UNITED STATES
COURT OF FEDERAL CLAIMS

CONCURRENT VACCINE PROGRAM/)
VACCINE COMPENSATION UNDER)
THE ACT: A MIX OF SCIENCE)
AND POLICY?)

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IN THE UNITED STATES COURT OF FEDERAL CLAIMS

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THE ACT: A MIX OF SCIENCE)
AND POLICY?)

Senate Room
Capital Hilton
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Washington, D.C.

Wednesday,
November 19, 2008

The parties met, pursuant to notice of the Court, at 9:35 a.m.

BEFORE: HONORABLE GARY J. GOLKIEWICZ
Chief Special Master

ATTENDEES:

Moderator

SENIOR JUDGE LOREN A. SMITH

Panelists

DR. PAUL A. OFFIT
Children's Hospital of Philadelphia

KEVIN P. CONWAY
Conway, Homer & Chin-Caplan

RANDOLPH D. MOSS
WilmerHale

RUTH J. KATZ, Dean
School of Public Health & Health Services
George Washington University

MARGUERITE EVANS WILLNER
Advisory Commission on Childhood Vaccines

P R O C E E D I N G S

(9:35 a.m.)

CHIEF SPECIAL MASTER GOLKIEWICZ: Okay. They're going to be bringing in some more chairs for those that are standing back there.

I'd like to introduce myself. I'm Gary Golkiewicz. I'm the Chief Special Master of the Court. I'd like to welcome you this morning to the Vaccine Session, which is Vaccine Compensation Under the Act: A Mix of Science and Policy? The question mark was missing from the brochure.

It might strike some as odd going into this twenty-first year of litigation that our panel here is going to discuss the bases for compensation under the Act, so I want to give you just a very, very brief introduction to this morning's panel.

As we know, the Vaccine Act was enacted to address the litigation crisis affecting vaccine supply. That's as far as I'm going to go because our panel is going to discuss more of the history of the Act.

Specific to the issue of compensation, to ease the finding of causation Congress created a vaccine injury table, which we also know created a rebuttable presumption of causation if you proved

receipt of a covered vaccine, described injury within a prescribed timeframe.

However, over the years the table has taken on less importance in the program, and cases are primarily resolved under traditional tort standards of causation. This in turn has highlighted a debate over legal versus scientific causation.

The Federal Circuit has stepped in with several recent opinions which emphasize the reduced standard of proof, a simple preponderance Congress required to prove causation under the vaccine program.

For example, the Circuit has said that the system created by Congress is one in which close calls regarding causation are resolved in favor of injured claimants. However, even with the Circuit's explanations of the causation standards, in some circles the vaccine decisions are criticized as not reflecting science.

This brief background leads us to the subject of the vaccine session and whether decisions to compensate under the program should reflect science or whether they should reflect the congressional policy desire that "the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from

litigation," or should they reflect some combination of science and policy.

To explore these issues and more, I'll turn the panel over to my former boss and very close friend, Loren Smith.

(Applause.)

MR. SMITH: Thank you very much, Chief Special Master. One of actually my things I'm most proud of is the people who I've worked with. When Gary Golkiewicz was my chief of staff, a Chief Judge couldn't have asked to work with a better person.

We struggled with this Act at the very inception when it was passed in 1986. There was a period of course in the interim before any funding was provided, so there was this Act out there with potential cases, but no way in which those cases could be handled because of the split between the authorization and appropriation processes.

But in the interim, Gary and I worked with, and this is what I think the Court is most proud of. We worked with the whole Vaccine Act community -- with the attorneys for petitioners, attorneys from Department of Justice and the Department of Health and Human Services, pediatricians, drug manufacturers or vaccine manufacturers, a whole range of individuals

and representatives of the parents, of children who had been injured by vaccines who really saw this with the real depth that no one else sees it.

Through that process we created an advisory panel to help the Court in implementing this Act so we had rules and a system that not only was efficient, but fair to the parties. I think this was a particular challenge, and this was a unique kind of program.

While government doesn't do many things the same way next time they do them -- there's always significant variations -- this was kind of a new model which there was no set of blueprints for, no template for. Instead, kind of we built it as we went along, sometimes with missteps, other times with surprising luck in doing that.

Even the numbers. No one had a real grasp on how many of these cases there would be. I think one high estimate said 900 over the next number of years, and it would never be more. It was inconceivable to be more than 900 a year. Some said it might be 50. There were some people who said, in making decisions on funding, that it might be virtually nothing that we would get.

No one really had a sense of the magnitude

of the program, and in the first year or just before the statute of limitations expired there wasn't a lot of cases in the first year, year and a half, but then they started to build up very rapidly to really a peak climax in about four or five days when our Court, which normally has two to three new cases a day --

Most of the business of our Clerk's Office are the ongoing 2,500 or so cases of nonvaccine cases at that time. There were being filed every day motions and such, but new cases were about two to three a day. The peak day of that last week was 1,200 cases. That was supposed to be like the total universe of cases.

I remember there was a line -- the only time I've seen it -- outside the building. Fortunately it was warm weather, but it was outside the building where people were just lining up in some cases with boxes. I remember I saw one attorney who had 90 cases they were filing.

So those challenges really created a program that I think we have a good reason to be remarkably proud of, a new system. New systems are never completely perfect, but that was really through the cooperation of the people in this audience, the employees of the Court, the people who represented the

United States, the private bar and the parents of children, all of these participating to making a program work. No program works perfectly, but this program I think has pretty high marks for doing things that help people.

Well, we have a great group of people here who are going to try to help explore this particular issue, and we're going to do it kind of in a conversation manner. First I should, though, introduce each of these people very, very briefly because you have their full and very distinguished resumes in your materials.

Dr. Paul Offit is Chief of Infectious Diseases and Director of the Vaccine Education Center at Children's Hospital of Philadelphia;

Kevin Conway is a partner in Conway, Homer & Chin-Caplan. He's been a petitioners' counsel for 20 years, and I think this is Kevin. I thought for a moment it was Tony Shalhoub sitting there, Mr. Monk, because Tony Shalhoub played Kevin in *A Civil Action*;

Randolph Moss is a partner in WilmerHale and has represented vaccine manufacturers;

Ruth Katz, who is a professor, and Walter Ross, Professor of Health Policy, at the School of Public Health & Health Services at George Washington

University drafted the Act for Congressman Henry Waxman, and I know it's great to see Ruth because we worked together for a period of about two or three years, which doesn't seem like it was 20 years ago. Neither of us has aged. We immediately looked like we were back to discussing the Act, and we are;

And Marguerite Willner is former Vice Chair of the Advisory Commission on Childhood Vaccines.

I want to give this panel a round of applause.

(Applause.)

MR. SMITH: That's always good to do in advance because if you don't like what they say then you get mad at them, but now everyone is happy with everyone.

All right. Let me first ask Ruth. How and why was the statute adopted? What was its background and its theory?

MS. KATZ: Before I go into a little bit of the background, let me say how delighted I am to be here some 22 years later since we enacted what I think has been a very important and very successful piece of legislation.

Judge, while you and I haven't gotten any older over the past 22 years, Gary certainly has.

When I first met him he wasn't wearing glasses. I just noticed them up there this morning.

In any event, it's great to be here and to have this opportunity to participate in this conference.

Since I imagine that virtually everyone in this room is involved in this program one way or another, I'm not going to go into much detail about what is in the program, but let me give you a little bit of historical background.

As you've just heard, the legislation was enacted in 1986. That was the authorizing piece of legislation that actually set up the framework for the program that is now in place. It took us another year of work -- it took us until 1987 -- to actually enact the funding mechanism, a tax which was placed on the vaccines that actually provides the source for the compensation that is provided.

Going back now to 1986 when we were working on the legislation, there were really three overriding issues that I think led to the enactment of the legislation. First, and they're actually not in any particular order.

First was the inadequacy I think from both the perspective of vaccine injured people and their

families, because mostly we're talking about children here, as well as vaccine manufacturers themselves of the then current, meaning 1986 and previous to that time; the then current approach to compensating those injured by doing, if you will, their public health duty. That is, getting vaccinated.

After all, all children in this country, virtually all children, are required under state law to be vaccinated in order to go to school, so we're requiring them to do something to protect the public health.

If they're injured in that line of duty the sense was that we should find a way to compensate them in a system that was better designed than the one we were operating then, the tort system, which was long, it was complicated, and it was unpredictable.

The second overriding issue that was a concern at that time was the instability and the unpredictability of the childhood vaccine market at the time. In 1986, as some of you may know, there were only three manufacturers in the United States of childhood vaccines. They were threatening to leave the market because of a perceived threat of liability.

The committee actually had done a report that I think one could argue that it was more of a

perception than actually how much these manufacturers were paying out, but, nonetheless, the perception was that manufacturers were being sued right and left and that they were making big payouts.

They threatened that they would leave the market, and from our perspective on the Hill that would leave this country with perhaps no manufacturers of vaccines, something that we felt we had to have on the domestic front.

Finally, and actually maybe perhaps most importantly, the third overriding concern was our ability and our commitment to maintain a high level of child immunization rates in this country. That is something that the country, the states and the federal government have long been committed to, and unless we were willing to address the first and the second issues our concern was that we would not be able to maintain these high levels of immunization rates.

So with those three overriding concerns we really had three major players, if you will, in working on the legislation. First was the parents of those kids who have been injured, secondly were the manufacturers, and third were the pediatricians who were very, very involved in enacting this legislation.

As an aside, I might say having really only

three main players to work with made it a lot easier to work through all these issues. If you take a piece of legislation like healthcare reform where you have lots and lots and lots of players it's far more difficult to try and find consensus.

The legislation that was finally enacted was no one's first choice -- therefore, a compromise in many ways -- but certainly was a piece of legislation that all three of these groups and other organizations and players who were not as directly involved, but the general consensus that this was a very good way to go.

So under the legislation itself we established, as you just heard, a new system for vaccine injury compensation that was designed really we felt to be fair, simple, quick and generous, so we established a no-fault system under which all individuals who claimed to have been injured by a vaccine had to go through.

In other words, you couldn't go through the regular tort system, although we did leave open that opportunity at the end of this process, but you had to first go through the no-fault system.

