# UNITED STATES
# COURT OF FEDERAL CLAIMS

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| 19TH JUDICIAL CONFERENCE - THE TRIAL | ) |
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| VACCINE BREAKOUT | ) |
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| PANEL I: THE ROLE OF TRADITIONAL TORT LAW AND THE IMPACT OF ALTHEN, CAPIZZANO, AND PAFFORD ON PROOF OF CAUSATION IN VACCINE CASES | ) |
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| PANEL II: THE SCOPE OF REVIEW AND GENERAL ADVOCACY AND APPELLATE ISSUES IN VACCINE CASES | ) |

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Crystal Room
The Willard InterContinental Hotel
1401 Pennsylvania Avenue, N.W.
Washington, D.C.

Wednesday,
October 25, 2006

The parties met, pursuant to notice of the Court, at 1:53 p.m.

MODERATORS:
Panel I - DENISE K. VOWELL
Special Master, U.S. Court of Federal Claims

Panel II - MICHAEL GREEN, Professor of Law
Wake Forest University
BETSY GREY, Professor of Law
Arizona State University

PANELISTS:

Panel I:

MICHAEL GREEN
Professor of Law
Wake Forest University

BETSY GREY
Professor of Law
Arizona State University

Panel II:

THE HONORABLE ERIC G. BRUGGINK
U.S. Court of Federal Claims

THE HONORABLE WILLIAM CURTIS BRYSON
U.S. Court of Appeals for the Federal Circuit

THE HONORABLE RAYMOND C. CLEVENGER III
U.S. Court of Appeals for the Federal Circuit

THE HONORABLE LAWRENCE BLOCK
U.S. Court of Federal Claims

P R O C E E D I N G S

(1:53 p.m.)

JUDGE VOWELL: I want to thank the Vaccine Bar and the Department of Justice attorneys who so graciously contributed suggested questions. We've rephrased some of them, but I hope that we've included the substance of many of them in the program.

Two years ago, the topic for discussion of the Vaccine Act Breakout Session during the Court of Federal Claims 17th Judicial Conference was causation. Today, we return to that topic, but we do so with the benefit of the Federal Circuit opinions in Althen, Capizzano, and Pafford. Those opinions are going to form a large part of today's discussion.

For our first session this afternoon, we have two distinguished law professors to enlighten us. First, Professor Mike Green from Wake Forest School of Law. Professor Green was a member of that panel two years ago discussing causation, and we look forward to hearing his comments on the impact of these three decisions on what he had to say two years ago.

He's also joined today by Professor Betsy Green of Arizona State School of Law. Let's try again. Professor Grey -- I'll get the right color here -- Professor Grey and her colleagues at Arizona

State have spent the last two years studying the vaccine program, and while their thoughts and conclusions are not yet ready for primetime, we know that that perspective will bring us some unique observations on the vaccine program.

And I trust that both of their discussions will benefit the vaccine bench and Bar alike.

And in the interest of time, I'm going to go ahead and introduce our second panel this afternoon so we can take things fairly quickly after our break. Our second session features Judges William Bryson and Raymond Clevenger of the Court of Appeals for the Federal Circuit. They're seated up here in front. Gentlemen, thank you. And Judges Eric Bruggink and Lawrence Block of the Court of Federal Claims. Your program indicates that Judge Wiese was supposed to be a member of this panel, but he developed a trial conflict, and Judge Block, did you volunteer --

JUDGE BLOCK: I volunteered, but really Judge Wiese --

(Away from microphone.)

JUDGE VOWELL: Blame it on Judge Wiese. Professors Green and Grey will moderate our second panel this afternoon, so take the brand new Special Master off the hook.

Well, with that, I'd like to get started on our general discussion of causation, and I'll start with you, Professor Green. Based on your observations of the opinions in the vaccine case, what's changed in two years?

MR. GREEN: Well, I read an awful lot of cases in the toxic substances area. I've worked in that area for a long time. I assume that's why I'm here, and it's one of my particular research interests.

