Excerpts from the Deposition of Dr. Stanley Plotkin – January 11, 2018

☛**Dr. Stanley Plotkin** is an American physician who works as a consultant to vaccine manufacturers, such as Sanofi Pasteur, as well as biotechnology firms, non-profits and governments. In the 1960s, he played a pivotal role in discovery of a vaccine against rubella virus while working at Wistar Institute in Philadelphia. Plotkin was a member of Wistar's active research faculty from 1960 to 1991. Today, in addition to his emeritus appointment at Wistar, he is emeritus professor of Pediatrics at the University of Pennsylvania. His book, "Vaccines",[1][2] is the standard reference on the subject.[3][4] He is an editor with *Clinical and Vaccine Immunology*, which is published by the American Society for Microbiology in Washington, D.C..

☛**Aaron Siri** earned his law degree at the University of California, Berkeley School of Law where he received four Prosser Prizes and ten High Honors. He was also the Editor-in-Chief and founder of the Berkeley Business Law Journal, which he developed into a nationally recognized publication, ranked in the top 10 of 132 peer journals. He has his own practice in NYC. (Mr. Siri earned a Bachelor of Science in Accounting with Honors from Yeshiva University. and clerked for the Chief Justice of the Supreme Court of Israel.)

Transcript of the deposition can be found at this link:

https://www.scribd.com/document/389327361/1-11-18-Matheson-Plotkin?fbclid=IwAR34exe-FUcadbyrorG7WybKcU7wywNftBeaYAnVnAhew-VPBPtPGhaells

(After the deposition, Dr. Plotkin recused himself from being an expert witness in the case.)

Below are extracts from the deposition, with page numbers included:

Page 20:

Q Have you reviewed any medical records related to this case?
A Medical records? No.
Q Have you done anything other than what we've already discussed to prepare for this deposition today?
A No. Basically, no.
Q Have you discussed the child at issue in this case?
A No.

Q So you don't know anything specific about the child at issue in this case, correct?
A I do not.
Q You don't know anything about her medical history, correct?
A Correct.
Q And you don't know anything about her family's medical history, correct?
A Correct.

Page 26:

Q What's the name of the defendant in this case?
A As I understand it, they're a married couple, but that's all I can tell you. So I presume they're both named Schmitt.
Q What's the name of their child?
A I do not know.
Q How old is their child?
A I do not know.
Q Do you know whether the child has received any vaccines?
A I do not know.

Q The name of the child is Faith. I'll refer to the child as Faith during this deposition, okay?
A Mm-hmm.
Q Faith's father believes that Faith's mother was wrong to not have given Faith all

Page 27:

CDC-recommended vaccines on time.

Do you agree with the father?

A Yes.

Q Is it your understanding that the father wants Faith to receive all vaccines she has missed and continue to receive all CDC-recommended vaccines?

A That is my understanding, yes.

Q Do you agree with the father that Faith should receive these vaccines?

A Absent any contraindication, yes.

Q Sitting here today, do you know whether Faith has any contraindications?

A I do not know.

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

A In the absence of a contraindication, Faith should receive the vaccines.

Q But you don't know whether she has a contraindication?

A I do not know the medical history of the child.

Q What vaccines has Faith missed according

Page 28:

to the CDC schedule that you believe she should get?

A Well, the CDC's schedule includes the diphtheria, tetanus, pertussis, hepatitis B, haemophilus influenzae, polio, measles, mumps, rubella.

I don't know how old she is, so I don't know, you know, where to stop. But there are vaccines recommended in preadolescents. So she should receive those when she reaches the appropriate age.

Pages 33-37

Include testimony that Dr. Plotkin feels Faith should get these vaccines:

Hepatitis B – 3 doses; rotavirus – 2-3 doses; Dtap – at least 3 doses, and then two boosters later on; HiB – 3 doses; PCV 13 – 3 doses; IPV (polio) – 3 doses; Flu – annually; MMR – at least 3 doses; Varicella (chickenpox) – 2 doses;

Hepatitis A – 2 or 3 doses. As an adolescent, she should get the meningococcal vaccine and the HPV vaccine, and as an adult she should get all the CDC recommended adult vaccines.

Dr. Plotkin states that the four major vaccine manufacturers who supply these vaccines are Glaxosmithkline (GSK), Merck, Sanofi, and Pfizer, and that all the vaccines he recommends for Faith are produced by one of these manufacturers. He adds in (pages 32-33) that he himself developed one of the rotavirus vaccines – Rotateq.

(CONFLICT OF INTEREST)

Page 37:

Q Have you received any payments from Sanofi or any of its related or predecessor entities?
A Yes. Certainly.
Q In what years did you receive payments?
A Oh, geez. Well, first of all, as you should know, in the 1990s I was medical and

Page 38:

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.
And so I have been remunerated by companies, not by nonprofits, obviously, and that is essentially what I do.
Q Is there a year since 1990 that you've not received any kind of payment or remuneration from Sanofi?

A Probably not, no.

Q How much did you receive -- what would you say is approximate total amount of payments and remunerations you've received from Sanofi during your lifetime?

A Oh, my God. I have no idea. I'm sure it's a sizable amount of money. But I, you'd have to ask my wife, who's essentially my accountant.

Q Is your wife the person that would have the records to know that amount?

A Yeah. She probably would.

Q Okay. Would you say it's more or less

Page 39:

than a hundred thousand dollars?

A Oh, I'm sure it's more than that.

Q Would you say it's more or less than 500,000?

A Probably, yes. Over the years, I imagine it is.

Q Would you say it's more or less than a million dollars?

A Well, again, I'm not prepared to answer this question, but I'm sure it's a considerable amount of money. And over the years, it could well be more than a million.

Q Do you believe it could be a few million?

A You know, Counselor, I cannot give you a precise figure. It is a considerable amount of money. I do not doubt. But I could not give you a specific number because I've never looked at it.

Page 40:

Q So what I'm asking, has any entity, so any business company, that you've had directly or

Page 41:

indirectly more than 1 percent ownership interest, okay, has any company like that received money from Sanofi?

A Well, again, I'm not sure I understand the question. But I am the principal of a company called Vaxconsult --

Q Okay.

A -- which essentially was organized to make things easier from the tax point of view. 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.

Q Okay. So who owns Vaxconsult?

A I do -- well, my wife and I do.

Q And what percent do you own?

A A hundred percent.

Q Okay. And is there any other company -- and payments have been made to Vaxconsult by Sanofi?

A Sure.

Q And what's the total amount of payments that have been made to Vaxconsult by Sanofi?

A Well, again, I do not have an exact number. I am sure that over the years, it's a

Page 42:

considerable amount, but I cannot tell you exactly how much.

Q Is there any other company in which you have an ownership interest that's received money from Sanofi?

A No.

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

A As long as my health holds out, yes.

Q What are those payments for?

A For advice.

Q Have you received any payments from Merck or any of its related or predecessor entities?

A Yes.

Q What year did you receive payments?

A All I can say is since I stopped working for Sanofi, which was in early 2000s, I've consulted for essentially all of the major manufacturers. I do not know how much I received. But I have certainly received payments from Merck, from Glaxo, from Pfizer, and many other entities.

Q So what was approximately the first year that you received payments from Merck?

Page 43:

A Sometime in the 2000s.

Q Would you say that you've received more than a hundred thousand dollars in payments/remuneration from Merck since then?

A I have no idea.

Q But you would have records that would be able to determine that amount, correct?

A Yes. I doubt -- actually, I doubt that it's a hundred thousand, but I don't, I don't recall. As I said, my wife does the accounting, and I pay no attention to it.

Q Do you anticipate receiving any payments or remuneration from Merck in the future?

A Sure.

Q You said that you received payments and other remuneration from GSK in the past?

A Yes.

Q When did those payments start?

A 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.

Q Do you expect to continue to receive payments or remuneration from GSK in the future?

Page 44:

A Yes.
Q I'll ask you the same question about Pfizer. You indicated that you have received payments or remuneration from Pfizer?
A Yes.
Q Do you remember when you first received any payments from them or any remuneration?
A No, I don't recall what year that would be.
Q And do you have a sense of approximately how much you've received?
A No.
Q Do you anticipate continuing to receive payments or remuneration from Pfizer?
A Very likely.

Pages 48-54:

Includes testimony from Dr Plotkin that "Voices for Vaccines" receives administrative support from the "Task Force for Global Health." Under the direction of Dr. Adam Hinnan, this Task Force does the financial paperwork for Voices for Vaccines needed by the government, but according to Dr Plotkin they do not give any funds to the "Voices for Vaccines." Court document Exhibit Plaintiff -3 shows that the "Task Force for Global Health" receives funding from Glaxosmithkline, Merck and Pfizer.

Page 56:

Q Have you ever worked on developing a vaccine that was eventually used by the public?
A Yes.

Page 57:

Q Which ones?
A Let's see. Well, rubella, rotavirus, rabies, and I made contributions here and there to anthrax, cytomegalovirus, varicella. That's all I can remember at the moment.
Q The varicella vaccine, you're talking about VARIVAX?
A Yeah.
Q When you say you contributed to it, how did you contribute to development of varicella?
A Essentially by showing how it could be used and demonstrating that it was safe and effective.

Q Did you work directly with Merck on that?
A I don't recall whether it was directly with Merck or not. Certainly it was the vaccine produced by Merck. But whether -- I don't recall that they actually funded my studies of varicella vaccine. But they were, they were the producers of the vaccine, certainly.
Q Where were you working when you did this work?
A At Children's Hospital of Philadelphia.
Q Did Children's Hospital ever acquire any

Page 58:

intellectual property rights on what was --
A For varicella, no.
Q 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?
A 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.
Q Which were those?
A Sorry?
Q Which vaccines are those?
A Mainly rubella, rotavirus, and rabies.
Q And the rubella vaccine that you developed is currently used as part of the MMR vaccine?
A Correct.
Q And this is one of the vaccines you

believe Faith's pediatrician should purchase and administer to her?
A Absolutely.
Q What is the total amount of payments in

Page 59:

any form you have directly or indirectly received from the sale of the rubella vaccine?

A 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.

Q Was it in the millions of dollars for rubella? Just rubella.

A I don't think so. That's all I can say. I don't think so.

Page 60:

Q 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?

A Correct.

Q But it could have been?

A I doubt it, but it could have been. I don't think so.

Q Who provided you those payments?

Page 61:

A The Wistar Institute.

Q Did it come from any other source other than Wistar?

A I don't think so because the Wistar holds the patent.

Q Were you listed as one of the patent --

A One of the inventors?

Q One of the inventors?

A I believe so, yes.

Q But the Wistar was the assignee; is that right?

A Yes.

Q And so they received the -- they're the ones who had the, gave the license to Merck?

A Yes. Yes.

Q So Merck would pay Wistar, and then Wistar would remit some of that to you; is that correct?

A 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.

Q And you indicated that you've also developed the rotavirus vaccine earlier. I believe you said it was RotaTeq?

Page 62:

A Yes.

Q That's, and I think you said earlier that's currently one of two rotavirus vaccines currently on the market in the U.S.?

A Yes.

Q And you obtained a patent for RotaTeq?

A Wistar and Children's Hospital developed patents.

Q Who is listed as the inventor or co-inventors?

A Myself, Paul Offit and Fred Clark.

Q Who are the assignees of the patent for RotaTeq?

A Assignees, you mean who used the --

Q Well, you know, when you file a patent, there's usually an inventor listed and then there's who you, the patent is assigned to.

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

Q Okay. And so they were the ones who had the rights to the patent?

A Yes.

Q How much remuneration to date have you received from sales of RotaTeq?

Page 63:

A I couldn't tell you exactly, but it's been a considerable amount.

Q Has it been in the millions?

A I hesitate to say exactly. It could be, but I really do not know.

Q You were entitled -- so you indicated that Children's Hospital of Philadelphia, is that sometimes referred to as CHOP?

A Yes.

Q CHOP was entitled to receive revenue from the sale of RotaTeq?

A Yes.

Q What portion from the sale of RotaTeq was CHOP entitled to?

A Well, as I understand it, 50 percent.

Q And what percent of that 50 were you entitled to?

A I don't know.

Q Do you know how much revenue CHOP received from the sale of RotaTeq?

A I do not.

Q Did there ever come a time where CHOP sold its interest in the RotaTeq virus vaccine?

A I believe so, yes.

Page 64:

Q Do you remember how much approximately it was sold for?

A No.

(Exhibit Plaintiff-4 was marked for identification.)

BY MR. SIRI:

Q 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 RotaTeq from the Children's Hospital Foundation for 182 million.

MS. RUBY: Ms. Nieusma, you should have that in just one second.

BY MR. SIRI:

Q Looking at Exhibit No. 4, does that refresh your recollection of how much CHOP sold its interest in RotaTeq for in 2008?

A Assuming it's correct, yes.

Q Does that sound about right?

A I have no idea, but presumably it's correct.

Q Do you have any reason to doubt the authenticity of this press release?

Page 65:

A No.

Q Do you have any reason to doubt that CHOP sold its RotaTeq interest in 2008 for $182 million?

A I have no reason to doubt it.

Q Did you receive a portion of those proceeds?

A I believe so, yes.

Q What was that amount?

A 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.

Again, if I had realized this was going to be the tone of this deposition, I would have asked my wife to come along.

BY MR. SIRI:

Q You're here today opining that Faith should receive vaccines that are made by the big four pharmaceutical companies, correct?

A I am, yes.

Q Okay. And you didn't anticipate that your financial dealings with those companies would be relevant in that issue?

A I guess, no, I did not perceive that that

Page 66:

was relevant to my opinion as to whether a child should receive vaccines. 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.

Page 67:

Q 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?

A I could have received more than a million dollars. I don't have an exact figure.

Q You stated earlier your co-inventor on this was Paul Offit?

A Yes.

Q Were you entitled to similar remuneration as he was?

A Yes.

Q Are you aware that he has stated publicly how much he's received from that sale?

A I am not aware that he has.

Q If I told you he said that he received approximately $6 million, would that --

A Mm-hmm

Q -- would that help you recall how much you received?

Page 68:

A Not really, but I believe whatever Paul has said I'm sure is correct.

Q So is $6 million a lot of money, in your opinion?

A Yes.

Q If you received $6 million, do you think you'd remember?

A 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. I actually do not read my own tax returns. I say that in complete honesty.

Q How about the Wistar Institute; I believe you stated earlier they also were held to intellectual property on RotaTeq, correct?

