTaP or Tdap cause autism.

I'm asking you, knowing that, isn't it just a bit premature to make the unequivocal sweeping statement that vaccines do not cause autism?

[Stanley Plotkin] A. I would say it is logically true that you cannot point to proof that it doesn't cause autism.

[05:35:11] But as physicians and public health specialists, one has to make decisions in the absence of thousands of pieces of information that one would like to have. And one of them is that vaccines protect against serious infectious diseases and there's no evidence that they cause autism. So, therefore, I recommend vaccinations to this child and every other child who does not have a contraindication.

[Aaron Siri] Q. But since there's no evidence that DTaP or Tdap don't cause autism, you can't yet say that vaccines do not cause autism, correct? A.

[Stanley Plotkin] I cannot say that as a scientist or a logician, but I can say as a physician that, no, they do not cause autism.

[05:36:05] Because as a physician, I have to take the whole body of scientific information into consideration when I make a recommendation for a child.

[Aaron Siri] IOM reviewed the science. They didn't find a single study that supported whether or not vaccines…

[Court Reporter] A. Forgive me. Counsel, your connection's not that great. It's very choppy and I cannot hear anything you're saying, but I do hear your voice. Please repeat.

[Aaron Siri] Q. All right.

[Laura Nusma] At this point, Dr. Plotkin, just wait for him to move on to the next question.

[Aaron Siri] A. I'm not asking the same question, Counselor. Your objection is noted. I'm responding to his comments, which are different every time. So what you're saying is, as a physician or a logician, then you couldn't say vaccines do not cause autism.

[05:37:02] But as a pediatrician, you're saying that you would say that to a parent because you want to make sure they get the vaccine. Is that right? A. You know, I can't be sure that DTAP doesn't cause leprosy.

[Stanley Plotkin] That doesn't mean that that stops me from using a DTAP vaccine.

[Aaron Siri] Q. Are people claiming that DTAP has caused leprosy? Are you aware of any such complaints?

[Stanley Plotkin] A. I'm not aware of any such complaints, but I wouldn't be surprised to see it on the web one of these days.

[Aaron Siri] Q. But people have made enough complaints about DTAP, TDAP causing autism that the Institute of Medicine at the commission of HHS thought it was serious enough to do a scientific review, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. They didn't review whether DTAP causes leprosy, did they?

[05:38:01] A. No.

[Stanley Plotkin] Q.

[Aaron Siri]

And after conducting that review, they found that there was no evidence at all that they could find whether DTAP or TDAP caused autism.

I'm just asking you a simple question, which is, since there's no evidence that whether DTAP or TDAP caused autism, isn't it a little premature to say, to make the sweeping statement, that vaccines do not cause autism? A. No.

[Stanley Plotkin] I do not agree with that, because absence of evidence works both ways. There's no evidence that they do, and the ideal study has not been done. I agree with that. But in the absence of any reasonable evidence that they do, I continue to recommend their use.

[Aaron Siri] Q. So you're willing to make a statement that a vaccine does not cause a condition, even in the absence of any evidence?

[05:39:07] A.

[Stanley Plotkin] I'm willing to state that there is no evidence that the vaccine causes the condition, and there is a lot of evidence that they do protect against disease, and therefore the child should receive the vaccines. I mean, there are a million things on the Web, including all kinds of diet advice based on ridiculous information. So why should I adopt that?

[Aaron Siri] Q. Are you saying that the IOM was engaging in a ridiculous review here?

[Stanley Plotkin] A. They were doing a scientific review, which is certainly legitimate, and their conclusion that there are insufficient data to draw a formal conclusion, I can understand that and appreciate that.

[05:40:11] But that does not mean that the vaccines cause autism.

[Aaron Siri] Q. You've never been asked that. The only thing I've asked you is whether or not one can assert that vaccines do not cause autism.

[Stanley Plotkin] A. Counselor, let's be real. You're asking me these questions because you want me to legitimize a view that vaccines cause autism, and I will not do that because absence of evidence is no proof whatsoever. Q.

[Aaron Siri] I think that record is very clear, Dr. Plotkin. I'm not trying to legitimize anything. I'm just asking you to — I'm not trying to legitimize that vaccines cause autism. A. I'm glad to hear that. We have very clearly established what the IOM found.

[05:41:00] The IOM found, in their estimation, no evidence. Right? Q. Right. A. They found no evidence that vaccines do cause — excuse me, that D-taproteba cause autism. Let's make that very clear, right? Q. Right. A. They found no evidence that D-taproteba cause autism. Q. Yes. A. Period. They found one study which they said was unreliable because it relied on theirs data, and it had no control. Q. Right. A. Okay.

But similarly, in the same vein, they also didn't find any evidence that D-taproteba do not cause autism.

Now, that doesn't mean that D-taproteba do cause autism, correct? Q. Correct. A. It doesn't mean that, right? Q. Yes. A. That's right. All it means is that they couldn't find a study that supported that it does not cause autism, right? Q. Yes. A. Okay. Until — and that's why they reached the conclusion that they did, which is they said the data is insufficient, right?

[05:42:09] I assume you — was that a yes?

[Stanley Plotkin] Q. Yes. A. All right.

[Aaron Siri] Q. Do you agree with the IOM's conclusion that the data, the evidence is insufficient to determine whether or not D-taproteba cause autism?

[Stanley Plotkin] A. I agree with their conclusion, but that doesn't mean that I don't act on other information.

[Aaron Siri] Q. Okay. Okay. I can understand that. I can understand that. But you're making — I'm not saying that — I'm not asking you to ignore any benefits you believe accrue from vaccines, okay? I'm not asking you to do that at all, Dr. Plotkin. I'm simply asking you as a pure matter of logic, as a pure matter of logic, in common sense, if you don't know whether A causes something, can you say A, B — let me not use a hypothetical — if you don't know whether D-tap or T-dap cause autism, shouldn't you wait until you do know, until you have the science to support it, to then say that vaccines do not cause autism?

[05:43:29] A.

[Stanley Plotkin] Do I wait? No, I do not wait, because I have to take into account the health of the child.

[Aaron Siri] Q. And so for that reason, you're okay with telling the parent that D-tap, T-dap does not cause autism, even though the science isn't there yet to support that claim? A.

[Stanley Plotkin] Absolutely. I'm also willing to tell them it doesn't cause leprosy.

[05:44:02] Q. Okay.

[Aaron Siri] Again, did the IOM review whether D-tap caused leprosy? Q. All right. Dr. Plotkin, has there ever been a study which looked at the total health outcomes of children following the CDC's vaccination schedule and those who are completely unvaccinated, such as Faith?

[Stanley Plotkin] A. Not that I'm aware of. No, I don't think so. But, you know, there are all kinds of studies. There's a study that suggests that

children who are vaccinated compared to unvaccinated children have lower rates of leukemia. Now, do I believe that study? I find it interesting, but I would want confirmation of that study before I believed it.

[05:45:03] But just to point out that Peter Abbe, for example, as I mentioned before, found that measles vaccination had a positive effect on health and reduced mortality. So I think there is abundant evidence that vaccines do contribute to the health of children.

But in answer to your question, there is no study that I know of that compared the health of vaccinated children with unvaccinated children.

[Aaron Siri] Q. Why is that study not been done? A.

[Stanley Plotkin] Probably because it is considered bad malpractice not to vaccinate a child. Q.

[Aaron Siri] So you're saying a prospective study might be improper because it will leave a child unvaccinated? A. Correct. Q. What about a retrospective study?

[Stanley Plotkin] A. That, I suppose, could be done, but it wouldn't be randomized.

[05:46:02] Q.

[Aaron Siri] When I say retrospective, that means using existing data, correct?

[Stanley Plotkin] A. Using children.

[Aaron Siri] Q. Why don't I ask you to strike that? Can you define retrospective, please?

[Stanley Plotkin] A. I mean, looking at children who had been vaccinated and comparing them to children who had not been vaccinated. Q.

[Aaron Siri] Okay. Presumably, HMOs, insurance companies would have health data on enough vaccinated and unvaccinated children to conduct such a comparison, correct?

[Stanley Plotkin] A. Well, I don't know, because the percentage of unvaccinated children, fortunately, is quite low. So I'm not sure how easy it would be to do that study. I would suspect that many of those unvaccinated children are not in registers that could be used.

[Aaron Siri] Q. You're familiar with the Vaccine Safety Data Link?

[05:47:00] A. Yes. Q. Are you aware that there are a few thousand children that are, are you aware that there are reports from the government reports that show that there are a few thousand children that are, my understanding, completely unvaccinated in the VSD? A. Oh, I don't doubt it. Q. Couldn't the Vaccine Safety Data Link be used to conduct a retrospective vaccinated versus unvaccinated study to look for health outcomes? A. Well, I don't know.

[Stanley Plotkin] Theoretically, perhaps. But one would have to be convinced that the children were comparable in other ways besides being vaccinated or unvaccinated. Q.

[Aaron Siri]

Every time you do a retrospective study, you always need to control for potential co-founders, correct?

A. Correct. Q. And that's what you're talking about, controlling for co-founders, right?

[05:48:00] A. Yes. Q. And, you know, if you're doing a case control and properly matching cases, or if you're, right? Are you saying that, so CDC, pharma, they conduct studies all the time, right? A. Uh-huh. Q. Including studies? A. Yes. Q. Yes. Including studies that have co-founders that need to be controlled for, right? A.

[Stanley Plotkin] Yes, they try, yes.

[Aaron Siri] Q. Vaccine studies, especially for efficacy, happen all the time, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Okay. So, again, if the data is there, why not do a study comparing vaccinated to completely unvaccinated children to look for the total health outcomes so you know what the real risks are from vaccine, or get at least a sense of what the real risks are from vaccination?

[05:49:03] A.

[Stanley Plotkin] Well, I can't completely answer that question. I'm sure it would be a difficult study to do. But I will repeat what I said earlier about measles vaccination. I would just remind you again that among those children who were not vaccinated …

[Aaron Siri] Q. You've already said all this, Dr. Ponca. A. Yeah, well, I'm going to repeat it. Q. I've got it. A.

[Stanley Plotkin] There were three deaths and 24 cases of encephalitis. Q. Okay. A. And that's unbearable. Q. I'm sorry.

[Aaron Siri] Can you read back what Dr. Plotkin just said? A. We're talking over each other.

[Court Reporter] Q.

[Aaron Siri] I apologize.

[Court Reporter] A. Well, I can't completely answer that question. I'm sure it would be a difficult study to do. But I will repeat what I said earlier about measles vaccination. I would just remind you again that among those children who were not vaccinated … Q. You've already said all this, Dr. Plotkin. A. I've got it. Q. I'm sorry. Can you read back what Dr. Plotkin just said? A. Well, I'm going to repeat it. Q. There were three deaths and 24 cases of encephalitis. Q. That's unbearable.

[05:50:01]

[Aaron Siri] A. Okay. Q. Dr. Plotkin, who prepared the notes that are in front of you? A.

[Stanley Plotkin] Me.

[Aaron Siri] Q. Okay. When did you prepare those? A. About a week ago, I guess. Q. During the break, our lunch break, did you talk with anybody?

[Stanley Plotkin] A. No. Well, yes, I talked with my wife.

[Aaron Siri] Q. Anybody else?

[Stanley Plotkin] A. No. Q. Okay.

[Aaron Siri] So I understand that you find injuries that can result from what you've called, I believe, vaccine-preventable diseases.

[05:51:15] What we're trying to do is understand the risks of vaccinating, and in particular for faith. And can you appreciate that, strike that? So you just think it's too difficult to look at, to do a study comparing vaccinated and unvaccinated children, even though the data exists to do that. Is that right?

[Stanley Plotkin] A. Well, I simply am saying that I don't know how feasible it is.

[05:52:01] I've never been asked to look at it before, but I do think a priori that it would be difficult because those children are very likely from different socioeconomic groups and different racial groups, and so it would be a difficult study to do. I don't know if it's feasible or not.

[Aaron Siri] Q. So with all of the government, so the pharmaceutical industry, you said, made approximately $20 billion last year in revenue from vaccine sales?

[Stanley Plotkin] A.

[Aaron Siri] I think so. Q. I have the financial statements. Should we review them, or do you think $20 billion is about right?

[Stanley Plotkin] A. I think it's about right. I'm not an accountant. I don't read those.

[Aaron Siri] Q. Give or take a billion or two, would you say? A. I think so, yes. Q. So the pharmaceutical industry had $20 billion in revenue, and the CDC spends hundreds of millions of dollars buying vaccines every year.

[05:53:07] Is that right? A. I think so. Q. But yet you don't think that the resources can be done to do a single, solitary study comparing the health outcomes of a for-profit product given to almost every child in this country to assess what the rate of adverse reactions are between those who get all those products and those who don't?

[Stanley Plotkin] A. What I said is I simply don't know whether such a study is feasible or not, but I think it would be difficult to do because it would not be a randomized study, and therefore the conclusions might be questionable. I don't know whether such a study is feasible or not.

[05:54:03] Q.

[Aaron Siri] Aren't most studies that are done that you rely upon in that book that you have in front of you not randomized? A.

[Stanley Plotkin] Many of them are not. Many of them are. Q.

[Aaron Siri] Do you throw out the ones that are not randomized?

[Stanley Plotkin] A. It depends on what the purpose of the study is. If it's studying immune responses, it doesn't necessarily have to have a control group. Q.

[Aaron Siri] Dr. Plotkin, I want to hand you what's being marked as Plaintiff's Exhibit 23. Q. Dr. Plotkin, what's an ICD-9 code? A.

[Stanley Plotkin] Well, it's essentially a way of coding diseases usually for remuneration purposes.

[05:55:03]

[Aaron Siri] Q. Okay. So when a doctor administers a drug or diagnoses a patient or something similar, there's a code that they would enter into the system, right? A. Yes. Q. And the ICD-9 codes are published by the American Medical Association, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Please take a look at the exhibit I just handed you is the 2015 ICD-9-CM Professional Edition for Physicians
Codebook, correct? A. Yes. Q. Or at least the front page in one excerpt, correct? A. Yes. Q. So if you go to the second page, do you see there's a code V64.07? A.

[Stanley Plotkin] Yes.

[Aaron Siri] Q. What is that code for?

[Stanley Plotkin] A. Vaccination not carried out for religious reasons. Q.

[Aaron Siri] So wouldn't it be feasible, for example, to compare children who have this coding, who are not being vaccinated, with those who are being vaccinated, who are in similar communities, have similar demographics, and otherwise avoid as much as possible other potential co-founders?

[05:56:25]

[Stanley Plotkin] A.

Well, if you could eliminate the co-founders, it would be feasible.

[Aaron Siri] Q. And what are the co-founders, Dr. Plotkin?

[Stanley Plotkin] A. Well, as I said before, the co-founders include socioeconomic level, racial grouping, exposure to agents. In other words, are they living in a community where it's unlikely that someone unvaccinated from Ethiopia is going to come into the community and be able to transmit diseases?

[05:57:06] I mean, I'd have to sit down and write up a list of possible co-founders, but there would be many of them. Q.

[Aaron Siri] So when you do studies for efficacy, are you able to control for all of these co-founders?

[Stanley Plotkin] A. Well, usually the effort is to include as many different types of individuals as possible, so that if there is a problem with a particular group, you can identify it. But doing clinical studies is not always easy, and that's why the conclusions from clinical studies have to be seen in relation to other clinical studies.

[Aaron Siri] Q. Why is it you can control for co-founders in various other vaccine studies, including in vaccine safety studies that are cited in your book, but you'd believe, are you saying you couldn't control for these same co-founders in the study of a vaccinated versus unvaccinated population?

[05:58:17]

[Stanley Plotkin] A. I am unable to draw a conclusion about whether such a study is feasible.

What I'm pointing out is that the likelihood of there being multiple co-founders, confounders, sorry, is very high, and therefore it wouldn't be an easy study to do.

That's all I can say. I've never sat down to try to figure out how to do such a study.

[Aaron Siri] Q. Okay. Well, we've got socioeconomic, which are probably pretty easy to control for, racial grouping, pretty easy to control for, exposure to agents. Since it's retrospective, you'll know if there's been an outbreak in a community. What other co-founders do you think might exist?