When I was here two years ago, I remarked on something I observed in reading cases, including vaccine cases, and that is how impressed I've been with the opinions in the Vaccine Act cases. The special masters' opinions reveal a real understanding of what scientific evidence can and can't do, the significance of the scientific evidence before them, and an acute sense of resolution of the uncertainty that exists in these cases, and that's substantial.

And that may reveal the benefit of specialist courts. The special masters devote full time to these cases, and really the issue in these cases is causation. They can invest in educating themselves in this intersection of science and law.

By contrast, for generalist judges, it's a

lot harder. I remember talking to Judge Carl Rubin of the Southern District of Ohio who tried the consolidated Bendectine cases. He had 1,100 consolidated cases that involved the question of a drug causing a variety of birth defects. And he said to me, Mike, I just was flabbergasted. I was a modern European history major in college. What did I know of toxicology and dysmorphology?

Well, I think in the time since then, the federal judiciary is getting better at handling those cases with the education and publication efforts of the Federal Judicial Center. There is a reference manual now available to federal Judges that I think has helped and improved the quality of their work in that area.

But to conclude a long-winded answer and to be frank, two years later I'm much less impressed with the emerging jurisprudence of the Federal Circuit that we'll discuss today than I have been with the special masters' opinions that I've read over the years.

JUDGE VOWELL: Professor Grey, your general observations based on your study or anything else.

MS. GREY: Well, I just want to say a few introductory things and reiterate some things that Professor Green just said. Basically, you're the

experts in this field. What I think Michael and I come to bring to you is our knowledge of tort civil cases and how it could possibly be used in this area.

More specifically, there's a lot that's happened in the proof of causation since the mid-early 1990s obviously in the toxic tort area that Michael is referring to that could be used probably more prominently in this area.

I also want to say exactly what he just said. This is an enormously complex area, and I come to this panel with enormous respect for what's happened through this Court system. This is a very challenging area, and there have been enormous efforts on the part of the special masters, the Court of Claims, the Federal Circuit, the lawyers, the specialized Bar that have been made to try to answer these extremely complex areas of sufficiency of evidence in the area of causation, which in many ways are just simply unanswerable.

The other thing I want to say at the outset before we start answering specific questions is I'm just coming with certain premises here. One is that there really isn't a large body of significant evidence for off-table claims. And the quote that you keep seeing from often is the field bereft of complete

and direct proof of how vaccines affect the body. We're taking that as a given, and it's a hard thing to deal with.

I'm also observing something that you all know, which is that the vaccine program has some unique policy concerns that may warrant applying certain standards here that you wouldn't find necessarily in traditional civil tort cases. I also want to observe something I just said, which is that in the last 13 years, civil Courts have applied a heightened scrutiny to scientific evidence, and that's going on at the same time that these cases are going on.

And finally, something also that Michael said is that these special masters are very unique. You have a very unique system here, which is that you have a group of experts that are the fact finders -- that's very unusual -- and a specialized Bar, a specialized expertise Bar with the respondents and the petitioners, and that might have an impact on the analysis of these cases, also.

JUDGE VOWELL: All right. Well, moving to the subject of causation, we deal with a statute that is a no-fault statute, and it requires us to find that a vaccine caused an injury in an off-table case in

order to award compensation to a petitioner. Is causation under a no-fault system such as the Vaccine Act the same as causation in the traditional tort arena?

MR. GREEN: I don't think there's a difference. I said this two years ago. I continue to believe that causation is causation is causation, at least cause in fact. In tort law under the Vaccine Act and in workers comp, what has to be the cause may change. It may be vaccination. It may be negligent conduct by a defendant. It may be that the agent that causes it is employment.

But when we ask the question, is the employment, is the vaccine, is the negligent conduct responsible for the outcome, that's a cause-in-fact question. That's the same. Let's not mystify or complicate unnecessarily. Cause-in-fact is but for. Without it, it wouldn't have happened.

Now, it may be different. We may take different proof, and we may have different levels of acceptable proof in those areas. I think that's the nub of what's going on in the Vaccine Act now, but it doesn't change the definition, in my opinion, of what causation is.

JUDGE VOWELL: Professor Grey, do you want

to address that as well?