A Yes.

Q Did there ever come a time -- and you receive a portion of the proceeds that Wistar receives, correct?

A Yes.

Q And you continue to receive payments from Wistar for the sale of RotaTeq?

Page 69:

A I don't think I received anything in the last couple of years, but I have in the past.

Q How much approximately have you received in the past?

A I don't remember.

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

A I believe they have.

Q Do you remember approximately how much?

A No.

Q I'm going hand you what's been marked as Plaintiff's Exhibit 5.

(Exhibit Plaintiff-5 was marked for identification.)

BY MR. SIRI:

Q It's a PR Newswire article. Can you read the title, please?

A "The Wistar Institute Sells Partial Royalty Interest in Merck's RotaTeq to the Paul Royalty Fund."

Q Does that refresh your recollection of how much they sold their royalty interest?

A No.

MS. RUBY: Ms. Nieusma, did you receive

Page 70:

Exhibit 5?

MS. NIEUSMA: I did. I believe Exhibit 5 I have, yep, just got it.

MS. RUBY: Thank you.

BY MR. SIRI:

Q Can you please read the first sentence of the article, Dr. Plotkin.

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

Q Does that refresh your recollection of how much they received for selling a portion of their interest in RotaTeq?

A 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.

Q The Wistar Institute is entitled to what percentage of the sales from the RotaTeq?

A I do not know.

Q From this $45 million sale, any recollection at all of how much you received?

A No recollection. I'm sure I received some.

Page 71:

Q Do you think it was sizable?

A I think it was probably sizable, yes.

Q More than a few hundred thousand?

A I think so. I don't have a figure in my head.

Q Do you have documents that would indicate how much you received?

A I would imagine so, yes.

MR. SIRI: We'll make a request for those as well.

Q Are you familiar with the Immunization Action Coalition?

A Yes.

Q What is your understanding of what this group does?

A They promote vaccination through education and emails and meetings.

Q Would you say it's one of the main advocacy groups for vaccines in this country?

A I think it's an important one, yes.

Q Does it receive funding from pharmaceutical companies?

A I believe -- I think so. I'm not certain.

Page 72:

I don't know exactly where their financing comes from, but I think they very well may.

(Exhibit Plaintiff-6 was marked for identification.)

BY MR. SIRI:

Q I'm going to hand you what's been marked as Plaintiff's Exhibit 6. It's a printout from the Immunization Action Coalition web page showing their funding for 2017. If you could kindly take a look at that and the section that says, that lists the pharma company donors.

A Mm-hmm.

Q Are any of the companies listed there vaccine manufacturers trying to develop vaccines?

A Yes.

Q Which ones?

A AstraZeneca, Glaxo, Merck, Pfizer, Sanofi, Seqirus.

Q So all of them?

A Yes.

Page 73:

Q Do you know approximately what percent of Immunization Action Coalition's funding comes from those pharmaceutical companies?

A No idea.

Q 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?

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

Q Sitting here today, you don't know of one?

A I don't know what funding, for example, AAP receives from manufacturers, no.

Q So sitting here today, you're not aware of any medical group that does not receive any support from pharmaceutical companies, correct?

A I am not aware of the funding of medical organizations and whether or not they receive funding from pharmaceutical companies.

Page 74:

Q 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?

A 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.

Q So the answer is yes?

A 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.

Pages 79-84:

Testimony discusses Dr. Plotkin's CV, dated June 2017, which was given to the defendant's counsel. It was 200 pages long. Included: 794 articles cited that he had authored, 13 faculty appointments at a number of universities, a teaching position at University of Pennsylvania (a vaccine course), medical and scientific director at Sanofi from

1991-1997, and executive advisor to the CO of Sanofi from 1997-2009. (Missing was his adjunct professor position at Johns Hopkins, and work that he had done for Merck, Glaxo and Pfizer. He explained that he had just consulted for these three companies, and did not have any official appointments there so he did not include them on his CV.)

Pages 85-93

Although not stated on Dr. Plotkin's CV, he confirmed that he was on the Board of the following companies:

Dynavax (working on adjuvantation of vaccines and recently licensed a Hep B vaccine; Dr. Plotkin had advocated on their behalf in govt)

VBI Vaccines (biotech company developing vaccines)

MyMetics (chairman of the scientific advisory board of this biotech company developing vaccines)

Inovio Biomedical Corp (biotech company developing vaccines based on DNA)

CureVac AG (biotech company developing vaccines)

GeoVax Labs (biotech company working on a HIV vaccine)

GlycoVaxyn AG (European biotech company working on vaccines)

Adjuvance Technologies (company working on developing adjuvants for vaccines)

BioNet-Asia (company developing a new pertussis vaccine)

Hookipia (European biotech company working on vaccines)

Page 103:

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 I imagine so. But I certainly have no knowledge.
Q Do you think it was in the billions?
A I don't, do not know.

Q Do you know what the, do you know what the global sales of vaccines were, approximately, last year?

A My vague recollection is something like 30 billion.

Q Thirty billion. Do you know what percent approximately Merck's share of that was?

A No.

Q Sanofi's?

A No.

Q Glaxo?

Page 104:

A No.

Q Or Pfizer?

A No.

Q Do you -- combined what, do you have a sense of what those four represent in terms of that $30 billion in vaccine sales?

A Probably. I would guess, but it's purely a guess, 20 billion.

Q And 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 from the big four vaccine makers?

A I said 20. I really don't have an accurate idea, but that's my guess.

Q Twenty?

A Billion.

Q Oh, billion. You said what percent of that was related from the four, to the four big

Page 105:

vaccine manufacturers?

A What I said was that I thought the overall income was 30, but that the big four probably account for 20. But that's, those are purely guesses.

Q Then let's do this. When you say it's a guess, how off do you think you might be?

A If it's a guess, how do I know how off I am?

Q How did you come up with the 20 billion?

A Because I vaguely recall having seen a paper with those numbers. But my memory may be incorrect.

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

A Yes, of course.

Page 106:

Q What is your opinion about this, the New England Journal of medicine?

A It is an influential medical journal.

Q I'm going to read you a quote from a Dr. Edmond J. Safra, professor at Harvard Medical School and 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. 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 Okay. Let me read you a different quote, again, by Dr. Angell, in which she blames the issue

Page 107:

that I just quoted, the issues with truths in medical publishing, on individuals that use legitimacy of academia to push pharmaceutical company agendas. Here's what she said about those individuals.

She says, quote: 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, promote drugs and devices at company-sponsored symposia, and allow themselves be plied with expensive gifts and trips to luxurious settings. Many also have equity interest in sponsoring companies.

Are you familiar with that quote?

A Yes. I think I have read that, mm-hmm.

Q You consulted for the big four vaccine manufacturers, correct?

A Yes.

Q You're in the corporate advisory Board of numerous vaccine developers, correct?

A Yes.

Page 108:

Q You've received royalties from the sale of one or more vaccines, correct?

A Yes.

Q Have you received -- you have received royalties from the sale of one or more vaccines, correct?

A Yes.

Q You are listed as an author on at least one or more papers where individuals authoring papers receive compensation from vaccine makers, correct?

A Would you repeat that question.

Q Sure. Have any of your co-authors 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 I'm going 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?

Page 109:

A Health and Human Services.

Q Okay. CDC.

I know these, 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 Well, actually, I was an epidemic intelligence service officer in the 1950s, and I have served on committees. 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 And it stands for the Food and Drug Administration?

A Food and Drug Administration, yes.

Page 110:

Q And the FDA is an agency within HHS, correct?
A Yes.
Q And CDC's also an agency within HHS?
A Yes.
Q Okay. NIH?
A Yes, of course. National Institutes of Health.
Q Right. And you've been involved with the NIH?
A Yes.
Q And how have you been involved?
A Served on committees, worked with people at NIH, scientific collaborations.
Q NIH is an agency within HHS as well, correct?
A Yes.
Q HRSA?
A I'm not sure --
Q Health Resources Services Administration?
A Okay.
Q They're also an agency within HHS, correct?
A Yes.

Page 111:

Q Any involvement with HRSA?
A I don't think so.
Q ACIP?
A Well, yes. The Advisory Committee for Immunization Practices. I have attended their meetings since 1960s, probably.
Q Have you ever served on the Board at ACIP?
A On ACIP itself? No.
Q Okay.
A No.
Q Have you served on any Board related to ACIP?
A To ACIP? I've worked, I have 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?
A Actually, no.

Page 112:

Q And measles?
A Measles? No.
Q Not measles. I'm sorry.
Rubella?
A No, not for ACIP, no.
Q A different government agency?
A No. Actually, that was for WHO.
Q For the rubella?
A Yes.
Q And for rotavirus, did you serve on a committee --
A No.
Q -- for any other governmental entity?
Strike that. That's okay.
Oh, and WHO stands for?
A World Health Organization.
Q 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? VRBPAC? VRBPAC? How is it normally pronounced?
A "VRBPAC." Vaccines and Related Biologicals Advisory Committee.
Q And that's V-R-B-P-A-C?

Page 113:

A Yeah.
Q Any involvement with that committee?
A I have testified, but not, I have not served on the committee.
Q What did you testify there for?
A On the, at least the last time concerned the Dynavax vaccine.
Q Oh, the, for the company you're on the Board for?
A Yes.
Q And this was to try to seek approval of that vaccine?
A Yes.
Q Which ended up getting approved?
A Yes.
Q The NVAC?
A National Vaccine Advisory Committee. I've given talks to the committee.
Q Okay. About what?
A About vaccines.
Q Fair enough. Anything in particular about vaccines or particular vaccines?
A No. Actually, there was more or less general. It was not pushing any particular vaccine,

Page 114:

but relation to the administration and the development of new vaccines.
Q 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, VRBPAC, and NVAC, they're all under HHS?
A I believe so, yes.
Q And what's the, what about IOM; what does that stand for?
A Institute of Medicine, now the National Academy of Medicine.
Q Have you ever been involved with IOM?
A Well, I'm a member of the National Academy. So yes.

Q Since when have you been a member?
A Oh, gosh. Ten years, but that's just a guess.
Q What is the National Childhood Vaccine Injury Act of 1986?
A Well, that's, in effect, it funds the organization that, shall I say, receives requests from individuals who believe that they've been

(Vaccine Injury Compensation Program)

Page 115:

injured by vaccines and remunerates them if they decide that, that there was a possibility that the vaccine did cause injury.
Q So if somebody is 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?
A Yes.
Q Administered in DC?
A Yes.
Q So, and the respondent in those cases is HHS, the secretary of HHS?
A Yes.
Q And the secretary of HHS in those cases is represented by the Department of Justice?
A Yes.
Q To defend against claims that the vaccines cause injury, right?

Page 116:

A 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.

When this was first organized --

Q Do you have a study that supports what you just said or any type of --

A About what?

Q That they are very, that they are open to giving awards? 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. I'd have to look that up.

Q Okay.

A But the principle was enunciated years ago by the, particularly 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

Page 117:

opposed to the situation 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 -- how 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.

Q So is it your testimony that the national, that the Vaccine Injury Compensation Program is not an adversarial system?

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 a vaccine or whether it's a chance occurrence fortunately does not have to be adjudicated under this kind of system.

Q That's only if it's a table injury, correct?

A Yes.

Page 118:

Q But if it's not a table injury, then the petitioner would need --

A Yes.

Q -- to show that it was the vaccine that caused the injury?

A Yes.

Q 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.

A Yes.

Q And you have to -- yeah, okay, for injuries caused by vaccines.

Page 123:

Q Okay. Are you familiar with how the CDC makes changes to its pediatric vaccine schedule?

A Yes.

Q Have you ever been part of that process?

A Not part of the process, but certainly part of the discussion.

Q In addition to changes to the CDC pediatric schedule voted upon by ACIP, correct?

A Yes.

Q What happens when ACIP votes for a pediatric vaccine to be added to the CDC's pediatric vaccine schedule for universal use?

A It is adopted by various medical organizations and recommended to the physicians.

Q And so the pediatricians around the country rely on those recommendations to decide whether or not to administer a vaccine?

A Absolutely.

(Vaccines for Children Program and 1986 National Childhood Vaccine Injury Act)

Page 124:

Q What about children in the United States that can't afford the vaccines recommended by ACIP?

A Well, until the present time, remains to be seen whether that will still be the case, the government pays for those children to receive vaccines.

Q Is that called the Vaccines for Children Program?

A Yes.

Q And ACIP votes on whether or not to add a vaccine to that program, correct?

A Yes.

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 Vaccines for Children Program?

A Fifty to 60 percent.

Q So when ACIP recommends a vaccine for universal use, it will essentially create a

Page 125:

liability-free market of millions of children for the pharmaceutical company manufacturing that vaccine, right?

A The act provides payment to the pharmaceutical company to manufacture the vaccine; 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 Unless it is the result of bad manufacture.

Q But not for, if it wasn't, not for design defect claims?

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? Strike that. I didn't want the names.

Let me ask it a different way. Are the individuals that serve on ACIP government employees?

(ACIP – Conflict of Interest – Rotavirus Vaccine)

Page 126:

A No.

Q Where do these individuals come from?

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.

Q So none of the members of ACIP have any conflict with regards to the manufacture, development, or -- of vaccination?

A Right.

Q When was the first rotavirus approved by ACIP for universal pediatric use?

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

Q If I tell you June 25, 1998, does that jog your memory?

A Yeah, that could be right.

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.

Page 127:

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? I don't remember whether he was still on the committee or not. 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 RotaTeq or on the administration of RotaTeq.

Q For the first, what was the first rotavirus vaccine that was approved for universal use in this country?

A RotaTeq.

Q Is that the rotavirus vaccine that you worked on?

A Yes.

Q There wasn't a rotavirus vaccine that was approved before that?

A I don't believe so, no -- 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.

Q Paul Offit 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?

A Yes.

Q He didn't recuse himself from voting on recommending the rotavirus vaccine for universal use at that meeting, correct?

A 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. So in effect, he was voting for a competitor.

Q When you have one vaccine for a given

Page 129:

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

Q So approval of the first one paves the way for the second one, doesn't it?

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 in one vaccine, there's an alternative.

Q So there's, 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 Yeah. 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?

A No.

Q Are you aware that this report found that,

Page 130:

quote, the overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry, end quote?

This next statement was attributed to Siri, but I think it was made by Dr. 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, with industry.

And I understand why that is the case, but it does result in the 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.