[05:59:02] I mean, I'd like to hear one that, can you tell me a co-founder that's not easy to control for?

[Stanley Plotkin] A. In principle, one can control for any confounding problem. The issue would be just how many there are and just how large a group you would need for statistical significance. See, that's another issue. I mean, we accept as a valid conclusion something that is false five times out of 100. And so not only do we have to try to eliminate confounders, but we also need repetition of studies to be sure that the results we got in the first study were not in the five studies that were false in their conclusion.

[06:00:09]

[Aaron Siri] So you would need multiple studies. Okay. And since these are retrospective, they're really just running data, right?

[Stanley Plotkin] If the data are encoded, yes.

[Aaron Siri]

So I asked earlier, what co-founder can you list that's not easy to control for?

And I did not hear another co-founder. Can you tell me a co-founder in this proposed study that would not be easy to control for?

[Stanley Plotkin] Exposure would be probably the most difficult. In other words, whether a child is living in a community where exposure to disease is rare or absent, or whether a child is living in a community where there are significant possibilities of exposure.

[06:01:04] I think that would be probably the most difficult to account for.

[Aaron Siri] When's the last case of polio in the United States, wild polio?

[Stanley Plotkin] Oh, I forget the exact year, but it's been probably 20, 25 years.

[Aaron Siri] Would 1979 sound correct to you?

[Stanley Plotkin] Yeah, it could be.

[Aaron Siri] So that wouldn't be an issue, correct? No, polio would not be an issue. How many cases of diphtheria have there been in the last 10 years in the United States?

[Stanley Plotkin] It's very rare or absent.

[Aaron Siri] Less than five, right? Yeah. Isn't that true for most of the diseases except for maybe pertussis, right?

[Stanley Plotkin] Well, pertussis, HIV, hepatitis, those are diseases that are still common.

[06:02:06]

[Aaron Siri] Okay, so if we excluded ...

[Stanley Plotkin] Mumps.

[Aaron Siri] Mm-hmm.

[Stanley Plotkin] Yeah.

[Aaron Siri] Go ahead. Mumps, pertussis, okay. So since this is retrospective, we would know where those outbreaks are, right? Yes. They're very carefully tracked by the CDC, correct? Mm-hmm. Since we know where the outbreaks are for those diseases, that could be — was that a yes? Yes. Since we know where those outbreaks are, that could be actually probably pretty easily controlled for as well, correct?

[Stanley Plotkin] In principle, yes.

[Aaron Siri] Okay.

So can you name me a co-founder that would be difficult to control for in this study?

[Stanley Plotkin] Well, at the moment, I can't think of any other that would be material, although I think one would have to look at genetic issues and the health of other members in the family and so forth.

[06:03:26] But again, I am not saying that such a study is impossible. I'm just pointing out that it would be a very difficult study to do, and the conclusions that you could draw from the study might be very limited.

[Aaron Siri] Well, when you keep saying it's difficult, and your reason for that, I understand, is potential co-founders, and I'm just trying to understand what those are. So you said familial history. Presumably the parents would be in the same health plan as the children, so you'd have the parents' medical history, too, correct?

[06:04:01] Mm-hmm. So that could be controlled for as
well, right? Yes. And you said, mm-hmm, two questions ago? Yes. That was a yes? Okay. So that could be easily controlled for, correct? Yes. Okay. Can you tell me a co-founder that would actually be difficult to control for in this study?

[Stanley Plotkin] Well, other than the ones that I've mentioned and not having thought about doing such a study, that's all I can say.

[Aaron Siri] Okay. If you did such a study, isn't it, are you aware that advocacy groups and other people interested in this issue have been calling for this exact study of comparing vaccinated and unvaccinated for 30 years already?

[06:05:14]

[Stanley Plotkin] I don't spend a lot of time on the web, so I can't say that I know that such a study is being requested.

[Aaron Siri] But you do read IOM reports and CDC reports? Okay.

And you never come across any IOM or CDC reports in which they specifically address the repeated calls for such a study?

No. Okay. Would it be surprising to you if I told you those existed?

[Stanley Plotkin] That what existed?

[Aaron Siri] That CDC and IOM reports in which they document the calls for such a study.

[Stanley Plotkin] Well, I wouldn't be surprised, no.

[06:06:00]

[Aaron Siri] Would you be surprised to know that the CDC, in fact, issued an entire report regarding conducting such a study and the calls for conducting such a study? And they issue the what, did you say? I said, would you be surprised to know that the CDC, in fact, issued a report in response to the request for the calls for such a study?

[Stanley Plotkin] No, I wouldn't be surprised if there was a response, no.

[Aaron Siri] Okay. So, in looking for such a study, isn't it true that there actually has been one such study conducted for the first time ever in the last year, correct?

[Stanley Plotkin] I am not aware of that study.

[Aaron Siri] Okay. I'm going to hand you what's been marked Plaintiff's Exhibit 24.

[06:07:14] The title of this study is A Pilot Comparative Study of the Health of Vaccinated and Unvaccinated 6- to 12-Year-Old United States Children, correct? Yes. Okay. And the authors of this study are professors at the Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, correct? That's what it says. I'm sorry, let's just wait for co-counsel to get a copy.

[Laura Nusma] Sorry about that.

[Aaron Siri] I thought it had gone through.

[06:08:01] Okay.

[Court Reporter] Ms. Nusma, do you have it? Thank you. Sorry about that.

[Aaron Siri] Are you familiar with this pilot study, Dr. Plotkin? No. Okay.

[Stanley Plotkin] I see it's been published in the Journal of Translational Science, which is not one of the journals I read, and it's probably one of those multiple so-called predatory journals that we are trying to deal with currently.

[Aaron Siri] So is anybody in any university that publishes anything that's negative about vaccines predatory? No, it's not that.

[Stanley Plotkin] It's that there are journals now that will publish anything for money, and I get about 10 of those invitations a day.

[06:09:02]

[Aaron Siri] So does money influence judgment? It may. Conduct?

[Stanley Plotkin] It may. I cannot tell until I read this study.

[Aaron Siri] I understand. So, well, in this study, if you look, if you take a quick look at it, you'll see that it involves looking at total health outcomes between vaccinated and unvaccinated homeschool children. Okay. When you're ready, please turn to page 5. Do you see the row that says chickenpox? Yes. Okay. So the odds ratio for the unvaccinated were twice as likely – no, I'm sorry, four times as likely to get chickenpox, right?

[06:10:12] Yes. Yeah, 0.26, so odds ratio of about four. The kids who are unvaccinated were about four times more likely to get chickenpox? Mm-hmm. Okay. Is that a yes? Yes. And do you see for whooping cough, the unvaccinated children were three times as likely to get whooping cough? Yes. Yes. Go down to where it says allergic rhinitis. What is that?

[Stanley Plotkin] Well, it's essentially running nose because of allergy. Okay.

[Aaron Siri] Do you see that it says that the vaccinated children were 30 times as likely to have allergic rhinitis?

[Stanley Plotkin] Yes, I see that number.

[Aaron Siri] Do you see that it says that vaccinated children were 3.9 times as likely to have allergies?

[06:11:04] Yes. 4.2 times as likely to have ADHD? Yes. 4.2 times as likely to have autism spectrum disorder?

[Stanley Plotkin] Yes.

[Aaron Siri] 2.9 times as likely to have eczema? Mm-hmm, yes. 5.2 times as – Same. Sorry. 5.2 times as likely to have learning disability? Yes. 3.7 times as likely to have neurodevelopment disorder?

[Stanley Plotkin] Yes.

[Aaron Siri] And 2.4 times as likely to have any chronic condition? Yes. Okay. Wouldn't you like to see a larger-scale study that refuted these claims?

[Stanley Plotkin] It would be ideal, yes. It would certainly be important to repeat the study and to enroll patients in a blinded fashion.

[06:12:01] I really would have to read this to see exactly how they enrolled the children or the parents in the study.

[Aaron Siri] Doesn't the existence of the study, though, I mean, strike that? So it at least calls for further similar studies, hopefully, to either confirm or disprove the findings in the study, correct?

[Stanley Plotkin] Yes. Mm-hmm. Yes, I would agree.

[Aaron Siri] Okay. I'm going to show you one more study that was done with the same data from this author.

[06:13:45] Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 25. Has it been sent? Okay. This is another study by the same author.

[06:14:00] This is another publication using the same data, I believe, from the same group of professors at the Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, correct?

[Stanley Plotkin] It appears that way, yes.

[Aaron Siri] Okay.

And the title of this one is Preterm Birth, Vaccination, and Neurodevelopmental Disorders, a Cross-Sectional Study of 6- to 12-Year-Old Vaccinated and Unvaccinated Children, correct?

Yes. Okay. I'll give you a moment to read the abstract. Have you ever seen this study before? No. Okay, so just take a moment, please, and read the abstract.

[Stanley Plotkin] Mm-hmm.

[Aaron Siri] Okay.

[Stanley Plotkin] Yes.

[Aaron Siri] So in the middle of the abstract, I'm going to read two sentences, and you can tell me if I've read them correctly.

[06:15:05] No association was found between preterm birth and NDD in the absence of vaccination. Strike that. Actually, Dr. Plotkin, could you, 1, 2, 3, 4, 5, 6, 7 lines down in the abstract, you see where it starts, no association?

[Stanley Plotkin] Yes.

[Aaron Siri] Can you start, can you read that sentence in the next one?

[Stanley Plotkin]

No association was found between preterm birth and NDD in the absence of vaccination, but vaccination was significantly associated with NDD in children born at term, odds ratio 2.7.

Is that sufficient?

[Aaron Siri] In the next sentence, please, sir. Thank you.

[Stanley Plotkin] However, vaccination coupled with preterm birth was associated with increasing odds of NDD, ranging from 5.4 compared to vaccinated but non-preterm children, to 14.5 compared to children who were neither preterm nor vaccinated.

[06:16:22] Okay.

[Aaron Siri] What does NDD stand for? Neurodevelopmental disorders. And in this study it was defined as learning disability, attention deficit, hyperactivity disorder, and autism spectrum disorder, correct?

[Stanley Plotkin] Yes. Okay. But I will also point out that the abstract says that it was a convenience sample of 666 children. So clearly it was in no way a randomized study.

[Aaron Siri] Shouldn't we do better studies?

[Stanley Plotkin] One would have to do a better study.

[06:17:02]

[Aaron Siri] Larger samples?

[Stanley Plotkin] Larger samples and enrollment not by convenience.

[Aaron Siri] Right. I believe Dr. Mawson calls these pilot studies, correct? Because nobody else is doing them, so he tried with limited resources, not the resources of pharmaceutical companies and the CDC, to conduct such a study, right?

[Stanley Plotkin] Well, that's your interpretation. I would have to read the study.

[Aaron Siri] Fair enough. More than fair. Is it possible that his findings in both of these studies could be correct?

[Stanley Plotkin] Is it possible? Yes, of course. Possibility is always possible.

[Aaron Siri] And ideally you would conduct a larger or at least additional similar studies to either confirm or dispute the findings in these studies, correct?

[06:18:07]

[Stanley Plotkin] Ideally, yes.

[Aaron Siri] Okay. Now, let me ask you a question. In terms of randomization, to make sure I understand the concept, if I, for example, choose to vaccinate based solely on birth dates, would that be randomized? Yes. And that would be considered a randomized study? Yes. I'm going to hand you what's been marked, what is being marked as Plaintiff's Exhibit 24.

[06:19:03] 26. Okay. 26. Thank you. This is the Peter Abe study that you and I were talking about earlier, correct? No, this is one of them. Right.

This is the study in which Peter Abe found that children who received DPT in the first six months of life versus those who got no vaccines died at 10 times the rate, correct?

Right. And in this study, you earlier said that your concerns with Abe's prior studies that had similar conclusions was that they weren't randomized.

[06:20:08] But in this study, it was randomized, correct? Because it was – let me strike that. In this study, the vaccinated versus unvaccinated children were simply vaccinated or unvaccinated purely by the chance of when their birthday happened to be. Isn't that correct?

[Stanley Plotkin] Yes, it says they were allocated by birthday. I have to – let's see.

[06:21:25] Well, you know, it's not absolutely clear as to how the randomization was done. Apparently, there were periods of time when they were vaccinating and other periods when they were not vaccinating. I think that if you – have you read the study before, Dr. Plotkin? I've glanced at it, yes. I haven't read it thoroughly. But the – as I said before, this kind of study is useful, there's no doubt about that.

[06:22:05] But one needs to have some sort of immunological correlate to really confirm that the findings are real. The other point is that Peter is working in an African community where there was a high mortality to begin with, and that's, of course, because of other factors. And so whether this would be true in, let's say, Denmark or elsewhere is not clear. And if my memory serves, attempts to show in Denmark what Peter has found in Africa have not been positive.

[06:23:00]

[Aaron Siri]

Are you saying that there's a randomized study in Denmark comparing death rates between DPT and T?

It was – One second. Dr. Plotkin, hold on, hold on a second. I'm sorry, you've got to let me – because the core reporter can't take down both of us talking. Okay? I'm asking is, is there a study from Denmark that compared children who received DTP versus children who received no vaccines at all that was randomized, like this study was, and that compared the death rate between the two groups?

[Stanley Plotkin] Well, I'd have to go back and look, but my recollection is that because in Denmark everything is registered and they had excellent data on vaccines being given, that they did not find an effect on mortality of giving DTP.

[06:24:02] But regardless, my point is that mortality in the developed world is relatively rare in childhood, whereas in Africa it's obviously common. But let me repeat what I said about Peter Abbe's work. It's not that I discard it or think that his conclusions are wrong. What I'm saying is that they are observational data and they have to be confirmed by studies of the immune responses, and those have been done only to a certain degree.

[Aaron Siri] When you say studies of immune response, what do you mean?

[Stanley Plotkin] I mean whether the immunity of the child is interfered with by DTP, that is, immunity to other diseases.

[06:25:09] And as I mentioned before, he has shown that measles vaccine has a positive effect, and that has been confirmed by showing that measles vaccination influences immunity to other diseases.

[Aaron Siri] So what you're saying is that you don't dispute his findings that at least in this African country there is a 10 times greater death rate amongst those who got DTP in the first six months of life versus those who got no vaccines, correct?

[Stanley Plotkin] I don't dispute his findings. I would have to look further to make sure that the populations that were studied were absolutely equal in other respects. But again, I'm not one who discards Peter's studies a priori.

[06:26:09]

[Aaron Siri] Well, because earlier you told me the issue was it wasn't randomized.

[Stanley Plotkin] That is an important issue, yes.

[Aaron Siri] And this one is randomized.

[Stanley Plotkin] Well, again, I just have to be sure that it was randomized, that both groups were vaccinated or non-vaccinated at the same time, rather than sequentially.

[Aaron Siri] Yes, because it was done by birthdays. When people came into the clinics, right, depending on their birth date, they either got the vaccine or they didn't, correct?

[Stanley Plotkin] I need the 1984.

[Aaron Siri] Oh, you know what? I don't need it.

[06:27:02]

[Tom Liebman] I have it. I'm sorry. Correct?

[Stanley Plotkin] Well, subject to my reading of this carefully, I agree that he is claiming that it's randomized.

[Aaron Siri] So DTaP has been used around the world for, what, 30, 40 years now, 50 years?

[Stanley Plotkin] Mainly since the 1990s, so about 20 years.

[Aaron Siri] And Peter Abe has been claiming, making this claim, a respected scientist whose conclusions you said you take seriously, that DTaP might cause more deaths than people it saves. But let me just finish my question, please. When do you think the extra science on immunology you think is necessary is going to get done so we know whether or not DTaP is saving more children than it kills?

[06:28:06]

[Stanley Plotkin] Yeah, well, I would imagine that WHO is looking into it. I don't know that for a fact. But it also has to be pointed out that the vaccine that he's studying is whole-cell vaccine. It is not the vaccine being used in the United States.

[Aaron Siri] That's right, but it is being used in most third-world countries, correct?

[Stanley Plotkin] The vaccines being used in the United States are being used in the U.S. and Europe. But DTaP, the whole-cell vaccine, is used very largely in Latin America and Africa.

[Aaron Siri] In developing countries? Yes. Any reason that the life of a child in a developing country is not equal to that in a first-world country? No, but the whole-cell vaccine is considerably cheaper.