MS. GREY: I just want to add one thing, which is that, as Michael said, it's a question of sufficiency perhaps is what the difference is, but I agree that you're not going to look at causation differently in a civil setting than you would in a vaccine setting. It's just a question of sufficiency of the evidence in a preponderance standard, but causation, like you said, is causation is causation.

JUDGE VOWELL: Well, causation is frequently found based on a preponderance of the evidence standard in civil litigation. We have language in Knutzen, an older decision from our Federal Circuit, saying that when the evidence in equipoise, the party with the burden of proof loses. We have language in Althen that indicates from the Federal Circuit that Congress created a system on which close calls should go to the petitioner. How do you interpret or can you reconcile those two decisions?

MS. GREY: I don't know whether the language in Knutzen -- is that how you say it, Knutzen?

JUDGE VOWELL: Knutzen, that's how I pronounce it, but then I'm new. One of you out there, please tell me how to pronounce it.

MS. GREY: I don't know whether the language

in that case and the language from Althen frankly are reconcilable or not. I'm not even sure that the Althen Court, looking at the language in that decision, intended to say something different from Knutzen.

I think that Knutzen correctly states that when the evidence is in equipoise, then in a traditional civil case the party with the burden of proof loses. I think that I'd interpret the language in Althen -- when you read Althen, if you look at the next sentence after that sentence, it says, "The purpose of the Vaccine Act's preponderance standard is to allow a finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."

I take those two sentences together, and I would suggest that the language in Althen is telling us that it would be inconsistent with the nature and the purpose of the Vaccine Act to require injured claimants to lose every case when there's no direct evidence or very strong evidence of general or specific causation.

So I think that the Althen Court wants the preponderance standard to remain with the petitioner, but how you reach that, how you can fulfill that maybe

wouldn't be as high a standard as you'd find in a civil tort lawsuit.

Now, this goes to a question that pervades everything that I have when I read these cases, which is, is this a tort-based system, or is it a policy-based system that we're trying to administer here, this compensation program? I think that the trilogy of cases that we've seen in the last few years are moving us more toward a policy-based compensation program, but the Court has never explicitly, as far as I read it, said that.

If that's what they mean, then they should say it, but right now we're struggling with whether you mean, is this a tort-based system, or is it a policy-based system? You might end up coming at different conclusions with regard to what you mean by preponderance of the evidence standard if you take different policy approaches there. We'll probably talk more about that a little later, too.

MR. GREEN: Let me elaborate on and illustrate what I think Betsy was talking about, and it really goes to this sufficiency, and maybe this is how I can reconcile what looks like statements that look irreconcilable, which I think is the basis for your question, Denise. And let me go to a standard

tort case to illustrate this.

Imagine that we have a person who falls down stairs that are unlit negligently by the landlord. The person who falls down falls and kills herself. So a wrongful death case is brought against the landlord. The landlord defends on the basis that there's no evidence to show that the cause of the fall was the lack of light in the staircase.

People fall down staircases for lots of reasons, and there's really no basis here to say that it was the lack of light. And so the plaintiff loses because the State doesn't have sufficient evidence to show causation.

Now, a judge in a case like that would confront that case and ask the question, the standard sufficiency of the evidence question. This is the burden of production. Has the plaintiff introduced sufficient evidence to permit a jury to find this? If a Court thinks that this evidence, circumstantial evidence to be sure, is sufficient, they say, well, the evidence here is such that a jury reasonably could infer from the facts that the likelihood is that this was a result of lack of light.

Another judge or another court on a different day or with a different outlook might say,

look, this evidence just doesn't tell us what happened. This would require the jury to speculate. Impermissible speculation is not permitted, and we would dismiss the case as a matter of law because of the insufficiency of the evidence.

I think that's exactly what's going on in these toxic substances cases in the Vaccine Act. And if I read Althen right, and that's a heroic maybe assumption, but if I read it right, I think what Althen is saying is we want to not have a high threshold of what's expected of the petitioner in order to permit a finding by a preponderance of the evidence. After all, this is, as Betsy said quoting I think Althen, we're bereft here, or we have very little evidence that exists, but we should take what we have and do the best that we can with it to find by a preponderance of the evidence.

