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COURT OF FEDERAL CLAIMS

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17th JUDICIAL CONFERENCE)

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IN THE UNITED STATES COURT OF FEDERAL CLAIMS

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17TH JUDICIAL CONFERENCE)

Fourth Floor
National Courts Building
717 Madison Street, N.W.
Washington, D.C.

Tuesday,
November 9, 2004

The parties met, pursuant to notice, at 2:11 p.m.

BEFORE: HONORABLE GARY GOLKIEWICZ
Special Master
HONORABLE RANDALL RADER, Moderator
KATHERINE REEVES, Moderator

PANEL MEMBERS:

TIMOTHY M. WESTMORELAND
NEAL HALSEY
KATHLEEN STRATTON
MICHAEL D. GREEN
RICHARD B. ABELL
MARK W. ROGERS
MINDY M. ROTH
JOHN H. KIM

P R O C E E D I N G S

(2:11 p.m.)

SPECIAL MASTER GOLKIEWICZ: As the Chief Special Master of the United States Court of Federal Claims, I welcome all of you to this session on vaccine causation.

I'm very appreciative, not only of the panelists, but all the help I received in putting this session together, Linda Renzi from the Department of Justice, Professor Meyers from George Washington Law School, and Ghada Anis from Miller & Associates particularly for putting in a lot of time and helping me out.

I'd just like to make a couple of announcements so that we can get started very quickly. We have a lot to cover on this topic. We've spent over 10 years doing it; we have three hours to discuss it today. One is cell phones. I've been told to make sure no cell phones. Turn them off, please. The other thing is food and drink. No food and drinks in the room other than the panelists.

PARTICIPANT: How about cigars?

SPECIAL MASTER GOLKIEWICZ: No cigars today. Lawrence Smith is not here, so no cigars today.

Let's see. The handouts that you received

at your seats, those are simply hard copies of everything that's been sent out to you electronically. I will tell you that the moderators are assuming that you have read the bios and the fact patterns, so that will not be delved into here. So if you haven't read the fact pattern, get it out now -- it's only a paragraph or two long -- and read it.

We are recording the session. We will have not only the materials but also a transcript of this session. We will make it available online for anybody that's not only here, but we have a lot of inquiries from people who were unable to attend, so that will be done.

I'd like to very quickly introduce my colleagues so that you can see them. Please introduce yourself to them. I even wrote them down. The last time I did this I forgot one of them. John Edwards. Why don't you stand, John, so they know who you are? Okay. Laura Millman. There's Laura. George Hastings? He was making the walk over behind me somewhere. Okay. I'm sure he'll be in. Margaret Sweeney? Margaret. And Richard Abell's up on the bench.

I'd like to make a special announcement for my last colleague. My most favorite I will say. I've

spent 16 years with her. She's retiring in January. It's a tremendous loss for all of us, but it's a tremendous gain for her family, especially her grandchildren. LaVon French, how about standing, and please join me in an ovation.

(Applause.)

SPECIAL MASTER GOLKIEWICZ: There's George Hastings. He's a little slow moving there. Okay, George.

PARTICIPANT: A long walk.

SPECIAL MASTER GOLKIEWICZ: His long walk. Okay. The other thing I'd like you to know is that we are not going to break today. We're going to move right into the second session. Okay? So anybody that needs that break, just quietly exit and come on back. And the panelists, you may want to monitor your water intake.

(Laughter.)

SPECIAL MASTER GOLKIEWICZ: It's going to be three hours we're going to go, and I was going to add some crack about you could appeal to Judge Rader, but he's not here right now. I see Judge Wiese -- oh, there he is, there he is. Okay. I was going to say, based on my current record of late, you can appeal to Judge Rader and more than likely I'd get reversed.

Okay. Why don't we started. Katherine Reeves? Where's Katherine?

MS. REEVES: Right here. Somebody said they can hear my mic, so I don't think I really need it. The one thing that the Chief Special Master neglected to mention is apparently someone has mistakenly picked up Professor Westmoreland's ID, so if you have it please give it back to him because he needs it.

I'm the moderator for the Vaccine I panel today, and each of the four panelists on the first panel is going to talk about causation-in-fact; what does it take to establish a logical sequence of cause and effect? They're going to talk about this, each from their own individual and unique perspectives.

This part of the panel discussion is going to last 90 minutes, and then we're going to go on to the second panel. And then we're also going to have sort of a joint panel discussion with both panels looking at the hypothetical fact patterns in your materials. And with no further ado, I'm going to ask Professor Michael Green to begin the discussion.

PROF. GREEN: Thank you, Katherine. As I understand, what I'm supposed to address is, what does causation mean to me or others in the legal profession, and how is that meaning distinctive from

other people who are on the panel or other disciplines?

I resist the idea that there is any difference in our usage of the word "causation" among any of us. Now, in saying that, I should be qualified and say, when I say "causation," I mean cause-in-fact which is what I understand we're discussing here. The legal profession has a long and tortured history of torturing the term "proximate cause," and I'm not here talking about our usage of the word "proximate" cause.

And what I think causation means, absent some special cases, is that but for the conduct or the agent of interest, the outcome or harm would not have occurred. It's that simple. That is, this idea, but for the agent, is a necessary but not sufficient condition for the outcome.

Now, having said that, as I often tell my students, the critical matter of causation is what I think of as the framing of the causal inquiry question, and in that respect, often different disciplines or for different purposes we may frame the causal inquiry in different ways.

What do I mean by the framing question? The framing question involves two "what"s on either side of causation. The first "what" that needs to be

identified is the event, the agent, the conduct, or other intervention that we are interested in and asking the causal question about. The second "what" is the harm, behavior, outcome, or other phenomenon of interest that we want to know whether it was caused by the first "what."

Now, in the area that I'm involved in, tort law, almost always, that causal inquiry is framed in the following way: Did the defendant's tortious conduct, was the defendant's tortious conduct a cause of the plaintiff's injury, whatever that was.

In epidemiology, although I think epidemiologists use the term "causation" similarly, they frame it differently. What they want to know is whether the agent that they're interested in, the intervention, was a cause of an increase in disease in a group. They want to know whether that agent did indeed increase the incidence of disease in some group that's being studied.

And in both epidemiology in some recent work by Sander Greenland and Jan Beyea, and in law, we may be interested not in whether a disease was caused by a toxic agent, but whether the toxic agent accelerated the onset of the disease. That is, the plaintiff would have contracted breast cancer in five years,

even without the intervention, but because of the intervention, the agent, it accelerated its onset.

And of course, that reveals that wrongful death claims are really wrongful shortening of life claims, rather than wrongful death claims. Now, why is toxic causation and proof of it different from the more traditional causal inquiries that we face, and, let me pick out, in tort cases?

I want to consider an automobile accident in which a driver negligently runs into a tree and her passenger gets out of the car with a broken arm. The passenger sues the driver for that broken arm. That causation issue is easy while off-table diseases that arise under the National Childhood Vaccine Act are often very difficult.

Well, one reason I think they're different is because the mechanism by which the injury occurs is well understood when it comes to traumatic injury. We know that certain traumatic events to the site can result in a bone that has some degree of brittleness breaking. And we can describe it in more detail if we wanted, and we well understand that.

So we know from the mechanism and from common experience that sudden blunt trauma is capable of causing such harms, and if the plaintiff did not

have a broken arm when she got into the car and had one after the accident, it's pretty easy to rule out other potential causes of broken arms. That is, if the driver wasn't carrying a great big sledge hammer in the front seat along the way.

By contrast, when it comes to disease cases, we almost never have a full, and often it's less than even a half decent, understanding of the mechanism, biological mechanism, by which that disease progresses from exposure to some agent to manifestation of the disease. Someday I think molecular biologists will be able to tell us in some degree of detail about that pathology, about that process, but as the old Honeywell ad goes, that day is not today.

Often, we don't know whether the agent of interest is capable of causing the disease in humans. That's the general causation inquiry that courts have undertaken and which epidemiology and animal toxicology attempt to answer. And then there's the problem of other background causes of the disease. If there are not, and the disease occurs frequently enough, it's not hard to figure out.

We figured out that the horrible epidemic of birth defects, limb reduction defects, that occurred in the early 60s were due to Thalidomide without a

single epidemiology study. Didn't need it, because the incidence of those kinds of outcomes was so rare that it was easy once we identified the common agent to figure out the causal relationship.

That's not the case when it comes to diseases that exist due to interventions other than the one we're interested in, and most often that is the case. When it's not, we have a signature disease and proof is relatively easy. Often, those other causes are unknown, as, for example, in the fact patterns that we have for today.

By the way, let me just take, if I have it, one minute or two minutes to say a word about the controversy over threshold relative risks. Those of you who work in the area know something about the controversy over a minimum relative risk of 2.0. That's not about causation.

It has enough epidemiologists that I talk to when I say, well, we're infatuated with this threshold 2.0, they don't understand why. And that's because the idea of a threshold relative risk of 2 is all about a legal requirement, namely the burden of proof, the civil burden of proof which is a preponderance of the evidence.

And that's where we get this idea that

there's something magical about a relative risk that is something greater than 2. Those in the science field don't understand that, and it's because they're not interested in our standard of a preponderance of the evidence as the burden of proof.

MS. REEVES: Thank you, Professor Green. Dr. Halsey, if you would take up the discussion.

DR. HALSEY: I would be happy to. I was asked to address the issue of establishing causation on the basis of scientific investigations, and this long history of the evolution of the science of assessing causal assessment.

Sir Bradford Hill, who initially came to the conclusions that smoking caused lung cancer in the 1960s, was the first to publish formal guidelines. They have been revised several times by epidemiologists and other scientists, and there are other sciences that do come into play, not just epidemiology here.

These criteria have been accepted by the scientific community and have been applied to many different situations. There are nine criteria, all of which should be considered, but no one criterion can establish a causal association, and not all are needed in order to establish a causal association. I'll just

mention each of those briefly.

One is the strength of an association, which is a measure of whether or not that association is due to chance alone or whether the risk that people have for exposure to vaccine is greater with regard to developing the outcome in question than to people who don't receive the vaccine.

Consistency is probably the most important criterion, and that is, through different investigators working in different populations and sometimes with different methods come to the same conclusions.

Specificity: Most adverse events are a defined clinical syndrome, and that's one of the things that I sometimes don't see in situations that are being brought before the injury and compensation program.

Temporality: There are two aspects to this. One of them is that the disease onset should occur after exposure, which is self-evident and common sense to anybody, but also that's there is usually a defined window of time when the increased risk of the event occurs associated with the vaccine.

Biological gradient, dose response, that actually applies much more to the toxic exposure

investigations, but there is evidence that dose may be a factor in increasing the risk of some adverse events, whether it's the number of doses of vaccine or whether it's the amount of certain components of the vaccine, including the vaccine agent, that may be associated with increased risk of adverse events.

Plausibility: The issue here is whether the adverse event is consistent with known biologic effects that might explain this adverse event.

Coherence: Does the evidence all fit together in a reasonable explanation?

Experimental evidence may be brought into play when there are additional studies, sometimes in the laboratory, in animals, or even with interventions with humans.

And analogy, the last criterion, which is also with weakest criterion, where we look at situations and other biologic systems such as animal studies or even analogy with other vaccines that might be associated with certain adverse events.

We have two basic approaches to investigating individual cases for establishing what you call causation-in-fact. Causation can be established sometimes by definitive by laboratory tests. If not, then we look for a demonstrated

increased risk of the event in people who receive the vaccine versus those who don't.

For example, some definitive laboratory tests include identification of the vaccine agent, let's say, in a place where it shouldn't be, such as in the spinal fluid for a child with encephalitis following mumps vaccine, which has been known -- or measles virus vaccine. The measles vaccine virus in the lung of an immunocompromised individual who has a progressive pneumonia.

Other examples exist. Most recently, the yellow fever vaccine virus isolated from the liver of patients with hepatitis and other clinical syndromes. In all of these investigations looking for a definitive laboratory test, one must be very careful to rule out contamination or the presence of intercurrent illnesses due to other viruses, or wild-type agents that also could be causing the disease.

You can use these definitive tests to actually rule out a causal relationship, something that I don't see discussed in the other documents that have been brought in front of us. For instance, if you do find a different agent that has been responsible for causing the disease in the tissue that you examine, the tissue that's affected.

Examples of this are persistent infections in the brain in children with measles virus who have had subacute sclerosing panencephalitis, or SSPE. To date, all of the isolates are wild-type virus, even in children who have received the vaccine and people thought were possibly due to the vaccine virus.