Pages 131-135

Dr. Plotkin stated that the CDC "certainly recently" has tried to avoid people with conflict of interest on ACIP, and that ACIP meetings are open to the public. However the "work groups" who review vaccine studies and present info to ACIP conduct their meeting out of the public eye, and any conference calls that they have leading up to the ACIP meeting are not transcribed. According to Dr. Plotkin, these working groups "may" have forms of conflict of interest. Dr Plotkin stating that at ACIP meetings, he can get up and talk whenever he wants to, and pharma companies can speak up as well, even when the public is not present.

(Vaccine Clinical Trials)

Page 148:

Q Dr. Plotkin, earlier you testified that

Page 149:

there are two hep B vaccines on the market. One by Glaxo, GSK, that's Endrix-B; and the other one is by Merck, Recombivax HB, right?

A Yes.

Q For the Recombivax HB, how long was the safety review period in the prelicensure clinical trial for this vaccine?

A I don't know.

(Exhibit Plaintiff-10 was marked for identification.)

BY MR. SIRI:

Q Dr. Plotkin, I'm going to hand you what's been labeled Plaintiff's Exhibit 10. This is the product, the manufacturer insert for Recombivax HB, correct?

A Yes.

Q And the clinical trial experience would be found in Section 6.1, correct?

Correct? Dr. Plotkin?

A Yes.

Q In Section 6.1, when you look at the clinical trials that were done prelicensure for Recombivax HB, how long does it say that safety was monitored after each dose?

Page 150:

A Five days.

Q Is five days long enough to detect adverse reactions that occur after five days?

A No. They would be --

Q Is it --

A They would be reported separately as observed in the clinic.

Q In Section 6.1 of the manufacturer insert which under the Code of Federal Regulations are supposed to describe the clinical trial, does it provide for anything other than five days of monitoring after each dose for adverse events?

A It does not specifically say that, no.

Q Okay. Is five days long enough to detect an autoimmune issue that arises after five days?

A No.

Q Is five days long enough to detect a seizure that arises after five days?

A It would be unlikely to have a seizure occur after five days.

Q Is five days long enough to detect any neurological disorder that arose from the vaccine after five days?

A No.

Page 151:

Q Was there any control group in this trial? Let me rephrase that.

There's no control group, correct?

A Not -- let's see.

Well, they mention 3,258 doses were administered to 1,252 healthy adults.

Q That's right. But does it mention any control group, Dr. Plotkin?

A It does not mention any control group, no.

Q If you turn to Section 6.2, what is the list of adverse reactions listed in this section?

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

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

A Yes.

Q Have there been reports of hypersensitivity syndrome?

A Yes. That's what it states.

Q Does it, reports of arthritis?

A It is mentioned.

Page 152:

Q There are also reports of autoimmune diseases, including systemic lupus, erythematosus, lupus-like syndrome, vasculitis, and polyarteritis nodosa as well, correct?

A Yes. That's what it states.

Q And also it states that, under the nervous system disorders, it states that after that, there have been reports of Guillain-Barré syndrome?

A Yes.

Q As well as multiple sclerosis, exacerbation of multiple sclerosis; myelitis, including transverse myelitis; seizure, febrile seizure; peripheral neuropathy, including Bell's palsy; radiculopathy --

A Radiculopathy.

Q Thank you very much.

-- muscle weakness, hypesthesia, and encephalitis, correct?

A Correct.

Q Okay. Now, it says at the top --

A Before you go on, these reports are required to be included because they have been reported to the authorities as happening after vaccination. That is not proof that the vaccine

Page 153:

caused those reactions, because things happen to people all the time, whether or not they've been vaccinated. And as I've 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 phenomena.

Q 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?

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

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

A Yes.

Q Are you aware that one of those conditions they looked at was multiple sclerosis?

A Among others, yes.

Q Among others. And that they specifically looked at it with regards to hepatitis B?

A Yes.

Q And do you know what their finding was?

A I don't remember the exact wording, no.

Q Maybe this will remind you: Inadequate to accept or reject a causal relationship.

They didn't know, correct?

A Yes. 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.

Page 153:

So what that statement means is that they don't have data that confirm that multiple sclerosis is caused by the hepatitis B vaccine and they, that they don't regard that they have enough data to positively exclude it. So you cannot read that as saying that multiple sclerosis is caused by hepatitis B vaccine.

Q I never said that. The IOM did for some of the vaccines and adverse reactions, did conclude

Page 155:

that it favors rejection of a causal relationship, correct?

A Yes, that's correct.

Q But it didn't reach, sorry, it didn't reach that conclusion for hepatitis B and multiple sclerosis, correct?

A It did not reach that conclusion.

Q Okay.

A But other data suggests that that conclusion is warranted, that there is no relationship.

MR. SIRI: Well, I'll make a demand for that. You can produce that after this deposition.

BY MR. SIRI:

Q 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've said earlier, placebo-controlled study, correct?

A Correct.

Q Okay.

A And, also, I would point out that multiple sclerosis is a disorder of adults, and the issue

Page 156:

that arose in France was related to vaccination of adults.

Q Okay.

A There, that does not mean that it would be an issue, even if it were an issue, for children.

Q 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. 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?

A Correct.

Q Okay. So that's what it says right at the top of 6.2?

A Mm-hmm.

Q But these are events that are reported after vaccination. And as you've just, we just

Page 157:

discussed, in order to establish whether it's causal between the vaccine and the condition, you need a randomly, a randomized, placebo-controlled study?

A Yeah.

Q But that was not done for this hepatitis B vaccine before licensure, was it?

A No.

Q 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?

A It would be, yes, it would be ethically difficult.

Q So let's take a look at Engerix-B. That's the other the hepatitis B vaccine that you testified that you recommend Faith receive.

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

A Not offhand, no.

(Exhibit Plaintiff-11 was marked for identification.)

BY MR. SIRI:

Q I'm going to hand you what has been marked

Page 158:

Plaintiff's Exhibit 11. This is the manufacturer insert for the Engerix-B, correct?

A Yes.

Q 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 prelicensure clinical trials after each dose?

A All subjects were monitored for four days post administration. That does not necessarily mean that they didn't collect reactions after four days.

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

A I daresay 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.

Q Is four days long enough to detect an autoimmune issue that arises after four days?

A No.

Page 159:

Q Or a neurological disorder that arises after four days?

A No. That would be reported later.

Q Uh-huh. And can you provide any proof that there was any reports or follow-up after those four days?

A 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.

Q But as you sit here today, that's just speculation, correct?

A Yes, that's speculation based on experience.

MR. 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.

Page 160:

Q So, and there's no, there was no placebo group, correct? In the 13,000, in the trial at the top where it talks about 13,000 doses being administered.

A 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.

Q And do you believe, so you think there -- but you're just speculating that there might have been a control group?

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

Q 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 Engerix-B? Glaxo? One of your clients.

If there was a control group, they needed to have disclosed that. And I assume they're

Page 161:

not disclosing it because there was none.

A Well --

Q Go ahead.

A All right. Go ahead.

BY MR. SIRI:

Q So let's go back to section, now Section 6.2 on this manufacturer insert for Engerix-B. It talks about the post-marketing experience for this vaccine. This one lists for immune disorders, immune system disorders that were reported, a whole number of them, correct?

A Mm-hmm.

Q And it also lists a number of nervous system disorders, including encephalitis, encephalopathy, migraine, multiple sclerosis, neuritis --

A Mm-hmm.

Q -- neuropathy, paresthesia -- I'll ask the

Page 162:

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?

A Yes.

Q Okay. But to know whether or not these are actually caused by Engerix-B, again, you would need a properly randomized, placebo-controlled study, correct?

A Correct.

Q But this study wasn't done prelicensure for this vaccine, right?

A 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.

Q That's 6.2. Okay. And, again, given 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?

A In children it would be unethical. It could be done in adults.

Q Now, if you please go to page 11 of this

Page 163:

same manufacturer insert for the hepatitis B, 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?

A Yeah.

Q Do you see there was a 12-month and an 18-month follow-up?

A Yes.

Q So just to be clear, efficacy of the vaccine was followed up for at least 12 months or 18 months, but safety was only done for four or five days?

A I do not agree with that statement.

Q Okay.

A 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.

Q And if they didn't do that, you would agree that that is completely inadequate in terms of assessing safety prelicensure?

A I would say that would be inadequate, yes.

Q Do you agree with the CDC's recommendation

Page 164:

that babies receive a hepatitis B on the first day of life?

A Yes.

Q And these are, the Engerix-B and Recombivax HB are the only two hepatitis B vaccines approved for one-day-old babies, correct?

A Correct. "And why is that?" you may ask. It is because if the baby is not vaccinated --

Q I didn't.

A Well, I'm telling you that if the baby is not vaccinated at one day of age, transmission may occur from an infected mother. And the 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.

Q I'm not, I wasn't asking you any questions about efficacy or why it's done.

A I'm telling you that's why it's given.

Q Thank you. But, obviously, I'm just trying -- like any product, obviously, you want to have informed consent to understand the risks and benefits. I'm just trying to understand what was done prelicensure for these vaccines. I think you've explained that to me.

Page 165:

One of the things you said in the past and I believe is that without clinical trials, without a control group in a clinical trial, you're in la-la land, right? You said that one time? Do you recall?

A 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.

Q There's only one standalone polio vaccine currently licensed in the United States, correct?

A 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.

Q IPV?
A Yes.
Q Right. And there's only one company -- Sanofi, there's only one, IPOL by Sanofi?
A Yes.
Q A vaccine -- strike that.
How long was the safety review for each dose of IPOL in the preclinical trials for that vaccine?

Page 166:

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.
Q I'm asking you in the prelicensure clinical trial for --
A That goes back to Jonas Salk where he -- well, he, where millions of children actually were vaccinated with IPV back in the '50s.
Q And is there clinical trial data on safety?
A Yes.
Q Is that the same vaccine that's used today?

A Yes.
Q Are you prepared to produce that clinical data?
A 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 If it's so safe, then how come the safety

Page 167:

review period for the prelicensure clinical trial as provided in the manufacturer insert for IPOL only reviewed safety for 48 hours?

A 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 I'm going to hand you what's being marked as Exhibit 12. This is the manufacturer insert for the IPOL polio virus vaccine inactivated.

(Exhibit Plaintiff-12 was marked for identification.)

BY MR. SIRI:

Q If you could please turn --

A So let's --

Q -- to Section 6.1, Dr. Plotkin. This is an older one. If you could turn to the adverse reactions, which is on page 12, 14.

MS. NIEUSMA: I'll preserve the objection.

Page 168:

To my understanding, Dr. Plotkin had no role in study design. You're asking him to speculate as to the reasoning of other people that he had no contact with.

MR. SIRI: Okay. He's testifying that my client should receive this vaccine. I can certainly ask him about the prelicensure clinical trials that were done to assess its safety. And you've put him up as an expert in vaccinology. But your objection is noted and preferred for the record.

Thank you, Counselor.

BY MR. SIRI:

Q Okay. So if you go to page 14, Dr. Plotkin, how long does it say that adverse reactions were observed after vaccination?

A Forty-eight hours.

Q Okay. And did the subject group that received IPV only receive IPV or did they receive another vaccine along with it?

A Concurrently with DTP.

Q And what did the control group receive?

A I don't see that stated.

Q If DTP is given along with IPV, how could

Page 169:

you know whether a reaction was caused by DTP or IPV?

A You could not.

Q Okay. If you --

A However, they do say these systemic reactions were comparable in frequency and severity to that reported for DTP given alone without IPV.

Q And DTP was the vaccine we talked about earlier that was withdrawn from the market, correct --

A Yes.

Q -- for safety issues?

The only MMR vaccines available in the United States are made by Merck, correct?

A Correct.

Q How long was the safety review -- do you know how long the safety review period for each dose of MMR in the prelicensure clinical trials for this vaccine?

Do you know how long the safety review period for each dose of MMR in the prelicensure clinical trial was for this vaccine?

A Not offhand. The vaccine has only been used now for about 50 years.

Page 170:

Q So it's more recent, right?

A (No response.)

Q Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 13.

(Exhibit Plaintiff-13 was marked for identification.)

BY MR. SIRI:

Q This is the manufacturer insert for MMR II, correct?

A Yes.

Q 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?

A I doubt very much that's the case.

Q You're not aware that it's -- is it -- are you aware that it is a grandfathered product?

A I am not aware that it's grandfathered. I was alive and well when the product was first licensed, and it was tested extensively before it was licensed.

Q So --

A So to say that it hasn't been tested is absolute nonsense.

Page 171:

Q How come there's no clinical trial data in the manufacturer insert?

A That is something that the FDA would have decided isn't necessary.

Q Are you willing to --

A But 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.

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. So --

Q Dr. Plotkin, we'll get to that piece of this, but right now I'm trying to talk to you about the prelicensure clinical safety --

A What I'm telling you is millions of doses --

Q I understand that.

A -- have been used of this vaccine --

Q I understand you want to --

A -- and that there was prelicensure

Page 172:

trials --

Q Okay.

A -- which I am absolutely confident about.

Q Okay.

A You're talking about stuff that's in a package circular that the FDA has approved and full knowledge that safety and efficacy have been demonstrated.

Q So you're saying there were clinical trials before the MMR was licensed --

A Absolutely.

Q -- is that correct?

And can you provide those?

A 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 Sitting here today, when did these, can you tell me what year these clinical trials occurred?

A Yes. Yes. They were done in the 1960s and the 19 -- yes, mainly in the 1960s.

Page 173:

Q So you're claiming something happened, but you're not willing to provide any proof that it happened?

A The proof is in the publications which you can read --

Q Can you please turn to the page where it's in there?

MR. SIRI: 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 Vaccines, Seventh Edition.

THE WITNESS: 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.

BY MR. SIRI:

Q So which, are you saying that that was a prelicensure clinical trial --

A Yes.

Q -- that you just read from?

A Yes. But, again, I insist the prelicensure or post licensure, the fact remains

Page 174:

that the vaccine has been studied extensively over a period of 50 years.

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.

A That's what you'll find in there.

Q So, you know, I understand that you're getting a little upset about me trying to ask for the data, but that's -- I'm just trying to get to the substance. The FDA requires a clinical trial be on the insert. They're not here. Okay?

So let's -- you're saying that this table -- and let me take a look at it. This would have been post licensure, not prelicensure. And it doesn't indicate a placebo group, nor that it was -- so I'm not -- this is not a clinical trial, as far as I can tell.

