

EVERY CHILD BY TWO TELECONFERENCE
5/7/2008 – 11:30 A. M. EASTERN TIME

OPERATOR: Hello and welcome to the Omnibus Proceedings media briefing. As a reminder, all lines will be on listen-only mode, and we will conduct a Q and A session at the end of the call. If you need any technical assistance during this call, please press star, zero to speak with an operator. At this time, I'd like to turn the call over to Ms. Amy Pisani with Every Child By Two, so that we may begin. Go ahead, please.

AMY PISANI: Good morning. I am Amy Pisani and I've been with Every Child By Two since 1996. I've been serving as the Executive Director since 1998 and I want to sincerely thank everyone who has called in to be updated about the Omnibus Autism proceeding. We have several experts in this area that will be talking to you about vaccine court, as well as the vaccine and autism issue, which many of you may have questions about. As you're aware, on Monday, the U.S. Federal Claims Court in Washington will begin hearing a second method of causation. This time, they will examine the claim that thimerosal-containing vaccines alone can cause autism.

Just a brief note about my organization, then we'll go right to the speakers. Every Child By Two is a campaign for early immunizations and our cofounders, First Lady Rosalynn Carter and former First Lady of Arkansas, Betty Bumpers have been working to promote timely immunizations for nearly 30 years now. They founded Every Child By Two in 1991 in response to the measles epidemic that killed, actually, hundreds of folks out there and many of them were children. Our goal is to ensure that all children have access to timely and life-saving vaccinations. And now without further ado, I will introduce all three of our speakers and then they will follow each other one at a time, obviously.

I wanted to also mention that at the end, we will have time for questions and each speaker will speak for about five minutes and that will leave us about 15 to 20 minutes at the end for questions.

Now our first speaker will be Randy Moss and he will be talking to us about the vaccine court. Mr. Moss is a partner at the law firm, Wilmer Hale, where he partners or cochairs several departments, including the Government and Regulatory Litigation Process Group. He's also a member of the firm Appellate and Supreme Court Litigation Group. Mr. Moss is an expert in the vaccine court.

Following Mr. Moss, you will have Dr. Paul Offit and he is the Chief of the Division of Infectious Diseases and the Director of the Vaccine Education Center at the Children's Hospital of Philadelphia. Dr. Offit is the coinventor of the rotavirus vaccine and this vaccine combats the most common cause of severe diarrhea among children. Dr. Offit is the author of three books and he has written more than 130 papers, which have been published in medical and scientific journals.

And Dr. Gerber will be our final speaker today. He is a research fellow at the New York State Psychiatric Institute and Columbia University Division of Child and Adolescent Psychiatry. Dr. Gerber is a board-certified psychiatrist and a psychiatric researcher who studies the applications of brain imaging and genetics related to autism spectrum disorder. He's also an adult psychiatrist. Mr. Moss, I'll let you start, and then I'll have Dr. Offit follow after you, and then Dr. Gerber will continue. Thank you.

RANDOLPH D. MOSS: Thanks Amy. I'd like to spend a few minutes talking about the history of the National Vaccine Injury Compensation Program and how it operates and then a couple of minutes talking about the autism proceedings that are underway right now. By way of background, and as Dr. Offit and others know far better than I do, vaccines are really one of the miracles of modern medicine. They prevent thousands of childhood deaths every year and they prevent more serious illnesses. But all medical interventions carry with them at least a very small risk of injury.

In the 1980s, there was a - - number of manufacturers of childhood vaccines. There was also a large

increase in litigation, mostly involving claims that the DTP vaccine caused brain injury. In 1980, just to give you an example of the increased litigation, in 1980 there were 24 lawsuits that were filed involving vaccines. By 1985, that number had climbed to 150. The litigation cost increased dramatically and it also became extremely difficult and expensive for manufacturers of vaccines to - - insurance. One company - - actually dropped out of the market for a period of time 'cause it was unable to obtain insurance. The price of the DTP vaccine increased over a period of - - years by 2,000%. By 1986, a single dose of vaccine costs \$11.40, \$8.00 of which was for an insurance reserve, and critically, or importantly, there was only one manufacturer of DTP that - - the U.S. market. Overall, there were only three U.S. manufacturers of childhood vaccines.