Also with varicella. We can -- with the varicella vaccine, sometimes it does cause a persistent infection. It can come out later as shingles or zoster and you can't isolate the virus from those diseases, but it also may be due to wild type.

There are other agents which can cause some of the clinical syndromes which are suspected to be caused by the vaccine, and I mentioned encephalitis. West Nile virus, for example, has been found in people who have had encephalitis that was temporarily associated with a vaccine of some kind or another. So we need to be encouraging the use of these diagnostic tests and whatever procedures are followed by the decision made within the legal profession. We shouldn't be discouraging people to look for those other agents.

And the absence of any evidence of this other agent doesn't mean that people have always

looked for those other agents. There should be some standards where people need to be looking for those other agents. In the absence of a definitive lab test, one can determine a causal association.

Most recently we've had a couple of examples: intussusception, the infolding of the portion of the intestine on itself, associated with the rhesus rotovirus vaccine, and myocarditis associated with the smallpox vaccine. Those conclusions have been reached by expert panels in the last few months actually. They haven't yet been brought fully in front of the Institute of Medicine. We just happened to step into the right to comment on them.

But you need to, in those situations, you demonstrate that the event occurs at a higher rate in people who have received the vaccine than other people who are similar who have not received the vaccine or controls. The strongest evidence comes from randomized, double-blind placebo-controlled trials that are usually conducted before licensure of a vaccine. Randomization is probably our most powerful tool for ruling out all of the biases and other variables that we spent hours and days and years evading in front of courtrooms.

But if you have randomization, you basically go around those problems. You don't have those problems. Unfortunately, these prospective trials are limited in the numbers of people who can be studied, and so rare events are sometimes not detected, and not detected until after licensure. Postlicensure, the most common approach is to do case-controlled studies where the question you're asking is, are people who have the disease more likely to develop the outcome in question than appropriately matched controls?

And there, we generate odds ratios, not relative risk. There's been no discussion of odds ratios, and odds ratios is an attempt to approximate a relative risk, but it is not the same. It is possible sometimes postlicensure to investigate these rare events. There are cohort studies and some other study designs which we won't go into detail, but there always are potential problems with selection bias and a variety of others that must be carefully examined with regard to the methods that were employed to determine that they did not play a role in getting us to a false conclusion, and false conclusions have been reached by some such studies.

In the absence of a definitive test, it's very difficult on an individual case alone, such as

what is brought before the program, to establish a causal relationship. And that's part of the complaints that we hear, but it's just the nature of science. And the decision should be science based. It's very difficult to do that on a single case. And there is no definitive test to investigate that.

One misunderstanding and one area of disagreement with what I see happening in the legal system is that the numbers of such cases should not influence the decision. If you only are looking at people who have an outcome, all of whom say that they had received a vaccine sometime before they get that outcome, it doesn't matter if you got 1, 10, 100 or even 1,000 such cases. That does not constitute evidence that there is a causal relationship. And that's because you don't know whether or not the risk was increased. One needs to have controlled trials. Those numbers can serve as a signal in order to investigate and conduct such controlled studies.

For example, the whole issue of multiple sclerosis and hepatitis B vaccine. There are hundreds of individuals who develop multiple sclerosis at some time after getting hepatitis B vaccine, but the careful scientific studies have shown that there is no increased risk.

Peer review. Just a comment on a couple of other issues where there may be some disagreement. Peer review is important, but certainly it is not sufficient evidence that good science has taken place. And as per the Daubert decision that we all have read, peer review should provide an objective, independent validation.

But a case report of a temporal association, even with a biologically plausible mechanism, doesn't really add to the evidence that might be brought in front of the program with regard to a single case that's based primarily on temporal association and biologic plausibility. So other similar cases really doesn't add to the science even if there are peer reviewed publications.

There are some studies that basically are bad science which are supposedly controlled studies, but they were not conducted properly, that do get published in peer review journals and do make it through the peer review process. Oftentimes, especially with case reports, the editors and others allow for speculation of causal associations. There are no guidelines at this time for publication of these case reports. And oftentimes people reporting things are free to speculate far beyond what they

should and far beyond what the science allows.

The issue of rechallenge comes up in some of the readings. Rechallenge data provides suggestive evidence of a causal relationship, but it's not definitive. There can be disorders that are recurring that might have occurred naturally and some people may get sequential or repetitive doses of a certain vaccine such as influenza vaccine. And that does not establish the fact, finding one or two or three such people who have had let's say relapses of multiple sclerosis, and they had a relapse within one or two months after getting their annual influenza vaccine. It does not necessarily mean there is an increased risk there, as has been determined now in a couple of recent publications. So in one case, it's very difficult to determine whether or not rechallenge is sufficient evidence for a causal relationship.

I also believe that the Elphin criteria which are in the readings are insufficient and inappropriate to establish a causal relationship. They use opinion, a logical sequence of cause and effect and a medical theory -- those last two are both biologic plausibility -- and a temporal relationship in the absence of other causes. One needs to look at the other factors and take them into account as well.

Comment on the relative risk greater than 2, I hold to the belief that there is too much credence given to this number. The real question that should be being asked is whether or not the evidence, the scientific evidence, supports the fact that this relationship is not due to chance alone. Much greater attention should be placed to the confidence interval.

There are studies that clearly show a relative risk or an odds ratio of greater than two, but they're based on two small numbers and there isn't sufficient power. That doesn't provide scientific evidence that there's a causal relationship. Or if the matching of the controls with the cases was inappropriate, and that has happened to very good epidemiologists sometimes inadvertently, that's not good evidence of a causal relationship.

I also agree with Professor Green and some of the things that he's written with regard to a relative risk of 1 to 2, but not greater than 2, doesn't disprove a causal relationship. Again, one should be looking at the confidence interval.

After general causality has been established, and again, you use different terminology here, then the criteria for determining an individual case are relaxed. When you know that a vaccine can

cause a certain disorder, then usually all we need is evidence that there was exposure to the vaccine and the disorder in question occurred at a defined time window that we know is a time when there's an increased risk of this disorder recurring, and somebody has looked and there is an absence of evidence for other causes. Most of these make it into the vaccine injury table, and those are the general criteria that people use for putting things in the table.

The last comment I'd like to make is that we need to be basing these decisions on compensation on the basis of rigorous scientific evidence. Compensating cases that are not based on good science creates problems for many people. It creates false expectations that people can have to come to this program to be compensated for injuries or for disorders that occur that aren't based upon good scientific evidence, and it promotes false believe regarding vaccine safety, and the safety of vaccines. It can cause harm and does influence some people not to receive vaccines who would benefit from those vaccines. I think it also can contribute to flooding the system and a waste of all of our resources in trying to deal with a multitude of disorders for which

there isn't good scientific evidence of a causal relationship. That's all I was planning to say.

MS. REEVES: Thank you, Dr. Halsey. I'll ask Professor Westmoreland to pick up where you left off. Thank you.

PROF. WESTMORELAND: Thank you. I need to begin with a few disclaimers. The views I present are my own. They should not be construed to represent past, present, or maybe someday future employers. That's most notable because I still do work for Congressman Waxman and the Democratic staff of the Government Reform Committee and the views I'm expressing today are my own and not his or that committee.

The second disclaimer I should give is, unlike many of you, and many of the people on the panel, the views I give are an abstraction. I don't litigate, I don't usually work with people who litigate, I don't usually work with people who work with people who litigate. I work with the lobbyists of people who work with people who work with people who --

(Laughter.)

PROF. WESTMORELAND: So I'm seven levels removed from the daily concerns of vaccine injury and

vaccine compensation.

And then the final disclaimer I give you is one that I warned Gary Golkiewicz about, is that my views are antique. I have not kept pace with the field. I have not worked on vaccine injury compensation since -- well, not closely since 1994, but Gary has invited me because I worked on the original enactment of these statutes, and so I'm speaking from that historical perspective of Congressional intent, Congressional activity, Congressional understanding of statutory interpretation here.

So with those three disclaimers, let me begin by saying I think it's important to remember that the program was enacted for multiple reasons, the overall program. It was enacted to provide compensation to injured people.

It was enacted to reassure patients, or by and large the parents of patients, that adverse events would be compensated and thus, to the extent that fear of uncompensated healthcare costs was part of the decision to immunize, that that would be removed from the parents' decision of immunization, and thus encourage immunization. And then finally, to provide limited liability compensation for companies and those

who administer vaccines.

With those three in mind, I would then point out that like all compromises especially Congressional compromises, that the program is everyone's second choice. The parents wanted uncapped liability, the companies wanted an exclusive remedy and the administration at the time wanted no cost to the program, so it was everyone's second choice in trying to come to it.

With that understanding, I think that there's a guiding mantra and in statutory interpretation when you observe that the language is perhaps unclear, then you may in some people's taxonomy look at intent for a problem to be solved or purpose for the legislation.

The guiding mantra I think in this one is an overall goal to produce a system that is: quick and simple, in contrast to product liability litigation at the time; predictable, in contrast to the roulette of litigation in which one out of 10 people would get a lot of money, and the other nine would get nothing, at the time; and generous, in order to encourage petitioners to accept compensation and in order to meet the original goal of reassuring parents.

The perceived giant step at the time of the

enactment of vaccine injury compensation was the table. This was sidestepping causation proof. It was deeming causation. And I am reminded when my professor said whenever the word "deeming" comes up in a court decision, Katy bar the door.

And it is doubly true when the Congress comes up with the phrase "deemed." And I'm also reminded of the Oxford Union statement that dogs are prohibited in the Union and any animal providing service to the blind is hereby deemed to be a cat.

That is indeed what the Congress did in causation with the table. It was quick, simple, and predictable in the table, and it was generous. It was not generous in dollars in the table per se, -- generosity in the compensation is in another section -- but generous in the standards for deeming causation. The table was based on science, but the table was not pure science. The table erred on the side of compensating both in injuries and in timeframes, and for our purposes today, causation.

Those who voted for the program I think would be very surprised to find that the masters in the court have ended up working so hard on off-table cases. They were almost an afterthought in the creation, or a safety valve in the creation of the

vaccine injury program. It is perhaps analogous I suppose to a rare event that does not show up until you have a more robust statistical sample.

But let me stay with that point for a second because I think it's important in understanding causation inside this program. The table is a policy document. It is not a scientific document. It did not require a risk factor of 2. It did not require the five prongs of Stevens. It does not now require the Secretary to meet a preponderance of evidence standard in making changes to the table.

And the standard for changes in the statute for injuries, it's only about injuries associated with vaccines, not caused by vaccines. The temptation I think in looking at this is to make the preponderance of evidence decision on the basis of the generous portion of the mantra and policy of the intent of the purpose of the problem to be solved.

But I don't think that's the Court's decision to make as it's laid out in the statute. Preponderance of evidence, as a couple of people have already noted, means, perhaps, a risk factor of 2 within well constructed statistical models. I don't want to fall prey to insufficiently powered studies.

And in some ways it is up to the petitioners

and others to take it elsewhere to get the generosity for standards below preponderance of the evidence. I do want to point out that that's a legitimate decision for the Secretary to make. For policy decisions, the Secretary could use a risk factor of 1.001 and decide to put something on the table. And the Congress could amend the table on the basis of other than the preponderance of the evidence or strict causation also.

And they could use a risk factor of 1.001. And indeed for policy reasons, harking back to one of the other cases, Congress could deem all events within 10 days of a vaccine to be vaccine related. They could do that, but they didn't, and there are significant downsides to some such generosity whether it's done within the Congress, the executive branch or the courts. There's obviously cost.

But more importantly that I think would be a policy concern here, reading the Congress's intent, is the possibility of reification of causality. That the public may come to believe that risk is substantial if the Secretary deems causality, or if the Congress deems causality. And they may in turn shy away from immunization, thus undermining one of the other three-prong principal purposes of the statute.

I think for the Court there is no option to avoid the decision without adequate information and so quickly looking down the cases that have been worked within this and trying to figure it out with Congressional purpose, "some linkage is necessary" is one of the statements here. And I think that's right. Not just coincidental timing.

And full well knowing that unless the background level of the event that we're looking at is an absolute zero, that there will always be some coincidental compensation going on, but that's the generous part of the standard and an element of the simplicity.

The Stevens methodology, the five prongs, or some variant of that I believe is perfectly compatible with the text and with the Congressional purpose of the original enactment. Establishment of routine tests of causality advances simplicity and a predictability test towards that goal.