Do you have a, can you point me to something that had a placebo group and was prelicensure, please, sir?

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

Page 175:

absolutely certain that they were done when the measles -- the rubella vaccine I developed was incorporated into MMR.

Obviously clinical trials were done before licensure. I'm absolutely certain about that.

Q Well, maybe they're not included because they didn't include a placebo group.

A They may not have included placebo group, yes.

Q So maybe they weren't deemed valid enough to consider a clinical trial?

A 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.

Q So you don't, so you're not aware of any

Page 176:

trial that assess safety in MMR with the control group, correct?

A I cannot cite such a study offhand. I'd have to go back and look to see whether control groups were included.

Q I'm just, we've, 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 to anything in there right now.

So I'm happy to get a copy from you if you like to provide it after this deposition. Would you like to do that?

A I will look.

Q Going back to page 6, there are, 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?

A Yes.

Q I'm not going to read through all the ones in the -- because it's a page and a half long, but

Page 177:

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?

A Correct.

Q When I say "these," I mean all the adverse reactions listed in the manufacturer insert for MMR on pages 6, 7, and 8, right? You understood that's what I meant?

A Yes.

Q Okay.

A Umm--

Q Let me ask you this. Listen, let me ask you this. Maybe you can help clarify, okay? You know what? I'll leave that alone.

You also testified that Faith should be vaccinated for Hib, correct?

A Yes.

Q Okay. Do you know how long the safety review period was for each dose of ActHIB in the prelicensure clinical trials for this vaccine?

A Not offhand, no.

(Exhibit Plaintiff-14 was marked for identification.)

Page 178:

Q I'm going to hand you what's been marked as Plaintiff's Exhibit 14, Dr. Plotkin. This is the manufacturer insert for ActHIB, correct?

A Yes.

Q 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?

A Yes.

Q What were the safety review periods in these trials?

A Forty-eight hours. 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 Now, I'm going to read you a sentence from the paragraph at the bottom of that page.

It says: In study P3206, within 30

Page 179:

days following any dose, one through three of DAPTACEL plus IPOL plus ActHIB vaccinees, 50 of 1,455 -- that's 3.4 percent -- participants experienced a serious adverse event, right?

A Yes.

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 Right. And the control group here received other vaccines, correct?

A Yes.
Q And --
A Well, actually, it does appear to be -- well, for dose four, anyway -- oh, no, I'm sorry. Excuse me.
Q Yeah. It's... It's all right.
Anyway, so since there is no placebo group receiving an inert substance, then it's left to the vaccine manufacturer seeking licensure to

Page 180:

determine whether or not the 50 -- the adverse events that arose are or are not related to the vaccine, correct?
A 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.

Q Let's look at that more carefully. This is out of the, out of 1,455, correct?
A Yes.
Q And it was 50 children that had a serious adverse event within 30 days, correct? And this --
A They had -- let's see. Where is that?
Q That's the bottom of page 8.
A Yes. But you have to understand what is meant by "a serious adverse event." They try to

Page 181:

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. And then they evaluate whether or not the serious adverse events 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. 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?

A Yes. They set up the Board, and they choose individuals who are not employees of the company.

Q But they choose the individuals, correct?

A They choose the individuals, yes.

Q Okay. 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?

A Yes. That's quite possible.

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 That's what that means; yes.

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 Yes. That's correct.

Q Okay.

A 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?

Page 182:

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 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; and those that got the flu

Page 183:

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.

Q We can get to it later.

A But influenza vaccine is a whole story in itself.

Q Okay. That's fine. If you haven't read it, that's, you know, we can get to it. I have it. We'll come back to it.

Now, there was, there's another Act, there's another Hib vaccine called Hiberix, right, and then -- which was licensed after ActHIB, correct?

A Yes.

Q And in that clinical trial, they used ActHIB as the placebo to assess safety, correct?

A If you say so.

Q Okay. The CDC's pediatric schedule, you testified earlier, also includes vaccination for HPV, correct?

A Yes.

Q I'm going to hand you what's been marked as Plaintiff's Exhibit 15.

(Gardasil Clinical Trials)

Page 184:

Q Sorry. Handing it to you. This is the manufacturer insert for GARDASIL, correct?

A Yes.

Q Which is a vaccine against HPV?

A Yeah.

Q GARDASIL is currently the only HPV vaccine used in -- 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.

MS. NIEUSMA: You can keep going. I have seen the GARDASIL inserts.

MR. SIRI: Okay. Thank you.

BY MR. SIRI:

Q So GARDASIL is currently the only HPV used in the United States, correct?

A 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.

Q Can you please turn to page 8, table nine, of this insert.

Page 185:

A (Witness complies.)

Q Okay. This table reflects girls and women nine through 29 years of age who reported an incident condition potentially indicative of a systemic autoimmune disorder during the clinical trial, correct?

A Yes.

Q The subjects receiving GARDASIL show a rate of 2.3 percent. All 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?

A Yes.

Q Okay. 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?

A Well, it says 9,412.

Q That would be the total number for both groups, correct?

A No. For the placebo group.

Q For the placebo group, correct. But some

Page 186:

of them received AAHS, and some of them received a saline injection, correct?

A Correct.

Q Okay. Do you know how many received a saline injection over an AAHS injection?

A Don't know.

Q Okay. Let's go to page 4, and table one is for girls and table two 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 Well, I have to do the arithmetic. But it appears that there were about 5,000, more than 5,000 in the AAHS control and about 600 in the saline placebo.

Q Right. It's about 594. It's about 600. That's right, right?

A Mm-hmm.

Q Okay. So if we go back to page 8, the saline placebo group had about five in 600, and the rest of them were AAH control, correct?

A Apparently, yes.

Q Yeah. What does AAHS stand for?

Page 187:

A The aluminum adjuvants.

Q And I see it's defined here as amorphous aluminum hydro --

A Hydroxyphosphate sulfate.

Q Right?

A Yes.

Q Thank you.

Which we'll refer to as AAHS or the aluminum adjuvant?

A Yes.

Q Good?

Okay. AAHS is not an inert substance, correct?

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.

Q Let me try and understand that. Are you saying they're trying to determine what the rate of reactions is between the group that gets GARDASIL --

A Yes.

Q -- with the group that gets the

Page 188:

aluminum --

A Yes.

Q -- with the group that gets saline?

A Yes.

Q So they want to compare between those three distinct groups, correct?

A Yes. Mm-hmm.

Q Okay. And they did do that in table one and two that we just looked at on page 2 --

A Yes.

Q -- page 4, correct?

A Yes.

Q Why is aluminum added to the GARDASIL vaccine or any vaccine?

A To increase the immunogenicity of the active part of the vaccine.

Q If I may, what you mean is that, if I could use a little more laymen terms, are you saying it's intended to stimulate the immune system to create antibodies?

A Yes.

Q Would that be correct?

A Yes. Not by itself, but by enhancing the response to the vaccine antigens.

Page 189:

Q The antigens bind to the aluminum?

A Yes.

Q And the aluminum is persistent?

A Yes.

Q And it remains in the body such that it continues to present the antigen such that antibodies can be created to it, correct?

A Well, at least during the immediate period of vaccination, yes.

Q Okay. There is, in fact, a syndrome called autoimmune/autoinflammatory syndrome induced by adjuvants, correct?

A That is a debatable point. There's a fellow named Yehuda Shoenfeld, an Israeli, who has pushed this idea for many years, as I think it's fair to say that he has never had acceptance by the larger community of immunologists or rheumatologists.

(Exhibit Plaintiff-16 was marked for identification.)

BY MR. SIRI:

Q I'm going hand you what is being marked -- I'm going hand you what's being marked as Exhibit 16.

A Yes.

Q Are you familiar with this book?

A Generally speaking, yes. I can't say I've read it all, no.

Q Okay. And it's entitled Vaccines In Autoimmunity, correct?

A Yes, correct.

Q Okay. And it extensively discusses, it's -- it discusses many autoimmune conditions that the authors believe can be caused --

A Yeah.

Q -- by vaccine, and in particular by aluminum adjuvants?

A I don't know about particularly aluminum adjuvants, but that's one of their arguments.

Page 190:

Q Can you please turn to the contributors, which starts on Roman, little Roman numeral nine.

A (Witness complies.)

Q There are, I think, somewhere around 77 contributors listed here. You said that Yehuda Shoenfeld was kind of alone, I think, or something like that with regard to the claim that autoimmune/autoinflammatory syndrome induced by adjuvants.

Page 191:

A 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 Well, first of all, Counselor, I have to go over the CVs of each of the people here. You know, I don't know what their role is at the universities. As I said before, Shoenfeld -- first of all, Shoenfeld himself is not anti-vaccination. I know that for a fact.

On the other hand, at least one of his co-authors, Tomljenovic, is a well-known anti-vaccination person who has written a lot about how terrible vaccines are. 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 a, certainly a legitimate field of study; in other words, how do you vaccinate people who already have autoimmune disease? Could their vaccinations make

Page 192:

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 Shoenfeld himself is one of the authors. I am -- what shall I say? I do not believe there is any solid evidence that measles, mumps, and rubella disease 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'm almost certain there's a lot of bull in it, judging from the editors.

Q Without reading it, right?

A Without reading all of it, yes.

Q Okay. Are you familiar with the Tel Aviv Sourasky Medical Center?

A No.

Q Are you familiar with the University of Paris?

A University of Paris. Paris has many different universities. They're sort of numbered.

Page 193:

Q Familiar with University of Pisa?

A No. I'm sure there is a University of Pisa.

Q Okay. Are you familiar with the Technion-Israel Institute of Technology?

A Yes.

Q The Rappaport School of Medicine?

A Mm-hmm.

I can tell you one thing because I've talked to Israelis about Shoenfeld, and Shoenfeld's opinions are not majority opinions even in Israel.

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?

A There is -- Shoenfeld has postulated the syndrome, yes.

Q And there's at least 70 professors at universities around the world that are in agreement with that syndrome in his book --

A No, absolutely not. I'll bet if you go through that book and talk to them, you would find

Page 194:

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. There has been concern raised that aluminum adjuvants of vaccines can cause autoimmunity.

A There has been concerns raised, yes.

Q Okay. So if there's been concerns raised that aluminum in vaccines can cause autoimmunity and there's this medical text with which I understand your opinion on, why combine the autoimmunity rate in the aluminum adjuvant control with the autoimmunity rate in the saline placebo? Why not break those out to show them separately?

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 adjuvants. So I can judge that's why they did that.

Q Well, under that logic, then they

Page 195:

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 the girls, of girls and women in this country between the ages of nine and 26 to develop a systemic autoimmune condition in a six-month period?

A Well, that's a hard question for me to answer. I am not a rheumatologist. But the, when they say "autoimmune conditions," I'd have to read exactly --

Q There's a list --

A -- what they mean.

Q If you go to page 8, they've got a long list right there of the conditions. Starts with arthralgia.

A Right. Yeah. So they have included just about everything that you could consider in

Page 196:

autoimmune disorder. And all I can say is that they have, as I -- well, as I've just said, they've attempted to include everything. And those are the data. You know, what can I say?

As far as 2.3 percent autoimmune disorders in six months, these are women nine 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.

Q Okay. So 2.3 percent in six months, 4.6 percent in a year, in ten years half the women in this country would have autoimmunity. In your experience, would that be accurate?

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.

Q What, do you know the percentage of girls in the saline placebo group that developed a systemic autoimmune condition during this clinical trial versus the AAHC control --

Page 197:

A No, I --

Q -- AAHS?

A No, I did not, without going back to the original study.

(Exhibit Plaintiff-17 was marked for identification.)

BY MR. SIRI:

Q Dr. Plotkin, I'm going to hand you what's been marked as 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, right? Or 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 preadolescents and adolescents, correct?

A Yeah.

Q Page 2, you can see this. It has the 596 saline placebo recipients. Can you please turn to the serious adverse event section, which is one, two, three, four, five, six, seven, the seventh page. They don't print with page numbers,

Page 198:

unfortunately.

A Serious adverse events.

Q Okay. Now, if you go to the next page, one right after that, take a look at that. You can see that the second column is the placebo, the results of the placebo group, correct?

A Mm-hmm.

Q 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?

A No, I don't see any.

Q 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.

Let me ask -- go ahead, please.

A Again, you have to do the arithmetic. But if you subtract the 600 or so from the total, you can easily figure out the percentage in the aluminum group.

Q Right. So let's do that. Let's do that. So there's 900,412 in the aluminum group -- excuse

Page 199:

me, in the total, in all of, in both groups combined.

A Yeah.

Q 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?

A 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 8800. So I guess that would be in here, right?

Q Go to page 8.

A Right.

Q The point is, is that if they would have broken out --

A Two hundred over 8800, and I doubt if that would show a significant difference between the GARDASIL and the AAHS group.

Q So the GARDASIL group would 2.3, shows 2.3 percent?

A Yeah.

Q If we took out the saline placebo group from the second column, it would show 2.3 or above, around 2.3 still, correct?

A Maybe.

Page 200:

Q A little higher, 2.4, 2.5?

A 2.5. Yeah.

Q 2.5. And then if we had a third column that was just the saline placebo, it would show 0 percent?

A Yeah.

Q Wouldn't that have been a significant finding to report?

A I don't -- you'd have to ask a statistician. But I doubt the statistical difference would be significant.

Q 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 --

A Yeah, they might have done that, if they --

Q But they didn't do that?

A 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.

Q Here's the clinical, prelicensure clinical

Page 201:

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?

A Yes.

Q But the saline placebo group that didn't get the aluminum adjuvant had a 0 percent, right?

A A small group, yes.

Q Of 594?

A Yeah.

Q And so the vaccine apparently -- if you turn back, Dr. Plotkin, to page 4, please of the GARDASIL insert.

Are you there?

A Yeah.

Q Do you see they break out GARDASIL in one column, those who received AAHS control in another, and those that had saline placebo in a third column?

A Right.

Q And that's with only 320 participants in the saline group in table one, correct?

A Yes.

Q Okay. And in table two they break it out as well, correct, the saline group from AAHS control

Page 202:

group?

A Yes.

Q If you turn to page 5, they, again, break out the GARDASIL/AAH control and saline placebo groups in tables three and four, correct?

A Yes.

Q But they chose to conveniently combine it when it came to systemic autoimmune disorders, right?

A Well, in the case of the page 4 and 5, they were looking at local reactions. And, of course, aluminum does give local reactions.