That makes perfect sense to me. It seems to me it's different from what's going on in tort cases generally today where at least the federal judiciary is cranking up the sufficiency standard in these cases and maybe reflects in part that sort of policy or public health notion behind the Vaccine Act. If that is the judgment here, that's fine, and it makes some sense to me.

JUDGE VOWELL: And if you substituted reasonable fact finder for reasonable jury --

MR. GREEN: Sure.

JUDGE VOWELL: -- the example would apply in our cases.

MS. GREY: As you said, the plaintiff in the civil case would lose in that circumstance if there isn't enough evidence.

MR. GREEN: I think if cases like Althen were being litigated in Federal Court today with Daubert, and what Courts are doing in Daubert is really to apply a sufficiency of the evidence standard to experts' testimony in causation cases. They're saying, show us what you've got, and we're going to make a judgment about whether it's sufficient to let a jury in for a causation here.

Yes, I think these cases would come out differently in the Federal Courts. I don't know about State Courts. They have a very variable view about this in different states in different situations. But I think generally that's been the gist of what's gone on. We were talking about what's happened in the last 10 or 12 years. I think that's right.

JUDGE VOWELL: Well, let's pick up on the issue of Daubert and Kumho Tire. Those decisions are

mentioned nowhere in our trilogy of cases. In a program such as the vaccine program where there are no juries to be unfairly influenced, what role does Daubert play, or what role should a Daubert analysis play?

MS. GREY: I think that Daubert -- Daubert, Daubert --

JUDGE VOWELL: Daubert.

MS. GREY: It's like Knutzen, Knutzen. I think that, like you said, in many ways they wouldn't be applicable. We don't have juries. We have a very sophisticated fact finder. Federal Rules of Evidence, Federal Rules of Procedure don't apply here.

But there is a reason why Daubert developed that is still applicable here, and that is to test the basis for an expert's opinion. Why do we need that? Because when you have an area that is bereft of evidence like this, you don't have the normal processes of a trial to test the assumption.

So you don't have cross-examination that's going to work as well. You don't have the opposing evidence that will work as well. And that's why you probably would be well-suited to take Daubert and apply it in this setting, even though you're not protecting the jury from junk science. There are

other reasons that underlie Daubert that would be applicable here.

So what do you want to look for? You always, I think, want to probe the underlying basis for whatever opinion is being proffered in the Special Master's Court. We don't want to just rely on expert credentials alone. You want to see, was there any adherence to professional or technical standards? What is the basis for the opinion?

Just like any other witness, a scientist, a doctor is going to be subject to biases, to value judgments that are coming from his own setting that could affect his view on the question of causation, which is why you want the Special Master or the trial Court to still probe the basis for the decision rather than just relying solely on the fact that the expert is making that assertion and is well-credentialed in that area.

MR. GREEN: Yeah, I agree with Betsy on that. This is the place where we can look at the sufficiency of the basis of the expert's opinion. I don't know if that has to be done prehearing. Indeed, one of the things that distresses me about Daubert is how much added expense it's adding to the litigation of ordinary tort or product liability cases.

But at some point the idea of, okay, put up, expert, what have you got, is something that needs to be done, and Daubert is doing that under the aegis of Rule 702 and the admissibility of an expert testimony. It could be done at the hearing when an expert testifies, but it needs to be done.

JUDGE VOWELL: Well, again to follow up on that point, Capizzano tells us that special masters may not require epidemiologic studies to show causation in vaccine cases.

We've got a fact pattern that we've handed out to you all and to the people here. Assuming that there's an epidemiologic study that shows no association between vaccine and transverse myelitis -- and I'm making no opinion as to whether there are any; that's just a hypothetical -- what role would negative epidemiologic evidence play in a causation analysis, or should it play for the Special Master?

MR. GREEN: That's a very difficult and variable question to answer, Denise. First of all, we need to know what the epidemiology is. Is it one study or many studies? We need to know what the studies examined. Did they examine the same questions that are at issue here?

One of the things that we see going on in

Daubert is, experts say, I'm relying on this literature, and then judges looking at the literature to see whether in fact it supports the expert's opinion. I don't know how many cases I've seen where judges say, no, this study which you claim supports your opinion doesn't. It doesn't address the question or for some other reason is inapplicable to the issue here.