I don't think you can view Stevens or any other variant of it as the exhaustive standard. That is clearly not contemplated by the statutory language of their purpose, but it can be a guideline for petitioners and respondents and if so, to improve simplicity and predictability, I think it's

appropriate to do so with the petitioners perhaps looking elsewhere for generosity.

I would quickly say in conclusion that the current Congress may feel quite differently about this than the Congresses for whom I used to work in enacting this legislation. I think the evidence in the smallpox injury compensation legislation that's more recently enacted shows that they indeed do feel differently about that.

And with that understanding I would warn people that there is a risk to taking requests to the Congress instead of the executive branch or the courts to fine-tune things. The Congress is a blunt instrument. It should not be used for fine-tuning Swiss watch constant mechanisms.

But having said that, I think that the causation standard is one that needs predictability and needs simplicity and needs guidance, and that generosity is built into the table, and further generosity should be built into the table changes. Thank you.

MS. REEVES: Thank you, Professor Westmoreland. Finally, I ask Dr. Stratton to talk about causation-in-fact. Thank you.

DR. STRATTON: Thank you. I've been asked

to talk about the analysis of causation from the point of view of the Institute of Medicine committees. And just to be clear, the IOM reports are reports of ad hoc committees of independent and unbiased and financially unconflicted national experts who volunteer their time. They actually don't get paid for all the work they do in preparing this material.

And I'm the senior staff person who provides managerial and technical support to these committees. And the committees are a product of VAERS that I'm honored to be associated with. The IOM role is that of the protector of some important processes and procedures that help assure high-quality reports.

The IOM committees of the early 1990s, the committees that prepared the 1991 and 1994 reports as requested in the '86 legislation were used to provide evidence; the evidence, say, for the table, for table injuries and for review of the table. That was its primary contribution.

And all those associations that didn't make it to a table injury are now reviewed in this causation-in-fact part of your program. And the IOM reports I know are used as evidence in this part of your program, the causation-in-fact part of your program. However, the IOM committees focus on a

standard of causality and a scientific comfort with a conclusion that is more relevant to table injuries than to causation-in-fact cases.

The other committees have used a fairly typical scientific or academic approach to assessing causality, as so nicely described by Dr. Halsey, and I think that none of the IOM committees, and there have been four of them since 1991, involved in these issues would take exception at all to Dr. Halsey's picture or his presentation about the general principles of causation particularly as based on epidemiologic studies, which has been what they focused on.

These causality assessments are primarily based on population-based epidemiological studies, and Dr. Halsey has told you what the hallmarks of the best of those studies are. Very occasionally have IOM committees had other data very strongly influence causal conclusions; the challenge/rechallenge cases in Pollard and Selby, the Australian carpenter who got Guillain-Barré after the tetanus vaccine is a key example, and there's a subsequent example in a case report of twins who died after getting DPT in a recent report the committee has issued, but that's very, very rare. And they take extremely unusual circumstances for something short of epidemiologic studies to lead

to the IOM committees to conclude there's a causal relationship.

The committee use very standard approaches, as Neal just described, to assess in both the individual papers for its strengths, its weaknesses, its overall quality as well as the body of evidence that is put forward to bear on causality. You can make your conclusion about causality, and committees have, based on very few scientific papers if they are strong and they're consistent and they're coherent and they meet a lot of the other criteria that Neal described.

For example, the conclusions about multiple sclerosis following hepatitis B vaccine was not a huge body of epidemiologic literature that the committee felt very strongly that it supported rejecting a causal relationship. They just made a conclusion rejecting causal relationship there. There are other times when there are many, many studies and the committee was not able to add them up to the definitive conclusion one way or another.

So it's not a number count as to how many papers you have, how much evidence you have. And there's no magic formula for how a committee adds studies up, you know, committees have not used formal

rating schemes where you get an ultimate score and if you're above 85 you pass. Those schemes don't exist and the committees haven't used them.

The committees have discussed biologic evidence, as those of you who followed the reports know, separately from the causality assessments. The epidemiologic studies, but obviously, biological theories and knowledge of pathophysiology and all related fields of medicine play a role in a committee's consideration of whether the epidemiologic studies, particularly those that are finding positive association, make sense, again, as Neal described, in how you'd think about the Bradford Hill criteria.

So the committee thinks about biology when it evaluates the epidemiologic studies, but then it treats biology as a separate entity in the way these committees have done their reports throughout the years.

With regard to the material that the Institute of Medicine committees have reviewed that bear directly on causality, I think it is absolutely true that IOM committees have been more generous in terms of the material that they review. Some of the material that they've included in their reviews would not make the criteria that other evidence-based

medicine evidence-based assessment groups would even consider.

For example, case reports, VAERS reports, uncontrolled studies, and unpublished studies. There are certain bodies who simply wouldn't even count them in the material that they would use, but the IOM committees have always done that to the best of their ability. This was done in part so that it could never be said a-ha, but if only you had reviewed this stack of material you would have had a different opinion, and also because sometimes you learn very interesting things from these other studies. They may not prove causality, they may not weigh very heavily, but there can be things to be learned from this other material. And so committees have reviewed them.

One aspect of the causality conclusions that is integral to the Institute of Medicine work in this regard is there are category -- for those of you who know the numbering system, category two, which is the evidence is inadequate to accept or reject the causal relationship.

The committees decided in 1991 with the very first of these reports to work from a position of neutrality. And what that means is that the absence of evidence of an effect does not translate into a

conclusion that there is no causal relationship.

The committee requires epidemiologic studies that support no increased risk before they will say that there is no risk from the vaccine. They don't just look for the absence of a positive finding. And I think that that's been very important and occasionally misunderstood as people look at the summary judgments of these committees.

With regard to the biologic mechanisms, I think that has played an important role in a lot of the causation-in-fact cases, at least in some of the cases that I've read. And by biologic mechanisms, these are not the epidemiologic studies, but the in vitro studies, the animal studies, the human experimental studies or clinical studies that are reviewed.

At one time the IOM committees categorized their biologic evidence as theoretical or demonstrative. I think that was the big chart in the 1994 report on adverse events. That was never intended as anything more than a simple cut at "there's no real evidence in biology that could possibly explain this relationship" versus everything else; there is *some evidence* of biologic results of biological studies that would be relevant to the

adverse event in question.

The Immunization Safety Review Committee in its second report, which was the first report on thimerosal, used the term "biologic plausibility," and it was found severely lacking and confusing to most of the its audience. There was no agreement on what "plausible" meant, and no gradations of plausibility expressed within that particular report.

So the beauty of having the same group just keep doing it over and over again for eight reports, which this one group did, was that they could revise, and refine, more importantly, their language, but not the way they viewed the evidence but how they communicated their understanding of it.

The committee moved to using the phrases "theory only" or "weak," "moderate," or "strong" evidence that biologic mechanisms are operative in response to a vaccine that could lead to the adverse event in question. Without a good understanding in terms of physiology of the adverse event in question, this is difficult. But the committee's tried as best it could, and for the most part, they were able to find some biologic evidence that supports the theory. That is not true for all of them, of course.

There's no formal rating scheme for biologic

mechanisms or biologic plausibility that exists as far as I know. I hear there's some efforts to work on it now. Dr. Douglas Weed of the National Cancer Institute has actually written about this extensively, about the problem of there not being a standard framework for assessing the biologic evidence along the lines of Bradford Hill criteria or something even stronger such as other evidence-based criteria.

So this is a field of assessment, the biologic evidence data, that is much less developed than causal inference. It's been used so often in medicine and public health.

I just want to make one, two parting comments about how the committees operate when they prepare their reports. The committees do not and have never discussed amongst themselves, although I don't know whether they worry about it at night, the implications of their conclusions for the compensation program, whether as it applies to table injuries or to the causation-in-fact determinations.

They do the best job they can at describing what the science means to them and what the level of evidence is to them, and they don't talk about trying to fit it into your system here of causation-in-fact, or even the table injuries. They don't wonder if this

is going to lead to awards or not lead to awards, and is it going to make somebody a table injury or is it going to throw out cases. They simply don't discuss that.

The committees make no statements about causality or association other than those formal causality assessments that I described to you; the evidence favors acceptance of a causal relationship, the evidence favors rejection of a causal relationship, and the evidence is inadequate. They don't tie in the separate discussions of the biologic theories and the biologic evidence with the information that's fed into the causality conclusion to a separate summary statement about whether they think it is more likely than not that the vaccine can cause the adverse outcome short of epidemiologic evidence that supports or rejects causality.

So they don't end up, and they never have, with a statement that is directly useful in the argumentation of causation-in-fact, which is whether or not this adds up to something that is more likely than not, nor have they ever, with the rare exception of the case reports that they used in causality, made statements about individual cases. And with those case reports, of course, all they did was accept what

was written in those cases reports as evidence.

I mean, they don't make judgments about individual cases even if they reviewed them themselves as evidence, you know, presented to them under our public sessions, or materials, that is. And I think I'll stop there.

MS. REEVES: Thank you very much, Dr. Stratton. The panels have done such a good job of keeping within the time constraints that we ask them to -- we have time to ask them a couple of additional questions. Actually, Professor Green, I'd like you to ask you to address, what do you think are the most difficult issues with adjudicating cases such as this involving, as you put it, toxic causation, that exist today?

PROF. GREEN: There's two, and they're related. And actually, Kathleen -- right?

MS. REEVES: Yes.

PROF. GREEN: -- adverted to them, and that is, when does the evidence, whatever it is, justify an inference -- and it is an inference, whether we use Bradford Hill criteria, whether we're looking at biological mechanism, whatever we're looking at -- when does that evidence justify an inference that causation exists, or on the other hand, when is it

mere speculation, to put in the terms that judges and lawyers are accustomed to.

We have that problem all the time even in standard nondisease cases. Somebody falls down stairs that are unlit, negligently unlit. Did the person fall down because of the lack of light, or because of clumsiness? And unfortunately, the person who fell can't provide us any evidence because she's dead. Courts have gone both ways on that question, that is, whether a reasonable inference could be drawn, whether a jury could find that or not.

I think we face the same problem, a very similar problem, when we don't have very, very powerful evidence, the sort of evidence that the IOM would say, oh yes, it's established, or it's not, or the evidence is unclear category that you're describing. Yet the standard is the preponderance of the evidence which may be less than the IOM committees would want. That to me is a very, very difficult question, one that I haven't sorted out in my own mind. What is going to be sufficient to draw that inference?

The related question is, how do we evaluate biological mechanism evidence? As Doug Weed persuaded me, Kathleen, there's good biological mechanism

evidence and there's pretty cruddy biological mechanism evidence. To put it another way, it's just a hypothesis that somebody came up with when they were taking a shower in the morning. And the difficulty for us, frankly, is we don't know biology. And I'm speaking for all the lawyers here.

I don't know biology, and my eyes glaze over when people start talking about biological mechanism. And that becomes very specific to agent and disease. We can't just learn epidemiology or toxicological methods and understand it. Now we need to understand inside the body, which has always been mystery to me. So, to me those are the two very, very difficult things that we confront in these kinds of cases.

MS. REEVES: Thank you very much, Professor Green. Dr. Halsey, you've been sitting here listening to the discussion. Are there any specific aspects of some of the criteria that have been suggested today that could be used to look at cause-in-fact that you take issue with, and if so, why?

DR. HALSEY: Well, I mentioned a couple of issues regarding the overreliance on the relative risk of better than 2, but I think we'll get to that with the case that you have developed a little bit more. An additional one is the so-called absence of evidence

of other possible causes. There doesn't seem to be any good criteria for what people should have done to investigate the case.

As I give a couple of examples of encephalitis, somebody gets a particular vaccine and then 10 days later they develop encephalitis. There should be an onus on the clinical evaluation of that situation to look for well-recognized causes of viruses and other things that can cause encephalitis. And that evidence should be brought before the special master who is reviewing the case.

And I can envision the potential situation of somebody evaluating a patient and from a clinical standpoint and saying, well, they received X vaccine 10 days ago. They are subject to getting compensated. But if I happen to find that West Nile has caused it then, you know, they're not going to get compensated, so I don't want to look for that. And that would be a mistake.

I can't say that that has ever happened, but I think that there should be some standard of what studies were done to look for recognized causes of these diseases. I see in some of the arguments that people say that there's an absence of evidence of anything else. But in some situations nobody looked,

and you should have some obligation to look for what is known to cause the disease.