Congress looked at the system and concluded two things. First they concluded that the tort system did not work very well. It was expensive, time-consuming, and - - there were cases where people really did not suffer injuries as a result of vaccines were compensated, and where people were not compensated who should have been compensated. Second, the tort system was creating disincentives for developing and manufacturing vaccines and Congress was concerned about this. Congress recognized, and I'm quoting here from the report that Congress adopted when it passed legislation, it say with all of these in a single manufacturer, there's a very real possibility of - - reported concern to members of unimmunized children, perhaps there were surgeons of preventable diseases. The Congress designed the vaccine court process with two goals in mind. First they wanted to provide a fair, prompt, and generous compensation system. There was very few people - - buy backs. The idea was really to - - that society benefits enormously by vaccinating children, but on very, very rare occasions, there is a child who's injured and society as a whole ought to help share that cost. And then the second goal was to reduce the amount of litigation involving vaccines and thus to ensure a continuing supply of affordable vaccines and also to ensure continued investment, developing new vaccines.

What Congress did was they imposed a tax on each dose of a covered childhood vaccine, which was then

used to pay claims in a no-fault federal program. What the act did was it created a table of vaccines that were recommended for routine administration to children. And the table, then, listed conditions or injuries that were associated with particular vaccines and a time period in which the condition or injury might be expected to appear. The Secretary of Health and Human Services was authorized to amend the table to include new vaccines or to remove particular vaccines and to change the listed injuries or conditions and time periods.

A claimant can recover under the program in one of two ways. First he or she, or his or her, legal representative can show that he or she received one of the vaccines that was listed on the table and developed one of the listed conditions or injuries within the time period specified on the table. The claimant doesn't have to, this way, show the vaccines actually caused the injury. It's enough to simply show that as a matter of law, under the table, that type of injury during that time period is associated with the vaccine. And if the claimant can do that then he or she is entitled to compensation, unless the government can bear the very substantial burden of coming back and showing that the injury was caused by some other factor.

Alternatively, if the vaccine is either not on the table or a particular condition or injury is not on the table—and I should say that this program only applies to the vaccines that are recommended for routine administration to children, although it does apply to adults who received one of the vaccines that are recommended for routine administration—but if the injury or condition is not on the chart or if the injury occurred within a different time period, then the person who received the vaccine and was claiming an injury, can try and demonstrate or prove that the vaccine actually caused the injury or condition, and the standard of proof is a preponderance of the evidence. You have to show that its more likely than not that the vaccine actually caused the injury and if you do that, then you can recover under the program as well.

And what's important here is that you're actually not required to prove that anybody is at fault as you

would be, at least in many states, if you went under the tort system. You're not required to prove that the vaccine was defective in any way. They're relaxed rules of evidence and it's supposed to be an informal proceeding.

The cases are heard by special masters that are appointed by the Court of Federal Claims. And either the claimant or the government can appeal a case to the Court of Federal Claims or the Court of Appeals for the Federal Circuit if they disagree with the decision. If the claimant prevails, he or she is entitled to various types of compensation, expenses that are not otherwise covered or reimbursable, lost earnings after age 18, pain and suffering up to \$250,000. Also you know, sort of, unusually in our system, whether the claimant wins or not, they're often entitled to, actually, reimbursement of their attorney's fees under the program, and also amounts that are paid to experts who may need to help with the process.

To make the program work what Congress did was—and to serve the purpose of reducing tort litigation, they had to find some way to actually create an inducement for people actually filing the claim in this program—and so what the rules require is that before someone can actually bring a lawsuit, they have to file a claim in the program and comply with the rules of the program. But if they do that, they're not foreclosed from deciding, you know what, I actually would rather bring a lawsuit. And they can bring the lawsuit in one of two ways. They can either wait a specified period of time and if the process in the vaccine court is not going quickly enough, they're allowed to opt out of the program after a period of time and go file a claim in court, or alternatively, they could take the process all the way to the end, get the judgement from the vaccine court, find out how much compensation they're entitled to, and then they can decide whether to accept it or reject it. If they accept it, then they can't bring a lawsuit. But if they reject the decision of the court, they're then entitled, as long as they comply to the rules of the vaccine court, to go ahead and file a private lawsuit. But the hope was that that would at least discourage the bringing of lawsuits because people would have a somewhat expert panel or judge impartially hear the claim and decide whether there was any merit to it and with standards that are not as tough as the standards that

would apply in a court proceeding.