[06:29:02] Dr. Plotkin, I'm going to hand you what's being marked as Plaintiff's Exhibit 24. 27. 27? What is that? What does it say on there? 27. 27. Sorry. Looks like a four to me. Got that. Okay, this is an excerpt from the 1994 IOM report, correct? Okay. Under risk-modifying factors, the first sentence there says, the committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not.

[06:30:05] Yes. Correct? Yes. Okay. I'm handing you what's being marked as Plaintiff's Exhibit 28.

[06:31:09] I'm going to read you an excerpt from this, and then I'm going to ask you a question. Okay, Dr. Plotkin? Yes. Okay. It says, both epidemiologic and mechanistic research suggests that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons, genetic variations in human or microbiome DNA, environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few, all of which can interact, as suggested graphically in Figure 3-1. Some of these adverse reactions are specific to the particular vaccine, while others may not be.

[06:32:04] Some of these predispositions may be detectable prior to the administration of vaccines. And then skipping down a little, much work remains to be done to elucidate and develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients. Do you disagree with what the IOM wrote here? Well, not in principle. If such factors can be identified, so far it has been very difficult to

identify so-called predispositions. Isn't that because, Dr. Plotkin, the science is just not being done to identify?

[Stanley Plotkin] Well, some attempts have been made. There's a whole literature by Dr. Poland at the Mayo Clinic on such.

[06:33:08] But the things that he's studied have been relatively minor reactions.

[Aaron Siri]

Are you aware of any serious large-scale studies that have been done to assess these predispositions that might result in an adverse reaction from a vaccine?

[Stanley Plotkin] There have been some genetic studies done. By who? As I said, by the Mayo Group in particular, and also some studies done at Vanderbilt. Okay. Who did the studies at Vanderbilt? Well, James Crow was one of the authors. Okay. And what did the studies involve? The studies involved looking at certain enzymes, particularly to see if there was an association with, let's see, it was with, I'm trying to remember which vaccine it was, based on, oh, smallpox vaccine.

[06:34:36]

[Aaron Siri] Smallpox. Do people routinely get smallpox vaccine in America? No. Okay. Other than the researcher at Vanderbilt and the one at the Mayo Clinic that you mentioned, is there anybody else that you know of that is conducting any serious science to identify what would render a child susceptible to a vaccine injury?

[06:35:03]

[Stanley Plotkin] No. I think the people at British Columbia are doing some work.

[Aaron Siri] Who's that?

[Stanley Plotkin] I can't remember the guy's name.

[Aaron Siri] Is it Chris Shaw?

[Stanley Plotkin] Sorry? Is his name Chris Shaw? Could be. It's a whole group of people at British Columbia.

[Aaron Siri] And they've published good science in this area? Yes. Respectable science?

[Stanley Plotkin] Yes.

[Aaron Siri]

And they are the ones who've looked at aluminum adjuvants injected into lab animals in particular, correct?

[Stanley Plotkin] They have done some work with aluminum adjuvants, yes.

[Aaron Siri] Showing that injecting aluminum can go to different parts of the animal, right? Yes. I just want to make sure we're talking about the same group of scientists at the University of British Columbia.

[06:36:04] Do you recall if it's Chris Shaw and his group?

[Stanley Plotkin] I don't recall specifically.

[Aaron Siri] Okay. But it's the group at the University of British Columbia that's looking in particular at aluminum adjuvants in vaccines, correct? Well — In animal models?

[Stanley Plotkin] They're looking at a lot of different things, including adjuvants. Okay.

[Aaron Siri] Understood. Okay. And other than the group at British Columbia, Mayo Clinic, and Vanderbilt, are you aware of anybody else doing such science?

[Stanley Plotkin] Not that I recall, no. Okay.

[Aaron Siri] If anybody would know, it would be you, right, Dr. Plotkin?

[06:37:03]

[Stanley Plotkin] Well, I don't read — I cannot read every published scientific paper.

[Aaron Siri] I know. Okay. Dr. Plotkin, I'm going to refer to the various forms of aluminum adjuvant. I'm sorry? To various forms of aluminum adjuvant used in vaccines as alum. Is that okay? Yes. Because there are different kinds, correct?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay. What is an antigen?

[Stanley Plotkin] An antigen is usually a protein that induces an immune response.

[Aaron Siri] Antigens in killed vaccines, though, produce a very weak immune response, hence the need to add alum to the vaccine formulation, correct? Frequently, not always.

[06:38:00] Okay. And alum, injected alum, can increase the production of all kinds of cytokines, including IL-1, IL-2, IL-6, IL-17, correct? Yes. Okay.

Alum can be recovered from the injection site months or years after intramuscular injections, correct?

[Stanley Plotkin] Well, yeah, it's possible to find alum. Of course, aluminum is a frequent, what shall I say, is present in all of us. We ingest a lot of it.

[Aaron Siri] I'm talking about injected aluminum. I'm asking, can it be recovered from the injection site months or years after intramuscular injection?

[Stanley Plotkin] I believe it's possible, yes.

[Aaron Siri] Okay.

[06:39:02] If I were to read a quote in your book that you're holding in front of you, do you know if it says, quote, it is established that aluminum salt can be recovered at the injection site months or years after intramuscular injections?

[Stanley Plotkin] Well, I'd have to look at it, but I don't doubt that that could be in the book, yes. Okay.

[Aaron Siri] An antigen that is absorbed by alum can be taken up by macrophages and dendritic cells.

[Stanley Plotkin] Yes. I'm sorry.

[Aaron Siri] No problem.

Antigen that is absorbed by alum are taken up by macrophages and dendritic cells.

Incorrect. Macrophages is M-A-C-R-O-P-H-A-G-E-S.

[06:40:02] Macrophages are immune cells, correct?

[Stanley Plotkin] Well, they are scavengers, basically.

[Aaron Siri] What do they do?

[Stanley Plotkin] They take up antigens and present them to other cells.

[Aaron Siri] Okay. So that means that the alum, as well as the antigen that's bound to it, are taken up by macrophages and dendritic cells, correct? Yes. Okay. Aluminum injected into the body can travel to the brain, correct?

[Stanley Plotkin] I don't know that for a fact, but I wouldn't be surprised.

[Aaron Siri] Have you never seen any studies that show that aluminum injected into the body can travel to the brain?

[Stanley Plotkin] I have not seen such studies, no. I've not read such studies.

[06:41:06]

[Aaron Siri] I'm going to hand you what's being marked as Plaintiff's Exhibit 29. Please take a look at that. Did you send it? Okay. In this study, do you have a problem with the journal that this study was published in?

[06:42:00]

[Stanley Plotkin] No.

[Aaron Siri] Is the name of the journal Vaccine?

[Stanley Plotkin] Yes.

[Aaron Siri] Are you an editor in that journal?

[Stanley Plotkin] I was at one point.

[Aaron Siri] And you consider that to be a prestigious journal?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay.

So in this study, they found that injecting rabbits with aluminum and then they dissected them, they found aluminum in the brain of the rabbits, correct?

Yes. Okay. Does that change your opinion of whether injecting aluminum can travel to the brain?

[Stanley Plotkin] Well, it shows experimentally that that's the case. I'd have to look at the concentrations that were injected, whether they were reasonable with respect to what's injected into humans.

[Aaron Siri] Here's another study that's being marked as Plaintiff's Exhibit 30.

[06:43:03] In this study involved mice. Can you please take a look at it? And that study is from 2009, correct? Yes. Okay.

[Laura Nusma] Ms. Nussbaum, did number 30 go through for you? Yes.

[Aaron Siri] Okay.

[Laura Nusma] I'll let you know if it doesn't have an effect.

[Aaron Siri]

And that study found that injecting aluminum in mice caused motor deficits and motor neuron degeneration, correct?

[Stanley Plotkin] Apparently, yes. But, again, one has to compare the amounts injected with what amounts are injected with vaccines.

[06:44:01]

[Aaron Siri] So in this study, the authors note that they were attempting to use dose-equivalent amounts of alum vis-a-vis the vaccination schedule. And I'll pose that as a question, but I'll leave it to you to take, you know, you obviously, it sounds like you've never read this study, so you could take your time. And Dr. Plotkin.

[06:45:42] Okay, Dr. Plotkin, there's no question pending about that study anymore, so let's move on. Okay. Okay. So are you familiar with a study entitled Delivery of Nanoparticles to Brain Metastases of Breast Cancer Using a Cellular Trojan Horse from the Indiana University School of Medicine and Rice University?

[06:46:10] No. Okay. Are you familiar with a study from 2013 entitled Slow CCL2 Dependent Translocation of Biopersistent Particles from Muscle to Brain? No. Okay. Are you familiar with a – and after this deposition, I'm

happy to provide you copies of all these studies. You can take an opportunity to look at them.

[06:47:03] Are you familiar with a 2015 study entitled
Highly – Oh, actually, you know what, before we continue, I'm going to mark this one. The study I just spoke about, I'm going to mark as Plaintiff's Exhibit 32. I'm going to hand this to you. Yeah, I'll get that to you in a second.

In this study, if you turn to page 5, you can actually see pictures of the brain of dissected mice injected with aluminum and pictures of the aluminum in the brain.

Let me know when you've had an opportunity to look at that.

[Stanley Plotkin] Yes, okay.

[Aaron Siri] That's from 2013.

[06:48:00] I'm going to show you another study from 2015. I'm being marked to Plaintiff's Exhibit number 33. Okay. This study involved 155
mice, again, injected with aluminum, and again, you can find pictures of the aluminum in the dissected mice in their brains. Since we're running short on time, I won't hand you all the studies on this, but having had an opportunity just for the last few minutes to look at a few of these studies, do you have any – can aluminum injected into the body travel to the brain?

[06:49:01]

[Stanley Plotkin] Well, there are experiments suggesting that that is possible. Okay. In particular, I know there's a French group that's been, let's say, working on the potential dangers of aluminum, as well as the British Columbia group. What we lack is evidence in humans that such phenomena are causing the problems that are being caused in mice, and that may relate to dose issues.

[Aaron Siri] Isn't that because those studies would be unethical, Dr. Plotkin?

[Stanley Plotkin] No, I wouldn't say they'd be unethical. I would say that looking for aluminum deposits in the brains of people at autopsy, et cetera, that's entirely feasible.

[06:50:07]

[Aaron Siri] And so if they did autopsies of people's brains and they found aluminum, then that would be a cause for concern?

[Stanley Plotkin] It could be, but one would need to combine that or look at the symptoms of the patients whose brains are being examined.

[Aaron Siri] I'm going to hand you one final study on this. It's been marked Plaintiff's Exhibit 34. This one, they were very careful, my understanding, is to do a number of different dose responses to see the response.

[Stanley Plotkin] This is the French group.

[Aaron Siri] That study is the French group, right, that I think you were referring to earlier?

[Stanley Plotkin] Yes.

[Aaron Siri] Okay.

[06:51:00] In any event, if aluminum bound to antigen does travel to the brain, Dr. Plotkin, and remains there, would that cause an immune activation event in the brain?

[Stanley Plotkin] I don't know whether it would or not.

[Aaron Siri] Do you think it could result in neurodevelopmental disorders?

[Stanley Plotkin] Again, there's no evidence that that's the case.

[Aaron Siri] I'm going to hand you what's being marked. I don't see it. I'm going to hand you what's marked Exhibit 35. Are you familiar with the- let me know. Go ahead.

[06:52:01] That's 104. Are you familiar with this book? No. Okay. Well then, I'll give you a copy today when you leave. Okay. Dr. Plotkin, has an increase in IL-6 been shown to induce autism-like features in lab animals?

[Stanley Plotkin] Well, IL-6 is an inflammatory cytokine, and its relationship to autism, I would say, is not clear. But it is an important cytokine.

[Aaron Siri] Has it been shown to induce autism-like features in animals when injected into animals for experimentation?

[06:53:07]

[Stanley Plotkin] I'm not aware of that, but it's quite possible that that could happen if you use enough IL-6. Do you know the maximum amount?

[Aaron Siri] Just write that. No, I don't have time to do the marking. Are you familiar with the study out of- are you familiar with the study entitled Inhibition of IL-6 Transsignaling in the Brain Increases Social Ability in the BTBR Mouse Model of Autism?

[06:54:00]

[Stanley Plotkin] No.

[Aaron Siri] Okay. Are you familiar with the study called Maternal Immune Activation Alters Fetal Brain Development Through Interleukin-6?

[Stanley Plotkin] Vaguely, yes.

[Aaron Siri] Yeah. Published in the Journal of Neuroscience? Yeah, well, I don't remember the journal. Is that one of the journals you consider respectable? Yes. Okay. And this was out of the University of California Medical Center. This is from California Institute of Caltech. That institution did a number of studies regarding immune activation and its effects, right? Respected group. I'm sorry, repeat the question. Sorry, that group did a number of studies related to immune activation and neurological disorder, correct?

[06:55:06]

[Stanley Plotkin] Yes.

[Aaron Siri] And they found a connection between immune activation and neurological disorders, correct? Mm-hmm. Okay. And one of the- is that a yes? Yes. Okay. And one of the studies- findings they had was that immune activation alters fetal brain development through interleukin-6, correct?

[Stanley Plotkin] As I said before, IL-6 is an important cytokine. I would point out in relation to immune activation that immune activation occurs as a result of disease and exposure to a variety of stimuli, not just vaccines.

[Aaron Siri] But it can be caused by vaccines, correct?

[06:56:00]

[Stanley Plotkin] Immune activation is the objective of vaccines.

[Aaron Siri] Do you know the maximum amount of aluminum that is injected into a child who follows the CDC schedule?

[Stanley Plotkin] I haven't done the arithmetic, but I believe it would amount to several milligrams. Mm-hmm.

[Aaron Siri] Let me mark these. Mark these two. I'll mark this one. I'm going to hand you what's been marked as Plaintiff's Exhibit 36, okay? And before I do that, there's a question for you. The group out of the British Columbia that you were- Questions? The group out of the University of British Columbia, that's out of the Department of Ophthalmology and Visual Sciences?

[06:57:05] Yeah. All right. Okay. Well, I'm going to hand you a letter from what's been marked as Exhibit 36, which is a letter from one of the professors that runs the lab in that group.

[Tom Liebman] We have four minutes left in the day.

[Aaron Siri] Okay. Have you seen this letter before?

[Stanley Plotkin] No.

[Aaron Siri] Okay. This letter is from the group at the University of British Columbia you mentioned before, correct?

[Stanley Plotkin] Yes.

[Aaron Siri] And it's addressed to HHS, correct?

[06:58:01] Yes. As well as NIH? Yes. FDA and CDC, correct? Yes. Okay. In the first paragraph, can you read the first paragraph?

[Stanley Plotkin]

I am writing to you in regard to aluminum adjuvants in vaccines.

The subject is one my laboratory works on intensively and therefore where I feel I have some expertise. In particular, we have studied the impact of aluminum adjuvants in animal models of neurological disease, including autism spectrum disorder. Our relevant studies on the general topic of aluminum neurotoxicity in general and specifically in regard to adjuvants are cited below.

[Aaron Siri] Can you read the last sentence in the next paragraph?

[Stanley Plotkin] In children, there is growing evidence that aluminum adjuvants may disrupt developmental processes in the central nervous system and therefore contribute to ASD in susceptible children.

[06:59:06]

[Aaron Siri] And just the next paragraph.

[Stanley Plotkin] Despite the foregoing, the safety of aluminum adjuvants in vaccines has not been properly studied in humans, even though pursuant to the recommended vaccine schedule published by the Centers for Disease Control, a baby may be injected with up to 3.675 micrograms of aluminum adjuvant by 6 months of age.

[Aaron Siri] And just the next sentence, and I guess we can wrap up.

[Stanley Plotkin] In regard to the above, it is my belief that the CDC's claim on its website that vaccines do not cause autism is wholly unsupported. So, my comments are, one, that my estimate was pretty much correct. Second, that unfortunately Dr. Schor has been associated with the party that I mentioned before, Tomlijanovich, who in my view is completely untrustworthy as far as scientific data are concerned.