I thought I would be disagreeing with Professor Westmoreland on the issue of generosity, but I actually don't think that I do. I agree that the program should be generous in the way that he outlined, especially when looking at the windows of time and there's an increased risk, if somebody's on a margin, then you should get the benefit of the doubt in those situations, and I think that that happens for the most part, and some of the other issues.

And he, I believe, agrees with me on the potential harm from giving compensation for situations where there really isn't great scientific evidence of a causal relationship. And that's something that I worry about. I think there is a natural tendency for all of us to want to help people who have been injured by something, and that, before we had the injury compensation program, that did happen. Some well known cases, Reyes v. Wyeth with regard to polio. You know, temporal association between receiving an oral polio vaccine and somebody who got paralyzed, while in that particular situation, they got a wild-type virus from the child. But yet they were still compensated. The Judge decided that this family needed compensation.

The compensation program has helped immensely to get us past that kind of thinking, but we must be cautious that we can do harm by overcompensating. And so the most important message I would probably give is that greater information should be provided on what the program is going to use. What are the standards of science that -- what are the standards that they're going to use to provide compensation? I think this effort today is a part of that process and I hope that will make it easier in the future.

I do believe that most of the compensation should be for the table injuries and that there is way too much time and resources being spent on these attempts to get compensation for off-table injuries.

MS. REEVES: Thank you, Dr. Halsey, and thank you to all the panelists. I think now I'm going to turn it back over to the Chief Special Master.

SPECIAL MASTER GOLKIEWICZ: Okay. Well, we have a choice here. We're back on time track here. We could take the break or go forward. My tendency in trials is to just keep going because if you give people a break they'll just talk longer and more and so forth, so --

(Laughter.)

SPECIAL MASTER GOLKIEWICZ: If we get done earlier, so be it. There's a cocktail party to go to.

Our next moderator, I'm very pleased. I'll intrude a little bit on our friendship. He reminded me of it today as he started getting involved with the materials what a difficult task he had to take on here. Judge Randall Rader of the Court of Appeals for the Federal Circuit. In a prior life, though, he was a judge of this Court, a trial judge, and issued one of the first causation-in-fact opinions. I'm sure you'd recognize him under the name of Strother. You probably don't get to the point where you see who the author is, but it's Judge Rader. So he is not new to these issues, although he's kind of in the same boat as Tim Westmoreland in that he's a little bit ancient to the issues.

(Laughter.)

SPECIAL MASTER GOLKIEWICZ: I'm sure he's proud of it. As Professor Westmoreland, he's right up to speed I'm sure. Judge Rader, do you want to take us to the next step?

JUDGE RADER: Do I have to sit here and listen to you call me ancient?

(Laughter.)

JUDGE RADER: We first need to hear from a

few more folks, and then we're going to look at our problem. The rest of our panelists, however, are lawyers. That means we can ask more of them. Five minutes, John Kim.

(Laughter.)

MR. KIM: I can't say hello in five minutes.

(Laughter.)

MR. KIM: You know, when we first started this program, when I first came into this room I'd never been involved in the vaccine program. I was very skeptical of the program, of whether it was truly a viable and worthy arena for vaccine victims. I have become a supporter of this program. I'm a champion of this program. I think it is a program that works, but it is a program that needs change.

It is a program that is faced with a number of cases that I don't think Congress ever intended to be included in the Act. It is burdened with developing science that shows that table injuries are not going to be the primary focus of compensation issues anymore. They're going to be the off-table injuries.

And it brings in this whole debate, and this whole dichotomy between the traditional systems of recovery. On the one hand you have what Ms. Stratton

and Professor Halsey talked about and that's a level within the scientific field of scientific certainty, scientific comfort. Making sure it's statistically significant. Making sure there's adequate power, making sure we get rid of the biases.

In other words, you have to have epidemiology to draw that causal relation, and that epidemiology has to be sufficiently powered to about 99.5 percent. Unfortunately, in the legal system, you have a burden of proof of a preponderance of the evidence; more likely than not; fifty-one percent.

And it's within that great disparity when science begins to debate the legal side of it that there has to be some sort of solution that we find, especially in this program. Because I think underpinning this program is, as Professor Westmoreland talked about, an overwhelming presumption of not only do we want to compensate, not only do we want to continue to promote vaccinations, but there is an overwhelming issue of public health.

We want a mechanism and we want an avenue by which, from a public health standpoint, we can determine what our policies are, whether our vaccinations are safe. And if you take that from the Act in part, then I'll submit that the closer you come

to the Daubert standards, the closer you come to the traditional tort definitions with respect to causation, the worse you become in terms of public health.

Proof of that is, when the Daubert opinion was written, when it was already to the Supreme Court, amici briefs were filed by doctors, physicians, public health officials saying it was an anathema to public health. To not act from a public health standpoint until you have relative risk of 2.0 is reactive. It is not proactive as public health should be.

If you take this inherent conflict and then you have to look at the state of the science or what's available to individuals who ultimately have to make a determination with respect to causality. And there's conflict within the source of that information.

We know industry has its hand in science. We know industry is facing some criticism for repression of studies, negative studies, for maybe misrepresenting certain things. We know that the FDA on the other hand is overworked, overtaxed, understaffed, underfunded. And we know that even the NIH has recently gone through a period where they're in an abeyance right now on allowing consulting because there was too many unreported and reported

conflicts between NIH, the studies they were doing, and the manufacturers they were associated with.

Those are all biases that have to be taken into account. Those are all biases that often are unaccounted for in epidemiology. And if you want to say within this program now as we try and promote a new causation-in-fact standard that we're going to require epidemiology, that we're going to require an increased relative risk of 2, then I think we run a very dangerous course within the program because you have to be able to test those biases, the compounders, things of that nature, and this program is not established and set up to do that.

You have limits of discovery here. You don't have the traditional in-depth examination that you can do into the background behind these studies. And, you know, I know it sounds like I'm attacking, and I think to some extent, Special Master Golkiewicz expected me to, but there's a difference between getting home and expecting more from your doctors when they enter a legal setting to testify than what you would expect them to do on a daily basis when they're treating your child. And to require epidemiology is to accept the notion that science is always contemporaneous and current, and we know that's not

true.

We've had examples throughout history. Asbestos was once thought to be safe. Tobacco was once thought not to be addictive. The Gulf War Syndrome was once thought to be imagination. You had the expert representing the Tylenol manufacturer testify that yeah, we lagged behind and then the legal system jumped us forward with respect to the association between alcohol and acetaminophen. You had PPA which science lagged behind before the Yale study finally came out.

And epidemiology in and of itself doesn't get there, you know, oftentimes. Especially the ecological type of epidemiology because unless you're actually studying an at-risk population and then comparing it to a control group, you're not going to find anything, and oftentimes you're not going to find an increased relative risk of 2.

A prime example is neural tube defects in folic acid. Traditional epidemiology missed it, blew it. And it was only until the at-risk population study that you finally got home and found the causal link. Now, the problem with that is, no manufacturer, no industry, no one wants to do that type of epidemiology for a number of reasons, but number one,

the cost. The cost is enormous. The resources are enormous.

Number two, the FDA doesn't require it in their protocols to get a drug approved to go on the market. And number three and perhaps most important, is they don't want to know the answer. They want the drug on the market. And to require epidemiology as the threshold to get home on a causation-in-fact case is an unbelievably unfair burden to victims.

JUDGE RADER: Thanks, John.

(Laughter.)

JUDGE RADER: Don't challenge my credibility. Art?

MR. ROGERS: Yes, sir. Thank you, sir. Five minutes is going to be tough. We've covered a lot of ground here.

JUDGE RADER: Then I'll give you about seven or eight.

MR. ROGERS: Thank you. I don't think first of all that the statement that to require epidemiology is unfair -- I think it's an oversimplification of the problem. The problem is, and I think Professor Green ably stated it, is that you need something beyond mere conjecture, that these illnesses, the kind of illnesses and conditions that are alleged in these

cases following vaccinations, they occur in the absence of vaccinations for the most part. And in a large population, they occur a lot. They're not rare.

And we vaccinate widely. And therefore you can expect some of these conditions to occur following vaccination strictly by chance, so you turn to the fact finder and you say -- does anybody have any trouble hearing? And you say, my condition was caused by the vaccination. And you're the burdened party. You have to prove it. You have to do it with something.

Now, we've talked a lot about epidemiologic evidence, but the fact of the matter is, that's not required, but something is. And because it ends up for the most part an epidemiologic question, that's the kind of evidence that the fact finder looks to. But you've got to come up with something. You have to provide something to meet your burden, the petitioner's burden.

Now, Mr. Westmoreland talked about the generosity of the Act. Certain portions of the Act are generous, but this standard for proving actual causation is not. It's a preponderance standard. It's exactly the same standard in the civil sphere. There's nothing different about it.

And I will contend that it's very straightforward. And we can incorporate, because of that same standard, we can incorporate the learned treatises that have been supplied here, the ALI restatement on torts, the IOM's discussion of causation, the numerous cases including Daubert that's been alluded to. And all of them point to the same thing. That is, you need evidence. And that evidence has to meet standards of scientific reliability.

That's not certainty. It still fits within the preponderance standard, but it has to be scientifically reliable evidence. And again, I beg to differ with Mr. Kim. He talked about the problem that the evidence isn't there yet. The claims are coming in but the studies haven't been done. That works against the burdened party, and the burdened party in off-table cases is the petitioner. That's the way this statute is written, that's the way we have to apply it, that's the way we have to enforce it.

I would note that, you know, another comment I completely agreed with was Mr. Westmoreland's comment that the table was intended to be generous. It's a unique feature of the Act. That is, you show that you suffered a certain condition within a certain timeframe, the causation is presumed.

The Federal Circuit said in Hodges that the statute does that heavy lifting that we talked about with the off-table case. Well, then the tables have turned. Then it's the respondent that's having to do the heavy lifting of proving an alternate cause in order to defeat compensation, which if you look at the case law is very, very rarely done. And all of the problems we've been talking about work against the respondent.

So I would suggest that perhaps the program is the victim of some of its successes, and that is the table. Because what the Secretary does is it takes those conditions for which there is the kind of evidence we're talking about, puts them on the table, and so the best of the cases that a petitioner might bring aren't off-table because they've been put on the table. So there's an inherent problem, if you get my drift, that the program creates. By putting certain injuries on the table, they don't leave much for petitioners, in many cases, for petitioners to bring.

I can't sit here and deny that it is heavy lifting for petitioners bringing these cases, but that's a matter of law. That's settled law. That's what the Federal Circuit observed in Hodges and nothing we say here can change that. The Federal

Circuit has determined that Daubert applies to this program in Terran. We can't change that here, so I would respectfully suggest that some of the suggestions or concerns that Mr. Kim has raised is this is the wrong form to do it. That's for the legislature. So those are my comments. Thank you, sir.

JUDGE RADER: Thank you. Mindy, you're next.

MS. ROTH: Gee, what's left?

(Laughter.)

MS. ROTH: Just by way of background, I think that I'm hear today -- can you hear me now -- because I practice in the State of New Jersey on medical malpractice, product liability, personal injury, as well as vaccine litigation both in the fund and in civil actions. And as a practitioner in that area, I think that the causation-in-fact cases are something that I was asked about because quite honestly the proofs in state court have become less stringent than the proofs here in the Vaccine Act.

Over the years, my experience has been that the confusion is more of a scientific probability necessity in the Vaccine Court than a scientific proof standard, which is really what I need to prove in the

medical malpractice in the state. Thanks to Mr. Monday, I've spent the last week reading volumes of information that I downloaded and has been handed here in a nice file.

And I have to say that in comment to some of the things that I've heard here today, it was interesting to me to hear that the vaccine table was really a policy document, and not a scientific document. That has created an inherent inequality for a petitioner who happens not to have a reaction within the timeframe of the table or not to have a reaction that's listed on the table. They're unfairly treated. Now they've got to prove their case, where the heavy lifting was done by the vaccine table if they happened to be lucky enough to fall on it.

It's also interesting to me that the Institute of Medicine speaks more of biological plausibility of a vaccine reaction or the adverse reaction event association being plausible and coherent with the current knowledge about the vaccine. The IOM committee favors acceptance of a causal relationship between a vaccine and an injury solely on the basis of or convincing case studies where the case studies clearly establish that the vaccine has been tested and that there are cases of a specific

reaction.