That system of course includes, which I know will be a big topic of discussion today. That no-fault system includes a vaccine injury table that's

actually established in the legislation. The legislation also allows for the Secretary to update it periodically, and I understand that that in fact has been done over the 22 year history of the program.

Basically if a petitioner has an injury that appears on the table, the idea was the only question that had to be resolved was how much compensation would that individual actually receive.

As I just suggested a moment ago, the legislation also preserved the right of individuals to go to Court if they were not satisfied with the compensation that they received under the system. They could go through the regular tort system, although, as I'm sure you all know, the rules for how you could proceed through that process were altered in the legislation.

I know we're going to get into much more of a discussion about the individual parts of how the program works, but, looking back over the 22 year history, I think from my perspective it's fair to suggest that the program has been successful on many fronts.

One, for those individuals who have injuries that are on the table, I think the system has been very good in being quick and fair and compensating

very fairly and generously indeed.

Secondly, I think there's no doubt that we have more manufacturers, more vaccine manufacturers out there. We have lots more vaccines that are on the market.

Finally, although certainly we see in the papers and certainly have some concern about children or their families who elect not to be vaccinated, by and large overwhelmingly kids and their families do get vaccinated, and we have been able to maintain a very strong level of vaccine rates in this country.

So I think that's a brief introduction.

MR. SMITH: Ruth, thank you.

Let me ask other panelists if they have any comments. The one comment I would make is in those early days it was really tense, and Gary and I were both pulling out our hair. Mine grew back. Gary's is still coming a little slower.

Does anyone want to comment on that early history or the theory on the panel?

MS. KATZ: Kevin has a comment.

MR. SMITH: Okay. Kevin?

MR. CONWAY: Yes. I'll make a comment. First of all, I'm Kevin Conway. I actually in my work as a lawyer have worked for major corporations, I've

worked for governmental agencies, but for the past decades I've worked representing vaccine injured people.

I was actually involved before the program was enacted. I was one of those attorneys that were suing manufacturers for vaccine injuries. At that time there were basically two vaccines that were causing the problems. There was a polio vaccine and a DPT vaccine.

In the civil theory you had to show that there was something wrong and that the manufacturers were at fault. They did something wrong. It was a fault system. We actually thought it was working fine because we were doing well, making lots of money.

We didn't think there was anything wrong with the civil system, but it did create a crisis because the manufacturers thought there was something wrong, and they decided to stop making vaccines because it wasn't profitable. You know, they're a business, and it wasn't profitable.

So Congress stepped in, and they made a policy decision. The policy decision was to promote our public health you've got to maintain the current supply of vaccines and encourage the development of new vaccines, and the policy was they're going to do

this by stopping lawsuits. That was the primary purpose.

Although Ruth said that there were three main purposes, I'll put it in order. Number one was stop losses. How do you stop the losses? First of all, you require that people go through the vaccine program, and you create an attractive alternative to it.

The attractive alternative is to be generous, be quick, to have a streamlined system, and even though you're allowed to reject the program it says and come back later and actually go into the civil system, they discouraged that.

They discouraged that in many ways. They discouraged it by being generous first, by saying that the program will pay attorneys like me. There are no more contingency fees, no more 40 percent for the attorneys. It designed a system unlike the system that existed before for those cases that did come out of the program. It limited the theories of liability. It staged the proceedings. It made it harder.

But the biggest thing that it did, and this has to do with the second policy, is that it had a relaxed standard of scientific proof, and the relaxed standard of scientific proof was so that people

wouldn't reject the program because they could prove it in the program, but they couldn't prove it out of the program. It was to encourage them to stay there.

The Federal Circuit has said what is that relaxed standard of proof? Basically if you're healthy and you get a vaccine, the vaccine can cause the injury you have. It did cause it if the first systems were within a reasonable period of time and there's no alternative case. That's the relaxed standard of proof. That's what you need to prove in the vaccine program.

As Ruth said, the program has worked in many ways. Certainly there's many new vaccines. There's multiple vaccines. The vaccine table is nonexistent. You know, that quickly became irrelevant to the program. Most -- 99 percent -- of the cases in the program are off-table cases.

Before the program, all scientists agreed that sometimes vaccines cause harm, but you can never prove it in the individual case. That's the same today as it was back then, but Congress said so you can resolve cases in the program it's okay. The worst thing that could happen is somebody gets compensated who wasn't injured by a vaccine, and as a matter of policy that's acceptable to us.

MR. SMITH: Dr. Offit, do you agree with Mr. Conway's point?

MR. OFFIT: There are two points that I find surprising.

The first is it's too bad Albert Sabin is not here to find out that he made his oral polio vaccine wrongly. I mean, when Sabin made his vaccine in the late '50s and early '60s he did it using a fairly conventional means of weakening the virus by passing it in cell culture.

When that vaccine was then licensed and recommended and used in this country in the early 1960s, you went basically from 15,000 -- anywhere from 15,000 to 50,000 -- cases of polio a year down to essentially eliminating that disease. You eliminated a disease that clearly caused paralysis and death in this country.

Now, the vaccine had a side effect which was awful, which was that the vaccine itself could cause paralysis, and as we got better with the science, with protein chemistry and protein purification, and could make a better inactivated polio vaccine one vaccine replaced the other.

But to say that the oral polio vaccine was made wrongly I think is just not correct. It had a

side effect which was bad, but certainly at the time when polio was epidemic in the United States, epidemic and endemic, that vaccine was much more likely to save your life than hurt you.

Secondly, I think just the terms I guess I disagree with a little bit. I mean, first of all, the notion that one has a scientific proof in Court is just not one I'm familiar with. I think that scientific questions are answered in scientific venues. The Court seems to me a place where one settles disputes only.

MR. SMITH: Let me ask before I get to Randy.

Dr. Offit, how does science, as distinguished from law, make causal decisions? That's one of the issues I know that the Supreme Court has grappled with in the Daubert line of cases.

What is the difference? Because in this program we have a little bit of both, don't we?

MR. OFFIT: Yes. Actually, that's what I was going to talk about for about five minutes. Do you want me to sort of do my little five minute thing now?

MR. SMITH: Yes. Why don't you do that now?

MR. OFFIT: Okay.

MR. SMITH: Then I'll let Randy come in.

MR. OFFIT: So I was going to use actually as an example a true story in our hospital that occurred about a year, year and a half ago.

There was the mother of a child with leukemia who came in and brought her five-year-old who had a bleeding disorder, and she wondered what could have caused that leukemia.

She racked her brain trying to figure out what it was, and to her the thing that had caused this boy's leukemia was that about six months earlier for the first time in his life and the only time in his life -- and this is true; I'm not making this as a joke -- he had eaten a peanut butter sandwich. She was convinced that it was that peanut butter sandwich that had caused his leukemia.

Well, that's actually a question which is a scientific question that can be answered in a scientific venue best by doing epidemiological studies. You could then look at children with leukemia. Acute lymphocytic leukemia is not an uncommon disorder.

You could look at thousands of children with leukemia and try and match them with thousands of children that don't have leukemia and make sure that

they're alike in all other aspects in terms of their medical background, their socioeconomic background, so that you can try your best to isolate that one variable, which in this case is the ingestion of peanut butter sandwiches, and see whether or not those who have leukemia are more likely to have eaten peanut butter sandwiches than those who haven't.

I mean, I don't know if those studies have ever been done. I suspect they never have, but I'm going to make the assumption that if one did those studies you would find that there was no association between eating peanut butter sandwiches and having leukemia.

The best way to do that would then be to have a number of investigators do that study using different populations of children, different countries, different groups of investigators, and I think one could say then that the truth has emerged.

If that came to this Court I think the first thing that would happen is that the epidemiology would largely be set aside. It would be set aside for two reasons. One, because one would argue or plaintiffs' lawyers may argue that epidemiological studies are only so sensitive.

In other words, a powerful epidemiological

study can detect an association of say one in 100,000, but it's not going to detect an association of one in several million. So if there's one child every year in a birth cohort of three and a half to four million that gets leukemia following a peanut butter sandwich ingestion, you're not going to be able to show that.

The second thing is that the epidemiological studies really never offer proof. I mean, you can argue that at least from an epidemiological study standpoint there are no proofs. I mean, the head of our Center for Epidemiology and Biostatistics at Penn -- probably many of you know him, Brian Strom -- calls it the P word. I mean, you're not allowed to say the word proof because you cannot prove anything.

What you do is you show that there are statistical associations that become stronger and stronger the larger the study and the more numerous the studies.

For example, when I was a child I watched Superman on TV -- you know, the George Reeves version -- and he would fly. I mean, he would put his arms in front of him. He would have a cape on his back, and he would fly.

I believed since it was on TV and therefore it had to be true that I too could fly, and so I put a

towel on my back and stood on a small height in my backyard and tried to fly maybe five times unsuccessfully. It was probably no surprise to you that it was unsuccessful, but that doesn't prove I couldn't fly.

I could have tried a billion times, and that too wouldn't have proven I couldn't fly. It only would have made it all the more statistically unlikely, which is to say that you cannot statistically prove that something is statistically impossible.

And so all that good epidemiology at least, it seems to me, in this Court would get set aside. So then we're left with how would you then handle that peanut butter case in this Court?

And so using the Althen decision in 2005, the Court held, and this is where I get out of my league, which is talking about the law, but you can correct me on this. The Court held that one need only show 1) A medical theory showing a causal connection; 2) A logical sequence of cause and effect; and 3) A proximate temporal relationship.

This isn't hard to do for a peanut butter sandwich. Here's how you do it. Peanuts are grown in the soil. Many of them are contaminated with or have

living on the surface of the peanut something called aspergillus flavus, and so aspergillus flavus makes a toxin called aflatoxin. You cannot find a jar of peanut butter in this country that doesn't contain trace amounts of aflatoxin.

Well, aflatoxin at high concentrations is a potent toxin. It actually can cause liver cancer. That's clear. I mean, that's not a question. And so is it possible then that since aflatoxin is present in peanut butter and that aflatoxin is known to cause cancer -- at least a kind of cancer, liver cancer -- that it's possible that it could cause a different cancer in a small group of genetically susceptible individuals? This is what one always says, a small group of genetically susceptible individuals.