[07:00:19] So, I'm concerned about Dr. Schor being influenced by that individual. And I'm not aware that there is evidence that aluminum disrupts developmental processes in susceptible children.

[Aaron Siri] Q. Dr. Schor is a scientist that studies aluminum regularly, correct? A. Yes. Q. Do you study aluminum regularly? A. No. Q. Are we done?

[Tom Liebman] A. Yes. This ends Tape 4 of the deposition of Dr. Stanley Plotkin.

[07:01:01] We are going off the record. The time is 1643. This is the beginning of Disc 5 of the deposition of Dr. Stanley Plotkin. We are on the record. The time is 1643. Q.

[Aaron Siri] Dr. Plotkin, I'm handing you what has been marked as Plaintiffs' Exhibit 37 and 38. Are these letters also written by individuals who are very experienced in studying aluminum adjuvant?

[Stanley Plotkin] A. Yes. Well, one of the letters is from a French group, and I would point out that the French Government – Yes.

[Aaron Siri] Q. Is the content of these letters similar to that of the letter from Chris Shaw? A. Yes.

[07:02:01] Q. Dr. Plotkin, I'm going to hand you what's been marked as Plaintiffs' Exhibit 39. Okay. This is a study entitled Aluminum in the Brain Tissue in Autism, correct? A. Yes. Q. Okay. And it was published in the Journal of Trace Elements in Medicine and Biology, correct? A. Yes. Q. And it found – and according to its author, he found what he says is some of the

highest values of aluminum in human tissue yet recorded in the brains of these autistic children who died prematurely, correct?

[Stanley Plotkin] A. Well, I'd have to read the paper, but apparently that's the case. Q.

[Aaron Siri] And do you know that the standout observation in this study is that the aluminum that he found was in the immune cells of the brain, including within immune cells traveling into the brain?

[07:03:01]

[Stanley Plotkin] A. Yes. Q. Okay. A. But they were not associated with neurons.

[Aaron Siri] Q. They also found aluminum in the neurons as well, Dr. Plotkin, correct?

[Stanley Plotkin] A. But mostly in other cells.

[Aaron Siri] Q. In immune-related cells, right? Immune system-related cells? A.

[Stanley Plotkin] Cells that travel, yes.

[Aaron Siri] Q. What is encephalitis? A.

[Stanley Plotkin] Inflammation of the brain. Q.

[Aaron Siri] What is encephalopathy?

[Stanley Plotkin] A. Well, it's a vague term that means something's wrong with the brain.

[Aaron Siri] Q. And what is encephalomyelitis? A.

[Stanley Plotkin] Inflammation of the brain.

[Aaron Siri] Q.

Do all five of the DEEP-TAP-containing vaccines sold in this country list encephalopathy within seven days of a prior pertussis-containing vaccine as a contraindication?

[Stanley Plotkin] A. In other words, if encephalitis is present at the time of vaccination?

[07:04:03] Yes, I imagine so.

[Aaron Siri] Q. Meaning that if there was encephalopathy within seven days of a prior pertussis-containing vaccination, that's a contraindication to getting more pertussis vaccination?

[Stanley Plotkin] A. Oh, yes. Q.

[Aaron Siri] And do all three of the hepatitis A-containing vaccines sold in this country list encephalitis or encephalopathy as a reported adverse reaction in Section 6.2 of their product inserts? A.

[Stanley Plotkin] Well, I don't know that for sure, but I imagine that it is a contraindication. Q.

[Aaron Siri] Do all three of the hepatitis B-containing vaccines sold in this country list either encephalitis or encephalopathy as a reported adverse reaction in Section 6.2 of their product insert? A. Yes. Q.

Do almost all of the flu vaccines sold in this country list encephalopathy or encephalitis?

A. I'm sorry. Q. Do almost all of the flu vaccines sold in this country list encephalopathy or encephomyelitis as a reported adverse reaction in Section 6.2?

[07:05:08] A. Yes. Q. Of their insert? A. Yes. Q. Does the only chickenpox vaccine sold in this country list encephalitis as a reported adverse reaction?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Why do you think brain swelling after vaccination is being reported in all of these vaccines?

[Stanley Plotkin] A. Anything that happens after vaccination is included in contraindications. That they are related causally is not necessarily the case. Q.

[Aaron Siri] What is the total quantity of antigen in most pediatric vaccines? A.

[Stanley Plotkin] Well, that's very variable. I mean, perhaps up to 50 milligrams.

[07:06:00] Depends entirely on the vaccine.

[Aaron Siri] Q. Minuscule amount, though? It's very tiny.

[Stanley Plotkin] Q.

[Aaron Siri] Could you even see it with the naked eye if you had it?

[Stanley Plotkin] A. Yeah, you could in some cases, yes.

[Aaron Siri] Q. Some cases. But for most vaccines, it would probably be very difficult.

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] Okay. Are there any ingredients in vaccines that you're aware of that can damage neurons? A.

[Stanley Plotkin] Not that I'm aware of, no.

[Aaron Siri] Q. Okay. Are there any vaccines, any ingredients in vaccines that you're aware of that can damage human cells?

[Stanley Plotkin] A. Oh, well, I mean, that depends on the concentrations and so forth. Human cells, of course, are susceptible to lots of substances. But again, it's very much dependent on the concentration.

[Aaron Siri] Q.

Do any of the vaccines on the childhood schedule contain monkey kidney cells?

[07:07:00]

[Stanley Plotkin] A. Well, the polio vaccine does.

[Aaron Siri] Q. Okay. Go ahead. I'm sorry. A. Oh, go ahead. No, I'll stop there. Q. Okay. Are the monkey kidneys used in making the polio vaccine removed from the monkey while the animal is still alive?

[Stanley Plotkin] A. These days, much of the polio vaccine is produced in a continuous cell line derived from monkeys rather than from monkeys, from live monkeys, so to speak. So I'm pretty sure that the iPole vaccine, for example, is produced in virocells.

[Aaron Siri] Q. Okay. And when you say continuous cell line, what do you mean by that?

[Stanley Plotkin] A. I mean a cell that grows continuously derived from tissues that were normal tissues to begin with.

[07:08:03] Q.

[Aaron Siri] I'm sorry. Say that again, doctor. A.

[Stanley Plotkin] So they are cells that continue to multiply, unlike cells from a, let's say, from a kidney that will not continuously multiply.

These are cells derived from the kidney that will continue to multiply and therefore can be used to make vaccines in.

[Aaron Siri] Q. Cells that continue to multiply unabated are typically considered cancerous, right? A.

[Stanley Plotkin] Well, it depends on the circumstances and the cells, but it's true that cancer cells do continue to replicate indefinitely. The virocells are only used at certain passage levels. They're not used, you know, a thousand passages further on.

[07:09:00]

[Aaron Siri] Q. In relation to the amount of polio antigen in the final polio vaccine product, how much monkey kidney cell material is there in the final product? Is it about the same amount? Is there more monkey kidney cell? Is there less? A. No.

[Stanley Plotkin] I can't give you a figure offhand, but I am pretty sure that the amount of polio antigen is superior to the amount of kidney antigen. Q. But you're not sure? A. I don't recall the exact amounts.

[Aaron Siri] Q. Monkey cellular material remaining in the vaccine is considered either impurities or byproduct of the manufacturing process, correct? A. Yes. Q.

Do any of the vaccines in the childhood vaccine schedule contain blood serum from calves or other bovines?

[07:10:01] A.

[Stanley Plotkin] Well, frequently calf serum is used to make the vaccine, but calf serum is removed before the vaccine is used because you don't want to sensitize the vaccine to cows.

[Aaron Siri] Q. Meaning if there was cow serum remaining in the vaccine, the child could develop antibodies to essentially cow products?

[Tom Liebman] Q.

[Aaron Siri] And that would be, and they could develop an allergy to it?

[Stanley Plotkin] A.

[Aaron Siri] If there were, yes. Q. If there were calf serum in the vaccines, correct? A. Yes. Q. But you're saying there's no calf serum in vaccines, right?

[Stanley Plotkin] A. It is removed, yes.

[07:11:14]

[Aaron Siri] Q. Dr. Plotkin, I'm going to hand you what's in Marcus Plankton's Exhibit 40. What is this? A.

[Stanley Plotkin] Vaccine Excipient and Media Summary. Q. And who produces this document? A. The CDC. Q. The CDC, correct?

[Aaron Siri] Or the FDA? A. I think it's the FDA. Q. Okay. And this lists the ingredients contained in various vaccines, correct? A. Yes. Q. Okay.

[07:12:04] Q. Can you go to KINRIX on the first page? That's K-I-N-R-I-X.

[Stanley Plotkin] A.

[Aaron Siri] Yes. Q. Z-Tap-IPV. Do you see in the third line down, it says calf serum? A.

[Stanley Plotkin] Yeah. Well, that is used to grow the poliovirus.

[Aaron Siri] Q. Right. And this is one of the ingredients that remains in the vaccine? A.

[Stanley Plotkin] I do not believe so.

[Aaron Siri] Q. Okay.

[Stanley Plotkin] A. I mean, the vaccine, as I said, is made using calf serum as a nutrient, but is then removed. Q.

[Aaron Siri] Removed. Because otherwise it would be dangerous, you said, right? A. Yes. Q. Can you go to the top of this document? You see it says, you know what?

[07:13:01] Let me ask you a few other questions, then we'll come back to this document, Dr. Plotkin. A few quick questions, then we'll come back to it.

Do any vaccines on the childhood schedule contain embryonic guinea pig cell cultures?

[Stanley Plotkin] A. Embryonic guinea pig. I don't think any current vaccine is made in guinea pig cells. Varicella vaccine was passaged in guinea pig cells, but certainly not made in guinea pig cells.

[Aaron Siri] Q. Do you know of any vaccines containing cow's milk in it?

[Stanley Plotkin] A. Cow's milk?

[Aaron Siri] Q. Any product derived from cow's milk, any component derived from cow's milk?

[Stanley Plotkin] A. Oh, well, casein, for example, could be used.

[Aaron Siri] Q. And, Dr. Plotkin, if there was casein in the vaccine, the child could become sensitized to that, correct?

[07:14:05]

[Stanley Plotkin] A. Well, I'm not sure about that.

[Aaron Siri] Q. You're not sure anymore about that?

[Stanley Plotkin] A. No. I think there are other sensitizing things in calf serum.

[Aaron Siri] Q. Dr. Plotkin, can I see that one second? Let me make sure. Did I give you the right one? I'm not sure. So earlier you said, okay, so do any vaccines contain egg protein?

[Stanley Plotkin] A. Yes, influenza vaccines.

[Aaron Siri] Q. And do those remain in the final product? A.

[Stanley Plotkin] I believe they do, yes.

[Aaron Siri] Not huge amounts, but there are traces, certainly. Q. Do any vaccines contain gelatin from pigs? A. Yes. Q. Do any vaccines contain gelatin from cows?

[07:15:00] A.

[Stanley Plotkin] Actually, I think in Muslim countries they have tried to do that.

[Aaron Siri] But mostly it's from pig. Q. Do any vaccines contain recombinant GMO yeast? A. Recombinant GMOs. Yes, I imagine so, yes. Q. Are there any other animal products, parts, cells, material, or any other kind that you are aware of that are contained in any vaccine in the pediatric schedule?

[Stanley Plotkin] A. Well, aside from trace amounts, no.

[Laura Nusma] A. Yes. Guys, unfortunately my 5 o'clock's here, so I've got to cut this short.

[Aaron Siri] Q.

[07:16:00] Well, we're not done, so can you come back tomorrow morning, Dr. Plotkin?

[Stanley Plotkin] A. No, absolutely not.

[Aaron Siri] Q. Okay. Well, counsel, you need to move whatever you have right now, then.

[Laura Nusma] A. No, I don't.

[Aaron Siri] Q. I'm not done with the deposition. A.

[Laura Nusma] Then just re-notice it for a second day.

[Aaron Siri] Q. I don't know. The notice says from day to day. He's under subpoena. He needs to be here today. A. No, he's not under subpoena. Q. It's only 5 o'clock, and it says from day to day, so tomorrow's the next day. A.

[Laura Nusma] If he's not available, he's not available. You guys can feel free to try and have him held in contempt while he's in Pennsylvania, but I've got to go.

[Aaron Siri] Q.

[Court Reporter] How often are you available in a half an hour or something that we could take a short break? A. Yeah, I can do that.

[Aaron Siri] Q. Okay, so then let us know when you're done.

[07:17:00] Half an hour? We'll start at 5.30 then, or if you get done earlier. A. Does she have to be present? Q. Do you mind if we continue without you being present? Dr. Plotkin says he's fine with continuing without you.

[Laura Nusma] A. As long as he's okay with that, that's fine with me. I think he's got a pretty good handle on things, so I'm not too concerned.

[Aaron Siri] Q. Okay, great. Then we'll continue. A.

[Court Reporter] All right.

[Aaron Siri] Q. Thank you.

[Court Reporter] MS. NUSSBAUM, IF YOU WANT TO REJOIN THE CONVERSATION, OBVIOUSLY YOU CAN DIAL BACK IN.

[Laura Nusma] MS. NUSSBAUM, I'M JUST GOING TO LEAVE YOU GUYS ON SPEAKER IN MY OFFICE AND DO THIS IN A CONFERENCE ROOM AND I'LL BE BACK. MS. NUSSBAUM, O.K. Q.

[Aaron Siri] Do any vaccines on the childhood vaccine schedule contain MRC-5 human diploid cells? A. Yes. What are these?

[Stanley Plotkin] Rubella, Varicella, Hepatitis A.

[Aaron Siri] Q. What are MRC-5 cells?

[Stanley Plotkin] A. They are human fibroblast cell strain.

[07:18:03]

[Aaron Siri] Q.

[Stanley Plotkin] And how were they created? A. They were created by taking fetal tissue from a particular fetus that was aborted by maternal choice, and the cells, the so-called fibroblast cells, were cultivated from that tissue. The fibroblast cells replicate for about 50 passages and then die.

[Aaron Siri] Q. So MRC-5 cells are cultured cell lines from aborted fetal tissue? A. They're not cell lines.

[Stanley Plotkin] Q. What are they? A. They're cell strains cultivated from an aborted fetus, yes.

[Aaron Siri] Q. So cell strains from an aborted fetus?

[Stanley Plotkin] A. Yes. They are not immortal. Q.

[Aaron Siri] Okay. So they live for five generations and then they die?

[07:19:01]

[Stanley Plotkin] A. About 50 generations. Q.

[Aaron Siri] About 50 generations and then they die?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. And then how is more MRC-5 created?

[Stanley Plotkin] A. Well, a seed stock is made of early passage cells so that one can go back to the seed stock, which is, let's say, at the more or less the eighth passage, and make new cells at the 20th passage and use those to make the vaccine.

[Aaron Siri] Q. So these cell strains are human cells? A. Yes. Q. Do any vaccines on the childhood vaccine schedule contain WI-38 human diploid lung fibroblasts? A.

[Stanley Plotkin] Well, they used to, but I don't think anything is made in those cells anymore. They have been replaced by MRC-5. Q.

[Aaron Siri] So you're not aware of any vaccine that has in its final formulation WI-38 human diploid lung fibroblasts?

[07:20:04]

[Stanley Plotkin] A. Well, as I said, at one point in the past, RA-27-3, for example, rubella vaccine, was grown in WI-38. But the supply is insufficient, so MRC-5 is now used.

[Aaron Siri] Q. And WI-38 was created from an aborted fetus? A. Yes. Q. They took the lung tissue from the aborted fetus? A. Yes.

[Stanley Plotkin] Q.

[Aaron Siri] And from that they've grown this cell line, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Cell strain. Q. Cell strain. Is this cell line immortal? A. No. Q. Do any vaccines on the childhood vaccine schedule contain human albumin? A. Oh, yes.

[07:21:00] Q. What is human albumin?

[Stanley Plotkin] A.

Human albumin is part of human serum.

[Aaron Siri] Q. And what is human serum?

[Stanley Plotkin] A. What is human serum? Human serum is part of the blood that is liquid. Q.

[Aaron Siri] It's the non-red blood cell part of the blood, right? Q. From where was it obtained?

[Stanley Plotkin] A. The human serum? Q.

[Aaron Siri] Yes.