And the program, over the years, has been quite generous in the amount of compensation that it has provided. If you look just at the claims for vaccines that were administered after 1988, when the program took effect, the program has paid out over three-quarters of a billion dollars. In 2007 alone, the program awarded compensation in 82 cases, and on average paid out over 1.1 million dollars to each of the individuals who was compensated.

Let me say a few words about the autism cases 'cause they have really presented some very new issues and some difficult issues for the vaccine court. Since 2001, over 5,000 autism-related claims have been filed in the program and there are currently over 4,800 claims that are still pending there. And to give you some idea of the magnitude of this, if you go back to the beginning of the program and look at all claims from the beginning of the program for conditions other than autism that have been alleged for vaccines administered after 1988, there have been fewer than 3,000 other claims for all other vaccines, say, back to the very beginning, and now we have 5,000 claims relating to autism.

In July 2002, to try and deal with these massive claims, the chief special master created what they referred to as an Omnibus Autism Proceeding. And the plan originally was to hold a single unified hearing on general causation and to reach a decision on general causation within two years, back by 2004, and shorter if possible. Ultimately, the petitioners who had proposed the unified hearing changed their minds and concluded that they'd prefer to have a proposed series of test cases and the special masters agreed to do that and to hold three sets of proceedings or test cases on the condition that within each of those three sets they would hear three test cases. And they appointed three special masters, so that for each of the three series, a special master would each have one case assigned to him or her. And they would hear the cases together and decide what they thought about general causation and then they move on to questions of specific causation.

And the three theories which are, I think, at time inconsistent with one another are first that the MMR vaccine in thimerosal-containing vaccines together causes autism, and that theory is based on the contention that the thimerosal in the vaccine somehow suppresses the immune system and that the MMR vaccine, then, somehow causes the injury. The second theory doesn't argue that the thimerosal-containing vaccine suppresses the immune system; it actually argues that the thimerosal itself is directly toxic and directly causes autism. And then the third theory is that it's the MMR vaccine alone that causes autism.

The first set of the three cases addressing the first theory, the theory that the MMR vaccine plus the thimerosal-containing vaccines cause autism was heard in 2007. The vaccine court has not issued a decision in any of those cases and it probably is not likely to do so, at least immediately in the future, because the petitioners' counsel have indicated that they want to go off and try and obtain additional evidence in those cases from proceedings that are in England, currently pending, where the information that they're seeking is under seal and the court has at least given them some opportunity to try and do that.

The second theory, the theory that it's the thimerosal-containing vaccines alone that cause autism, is about ready now to be heard. The court had originally heard—as I indicated, it plans to hear three cases starting on May 12th. Recently, one of the cases was withdrawn as a test case. They're down to two test cases on that theory. They're looking for a third, but the court said it wants to go forward and at least hear the evidence on general causation, as to the two test cases starting on May 12th, with the idea, I think, in mind that when a third test case is identified, it'll catch up, hopefully, with the others.

The fate of the third set of cases on the third theory that the MMR vaccine alone causes autism is somewhat uncertain at this point. The petitioners have only identified one test case and it may be that the

general causation issue is resolved based just on the evidence introduced at the hearings last year on the first theory, so its not at all clear, at this point in time, that there ever is going to be a third set of these test case hearings.

There's some other things I could say about this, but why don't I save the rest for questions and turn the floor over to Dr. Offit.

PAUL A. OFFIT, MD: Thanks, Randy. What I thought I would do—and I can do this in about five to seven minutes—is talk briefly about the Hannah Poling case and discuss to what extent, if any, this has implications for the Omnibus Autism Proceeding.