On page 8, whether we're looking at systemic autoimmunity, I guess they believed that aluminum in itself is reasonable control and would not cause autoimmunity.

Q So going into the study, they just assumed aluminum wouldn't cause autoimmunity and so that's how they proceed in designing it. I got it. All right.

(Safety Studies – IOM Reports)

Pages 218-221

Discussion of an Institute of Medicine report in 1991: "The Adverse Effects of Pertussis and Rubella Vaccines." Among other things the Institute said that there was not enough evidence from studies to determine whether autism can or cannot be caused by DPT, and that evidence showed there was a causal relationship between MMR in adult women and chronic arthritis and acute arthritis. (Dr. Plotkin said that a later study was not as definitive about the chronic arthritis, and that the term should be arthralgia, not acute arthritis, and that the MMR does cause joint pain in some adult women.)

Page 221:

Q On the next page, Dr. Plotkin, where it says -- of the report, under research needs, does the first sentence say: In the course of its review, the committee encountered many gaps in limitations and knowledge bearing directly and indirectly on the safety of vaccines?

A Yes.

Q And then the last says 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?

A Right. Correct.

Q Okay.

Pages 221-222:

Dr. Plotkin states that the vaccine community did respond to this concern by the CDC setting up Kaiser Permanente in California where they are doing safety studies on vaccinated vs unvaccinated populations, WHO setting up safety reviews, CDC has a safety department, and there are "funded sort of safety centers throughout the country."

Pages 226-229:

IOM put out another report in 1994: "Adverse Events Associated with Childhood Vaccines."The Institute looked at 54 serious injuries (adverse events) associated with a number of different vaccines. For some the evidence did not support a causal relationship and for some, the evidence did support a causal relationship. For the remaining 38 injuries a determination could not be made either way because "the science hadn't been conducted yet."

Page 230:

Q The IOM stated at the end of this report, quote: The lack of adequate data regarding many of the adverse events under study was a major concern to the committee. Presentations of 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 excerpts? Do you see that it says that on the first two lines under: Need for research and surveillance?

A Yes.

Q Dr. Plotkin, in 2011, the IOM then issued its, another report on vaccine safety. And this time it looked at 158 of the most commonly claimed serious injuries after vaccination, right?

A Yes.

Q The title of that report is Adverse Effects of Vaccines: Evidence of Causality?

A Yes.

Q You're familiar with that report?

A Yes.

Q Do you know who commissioned and paid for that report, by the way?

A Which commission?

Page 231:

Q I'm sorry. Who commissioned and paid for that report?

A No.

Q Would it be surprising to you if I told you that HRSA, the agency within HHS that defends against vaccine injury, claims they commissioned that report?

A Wouldn't surprise me.

Q Did you provide information to the IOM committee conducting this review?

A I don't recall specifically whether I did or not. A lot of people ask for my opinions. When asked, I give my opinions.

Q Dr. Plotkin, I'm going to hand you what's been marked as Exhibit 21.

(Exhibit Plaintiff-21 was
marked for identification.)

BY MR. SIRI:

Q Is this the 2011 IOM report we were just talking about?

A Yes.

Q Do you see there's Roman, little Roman numeral seven, page little Roman numeral seven, see a section entitled Reviewers?

Page 232:

A Oh, yes. I'm on the list.

Q Do you see -- I'm going to the first two sentences and can you 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.

Is that what it says?

A Yes.

Q And you're one of the people they gave the report to to review?

A Yes.

Q And next to your name, it says: University of Pennsylvania?

A Yes.

Q It doesn't disclose that at that time you

Page 233:

were working for all four of the major vaccine makers, correct?

A What do you mean working for them? I mean, at that point I was no longer at Pasteur Merieux Connaught.

Q In 2011, were you receiving compensation or remuneration from Sanofi?

A I was, yes, as I've said before. I was consulting for Sanofi as well as others.

Q Were you consulting for Merck?

A Yes, probably at that time, yes.

Q And GSK?

A Yes.

Q Okay. And as well as a whole host of other for-profit companies seeking to develop vaccines, correct?

A Yes.

Q But I'm just saying, I'm just saying that's not mentioned here, correct?

A No.

Q 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?

A I have no knowledge of that.

Page 235:

Q Any reason -- the report indicates that for 135 out of the 158 reviewed, they found that it could not locate sufficient evidence to make a causality determination, right?

A Yes.

Q 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 -- let me ask you something.

Page 236:

You know, you earlier stated that, you stated that hepatitis B is, doesn't cause encephalitis, right?

A That's, that's my opinion, yes.

Q But the IOM, after doing its review, determined it couldn't find science to support a causal determination one way or another, correct?

A Yes. But that means that they don't have evidence for the supposition.

Q That it either causes or doesn't cause?

A Right.

Q They don't know?

A They don't know because there aren't enough data.

Q Okay. But you have --

A In the absence of data, my conclusion is that there are no, there's no proof that causation exists.

Q So if there's no data to show that it causes or doesn't cause --

A Yes.

Q -- your supposition is that -- am I understanding that correctly?

A Yes.

Page 237:

Q Is that it doesn't cause it?

A That there's no proof that it does.

Q Okay. That's different than saying it doesn't cause it, correct?

A Correct.

Q So when you were saying earlier when I asked you at the beginning of this whether certain vaccines caused 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?

A I mean that there's no knowledge known to me that they do certain things that are, that some may have alleged happen after vaccination.

Q Like, for example, you know, 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. You indicated --

A Right.

Q 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

Page 238:

a mechanism by which it could cause it; is that right?

A Yes. That's correct.

Q Okay. But the science really isn't available to make a determination on causation yet, right?

A 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.

Page 241:

Q What was the IOM's conclusion in 2011 about whether these vaccines can cause autism?

A I'd have to look that up, but I feel confident that they do not cause autism.

Q You feel confident that that's what the IOM concluded?

A I don't remember what the IOM concluded. But I don't believe there's any evidence that that's the case.

Q Is there any evidence that that's not the case?

Why don't I show you this, Dr. Plotkin.

(Exhibit Plaintiff-22 was marked for identification.)

BY MR. SIRI:

Q 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.

Nope. I gave you the right one. Here you go. Thank you.

This is an excerpt from the IOM's report, right?

(Autism and Vaccines)

Page 242:

A Yes.

Q And this is where the IOM discusses the evidence with regard to whether DTaP or Tdap cause autism, correct?

A Correct.

Q Okay. If you the turn to the second page, can you read the causality conclusion with regard to whether DTaP and Tdap cause autism?

A 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.

Q Dr. Plotkin, I'm sorry. Can you please read -- Dr. Plotkin, can you please read the

causality conclusion with regard to the -- one second, Dr. Plotkin. I'm sorry. The court reporter has 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.

A The evidence is inadequate to accept or reject a causal relationship between diphtheria

Page 243:

toxoid-, tetanus toxoid-, or the acellular pertussis-containing vaccine in autism.

Q 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?

A Yes. But the point is that there were no studies showing that it does cause autism except one study by two well-known anti-vaccination figures, Geier and Geier, 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's no positive evidence to do a proper study, as we've been discussing, which would disapprove it, would involve the controlled administration of vaccines and withholding vaccines from children who should have them.

Q Dr. Plotkin, is there, was the IOM able to identify a single study that supported your claim -- strike that.

If you take a look at that section, please, was the IOM able to identify a single study

Page 244:

supporting that DTaP or Tdap do not cause autism?

A No, they did not identify a study.

Q Okay.

A But the point is, and I have to repeat myself, that absence of evidence does not allow you to conclude that the two phenomenon are related.

Q You're making assumptions, Dr. Plotkin, about, I think, what's built -- I understand that. I mean, I only interrupt because, you know, it's 3:00. And I don't mind letting you give a lot of discussion about things that aren't relevant, but to the question --

A I think it's relevant in the reports issued by the IOM --

Q Yes.

A -- that their conclusion about evidence not being available --

Q Yes.

A -- does not allow you to conclude that the phenomena, that there is a causal relationship.

Q I'm not sure -- I never said that. I'm not sure anybody in this room said that, Dr. Plotkin.

A Good. I like to hear that.

Page 245:

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?

A There is not evidence to say a million different things --

Q Okay.

A -- but you have to prove --

Q Did the IOM report look at whether the MMR vaccine can cause autism?

A I'd have to look and see.

(Overtalking.)

BY MR. SIRI:

Q Yes --

A I believe it did.

Q -- it did.

MR. SIRI: I'm sorry. He said it did.

THE WITNESS: I'm looking to see.

BY MR. SIRI:

Q 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

Page 246:

determine whether or not a vaccine does or does not cause, 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?

A A study that would definitively show that it doesn't has not been done, but there's no evidence that it does.

Q 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 In the absence of evidence, one should not draw any conclusions except that there's 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's some suspicion that, of a relationship.

But in, we have no suspicions, at

Page 247:

least I don't, that autism is caused by DTaP.

Q 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 just, I'm not saying, 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?

A As a scientist, I would say that I do not have evidence one way or the other.

Q Right.

A 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 that, 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.

Q I'm asking you a simple question. I'm

Page 248:

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?

A I can make the statement that there is no evidence that vaccines cause autism, and, therefore --

Q I'm not asking you that question --

A -- and, therefore, and, therefore --

Q -- Dr. Plotkin.

MS. NIEUSMA: (Inaudible.)

It's time to move on.

MR. SIRI: He's not answering the question.

THE WITNESS: -- and, therefore, vaccines should be given to protect against serious diseases.

BY MR. 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?

Page 249:

A I would say it is logically true that you cannot say, you cannot point to proof that it doesn't cause autism. 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.

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?

MS. NIEUSMA: (Inaudible.)

THE WITNESS: I could not say that as a, as a scientist or a logician. But I can say as a physician that, no, they do not cause autism, because as a physician, I have to take the whole body of scientific information into consideration when I make a recommendation for a child.

Page 250:

Q The IOM reviewed the science. They didn't find a single study that supported whether or not vaccines --

(Discussion off the stenographic record.)

MS. NIEUSMA: At this point, Dr. Plotkin, just wait for him to move on to the next question.

MR. SIRI: I'm not asking the same question, Counsel. Your objection is noted. I'm responding to his comments, which are different every time.

BY MR. SIRI:

Q So what you're saying is a physician or logician, then, you couldn't say vaccines do not --

you could not say vaccines do not cause autism

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. That doesn't mean that stops me from using DTaP vaccine.

Q Are people claiming that DTaP has caused leprosy? Are you aware of any such complaints?

Page 251:

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.

Q Okay. 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?

A Yes.

Q Okay. They didn't review whether DTaP causes leprosy, did they?

A No.

Q Okay. So, 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 whether DTaP or Tdap cause autism, isn't it a little premature to say, to make the sweeping statement that vaccines do not cause autism?

A No, 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

Page 252:

of any reasonable evidence that they do, I continue to recommend their use.

Q So you're willing to make a statement that a vaccine does not cause a condition even in the absence of any evidence?

A I'm willing to state that there is no evidence that the vaccine causes the condition and, therefore -- 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?

Q Are you saying that the IOM was engaging in a ridiculous review here?

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.

But that does not mean that the vaccines cause autism

Q You've never been asked that. The only thing I've asked you is whether or not one can

Page 253:

assert that vaccines do not cause autism, that they do --

A Counselor, let's be, let's be real. You're asking me these questions because you want me to legitimize the view that vaccines cause autism, and I will not do that because absence of evidence is no proof whatsoever.

Q 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. I think I'm very clear --

A I'm glad to hear that.

Q -- we have very clearly established what the IOM found. The IOM found in their estimation no evidence, right?

A Right.

Q They found no evidence that vaccines do cause -- excuse me -- that DTaP or Tdap cause autism. Let's make that very clear, right?

A Right.

Q They found no evidence that DTaP or Tdap cause autism--

A Yes.

Page 254:

Q -- period.

They found one study which they said was unreliable because it relied on VAERS data and it had no control, right?

A Right.

Q Okay. But similarly, in the same vein, they also didn't find any evidence that DTaP/Tdap do not cause autism. Now, that doesn't mean that DTaP/Tdap do cause autism, correct?

A Correct.

Q It doesn't mean that, right?

A Yes.

Q That's right. All it means is that they couldn't find a study that showed, that supported that it does not cause autism, right?

A Yes.

Q Until -- and that's why they reached the conclusion that they did, which is they said the data is insufficient, right?

A Mm-hmm.

Q I assume you -- was that a yes?

A Yes.

Q Do you agree with the IOM's conclusion that the data, the evidence is insufficient to

Page 255:

determine whether or not DTaP/Tdap cause autism?

A I agree with their conclusion, but that doesn't mean that I don't act on other information.

Q Okay. Okay. I can understand that. I can understand that. But you make -- I'm not, I'm not saying that -- I'm not asking you to ignore any benefits you believe accrued 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 and common sense, if you don't know whether A causes something, can you say A, B -- let me not use that hypothetical.

If you don't know whether DTaP or Tdap 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?

A Do I wait? No, I do not wait because I have to take into account the health of the child.

Q And so for that reason, you're okay with telling the parent that DTaP/Tdap does not cause autism even though the science isn't there yet to support that claim?

A Absolutely.

(Vaccinated vs. Unvaccinated Studies)

Page 262:

Q So with all of the government -- so the pharmaceutical industry, you said, made approximately $20 billion last year in revenue from vaccine sales?

A I think so. I don't have --

Q I have the financial statements. Should we review them, or do you think 20 billion is about

Page 263:

right?

A I think it's about right. I'm not an accountant -- I don't make --

Q Give or take a few, give or take a billion or two, would you say?

A I think so, yes.

Q Okay. So the pharmaceutical industry has $20 billion in revenue, and the CDC spends hundreds of millions of dollars buying vaccines every year; 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?

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, might be questionable. But I don't know whether such a study is feasible or not.

Q Aren't most studies that are done that you

Page 264:

rely upon in that book that you have in front of you not randomized?

A Many of them are not. Many of them are.

Q Do you throw out the ones that are not randomized?

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.

Page 273:

Q 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?

A I wouldn't be surprised that there's a response, no.

Q Okay. So in looking for such a study, isn't it true that there actually has been one such study conducted in the past, for the first time ever in the last year, correct?

A I am not aware of that study.

(Exhibit Plaintiff-24 was
marked for identification.)