It appears to be that the Institute of Medicine views epidemiological studies, and I am a lawyer and not a doctor so I can't pronounce any of these things, more for their capacity to reject a causal connection if the study is controlled than it does to prove the causal connection. Now, I can only speak from experience and cases that I've had, and I think that Ron Homer's case that shall remain nameless is a good indication of what we're up against as attorneys today.

The totality of the circumstances is not taken into consideration when we try these cases. Simply because there are no concrete proofs doesn't mean that a person did not suffer a reaction to a vaccine. I recently had a case where my treating physician agreed to act as my expert in a case. He ran every test humanly possible on this gentleman to rule out every other cause, and the only thing he could come up with was the man had a vaccine. He had a reaction.

I actually went to trial on this case against an expert who said nothing more than case studies are insufficient. It's a quantum leap of faith to believe that this man had a vaccine reaction.

Now, if I was in state court in New Jersey and I received a report like that, I would file a motion with the Court claiming that the defense report is a net opinion and it should be barred from trial. And chances are that I'd win.

Either the defense would come up with a medical basis for their defending this case, or they'd pay on it because you can't simply have an expert say no, it's not, and end up in a trial in the state court.

So, basically, I think that the standard in the Vaccine Court has far exceeded anything that the state court requires for a preponderance of the evidence.

JUDGE RADER: Master Abell.

JUDGE ABELL: All right. When I first sat down here, Professor Green looked over at me and said I want you know that I've read a great number of your opinions, and I'm very, very impressed by your opinions, the Office of Special Masters' opinions, and they're far superior to what I've seen in many other Courts that have approached on these issues.

And I just sat there listening to that positive feedback for a moment. And then, of course, he looked me straight in the eye and he said, now,

when I say you, I do not mean you personally.

(Laughter.)

JUDGE ABELL: True story, obviously.

Now let me mention just a few things.

First, it is often the obvious that eludes us, so let me mention a couple of these decisions that are obvious. If you go back to the first seven or eight years of this Court, roughly 1989 to 1997, I don't think it would be hyperbole to indicate that perhaps 90 percent of the cases really were table cases because we had a different table.

And perhaps those 90 percent of the cases the Masters were more concerned with witness evidence of what indicia, what symptoms, what symptomatology occurred because, if certain symptoms were found and they were table symptoms, then suddenly all types of positive effects came down for the petitioners and counterburdens on the respondents. That is, that there was a factor unrelated; otherwise, the petitioner would prevail.

But, since the table changes of the mid- to late 90s, about 1997, that has reversed itself. And now I think it would be fair to say that perhaps 90 percent of our cases are causation-in-fact.

And, of course, that harks back to the

traditional tort principles that we are now concerned with. It gets into so much else that we have been talking about here today.

Before I forget it, let me mention several small items because there's been discussion. From my perspective, preponderance of the evidence is 50 percent and a feddle. Somebody else went so far as to say 51 percent. It's not really 51 percent.

I also should indicate there's been a great deal of discussion about epidemiological studies. In the last three or four years, I do not recall any cases that I had that relied on epidemiological studies.

Before we get into that too much, I want us to realize that that's only one of the items that may come up. What we're looking for is a mechanism generally, a link or linkage. Now some might argue that that should not be necessary. That's a different issue. Perhaps it's political.

And I must say and I'm presuming that all of my colleagues would agree that we are continually looking for guideposts, for guidance, direction, and whether that be from the public end of it in Congress or whether that be from other Courts or higher Courts to give us some direction, we're continually looking

for that.

I think I can fairly tell you that, inside chambers, we are constantly talking and discussing, and probably all of us are pretty much at the same bottom line -- the question is how to get there -- of issues such as flexibility, simplicity, expedition. Cases should be heard relatively quickly. That does not mean all of them are. But we're looking for consistency, and, of course, quite clearly, that isn't always there.

One of the items that bothers us and no doubt it bothers other Judges in other Courts, but since it bothers us, I'll mention it. And that is you can go to the same Special Master but have different attorneys and different experts. And perhaps the factual scenario is analogous, but you can get very different results. A fortiori, if you go to different Masters with different experts and different attorneys, you can get very different results.

That bothers us. I don't know if there's a resolution to that, but part of that is our seeking for guidance and direction, which is also one of the reasons that we are here today.

And, by we, I mean the Masters and their staff, their clerks, the ones who we really serve.

This is a user-friendly Court. Petitioner-friendly Court is what it should be, what it has historically has been, what, presumably, it still is.

But its metamorphosis has changed circa 1997. And, of course, if you have a metamorphosis, whether we have turned into moths or butterflies is a different issue and one I'll have to leave to all of you and perhaps to historical circumstances.

Again, I want to finish by saying we are continually concerned with thinking outside the box, finding solutions that really get to the bottom. That is, did this vaccine cause the harm alleged by a preponderance of the evidence, and how do we go about doing that?

Epidemiology is only one of the tools that is there. An explanation, a mechanism, perhaps a temporal association can assist in that. There's any number of items, and we try to keep ourselves as open as possible for that.

Well, I've probably said more than enough -- certainly, more than some of you wish to hear -- so I will adjourn.

JUDGE RADER: All right. Do me a favor. Stand up. Stand up for a second. Take 15 seconds. You know, we may avoid some heart attacks this way,

right, Doctors?

MALE VOICE: Pulmonary embolism.

JUDGE RADER: There you go. We don't want any liability here in the courtroom. Sit back down. All right. Fasten your seat belts because we're going to take a ride now. We've got a factual set, and we're all going to explore this together.

Let me give you the ground rules. You can participate as much as they can. The only difference is you have to raise your hand. They don't. But, please, if you have a question, if you have a comment, dive right in as acknowledged by me. Panelists, two- or three-minute responses to my questions.

We have a petitioner -- boy, I don't even get started.

You want to respond already. To me or to them?

JUDGE ABELL: No, no, no. I have a question that I thought you were asking -- if you wanted to ask questions of the panel from what they had spoken --

JUDGE RADER: Work it in, but let's get started and then you'll get your shot.

We've got a petitioner who takes the flu vaccine, 10 days later develops a juvenile myelopathy. We know that 60 percent of the time there's no prior

event associated with these myelopathies. They kind of come. They kind of go. Nobody knows to associate them with anything.

Forty percent of the time, though, there's a prior illness or, even in a few cases, a vaccine. We know that this myelopathy is associated somehow with the Epstein-Barr virus. Now let's start with Dr. Halsey.

Dr. Halsey, what likelihood is there of causation-in-fact here?

DR. HALSEY: Well, there are a number of questions that we would ask from a scientific standpoint about this study.

JUDGE RADER: Wouldn't you know. He has a question, not answers.

DR. HALSEY: We don't have the information we need to judge the quality of the study. Who are the cases? Who are the controls? Is this a cohort study? Case-control study?

JUDGE RADER: But there is a study.

DR. HALSEY: There is a study. But the first thing one does is to have to valuate the quality of the science that led to the results that we're seeing, and we don't have that information.

JUDGE RADER: Tell us what the study said,

Doctor, very quickly.

DR. HALSEY: Well, the study, as evidenced in the figure that we have, does appear to demonstrate an increased relative risk of this disorder, CJM, in varying periods of time following vaccination. It depends upon what these bars mean. If that's an error bar, a standard deviation, or a confidence interval, I don't know what they mean.

JUDGE RADER: Well, it looks like, when you get out there, what's that middle bar? When you get out there that far --

DR. HALSEY: There is a relative risk of three. Then there is a bar that shows it doesn't come anywhere near one.

JUDGE RADER: That's beyond the relative risk of two.

DR. HALSEY: Let's assume that's a confidence interval for right now.

JUDGE RADER: That's beyond two, though, so when we get there, have we got causation-in-fact?

DR. HALSEY: No. You don't have causation-in-fact from this study alone and from these results. You have what appears to be an elevated relative risk also in the period of time eight to 14 days, 22 to 28 days.

One of the points I was making about too much emphasis on the number two is that you can manipulate that relative risk by taking different time windows here. What if I just picked the one month?

JUDGE RADER: Well, let's stick with our case. We've got 10 days out. You say there's an elevated risk.

Dr. Stratton, can you give us some kind of a biological mechanism is the fancy word --

DR. HALSEY: Does he never let anybody finish?

JUDGE RADER: No.

(Laughter.)

JUDGE RADER: If you don't believe it, come visit me when you have 15 minutes to litigate a case you've tried for six months.

Dr. Stratton?

DR. STRATTON: I think that the information presented here doesn't help in terms of giving you confidence based on a biologic mechanism.

JUDGE RADER: Help us out.

DR. STRATTON: On this particular case, I don't think it shows a whole lot about any results about his immune system. And I don't think we know exactly how the immune system is affected in this

particular disease.

And, with regard to ruling out that it was some other kind of infection, it says there's no evidence that they suffered EBV within the past few months. But I'm not sure there's evidence that he didn't, so that's not clear given the way this is presented. Were there even any studies done?

JUDGE RADER: Kim? Mr. Kim? Your case seems to be slipping away here.

MR. KIM: Well, based on what I see here, I don't think I'd take it.

(Laughter.)

MR. KIM: I think you can see why.

JUDGE RADER: Oh, come on. It's got a great contingency fee.

MR. KIM: Well, but let me just say. I mean, I want to make it real clear, you know, remark that I don't think you need epidemiology. I agree with Dr. Halsey that if you look at just what's been provided to us here today that we would want to go behind it and look at it.

But I also think that, if I were assigned the case today, that you can look at case reports, you can look at textbooks to see whether it's consistent with traditional notions of medicine, you can look at

adverse event reports, you can look at the VSD data, you can look at the clinical trials that the manufacturer of the vaccine did prior to it being put on the market, you can look at the animal studies, you can look at the pharmacology. There's a number of things that you can look at to develop a logical sequence of biologic plausibility.

And then, if you have -- if it's supported, then I think if your clinician in his every day practice has done a big differential diagnosis, game over.

JUDGE RADER: I'm going to rule that, in this case, they have found no alternative causes.

Mr. Rogers, even Dr. Halsey here said there's an elevated risk there. There's no alternative causes. He's just a little short in terms of temporal association with going right into that period of more than two relative risk cause.

Isn't this a matter of fairness? He just missed it. Where is the equity here? He just misses falling into that category where I think even the doctors might begin to say looks like there's some relationship.

MR. ROGERS: Well, under Daubert, and we've talked about it a little bit here, it's a standard of

admissability. And I think, you know, accepting what's here at face value, this kind of evidence would be admissible.

Daubert talked about evidence of a relative risk greater than two, and this study shows it, you know, albeit it's at the margins and arguably outside the timeframe. So it would be something that would -- how to say it -- pass a threshold standard of admissibility.

Now, persuasiveness, whether it would put the claimant over the top by a preponderance, well, the experts are asking all the right questions. They'd look at the strength of the study. They'd look at --

JUDGE RADER: You don't have any equity bones resonating in your rib cage, in other words.

MR. ROGERS: Well, I hope so.

(Laughter.)

JUDGE RADER: I'm sure you do, too. I'm just kidding.

MR. ROGERS: I think what you have here is a patient who's completely convinced that their case is caused by the vaccine. They would be completely convinced and they'd be filing this claim in good faith.

If that were a table injury, of course, they'd prevail, but under a causation-in-fact standard, they're not there yet. They've got a reasonable basis for their claim. They've got evidence that's arguably admissible, but not persuasive.

JUDGE RADER: You know, Professor Green, the Federal Circuit has said, if you're off the table, you have to do something called heavy lifting is the term that the Federal Circuit used to talk about the burden of proof you're going to have to meet to show causation-in-fact. What's the heavy lifting that they're going to have to do here?

PROF. GREEN: Well, I think that means the burden of proof is on the petitioner. And as I understand it --

JUDGE RADER: But what's going to satisfy that? What kind of proof? If this is your case, are you going to want to --

PROF. GREEN: My inclination at least on the first part of this question from panel number one is I'm in agreement with Mr. Kim. I don't want this case. This is a terrible case, or to put it another way, my answer is no on number one.

It gets a little bit more interesting with

the epidemiology that you have at the end. And I'm not in favor of a threshold of epidemiology. That's I think a mistake in that sense. I agree with Mr. Kim.

And I think epidemiology can be very misleading. You know, this idea of an increased relative risk in focusing on two is really about specific causation. It's about whether this individual's disease was more likely than not caused by the agent. All right?

But there's a prior problem. Does exposure to the agent increase the risk at all? And the problem with observational epidemiology, that is, without randomization -- and, again, I don't whether this was a clinical trial or whether this was observational.