[Stanley Plotkin] A. Well, that would be variable from donors who are healthy donors.

[Aaron Siri] That's all I could say to that. Q. How is it used in the manufacturing process? A. I'm sorry? Q. How is it used in the manufacturing process? A.

[Stanley Plotkin]

Well, serum is used to keep cells healthy during the process of making a vaccine.

So in other words, since the vaccines or some vaccines have to be grown in cells, you have to keep the cells in a good state.

[07:22:13]

[Aaron Siri] Q. So the cells that are used, the virus or bacteria, the viruses used in some of the vaccines are grown in this human blood component?

[Stanley Plotkin] A. Well, yes. I believe that the serum is removed in the final product. But certainly it's important to keep the cells healthy during the manufacture of the vaccine.

[Aaron Siri] Q. Do you think that none of it remains in the final product? A. I don't believe so, no. Q. Because that could be problematic, right?

[Stanley Plotkin] A. Well, it could be, I mean, if the individual is not healthy.

[07:23:05]

[Aaron Siri] Q. Right. Or if maybe some of the, you know, human blood components bind to some of the aluminum and develop antibodies, self-antibodies, correct? A.

[Stanley Plotkin] If they develop antibodies against a serum component, that would not be good. Q. Right.

[Aaron Siri] Do any vaccines contain human material in them that – I'm sorry. Strike that. Apologies. Do any vaccines on the childhood vaccine schedule contain recombinant human albumin? A. Yes. Q. Okay. What is this? A. Sorry? Q. What is recombinant human albumin?

[Stanley Plotkin] A. It's made – it's albumin. Q.

[Aaron Siri] Recombinant human albumin. That's A-L-B-U-M-I-N. A.

[07:24:00]

[Stanley Plotkin] So it's a component of human serum, which is useful to stabilize cells and keep them healthy. And it's made by genetic engineering. Q.

[Aaron Siri] Okay. So it's genetically engineered human serum, basically.

[Stanley Plotkin] A. A part of human serum, yes. Q.

[Aaron Siri] Is that – are these genetically engineered protein structures? A.

[Stanley Plotkin] Yes. And the idea was to eliminate any possibility of a contaminant from human albumin obtained from donors.

So it's made in cells using the DNA for albumin, and that way one can be sure that there's no contaminant.

[07:25:00]

[Aaron Siri] Q. And again, you pretty much want to make sure that none of that remained in the final product, too, right? A.

[Stanley Plotkin] Well, human albumin is probably not much of a problem in terms of causing reactions.

[Aaron Siri] Q. But in terms of it potentially binding to the alum, that could be problematic, correct? A.

[Stanley Plotkin] Well, I don't know the answer to that question. Q.

[Aaron Siri] Okay. Q. The vaccines that contain human material in them, they also contain human DNA and protein, correct? A. They may, yes. Q.

Isn't it true that human DNA in vaccines is typically purposely fragmented to below 500 base pairs in length?

A. Yes.

[Stanley Plotkin] One doesn't, you know, I would say mostly for theoretical reasons, doesn't want to put DNA into – attack DNA into vaccines.

[07:26:15] Q. Okay. A. I think the actual risk is zero, but that's my opinion.

[Aaron Siri] Q. Isn't it true that MMR2 contains approximately 150 nanograms cell substrate, double-strand DNA and single-strand DNA per dose, purposely fragmented to approximately 215 base pairs in length? A. Yeah, that's probably correct, yes.

[Stanley Plotkin] Q.

[Aaron Siri] And is it true that Varivax vaccine for chickenpox is manufactured using WI-38 and MRC-5 and contains approximately 2 micrograms of cell substrate – A. No problem. Q.

[07:27:01]

And contains approximately 2 micrograms of cell substrate, double-stranded DNA, or approximately 1 trillion fragments of human DNA?

[Stanley Plotkin] A. It may be true.

[Aaron Siri] Q. Isn't it true that Havrix, a hepatitis A vaccine, also contains millions of fragments of human DNA? A.

[Stanley Plotkin] Likely. Q.

[Aaron Siri] Do you know whether strands of DNA below 500 base pairs are now known to insert themselves into living cells with which they come into contact?

[Stanley Plotkin] A. I do not have that information, but the likelihood that they would be genetically included in the genome of vaccinees, in my view, is zero. Q.

[Aaron Siri] Do you have a study to support that view?

[Stanley Plotkin] A. I do not have a study that supports that view, but it is, to me, unlikely that the DNA would travel from the site of injection to the semen or the ovaries.

[07:28:11] Q.

[Aaron Siri] Could it insert itself into DNA, even in the muscle tissue, or if it gets into the blood? A.

[Stanley Plotkin] Theoretically, but that's not going to mean that it's going to have any impact on the individual.

[Aaron Siri] Q. Are you familiar with insertional mutagenesis?

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] Do you have any study to show that injecting millions of pieces of human DNA into babies and children is safe? A.

[Stanley Plotkin]

The only studies are all the safety studies that have been done on vaccines.

Q. Okay.

[Aaron Siri] And you can produce those studies, right?

[Stanley Plotkin] A. Well, those studies are available from the manufacturers and from CDC, and I'm not aware of any data showing that a heritable characteristic was transmitted by a vaccine.

[07:29:08]

[Aaron Siri] Q. So you don't – so you personally don't know of any study that shows the safety of injecting human – millions of pieces of human DNA into babies?

[Stanley Plotkin] A. Such studies are general safety studies, and I haven't yet seen a vaccinee develop a new genetic trait as a result of vaccination. Q.

[Aaron Siri] Is it possible that it can cause cancer? A.

[Stanley Plotkin] Anything is possible, but there are no data to support that.

[Aaron Siri] Q. Is there data to show that it doesn't do that?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Okay.

[Stanley Plotkin] A. Observations made over millions of vaccinees.

[Aaron Siri] Q. Okay. And you have the study to show that, right?

[Stanley Plotkin] A. The studies are easily available in terms of vaccine safety studies that have been done by many, many people.

[07:30:02] Q.

[Aaron Siri] Excellent. Then it should be very easy for you to direct me to those and provide comments.

[Stanley Plotkin] A. Yes. You can read the chapter on vaccine safety.

[Aaron Siri] Q. Vaccines contain dead or weakened poliovirus, correct? A. IPV does, yes. Q. Beginning in the 1950s, poliovaccines were routinely grown on nonhuman primate kidney

cells, correct? A. Correct. Q. Are you aware of any simian monkey viruses, meaning viruses that come from primates, that contaminated poliovaccines and infected individuals receiving the poliovaccine?

[Stanley Plotkin] A. Yes, SV40. Q.

[Aaron Siri] And what does SV40 stand for? A. Simian virus 40. Q. Was it the 40th simian virus found? A.

[Tom Liebman] Yes. Q.

[Aaron Siri] Is that why it's called? A.

[07:31:01] Yes. Q.

Are you aware of any bovine virus that is in any vaccine?

A.

[Stanley Plotkin] At this stage, no.

[Aaron Siri] Q. Are you aware of any bovine virus that is in any vaccine? A. Well, bovine virus, nothing comes to mind at the moment. Q. Are you aware of any virus from any animal other than simian or bovine that is in any vaccine? A.

[Stanley Plotkin] Yes. There's a pig virus present in one of the rotavirus vaccines. Q. What's that virus called? A.

[Aaron Siri] Circovirus.

[Court Reporter] Q. Circo? A.

[Aaron Siri] Yes. Q. Is there more than one type, or is there only one? A.

[Stanley Plotkin] There's more than one type, but I think only one was recovered from the vaccine.

[Aaron Siri] Q. Which one is that?

[07:32:00] A. I think it was two. Q. Circovirus two? A. I think so. Q. Are you aware of any retroviruses that are in any vaccine?

[Stanley Plotkin] A. Retroviruses, no.

[Aaron Siri] Q. Are you aware of any prions that are in any vaccine? Q. Are you aware of any human viruses that are in any vaccine apart from the virus for which the vaccine is intended? A. No. Q. You indicated that they did find a porcine circovirus type two in rotavirus, correct? A. Yes. Q. Was that unintentional? A. Yes. Q. When it was released to the market, they didn't know that virus was in there, correct? A. Correct. Q. And when they released the polio vaccine on the market, they didn't know SV40 was in there, correct? A. Correct. Q.

[07:33:04] Are you aware of how many micrograms of 2-phenophenoxyethanol A.

[Stanley Plotkin] 2-phenoxyethanol.

[Aaron Siri] Q.

Are you aware of how many micrograms of 2-phenoxyethanol a child following the childhood vaccine schedule would be injected with?

[Stanley Plotkin] A. No. I'd have to look that up. Q.

[Aaron Siri] Do you think it's close to around 100 micrograms? A. It could be, but I'd have to look it up. Q. Do you know the safe level in terms of that ingredient?

[Stanley Plotkin] A. I am not aware that there is toxicity associated with 2-phenoxyethanol. It's a fairly harmless substance as far as I'm aware.

[07:34:03]

[Aaron Siri] Q. Do you know any vaccines on the childhood schedule that include ferric nitrate? A. Ferric nitrate? No, I don't recall that. Q. Are you

aware of how many micrograms of polysorbate 80 a child following the vaccine schedule will be injected with? A. I don't have the amount, no. Q. Now I want to give you back Exhibit 40, Dr. Plotkin. Take a look at that a moment. You indicated that you weren't aware that WI-38 was in the final vaccine product. If you could turn to Page 3 for MMR and MMRV. Do you see that within the ingredient list that lists WI-38, human diploid lung fibroblasts?

[07:35:04]

[Stanley Plotkin] A. Yes, I do see that.

[Aaron Siri] Q. I believe that of the ingredients that we discussed until now, the rest of them you indicated you are aware are in vaccines except for — are there any ingredients we've discussed until now that you believe are not in vaccines? A.

[Stanley Plotkin] Well, I'd have to go back over all the questions you asked. But I do want to say that WI-38, as I said before, was the original fibroblast cell line. And I think that manufacturers have shifted to MRC-5. But WI-38 could still be used, and I don't see anything wrong with that.

[07:36:00] Q.

[Aaron Siri] Are there any vaccine ingredients that are not listed on the FDA's official Vaccine Excipient and Media Summary Table that you're aware of?

[Stanley Plotkin] A. I don't see how I can really answer that question without reading the whole thing. But I imagine that it's a complete list. Q. Okay.

[Aaron Siri] Q. Isn't it true that an adjuvant will bind not only to the target antigen, but also to the impurities and byproduct of the manufacturing process? A.

[Stanley Plotkin] Probably yes.

[Aaron Siri] Q. And those impurities and byproducts are all listed in what has been marked as Exhibit 40, correct? A. Yes. Q. Okay. Q. Once the impurities

or byproducts are bound to the aluminum, the body may also develop antibodies to these impurities and byproducts, correct?

[07:37:09]

[Stanley Plotkin] A. May is the operative word, but not necessarily. Q.

[Aaron Siri] The entire purpose of the aluminum binding to a protein structure, be it an antigen or some other protein structure, is to cause an immune response and develop antibodies, correct?

[Stanley Plotkin] A. Yes. But the protein has to be of the right size and presentation in order to induce an immune response. And that will not always be the case if the protein is small or is something not recognized by the human immune system.

[Aaron Siri] Q. Do you know whether the protein structure for any of the ingredients on Exhibit 40 are not the right size to bind to alum?

[07:38:05]

[Stanley Plotkin] A. Well, I think it's unlikely that monosodium glutamate, for example, will cause an immune response. I'd have to look through the whole thing. But amino acids probably are unlikely to induce an immune response.

[Aaron Siri] Q. Anything else? A.

[Stanley Plotkin] You want me to read this whole thing?

[Aaron Siri] Q. No. I'm just asking, I mean, in terms of just the stuff that's got protein structures in it.

[Stanley Plotkin] A. Well, things like calf serum, if they were present, would possibly induce an immune response. But the things on this list, the vast majority of them are unlikely to do so.

[07:39:01]

[Aaron Siri] Q. Because they're not protein structures?

[Stanley Plotkin] A. They're not proteins or they're very small.

[Aaron Siri] Q. Okay. Other than the, let's write that. How about, and we talked earlier, human albumin, that would be of a big enough protein structure to bind to alum, correct?

[Stanley Plotkin] A. It could. Although the fact that it's human means that individuals might well not respond to, that is, not respond to human albumin as a foreign protein.

[Aaron Siri] Q. Right. Maybe not alone, right? But bound to alum, it might, correct? A. It might.

[Stanley Plotkin] But I'm not aware of evidence that it does.

[07:40:05]

[Aaron Siri] Q. Are you aware of a study that looked at that issue?

[Stanley Plotkin] A. I have not read such a study, no. No. Okay. Q.

[Aaron Siri] How about the human DNA? Do you believe that the human DNA strands can bind to the alum? A. No. Q. Why is that? A.

[Stanley Plotkin] I don't see any chemical reason why it shouldn't.

[Aaron Siri] Q. Any reason why it shouldn't? A. Proving a negative is always more difficult. Q. Well, I'm just trying to know if you know or you're just not sure. That's all. I'm not asking.

[07:41:00] I'm just saying if you don't know, just say you don't know.

[Stanley Plotkin] A. I have no reason to believe that DNA will bind to albumin. Q.

[Aaron Siri] But you don't know for sure?

[Stanley Plotkin] A. I have not done the experiment, no. Q.

[Aaron Siri] And do you know whether it will bind to any of the cellular debris from MRC-5 or WI-38? A. Whether human albumin would bind? Q. No. Whether alum would bind to MRC-5 or any of the cellular debris that's in the final product from MRC-5? A.

[Stanley Plotkin] I think it could, but I don't know that it does. Q.

[Aaron Siri] Do you know whether alum could bind to any of the cellular debris from WI-38?

[Stanley Plotkin] A. It might, but I don't know that for a fact. Q.

[Aaron Siri] Do you know whether alum would bind to any of the gelatin from pigs? A. I think that's unlikely. Q. Why's that? A. I don't think that alum would bind to gelatin, but I don't know that for a fact.

[07:42:08] Q. What about egg protein? Could alum bind to egg protein? A. Possibly. Q. Okay. And to casein? A.

[Stanley Plotkin] I suppose it's possible, but I'm not aware of any evidence. Q. Which you don't know? A. I don't know. Q.

[Aaron Siri] In your work related to vaccines, how many fetuses have been part of that work?

[07:43:11] A.

[Stanley Plotkin] My own personal work? Two. Q. Two.

[Aaron Siri] So in all of your work related to vaccines throughout your whole career, you've only ever worked with two fetuses?

[Stanley Plotkin] A. In terms of making vaccines, yes. Yes.

[Aaron Siri] Q. I'm going to hand you what's been marked Plaintiff's Exhibit 41. Are you familiar with this article, Dr. Plotkin?

[07:44:04] A. Yes. Q. Are you listed as an author on this article? A. Yes. Q. This study took place at the Wistar Institute, correct? A. Yes. Q. You were at the Wistar Institute, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. How many fetuses were used in the study described in this article?

[Stanley Plotkin] A. Quite a few.

But my answer to the previous question was, what did I use to make vaccines?

And the answer was two.

[Aaron Siri] Q. Can you read back the question I had asked? A. Just now?

[Court Reporter] Q. No.

[Aaron Siri] Prior. A.

[07:45:01]

[Court Reporter] In your work related to vaccines, how many fetuses have been part of that work? Answer. My own personal work? Two.

[Aaron Siri] Q. So I'm going to ask that question again. In your work related to vaccines, how many fetuses were involved in that work? A.

[Stanley Plotkin] There were only two fetuses involved in making vaccines. When fetal strains, fibroblast strains, were first developed, I was involved in that work trying to characterize those cells. But they were not used to make vaccines. Q.

[Aaron Siri]

Wasn't the purpose of this study to help develop a human cell line or to support the use of human cell lines in the creation of vaccines?

[Stanley Plotkin] A. The idea was to study the cell strains from fetuses to determine whether or not they could be used to make vaccines.

[07:46:01] Q. So this was related to your work? A. Well, yes, in a sense, yes.

[Aaron Siri] Q. To vaccines, correct? A.

[Stanley Plotkin] Yes. It was preparatory.