The third thing with epidemiology is, even if it exists, we need to ask the question whether it is exonerative. I don't use the term negative about epidemiology because at the end of the day epidemiology can only narrow what an agent can cause rather than tell us it's absolutely safe. Anybody who tells you that epidemiology can prove absolute safety, well, I disagree with that.

But is the epidemiology involved -- is it exonerative, or is it inconclusive? And that gets to the question of whether the study itself had sufficient power, enough people involved, enough incidence of the disease, to really find something or something that we'd be interested in if it exists. There are lots of epidemiological studies that are out there that are inconclusive and really don't tell us very much. We ought not take them.

On the other hand, and the two examples that best illustrate this are Bendectine, the morning sickness drug that was thought to cause birth defects, and silicone gel breast implants, where the litigations drove a lot of investigation, many studies that generally concurred around the proposition that if silicone gel breast implants or Bendectine cause these adverse events, they do so with such infrequency that we couldn't find them despite a lot of effort to find it. That's exonerative evidence, and it seems to me is significant. So we really need to distinguish what the body of evidence is.

MS. GREY: I just want to add to that -- I agree absolutely with everything you've just described -- that when you think about what weight should be accorded a study that finds no association, like you're suggesting, that's a matter of judgment. That's not a scientific question, right? So that's what Michael is describing.

You want to look at how many other studies were there. How big was this study? What was the sampling error? What other evidence was available here? Are there any confounding factors? Are there any biases in the study? Before you determine what weight you're going to use here, it's a judgment call.

It's not necessarily a scientific question that you're looking at.

I also want to take this opportunity to suggest that something I think that would be very helpful in this area generally is a sort of ranking of evidence.

JUDGE VOWELL: You've anticipated my next question.

MS. GREY: Sorry. Well, there you go.

MR. GREEN: Don't steal her thunder.

MS. GREY: Go on. Ask your question.

JUDGE VOWELL: Okay. Thank you. In our hypothetical case, we have conflicting opinions on causation. Could you suggest a methodology for special masters in our Superior Courts to assist in resolving these in a battle of expert questions, the hierarchy, I think you will, of scientific evidence?

MS. GREY: I have a couple of suggestions and maybe they're naive and I'll take your feedback on this. It seems to me when I read these cases, you're seeing the same kind of evidence over and over and over again in different forms. And so I think that it would be useful to have a general, not a specific, hierarchy of evidence in terms of the weight that you're going to accord it.

Now I think in Stevens when the Special Master started to do this in some sense, I think that -- and he was overturned for perhaps other reasons, but his instinct was correct here. I think it would be very useful to the general body here to have a sense that we think we put a lot more weight, say, on rechallenge cases than you would put on case reports.

Some civil courts won't even accept case reports. Parlodel cases, they reject it. They don't think it's strong enough. So I think that if you had a generalized sense of some kind of hierarchy going from top to bottom, it might be useful here to give more guidance, get more consistency perhaps in the findings that are being made.

JUDGE VOWELL: Mike, do you have anything to offer?

MR. GREEN: Yes, I think it's hard to categorize what's better and what's not. It looks to me like the audience here is old enough to remember something that my students don't know what I'm talking about when I refer to it, thalidomide. I assume most of you know what I'm talking about when I say "thalidomide," although I do see some blank faces out there.

You know there was never an epidemiological study done on thalidomide? Never, never. But there didn't have to be. It was such a powerful agent. Powerful in the sense that it caused such an enormous proportion of the birth defects that were occurring at the time that as soon as we found it, we knew it. Now, I mean, that was really case reports, if you'll forgive me, and some smart people who put together what the common agent was.

Do case reports help when something causes just a small proportion of the outcomes? No. I mean, then we really need to be very careful. So I guess, sure, epidemiology has advantages over toxicology, but if you guys have good epidemiology, you shouldn't be in an off-table case, you know. That should get on the table at least within the boundaries of what the epidemiology shows.