But, with observational, there's all sorts of risk of error. Dr. Halsey was talking about that. And, even if these are confidence intervals, and I don't know whether they are or not. They probably -- if they are, they're mistaken because there wouldn't be symmetrical around the relative risk that's bound. But, if they are, that still only addresses one of the sources of possible error in epidemiology.

JUDGE RADER: Let's stop there a second.

Dr. Halsey, I listened to you pretty

closely. You seemed to say, you know, experts speculate similar cases aren't relevant. You seem to say, as I was hearing you, that epidemiological studies are about all we have. Are you agreeing with Professor Green's concerns about those studies?

DR. HALSEY: No, I did not say that epidemiologic evidence is all we have. We do have lots of other studies that would take into account --

JUDGE RADER: But that's where you put your emphasis, right?

DR. HALSEY: In this situation where there is no test that we currently use to determine if the influenza vaccine caused this disorder and where we don't even understand the pathogenesis, you said in the fact pattern that scientific literature speculates that this might be immune-mediated, but there's no evidence that it is. We don't have a good clear pattern.

Actually, if this is a very good scientific study done with sound principles that meets all the criteria for a good study, and it's highly unlikely that another study likely could be done, the situation is not all that different than the Guillain-Barré syndrome following swine flu vaccine, or intussusception following rotavirus vaccine.

So, if I could have had the answers to the questions that I would like to ask about the quality of the study, then, in fact, as I look at that, I say okay, I don't understand how the disease is caused, but yet the scientific evidence from the very well done, valid epidemiologic study supports the fact that there is a relationship that is not due to chance alone, that there is an elevated relative risk, and that that elevated relative risk extends from the period of time eight to 14 days through the 22 to 28 days.

I don't just focus on this 15 to 21. As I believe Professor Westmoreland was saying, you know, I don't need a two. I mean, I would be willing to say there might be compensation there.

But, if there are questions about the study, and almost always there are with a single study, then you will read all the debates going on. Then I would want to see if we can get consistency with regard to other studies. And there are other types of studies that we can --

JUDGE RADER: Okay. So we're going to get into a series of studies.

Help me out here, Professor.

MR. WESTMORELAND: No. I just wanted to

point out that, in your fact pattern, the question is posed as more likely than not. And that has to influence the decision here because, if you look at -- assuming, as Neal has, that this is a very sound study here, a relative risk of 1.5, at this point, two out of three of the cases --

JUDGE RADER: Getting close, isn't it?

MR. WESTMORELAND: No. Two out of three of the cases can be caused by background stuff, but it's quite possible that this is the one-third case, and your fact pattern asking more likely than not, as does the statute.

JUDGE RADER: I'm going to have to be my own web expert here.

MR. WESTMORELAND: Okay.

JUDGE RADER: I am now Dr. Rader with credentials just short of a Nobel prize. My fact pattern has been published in peer review.

Master Abell, here's my testimony. I see a real triggering of the autoimmune response that also brings in the Epstein-Barr virus, and it's causing this reaction in those people who are particularly sensitive to it.

That sensitivity seems to be about 15 percent of the population. My client is one of them.

I testify that, in my opinion, this is more likely than not causation-in-fact. Are you going to accept that testimony?

JUDGE ABELL: First, I'm going to state that this is a Court of equity and a Court of chancery. And, once you feel good, then I'm going to say, essentially, no.

JUDGE RADER: I am the Nobel prize winner here.

(Laughter.)

JUDGE ABELL: What you've done is you've suggested a possible correlation, and it's less than 50 percent. You've done some good suggesting and all that's probative. The study is probative. Your opinion is probative. Everything I would have heard is probative, but it doesn't go over the 50 percent and a feather yet.

JUDGE RADER: Mindy, I'm your witness. Defend me.

MS. ROTH: Well, I don't have to defend you. You're defending me. That's why we pay you big bucks to be there as the expert.

JUDGE RADER: But what would you say then to Master Abell to cause him to keep my testimony and to move past at least that medical plausibility step?

MS. ROTH: This would be a tough case. I wouldn't take it either. And I'd probably have to dismiss it somewhere in the middle because it would seem a lot better when it came in the door than it did at this point in time.

JUDGE RADER: But aren't you troubled that, you know, frankly, if you've got the epidemiological study up above the relative risk of two, it's almost like a table case, isn't it, John?

MR. KIM: Yes, I think --

JUDGE RADER: I mean as long as your going to win, aren't you?

MR. KIM: You should. But I mean --

JUDGE RADER: And this one falls just a couple of days short.

MR. KIM: Everybody's right, though. I mean, you didn't have to gloat at the quality of the study. You do have to look at the quality of the study. You have to see what biases or confounders were there.

And just as in your presentation that you made before the Special Master, I mean, I think, if you had sufficiently backed your opinions up with credible medical literature and shown that you had an exhaustive differential diagnosis, that you had

excluded other prominent causes, then I think you do meet the threshold. And we'd be appealing.

PROF. GREEN: Just one quick comment.

JUDGE RADER: Yes.

PROF. GREEN: I think Daubert, where it's applied in Federal Courts -- and I appreciate your comment about the state courts -- has -- would say your testimony, what you had to say as an expert adds nothing. What we want to see is what is the science behind what you're saying. And we really don't care.

This is a very different change. This is a revolution from the old days. In the old days, your testimony would be great. We'd let it go to the jury. Daubert has changed all that. It's not what you say; it's the basis that you can come forward with to support what you're saying.

JUDGE RADER: Yes?

GALLERY: Well, to answer Abell's -- that was my question. Why not? Why is not the study and the support of the expert's testimony enough? That's my biggest question. Where is the hurdle? I'm always jumping them, and I don't know where they are.

JUDGE ABELL: Yes, and that is the issue. I understand that, but your expert did not. He gave conclusions. He did not really explain the mechanism.

We're looking for a linkage. We're looking for a viable explanation. And, as I think we've stated before, it doesn't have to be a majority --

JUDGE RADER: Is it just a matter, Master Abell, of me putting all the medical bells and whistles in there, if I do that --

JUDGE ABELL: If you had a lot more bells and whistles, yes, you could be.

JUDGE RADER: Well, if I add some more bells and whistles, would you take it?

JUDGE ABELL: It depends what the bells and whistles were.

MR. KIM: Well, hang on because we're running into a problem because the more you require in terms of the exact biologic mechanism, the more you depart from Daubert and what the law in every Circuit Court in this country is, and that is you don't have to know the exact mechanism of action between the agent and the harm.

So we're again getting to a point where the onus and the burden as we drift into a more traditional causation-in-fact situation in this Court is more onerous than what is out there in the traditional civil systems.

JUDGE RADER: Mark, you don't have to know

this?

MR. ROGERS: You don't. You don't have to know the specific mechanism, and I think epidemiologic evidence is a good example where you can show an association and yet not know what the mechanism is.

And you can arguably -- if you show a relative risk over two, there's a lot of legal literature accepting that as admissible evidence of causation. Whether it's persuasive or not, it depends on the strength of the study and all of that.

So you don't per se have to know the mechanism, but I would disagree with the Special Master that, just having a theory, that is, to propose a mechanism theoretically that might be causing the condition is not enough.

And I'd agree with Professor Green that, under Daubert, you have to have more than just a theory whether it's a theoretical mechanism or an opinion that there's a causal relationship that's been shown.

Daubert, on remand in the Ninth Circuit, the Ninth Circuit said these are unadorned assertions, and they were very learned experts who were concluding that Bendectin had caused a case of birth defects, but they were unadorned. There was no evidence to support

it.

GALLERY: We're limited here by the facts somewhat, but this says that the literature suggests that CJM might be immune-mediated resulting from infection. If that's true and we have to take it at face value, then the flu vaccine, unless they were given flu mist, which is a live infection, it would have been caused by an infection.

If, however, the epidemiology shows an onset of 15 to 21 days, we're probably dealing with an autoimmune reaction. Therefore, if we can add to the facts that, of those 40 percent of people who have a prior history of illness, the large percentage of them had influenza, then we can add to the facts that, in researching, I found a lot of people have elevated antibodies to Epstein-Barr virus even in the normal population.

And a lot of people that have infections of any kind have an elevated Epstein-Barr virus that comes up along with whatever else they're infected with. So the Epstein-Barr virus, as my expert's going to tell you, and he's a Nobel laureate, so, I mean, he's going to tell you that Epstein-Barr virus is a red herring. It doesn't mean anything. That, if I can change the facts to flu mist where I've got an

active infection, therefore, it fits with the facts, and I don't even have to go to the epidemiology.

But, if I go to the epidemiology, nobody's discussed the fact that it shows a bell-shaped curve, which is also proof of correlation, which is what we saw in the swine flu program where you're not dealing with something that goes up and then comes back down to baseline. We're dealing with a bell-shaped curve.

JUDGE RADER: I like my witness.

JUDGE ABELL: What's your phone number so I can refer --

(Laughter.)

JUDGE RADER: Dr. Halsey has another question.

GALLERY: This is a large study. We have to accept that it's large and shows confidence intervals that are very tight. So it's a good study. You can't criticize a study that's this tight and it's large.

JUDGE RADER: Yes, Dr. Halsey?

DR. HALSEY: I would not put great credence on a bell-shaped curve. Again, I can manipulate the shape of that curve based upon the windows that I would pick to present the data in.

GALLERY: Well, that's when I would -- criticize my 10 days because they didn't give me 10

days here. I want to see eight to nine, nine to 10.

DR. HALSEY: That's correct. If you pick smaller windows, then you might be able to reach your little 2.0 for some of those and not for others, and you may do that. And those are some of the things that people need to examine when they're doing studies.

Also, when you set out to do a study, you establish what analytic methods are going to be and what those windows are going to be so you don't manipulate the data afterward. Those are the questions I would ask about the science.

But let me agree with some of what you have said, that, if, in fact, there was stronger evidence for an immunologic effect and, if, in fact, influenza was a preceding illness for the majority of those infections that occurred, it adds to the biologic plausibility that an influenza infection or an immune response to an inactivated vaccine could conceivably contribute. But those are all data we're avenging.

GALLERY: One more question for Dr. Halsey.

JUDGE RADER: Yes.

GALLERY: Are you going to penalize my client because his doctor, at the time that this all happened, didn't do all the tests to rule out every

alternate cause that he can think of?

And are you also going to penalize my client because, at the time, the doctor could have done some test to prove that he was having an influenza infection and to prove that it was causing it, and he didn't do that either?

DR. HALSEY: First of all, I'm not penalizing your client. Nobody would do that. But there is a responsibility of a physician caring for a patient with a disorder that has a known cause to look for that cause. And so --

GALLERY: Then should I go out and sue the doctor for failing to provide that to my client?

FEMALE VOICE: After you lose here.

DR. HALSEY: And so that, if, in fact, there actually are some refinements to Epstein-Barr virus testing that might possibly in some situations contribute to your knowledge about the time when the infection occurred. But you're right about most of the testing is not valuable, but you should look for that.

The same situation exists with Guillain-Barré syndrome where we know that campylobacter is responsible for 30 to 40 percent of those. And, if you don't look for something that you know causes it,

and then you're trying to create an argument that something else might cause it, that's a weak argument.

GALLERY: But, in this program where parents didn't order the tests, their doctor did, and they're bringing their child into the program, does the purpose of this program deny them compensation because the doctor didn't run a campylobacter jejuni test?

DR. HALSEY: The purpose of the program is to provide compensation to people who have injuries where there is sufficient evidence that there was a causal relationship.

JUDGE RADER: What's sufficient evidence, Doctor?

DR. HALSEY: And that is what we're arguing --

JUDGE RADER: That's what we're trying to find out.

DR. HALSEY: -- I have outlined what I consider to be sufficient evidence.

JUDGE RADER: Let me ask you, all of you, a question here. We've kind of been assuming that there is some threshold at which you can find sufficient evidence. There would be a point, a multitude of epidemiological studies, a multitude of medical journal articles establishing causation.

What about the problem of this perhaps being the first case of AIDS, the first case of some association with a new infection, a new virus? How do we as legal and medical officers deal with the prospect that this really might be causation-in-fact, but we have to start somewhere to acquire the sufficient evidence of that?

Let's start with John. And I want all of you on this one. John?

MR. KIM: Daubert answered that.

JUDGE RADER: Daubert answered.

MR. KIM: Daubert answered.