BY MR. SIRI:

Q Okay. I'm going hand you what's been marked as Plaintiff's Exhibit 24. The title of the study is a "Pilot Comparative Study of the Health of Vaccinated and Unvaccinated 6- to 12-Year-Old United States Children," correct?

A Yes.

Q And the authors of this study are Professors at the Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, correct?

A Yes.

Q And the authors of this study are Professors at the Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, correct?

Page 274:

Q Are you familiar with this pilot study, Dr. Plotkin?

A No. I see it's been published in the Journal of Translational Science, which is not one of the journals I read and is probably one of those multiple so-called predatory journals that we are trying to deal with currently.

Q So is anybody in any university that publishes anything that's negative about vaccines predatory or -- I forgot the other adjectives you used earlier today.

Page 275:

A No, it's not, it's not that. It's that there are journals now that will publish anything for money.

Q Oh.

A And I get about ten of those invitations a day.

Q So does money influence judgment?

A It may.

Q Conduct?

A It may.

Q Okay.

A I cannot tell until I read this study.

Q 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 homeschooled children?

A Yes.

Page 276:

Q Do you see that it says that vaccinated children were 3.9 times likely to have allergies?

A Yes.

Q 4.2 times as likely to have ADHD?

A Yes.

Q 4.2 times likely to have autism spectrum disorder?

A Yes.

Q 2.9 times as likely to have eczema?

A Yes.

Q 5.2 times as likely to have learning disability?

A Yes.

Page 277:

Q 3.7 times as likely to have neurodevelopment disorder?

A Yes.

Q And 2.4 times as likely to have any chronic condition?

A Yes.

Q Wouldn't you like to see a larger-scale study that refuted these claims?

A It would be ideal, yes. It would certainly be important to repeat the study and to enroll patients in a blinded fashion. I really would have to read this to see exactly how they

Page 278:

enrolled the children or the parents in this study.

Q Doesn't the existence of this study, though, I mean -- strike that.

So it at least calls for further similar studies, hopefully, to either confirm or disapprove the findings in the study, correct?

A Yes. Mm-hmm. Yes, I would agree.

Q I'm going to show you one more study that was done with the same data from this author.

(Exhibit Plaintiff-25 was marked for identification.)

BY MR. SIRI:

Q Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 25. This is another study by the, 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?

A Appears that way, yes.

Q 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?

Page 279:

Q Can you start, can you read that sentence and the next one?

A No association was found between preterm birth and NDD in the absence of vaccination, but vaccination was significantly associated with NDD in

Page 280:

children born at term. Odds ratio, 2.7.

Is that sufficient?

Q And the next sentence, please, sir. Thank you.

A 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.

Q What does NDD stand for?
A Neurodevelopmental disorders.
Q And in this study it was defined as learning disability, attention deficit hyperactivity disorder, and autism spectrum disorder, correct?
A Yes. But I will also point out the abstract says that it was a convenient sample of 666 children. So clearly it was in no way a randomized study.
Q Shouldn't we do better studies?
A One would have to do a better study if --

Q Larger samples?
A Larger samples and enrolling not by convenience.
Q Right. I believe Dr. Mawson calls these

Page 281:

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?
A Well, that's your interpretation. I would have to read the study.
Q Fair enough. More than fair.
Is it possible that his findings in both of these studies could be correct?
A Is it possible? Yes, of course. Possibility is always possible.

Q Hopefully and ideally, you would conduct a larger or at least additional similar studies to either confirm or dispute the findings in these studies, correct?
A Ideally, yes.

(DPT)

Page 288:

DPT was taken off the market in the 1990s in the USA because of safety issues.

A But the DTP, the whole-cell vaccine is used very largely in Latin America and Africa.
Q In developing countries?
A Yes.
Q Any reason that the life of a child in a developing country is not equal to that in the first-world country?
A No.
Q Okay.
A But the whole-cell vaccine is considerably cheaper.

(Risk factors for adverse effects - Studies)

Q Dr. Plotkin, I'm going to hand you what's being marked as Plaintiff's Exhibit 24 -- 27. This is an excerpt from the 1994 IOM report, correct?
A Yes.
Q 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, correct?
A Yes. Mm-hmm

Page 289:

Q Okay.

(Exhibit Plaintiff-28 was marked for identification.)

BY MR. SIRI:
Q Handing you what's being marked as Plaintiff's Exhibit 28. I'm going to read you an excerpt from this, and I'm going to ask you a question. Okay, Dr. Plotkin?
A Yes.

Q Okay. It says: Both epidemiologic and mechanistic research suggests that most individuals who experience an adverse reaction to vaccines have a pre-existing 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. Some of these predispositions may be detectable to prior to the administration of vaccines.

And then skipping down a little:

Page 290:

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?

A Well, not in principle. If such factors can be identified. So far it has been very difficult to identify so-called predispositions.

Q Is it not because, Dr. Plotkin, the science is just not being done to make those identified?

A Some attempts have been made. There's a whole literature by Dr. Poland at the Mayo Clinic on such. But the things that he studied have been relatively minor reactions.

Q Are you aware of any serious large-scale studies that have been done to assess the predispositions that might result in adverse reaction from a vaccine?

A There have been some genetic studies done.

Q By whom?

A As I said, by the Mayo group in particular, and also some studies done Vanderbilt.

Page 291:

Q Who did the studies Vanderbilt?
A Well, James Crowe was one of the authors.
Q What did the studies involve?
A 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. Smallpox vaccine.
Q Smallpox. Do people routinely get smallpox vaccine anymore in America?
A No.
Q 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 might, what would render a child susceptible to a vaccine injury?
A I think the people of British Columbia are doing some work.
Q Who is that?
A I can't remember the guy's name.
Q Is it Chris Shaw?
A Sorry?
Q Is his name Chris Shaw?

(Aluminum in Vaccines)

Page 292:

A Could be. It's a whole group of people at British Columbia.
Q They've published good science in this area?
A Yes.
Q Respectable science?
A Yes.
Q And they are the ones who looked at aluminum adjuvants injected into lab animals in particular, correct?
A They have done some work with aluminum adjuvants, yes.
Q By showing that injecting aluminum can go to different parts of the animal, right?
A Yes.

Q I just want to make sure we're talking about the same group of scientists --

A Mm-hmm.

Q -- at the University of British Columbia. Is, so do you recall if it's Chris Shaw and his group?

A I don't recall specifically.

Q Is -- okay. But it's the group at the University of British Columbia that's looking in

Page 293:

particular at aluminum adjuvants in vaccines, correct, in animal models?

A They're looking at a lot of different things, including adjuvants.

Q Okay. Understood. And other than the group at British Columbia, Mayo Clinic, and Vanderbilt, are you aware of anybody else doing such science?

A Not that I recall, no.

Q Okay. If anybody would know, it'd be you, right, Dr. Plotkin?

A Well, I don't read -- I cannot read every published scientific paper.

Q Dr. Plotkin, I'm going to refer to the various forms of aluminum adjuvant used in vaccines as alum; is that okay?

A Yes.

Q Because there are different kinds, correct?

A Yes.

Q Okay. What is an antigen?

A An antigen is usually a protein that induces an immune response.

Q Antigens in killed vaccines, though,

Page 294:

produce a very weak immune response, hence the need to add alum to the vaccine formulation, correct?

A Frequently, not always.

Q And alum, injected alum can increase the production of all kinds of cytokines, including IL-1, IL-2, IL-6, IL-17, correct?

A Yes.

Q Alum can be recovered from the injection site months or years after intramuscular injections, correct?

A Well, it's, yeah, it's possible to find the alum. Of course, aluminum is a frequent, shall I say, present in all of us? We ingest a lot of it.

Q I'm talking about injected aluminum. I'm asking, can it be recovered from the injection site months or years after intramuscular injection?

A I believe it's possible, yes.

Q 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?

A Well, I'd have to look at it, but I don't doubt that that's, that could be in the book, yes.

Q Okay. And antigen that is absorbed by alum can be taken up by macrophages and dendritic cells?

A Yes.

Q Macrophages is M-A-C-R-O-P-H-A-G-E-S. Macrophages are immune cells, correct?

A Well, they are scavengers, basically.

Q What do they do?

A They take up antigens and present them to other cells.

Q So that means that the alum as well as the antigen that's bound to it are taken up by

Page 295:

macrophages and dendritic cells, correct?

A Yes.

Q Okay. Aluminum injected into the brain -- into the body can travel to the brain, correct?

A I don't know that for a fact, but wouldn't be surprised.

Q You've never seen any studies that show that aluminum injected into the body can travel to the brain?

A I have not seen such studies, no, or not read such studies.

Page 296:

BY MR. SIRI:

Q I'm going to hand you what's being marked as Plaintiff's Exhibit 29. Please take a look at that.

In this study, do you have a problem with the journal that this study was published in?

A No.

Q Is the name of the journal Vaccine?

A Yes.

Q Are you a editor in that journal?

A I was at one point.

Q And you consider that to be a prestigious journal?

A Yes.

Q Okay. So in this study, conduct -- they found that injecting rabbits with aluminum and then dissected them, they found aluminum in the brain of the rabbits, correct?

A Yes.

Q Does that change your opinion of whether injecting aluminum can travel to the brain?

A Well, it shows experimentally that that's

Page 297:

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.

(Exhibit Plaintiff-30 was marked for identification.)

BY MR. SIRI:

Q Here's another study. Here's another study that's being marked as Plaintiff's Exhibit 30. And this study involved mice. Can you please take a look at it. That study is from 2009, correct?

A Yes.

MS. RUBY: Ms. Nieusma, did number 30 go through for you?

MS. NIEUSMA: Yes. I'll let you know if I don't have anything.

Q And that study found that injecting aluminum in mice caused motor deficits and motor neuron degeneration, correct?

A Apparently, yes. But, again, one has to compare the amounts injected with what's, what amounts are injected with vaccines.

Q So in this study the authors note that they were attempting to use dose-equivalent amounts

Page 298:

of alum vis-a-vis the vaccination schedule. I'll post that as a question, but I'll leave it to you to take -- you obviously, sounds like you never read this study, so you can take your time.

Okay. Dr. Plotkin, there's no question pending about that study anymore. So let's move on.

A Okay.

Q 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?

A No.

Q Are you familiar with a study from 2013 entitled "Slow CCL2-dependent Translocation of Biopersistent Particles from Muscle to Brain"?

A No.

Q Are you familiar with the -- after this deposition, I'm happy to provide you copies of all these studies. You can take an opportunity to look at them.

Are you familiar with a 2015 study entitled "Highly" -- actually, you know what?

Page 299:

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.

(Exhibits Plaintiff-31 and Plaintiff-32 were marked for identification.)

BY MR. SIRI:

Q I'm going hand this to you.

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.

A Yes. Okay.

(Exhibit Plaintiff-33 was marked for identification.)

BY MR. SIRI:

Q Okay. That's from 2013. I'm going to show you another study from 2015 being marked Plaintiff's Exhibit No. 33.

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.

Page 300:

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?

A Well, there are experiments suggesting that that is possible.

Q Okay.

A The, in particular, there's a, 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.

Q Isn't that because those studies would be unethical, Dr. Plotkin?

A 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.

Q And so if they did autopsies of people's brains and they found aluminum, then that would be a

Page 301

cause for concern?

A It could be. But one would need to combine that or look at the symptoms of the patients whose brains are being examined.

(Exhibit Plaintiff-34 was marked for identification.)

BY MR. SIRI:

Q 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 doses to see the response.

A This is the French group.

Q That study is the French group, right, that I think you were referring to earlier?

A Yes.

A Yes.

Q Okay. So 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?

A I don't know whether it would or not. I'm not --

Q Do you think it could result in neurodevelopmental disorders?

Page 302:

A Again, there's no evidence that that's the case.

(Exhibit Plaintiff-35 was marked for identification.)

BY MR. SIRI:

Q I'm going to hand you what's being marked -- I'm going to hand you what's marked Exhibit 35. Are you familiar with -- are you familiar with this book?

A No.

Q Well, then I'll give you a copy today when you leave.

MS. RUBY: Okay. Ms. Nieusma, Exhibit 35 is uploading, but it might take just one second.

MS. NIEUSMA: Okay. No problem.

BY MR. SIRI:

Q Dr. Plotkin, has an increase in IL-6 been shown to induce autism-like features in lab animals?

A Well, IL-6 is an inflammatory cytokine. And its relationship to autism, I would say, is not clear. But it is an important cytokine.

Q Has it been shown to induce autism-like features in animals when injected into animals for

Page 303:

experimentation?

A I'm not aware of that, but it's quite possible that that could happen if you use enough IL-6.

Q Do you know the maximum amount -- strike that.

Are you familiar with the study out of -- are you familiar with the study entitled "Inhibition of IL-6 Trans-Signaling in the Brain Increases Social Ability in the BTBR Mouse Model of Autism"?

A No.

Q Are you familiar with the study called "Maternal Immune Activation Alters Fetal Brain Development through Interleukin-6"?

A Vaguely, yes. Yeah.

Q Published in the Journal of Neuroscience?

A Yeah, well, I don't remember the journal.

Q Is that one of the journals you consider respectable?

A Yes.

Q And this was out of the University of California Medical Center. This is from California Institute, CalTech. That institution did a number

Page 304:

of studies regarding -- that group did a number of studies relating to immune activation and neurological disorder, correct?

A Yes.

Q And they found a connection between immune activation and neurological historical disorders, correct?

A Mm-hmm.

Q And one of the -- is that a yes?

A Yes.

Q Okay. And one of the study's findings they had was that immune activation alters fetal brain development through interleukin-6, correct?

A 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.

Q But it can be caused by vaccines, correct?

A Immune activation is the objective of vaccines.

Q Do you know the maximum amount of the aluminum that is injected into a child who follows the CDC schedule?

Page 305:

A I haven't done the arithmetic, but I believe it would amount to several milligrams.

(Exhibit Plaintiff-36 was marked for identification.)

BY MR. SIRI:

Q I'm going hand you what's been marked as Plaintiff's Exhibit 36. Okay?

And before I do that, question for you: The group out of the British Columbia that you were -- the group out of the University of British Columbia, that's out of the Department of Ophthalmology and Visual Sciences?

A Yeah.

Q 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?

VIDEO OPERATOR: We have four minutes left on the disc.

MR. SIRI: Okay.

BY MR. SIRI:

Q Have you seen this letter before?

A No.

Q Okay. This letter is from the group at

Page 306:

the University of British Columbia you mentioned before, correct?

A Yes.

Q And it's addressed to HHS, correct?