I don't know. I think the problem that you deal with is you've got a little bit of biological mechanism evidence, which may be good or may be just theory. You have some adverse events, and you have maybe some analogies to draw from, similar vaccines and/or similar diseases. I don't know how you prioritize those. I think all you can do is look at them in the context, and make your best judgment about

them. I don't think any ranking is really going to help in trying to figure out whether, based on them, you think it's more likely than not.

JUDGE VOWELL: Well, let's follow up a little bit then with other specific types of evidence a Special Master might consider. We're frequently faced with the statements of treating doctors in a medical record, that if there's a differential diagnosis of a vaccine caused whatever in this case or that he has transverse myelitis secondary to *X* vaccine.

I know, Professor Grey, you've got an interest in this. Would you comment on treating doctors and their opinions and how they ought to be analyzed?

MS. GREY: Sure. For 100 years, courts would allow treating physicians to testify about causation or about any subject as long as it was an inference that was the type that physicians normally make in the course of their practice. That would be the test; that we wouldn't look beyond that.

But that, as we keep describing, has changed gradually, especially in the last 10, 15 years. Why? What happened, we had an explosion of toxic tort cases, and there were a lot of experts that were

willing to testify about causation without real strong scientific studies. The classic example, of course, is Bendectine. That brought us Daubert and the trilogy of cases there.

The other thing that happened is that within even medicine itself, there were certain assumptions that began to be tested through observational studies, through certain controlled experiments, epidemiological studies, and it began to give us the realization that there were certain number of assumptions that we made within medicine that were wrong, and the classic example of that is HRT, hormone replacement therapy. We began to test that assumption that it was a good treatment, and it was actually not. Mastectomies for cancer victims is another example of that.

So as a result of that, in civil courts we began to test much more strongly even the treating physician's testimony along with other experts' testimony. Now, specifically what you're usually looking at when you talk about treating physician's testimony is a differential diagnosis, which is of course a standard medical technique for trying to figure out what is causing the patient's symptoms.

Usually a doctor is looking at a variety of

diseases and trying to determine which disease among many is the cause of the plaintiff's symptoms. Here what we're looking at is whether there are causes that are external to the patient, not just disease causes. And so we're asking the treating physician to testify about causation with regard to an external cause, and generally many times that's simply outside the expertise of the treating physician.

In other words, unless he's immersed in the literature regarding the possible external causes of the plaintiff's health problems -- in this case, it happens to be vaccines -- the physician is really testifying outside his area of expertise.

The other problem with using treating physician testimony is that they're prone -- as many of us, as I'm prone to do -- is to engage in a kind of post hoc ergo proctor hoc kind of thinking, which is fallacious after which, therefore because of which.

Let me just give you an example that will seem very exaggerated, but it'll just show my point. If an infant develops a brain tumor after he gets a measles vaccine, this kind of post hoc reasoning would say, the vaccine caused the tumor. This kind of reasoning is going to be rejected by scientists. Why is that? Hundreds of thousands of infants receive a

measles vaccine every year. A few of them will develop brain tumors. That's the coincidence factor.

A physician who has seen a few infants who develop a brain tumor after they get a vaccine but not the thousands of kids who didn't, is simply not in the position to infer causation in that kind of setting. And the FDA, when they're trying to determine whether a drug is safe or the efficacy of drugs, has in its requirements isolated case reports, random experience in reports, lack in details, which permits scientific evaluation will not be considered.

But that's precisely the type of evidence that a treating physician is relying on a lot of times. So what do you do? Well, at the very least when you're talking about using treating physician's testimony, you have to probe to see whether they have developed that kind of expertise, whether they have it. What's their background? Did they specialize in genetics, epidemiology, teratology, whatever it is? Does their professional work relate to their subjects? Did they receive formal training since med school in those kinds of areas?

When you rule out certain alternative causes, that's logically insufficient to say that a suspected factor is the cause of the observed

condition. In other words, ruling in is as important as ruling out causes. You have to rule them in as well as rule them out. So the fact that a physician observed soon after a vaccine a certain effect shouldn't necessarily be sufficient to qualify him as an expert with regard to causation.

The other thing is that I've seen in a couple of the cases that there's a suggestion that because the treating physician isn't picked by the plaintiff, isn't paid by the plaintiff ahead of time, that gives more weight to their testimony. Also, the suggestion is that the physician might change their course of treatment during the treatment, and so that's why their testimony is more trustworthy because of that.