JUDGE RADER: That was one of Daubert's exceptions, wasn't it?

MR. KIM: Daubert talked about that you couldn't chill science, that you had to deal with the innovative, and that you couldn't penalize people for being first in line. Daubert said that this required general --

JUDGE RADER: But it didn't give us any standards for how we do that, did it, John?

MR. KIM: Well, yeah.

JUDGE RADER: I mean, you just acknowledged that that may be the case.

MR. KIM: No, I disagree. I think it did.

JUDGE RADER: Okay. Tell me what you think.

MR. KIM: I think it gave us a framework. It said that you didn't need to meet this general acceptance theory if there was an indicia of reliable science. And it took us back and said that, if you can go through the medical literature, the pharmacology, the pharmokinetics, and find proper proof, that it was okay.

And it even told us that even though, at first blush, you may think this evidence is shaky, you may think it's not credible, the solution is vigorous cross-examination, presentation of contrary witness, and careful instruction on the burden of proof. That's the Supreme Court.

JUDGE RADER: But you were telling me, John, you weren't going to take this case right up front because you could look at it and there weren't enough studies and there weren't enough doctors to help you out. And so you didn't want this case. You have better prospects elsewhere.

MR. KIM: That's because I knew --

JUDGE RADER: How do we know you were right?

MR. KIM: That's because I knew why you didn't get the Nobel prize.

(Laughter.)

JUDGE RADER: I'll get it next year. I'll get it next year.

Mindy?

MS. ROTH: The comment that I have on that with the first case coming through, it's not only the medical science. The medical science plays a huge part in it, but the totality of the circumstances for that specific individual has got to come into play.

What was their medical history? Did they come into this with no prior illnesses? Is there no other cause for this because all the tests have been run, and everything else has been ruled out? You've got to look at the person as a whole and not just the medical science that may be lacking in this particular instance.

JUDGE RADER: Okay. I know I want the professor and the doctor both. Let's get the professor first.

PROF. GREEN: There's been a lot of talk about ruling out and about differential diagnoses and considering alternate causes. That's all well and good when we know the alternative causes. We don't know the alternative causes of CJM. We don't know any of them according to this fact data sheet. I don't know what we're ruling out because we don't know what

we're looking for to rule out.

Second comment, with regard to no evidence, and I take it you meant no evidence as to the first one, the first thing we should do is do away with the statute of limitations and wait until the evidence catches up, which may develop.

(Applause.)

PROF. GREEN: Because in less ordinary cases, the evidence gets better.

JUDGE RADER: Just one second. Just one second.

Mark, do you agree with that? Mark, would you do away with the statute of limitations?

MR. ROGERS: That's another discussion that goes to --

JUDGE RADER: Do I take that as a no?

MR. ROGERS: The statute of limitations is what it is, and I would add to that that the Vaccine Act actually is biased against the novel theory because it requires that you come in with your case up front, and then it puts a deadline on the processing of it by the Courts.

JUDGE RADER: Just a second. Let's ask -- this is back to Professor Westmoreland's area.

MR. WESTMORELAND: Yes.

JUDGE RADER: Did Congress think about this? And what's your thought on this novel case problem?

MR. WESTMORELAND: As I say, I think that the Congress at the time thought that it was solving only the table injury cases. It was trying to expedite things that we already understood and that we thought that people were simply being delayed in Court rather than actually getting through to a compensation that an epidemiologist or a pediatrician with good credentials would have said that this is about.

We thought we were redoing the -- I'm sorry, the Congress thought that it was redoing the process, but not the proof. And it was deeming things to be proof.

The causation-in-fact cases, as I say, I think were an afterthought, a safety valve, to make sure that you didn't shut out some things that the Secretary hadn't gotten to or that the Congress hadn't received evidence of. But that is perfectly appropriate for the Secretary to put something novel on. He or she is given the authority to do that with only association, not causations.

JUDGE RADER: Doctor, we've missed you a couple times --

DR. HALSEY: The first case of a new

disorder that, sometime down the road, was shown to be causal is not going to meet anybody's acceptable criteria unless there is a specific diagnostic test that can link the vaccine to the cause, so that there won't --

JUDGE RADER: But that's not happening.

DR. HALSEY: But, when the scientific evidence is accrued that demonstrates a causal relationship and a decision is made to add this to the table, one can go back and make it retroactive for whatever period you want.

And that has been done, so we already have a process for dealing with it. And that's been done for rotavirus intussusception. It's been done for the initial DTP cases, and so forth. So nothing has to change here. You just wait for the good scientific evidence.

MR. KIM: But these victims can't wait 20 years. They need the money now. They need the healthcare now.

DR. HALSEY: It would be a crime to loosen the standards so much that you compensate for everything that might possibly be later shown to be causal. That would be inappropriate and harmful.

PROF. GREEN: John, that's equally true of

the people who suffered this disease who didn't get vaccine before they suffered the disease.

GALLERY: One of the things that we have is a question of access to proof as well. Your first case, the first case that comes in, are you going to let, is the Act going to let us get right into the manufacturer's tests? And are you going to apply the same level of scrutiny on the manufacturer's studies, assuming that the manufacturer of the vaccine has this CJM, has the statistical incidental finding, and put it in --

JUDGE RADER: Master Abell, are you going to give him discovery of the manufacturer's files completely?

GALLERY: This is the first case, though.

JUDGE ABELL: He's going to have to show an offer of proof of that. Otherwise, you're going to get into a fishing expedition.

JUDGE RADER: How much would he have to show?

JUDGE ABELL: I suspect that the attorneys for the manufacturers are going to vigorously oppose that.

JUDGE RADER: How much would he have to show before you start thinking about letting him have

access to manufacturers' files?

JUDGE ABELL: Probably a little bit more than this one injured petitioner.

GALLERY: What if I had this relative risk, though?

JUDGE ABELL: That epidemiological study is highly probative. First of all, I suspect that the, you know, Wyatt Laboratories is going to vigorously oppose that, and I would want an offer of proof of what it's going to cost because we're ultimately going to pay for that.

JUDGE RADER: Mark, do you have -- does the Justice Department have any skin in this particular game, getting to the manufacturer's records?

MR. ROGERS: Well, those issues are currently being litigated. I would say that, under the Act, there's no discovery as a matter of right. It's discretionary with the Special Master, and the focus is that, if the Special Master needs the information, the Special Master can seek it.

JUDGE RADER: What if he says yes? Are you going to take it to us? The Federal Circuit?

MR. ROGERS: It depends.

JUDGE RADER: Depends. That's a good legal answer.

GALLERY: Professor Westmoreland, at the time that the Vaccine Act was passed, Congress obviously was attempting to deal with science as we knew it then.

But was there not a section of the statute that recognized that vaccine injuries would change over time, something would fall off the table, something would be added on, and, if they did recognize that, did Congress say who or what should determine what is and is not a vaccine-related injury for the purposes of the vaccine?

MR. WESTMORELAND: Hey, you know, I'm happy to be corrected by people who remember this statute better than I, but I think that the Secretary has the ability to add or detract vaccines and illnesses or disabilities associated with. And it's that that I keep coming back to as a plain text argument in here, that it's associated with. It's not caused.

And that the Vaccine Advisory Commission, whose initials I always get wrong, can also recommend to the Secretary, and the Secretary has to take up those recommendations. In fact, anybody can recommend to the Secretary. Unless it's clearly frivolous, the Secretary has to refer it for review.

GALLERY: I guess my point in raising it is

I thought there was a section of the statute in which Congress talked about the NIH, the Institutes of Health.

MR. WESTMORELAND: Oh. The title before this in the vaccine statute which is not directly related to vaccine injury compensation set up a review process and a scientific process to start rationalizing the NIH's review of vaccines.

To my mind, I don't think that's ever been thoroughly implemented by any administration.

JUDGE RADER: All right. Over here.

GALLERY: Isn't it a fact, Dr. Stratton, that, in a recent report, the IOM threw out epidemiological data because the vaccine manufacturer did not reveal all the data, and you wanted to see all the data? And, without being able to get the data, nobody's going to win a case here.

DR. STRATTON: I'm afraid I don't understand. Nobody threw out --

GALLERY: But you had a study on SB 40.

DR. STRATTON: Right.

JUDGE RADER: Well, we don't want you to talk about any specific cases, but is there a situation where you could see yourself wishing to see the manufacturer's data, Dr. Stratton?

DR. STRATTON: If there were good epidemiologic studies with the manufacturer that were large enough to look at rare adverse events and powerful enough that those studies would be meaningful, then that would be nice to see.

MR. KIM: Or, even if they were bad studies, you'd want to see the data --

JUDGE RADER: Yes. Somebody said they --

MR. KIM: -- so you could object to the credibility of the study.

JUDGE RADER: -- were biased. I think it was Mindy who said there were biases in these studies sometimes.

MR. KIM: But, Judge, that's where we're getting into a problem because, you know, everyone's talking about wanting more information, wanting to see how strong and credible and how -- the lack of biases of things. And the more you do that, the more incumbent it is upon lawyers then to engage in more discovery, and I'm not sure the rules of the Court as they exist are equipped to deal with that as the traditional Court system is.

JUDGE RADER: Well, I want to get here, but let's throw a curve here.

Are the Special Masters equipped to handle

this kind of problem? To decide whether there ought to be discovery of manufacturer's records and things of that nature?

SPECIAL MASTER GOLKIEWICZ: We did the rules initially back in '88 and redid them in '89. We certainly did not anticipate this type of discovery. It was all geared -- going back to the comments that have been made over and over again, we were doing the table cases, and rules were written geared more towards the table cases.

I think it's fair to say, up through '97, the date that was thrown out when we started doing more and more causation-in-fact, I don't know if we ever did any discovery, but now we are getting into areas and requests.

No. I think the simple answer is no, that the rules were never geared -- they were not geared and we were not prepared to deal with these discoveries.

JUDGE RADER: And is that under review or something?

SPECIAL MASTER GOLKIEWICZ: No. Not at this point. I think Mr. Rogers talked about it. We're mired right now into these discovery requests in the autism area. How that plays out and what appeals and

so forth come out of that --

JUDGE RADER: It's starting to sound like a case, and we don't want to talk about that.

Right here.

GALLERY: I want to say that I think Congress anticipated that the table would expand more than contract. And, in reality, it has dramatically contracted, while there have been tiny expansions. And I think that the medical community in HHS and outside in the pediatric community should be aggressively moving to expand into areas in which they recognize a causal relationship in which there is no table injury, like the varicella cases, like the encephalitis and ADEM, acute disseminated encephalomyelitis after measles vaccine.

I think there are areas in which the medical community recognizes vaccine reactions in which there has not been an expansion of the table, and I think we would avoid at least some of this discussion of proving causation-in-fact if the agency is expanding the table instead of just contracting.

JUDGE RADER: Dr. Stratton, should they expand the table?

DR. STRATTON: I'm not touching that one.

(Laughter.)

JUDGE RADER: Let's ask Professor Westmoreland. Should they expand the table?

MR. WESTMORELAND: Well, first, I'd like to agree that I think that people did not anticipate the table would have been dramatically abbreviated. I think that was done as a safety valve in case we've gotten something completely wrong, that they could abbreviate it. But I think that, at the time, the expectation was that it would have been broadened, not drastically narrowed.

Having said that, it's my distant -- remember, I'm dealing in worlds of abstraction -- observation that the people who mostly pressed to have a vaccine added to the table are the manufacturers, and that that's done in many ways I think because of liability concerns.

But there is a public health responsibility -- I agree -- for public health advocates, be they doctors, physicians, nurses, whoever it may be, the public health people, to press to have more and more things that may be dissuading parents from getting their kids immunized added to it.

I want to be very careful that I'm not saying simply do it because it's generous, because my client needs this.

You know, lots of people have injuries from birth and they don't get national health insurance in this country. This is not what this program is about. But I do think that there is a responsibility to look very carefully at that quick, simple, predictable, those kinds of things, and, for public health reasons, get people more reassured and expand the tables.

JUDGE RADER: Thank you, Professor.

GALLERY: I'd like Professor Green to take the role of Special Master for a minute, and there are two things I'd like to do to help my client in this case. One is I'd like to ask you to give me all the raw data behind this large epidemiological study because I want my experts to look at it. So I want you to order that data so that I can get access to it.

And secondly, I would like to perform a study on my client where I would test the lymphocytes from my client and determine whether or not those lymphocytes crossreact with something that I've seen, and whether those same lymphocytes can crossreact with the myelin which is being affected here in my client. And I want to be able to demonstrate in the lab that those are disease-producing lymphocytes.