Certainly the timing is right. I mean, chemical induced cancers or radiation induced cancers can occur within six months so the timing is right, so there you have it. You've got a medical theory, a logical sequence of events and a proximal temporal relationship between a peanut butter sandwich and that leukemia.

Or you could use, and I'll finish with this. You could use the Capizzano decision where in 2006 the Court determined that the treating physician is in the

best position to determine whether a logical sequence of cause and effect occurred, again the epidemiology be damned.

And so here it's not hard because physicians, as you all know, will say anything in Court. Sorry. This is me sort of talking about my own group, but, I mean, you can go back to the days of workmen's compensation decades ago where you can certainly find physicians who come into Court and say you got hit on the head. That caused brain cancer. You got hit in the chest. That caused lung cancer.

Doctors in Court have a long and checkered history, so it's not hard to find a doctor who would say that here's a child, this child. This child who has leukemia had immediate type hypersensitivities to egg proteins. He's had problems with contact type hypersensitivities to thimerosal or immediate hypersensitivities to gelatin.

Therefore, this is a child who is pretty reactive to toxins in his environment and so here even small quantities of aflatoxin contained in peanut butter could in fact cause leukemia. So there we have it. We have been able to, using the rules of this Court, indict a peanut butter sandwich as a cause of leukemia.

I think the difference is and what worries me, and hopefully we'll get to this, is that this country can live without peanut butter sandwiches, and sometimes I feel when we get away from the science sort of in the name of policy, and I think a causality is always a scientific issue. It's not a policy issue. It's always a scientific issue.

I think that you run the risk of sending the message out there that vaccines are causing harms that they don't cause, and that can be scary to people and cause them not to get vaccinated, witness the measles epidemic that we're seeing in the first half of this decade that's larger than anything we've seen in more than 10 years because those parents are choosing not to vaccinate their children.

So I think this Court has a tremendous responsibility and needs to realize that they do send a message with certain decisions that they make.

MR. SMITH: Thanks. The one thing I have a disagreement about, Dr. Offit, is I don't think we can live without peanut butter sandwiches. I was raised on those.

Kevin Conway wanted to respond directly to this, and then I'll let Randy Moss talk about his view on the issue.

MR. CONWAY: Yes. I'd like to respond. Where do you think these vaccine cases start? Do you think the lawyers make up theories and go out and try to find plaintiffs so they can bring these lawsuits to bring these claims of the petitioners?

That's not the way they start. They start with a differential diagnosis. The pediatrician or the neurologist looks at the child, looks at the injury, looks at the injury, looks at the history, and their primary concern is treatment.

They want to treat these patients, and so they put on the list of differential diagnosis vaccines. Happened three days ago. Vaccine is a possibility. All these other things are possibilities. Then they start ruling out other possibilities, and they wind up with one left, and that's the vaccine.

This is where these lawsuits or petitions begin. They begin with the pediatricians. The parents then say it's the vaccines. They go to look for a lawyer, and you've created a dispute.

Now you have dispute, and the legal system is to resolve the dispute. We're never going to know what the truth is and do the vaccine actually cause it, but now you've got a dispute that has to be

resolved, and that's what the vaccine program does and that's what civil litigation does. It resolves disputes.

It doesn't find scientific truth. It's dispute resolution based on probabilities, likelihoods, preponderance of the evidence.

MR. SMITH: Dr. Offit?

MR. OFFIT: Thanks, Kevin. One small point. And so, for example, you had the notion born in the 1970s and 1980s that the whole cell pertussis vaccine caused encephalopathy. I mean, it can cause seizure disorders, permanent seizure disorders, epilepsy or mental retardation.

And so at the time it was unclear what it was that was causing this encephalopathy. The doctor, as you correctly state, has a differential diagnosis of what it could be. The default position is not knowing what it is and then just seeing a temporal relationship between that and vaccines. The default is the vaccine.

But I'm sure you've seen this data over the last couple years published first in 2006 by Berkovich. Now looking back at those cases of kids who were claimed to have encephalopathy following receipt of whole cell pertussis vaccine, in fact they

had a specific genetic mutation that explains that encephalopathy that had nothing to do with that vaccine, which is to say that as time goes on and medicine learns more you have more information, which then teaches you something.

I mean, the notion that there's a conglomeration of anecdotes that then equals causation I think is just wrong. For example, just one quick example. I mean, in 1916 we had a huge polio epidemic in the City of New York, in New York, where there were tens of thousands of deaths from polio. It was terrible.

People were trying to figure out what it was. What was it that was causing polio? Many people believed that it was fleas. They were fine. They were bitten by a flea, and then they got polio.

And so as a consequence of this conglomeration of anecdotes thousands and thousands of feral cats and dogs were slain in the streets of New York City because they believed fleas caused polio. But that wasn't the cause.

I'm just saying common belief isn't always common wisdom, and doctors certainly can be wrong, as certainly was true with the whole cell pertussis story.

MR. SMITH: Let me ask Randy Moss to talk about the program, but first I'd like you to weigh in on this particular issue of science versus policy.

Is this program just a program designed because there were disputes, or is there a legitimate issue of causation by vaccines in this case?

MR. MOSS: Well, I agree with much of what Kevin said in his opening statement, but what I do strongly disagree with is the notion that the statute and part of the compromise that was struck in the statute and part of the inducement for people to participate in the statute was relaxed causation. That is just not there.

Let me in answering that question and your other questions sort of back up a little bit to the history of the program, what Congress was trying to do and how the program has actually operated in doing so.

Returning to Ruth's point about the purposes of the program, start here with the premise that vaccines save thousands of lives every year. I mean, they are not a miracle of medical science. They probably are the miracle of modern medical science.

You start with that proposition. You then in the 1980s face a liability crisis in this country. There's a liability and an insurance crisis. In 1980,

there were 24 lawsuits involving alleged injuries from vaccines. By 1985, there were 150 lawsuits mostly involving the DTP vaccine.

Just as an aside, it ultimately was demonstrated that the injuries that were allegedly caused by the DTP vaccine in fact were not caused by that, but that's just an aside.

In 1983, the cost to the manufacturers of the litigation was $4.6 million. By 1984, that amount had grown to $9.8 million. The cost of insurance in the country for vaccines skyrocketed. The price for the DTP vaccine was reported to have increased by 2,000 percent in two years. By 1986, one dose of DPT cost as much as $11.40. $8 of that was for an insurance reserve.

The number of vaccine manufacturers, as Ruth indicated, plummeted in the country, and Congress wrote in the reports that accompanied the legislation that withdrawal of even a single additional manufacturer would present the very real possibility of vaccine shortages and in turn increasing numbers of unimmunized children and perhaps a resurgence of preventable disease.

It was against that background that Congress legislated it, and in fact there were shortages of

vaccines. There were shortages of DTP vaccine, and there was rationing of DTP vaccine as a result of all this.

Congress was also concerned, as Ruth mentioned, about making sure that there was fair compensation for folks. On very rare occasion there are some individuals who sustain injuries as a result of vaccines. Dr. Offit referred to the rare cases where someone actually could suffer polio as a result of the live oral polio vaccine.

Congress decided we ought to spread that risk. We ought to compensate those few unlucky people. There is a tremendous benefit to society as a whole, but those people who actually suffer the cost of national vaccine policy ought to be compensated, and there ought to be some fair, expeditious means of ensuring that you're doing that.

As Ruth also mentioned, another purpose was to ensure that we maintained a high rate of immunization in this country.

Over the years, the vaccine program I actually think until fairly recently has been very successful in achieving these goals. The amount of litigation fell off dramatically, and the program was very generous in providing compensation.

The program over the years, both combining the amount paid out in attorney's fees and compensation to those who have been compensated under the program, has been into the billions of dollars, close to $2 billion in compensation. Thousands of claims have been compensated.

I have two concerns, though, about things that have developed over the years with respect to the program. One thing that developed is in 2001-2002 we saw a surge again of litigation in the country, and it was a surge actually that the 1980s pale in comparison to. There were dozens and dozens of lawsuits brought, huge class actions brought, and they were brought without going into the program and seeking to circumvent the program.

While the Courts dismissed virtually all of those cases eventually, the notion that Congress was concerned about $10 million, roughly $10 million of costs of litigation back in 1984, the cost of simply getting those cases dismissed was in the multiple tens if not hundreds of millions of dollars, so that was a problem that arose.

But the second issue which has come up is the issue that Kevin has raised and is really raised by this panel, and the question is is there such a

thing as policy-based causation? Is there some different standard of causation that applies here?

On that I really strongly disagree with Kevin for a number of reasons. First of all, there's absolutely no basis for that in the statute. The statute is in many ways generous, and Congress' goal was to be generous. You don't have to prove fault in the program. That is a very strong inducement to participate in this program.

In addition, where there's a program that is actually on the table you don't have to prove causation, and that actually is an area where there's a relaxation of the causation standard.

There are some people over the years who have been compensated for table injuries where in fact the injury was not caused by the vaccine, but it fell within the table and Congress made that policy judgment that if it fell within the list of identified injuries on the table the individuals were entitled to compensation.

The program also pays attorney's fees. That's another generous aspect of the program.

But what the program doesn't do is diminish causation. I mean, the statute is very clear on this. It says that the petitioner bears the burden of

proving by a preponderance of the evidence that the vaccine caused the injury if it's an off-table injury and if that's what is being litigated.

There's just nothing in the Act itself or in the legislative history that would suggest that Congress intended any diminished standard to apply.

That brings me to the second reason why I disagree with Kevin. I think it is actually very much at odds with the policy of the statute to have a diminished standard of causation.

As Ruth mentioned, one of the principal purposes of the statute was to maintain high rates of immunization in the country. It was to protect kids. I mean, that ultimately was what this program was about is about protecting children and ensuring that those who were injured were compensated and maintaining the supply of vaccine so the kids could get vaccinated.

To have a diminished standard of causation, to say do you know what? We actually are not convinced that this vaccine caused this injury. This petitioner has not demonstrated by a preponderance of the evidence that this vaccine caused injury, but we're going to call it causation anyway. We're going to have a liberal policy of compensation under the

program, and we're going to say that it caused the injury and we're going to compensate that person.