[Aaron Siri] Q. So this study involved 74 fetuses, correct? A. I don't remember exactly how many. Q. Turn to page 12 of the study. A.

[Stanley Plotkin] Seventy-six.

[Aaron Siri] Q. Seventy-six. And these fetuses were all three months or older when aborted, correct? A.

[Stanley Plotkin] Yes.

[Aaron Siri] Q. And these were all normally developed fetuses, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. These included fetuses that were aborted for social and psychiatric reasons, correct?

[Stanley Plotkin] A. Correct. Q.

[Aaron Siri] What organs did you harvest from these fetuses?

[Stanley Plotkin] A. Well, I didn't personally harvest any, but a whole range of tissues were harvested by coworkers.

[07:47:08] Q.

[Aaron Siri] And these pieces were then cut up into little pieces, right? A. Yes. Q. And they were cultured? A. Yes. Q. Some of the pieces of the fetuses were pituitary gland that were chopped up into pieces? A. Mm-hmm. Q. Okay. Included the lung of the fetuses? A.

[Stanley Plotkin] Yes.

[Aaron Siri] Q. Okay. Included the skin? A. Yes. Q. Kidney? A.

[Stanley Plotkin] Yes.

[Aaron Siri] Q. Spleen?

[Stanley Plotkin] A. Yes. Q. Heart? A. Yes.

[Aaron Siri] Q. And tongue?

[Stanley Plotkin] A. I don't recall, but probably yes.

[Aaron Siri] Q. So I just want to make sure I understand. In your entire career, and this was just one study, so I'm going to ask you again. In your entire career, how many fetuses have you worked with?

[07:48:00] A.

[Stanley Plotkin] Well, I don't remember the exact number, but quite a few when we were studying them originally, before we decided to use them to make vaccines.

[Aaron Siri] Q. Do you have any sense? I mean, this one study had 76. How many other studies did you have that you used aborted fetuses for? A. I don't remember how many. Q. Are you aware that one of the objections to vaccination by the plaintiff in this case is the inclusion of aborted fetal tissue in the development of vaccines and the fact that it's actually part of the ingredients of vaccines?

[Stanley Plotkin] A. Yeah. I'm aware of those objections. The Catholic Church has actually issued a document on that which says that individuals who need the vaccines should receive the vaccines, regardless of the

fact. And I think it implies that I am the individual who will go to hell because of the use of aborted tissues, which I am glad to do.

[07:49:07]

[Aaron Siri] Q. Okay. Do you know if the mother is Catholic?

[Stanley Plotkin] A. I have no idea.

[Aaron Siri] Q. Okay.

[Stanley Plotkin] A. But she should consult her priest.

[Aaron Siri] Q. If she's, in fact, Christian, I guess, right? In any event, so we have 76 in this study. Would you approximate it's been a few hundred fetuses?

[Stanley Plotkin] A. Oh, no. I don't think it was that many. It was probably not many more than in this paper. And I should stipulate that we had nothing to do with the cause of the abortion.

[Aaron Siri] Q. Some of these were from psychiatric institutions, correct?

[07:50:01] A.

[Stanley Plotkin] Actually, all I can say is that the fetuses that I personally worked with actually came from Sweden, from a Swedish coworker. And so I in no case was able to determine what exactly the reason for the abortion was. Q.

[Aaron Siri] I'm just asking you, some of the fetuses that you did use did come from abortions from people who were in psychiatric institutions, correct? A.

[Stanley Plotkin] I don't know that. What I'm telling you is that I got them from a coworker. And if it's stated in the paper, it's true. But otherwise, I do not know.

[Aaron Siri] Q. So if it's in the paper, you don't contest it, right?

[Stanley Plotkin] A. I don't contest it, no.

[Aaron Siri] Q. Have you ever used orphans to study an experimental vaccine?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Have you ever used the mentally handicapped to study an experimental vaccine?

[07:51:03]

[Stanley Plotkin] A. I don't recollect ever doing studies in mentally handicapped individuals. At the time, in the 1960s, it was not an uncommon practice. Q.

[Aaron Siri] So you're saying – I'm not clear on your answer. I'm sorry. Did you – have you ever used the mentally handicapped to study an experimental vaccine?

[Stanley Plotkin] A. What I'm saying is I don't recall specifically having done that, but that in the 1960s, it was not unusual to do that, and I wouldn't deny that I may have done so.

[07:52:04]

[Aaron Siri] I've already marked this. A. I know, but that was wrong. Q. Okay. A. It's the task force. Q. I'm going to read you a sentence from what's been previously marked as Exhibit 7.

[Court Reporter] A. That's not what got marked as Exhibit 7. The task force was 7. So this should be 42. Q. Got it, got it, got it.

[Aaron Siri] Okay. So – well, in any event, you're not denying that you – that you – There's an article entitled, Attenuation of RA-27.3 rubella virus in WI-38 human diploid cells. Are you familiar with that article? A. Yes. Q. In that article, one of the things it says is 13 – is one of the things it says is 13 seronegative, mentally retarded children were given RA-27.3 vaccine.

[07:53:06]

[Stanley Plotkin] A. Okay. Well, in that case, that's what I did. Q.

[Aaron Siri] Okay. Have you ever expressed that it's better to perform experiments on those less likely to be able to contribute to society, such as children with handicap than with children without – or adults without handicaps?

[Stanley Plotkin] A. I don't remember specifically, but it's possible. And again, I repeat that in the 1960s, that was more or less common practice. I've since changed my mind, but those were – that was a long time ago. Q.

[07:54:02]

[Aaron Siri] Do you remember ever writing to the editor of Ethics on Human Experimentation? A.

[Stanley Plotkin] I don't remember specifically, but I may well have. Q. Okay.

[Aaron Siri] I'll mark this. Yes. I'm going to hand you with some markers, Exhibit 43. Do you recognize this letter you wrote to the editor? A. Yes. Q. Did you write this letter? A. Yes. Q. Okay. This is one of the things you wrote. The question is whether we are to have experiments performed on fully functioning adults and on children who are potentially contributors to society, or to perform initial studies in children and adults who are human in form but not in social potential.

[07:55:15]

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. It may be objected that this question implies a Nazi philosophy, but I do not think that it is difficult to distinguish non-functioning persons from members of ethnic, racial, economic, or other groups. A. Mm-hmm. Q. Okay. Um, have you ever used babies of mothers in prison to study an experimental vaccine? Q. Have you ever used individuals under colonial rule to study an experimental vaccine? A. Yes. Q. Did you do

so in the Belgian Congo? A. Yes. Q. Did that experiment involve almost a million people? A. Well, well, all right, yes.

[07:56:00] Q. Did you ever visit what was the Belgian Congo and Rwanda? A. Yes. Q. How many times? A. Once. Q. Yes. R-U-A-N-D-A-U-R-U-N-D-I. When was that visit? A.

[Stanley Plotkin] 1959. Q.

[Aaron Siri] And how long were you there? A. A couple of months. Q. Two months? A. I think so, yes. Q. Could it have been longer? A.

[Stanley Plotkin] No, I don't think it was longer than that.

[Aaron Siri] Q. What places did you visit? A.

[Stanley Plotkin] What was then called Leopoldville, Stanleyville, Kivu. Q. Kivu? A. Yes. Q. K-I-V-U?

[Court Reporter] A.

[Stanley Plotkin] Yes. Burundi. Q.

[Court Reporter] Ms. Newsom, are you back?

[Laura Nusma] Q. I am.

[07:57:00]

[Stanley Plotkin] A. Uh-huh. It could have been a couple of other places, but I don't remember.

[Aaron Siri] Q. Okay. I've heard some of your speeches, you remember this trip fondly, right?

[Stanley Plotkin] A. Well, fondly may not be the right word, but I do remember it as an important event.

[Aaron Siri] Q. In what order did you visit the places you just told me? Q. Which one do you think you visit

first? A. Leopoldville. Q. Okay. And then after
that? A. Stanleyville. Q. Then?

[Stanley Plotkin] A. Then the eastern part of the Congo. Q.

[Aaron Siri] Is that Kivu?

[Stanley Plotkin] A. Yeah. Q. Okay. A. And Bukavu.

[Aaron Siri] Bukavu. Q. Is that before or after Burundi? A. Before. Q. Can you spell Bukavu? A. B-U-K-A-V-U.

[07:58:03] Q. So Leopoldville, then Stanleyville, then Kivu, Bukam, and then Burundi. So how long were you in Leopoldville? A. Oh, gosh. I can't answer that question. Q.

[Stanley Plotkin] Approximately? A. I don't remember. A couple of weeks, probably. Q.

[Aaron Siri] How long in Stanleyville? A.

[Stanley Plotkin] I don't know. Three, four weeks. I can't possibly remember that far back. Q.

[Aaron Siri] And then Kivu approximately? A. Oh, short time. Q. Okay. And then Bukam? A. I'm
sorry? Q. Bukam? A. Bukavu? Q. Bukavu. Q. Bukavu? Approximately how long? A. A couple of days.

[07:59:00] Q. Okay. And then finally Burundi?

[Stanley Plotkin] A. Again, I don't know. Maybe a week. I'm not sure.

[Aaron Siri] Q. Okay. What were you doing in Leopoldville? A.

[Stanley Plotkin] I was examining the data on oral polio vaccination in the city. Q.

[Aaron Siri] Okay. Anything else? A. No. Q. Did you vaccinate anybody? A. Personally, no. Q. What were you doing in Stanleyville? A.

[Stanley Plotkin] I was visiting the chimpanzee laboratory and talking to scientists in Stanleyville. Q. Talking about what? A. Oh, about polio mainly. Q.

[Aaron Siri] Okay. What about polio?

[Stanley Plotkin] A. What about polio? Obviously, they were having polio, and we were talking about how to protect the people against polio.

[08:00:04] Q. Okay.

[Aaron Siri] And did you vaccinate anybody while you were in Stanleyville personally? A.

[Stanley Plotkin] Personally, no.

[Aaron Siri] Q. Okay. What did you do in Kivu?

[Stanley Plotkin] A. As I recall, I just visited the place.

[Aaron Siri] Q. Any purpose?

[Stanley Plotkin] A. I don't think so, no.

[Aaron Siri] Q. Did you vaccinate anybody personally?

[Stanley Plotkin] A. It was a scenic area.

[Aaron Siri] Q. Okay. Did you vaccinate anybody personally there?

[Stanley Plotkin] A. No.

[Aaron Siri] Q. Okay. What about Bukovu?

[Stanley Plotkin] A. I did not do any vaccination there either.

[Aaron Siri] Q. And what were you doing there?

[Stanley Plotkin] A. I was just visiting.

[Aaron Siri] Q. Like a tourist? A. Yes. Q. Same thing with Kivu as a tourist?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. And what about Burundi?

[Stanley Plotkin] A. Well, there I had some discussions with scientists.

[Aaron Siri] Q. Okay. About what? A. About polio.

[08:01:00] Q. Okay. Did you, other than that, did you do anything else in Burundi? A. No. Q. Did you vaccinate anybody personally? A. No. Q. Okay. During your entire trip, did you vaccinate anybody personally? A. No. Q. So your whole trip to the Belgian Congo and Rwanda, Burundi, you never vaccinated anybody personally? A.

[Stanley Plotkin] That is correct. I also stopped in Kikwet, which was to observe a vaccination campaign.

[Aaron Siri] Q. And that was between what cities? A.

[Stanley Plotkin] Well, geographically, it's between Leopoldville and Stanleyville. I don't recall in what order I visited.

[Aaron Siri] Q. You don't know if it was before or after Stanleyville? A. No, I don't. Q. How long were you in Kikwet? A. Well, just a day or two. Q. And that was just to observe a campaign? A.

[08:02:00]

[Stanley Plotkin] Vaccination campaign.

[Aaron Siri] Q. Did you observe a vaccination campaign in any of the other cities?

[Stanley Plotkin] A. Stanleyville, probably. Leopoldville was, as I said before, to collect data from prior vaccination.

[Aaron Siri] Q. And what were you doing in Rwanda, Urundi?

[Stanley Plotkin] A. Talking to people.

[Aaron Siri] Q. Again about polio vaccine? A. Yes. Q. But not vaccinating anybody? A. No. Q. Not part of any vaccination campaign there either? A. No. Q. Okay. Q. Do you believe that someone can have a valid religious objection to refusing a vaccine? A. No. Q. Do you take issue with religious beliefs? A.

[Stanley Plotkin] Yes.

[Aaron Siri] Q.

[08:03:00] You have said that, quote, vaccination is always under attack by religious zealots who believe that the will of God includes death and disease.

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Do you stand by that statement?

[Stanley Plotkin] A. I absolutely do. Q.

[Aaron Siri] Are you an atheist?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Do you accept that some people hold religious beliefs that are inherently unprovable? A. Yes, I'm sure they do. Q. Okay. Q.

You said that, quote, vaccination is always under attack by a legal system that profits from the failure of most people to understand risk-benefit ratios or public health issues.

A. Correct. Yes. Q. Can you explain what you mean by that shortly? A.

[Stanley Plotkin] I mean that the risk from vaccines, for example, is considerably less than the risk from disease. But people don't necessarily understand that. It's similar to the situation where people may not fly, but they're willing to drive in cars where the risks are much higher.

[08:04:07] And what was the second point about? Q.

[Aaron Siri] Public health issues.

[Stanley Plotkin] A. Public health issues, yes. Not understanding the importance of high vaccination coverage and prevention of disease. Q.

[Aaron Siri] One child can make a difference? A.

[Stanley Plotkin] One child probably doesn't make a difference, but a collection of one childs do make a difference. Q.

[Aaron Siri] At the most recent ACIP meeting, you spoke and gave ACIP three pieces of advice, correct? A. Yes. Q. All right.

One of them was to conduct more vaccine safety studies to prove the anti-vaccinationists wrong, right?

[Stanley Plotkin] A.

[Aaron Siri] Yes, correct. Q. Okay. If the science to prove vaccines safe already exists, why would more safety studies be needed to prove the anti-vaccinationists wrong?

[08:05:03]

[Stanley Plotkin] A. Because there are so many people, as you can see on the Web, who have these beliefs about vaccines. And as we have discussed throughout this long day, it would be valuable to have more safety data. Q.

[Aaron Siri] Like a vaccinated versus unvaccinated study, correct? A. If such a study is feasible. Q. Shouldn't vaccine safety studies be done for the sake of making vaccines safer, not for the purpose and with the predetermined objective of proving so-called anti-vaccinationists wrong? A.

[Stanley Plotkin] Oh, absolutely. I do not deny that there are known reactions to vaccines. Fortunately, they are rarely serious. But I support more research on every aspect of vaccines. Q.

[Aaron Siri] And your claim that they're rarely serious is from your book, right?

[08:06:03] A. Yes. Q. Okay. When's the last time that you received a vaccine, Dr. Plotkin?

[Stanley Plotkin] A. Zoster. Oh, no, influenza vaccine. Actually, not more than several weeks ago.

[Aaron Siri] Q. Do you get the flu shot every year? A. Yes. Q. Have you ever missed a year? A. No. Q. Have you received the Zoster vaccine? It sounds like you have. A. Yes. Q. The what vaccine? A. The Zoster, Z-O-S-T-E-R. When did you receive that? A.

[Stanley Plotkin] I've received now two doses, and I'm looking forward to receiving the new Zoster vaccine as soon as I can buy it.

[Aaron Siri] Q. Have you received a PCV13 vaccine? A. Yes. Q. Have you received a PPSV23 vaccine? A. Yes. Q. Hep B vaccine?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Let me do that again.

[08:07:00] Have you received a Hep B vaccine?

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] Have you received a Hepatitis A vaccine? A. Yes. Q. Have you received a MenACWY or MPSV4 vaccine?

[Stanley Plotkin] A. I believe so. That was a long time in the past because those vaccines have been available for a long time. I'd have to check my records, but I think particularly when I traveled to Africa, I believe I took it.

[Aaron Siri] Q. Have you received a MenB vaccine? A. Not yet, no. Q. Have you received a Hib vaccine? A. Oh, Hib. I was long past the age of Hib when it was developed. Q. When's the last time you got a tetanus diphtheria-

containing vaccine? A. Oh, within the last 10 years. I don't remember exactly when.