As Randy said, there are really three theories that have been proposed as to why vaccines could cause autism. One centers on the fact that MMR caused autism, the second that thimerosal caused autism, and the third is that the combination of the two did. The Hannah Poling case really represents, sort of, a fourth area that's been floating out there, promoted largely by people, such as Jenny McCarthy, and that is that children get too many vaccines too soon. So the Hannah Poling case went as follows. This is a girl who has a mitochondrial enzyme deficiency and has associated with that mitochondrial enzyme deficiency an encephalopathy, which means signs and symptoms associated with brain dysfunction and some of those symptoms or signs included autistic features. The timeline is that the parents—the father, actually, a neurologist, the mother, a nurse and lawyer—submitted the claim that multiple vaccines that the child had received when she was 19 months old had worsened an encephalopathy that included these autistic features. In November of 2007, the Vaccine Injury Compensation Program conceded that this was possible and decided to award her claim, and in March of 2008—and this is something you're all familiar with—the parents decided to take their case to the press and the public claiming that this was a landmark decision in the notion that vaccines could cause autism.

I just want to, sort of, go through a few reasons why I think the decision, or the concession, that was made by the court was a bad one. The first is, while it is clear that natural infections can exacerbate or worsen symptoms of children who have encephalopathy associated with mitochondrial enzyme defect, there remains no evidence that vaccines do this. In fact, for the reason, children who have mitochondrial enzyme deficiencies are recommended to receive all vaccines in the same timing and manner that other children are recommended to receive them.

The second is the belief that multiple vaccines can weaken or overwhelm the immune system is at variance with the current vaccines which we receive. I mean, I would argue, and actually did argue, in something that was published in the *New York Times* as an Op-Ed piece at the end of March, that if you look at the vaccine that we had 100 years ago, the smallpox vaccine, I mean, that vaccine contained about 200 immunological components. Pox virus, this is the largest known of the mammalian viruses, and so, had about 200 immunological components, counting any sort of bacterial polysaccharide, or bacterial protein, or viral protein as the immunologic component. If you look at the 14 vaccines that children receive today, given the advances that we have in protein chemistry and protein purification and recombinant DNA technology, the total number of immunologic components is about 150, so we actually have less in the way of immunological challenges with the 14 vaccines that children receive today than with the one vaccine that they received 100 years ago.

Third, although experts or anyone, I think, could reasonable argue in the Poling case that when a child receives a vaccine—and we know that vaccines certainly can cause fever—that that could be a stress on a child who has a known encephalopathy caused by a mitochondrial enzyme defect. That's certainly true. What I have trouble, however, understanding is how the court was able to separate that out as a more significant stress than the typical stresses that children occur in the first few years of life. I mean, this was a girl who had multiple episodes of fever associated with both upper respiratory tract infections and gastrointestinal infections. In fact, she had frequent ear infections that were severe enough to require her

to have receipt of bilateral placement of ear tubes, and Hannah's story is actually fairly typical. There was a study of 25,000 illnesses in Cleveland in the 1960s, which found that children less than six years of age will typically have four to six febrile episodes a year associated with respiratory or intestinal infections and that certainly is a far greater stress than anything that any child would receive from vaccines.

Fourth, and I think probably most importantly, is that the court, I think, inadvertently sent the wrong message here because the message is that children—I think its been taken this way—is that children who have mitochondrial enzyme deficiencies perhaps should have vaccines delayed, or withheld, or separated, and that would only mean then that those children would have a longer period of time to which they were susceptible to infections which are known to cause exacerbations of their encephalopathy and, I think, only has the possible affect of causing harm.

I think two other points I want to make and then I'll stop. It was striking to me, an interview that was done by Julie Gerberding with Sanjay Gupta at CNN where she made two statements that appeared to be contradictory, but when you look a little closer, I think, aren't. At the beginning of her interview with Sanjay Gupta on CNN, what Dr. Gerberding said was the court has determined that it is possible that children who have a mitochondrial enzyme deficiency that receive vaccines, which we know can be a cause of fever could cause a stress that would lead to a worsening of symptoms associated with—in this case, that included symptoms or signs of autistic features. But then later in the same interview, she said, but all the evidence to date shows that vaccines don't cause autism.

So how do resolve those two apparently contradictory statements? I think the way that you resolve it is to think about the way that Dr. Gerberding really defines autism. I think in the later case when she's saying that vaccines don't cause autism, what she really means is that they don't cause classic autism and that's distinct from children who have mitochondrial enzyme deficiencies, or Rett syndrome, or fragile X

syndrome, or Down syndrome where certainly those disorders can be associated with autistic features, but its really not what parents—I mean, I think its not what the press or public understands to be classic autism.