That has the laudable purpose of providing some compensation to a sick child, but it has a real negative which comes with it, and that negative that comes with it is what it says to the public about the safety of the vaccine.

We have seen this in recent times, and Dr. Offit can speak to this much more forcefully than I can, but there have been cases where even the decision by the Department of Justice not to contest a case has been reported on the news, has caused a stir, has been suggested by some to be evidence of the lack of safety of vaccines, so there are real world consequences that relate to public health with respect to those determinations.

A related point to that point is I don't even know what policy-based causation is. I mean, either you can demonstrate as the statute requires that a vaccine caused the injury by a preponderance of the evidence, and as to that there is a very large body of law and large history of causation and how it's handled through the Courts, and Congress never indicated in any way that it was going to apply anything different than that, or it didn't.

If it's policy causation, if the policy instead is when we have kids who are injured we ought to compensate them for it, we ought to pay their medical bills, that may be a very laudable thing to do and it may make a lot of sense, but that's just a different judgment for Congress to make, to say do you know what? We ought to have national health insurance for kids. We ought to have a compensation program for kids. If there are kids who suffer certain types of injuries, let's compensate them.

I think that that may well be a great idea, but what I object to and what causes me concern is a false suggestion that it's the vaccine that caused it or a suggestion that it's not based on the science because that ends up hurting kids in the process.

And finally with respect to this issue some have said that the vaccine manufacturers actually benefit from a reduced or relaxed standard of causation and that they support it or should at least support it because the more people that are compensated under the program the less likely it is that they're going to actually want to come out of the program and bring a lawsuit at the end of the day against the vaccine manufacturers.

Based on my conversation with people from

companies and my understanding, I'm not aware of any company, any manufacturer, that supports the notion of calling something causation, suggesting that it's causation, but having actually a relaxed standard, something less than scientific proof.

And the reason for that is because it calls into question the integrity of the vaccines themselves. It calls into question the safety of the vaccines themselves. It calls into question public confidence with respect to the vaccines.

I think that that ultimately is what this question comes down to. If Congress wants to go back and consider these issues again and say let's compensate kids, great. Let's do it. But let's just not do it under the guise of something that we're calling causation.

MR. SMITH: Let me ask Marguerite Willner, who has been on the Commission as vice chair, how you come down on this?

Is the program a dispute resolution program irrespective of causation, or is it important, as Dr. Offit and Mr. Moss have said, to have a standard of causation that really says causation in scientific terms?

MS. WILLNER: I think causation is policy-

based in the program. Maybe we can ask Ruth and go back to Ruth again, but I don't think Congress contemplated a lot, if any, off-table injuries.

There were vaccines on the table that were presumed to cause various injuries. Now we have a table full of vaccines that have been automatically put on the table, but they have no injuries.

I don't know what conceivable benefit a table full of vaccines without injuries could really have to the vaccine consumer who gets hurt by a vaccine. That's my concern.

MR. MOSS: Can I just respond to that?

MR. SMITH: Sure.

MR. MOSS: I mean, I agree with that subject to kind of your final sentence, or somebody who gets hurt by a vaccine, which I think ultimately is the question of whether in fact someone was hurt by the vaccine or something else.

But I think part of the problem and part of the issue that is driving the debate here is that in fact over time evidence has increased with respect to the actual safety of vaccines and vaccines have become safer.

And so to the extent that part of the reason that you're seeing less compensation and fewer

compensated programs in cases onto the table is a result of the fact that either vaccines are now safer or as a result of the fact that the evidence now supports the safety of those vaccines. That's a good thing.

My concern becomes sort of then kind of searching for some problem to fix where in fact one isn't really in a position to show that the vaccine caused the injury.

MS. WILLNER: Randy, if I may? If we now know that these vaccines are safe, even though they're labeled unavoidably unsafe biological products, then perhaps the program is no longer needed.

Maybe everybody is better off without the program. Your integrity for the reputation of the vaccine will remain intact because in the tort system no one is going to be able to win.

MR. SMITH: Let me let Dr. Offit respond, but before I let Dr. Offit respond I just wanted to ask Ruth.

Would we have been better off? You've looked at this now there at the creation. Would we, in your view, have been better off if we hadn't created the program?

MS. KATZ: No, I don't think so, and I think

the history over the last 22 years demonstrates that that's the case.

Let me just make a comment though about the table and how that evolved. The table itself was very much the centerpiece of the legislation, but I will tell you that in working on the legislation this may come as some surprise to all of you, but we didn't spend a whole lot of time putting together that table.

It was not controversial at all, and I think that's because -- in fact, I know that's because -- at the time we wrote the legislation the vaccines that were listed and the injuries that were associated with each of those vaccines were well understood at the time. There were a lot of data to support what went in that table and so there was quick agreement about what should be on there.

Obviously we've now got new vaccines. It raises a whole lot of different questions. We were very confident about what we were putting in the legislation about the table and about those injuries. There were lots of data to back it up.

MR. SMITH: Dr. Offit?

MR. OFFIT: Thank you. Yes. I think probably it's not reasonable to have the dichotomy for vaccines of safe/unsafe.

I mean, I think what you can say about vaccines is that they're very safe, but certainly anything that one puts into one's body that has an effect can have a side effect. Vaccines are no different, and some of those side effects can be quite severe.

My question is more of a procedural one and shows my naivete, but it seems to me that if you were going to try and determine, I mean, let's take an example of whether or not say -- you can answer this question. Whether or not the Hepatitis B vaccine causes demyelinating diseases or multiple sclerosis.

There's a couple ways you can do it. You can do it the way you do it, which is to bring it into an evidentiary hearing where there are experts that are paid by each side to give testimony that then is reviewed by a panel of Judges with lawyers, I mean, who have no particular scientific or medical or biological background, but who are then going to rule on what they've heard. That's the way it seems to happen here.

My question is the other way in which it could happen is, for example, you could have 15 or 20 people who were experts in the area of immunology or biology or virology who then look at the several

hundred papers that have been published and then issue a summary as, for example, the Institute of Medicine did on this very issue.

Why isn't that Institute of Medicine, which I think is the better way to do it. Why isn't that just used as okay, here is their conclusion based on a thorough vetting of the data and I think arguably a more thorough vetting of the data than occurs in an evidentiary hearing.

So this shows you my naivete on this. Why isn't that the way it's done?

MALE VOICE: Are you talking about medical certainty? For instance, a preponderance of the evidence in the legal system?

MR. SMITH: That's a good question from the audience. How do you see the difference between those two, medical certainty?

Well, I guess, Dr. Offit, you would say there was no medical certainty in the sense that the law looks at certainty.

MR. OFFIT: There are no proofs. I mean, what I think scientists look at ultimately is a confluence of data that leads I think one to a truth.

I mean, I think if you look at, for example, in this specific example in the Institute of Medicine

report for Hepatitis B vaccine demyelinating diseases, I mean it's a beautiful, 200 to 250 page document that goes through the 300 studies and makes sense of them I think to show why I think both from a biological and epidemiological standpoint at least the conglomeration of evidence you have would suggest that this vaccine doesn't cause that problem.

That just seems like a much more thorough vetting of the data than say having an expert or a couple experts representing each side, presenting something in front of a group of lawyers who then render a decision.

I mean, don't you think that the first way is the better way?

MR. SMITH: Let me let Mr. Conway approach that.

MR. CONWAY: I think that would be a terrible way. We have a jury system in this country. It's worked for many years, and I think juries are fully well equipped to eventually understand the science and give an unbiased like approach to the decisions.

I have a few comments to make about things that have been said in the past few minutes. First of all, every vaccine injury has a genetic component. I

mean, clearly genes play a role. Otherwise everybody would have a reaction to a vaccine.

However, there is a consensus among scientists that many conditions, many illnesses, many diseases have an environmental component, and that is something that we deal with every day in the vaccine program is the vaccine environmental trigger to an underlying genetic condition.

Again, these are based on probabilities, likelihoods, not scientific certainty. There is none. So genes play a role, number one.

Number two, I'd like to respond to what Randy said about the DPT vaccine being proven not to have caused all these illnesses. I think that's clearly wrong.

There has been lots of evidence in the program that the DTaP vaccine, the newer vaccine, the vaccine we said that they should have used before the program and that I wound up then settling all these lawsuits for multimillions of dollars, the DTaP vaccine is a far safer vaccine. It's had far fewer reactions.

I'll give you that literature if you'd like, Randy.

MR. MOSS: I'll send you some as well.

MR. CONWAY: Next, the standard of proof. There is a reduced standard of proof in the vaccine program. Special Master Abell, who is in the back of the room, says it's 50/50 plus a feather, 50 percent plus a feather. That's all it takes.

I think it's even less than that. I think it's 50/50, and that is the difference. There's a big difference between 50/50 and 50 percent and a feather. It's a recognition that if it could go one way or the other then you find in favor of the injured person. A policy consideration.

And the last thing I want to say is that yes, there were all these lawsuits back in early 2000, 2001, 2002 because for the first time since the program began it appeared to some that the vaccine manufacturers were at fault. There was a fault.

You know, we didn't really know much about these other vaccines. We didn't have the ability to do discovery like we did for the DPT vaccine, so you can't sue them. You can't discover what their documents are.

But all of a sudden they found out that there was mercury -- thimerosal -- in vaccines, a neurotoxin, and that's what inspired all these outside lawsuits which eventually were dismissed and

redirected into the program, and now there are 5,000 claimants in the program, autistic children who claim that mercury in their vaccines caused their autism or some disorder in the autism spectrum.

The true test of the program I think is going to be how we deal with these 5,000 people. Are these going to be resolved from the program? Are they going to be cast back into the civil arena where there's fault and where, as Randy said, the costs of defense alone are staggering and it's going to create a new crisis?

MR. SMITH: Randy? Yes?

MR. MOSS: Yes. Just two points to respond on that.

First of all, with respect to the question what the standard is in the program, I think Congress answered that question, and Congress said that the petitioner has the burden by a preponderance of the evidence, and that's an exceedingly well understood phrase in the law.

What it means is in fact 50 percent plus a feather. It means more likely than not. It absolutely does not mean, and I've never seen any Court suggest, the preponderance of the evidence means 50/50 and the tie actually goes to the party that

actually had the burden of proof. That's just not what preponderance means.