It's going to cost me $30,000 to do that study. I want you to approve that up front so I make

sure I can get it at the end of the program.

PROF. GREEN: Yes. Let me say something that's not going to be very popular. I was astounded to find out that attorneys' fees and expenses are paid regardless win or lose. Talk about creating incentives that are not right, it seems to me the system does that and we ought to relook at the system in that regard.

Having said that, I would think both the government and you would want to know what kind of study this was. That is, this study, you know, superficially, on its face, looks like it might support liability in some cases. And I think you'd both want to know was this a good study or not. I guess I'd want to know that as a Special Master.

As for the other test, gee, I don't know enough to answer the question of whether that's going to be valuable. And I also don't really understand the system that was set up, the procedure that was set up within the Act for dealing with discovery. So I want to stay away from that. I do, you know, civil cases. I don't do Vaccine Act cases.

JUDGE RADER: Thanks, Professor.

DR. HALSEY: Very quickly. I just want to make sure that the raw data is redacted in some

fashion to preserve medical confidentiality.

MALE VOICE: Certainly. Absolutely.

JUDGE RADER: Yes, ma'am.

GALLERY: As a clinician and an immunologist, I haven't heard the discussion, and this is what the clinicians who are caring for patients struggle with, which is very similar to reverse stroke because patients come with an adverse drug reaction history.

Take the vaccine word out of it. Adverse drug reactions are a huge problem in the medical establishment, can cause a lot of injury if the patients are clean, to have some erasure of that by I'm going to give you the drug again, and they make the person sick. It's a focus right now of the Joint Commission of Hospital Accreditation.

And vaccines are just drugs just like everything else. Every drug we give has a one to two percent rate of an adverse event where the clinician and the patient say gee, okay. We looked at the literature, but there is a concern of risk of giving the drug a second time.

So I read one of your cases which, in my medical world, would be malpractice to recommend rechallenge unless the life of the patient was at such

risk that it justified giving the drug again.

So the question for the entire panel, and it always helps to put yourself in the context of the patient, and I would ask Neal Halsey -- and he and I are friends that have struggled over this many, many times -- is, at the end of the day, assuming you had perfect data and you're that patient's doctor and you're sitting down communicating risks, and there are huge chasms of knowledge in immunology that we can spend a whole day on all the pitfalls, and that's what Dr. Halsey was trying to say. We do not understand these diseases except the fact that they do seem to be some type of inflammatory leaning process.

And that's about as far -- that's about as broad as a wall. But, at the end of the day, this patient, as a clinician, I struggle the next year, do I give him a flu shot because influenza kills and hospitalized, and I told neurologists, as we struggle with this case --

JUDGE RADER: I think your point is what we do with that one or two percent, right, who are hypersensitive.

GALLERY: Right. And, if the majority of clinicians would say gee, I'd be really scared unless it's a flu pandemic and people are dying to give

another dose of vaccine because it's plausible that it could exacerbate this problem.

JUDGE RADER: Well, let's ask him. What do you do with the one or two percent, the hypersensitives?

DR. HALSEY: What are you doing with a patient who has had this disorder if you don't know for sure whether or not the vaccine that preceded it caused it, you weigh, just as you talked about. You have to weigh the risks and the benefits of not giving or giving another dose, and that is what is done if it is done properly.

In addition, you try to do everything you can to determine if there is some test that will help you determine what was the cause of that disorder because, in fact, if proper studies were done and you actually could prove that it was EB virus that triggered this entity and not influenza vaccine, you would feel much more comfortable about giving this patient the dose of influenza vaccine, especially if they're at high risk of complications from that disease. So you need good science at every point.

JUDGE RADER: The doctor trusts his medicine. What about you, Mr. Kim? Do you agree?

MR. KIM: I trust the clinician. And I

think the problem is, when you impose a responsibility and a standard in a courtroom on a clinician, someone in the everyday practice, that greatly exceeds what their reasonable standard of care is. I think, with the issue of vaccines, it's particularly heightened, and I want to quote Dr. Halsey in his article.

JUDGE RADER: No fair.

DR. HALSEY: It's fair.

JUDGE RADER: --

MR. KIM: "Vaccines which are administered to healthy people are held to a higher safety standard than are medications used to treat people who are already ill because vaccines are often given universally to infants and children. Even a very low risk of having serious side effects can result in a substantial population attributable risk if the vaccine is given universally."

And so I think, from a clinical standpoint, if you have seen the sign of irritation, then I agree it may be malpractice to rechallenge, but -- because the person is healthy. You know, it's not like other pharmaceutical pills where you're using it to treat an illness, which would be another situation, which is why risk benefit gets --

JUDGE RADER: Mark?

MR. ROGERS: I think the clinician is asking a different that's being asked in our proceedings because our proceedings would keep getting back to the black letter of the law, if you will, the preponderant evidence standard. The clinician doesn't work on a preponderant evidence standard. The clinician decides, is there some chance that this vaccine caused it sufficient for me to wave off future vaccines? And so they won't.

If there's a risk that this vaccine caused that condition, they're not going to readminister it. We have to answer a different question. Is it the likely cause by scientific evidence? So I would say that that evidence, and I've heard it offered in our proceedings, doesn't really add to the question we have to answer, which is whether it's the likely cause.

JUDGE RADER: A comment back here.

GALLERY: Just a quick question, and maybe this is very basic. I don't want to appear too ignorant, but it seems like the Court is working on a preponderance of the evidence standard, and we've been talking about that. Yet we see a discrepancy where medical experts appear to be held to a medical certitude.

I mean, so a medical expert then has to be able to testify that he would say I'm 90 percent sure that this did cause it. And then the Court would have to say well, I'm 50, 50 percent and a feather. How should I believe you? Should the medical expert be required to testify to a medical certainty or, if they can say well, I believe 50 percent and a feather that it did cause it, should the Special Master be able to take that?

JUDGE RADER: That sounds like a Special Master question.

JUDGE ABELL: The answer is yes.

PROF. GREEN: Can I address --

JUDGE RADER: Yes. Go ahead.

PROF. GREEN: -- a piece of that, and it was actually what John suggested earlier. This is not medical doctors. I don't know what medical doctors use as their standard for judgment, but it was suggested that scientists, and particularly epidemiologists, use 95 percent.

Talking about significance testing and the 95 percent standard that many scientists use to control for random error is, as I said to Kathleen, it's about like trying figure out how to get from London to Oxford by looking at a map of New York. You

just can't compare the two.

The reasons are complicated, but it is not correct to say that epidemiologists require 95 percent certainty of a causal relationship before they're willing to call it. That's not what statistical significance testimony is about.

JUDGE RADER: Let's wrap things up by asking each of our panelists to address one question. What is the most important factor we should consider if you've established some kind of medical plausibility in a case, you've established that there's no alternative causes, you've got some temporal association?

What is the most important factor you would have us all look at to bridge that gap from where we are now, medical plausibility, temporal association, and no alternative causes to get the causation-in-fact? Start at this end.

MR. WESTMORELAND: Pass. Go on.

JUDGE RADER: Yes. Okay. That's fair enough.

DR. HALSEY: The most important --

JUDGE RADER: You got us into this.

(Laughter.)

MR. WESTMORELAND: Oh, I can point at a few

people in this room who got us into this.

MR. ROGERS: Let me tell you a secret. He was on the House side. I was on the Senate.

JUDGE RADER: Go ahead, Dr. Halsey.

DR. HALSEY: The most important factor there is, is there evidence of an increased risk of the disorder in people who receive the vaccine?

The information you've given us -- medical plausibility, no alternative causes, and a temporal association -- happens very commonly to people throughout the country following exposures of all kinds, not just vaccines. It does not provide anywhere near the evidence you need.

If you're looking for one, and you only asked me for one, then I want evidence of an increased risk in a well-defined study and, preferably, multiple ones so that I have consistency in the findings.

JUDGE RADER: Thank you. Good answer.

Dr. Stratton?

DR. STRATTON: Ditto.

(Laughter.)

JUDGE RADER: Anything else?

DR. STRATTON: No. It's some other kind of evidence that this --

JUDGE RADER: So it's scientific literature?

DR. STRATTON: You want some other scientific literature that this occurs more often in people who get the vaccine than not.

JUDGE RADER: And just that one footnote again, and what if this is early in the development of the literature?

DR. STRATTON: You know, I think that's a bit of a red herring, with all due respect.

JUDGE RADER: Is it?

DR. STRATTON: Yes. Because I think science always moves on. It's not just the first case. It can still happen. And you'll have 100 cases. You still won't know enough.

JUDGE RADER: Thanks. Great.

Professor Green?

PROF. GREEN: Well, I agree with the prior panelists. The problem is we're not going to have that for a year, several years, until 1,000 cases have been brought, as occurred with silicone gel breast implants and with Bendectin. There we have the law driving the science. Scientists became interested once a bunch of people started making claims. The question really is, how do we resolve those cases before we have that? And that's hard.

JUDGE RADER: Special Master?

JUDGE ABELL: I'm looking for a credible explanation of how and why. And it may not necessarily be what a majority of the scientific community is thinking, but I certainly wish to see it associated with that minority that have credentials that are to be taken seriously.

JUDGE RADER: Yes, but you excluded me when I tried to testify.

JUDGE ABELL: Well, that's because your degree's in acupuncture.

(Laughter.)

JUDGE RADER: You did your job, and you did it well, too, by the way.

Mr. Rogers?

MR. ROGERS: To the previous comments, I would add I would look for increased risk to get over the hurdle of showing that this condition can be caused by this vaccine, but to show that it did in this particular case, it would more than just some increased risk corresponding to let's say a relative risk of 1.1 or 1.2.

It would be, as Daubert so eloquently describes -- this is the Ninth Circuit's case on remand -- the relative risk with a good study that everybody agrees that is solid and powerful with a

relative risk greater than two to show not only that the agent can cause the condition, but that it likely did cause in this particular case.

But, beyond that evidence -- I'm not sure if your question goes this far -- I'd be looking for a signature disease that was mentioned here, a biological marker, as we would see in polio vaccine that was mentioned here as well with subacute sclerosing panencephalitis that Dr. Halsey talked about, or the rechallenge evidence with all its problems, but something that causally associates this administration of vaccine with this incidence of disease.

JUDGE RADER: Great.

Ms. Roth?

MS. ROTH: Well, I'm going to throw a wrench into the whole thing.

JUDGE RADER: Good. Throw it.

MS. ROTH: In the event that I have a case like this where I have done everything and, from my perspective, I've got the temporal relationship, I've got the no prior history, I've got a biological plausibility stated by my expert, I'd say that I proved it more likely than not. The burden should shift then to the government to show why it's not.

The government has no responsibility here whatsoever to in any way contradict what I'm saying. They just wait for me to not be able to show these tests. That's not fair to the individual who is injured who, by all accounts, there is not other explanation for it. Where does the defense expert come in?

JUDGE RADER: Thanks.

John?

MR. KIM: I would say that, in the absence of epidemiology, it doesn't mean -- I hearken back to what Dr. Halsey said earlier, that absence of evidence is not evidence of absence. And I would think that, if you had a credible biologic plausibility case, and it was supported with the medical records and an association to the vaccine and a good differential diagnosis by the clinician, then I think that's enough.

JUDGE RADER: I think they've done great.

(Applause.)

SPECIAL MASTER GOLKIEWICZ: Well, my goal coming in here today was to enhance everyone's understanding of the different perspectives on causation. Thanks to these panelists and the moderators, and I think that goal has been met. And

I appreciate everyone's attendance.

Now, just logistically here, those that are part of the conference, there's a cocktail party back at the State Regency. Those that were my invited guests, I'm a government employee. I didn't pay your way. I'm sorry. Thank you all for coming. I appreciate it.

Oh, lastly. Wait. Whoa. Stop. One more item. You have my e-mail address. The conference e-mail address, it was on all the letters I sent out. If you don't have it, call my office. I would greatly appreciate your comments. What we did right. What we did wrong. What we can do for you in the future. Please take five minutes to throw it out there. Thank you again.

(Applause.)

(Whereupon, at 4:34 p.m., the conference was concluded.)

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REPORTER'S CERTIFICATE

DOCKET NO.: --

CASE TITLE: 17th Judicial Conference

HEARING DATE: November 9, 2004

LOCATION: Washington, D.C.

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 9, 2004

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