So I'll conclude by saying that I think that this isn't the end of it. I think that what's so endearing to me about the anti-vaccine people is they're perfectly willing from one hypothesis to the next without a backward glance and I'm sure that we aren't going to have anymore backward glances as we move onto things like aluminum, or activating agents, or other preservative, or manufacturing residuals. And hopefully, the media will be a little skeptical about these continued new claims that pop up.

Thank you. And now I turn it over to Dr. Gerber who knows much more about autism than I do.

ANDREW J. GERBER, MD, PHD: Thanks, Paul. So I'm going to be very brief because, in every way, I really see my role here as answering questions about autism and supporting the issues that come up around autism, specifically because I'm not an expert in vaccines at all and know the literature, but don't do research in that area myself.

A few things that I wanted to say to pick up on some of the points that Paul and Amy and everyone has raised already, so the first think, I think, that I want to be clear about is where I think the general state of research in autism is, and to do that in a way that's both hopeful about the future, but also to acknowledge how little we know. I do brain imaging and I'm involved in some genetics research. And the truth is that we really do not have any comprehensive understanding yet of what are the causes of what people mean by autism and I'm going to come to the word autism in a little bit.

We do know that there is a strong hereditary component. And we know this through twin studies that look at identical twins and see that if one identical twin is diagnosed with autism, there is a very chance—

somewhere in the order of 90 to 95%—that the second twin will be diagnosed with autism. Whereas, fraternal twins, who share much less of their DNA, have a much lower chance, actually, one not that different from just if any sibling or direct relative had, which suggests to us—and of course, identical twins and fraternal twins, where they're raised in the same family, should have a very similar environment—so it suggests to us that the DNA code is playing a strong role, but, of course, its not 100%. And we don't yet understand what are the factors that lead the expression of this genetic predisposition to come out in some, but not others.

Now the term that then gets used—and I use it and genetics researchers use it all the time, but I think it's sometimes misunderstood and people help me understand it, is that we say well, if its not the DNA code, then its environmental. But by environmental, we mean everything other than the DNA code and that includes all sorts of random events that happen in utero, that have to do with the placenta, that have to do with the way the fetus develops, things that happen in terms of the reading of the genetic code, which are not specifically about the code itself, but things that are going on inside the body. We don't specifically mean environmental toxins and I think it's often heard that that's what we mean when we say environmental. Now of course, toxins from the environment could count, but we have no data to support, right now, that they do. And I think autism researchers are always very—me included—very hesitant of saying well, we know its this or that because we don't, but if there's anything that I think we have some decent data to suggest its that the toxins that have been implicated so far, or that people have suspected so far, have not turned out to be major causes of what we mean by autism. So that's to try to put into perspective a little bit of that.

Of course, we hope this is going to change. That we're going to be able to identify specific genes much better. We've identified some candidates, but nothing very specific yet, and then, of course, to understand why in some kids it develops into the full disorder and in some, it doesn't.

Now the second thing that I wanted to mention is this thing about what we mean by autism, and I think Paul was touching on this now. And I think it won't come as a surprise to anybody listening that it's not one disorder. It's at least several and it's probably hundreds. That is there are autisms. It's an autism spectrum disorder or disorders. And what that means is there are certain features in common that allow us to group them and you guys know what those are, the communications, repetitive behaviors, and social interactions, but that encompasses a lot of different things.

Now you can imagine that there are reasons to lump and there are reasons to split. The reason to lump is to say hey, listen, we need to understand better about how the brain develops these faculties and learn about something that they have in common. But in doing so, I think we sometimes give the wrong impression that it's a single disease that we can then find a single culprit and, of course, all the discussion and fears about an epidemic and the rising in rates, which itself is a complicated issue, feeds into that notion that it's a single thing that if we only figure out what's doing it, then we can solve it. But I think that the phenomenology and the clinical view of it is it's clearly not one thing, and it probably has many, many different causes, many of which are related to the genetic code and many of which are related to various complicated triggers.