With respect to the claims that are currently within the program, I think it's hard to contest the proposition that those cases ought to be handled in the way that Congress specified, and if at the end of the day the evidence demonstrates that the petitioners are unable to demonstrate by a preponderance of the evidence the causation that they ought to be resolved in that way.

I don't think anyone wants to see them resolved based on policy considerations or a notion of whether there's going to be litigation one way or the other. I don't think anyone knows what's going to happen with respect to the litigation in the Courts depending on what this Court does in handling those cases.

I think that everyone wants the cases to be handled not based on some general sense of policy, but based on the statute as Congress enacted it.

MR. SMITH: Let me ask a question which has emerged it seems here from this discussion.

Professor Katz pointed out that the focus was on the table, and at that point with four vaccines, where Congress at least thought and had good

enough data to say there was causation based on those factors.

Currently there are a bunch of new vaccines which have created clearly this problem that now we've juxtaposed scientific causation, which a couple of our panelists here really strongly indicated that it's not at all shown in these new vaccines, with Mr. Conway's very legitimate point that the purpose of the program was dispute resolution and somehow resolving a societal problem.

Where do we go from here? What do we do about this situation? Ms. Willner, do you want to comment? What do you think currently we should do, given those new vaccines?

MS. WILLNER: I think that the table is the issue.

You know, the preponderance standard is only -- again back to what Congress intended, I don't think they contemplated a lot of off-table injuries. The petitioners were going to have the legal presumption of causation. They were going to enjoy that because they were forced to go through this program.

Everybody is forced to go through this program whether they have an on-table or off-table injury. We have to keep this in mind. It's got to

benefit everyone or else it's just not fair.

So I think we need to look at the table, and I think maybe, and this is very radical, but I think we either don't put vaccines on the table without injuries or we take the injuries off the table so there's no presumption that the vaccines or safe. Sorry.

There's a number of things we can do with the table itself or just eliminate the table, but everyone has to benefit.

MR. SMITH: Do we need this matter to be really taken up at the Congress? Do we need another kind of table after the Congress had reviewed the science on this? Professor Katz?

MS. KATZ: Say the question again.

MR. SMITH: Do we need a new approach from Congress on this? Do we need in fact Congress to come up with a table for these new vaccines or exclude them from the list?

MS. KATZ: Well, since I no longer work for the Congress I would be very presumptuous to take a view on that.

But I think to the extent that there are ongoing issues that have not been resolved or continue to create problems for the program, either Congress is

going to have to step back and take a look and make changes, but in the meantime, like it or not, these decisions are going to have to be resolved or these issues are going to have to be resolved by the Court.

But whether or not Congress will ultimately decide to do something along these lines I'm just not in a position to evaluate at this point.

MR. SMITH: Okay. Dr. Offit wanted to also respond.

MR. OFFIT: Yes. And so a new vaccine comes to market, and maybe some of you know this. It may be in a handout. I'm the co-inventor of a vaccine called RotaTeq, which is the bovine human rotavirus vaccine sold by Merck, so I've watched this for the last 25 years from beginning to end.

It's pretty impressive. I mean, what has to happen prelicensure is that the vaccine is tested in now what's been more than 70,000 children. Then it's licensed by the FDA, who considers at least the data at hand to be safe and effective.

But as Maurice Hilleman at Merck used to say, I never breathe a sigh of relief until the first three million doses are out there. I think that's still true and true for any vaccine.

So now the vaccine gets out there, and

what's different about vaccines certainly as compared to drugs is that there are these wonderful catchment systems to really pick up I think relatively rare adverse events post licensure like the Vaccine Safety Datalink.

So as that vaccine then gets rolled out you have this group of health maintenance organizations which are computer linked so you can see who's gotten the vaccine, who hasn't, and then you can see whether or not there's any signal -- as in the case of our vaccine we're worried about an intussception, an intestinal blockage -- but you can see that.

And so now there's about 15 million doses that have been given, and you have this tremendous database of who has or hasn't gotten that vaccine to see whether or not there was any problem. I mean, certainly that doesn't exist for drugs.

On the other hand, if you're worried about whether or not this vaccine causes something else -- I mean, somebody got the vaccine and then had leukemia and so could the vaccine have caused leukemia -- you know you do have actually the resources at hand, I mean, through something like the Vaccine Safety Datalink where at least you can see whether or not there's any statistical association at the level of

say probably one to 50,000 or one to 100,000.

I mean, so then because you have money in this program or Congress used to have money -- we used to have money in this country -- you could actually say I'm interested in looking at this because we have this question in our system about whether or not one thing causes another. There are systems in place which can detect that. Can we put money into that system to detect it?

I mean, it's doable. That's a doable thing. The question is whether you believe it. I mean, when you get a lot of good epidemiological studies sometimes it seems that the Court just discards it. I guess that's the part that's upsetting for me.

I mean, there have been cases where the Hepatitis B vaccine has been claimed successfully to cause multiple sclerosis, which amazes me given all the biological and epidemiological evidence.

MR. SMITH: Isn't a problem here we really are asking the Court to do three things, none of which are traditional Court functions?

We have the goal of making sure that more children are vaccinated, not less, so the people have faith in the vaccines. We're concerned about the high costs of the litigation, which may impose severe costs

on vaccine producers and therefore necessarily the public, which may lead to the vaccine not being produced.

Both of those are really policy issues that generally are not addressed by the Judicial Branch. The Judicial Branch's role is dispute resolution in the case, not dispute resolution in light of a social policy, particularly a complex social policy like getting more children vaccinated or insuring that manufacturers are still making the vaccine.

How does the Court resolve that? How does the Court deal with the fact that a number of issues here, and there may be a third one is scientific causality, which of course Dr. Offit points out is something that is never certain. We never know exactly that that peanut butter sandwich wasn't the cause of leukemia.

MR. OFFIT: But you know a lot.

MR. SMITH: We know a lot.

MR. OFFIT: I mean, you know a lot. The question is when do you know enough?

MR. SMITH: But Courts have to at some point stop knowing and decide. We have timeframes.

So unlike the studies, we have to at least reach a point where the litigants are going to die and

their grandchildren are going to be litigating for the next hundred years if we have to wait until we know a lot more, so we've got to cut it off at some point arbitrarily and say we've got to issue the decision.

How do we do that? Any thoughts? Mr. Conway?

MR. CONWAY: Sure. You do it just the way the Federal Circuit says you do it, the way the Federal Circuit interprets the statute.

MR. SMITH: We always do what the Federal Circuit says.

MR. CONWAY: Right. What the Federal Circuit says is that this field of vaccine injuries is bereft of direct science, so therefore you resort to indirect science, circumstantial evidence. Circumstantial evidence is favored in the program in helping resolve disputes.

You do what the Federal Circuit said. If a healthy person gets a vaccine, gets an injury that can be caused by the vaccine, if symptoms occur within a reasonable, appropriate time after the vaccine and if there's no other likely cause then that's compensable.

Why do we have to go out there and find every one of those rare people that in truth in fact was caused by the vaccine? These people meet that

standard. They qualify. They should be compensated. That's what the program does, and that's what it should do.

MR. SMITH: Yes, Mr. Moss?

MR. MOSS: I think the key to that question or to what Kevin just said is what it means to say that the vaccine can cause the injury.

I think we don't really know yet what the law is in this area. I think that the Federal Circuit has provided some guidance, but I for one am not entirely sure that I understand exactly what follows from what the Federal Circuit has said.

The Federal Circuit has said quite clearly that it is a preponderance standard. Causation in fact must be demonstrated. The Federal Circuit has said that there needs to be a medical theory of causation concerning the vaccine.

To my mind, the important question that really needs to be resolved still is what the Federal Circuit meant by that and how it gets applied. If what you mean by can the vaccine -- well, let me put it this way. You could mean two things by the vaccine can cause the injury.

You could mean that the vaccine could cause the injury in the same way that Dr. Offit's peanut

butter sandwich could cause leukemia. It's possible. You know, one could conceive of a universe in which that proposition might be true.

MR. CONWAY: I've never seen a peanut butter sandwich on a differential diagnosis.

MR. MOSS: It was an analogy.

MR. CONWAY: Yes.

MR. MOSS: Or what you can mean by it is actually that there is proof that this vaccine in some cases causes this particular type of injury.

The vaccine can cause that injury, meaning there are cases in which we know by a preponderance of the evidence that the vaccine does, and the question is really then whether it did so in this particular case. That becomes a very different consideration then where looking to questions like temporal relationship, other causes, makes a lot more sense.

If by saying that the vaccine can cause the injury what you mean is that you've looked at the epidemiological studies, you've looked at the science and you've said do you know what? Looking at this we've concluded that by a preponderance of the evidence there are cases where this vaccine will cause that injury, and the question now is just whether this is one of those cases.

MR. SMITH: Okay. Dr. Offit wanted to add something.

MR. OFFIT: If you look in the medical literature you will find, for example, the disease aplastic anemia where your bone marrow shuts down and is unable to make any of the three major cell types. And so the question is what causes the aplastic anemia?

If you look in the literature, which you can find and it's replete with this actually, is that you find an association between infectious mono, which is Epstein-Barr virus, and aplastic anemia or a natural Hepatitis B virus infection and aplastic anemia, which is to say it's common in the medical literature where you'll find reported an association between an event that occurs commonly, which is to say mono or Hepatitis B infection, with an event that occurs uncommonly, aplastic anemia.

Statistically that has to happen. I mean, Kevin, when you make the case vaccines are on the differential diagnosis, vaccines are given to 85 to 90 percent of kids in this country. It's a default diagnosis for when you're not sure. And so that it's on there isn't shocking.

That you could come up with something that

is "biologically" plausible or a medical theory for plausible is also not very hard. I just think that the standards are critically low I think to try and indict vaccines, which is why I try to give the analogy of how easy it is to indict a peanut butter sandwich using the same criteria.

MR. CONWAY: I would just like to say that there is such a fear of -- I'm old enough to have been frightened to death by the disease polio. I stood in long lines in grammar school, and I was given a vaccine. I remember the terror. These vaccines were real. We've actually been spoiled because of them. They're gone now. We don't see them. Many parts of the world do see them.