[08:08:00] Q. Do you think all adults should be required to receive all vaccines on the CDC's adult immunization schedule? A.

[Stanley Plotkin] That's somewhat of a difficult question because adults, of course, have the ability to make their own decisions. Tetanus is a vaccine that, how shall I put it, I guess it's a choice whether you're willing to be susceptible to tetanus or not. For pertussis, I think there's increasing reason to say that all adults should be vaccinated against pertussis. So it's, let's say, open to discussion at this point for DTAP anyway.

[08:09:01] Q.

[Aaron Siri] Do you support a law that would require adults to get the DTAP? A.

[Stanley Plotkin] At this point, 2017, I wouldn't insist on that for all adults. I would insist on it for children and adolescents. But the data, the reason I say that is because the data showing protection against pertussis in older adults is really not that solid, not that available.

[Aaron Siri] Q. Did you ever experience an adverse vaccine reaction?

[Stanley Plotkin] A. Personally?

[Aaron Siri] Q. Yes.

[Stanley Plotkin] A. No.

[Aaron Siri] Q. Have you ever witnessed someone experience an adverse vaccine reaction?

[Stanley Plotkin] A. I've witnessed people fainting after vaccination. Q. Anything else? Certainly I've seen people complain of pain at the injection site.

[08:10:11] And in the rubella days, women complaining of joint pains after vaccination. I think that's it. Q.

[Aaron Siri] When you say fainting, after what vaccine was that?

[Stanley Plotkin] A. Oh, actually, that was tetanus, as I recall. It was a high school athlete.

[Aaron Siri] Q. Do you know anyone that's experienced a serious adverse reaction?

[Stanley Plotkin] A. Personally, no. Q.

[Aaron Siri] Did your grandchildren receive the hepatitis B vaccine on the first day of life, as recommended by the CDC?

[Court Reporter] A. Oh, of course.

[Aaron Siri] Q.

[Court Reporter] I'm sorry, say the question again.

[Aaron Siri] Q. I asked if his grandchildren have received the hepatitis B vaccine on the first day of life, as recommended by the CDC, and he answered yes.

[08:11:06] Q. Do you think there's a safe threshold of how many vaccines can be administered at one time?

[Stanley Plotkin] A. My answer to that is, I don't know. I don't think there's any evidence that the six that are currently generally given together is a problem. So I don't know if eventually there's some theoretical threshold, but I am not aware of any evidence for that yet.

[Aaron Siri] Q. Okay. But before you would say, for example, getting 30 vaccines on one day was safe, you'd probably want to get the data to support it? A. Yes. Q. That data doesn't exist, obviously, right? A. No. Q. Do you intend to appear at trial on this matter to testify?

[08:12:02] A. No, I do not. Q. Do you intend to appear via videoconference to testify in this trial?

[Stanley Plotkin] A. Well, I haven't been asked. I suppose I might consider a videoconference. But no one has asked me, and I'm not, I would say, very inclined to do that. And you know, while we're on tape, so to speak, I want to stipulate, since you were so interested in my income, that I'm doing this pro bono.

[Aaron Siri] Q. But as you sit here today, you're still receiving a remuneration from all four major vaccine
makers, correct? A. Yes. Q. Okay. So getting close to the end.

[08:13:07] I don't have much left. A few more. Q. There was a controversy revolving around the origin of AIDS and the OPV
vaccine, correct? A. Yes. Q. You disputed any connection between OPV vaccine and AIDS in two papers submitted to the Royal Society, in which you stated, quote, there was no gun, the chimpanzees, no bullet, the virus, no shooter, a manufacturer of the vaccine, chimpanzee cells, and no motive to use chimp cells or to hide the fact. Correct?

[Stanley Plotkin] A. Yeah. I also said that the only smoke was created by Mr. Hooper.

[Aaron Siri] Q. Right.

[08:14:01] Who is that?

[Stanley Plotkin] A. He's a British journalist, which puts him at the lower end of journalism.

[Aaron Siri] Q. Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 44. And I'm also going to hand you what's been marked as Plaintiff's Exhibit 45. Are these the two papers that you submitted to the Royal Society?

[08:15:02] A. Yes. Q. Disputing any connection between the OPV vaccine and AIDS? A. Yes. Q. Right? A. Yes. Q. Is everything that you wrote in

these two articles, strike that, is everything written in the two Royal Society articles that you submitted, which are marked as Exhibits 44 and 45, true? A. Well, I certainly hope so.

[Stanley Plotkin] Q.

[Aaron Siri] I'm sorry, Dr. Plotkin, is that a yes? A. Yes. Yes.

[Stanley Plotkin] And I should also add that my conclusions have been verified by other scientists who now have shown that HIV originated in the 1920s in Cameroon. Q.

[Aaron Siri] At the end of – which one was 44 and 45?

[08:16:03] A. Okay. Q. Sorry. Okay. Dr. Plotkin, at the end of Exhibit 44, the article entitled Untruths and Consequences you state that – strike that. I apologize. I'm sorry, Dr. Plotkin. Can you look at Exhibit 45? I'm sorry. At the end of Exhibit 45, it states that letters cited in this paper will be deposited in the Library of the College of Physicians of Philadelphia or the University of Leuven.

[08:17:12] A. Leuven. Q. Leuven, correct? A. Yes. Q. That's L-E-U-V-E-N. A. Okay. Q. Have you deposited those letters and papers? A. I have, yes. Q. Okay. When did you deposit all of those letters and papers? A. Oh, gosh. It's probably at least five years ago now. Q. So all of the letters cited in this document have been deposited in where? A.

[Stanley Plotkin] The College of Physicians of Philadelphia.

[Aaron Siri] Q. And they're in possession of all of the letters cited in this document? A.

[Stanley Plotkin] Well, I believe so. I'd have to go over the list, but that certainly was my intention, and I believe I have done so.

[Aaron Siri] Q. Okay. And is that publicly available at the University of Philadelphia?

[08:18:05]

[Stanley Plotkin] A. That's a good question. I imagine so. No. I deposited them there basically so that they could be examined after I'm dead. But I don't know. I've never been asked.

[Aaron Siri] Q. If they're not publicly available, would you provide copies? A. Well, I'd have to ask the College of Physicians to do that. Q. Would you authorize them to release copies? A.

[Stanley Plotkin] I'd authorize them, sure. Q. Okay.

[Aaron Siri] Q.

[Stanley Plotkin] If you could please take a look at the – A. I'm not sure why you're asking the question. Are you accusing me of launching AIDS, or what is the point?

[Aaron Siri] Q. Absolutely not, Dr. Plotkin. You made a promise in here to deposit papers, and I'm purely asking you if you made that – fulfilled that promise.

[Stanley Plotkin] A.

[Aaron Siri] Yes, I did.

[Stanley Plotkin] Q.

[Aaron Siri] That's it? That's all? Okay.

[08:19:00] I'm not accusing you of anything. And in the other paper entitled Untruths and Consequences, in the second paragraph it says, the evidence I present is based on papers and documents of the time for my personal files. Have those also been deposited in the Library of Philadelphia?

[Stanley Plotkin] A. No. Certainly not all of them. I have extensive files. I don't throw anything out.

[Aaron Siri] Q. So you still have all of those? A. Yes. Q. I assume you don't have an issue sharing copies of those? A. No.

[Stanley Plotkin] My wife would love to get rid of all of them, but I don't.

[Aaron Siri] Q. So you said that the AIDS OPV hypothesis has been disproven, correct?

[08:20:09] A. Yes. Q. A few quick questions. Approximately how many human samples that predate 1959 have been tested for HIV? A. That predate 1959?

[Stanley Plotkin] I don't know that there are any such samples available. The first samples that I recall being available were from 1960, and they had already some HIV seropositive individuals. But that was in Leopoldville, and they were individuals who had not received the oral polio vaccine.

[08:21:03]

[Aaron Siri] Q. But in terms of samples that predate 1959, have there been any such samples tested for HIV? A. I'll have to think about that.

[Stanley Plotkin] I – oh, well, there have been samples from elsewhere in the world, but from the Belgian Congo, I don't think any such samples have been available.

[Aaron Siri] Q.

Are you aware of whether there currently exists any samples of polio vaccine that was in the Belgian Congo at any time between 1959 and 1960?

A. Whether the Wistar has kept them or not, I don't know.

[Stanley Plotkin] Fortunately, at the time of the Royal Society, I was able to go to Wistar and find specimens that had been used in the Congo, or from the same lot that had been used in the Congo. But whether that still exists or not, I have no idea.

[08:22:03]

[Aaron Siri] Q. Well, I'm curious, is there any samples that were actually in the Belgian Congo that you're aware of? A. That were tested? Q. That were tested. A.

[Stanley Plotkin] I don't – I really don't know the answer to that question. The vaccine that was used, the oral polio vaccine that was used, I believe was entirely used up in the vaccination campaign. So I don't think it's likely that material used in the vaccination campaign was repatriated. But fortunately, we had material from the same lots that were used in the Congo and that had been retained at the Wistar.

[Aaron Siri] Q. But as far as you're aware, in terms of actual samples, a sample that was actually in the Belgian Congo, you're not – are you saying you're not aware of any such sample?

[08:23:09] A. No, I am not aware of any such sample. Q. Do you know of any such sample ever – are you aware of any such sample that existed after 1960? A. I'm not aware that anything existed. Q. I just have another question on this. Just curious. A. Yes. Q. So are you familiar with an article entitled Vaccination with the CHAT Strain of Type 1 Attenuated Poliomyelitis Virus in Leopoldville? A. Yes. Q. Belgian Congo? A. Yes. Q. Okay.

[08:24:00] In the article – you're one of the authors of the article? A. Yes. Q. Okay. Q. So on page 2 of this article, it states the titer of the vaccine after a day's use was checked periodically by sending frozen aliquots to the YSTAR Institute, Philadelphia, Pennsylvania, USA.

[Stanley Plotkin] A. Yes. Q. What does that mean? A. Well, it means that in order to be sure that the vaccine used still contained enough virus, they sent back samples to be titered for the quantity of virus.

[08:25:01]

[Aaron Siri] Q. So they sent back samples of the oral polio being used in the Belgian Congo?

[Stanley Plotkin] Q.

[Aaron Siri] And they did that periodically? A. Yes. Q. But to your knowledge, none of those survived after 1960? A.

[Stanley Plotkin] No. I think they were tested and then discarded. Q. Okay. A. Aside from legal value, they would have had no value because they were used. They could not ever be used again. So they would have been discarded.

[Aaron Siri] Q. It would be helpful for you if some of those were saved, right? A.

[Stanley Plotkin] It would have been, yes. But at the time, nobody thought about that. Q.

[Aaron Siri] If such a sample were to have survived someplace on the planet, where would you think that would be?

[08:26:00] A.

[Stanley Plotkin] Difficult to say. I mean, the laboratory in Stanleyville no longer exists. I have no idea where it could be. Q.

[Aaron Siri] Do you think such a sample will ever be located?

[Stanley Plotkin] A. I doubt it.

[Aaron Siri] Q. Last question on this topic, and we'll move on. Did you or any of your YSTAR colleagues ever carry any human cells such as WISH or WI-1 or polio vaccines grown in such human cells to the Belgian Congo? A. No. Well, at least I certainly have not. Q. Are you aware of any such vaccines being used?

[Stanley Plotkin] A. No. I am not aware of those cells being carried to the Congo. If they had been, it would have been for experimental purposes, certainly not for vaccination purposes.

[08:27:05]

[Aaron Siri] Q. So you're not aware they're being carried or used there, right? A. Not that I'm aware of, no. Q. Isn't it true that in 2014 the FDA announced, quote, although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, end quote? A. Yes. That's on the basis of the studies in baboons. Q. That's the Warfell study? A. Yes. Q. And we discussed earlier that the baboons would probably be the best surrogates for humans, right?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Because you couldn't ethically expose humans to pertussis, correct?

[Stanley Plotkin] A.

[Aaron Siri] Right. Q. So the Warfell studies would be the best evidence as to warfel, W-A-R-F-E-L.

[08:28:02] Would the Warfell studies, the one in 2014 and 2016, which were conducted by the FDA, correct? A. Yes. Q. Those would be the best evidence as to the ability, as to whether or not a cellular pertussis vaccine prevents infection and transmission of pertussis, correct? A. Correct. Yes. Q. And I think we talked about this earlier.

In your estimation, what percent of adults would you say are actually immune to pertussis?

A.

[Stanley Plotkin] That's a very good question. I don't know the answer to that because immunity to pertussis is complex. And so just measuring serum wouldn't necessarily give you a firm idea as to what percentage of adults are immune.

[08:29:10] But judging from the frequency of pertussis in adults, I don't think the immunity level is very high because clearly adults are getting pertussis. Q.

[Aaron Siri] Could you estimate what percentage of the adult population in the United States you think is immune to pertussis? A.

[Stanley Plotkin] Immune? Well, I think probably 50, 60 percent could be immune. But it's difficult because immunity wanes. And so they make people become susceptible again. And as I've said now twice, there is a lot of pertussis in adults. That's been shown. So a significant proportion of adults are susceptible and not immune.

[08:30:00]

[Aaron Siri] Q. Fifty to 60 percent is your highest estimation it sounded like, right? Q. No more than that? A. I don't think so. Q. Okay. Q. The diphtheria vaccine creates antibodies only to a toxin released by the diphtheria bacteria, correct? A. Correct. Q. It doesn't create any antibodies to the actual diphtheria bacteria itself?

[Stanley Plotkin] A. Yes, that's true. But it is also true, it certainly appears to be true, that if the organism can't produce a toxin, it has a great difficulty in surviving. And so the observation is that where the vaccine is used, the organism disappears. So it's very difficult to find it in the U.S., for example. But in Russia, where vaccination has not been always complete, there are still cases of diphtheria.

[08:31:00] Q.

[Aaron Siri] How do you define anti-vaccinationists or anti-vaxxers as you've used them here today? A. How do I define them? Q. Yeah. What does that mean to you? You use those terms and I'm just, I'm actually not exactly sure what you mean by that.

[Stanley Plotkin] A. People opposed to vaccination for a variety of reasons, some of which are based on false inferences from scientific data.

[Aaron Siri] Q. If somebody were opposed to vaccines because they believed there was insufficient data for them to make a decision about the actual risks, not the benefits, but the risks, would you consider that person an anti-vaxxer?

[Stanley Plotkin] A. If they refuse to be vaccinated themselves or refuse to have their children vaccinated, I would call them an anti-vaccination person, yes.

[08:32:01] Q.

[Aaron Siri] Is there anybody who could refuse a vaccine who you would not label anti-vaxxer?

[Stanley Plotkin] A. Yes. If they're individuals who are immunosuppressed, for example, and therefore have a contraindication to certain vaccines, that to me would be a reasonable decision on their part.

[Aaron Siri] Q. But otherwise you believe that anybody else who refuses a vaccine is doing so based on misinformation?

[Stanley Plotkin] A. Generally speaking, yes. Now, as I said before, I can imagine an adult deciding that they don't want the advantages of vaccination for whatever reason. I think the situation for children is quite different because one is making a decision for somebody else and also making a decision that has important implications for public health.

[08:33:06]

[Aaron Siri] Q. So in the case of an adult, you think it's okay for the adult to make a decision for themselves to take on a risk, even though it could implicate public health, but not the case for a child?

[Stanley Plotkin] A. No. It depends. For example, if you're a health care worker and you refuse to be vaccinated against diseases that you could potentially transmit to patients, I don't think you should have the option of making that decision. Q.

[Aaron Siri] Earlier we discussed that there hasn't been a wild case of polio in the United States since 1979, correct? A. Right. Q. Okay. The United States currently only uses inactivated polio vaccine, right? A. Yes. Q. And it does not – Q. Only uses inactivated polio vaccine, correct? A. Yes. Q.

[08:34:00] The United States does not use oral polio vaccine, correct? A. Correct. Q. If there were an outbreak of polio in the United States, isn't it true that we would have to return to using oral polio vaccine to stop the spread of polio in the United States? A.

[Stanley Plotkin] It might well be the case. However, individuals who have received the inactivated vaccines will not themselves get polio. They may get infected and transmit to others, which is one of the reasons why one might resort to OPV. But the individual himself would not be susceptible.