So I think that's, kind of, where I want to leave it and to say that I think that there's so much more we have to learn, but at the same time, of course, we have to be careful not to, sort of, in the vein of saying we don't know yet, give too much credibility to some of the theories for which there's really no support, like that vaccines cause it. Thanks.

AMY PISANI: Thank you, Dr. Gerber. This is Amy again, and we're now going to open up the line for you to ask questions. Operator?

OPERATOR: We have a question from Mike Stobbe. Go ahead, please.

MIKE STOBBE: Hi. Thanks for taking the question. Randy Moss, a question for him, you were giving, kind of, a history of the three sets of theories, and then you mentioned under the second theory, the thimerosal alone that we're down to two test cases. Do you mind just a little more background on what happened to the third that dropped out?

RANDOLPH D. MOSS: You know, I don't know the details of why it dropped out. I just know that the court indicated that it was withdrawn as a test case, but I don't know the details about that. And I should say one thing about this—there may be more information out there in the public domain about it—but one thing that is a little bit tricky in this area and it relates to, I think, the press reports about the Poling case and there's a rule in the Vaccine Act that says that information that is submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information. And so while there's a fair amount of information that is public and is available—actually, you can find it by going to the website for the court and they publish their orders and reports.

There's also a fair amount that is not public and not known. And in fact, the three special masters who are handling the autism cases—the test cases—issued, sort of, an unusual and, I think, fairly unprecedented statement in their March report and they said there have been reports concerning a certain case. They didn't identify the case. And they said these reports erroneously state that the court has rendered a decision, opinion, or ruling in that case. And the court said we're not at liberty to say more about it at this point in time in light of that provision that I just mentioned on the confidentiality of certain information that is in the proceedings and the government's hands are tied in the same way. I mean, the government can't go out and respond, I think, to some of the press reports relating to proceedings where there has not been the written consent of the person to make, you know, all the information public.

And so I just, sort of, raise that as both to indicate that at times it's a little bit tricky to know how to think and to talk about some of these cases because we ourselves don't know everything that's going on. I'm not sure that's true with respect to the withdrawn case or not, but in general, that's an issue. And also that I think there's just some caution that's necessary in speculating about what's going on in the court and what's actually driven particular decisions where it's not actually on the public record because some people's hands are tied on what they can say about it.

OPERATOR: Okay. Our next question is from Tom Corwin. Go ahead, please.

TOM CORWIN: Hi. Thanks for taking the question. I've been following some quadruplet boys who were diagnosed with autism about seven years ago and the mother's theory about how they got this was that they were premature, they were underweight for their age when they were vaccinated, and that there may be some genetic component, but that somehow, all of these things taken together, sort of, tipped the edge—you know, led to the tipping point, and that's how they developed the disease. I've talked to Dr. Offit about this idea and I was wondering if either Dr. Offit or Dr. Gerber would address that, sort of, theory that I think a lot of parents are, sort of, playing around with.

PAUL A. OFFIT, MD: This is Paul Offit. I can at least address part of it. I think, you know, the notion that vaccines could weaken or overwhelm the immune system of a premature infant, I just don't think is founded or well grounded in children—including premature children—are typically exposed to during the day.

You know, when you're in the womb, you're in a sterile environment. When you enter the birth canal and then the world, you're not. And very quickly you become colonized with billions, and later, trillions of bacteria to which you make an immune response. I mean, typically, premature infants will make—and they can start responding to foreign protein or foreign antigens by 14 weeks of gestation. I mean, the only

difference is, is that when you're in the womb, you're for the most part, are not exposed to foreign antigens, so your immune cells are likely naïve at birth. But when you're born, and including prematures, which is to say anybody who's less than 36 weeks gestation, I mean, you can respond, really start to make, you know, vigorous immune responses by the time, roughly, your 24–25 gestation and that's really, sort of, the limit of viability for prematures.

You know, and when you're colonized with these bacteria, you know, you have to be able to make an immune response that keeps those colonizing bacteria colonizing, otherwise, you know, they enter the lymphatics or the blood stream and cause serious defects or a serious disease. I mean, to give you a sense of the massive numbers that you encounter of bacteria, I mean, you have about ten times more bacteria that live on the surfaces of your body than you have cells in your body. Each individual bacterium has between 2,000 and 6,000 structural proteins to which many of which, you make an immune response to that. If you add up the total number of immunologic components in the 14 vaccines that we have today, it's only about 150. I mean, it's literally a drop in the ocean of what kids typically manage and respond to.