But you can't let your fear of vaccines and the fear of reduced immunization rates limit your ability to question. You almost always have the ability to question did this vaccine play a role. I think that the fear of a drop in the immunization rates prevents this from happening, and I think it's a real problem.

MR. OFFIT: I disagree completely for this reason. When, for example, the RotaShield vaccine was licensed by the United States, by the FDA, in 1998 it was put out onto the market and given to roughly a

million children.

There were reports to VAERS, the Vaccine Adverse Events Reporting System, that there may have been an association between that vaccine and intestinal blockage.

Very quickly the CDC mobilized, spent practically tens of millions of dollars to try and answer the question was this a causal or coincidental association and came to the conclusion -- I think the correct one -- that it caused it, that RotaShield caused intussusception, and that vaccine was taken off the market.

People at the CDC, people at the federal level, certainly public health officials or pediatricians want vaccines to be safe. Of course they do. If a vaccine isn't safe they don't want it to be out there.

The notion sort of questioning the motives of those who support vaccines or vaccine safety isn't the way to go. Certainly all of us want vaccines to be safe. We just don't want them to be tarred unfairly.

I mean, I think anybody can reasonably be concerned about anything they put in their body, but it should be based on good data, not on fear. I mean,

the notion that vaccines cause autism is just incorrect. People are scared about getting vaccines because of that, and it's just based on an ill-founded concern.

MR. SMITH: A different issue for a different day.

Actually, I was going to say I don't believe peanut butter sandwiches cause leukemia, but they did cause my nose to glow red. I don't know why that happened, but it did cause that. I'm sure it was the peanut butter sandwich. It happened right at two years after I had the peanut butter sandwich.

I did want to ask an exit question before we go to questions from the audience. I've seen Dr. McLaughlin do this.

On a scale of zero to 10, with 10 being metaphysical certainty and zero being of no value, how would you rate the vaccine program over its life to the present time? Give me just a number.

I'll start with Professor Katz.

MS. KATZ: Eight.

MR. SMITH: Okay. An eight. Mr. Conway?

MR. CONWAY: Seven.

MR. OFFIT: I'm going to give it different grades based on when. At the beginning of the program

I would have given it a nine plus. Now I'm giving it a six just because I think that it's losing its way a little bit.

MR. MOSS: I'd give it a 7.25. Actually, I think that overall the program has worked well and actually is a model of success in a lot of ways. I think we need to see what happens in the next few years.

MR. SMITH: Okay. Ms. Willner?

MS. WILLNER: A 9.5 at the beginning and probably a four now.

MR. SMITH: Okay. Actually, the correct answer is 9.168.

Let me ask for questions from the audience. We have a microphone, so if you can speak really loudly you don't have to go, but otherwise please go to the microphone so everyone can hear you. We'll get to as many people as we have time.

MALE VOICE: Dr. Offit, you used Dr. Sabin as an example of a good product that caused some harm, correct?

Are you aware that Dr. Sabin's product was found to be not a good product by the Supreme Court of the United States in a case called Berkovich v. United States, thereafter was found not to be a good product

in a case called In Re: Sabin, a nonjury case affirmed by the Fourth Circuit, found not to be a good product in Griffin v. United States of America, a Third Circuit case, Baker v. United States of America.

MR. SMITH: Why don't we let him answer the question?

MALE VOICE: And I need to add one other thing.

And in each instance the law firm WilmerHale represented the individuals who were paralyzed, all CDC reviewed cases found to be vaccine associated, and they claim not a single one was a victim of the vaccine.

MR. SMITH: Okay. Who wants to respond? Dr. Offit?

MR. OFFIT: So the polio vaccine was made by Albert Sabin for the purposes of preventing polio. At the time that that vaccine was released in the United States, which was in 1962 and 1963 -- it was three strains -- there were sort of in the low tens of thousands of cases of polio and lesser than that in --

MALE VOICE: Nine hundred and sixty-eight paralytic cases.

MR. OFFIT: Nine hundred and sixty-eight paralytic cases from the -- first of all, not all

states were required to report. That report was clearly low.

MALE VOICE: That is from the CDC national data.

MR. SMITH: Sir, please don't interrupt the speaker. You're being rude.

MALE VOICE: You're wrong.

MR. SMITH: You're being rude.

MALE VOICE: It was underreporting. It clearly was underreporting.

MR. OFFIT: In any case, there were certainly in the low thousands of cases of polio that were occurring.

Now, I would say in the low tens of thousands because most cases of polio don't result in paralysis, and there were many hundreds, probably low thousands, of cases of paralysis. In any case, that vaccine then was introduced in 1962-1963 where it proceeded to eliminate polio from the United States.

Now, it didn't eliminate paralysis because it itself caused paralysis probably in about six to eight cases a year, which when I was the head of the working group on the CDC that ultimately moved us finally from what was a sequential schedule to the full IPV schedule. Neal actually was involved in that

too.

And so was it flawed? Yes. Could the vaccine have been better? Did we eventually evolve to a better vaccine when we could make better inactivated polio vaccine? We didn't make very good inactivated polio vaccine in the 1950s for a variety of reasons.

I wrote a book about this called *The Cutter Incident* so I know about this.

MALE VOICE: I read it.

MR. OFFIT: You read it. Good. Thank you. So you were the guy who read it. But in any case, the --

MALE VOICE: I think I was one of the few.

MR. OFFIT: I mean, if your point of view is that vaccines can be unsafe, they can be unsafe.

If your point of view is that that vaccine was critically flawed at its inception, that I disagree with because I think it was the right vaccine at that time because we didn't have a very good inactivated vaccine because vaccination rates at that time were 40 percent.

We benefitted from the contact immunity that came from that vaccine, so I just disagree.

MALE VOICE: Well, Doctor, you haven't answered my question I don't think.

MR. OFFIT: And I think the Courts are not a place to determine whether or not something is safe or unsafe. Ultimately it's a public health decision.

MALE VOICE: Dr. Sabin himself testified in these cases. Dr. Sabin testified in Philadelphia, Pennsylvania, and admitted that if he was the one looking at the release of this product he wouldn't have released it.

MR. OFFIT: No. You're not talking about his vaccine. You're talking about the Cutter vaccine.

MALE VOICE: No. I'm talking about Albert Sabin's vaccine.

MR. OFFIT: Not true.

MR. SMITH: I think we've reached the end of this.

MALE VOICE: Doctor, I was the one who cross-examined him.

MR. SMITH: Yes. Thank you. I think we need to get to some other people.

MALE VOICE: Yes.

MR. SMITH: Yes? Next question?

MALE VOICE: Dr. Offit, I think it's really cool and brave of you to come to talk to a group of rabid plaintiffs' counsel, and I think very good things can come from these kinds of debates, those

being safer vaccines and a better working program.

I in general agree with your proposition that science can inform causation, and my question is this. I scoured the medical literature to try to find studies, published studies that look at the health outcomes of unvaccinated children versus vaccinated children.

It's my understanding as a matter of law and ethics that any medicine, including the vaccine schedule, must be presumed unsafe until it's proven safe by the traditional double blind control studies.

All of the studies of vaccine, including the concomitant use studies, look at adding one vaccine to an otherwise vaccinated pool of children or look at a chronic health or chronic adverse event for three to six weeks, but not longer than that.

And so my question is would you support a comprehensive study of the health outcomes of unvaccinated versus vaccinated children, say a group of matched 10-year-olds, against vaccinated controls?

If so, would you agree to serve on a steering committee for such a study? If not, please explain why you wouldn't support that kind of a study.

MR. OFFIT: Sure. First of all, thank you for complimenting my bravery.

I'll tell you that we all have sorts of our preconceived notions about what it would be like to be in a room full of plaintiffs' lawyers, and this was not mine. Mine was that it would be sort of in a dark orange glow with flames sort of lapping at the sides. That didn't happen.

And so your question, which is a reasonable one, is is it possible that by giving the 14 vaccines that we currently give to infants and young children were causing harm and how would one determine that. The only way arguably to determine that would be to do a study where you look at children who were vaccinated and those who weren't.

The problem with doing that study is, first of all, you could never do it prospectively because you can't prospectively do a study where you're not vaccinating children because the notion or the fact that vaccines prevent vaccine preventable diseases is not one in dispute.

Those unvaccinated populations have higher rates of vaccine preventable diseases than vaccinated populations. That's clear, so you can't prospectively do that study.

So now you're trying to do a retrospective study where you're looking at children who were

vaccinated and those who weren't. It's possible, but it's hard. It's hard because you would have to make sure that both of those groups are alike in all other aspects and so in terms of healthcare seeking behavior, in terms of socioeconomic background, so it would be hard to do.

It's not impossible. There certainly are home-schooled children who don't get vaccinated. About .5 percent of the country's children don't receive any vaccines.

You know, we have a birth cohort of three and a half to four million, so it's possible. I just think it would be very hard to do retrospectively to make sure that the two groups are alike and especially in healthcare seeking behavior.

You can't do that study ethically prospectively. You can't. I mean, suppose a child gets pneumococcal disease and dies. You've just subjected him to something.

MALE VOICE: Doctor, some children, according to state law, choose from a religious or philosophical context not to vaccinate so you could just sign those up prospectively in a trial.

MR. OFFIT: I don't think you can ethically follow a child who's not getting vaccinated.

I mean, there is obviously not a right or wrong answer, but personally I can't imagine how anyone could be part of a study where you're saying okay, we're going to see what happens to you knowing that an unvaccinated child is at risk for disease that are still common out there like pertussis or chicken pox or pneumococcus.

I mean, if a child gets pneumococcal disease and gets meningitis and dies, I just don't see how you conscience that knowing you were studying them. Personally that's just my --

MALE VOICE: Does that mean you're not on the steering committee, Doctor?

MR. OFFIT: I would call that an unethical study. It's a prospective study. Right. That's what it would mean.

MR. SMITH: Let me get a question from this gentleman at the microphone now.

MR. SCHWAB: My name is Curtis Schwab. I'm also a petitioners' lawyer.

I think just to comment first, and then I do have a question, and my comment is I think that especially from Dr. Offit and Mr. Moss there's an assumption that we know a lot more than we know.