[Aaron Siri] Q. Is that because the IPV creates IgG antibodies in the blood, but it doesn't create IgA immunity in the intestinal tract? A. Correct. Q. And it is in the intestinal tract where the polio virus multiplies, correct? A. Yes. Q. So a person vaccinated with IPV can still become infected and transmit polio virus, correct?

[08:35:10] A. Yes, although in point of fact, IPV does protect the nasopharynx.

[Stanley Plotkin] So in this country where hygiene and sewage, et cetera, are good, the possibility of transmitting from an IPV vaccine is much less than it is, let's say, in Africa where sewage contamination is great.

[Aaron Siri] Q. When you say nasopharynx, what is that? A. The throat. Q. So you're saying that IPV does create immunity within the throat? A. Yes. Q. Okay. There are studies that show that? A. Yes, absolutely. Q. Okay. And how do those studies make that determination?

[Stanley Plotkin] A. Well, by culturing people who are exposed to polio who have had IPV and also by showing that antibody diffuses into the throat much better than it does into the gut.

[08:36:10]

[Aaron Siri] Q. In the Warfell study, I'm sorry, strike that. Do you know the names of those studies by any chance? A. Oh, gosh.

[Stanley Plotkin] Again, they're in the book.

[Aaron Siri] Q. Are they in your book? A. Yes, absolutely. Q. And in terms of efficacy, does IPV vaccination in childhood last a lifetime? A.

[Stanley Plotkin] You know, that's an interesting question, and I think the answer is yes. Studies that have been done have shown quite good persistence of antibody after IPV. Now, does it last forever? I can't say that, but it certainly lasts a long time. Q.

[Aaron Siri] How about 30 years after vaccination? What do you think the efficacy is approximately?

[08:37:02] A.

[Stanley Plotkin] I would just be totally speculating, but I think most people would still be protected because you don't need much antibody against polio to be protected. Levels of dilutions of 1-4 or 1-A, they're probably protective.

[Aaron Siri] Q. But you're not sure?

[Stanley Plotkin] A. I'm not sure about 30 years. I'm sure about the levels that are protective. Q.

[Aaron Siri]

But 30 years, you're not sure about what percent of the people vaccinated are still immune to polio?

A.

[Stanley Plotkin] No, but I do know that that persistence is good, and that the likelihood is that most people, even 30 years, will still be protected. Q.

[Aaron Siri] Forty years?

[Stanley Plotkin] A. I can't really guess any more than that.

[Aaron Siri] Q. The data doesn't exist? A. No.

[Stanley Plotkin] I don't believe they exist.

[Aaron Siri] Q. What do you estimate is the current efficacy of the mumps vaccine shortly after vaccination?

[08:38:05]

[Stanley Plotkin] A. Shortly after vaccination, there's no doubt that the efficacy is high. It's 80, 90 percent. And after two doses, immediately after two doses, the efficacy is very high. Unfortunately, the efficacy diminishes with time, and that has caused the problem in universities that have outbreaks of mumps because the college kids are intimately
associated. A. Yes. Intimately associated. Although the efficacy even then is probably on the order of 70, 80 percent.

[Aaron Siri] Q. 70, 80 percent. What about 30 years after
vaccination? What's the efficacy? A. I have no idea. Q. 20 years?

[08:39:00]

[Stanley Plotkin] A.

I don't think studies have been done more than 10 years after vaccine.

[Aaron Siri] Q. What do you estimate is the current efficacy of the rubella vaccine 10 years after vaccination?

[Stanley Plotkin] A. Based on the data that are available, it is very high. The so-called B-cell memory after rubella vaccine, I'm happy to say, is very good.

[Aaron Siri] Q. How about 20 years?

[Stanley Plotkin] A. I think it will still be present.

[Aaron Siri] Q. 30 years?

[Stanley Plotkin] A. I think so. Q.

[Aaron Siri] High efficacy still, you think?

[Stanley Plotkin] A. I think so. Q.

[Aaron Siri] But no study has been done?

[Stanley Plotkin] A. Actually, there are studies, at least 20-year studies. I'm not sure about 30, but immunity is very long-lasting.

[Aaron Siri] Q. Okay. And the studies would be in your book? A. Yes. Q. What would you estimate is the current efficacy of the measles vaccine 20 years after vaccination?

[08:40:04]

[Stanley Plotkin] A. Well, again, it appears to be quite good. 20 years, again, I don't have in my head a study done 20 years later, but certainly studies done sometime after vaccination have shown good persistence of antibodies. And once again, you don't need a whole lot of antibody to prevent you from getting measles. Q.

[Aaron Siri]

Do you know a percentage of people that are still immune 20 years out from the measles vaccine?

A.

[Stanley Plotkin] Not off the top of my head, but I feel relatively sure that it's quite high.

[Aaron Siri] Q. Is it important to get a tetanus vaccine? A.

[Stanley Plotkin] Well, it's important if you don't want to get tetanus, yes.

[08:41:03] Q.

[Aaron Siri] The tetanus vaccine was introduced into routine childhood schedule in the late 1940s, correct? A. Yes. Q. When the tetanus vaccine was

introduced, there were only about four cases of tetanus per million people, correct?

[Stanley Plotkin] A. If you say so. I don't remember.

[Aaron Siri] Q. Are you familiar with the CDC pink book? A. Yes. Q. If the CDC pink book said that it was four cases of tetanus per million, would you dispute that?

[Stanley Plotkin] A. Okay. Well, I'll accept that.

[Aaron Siri] Q. You do accept that. And that's just the number of cases, not deaths, right?

[Stanley Plotkin] A.

[Aaron Siri] Yes. Q. Okay. And you think it's a public health imperative for people to be vaccinated against tetanus, correct?

[Stanley Plotkin] A. I think it's the wise thing to do if you don't want to be under risk of getting tetanus if you have an injury. Q.

[Aaron Siri] To prevent something that was a few cases in a million, correct?

[Stanley Plotkin] A. Yes, but a deadly disease.

[08:42:01] Q.

[Aaron Siri]

Do we know whether the tetanus vaccine causes more or less than a few cases of serious adverse reactions after vaccination?

[Stanley Plotkin] A. I don't believe it causes a whole lot of serious reactions, no.

[Aaron Siri] Q.

[Laura Nusma] Do you know how much longer we have to go, just so I have an idea? A.

[Aaron Siri] Yeah, sure. I think that we've only got about 15 more minutes. Q. That's exactly how much we have left.

[Tom Liebman] A. Perfect.

[Aaron Siri] Q. So we should be almost done. Q. The CDC and FDA maintain something called the Vaccine Adverse Events Reporting System, correct?

[Stanley Plotkin] A.

[Aaron Siri] Yes. Q. And that's where anybody, including doctors, can go and report what they believe to be an adverse reaction from a vaccine?

[08:43:05] A. Right. Correct. Q. Anybody can submit a report, right? A. That's correct. Q. And the FDA and CDC compile that data and make it available online, correct? A. Yes. Q. Okay. I'm going to hand you a What's Been Marked as Plaintiff's Exhibit 46.

And this is a printout of the VAERS data for all adverse reactions reported to tetanus-containing vaccines in the last 10 years.

If you take a look, do you see that in the last 10 years there have been 985 deaths reported to have followed any tetanus-containing vaccine?

[08:44:00] A. Yes. Q. That would average to about 98.5 reports of death per year over the last 10 years? And there's also 23,981 emergency room or office visits after tetanus-containing vaccine in the last 10 years? Q. And it also lists, I'll just last one, 1,256 permanent disabilities reported after tetanus-containing vaccine in the last 10 years, correct? A. Yes. Q. That would be about an average of 125 per year, right? But we don't, because these are just reports and not done in some kind of randomized, controlled study, we don't actually know whether or not the tetanus vaccine is causing these deaths and permanent disabilities, correct?

[08:45:02] A. Correct. Q. But it's possible it could be, correct?

[Stanley Plotkin] A. Anything is possible, yes.

[Aaron Siri] Q. Don't you think a study should be done to determine? Strike that. Strike that. Isn't it true that VAERS only receives a tiny fraction of the reportable adverse events after vaccination? A.

[Stanley Plotkin] Well, I can't give you a percentage, but all physicians are asked to report putative reactions to the VAERS system. So I don't think the VAERS system covers a tiny portion of alleged reactions. I think rather probably most are reported, but I cannot confirm that.

[08:46:02]

[Aaron Siri] Q. Dr. Plotkin, I'm going to show you what's been marked as Plaintiff's Exhibit 47. Seven. This is a report entitled Electronic Support for Public Health Vaccine Adverse Events Reporting System, correct?

[Court Reporter] A.

[Aaron Siri] Say it again. Q. Electronic Support for Public Health-Vaccine Adverse Events Reporting System, correct?

[08:47:36] Let me know when you're ready, Dr. Plotkin. A. I'm ready. Q. The title of this report, Dr. Plotkin, is Electronic Support for Public Health-Vaccine Adverse Events Reporting System, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. And this was a study conducted by Harvard Medical School and the Harvard Pilgrim Healthcare, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. And it was done via a grant from an agency within HHS, correct?

[08:48:03]

[Stanley Plotkin] A.

[Aaron Siri] Yes. Q. And the purpose of this study was to attempt to automate VAERS reporting. A. Yes. Q. The reason that Harvard did this study and the reason that HHS paid for it, if you look at page 6, A.

[Stanley Plotkin] Yes.

[Aaron Siri] Q. do you see where it says fewer than one, it's right in the middle paragraph, fewer than one percent of vaccine adverse events are reported?

[Stanley Plotkin] A. Well, yes. I see the statement. I don't see the reference, but. Q.

[Aaron Siri] Well, let's take a look at the results of that study then. A. Yeah. Q. If you go to the first sentence on the page that you're on right now where it says results, isn't it true that it says preliminary data were collected from June 2006 through October 2009 on 715,000 patients?

[08:49:07] Q.

And 1.4 million doses of 45 different vaccines were given to 376,452 individuals?

A. Yes. Q. So about 376,000 individuals received a vaccine, correct?

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] Out of these doses, 35,570 possible reactions were identified, correct? A. Yes. Q. So out of 376,000 people that received vaccines, they identified 35,570 possible reactions, right?

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] Okay. And now? A.

[Stanley Plotkin] Well, it's out of 1.4 million, which is 2.6 percent.

[Aaron Siri] Q. Doses, correct? A. Yes. Q. Okay. Meaning maybe some individuals had?

[08:50:01]

[Stanley Plotkin] A. More than one vaccine.

[Aaron Siri] Q. And had reactions at different times to different vaccines, right?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. Maybe some people were more susceptible to a vaccine reaction, and so they had a reaction every time they had a vaccine, right?

[Stanley Plotkin] A. Well, we don't know that.

[Aaron Siri] Q. We don't know. I mean, assuming that each individual only had one vaccine reaction, then 10 percent of the individuals would have had a vaccine reaction. A. Yes. Q. Now, at the beginning of this study, the CDC was cooperating with these grant participants, correct?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. And they helped define what is an adverse reaction, right? A. Yes. Q. And they helped define the algorithms to use, right?

[08:51:02]

[Stanley Plotkin] A. Yes. Q.

[Aaron Siri] And they also helped to define what reports should be excluded, correct?

[Stanley Plotkin] A. I guess so.

[Aaron Siri] Q. What events, I'm sorry, should be excluded from being considered, you know, reportable, right?

[Stanley Plotkin] A. Yes.

[Aaron Siri] Q. After, however, they collected this data and they generated these 35,000 reports, they then wanted to submit those reports to theirs and automate it so that those reports could continue to be submitted, correct? Q. But the CDC wouldn't cooperate with them, correct?

[Stanley Plotkin] A. Well, I have no idea whether that's true or not.

[Aaron Siri] Q. On page 5, Dr. Plotkin, at the end of the second paragraph, it says, does it say real data transmission of non-physician-approved reports to the CDC were unable to commence as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

[08:52:25] Is that what it says?

[Stanley Plotkin] A. That's what it says. Q. Okay.

[Aaron Siri]

And this study says that less than 1 percent of adverse events are reported to theirs, right?

A.

[Stanley Plotkin] Well, I'd have to check that, but I think that's correct.

[Aaron Siri] Q. Okay. Are you aware that there are other governmental reports that make similar estimates for theirs?

[Stanley Plotkin] A. I'm aware that not everything is reported to theirs, yes.

[08:53:00]

[Aaron Siri] Q. But are you aware that governmental reports show that governmental reports like this one show that the rate of reporting to theirs is extremely low? And in this instance, they'd say Harvard said less than 1 percent.

[Stanley Plotkin] A. Yes, apparently, yes. Q. Okay. A. However, it has to be reminded that reporting to theirs is supposed to occur whether or not you think there's been a reaction. So whether or not the reactions are true or not is not something the theirs decides.

[Aaron Siri] Q. Right. But let's just assume for a second here. So let's go back to what's been marked as Exhibit 46.

[08:54:06] Let's assume that a full 1 percent of associated adverse events are reported. Wouldn't that take the number of deaths to 98,000 then that were associated with the vaccine?

[Stanley Plotkin] A. I think it's likely that deaths are reported more often than trivial reactions. So I wouldn't be able to extrapolate from that number. Q. Right. A. But, you know, obviously death is more dramatic.

[Aaron Siri] Let me show you, I think, one final exhibit.

[08:55:03]

[Tom Liebman] Q. We have six minutes left on this. A.

[Aaron Siri] Okay. I'm going to hand you what's been marked as Plaintiff's Exhibit 48. This is the VAERS report for all adverse events for all vaccines just since January of 2016.

[08:56:00] Do you see that? A. Yes. Q.

[Stanley Plotkin] If this – A. My wife is getting upset. Q.

[Aaron Siri] Well, don't tell her you're offering her up for a deposition. If this represents even 3 percent or 5 percent of reported events, doesn't this concern you in that maybe it really indicates – strike that. It reports 751 life-threatening reactions, correct? A. Yes. Q. And that's only since January of 2016, correct? A. Yes. Q. If that's only – if that's a full 1 percent, then that would be 75,000 life-threatening reactions that would have been reported, correct?

[08:57:00] A.

[Stanley Plotkin] That's the arithmetic, yes. Q.

[Aaron Siri] That's the kind of event that would happen pretty soon after vaccination, correct?

[Stanley Plotkin] A. Well, events that happen after vaccination, yes. But not necessarily because of vaccination. Q.

[Aaron Siri] So – Q. But until a properly controlled saline placebo study is actually done, or – strike that. Until we compare the total health outcomes – strike that. Q. Would you support a study that compared total health outcomes between vaccinated and unvaccinated children, Dr. Plotkin?

[08:58:04]

[Stanley Plotkin] A. Would I support such a study? Yes. If the protocol was scientifically valid, yes, I would support such a study. I don't really put much faith into the VAERS system for a number of reasons, some of which you cited. I take much more – I put much more confidence in the vaccine safety data, data which are better controlled and which come from institutions that see large numbers of patients.

[Aaron Siri] Q. Would you work to support such a study? A.

[Stanley Plotkin] Again, if such a study were scientifically feasible, I would support it, yes. Q.

[Aaron Siri] Don't you want to know what the results of that study show?

[Stanley Plotkin] A. If the study is done, yes, of course.

[08:59:03] Q.

[Aaron Siri] In terms of the vaccine safety data link which you just mentioned, that's not available to the public, correct? A. No.

[Stanley Plotkin] I think they publicly report in the scientific literature what they find.

[Aaron Siri] Q. If independent researchers want to get access to the VSD, well? A.

[Stanley Plotkin] I don't know what the circumstances are regarding access to data.

[Aaron Siri] I simply don't know. Q. Well, then I won't ask you questions about that if you don't know it.

[09:00:05] A. That's all right. Is there something you should want to show me? I have something to check on. Well, I am done with my questioning, and I will, if opposing counsel intends to ask any question, then I reserve to ask some rebuttal questions as well.

[09:01:03] But otherwise, I am done with my questioning for today.

[Laura Nusma] You know what? If Dr. Plotkin is going to testify, I'm going to have him here in Michigan. So I'm not too concerned about it. Let's just call it a day. Dr. Plotkin, I'll give you a call tomorrow if you're available for a quick phone call.

[Aaron Siri] Actually, no.