I mean, if any mother wants to, sort of, you know, scare them self, just take a nasal swab, swab the child's nose, put it on a microscope slide and look at it under the microscope. It's teeming with bacteria, to which children make an immune response. So I think the theory that vaccines were somehow weakening or overwhelming even a premature child's immune system just doesn't jive with the facts.

ANDREW J. GERBER, MD, PHD: Okay. You know, the only thing I wanted to add to what Paul said—'cause I think he answered the question really—is that the notion of multiple factors coming together is, of course, one that we believe in. That these complex illnesses, like autism that are many different types of illness clearly have a myriad of factors, so that part of the theory I wouldn't want to lose. It's the part that says that one of those important factors is the vaccine that I think you have to listen

to the science and to the lack of evidence to support it, even as one small component of it, in order to evaluate it.

TOM CORWIN: As an aside, Dr. Gerber, have you come across anything that says multiple births may have a higher risk factor for autism?

ANDREW J. GERBER, MD, PHD: No, I don't know that. You know, there's a lot written and it's possible that something is out there, but that's not something that I'm aware of.

TOM CORWIN: Okay. Thank you.

OPERATOR: We have a question from Brenda Stansberg. Go ahead, please.

BRENDA STANSBERG: Yes, I think in the Hannah Poling case that the decision was that the injury was due to some underlying mitochondrial disorder, and I wondered how many of the cases now pending before the court might involve the same kind of situation that was involved with Hannah Poling.

PAUL A. OFFIT, MD: Randy can probably answer that better than I can. I'll take a stab at it, though. I mean, you know, the theories that are being proposed is that either MMR or thimerosal or the combinations of the two were what caused autism. I'm not sure to what extent the Poling decision, which at one point was part of the Omnibus Autism Proceeding, but was taken out of it is going to, in any sense, be reflective of these, you know, roughly 5,000 children whose parents have submitted their claims. Randy can speak to this better than that.

RANDOLPH D. MOSS: To my knowledge, there's not a fourth theory currently in the program and no one in the program has alleged that theory. You know, whether someone might do so in the future, you

know, we'll have to wait and see, but I'm not aware of it at this point in time.

BRENDA STANSBERG: So the Hannah Poling case is totally separate from the other, you know, 5,000 cases?

RANDOLPH D. MOSS: Well, it is not one of the test cases. And I guess I would just stress again about that case that, you know, I'd, sort of, point folks to what the special masters said when they said that, you know, it was a case where there have been press reports that there was a decision, opinion, or ruling, and that's not true.

PAUL A. OFFIT, MD: Its Paul Offit again, just one thing, I think first of all, it never went to court. I mean, it was conceded by the Department of Health and Human Services, but, you know, the question that one could reasonably ask is why was it taken out as one of the original test cases? And I think my sense is that—and, you know, obviously, its hard to know because the government doesn't tell us—but, I mean, one reason may be that its really not considered a case of classic autism and as Dr. Gerber alluded to before that there are autisms and that this is more appropriately labeled as mitochondrial enzyme defect with autistic features and so I think they were hoping to, sort of, take it out separately. I think they conceded it because there are, as the table injuries, certain vaccines, like measles-containing vaccine or pertussis whooping cough vaccine that can, you know, “be associated with encephalopathy,” although the science for that is actually fairly weak. And that may be why they choose to separate it out, although obviously, the parents saw this as an opportunity to go to the public with what they believed to be true which is that multiple vaccines, you know, can exacerbate symptoms of autism.

BRENDA STANSBERG: Okay.

OPERATOR: Our next question is from Arthur Allen. Go ahead, please.

ARTHUR ALLEN: Yeah, I had two questions. One is for Randy Moss. Kathleen Seidel has a - - that, sort of, tracks some of the stuff in the vaccine court, found a bunch of cases over the last 20 years in which there were children with autistic symptoms who, I think, got awards. They had a variety of underlying conditions. I think some of 'em had tuberous sclerosis and other conditions. And what I was just wondering was in the face of this Poling case whether anyone had combed through the records to see whether any previous children awarded by the court had underlying mitochondrial syndromes.