That was I think Congress' biggest mistake

when they created the program. They thought we knew what vaccine reactions were. They named some, but even those were controversial. The program began compensating controversial reactions, and now it should only compensate uncontroversial reactions I think is a flaw.

Now, I want to compliment Ms. Willner's suggestion that if we're going to have table vaccines we ought to have table injuries. My question is whether the folks on the panel think it would be appropriate to consider reactions that are likely -- not necessarily proven to even a preponderance standard, but reasonably likely -- to be caused by vaccines and add them to the table?

For example, Guillain-Barré after flu vaccine; for example, meningitis after varicella vaccine; disseminated varicella infections after varicella vaccine; demyelinating nervous system disorders after Hepatitis B because there is an epidemiological study that identifies it; meningitis after the Menactra vaccine; perhaps Guillain-Barré after the Gardasil vaccine.

These are areas in which legitimately plausible, possible reactions have been identified by the medical community, and that is the kind of thing

that ended up on the original table. My question for you is should we consider restoring the generosity by the program by putting those kind of things onto the table?

I'd like this to be responded by not just Dr. Offit, but the whole panel, the notion of using the table again as it was a substitute for science. It wasn't a reflection of science.

MR. SMITH: Okay. That's an interesting point. Also, would that eliminate the stigma of giving compensation from there being a danger in the vaccine? It would just be a compensation program.

MS. WILLNER: Yes. Actually, if you're going to keep the table I would definitely -- I mean, this is radical, but I would go through all the decisions that have been made in the program.

I would see if there are a number of decisions made in favor of GBS after the flu vaccine, I mean, that to me says it can cause. You still have to go to did it cause on an individual basis, so I don't see any problem with adding more injuries to the table.

Dr. Offit and everybody, maybe we could add to the Aides to Qualifications to the Table the table is policy-based so that everybody doesn't impugn the

reputation of the vaccine automatically by having an injury on the table associated with it.

So you could say it's policy-based and not scientific-based so that petitioners' counsel can't go into State Court and wave the table around and say well, because this injury is on the table associated with this vaccine it means that it can cause it if scientific validity to the case that it causes.

But I don't see how you can have a no-fault system that benefits industry and providers as much as it does and furthers our federal policy toward 100 percent vaccination and have a tort standard of proof, the preponderance standard. I don't see how that's right.

MR. MOSS: Just in light of the number of panelists and the time, let me just say something quickly and not exhaustively on that topic.

I think there's a difference between over compensating where you know that the vaccine in some cases will cause the injury, but you don't know that it caused it in the particular case.

An example I can give you of this is the RotaShield virus on the table, which there was evidence of increased incidents of intussusception, this blockage in the intestines, during the first

administration, somewhat less during the second administration and not at all during the third administration of the vaccine, but the table covers all three administrations of the vaccine.

There there's not a question that arises I think with respect to the reputation or the public health consequences of people being concerned about the safety of the vaccine because there is actually the scientific basis for it.

And then the other comment I'll make before passing the mic on is that I do think that if there is going to be a move away from a notion of actually causation of preponderance-based causation that Congress would have to be extremely clear that that's what's going on with the program so as not to create a false sense that there is a scientific basis to question whether you actually ought to be giving the vaccine to your children.

MR. SMITH: Dr. Offit?

MR. OFFIT: Yes. The questioner raised an interesting point regarding Guillain-Barré Syndrome and brought up the conjugate meningococcal vaccine, Menactra.

That's a great point because see, the problem with looking at those kinds of associations is

the background rate for Guillain-Barré Syndrome, which occurs naturally, is roughly one per 100,000, so if you're going to try and see whether the vaccine increases that you need these huge studies.

When Menactra first came out actually there was a question about whether at least in a certain age group that it did cause Guillain-Barré Syndrome. Now, as the vaccine has been out there since 2005 and you get more and more data that the CDC has accumulated that association, at least according to Bill Atkinson a couple months ago, isn't there anymore, so as you get the numbers you see that there wasn't an association.

But again for disorders that are that uncommon background, it's very hard to do those epidemiological studies.

The flu vaccine is also interesting. I mean, certainly the swine flu vaccine, that one in 1976, was associated with Guillain-Barré Syndrome and began at a rate of roughly one per 100,000, but all of the flu vaccines since then it's not clear that it is at least to the level of detection of an epidemiological study, which is probably about one in a million.

It's a hard question. You'd like to have

the resources to do those kinds of big studies to answer that question, but, see, I always approach this as a scientist, which is it's a scientific question. It does have a scientific answer. It may take a long time to get to those answers and have the resources to do those studies.

And you're right. At some point you have to make a decision, but I do think that certainly if let's say Menactra and Guillain-Barré Syndrome, the data to date suggests that there really isn't an association so why compensate it and scare people?

MR. SMITH: Mr. Conway?

MR. CONWAY: Yes. I will be brief. I think it's an excellent suggestion. I think that more injuries should be added to the vaccine table. I think that would be an excellent thing, but it's not going to happen. It never has happened.

The history of the program has been to remove injuries, again driven by the fear of reduced immunization rates due to fears of vaccines. So I think it would be a great thing, but it's not going to happen.

MS. KATZ: I just want to take issue with the point that was made that we didn't have data or scientific basis for the formulation of the original

table.

That in fact is not true. Now, you may disagree with what's in the table, but I have to say that at the time we developed the legislation there was across-the-board consensus about the injuries that went into that table.

As I said, we spent very little time actually formulating that table because there was such consensus, such strong data to back up what was on it.

MR. SMITH: Okay. Ask the next question.

DR. CASERTA: Good morning, everyone. My name is Vito Caserta. I'm a pediatrician with the vaccine compensation program, and my question has to do with the causation standard.

We as physicians don't think of preponderance of the evidence. That's just outside of our way of seeing things. The Court uses that as their guidance, and the Court I think has been misled to believe that science and medicine require 95 percent certainty before we consider a fact a fact or consider something to be real or consider something to be actionable.

I think the confusion stems from 95 percent comes from the confidence interval, which really only speaks to the likelihood that those results are simply

due to chance, and it doesn't really speak to the likelihood that they are actually true.

But I guess my question has to do with when we have something on a differential diagnosis from physicians, what level of proof do we need generally for that? My comment is that it varies.

If you have a test that maybe only has a two percent chance of being correct or a one in 1,000 chance even of being correct but it's going to cure that person of a very serious disease, that's going to be on the differential and the doctor is going to do that test.

So to imply that doctors require 95 percent certainty is a fallacy, and I just wanted to raise that for the panel if they wish to speak further on that.

MR. SMITH: Let me maybe add one thing to your question if this is consistent with it, and that is it seems to me that when medicine is operating there really is a cost/benefit analysis being done.

If a patient is dying and there's no chance with conventional therapies a doctor is willing to use some pretty exotic, pretty high chance of failure things because otherwise there's going to be death anyway.

So isn't that in part with the way medicine operates, as opposed maybe to epidemiological science? The doctor is making judgments all the time, and if the consequences aren't very high the old chicken soup remedy. Well, you've got a cold. We haven't got any other cure. Try chicken soup because if the chicken soup doesn't work, well, you're just going to be in bed for another day.

MR. OFFIT: Vito, I completely agree with you. I think that it's the rare moments actually where you make medical decisions with 95 percent certainty.

You know, we have our infectious disease conference every week and we present cases and we discuss them. There are always difficult management issues and trying to figure out as best we can with the data that we have what the best course is. So I agree with that general point.

And I think the point that you made, Loren, was the notion that what we try and train our residents to do is to always do the thing that is most likely to benefit the patient and so if, for example, you have someone who's going rapidly downhill there are three things that could happen. They can continue to rapidly go downhill, they could get better or they

could stay the same.

You want to make sure. Doctors often have this false notion that when someone is doing badly there's nothing you can do to hurt them. Of course there's something you can do to hurt them. The trick is to make sure that you don't do that thing.

So I think the thinking is one of always trying to do the thing that you think best benefits your patient. I can tell you we virtually never think about cost when it comes to taking care of a patient.

MR. SMITH: I mean cost not in the sense of a monetary cost, but the cost of the technique of harm versus hurt because when you have a patient who's dying and you have let's say an hour where you have to do something and you have five things to do and all of them have the potential of hurting him and of killing the patient, but there's some that also have a certain percentage of helping the patient.

The cost factor would be you'd use the cost, using cost in that way, the one that had comparatively the greatest chance of success and maybe the least chance of failure. In that case you probably wouldn't look at the failure rate because he's going to die anyway if we don't do something, so you take the one with the greatest chance of success, though it might

also cause further harm.

MR. OFFIT: I'll give you a perfect example. So a patient come in with bacterial sepsis, which is to say bacteria in the bloodstream causing a severe infection.

There was a time -- Neal probably remembers this, and others may remember it as well -- where the patient is doing very badly. Their blood pressure is low. You have to support their respiration, et cetera. The notion was this is probably at least immunologically mediated. Let's give steroids.

And so it was found, and finally when the right studies were done, that giving steroids to a patient with gram negative bacterial sepsis actually made them worse, so this patient who appeared to be dying in front of you could be made worse by giving steroids.

So the thinking should always be one of trying to put the -- you can still make the patient worse, even when they look like they're doing very badly.

MR. SMITH: Okay. The gentleman here?

MR. BROOKS: Thank you, Your Honor. My name is Albert Brooks, and I represent petitioners in this program, but I also have the honor of representing

individuals who have been injured by nonprogram vaccines.

I want to agree with Professor Willner that a table full of vaccines with no injuries is essentially a manufacturer immunity statute, and if that's how we're going to go there's been a lot of criticism of the relaxed causation standard, but I think there needs to be a recognition that we have our hands tied as plaintiffs' attorneys and petitioners' attorneys in how much we can learn.

Now, I've had the opportunity to review clinical trial data in nonprogram vaccines. I've seen people admitted to trials who shouldn't have been admitted. I've seen vaccine injuries being dismissed as preexisting conditions when it should have excluded them from the trial. I've seen placebos that have had adjuvants that have led to placebo cohorts with large adverse reactions.

And so the question goes to Dr. Offit and the reliance on epidemiology, and if it is the gold standard to do double blind trials would you as an affiliate of the vaccine manufacturer disagree with as a condition of a vaccine being covered that the entire regulatory file be made available to petitioners and their attorneys for prosecution of the case?