A Yes.

Q As well as NIH?

A Yes.

Q FDA and CDC, correct?

A Yes.

Q Okay. In the first paragraph, can you read the first paragraph?

A 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.

Q Now, can you read the last sentence in the next paragraph.

A In children there is growing evidence that

Page 307:

aluminum adjuvants may disrupt developmental processes in the central nervous system and, therefore, contribute to ASD in susceptible children.

Q And just the next paragraph.

A 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 adjuvants by six months of age.

Q Just the next sentence and I guess we can wrap up.

A And in regards 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. Shaw has been associated with the party that I mentioned before, Tomljenovic, who, in my view, is completely untrustworthy as far as scientific data are concerned.

So I'm concerned about Dr. Shaw being

Page 308:

influenced by that individual. And the, I'm not aware that there is evidence that aluminum disrupts the developmental processes in susceptible children.

Q Dr. Shaw is a scientist that studies aluminum regularly, correct?

A Yes.

Q Do you study aluminum regularly?

A No.

BY MR. SIRI:

Q Now, Dr. Plotkin, I'm handing you what has been marked as Plaintiff's Exhibits 37 and 38.

(Exhibits Plaintiff-37 and Plaintiff-38 were marked for identification.)

BY MR. SIRI:

Page 309:

Q Are these letters also written by individuals who are very experienced in studying aluminum adjuvant?

A Yes. Well, one of the letters --

Q Okay.

A -- is from a French group. And I would point out that --

MS. NIEUSMA: Remember, just yes or no answers, Dr. Plotkin. We're trying to get you out of here -- out of there.

THE WITNESS: Yes.

BY MR. SIRI:

Q Okay. And is the content of these letters similar to that of the letter from Chris Shaw?

A Yes.

(Exhibit Plaintiff-39 was marked for identification.)

BY MR. SIRI:

Q Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 39. Okay. This is a study entitled "Aluminum in the Brain Tissue in Autism," correct?

A Yes.

Q And it was published in the Journal of

Page 310:

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?

A Well, I'd have to read the paper, but apparently that's the case.

Q And do you know that the stand-out 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?

A Yes. But they were not associated with neurons.

Q They also found aluminum in the neurons as well, Dr. Plotkin, correct?

A But mostly in other cells.

Q And immune-related cells, right, immune-system-related cells?

A Cells that travel, yes.

Q What is encephalitis?

A Inflammation of the brain.

(Encephalitis side effect)

Page 311:

Q What is encephalopathy?

A Well, it's a vague term that means something's wrong with the brain.

Q What is encephalomyelitis?

A Inflammation of the brain.

Q Do all five of the DTaP-containing vaccines sold in this country list encephalopathy within seven days of a prior pertussis-containing vaccine as a contraindication?

A In other words, if encephalitis is present at the time of vaccination?

Q Mm-hmm.

A Yes, I imagine so.

Q No. Meaning that if there was encephalopathy within seven days of a prior pertussis-containing vaccination, that's a

contraindication to getting more pertussis vaccination?

A Oh, yes.

Q Okay. 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?

Page 312:

A Well, I don't know that for sure, but I imagine that it is a contraindication.

Q 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 encephalomyelitis as a reported adverse reaction in 6.2 --

A Yes.

Q -- of their insert?

Does the only chicken pox vaccine sold in this country list encephalitis as a reported adverse reaction?

A Yes.

Q Why do you think brain swelling after vaccination is being reported in all of these vaccines?

A Anything that happens after vaccination is included in contraindications. That they are related causally is not necessarily the case.

Q What is the total quantity of antigen in

(Vaccine ingredients)

Page 313:

most pediatric vaccines?

A Well, that's vary variable. I mean, perhaps up to 50 milligrams. Depends entirely on the vaccine.

Q Miniscule amount, though, very tiny?

A Yes.

Q Almost -- could you even see it with the naked eye if you had it?

A Yeah, you could in some cases, yes.

Q Some cases?

A Mm-hmm.

Q But for most vaccines, it would probably be very difficult?

A Yes.

Page 314:

Q Okay. Are there any ingredients in vaccines that you're aware of that can damage neurons?

A Not that I'm aware of, no.

Q Are there any vaccines, any ingredients in vaccines that you're aware of that can damage human cells?

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.

Q Do any of the vaccines on the childhood schedule contain monkey kidney cells?

A Well, the polio vaccine does.

Q Okay. Go ahead. I'm sorry.

A Go ahead. I'll stop there.

Q Are the monkey kidneys used in making the polio vaccine removed from the monkey while the animal is still alive?

A These days much of the polio vaccine is produced in a continuous cell line of, derived from monkeys rather than from monkeys, from live monkeys, so to speak. So I'm pretty sure that the IPOL vaccine, for example, is produced in vero cells.

Q Okay. And when you say "continuous cell line," what do you mean by that?

A I mean a cell that grows continuously derived from tissues that were normal tissues to begin with.

Q I'm sorry. Say that again, Doctor.

A So they are cells that continue to multiply, unlike cells from a, let's say, from a kidney that will not continuously multiply. These

Page 315:

are cells derived from the kidney that will continue to multiply and, therefore, can be used to make vaccines in.

Q Cells that continue to multiply unabated are typically considered cancerous, right?

A Well, if, depends on the circumstances in the cells. But it's true that cancer cells do continue to replicate indefinitely. The vero cells are only used at certain passage levels. They're not used, you know, a thousand passages further on.

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. I can't give you a figure offhand. But the, 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.

Q Monkey cellular material remaining in the vaccine is considered either impurities or byproduct of the manufacturing process, correct?

A Yes.

Page 316:

Q Do any vaccines in the childhood vaccine schedule contain blood serum from calves or other bovines?

A 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 vaccinee to cows.

Q Meaning if there was cow serum remaining in the vaccine, the child could develop antibodies to essentially cow --

A Yes.

Q -- cow products?

A Yes.

Q And that would be -- and they could develop an allergy to it, right?

A 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?

A It is removed, yes.

(Exhibit Plaintiff-40 was marked for identification.)

Page 317:

Q Dr. Plotkin, I'm going to hand you what's been marked as Plaintiff's Exhibit 40. What is this?

A Vaccine Excipient & Media Summary.

Q And who produces this document, the CDC, correct, 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 Can you go to Kinrix on the first page. That's K-I-N-R-I-X.

A Yes.

Q DTaP-IPV.

Do you see in the third line down it says: Calf serum?

A Yeah. Well, that is used to grow the polio virus.

Q Right. And this is one of the ingredients that remains in the vaccine?

A I do not believe so. I mean, the vaccine, as I said, is made using calf serum as a nutrient, but it is then --

Page 318:

Q Removed because, otherwise, it would be dangerous, you said, right?

A Yes. Yes.

Q Can you go to the top of this document. You see it says -- you know what? Let me ask you a few other questions, and then we'll come back to this document, Dr. Plotkin. Few quick questions and then we'll come back to it.

Do any vaccines on the childhood schedule contain embryonic guinea pig cultures?

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.

Page 319:

Q Do you know if any vaccines contain cows' milk in it or products from cow --

A Cows' what?

Q Any product derived from cows' milk, any component derived from cows' milk?

A Oh, well, could be, casein, for example, could be --

Q Casein --

A -- could be used.

Q Dr. Plotkin -- Dr. Plotkin, and if there was casein in the vaccine, a child could become sensitized to that, correct?

A No, I'm not sure about that.

Q You're not sure anymore about that?

A No.

Q Yeah.

A I think there are other sensitizing things in calf serum.

Q Dr. Plotkin, can I see that a second. Did I give you the right one?

So earlier you said -- okay. So do any vaccines contain egg protein?

A Oh, yes. Influenza vaccines.

Q And do those remain in the final product?

A I believe they do, yes. 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?
A Actually, I think in Muslim countries, they have tried to do that. But mostly it's from pig.
Q Do any vaccines contain recombinant GMO yeast?

Page 320:

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?
A Well, aside from trace amounts, no.

Page 322:

Q Do any vaccines on the childhood vaccine schedule contain MRC-5 human diploid cells?
A Yes.
Q What are these?
A Rubella, varicella, hepatitis A.
Q What are MRC-5 cells?
A They are human fibroblast cell strain.
Q And how are they created?
A They were created by taking fetal tissue and, from a particular fetus that was aborted by maternal choice. And the cells, so-called fibroblast cells were cultivated from that tissue. The fibroblast cells replicate for about 50 passages

Page 323:

and then die.
Q So MRC-5 cells are cultured cell lines from aborted fetal tissue?
A They're not cell lines.
Q What are they?
A They're cell strains cultivated from an aborted fetus, yes.

Q So cell strains from an aborted fetus?

A Yes. Yeah. They're not immortal.

Q They live for five generations and then hey die?

A About 50 generations.

Q About 50 generations and then they die?

A Yes.

Q And then how is more MRC-5 created?

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.

Q Okay. So these are, these cell strains are human cells?

A Yes.

Q Do any vaccines on the childhood vaccine

Page 324:

schedule contain WI-38 human diploid lung fibroblast?

A Well, they used to, but I don't think anything is made in those cells anymore. They have been replaced by MRC-5.

Q So you're not aware of any vaccine that has in its final formulation WI-38 human diploid lung fibroblasts?

A 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.

Q And these, and WI-38 was created from an aborted fetus?

A Yes.

Q They took the lung tissue from the aborted fetus?

A Yes.

Q And from that they'd grown this cell line, correct?

A Yes. Cell strain.

Q Cell strain.

Is this cell line immortal?

A No.

Page 325:

Q Do any vaccines in the childhood vaccine schedule contain human albumin?

A Oh, yes.

Q What is human albumin?

A Human albumin is part of human serum.

Q And what is human serum?

A What is human serum? Human serum is part of the blood that is liquid.

Q Right. It's the non-red blood cell part of the --

A Yes.

Q -- of the blood, right?

From where was it obtained?

A The human serum?

A Well, that would be variable from donors who are healthy donors. That's all I can 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 Well, serum is used to keep cells healthy

Page 326:

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.

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?

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.

Q Do you think that -- so none of it remains in the final product?

A I don't believe so, no.

Q Because that could be problematic, right?

A Well, it could be. I mean, if the individual is not, not healthy.

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 If they develop antibodies against the serum component, that would not be good.

Q Right. What, do any vaccines contain human material in them that -- I'm sorry. Strike

Page 327:

that. Apologies.

Do any vaccines in the childhood vaccine schedule contain recombinant human albumin?

A Yes.

Q What is recombinant human albumin, A-L-B-U-M-I-N?

A 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 Okay. So it's genetically engineered human serum basically?

A Part of human serum, yes.

Q Is that, are these genetically engineered protein structures?

A Yes. And the idea was to eliminate any possibility of a contaminant from human albumin obtained from the donors. So it's made in cells, using the DNA for albumin, and that way one can be sure that there's no contaminant.

Q And, again, you pretty much want to make sure that none of that remained in the final product, too, right?

A Well, human albumin is probably not much of a problem in terms of causing reactions. So --

Page 328:

Q But in terms of it potentially binding to the alum, that could be problematic, correct?

A Well, I don't know the answer to that question.

Q Okay. 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 purposefully fragmented to below 500 base pairs in length?

A Yes. One doesn't, you know, I would say mostly for theoretical reasons, doesn't want to put DNA into, attacked DNA into vaccines. I think the actual risk is zero, but that's my opinion.

Q Isn't it true that MMR II contains approximately 150 nanograms cells substrate double-strand DNA and single-strand DNA per dose purposefully fragmented to approximately 215 baste base pairs in length?

A Yeah, that's probably correct, yes.

Q And is it true that VARIVAX, vaccine for chicken pox, is manufactured using WI-38 and MRC-5 --

Page 329:

A Yes.

Q -- and contains approximately two micrograms of cell substrate double-strand DNA or approximately 1 trillion fragments of human DNA?

A It may be true.

Q Isn't it true that the Havrix, the hepatitis A vaccine, also contains millions of fragments of human DNA?

A Likely.

Q 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?

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 Do you have a study to support that view?

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.

Q Could it insert into itself DNA even in the muscle tissue or if it gets into the blood into --

A Theoretically. But that's not going to

Page 330:

mean that it's going to have any impact on the individual.

Q Are you familiar with the insertional mutagenesis?

A Yes.

Q Do you have any study to show that injecting millions of pieces of human DNA into babies and children is safe?

A The only studies are all the safety studies that have been done on vaccines.

Q And you can produce those studies, right?

A Well, those studies are available from the manufacturers and from CDC, and I'm not aware of any data showing that the inheritable characteristic was transmitted by a vaccine.

Q So you don't, you don't personally don't know of any study that shows the safety of injecting human, millions pieces of human DNA into babies?

A Such studies are general safety studies, and I haven't yet seen the vaccinee develop a new genetic trait as a result of vaccination.

Q Is it possible it can cause cancer?

A Anything is possible, but there are no data to support that.

Page 331:

Q Is there data to show that it doesn't do that?

A Yes. Observations made over millions of vaccinees.

Q Okay. And you have the studies to show that, right?

A The studies are easily available in terms of vaccine safety studies that have been done by many, many people.

Q Excellent. Then it should be very easy for you to direct me to those and can provide copies?

A Yes.

Q Wonderful.

A You can read the chapter on vaccine safety.

Q Vaccines contain dead or weakened polio virus, correct?

A IPV does, yes.

Q Beginning in the 1950s, polio vaccines were routinely grown on nonhuman primate kidney cells, correct?

A Correct.

Q Are you aware of any simian monkey

Page 332:

viruses, meaning viruses that come from primates, that contaminated polio vaccines and infected individuals receiving the polio vaccine?

A Yes. SV40.

Q What does that SV40 stand for?

A Simian virus 40.

Q Was it the 40th simian virus found?
A Yes.
Q Are you aware of any other simian viruses that are in any vaccine?
A At this stage, no.
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 Yes. There's a pig virus present in one of the rotavirus vaccines.
Q What is that virus called?
A Circovirus.
Q Is there more than one type, or is there only one?
A There's more than one type, but I think

Page 333:

only one was recovered from the vaccine.
Q Which one is that?
A I think it was 2.
Q Circovirus 2.
A I think so.
Q Are you aware of any retrovirus that are in any vaccine?
A Retroviruses? No.
Q Are you aware of any prions that are in any vaccine?
A No.
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 2 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

Page 334:

on the market, they didn't know SV40 was in there, correct?
A Correct.
Q Are you aware of how many micrograms of 2-phen, P-H-E-N-O-X-Y-E-T-H-A-N-O-L? How do you pronounce that?
A 2-phenoxyethanol.
Q Yeah. Are you aware of how many micrograms of 2-phenoxyethanol a child following the childhood vaccine schedule would be injected with?
A No. I'd have to look that up.
Q Do you think it's close to around a hundred micrograms?
A It could be, but I'd have to look it up.