PAUL A. OFFIT, MD: Interesting question. I have not done that and I don't know if anyone has, but that's an interesting question.

ARTHUR ALLEN: And my other question is just a general question about antigen load, I guess, for Paul. When you say that, I mean, the number of antigens is lower than it was when we were getting smallpox vaccine. I mean, when you get a single-antigen vaccine, or a vaccine that has a limited number of antigens, what's the actual, sort of, you know, number of antigens of particular type that you're getting in comparison to what you get when you get an infection with that disease, if you could give an example of that?

PAUL A. OFFIT, MD: Yeah, that's a good question, Art. I would say—and it's hard to quantitate exactly, but, for example, if you look at, let's say, the live weakened vaccines, like measles, or mumps, or German measles, rubella, or chickenpox, those viruses have been altered so that they can't reproduce themselves as well.

ARTHUR ALLEN: Right.

PAUL A. OFFIT, MD: So the question is how altered are they? I mean, so let's say measles is a virus,

you know, it's a small RNA virus that has ten proteins. Its when it reproduces itself under natural conditions of infection, it probably reproduces itself thousands of times, so that those ten proteins get expressed thousands and thousands of times, as the virus reproduces itself in cells of the skin, in cells of the lung, and in cells of the brain.

And interestingly, you know, if you look at children who are naturally infected with measles virus and give them chest x-rays, you know, all of them, what you find is about 75% have evidence of pneumonia, so the ones that get hospitalized, which is roughly one in five, is just the tip of the iceberg of what is a pretty significant viral infection.

If you look at measles vaccine virus, you know, its given, you know, underneath the skin and appears to replicate locally, but probably less than 20 times, so that, at least, gets at that somewhat. Obviously, you know, for disease like diphtheria, you know, which causes disease by making this toxin, this single protein, which, you know, can affect the brain and can affect the kidneys. You know, it's made in quantities, obviously, much, much greater than one sees with the vaccine, but the vaccine in that case, you know, takes that protein and completely inactivates it, so it's incapable of causing, you know, its poisonous affect.

ARTHUR ALLEN: Thank you.

ANDREW J. GERBER, MD, PHD: If I had just a second to correct something I said earlier, the miracle of conference calls is that I was able to look up this issue as to whether people have found a relationship between multiple births and the risk of autism, and in fact there are some reports of a link between them. I don't think it's a large enough contributor that a lot of people think about it, but there are some studies that show that link

OPERATOR: We have a question coming in from Brenda Stansberg, go ahead.

BRENDA STANSBERG: I wanted to ask, was thimerosal taken out of vaccines in 2001?

PAUL A. OFFIT, MD: Thimerosal was basically removed from all vaccines at preservative levels with the exception of some preparations of multi-dose influenza vaccine, which still contain thimerosal and probably will until at least 2009, probably 2010.

BRENDA STANSBERG: Ok.

OPERATOR: It looks like we have a question from an internal line, please go ahead.

ALISON YOUNG: This is Alison Young with the Atlanta Journal Constitution, I was hoping on the issues relating to what people can and cannot say about vaccine court cases, specifically there are those who are concerned on worried whether HHS made a mistake in settling the Polling Case. Under the rules of the vaccine court, if HHS is the party that submitted the documents to the court settling the case, would they be prohibited themselves from talking about why they made that decision?

RANDOLPH D. MOSS: In submitting something, it's likely that the Justice Department would report information that it received from the petitioner in the process, so if there was anything of substance about the condition it would have been based on information that they presumably would have received. The answer to your question is that I know that in respect to that particular matter they have taken the position that they are really not in the position that they can really say much.

OPERATOR: There are no more questions.

AMY PISANI: Ok, well I want to thank everyone for joining the call. I want to thank the speakers particularly for taking the time to educate us on the issues, and if you have any further questions you can always email me at amyp@ecbt.org. You can also call me at 860-443-1166, I'm happy to forward any of your questions to the speakers or I'll help you if I possibly can. Thanks again to everyone and have a great day.