MR. OFFIT: First of all, I'm not an affiliate of a vaccine manufacturer. I'm the co-inventor of a vaccine. My hospital licensed that patent to Merck.

I have really no direct relationship with that company other than the fact that we worked together to make a vaccine. They didn't pay for my research. I am not an affiliate of the vaccine makers, even though God knows if you look at the internet you would assume that's exactly what I am.

I really can't speak to that. I mean, I think the issue of what should be made publicly available is not the kind of thing I should speak to.

MR. BROOKS: Not publicly available. To people who have brought claims in the program subject to whatever confidentiality is necessary to protect trade secrets.

MR. SMITH: Discoverable, in other words.

MR. OFFIT: I think there are people in this room that are better able to answer that question than me.

MR. BROOKS: Would you like to see that available before the Court rules on causation?

MR. OFFIT: I guess what I would like to see is that I don't think the Courts should be the ones

that rule on causation. I think the people that should rule on causation are the people who are in the best position to determine whether or not something is causally related.

I mean, we talked about Hepatitis B vaccine and multiple sclerosis or demyelinating diseases. I think the 15 to 20 people that sat around that room who had an expertise on the science of vaccines, whatever part -- the epidemiology or statistics or whatever -- those are the best people obviously to rule on it, I mean, because they're the people who best understand it.

So I'm always uncomfortable actually when things go to Court because I feel like it's in some ways in the wrong hands.

MR. SMITH: Well, the methodology of the Court is anecdotal. Inherent methodology of law is anecdotal, whereas the inherent methodology of science is anti-anecdotal.

Mr. Moss, do you want to comment on the question about the files?

MR. MOSS: You know, I don't really know myself what are in the files and what aren't and don't know enough about the considerations to answer the question.

The one thing I would just sort of throw out there is that one of the goals, as Ruth mentioned, of the program was to come up with a program which was streamlined and efficient minimal discovery.

I would be somewhat concerned if the program became transformed into something that looked like the traditional litigation that Congress was trying to head off with extensive discovery.

MR. BROOKS: Yes. I agree.

MR. SMITH: Yes.

MR. BROOKS: But it is that on the respondents' end. It's not streamlined for us when it's a nontable injury, and that's what I think the Congress needs to revisit. I would hope that there would be support for that.

MR. CONWAY: And I would like to just say that the answer to your question is obviously it should be disclosed. However, it's not going to be disclosed for the fear of reduction of immunization rates. That is the issue once again, as always.

MR. OFFIT: I wish we could stop saying that. I mean, those who care about vaccines, whether it's at the Advisory Committee of Immunization Practice or the Committee of Infectious Disease, care about vaccines being effective and safe, and both of

those things are considered to be important.

There is a tremendous amount of data to prove that. I think the RotaShield experience is one of many examples. I mean, Neal Halsey has sat on the ACIP. So have I. Neal sat on the Committee of Infectious Disease and headed it, and he could stand up here and tell you just how important vaccine safety is to him.

If we're to maintain the public's trust, obviously we want to make the best vaccines and to make sure that they're well understood.

MR. SMITH: Okay. Let me --

MR. CONWAY: Can I just say one thing?

MR. SMITH: Very short.

MR. CONWAY: Dr. Offit, do you think that the vaccine program should take the advice of the Vaccine Advisory Commission, the unanimous advice? Do you think that that's relevant?

MR. SMITH: Let me move to the questions. I'll take three more questions, given our time.

The lady back there standing, are you a questioner?

FEMALE VOICE: Yes.

MR. SMITH: So the three people who are standing, and then we're going to have to with time --

otherwise we'll go on enough time to test a new vaccine.

The gentleman here? Please make the questions short and the responses also short.

MR. SHOEMAKER: Thank you, Your Honor. Cliff Shoemaker. I represent the petitioners as well. Just a couple of quick comments and then a question.

One is I agree with Dr. Offit. I sincerely wish that the Sabin vaccine would have been available in 1948 when my sister was paralyzed with polio and she's been paralyzed from the waist down ever since, so I'm very much an advocate of vaccines.

That's one of the reasons why I'm involved in this program, one of the reasons why I think this program had better work because if it doesn't we're back in the civil arena, and this program had better offer a better alternative and option to petitioners than it does today.

Secondly, I think we're misconstruing something here today. We're talking about the goals of a statute. We're not talking about the role of the Court. The role of the Court is not to determine the safety and efficacy of vaccines.

The role of the Court is not to determine whether or not the uptake rates of vaccinations go up

or down. The role of the Court is not to make any determinations about the value, the benefits, the risks or anything else do with vaccines. The role of the Court is to adjudicate disputes.

My question to you, Dr. Offit, is in that regard part of the way we adjudicate disputes is settlements. You've indicated on your speeches on line that you have reviewed the facts of the Poling case, and you disagree with that concession. Is that true?

MR. SMITH: Do you want to talk about specific cases?

MR. SHOEMAKER: Well, let me ask a specific question.

MR. SMITH: I don't want to go into specifics because it's going to take too long, but do you want to comment on whether you agree or disagree?

MR. SHOEMAKER: Let me make the question more specific, Your Honor.

Would you agree that you have reviewed the facts of the Poling case with Jeff Evans.

MR. OFFIT: No.

MR. SHOEMAKER: Okay. You said you did on line, so you're saying --

MR. OFFIT: No, I didn't. I never said I

reviewed the case with Jeff Evans.

MR. SHOEMAKER: You said you reviewed the facts of the case. Is that correct?

MR. OFFIT: I don't think I ever said that. Did I ever say that?

MR. SHOEMAKER: Okay.

MR. OFFIT: No.

MR. SMITH: Two more. This gentleman and the lady.

MR. OFFIT: That's your question, did I review the facts of the case with Jeff Evans?

MR. SMITH: And the answer was no. Okay.

MR. TAMALEO: Just a quick question. Al Tamaleo. I represent petitioners. There's been some discussion of MS and the Hepatitis B vaccine.

Dr. Offit, you seem to be a strong advocate of reliance on annals such as the IOM basically to be the final arbiter of what the science is on vaccine reactions, but if my recollection is correct soon after the IOM came out with their findings on MS and Hepatitis B vaccine wasn't that soon followed by a study finding an epidemiological causal relationship between those two things?

MR. OFFIT: Are you talking about the French study?

MR. TAMALEO: The Hernan study. The Harvard study.

MR. OFFIT: Not to my knowledge. I mean, I guess the --

MR. TAMALEO: I'll be glad to give you a copy. Thank you.

MR. OFFIT: I don't know if you've read the Institute of Medicine report, but the notion biologically that a vaccine which clearly is immunologically much less likely or is certainly far different in terms of what it does in the body than the vaccine itself is clear.

I think those two studies in the *New England Journal of Medicine* were excellently done studies, very well done studies. I mean, can you find epidemiological studies that are poorly done? Absolutely. They're published all the time.

But I think if you read that review, I can't imagine how one can come to the conclusion other than the vaccine never caused MS. You're not listening to me, but that's what I would say.

MR. SMITH: And our final questioner?

FEMALE VOICE: This is not a personal attack, Dr. Offit. It's a very general question.

MR. SMITH: You don't want to know what he

read or studied or said?

FEMALE VOICE: No. No. For mainly this side of the panel, and if anybody wants to comment. It may be a very basic question.

I'm a plaintiffs' attorney. I have varied experience in vaccine law, but I'm inspired to practice vaccine law. Just listening to this conference is very inspiring. I'm learning a lot.

My basic question is why would this area of law receive more focus and attention than just normal like product liability type of cases where if you're injecting a certain type of product into the consumer stream and the consumer receives it as a normal user would use and something weird happened and then there was a compensation by the deep pockets of the manufacturer, why would vaccines be different?

I mean, I can understand the health policy issue and the more exposure in the public, but why would some people advocate for a higher standard of proof? Why would this be different? You could say the plaintiff did whatever they were supposed to. There's no ultimate cause. This weird thing just happened and the person should be compensated.

Why would this be the type of thing that would be higher scrutinized and some people advocating

higher proof and that type of thing?

MR. SMITH: Your question is why is the vaccine different from having a program say --

FEMALE VOICE: From traditional product liability.

MR. SMITH: -- of the heart monitoring device or any other medical malpractice area or product liability area?

FEMALE VOICE: Yes. I mean, I guess that's my question. Why would this get so much more focus or more scrutinized signs? Some were saying a higher standard of proof, that type of thing.

MR. SMITH: Professor, did you want to --

MS. KATZ: I won't address the question of standard of proof, but I can tell you why I think there has been a lot of attention paid to this issue, and that is I am unaware of any other product that our children are required to take as a matter of law.

In our view, they are required to do their public health duty to protect across the country others from getting this disease, whatever the disease is, the vaccine preventable disease. I'm unaware of any other product where we require that by law.

So, therefore, Congress did want to take a very special look at how we address the issue of the

very small number of people who may be injured as a result of doing something that they are required to do to help protect the public health of the entire country.

MS. WILLNER: And I'd like to add that vaccines are administered to healthy people. Originally when the program was enacted it was mostly children, but now it's over 50 percent adults who file petitions to the program.

So it's healthy and it's the fact that they're healthy people and it's mandatory for school attendance that makes the difference.

MR. CONWAY: And I would just like to add that it's treated this way because of policy considerations.

It's the foundation of our national health program, and it's a big part of our national defense program. Vaccines are important. They're treated differently as a matter of policy.

FEMALE VOICE: Okay. Thank you.

MR. SMITH: Okay. Thank you. I thought I might need my handkerchief for the panel to keep people, but I didn't.

I want to thank just an absolutely outstanding panel and would like you to thank them

with a round of applause.

(Applause.)

MR. SMITH: With that, Gary, are there any announcements?

CHIEF SPECIAL MASTER GOLKIEWICZ: I think the only announcement is lunch.

MR. SMITH: And we avoided violence, so thank you all for being a great audience.

(Whereupon, at 11:20 a.m., the conference in the above-entitled matter was concluded.)

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REPORTER'S CERTIFICATE

DOCKET NO.: --

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HEARING DATE: November 19, 2008

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I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Court of Federal Claims.

Date: November 19, 2008

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