Q Do you think it's close to around a hundred micrograms?
A It could be, but I'd have to look it up.
Q Do you know safe level in terms of that ingredient?
A I am not aware that there, that there is toxicity associated with 2-phenoxyethanol. It's a fairly harmless substance, as far as I'm aware.
Q Do you know any vaccines in 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

Page 335:

schedule would be injected with?
A I don't have the amount, no.
Q Now, I'm going 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 MMR V.

A (Witness complies.)

Q Do you see that within the ingredient list that lists WI-38 human diploid lung fibroblast?

A Yes, I do see that.

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 discussed until now that you believe are not in vaccines?

A 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 significantly shifted to MRC-5. But WI-38 could still be used. I don't see anything wrong with that.

Q Are there any vaccine ingredients that are

Page 336:

not listed on the FDA's official vaccine excipient and media summary table that you're aware of?

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. 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 Probably, yes.

Q And those impurities and byproducts are all listed in what has been marked as Exhibit No. 40, correct?

A Yes.

Q Okay. Once the impurities or byproducts are bound to the aluminum, the body may also develop antibodies to these impurities and byproducts, correct?

A "May" is the operative word, but not necessarily.

Q 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 that would develop antibodies, correct?

Page 337:

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 recognize by the human immune system.

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?

A Well, I think it's unlikely. The monosodium glutamate, for example, will cause an immune response. I have to look through the whole thing. Amino acids probably are unlikely to induce an immune response.

Q Anything else?

A You want me to read this whole thing?

Q Oh, no. I'm just asking, in terms of just the stuff that's got protein structures in it.

A Well, things like calf serum, if they were present, would, would possibly induce an immune response. But the things on this list, the vast majority of them are unlikely to do so.

Q Because they're not protein structures?

A They're not proteins or they're very small.

Page 338:

Q Okay. Other than the -- strike that.

How about, and we talked earlier, human albumin, that would be of a big enough protein structure to bind to alum, correct?

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.

Q Right. Maybe not alone, right? But bound to alum it might, correct?

A It might. But I'm not aware of evidence that it does.

Q Are you aware of a study that looked at that issue?

A I have not read such a study, no.

Q 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 I don't see any chemical reason why it should.

Q Any reason why it shouldn't?

A Proving a negative is always more difficult.

Page 339:

Q Well, I'm just trying to know if you know or you're just, you're not sure. That's all. I'm not asking -- I'm just saying if you don't know, just say you don't know. That's fine.

A I have no reason to believe that DNA will bind to albumin.

Q But you don't know for sure?

A I have not done the experiment, no.

Q Okay. 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 or --

A Oh, I think it could, but I don't know that it does.

Q Do you know whether alum could bind to any of the cellular debris from WI-38?

A It might, but I don't know that for a fact.

Q Do you know whether alum would bind to any of the gelatin from pigs?

A I think that's unlikely.

Page 340:

Q Why is that?
A I don't think that alum would bind to gelatin, but I don't know that for a fact.
Q What about egg protein; could alum bind to egg protein?
A Possibly.
Q And to casein?
A I suppose it's possible, but I'm not aware of any evidence.
Q You don't know?
A I don't know.
Q Okay. In your work related to vaccines, how many fetuses have been part of that work?

(Fetal Tissue in Vaccines and Subjects used for Vaccine Experiments)

A My own personal work? Two.
Q Two. So in your, in all of your work related to vaccines throughout your whole career, you've only ever worked with two fetuses?
A In terms of making vaccines, yes. Yes.
(Exhibit Plaintiff-41 was marked for identification.)
BY MR. SIRI:
Q I'm going to hand you, I'm going to hand you what's been marked Plaintiff's Exhibit 41. Okay? Are you familiar with this article,

Page 341:

Dr. Plotkin?
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?
A Yes.
Q How many fetuses were used in the study described in this article?
A Quite a few. But my answer to the previous question was what did I use to make vaccines. and the answer was two.

Page 342:

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 There were only two fetuses involved in making vaccines. When fetal strains of, 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 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?

A The idea was to study the cell strains from fetuses to determine whether or not they could be used to make vaccines.

Q So this was related to your work?

A Well, yes, in a sense --

Q To vaccines, correct?

A Yes. It was preparatory.

Q So this study involved 74 fetuses,

Page 343:

correct?

A I don't remember exactly how many.

Q If you turn to page 12 of the study.

A Seventy-six.

Q Seventy-six. And these fetuses were all three months or older when aborted, correct?

A Yes.

Q And these were all normally developed fetuses, correct?

A Yes.

Q Okay. These included fetuses that were aborted for social and psychiatric reasons, correct?

A Correct.

Q What organs did you harvest from these fetuses?

A Well, I didn't personally harvest any, but a whole range of tissues were harvested by co-workers.

Q 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

Page 344:

pituitary gland that were chopped up into pieces to --

A Mm-hmm.

Q Included the lung of the fetuses?

A Yes.

Q Included the skin?

A Yes.

Q Kidney?

A Yes.

Q Spleen?

A Yes.

Q Heart?

A Yes.

Q Tongue?

A I don't recall, but probably yes.

Q So I just want to make sure I understand. In your entire career -- this was just one study. So I'm going to ask you again, in your entire career, how many fetuses have you worked with approximately?

A 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.

Page 345:

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 You're aware, are you aware that the, 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?

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 vaccine should receive the vaccines, regardless of

the fact, and that 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.

Q Do you know if the mother's Catholic?

A I have no idea.

Q Okay.

A But she should consult her priest.

Q If she has a -- 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

Page 346:

hundred fetuses?

A Oh, no, I don't think it was that many. Probably not many more than in this paper.

And I should stipulate that we had nothing to do with the cause of the abortion.

Q Some of these were for psychiatric institutions, correct?

A Actually, all I can say is that the fetuses that I personally worked with actually came from Sweden, from a Swedish co-worker. And so I, in no case, was able to determine what exactly the reason for the abortion was.

Q 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 I don't know that. What I'm telling you is that I got them from a co-worker; and if it's stated in the paper, it's true. But, otherwise, I do not know.

Q So if it's in the paper, you don't contest it, right?

A I don't contest it, no.

Q Okay. Have you ever used orphans to study an experimental vaccine?

Page 347:

A Yes.

Q Have you ever used the mentally handicapped to study an experimental vaccine?

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 So you're saying -- I'm not clear on your answer. I'm sorry. Have you ever used mentally handicapped to study an experimental vaccine?

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.

Page 348:

Q Well, in any event, you're not denying that you, that you -- well, 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?

A Okay. Well, then that's, in that case that's what I did.

Q 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?

A I don't remember specifically, but it's

Page 349:

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 Do you remember ever writing to the editor of "Ethics on Human Experimentation"?

A I don't remember specifically, but I may well have.

Q We'll mark this.

(Exhibit Plaintiff-43 was marked for identification.)

BY MR. SIRI:

Q I'm going to hand you what's been marked as Exhibit 43. Do you recognize this letter you wrote to the editor?

A Yes.

Q Did you write this letter?

A Yes.

Q 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?

(Vaccines and Religion)

Page 357:

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 Yes.

Q You have said that, quote: Vaccination is always under attack by religious zealots who believe that the will of God includes death and disease?

A Yes.

Q You stand by that statement?

A I absolutely do.

Page 358:

Q Are you an atheist?

A Yes.

(Adverse Reactions - VAERS)

Page 386:

Q Is it important to get a tetanus vaccine?

A Well, it's important if you don't want to get tetanus, yes.

Q The tetanus vaccine was introduced into routine child 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?

A If you say so. I don't remember.

Q Are you familiar with what, the CDC Pink Book?

A Yes.

Page 387:

Q If the CDC Pink Book said that it was four cases of tetanus per million, would you dispute that?

A I'll accept that.

Q You do accept that. And that's just the number of cases, not deaths, right?

A Yes.

Q And you think it's a public health imperative for people to be vaccinated against tetanus, correct?

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 To prevent something that was a few cases in a million, correct?

A Yes. But a deadly disease.

Q Do we know whether the tetanus vaccine causes more or less than a few cases of serious adverse reactions after vaccination?

A I don't believe it causes a whole lot of serious reactions, no.

Page 388:

Q The CDC and FDA maintained something called the Vaccine Adverse Events Reporting System, correct?

A Yes.

Q And that's where anybody, including doctors, can go and report what they believe to be an adverse reaction from a vaccine --

A Right.

Q -- right?

A Correct.

Q There's no, anybody can submit a report, right?

A That's correct.

Q Okay. And the FDA and CDC compiled that data and make it available online, correct?

Page 389:

A Yes.

Q Okay. I'm going hand you a, what's been marked as Plaintiff's Exhibit 46. Okay? And this is a printout of the VAERS data for all adverse reactions reported to tetanus-containing vaccines in the last ten years.

If you take a look, do you see that in the last ten years, there have been 985 deaths reported --

A Yes.

Q -- to have followed any tetanus-containi
vaccine?
A Yes.
Q That would average to about 98.5 reports
of death per year --
A Yes.
Q -- over the last ten years.
Okay. And there's also 23,981
emergency room or office visits after
tetanus-containing vaccine in the last ten years?
A Yes.

Q And it also lists, last one, 1,256
permanent disabilities reported after
tetanus-containing vaccine in the last ten years,

Page 390:

correct?
A Yeah.
Q That would be about an average of 125 per
year, right?
A Yes.
Q So, 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?
A Correct.
Q Okay. But it's possible it could be,
correct?
A It's, anything is possible, yes.
Q Don't you think a study should be done to
determine -- strike that. Strike that.

Page 390:

Isn't it true that VAERS only receives a tiny fraction of the reportable adverse events after vaccination?

A 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

Page 391:

reported. But I, I cannot confirm that.

(Exhibit Plaintiff-47 was marked for identification.)

BY MR. SIRI:

Q Dr. Plotkin, I'm going to show you what's been marked as Plaintiff's Exhibit 47. This is a report entitled "Electronic Support for Public Health - Vaccine Adverse Events Reporting System," correct?

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 Event Reporting System," correct?

A Yes.

Q And this was a study conducted by Harvard Medical School and the Harvard Pilgrim Healthcare, correct?

A Yes.

Q And it was are done via a grant from an agency within HHS, correct?

A Yes.

Q And the purpose of this study was to

Page 392:

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 Yes.

Q -- do you see where it says: Fewer than 1 -- it's right in the middle paragraph: Fewer than 1 percent of vaccine adverse events are reported?

A Well, yes, I see the statement. I don't see the reference, but...

Q Let's take a look at the results of that study, then. If you go to the first sentence of the page that you're on right now --

A Yeah.

Q -- where it says "results," isn't it true that it says: Preliminary data were collected from June 2006 through October 2009 on 715 -- 715,000 patients?

A Yes.

Q And 1.4 million doses of 45 different vaccines were given to 376,452 individuals?

A Yes.

Page 393:

Q So about 376,000 individuals received a vaccine, correct?

A Yes.

Q 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?

A Yes.

Q And now --

A Well, it's out of 1.4 million, which is 2.6 percent.

Q Doses, correct?

A Yes.

Q Meaning maybe some individuals had --

A More than one vaccine.

Q And had reactions at different times to different vaccines, right?

A Yes.

Q Maybe some people were more susceptible to a vaccine reaction, and so they got, had a reaction every time they had a vaccine, right?

A Well, we don't know that.

Page 395:

Q We don't know.

Assuming that each individual only had one vaccine reaction, then 10 percent of the individuals would have had a vaccine reaction?

A Mm-hmm. Yes.

Q All right. So, now, at the beginning of this study, the CDC was cooperating with these grant participants, correct -- grant recipients, correct?

A Yes.

Q And they helped define what is an adverse reaction, right?

A Yes.

Q And they helped define the algorithms to use, right?

A Yes.

Q And they also helped to define what reports should be excluded, correct?

A I guess so.

Q What events, I'm sorry, should be excluded from being considered, you know, reportable, right?

A Yes.

Q After, however, they collected this data and they generated these 35,000 reports, they then wanted to submit those reports to VAERS and automate

Page 395:

submitted, correct?

A Yes.

Q But the CDC wouldn't cooperate with them, correct?

A Well, I have no idea whether that's true or not.

Q On page 5, Dr. Plotkin, at the end of the second paragraph, it says: Real -- does it say: Real data transmission of nonphysician-approved reports to the CDC were unable to commence by the end of this -- as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity?

Is that what it says?

A That's what it says.

Q Okay. So, and this study says that less than 1 percent of adverse events are reported to VAERS, right?

A Well, I have to check that, but I think that's correct.

Q Okay. Are you aware that there are other, other governmental reports that make similar estimates for VAERS?

Page 396:

A I'm aware that not everything is reported to VAERS, yes.

Q Are you aware that governmental reports show that, that governmental reports like this one show that the rate of reporting to VAERS is extremely low, and in this instance they say Harvard said less than 1 percent?

A Yes, apparently, yes. However, it has to be reminded that reporting to VAERS 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 that VAERS decides.

Q Right. But let's just assume for a second here, so if, let's go back to what's been marked as Exhibit 46, okay? 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?

A I think it's likely the 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.

Page 397:

Q I'm going to hand you what's been marked as Plaintiff's Exhibit 48.

(Exhibit Plaintiff-48 was marked for identification.)

BY MR. SIRI:

Q This is the VAERS report for all adverse events for all vaccines just since January of 2016. Do you see that?

A Yes.

Q If this --

A My wife is getting upset.

Q Well, don't tell her you offered 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?

Page 398:

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?

A That's the arithmetic, yes.

Q That's the kind of event that would happen pretty soon after vaccination, correct?

A Well, events that happen after vaccination, yes --

Q Okay.

A -- but not necessarily because of vaccination.

Q But until a properly controlled saline placebo study is actually done or -- strike that.

Until we compare the total health outcomes -- strike that.

Would you support a study that compared total health outcomes between vaccinated and unvaccinated children, Dr. Plotkin?

A Will I support such a study? Yes. If the

Page 399:

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've cited.

END