That's very rational factors to take into account. It's very reasonable to take that into account when you're trying to determine the trustworthiness of the testimony. That deserves consideration, but that doesn't make the evidence more scientific. I think that that works best when the number of causes with regard to a certain adverse effect is known, but unfortunately that's not the case here. So that weakens the import of the evidence there.

JUDGE VOWELL: But what about the treating doc who says, don't get any more of these vaccinations?

MS. GREY: I think that that's an excellent clinical observation, and in fact there are certain biases that might incline him to do that. He doesn't want exposure to liability. His moral obligation is first to do no harm. So from a clinical point of view, that's exactly the right decision that he should be making. But in terms of whether that means the vaccine caused the injury here, I'm not sure that the weight of the evidence would go that far.

JUDGE VOWELL: Is it not, though, circumstantial evidence from which other circumstantial evidence I might reasonably infer causation?

MS. GREY: You could take it into account, but it doesn't qualify it. In other words, Capizzano probably in my mind went a little bit too far because it's relying on the treating physician's testimony to basically make out the whole case, and I think that that's not strong enough.

MR. GREEN: Betsy, I can also imagine a case in which a physician thinks that there's a 20-percent chance that the vaccine caused the outcome and says,

nevertheless, there's only a 20-percent chance that it caused the adverse event, but says, don't continue to be vaccinated. And the reason would be just the differential cause of making a wrong outcome; that is, the consequences of revaccinating, even with only a 20-percent chance, are so much greater than having the patient go without further vaccinations.

And I don't know if that's true, but I could imagine that judgment. And it's just a question, just like we say we don't convict people unless there's proof beyond a reasonable doubt, that's based on the differences in the consequences of wrongful convictions from wrongful acquittals. So, like Betsy, I don't know what that means without more. Yes, it means something, but it doesn't mean anything even about what the probability is that the physician might think that there was a connection between the vaccination and the outcome.

Let me -- can I just --

JUDGE VOWELL: Please.

MR. GREEN: Betsy and I thought -- we talked about this last night. We were going to shake this up. We were going to disagree. You know, this was going to be -- what's the show on TV? Chris Matthews, you know, Hardball. We haven't done that, and I

apologize. I haven't found anything that Betsy has said that I can say, that's outrageous.

But last night after dinner, I spoke with a doctor just because I was curious about this, and I said, you know, if you were going to attribute causation in the medical records, when would you do that? And she said to me, look, if I'm going to do that, it's going to be based on the literature. That's how I'm going to make some connection. I wouldn't say, it is. I'd say, maybe, because I'm not sure, but it would be based on the literature.

And I didn't explore it and say, okay, so tell me which literature because we're talking generally, but it seems to me what I want to know from the physician then is -- and this is consistent with what Betsy is saying -- the fact that his opinion doesn't do anything, the question is, what's your basis, doctor?

If you look at the cases, again, on the tort side, we have physicians testifying. Courts are letting physicians testify, but they let them testify when they come in and then they explain what the basis is of that opinion and you see them relying on the literature.

And although doctors don't generally know a

whole lot about epidemiology -- I once had a student who had gotten his M.D. -- and I teach my students about a week's worth of epidemiology -- and as we were beginning, I said, so how much epidemiology have you had? And he said, about the same amount that I got in this products liability class, and that was in four years of medical school.

But having said that, it's not that hard to read an epidemiology study. I mean, doctors do it all the time. That's part of the literature. I think they can at least interpret an epidemiological study and understand its implications for causal attribution.

So if they relied on that, if they'd gone to that, or they've gone to a textbook that attempts to summarize what the literature is, that's fine, too. But the question is is what have they gone to other than simply, this is my clinical assessment or my clinical judgment. That, it seems to me, falls pretty far short.

JUDGE VOWELL: Well, let's go back perhaps to --

MR. GREEN: Can I say one more thing?

JUDGE VOWELL: Of course.

MR. GREEN: And this is a take-off on

Betsy's -- you can't rule out with differential diagnosis until you rule in that an agent is capable of causing the outcome, and this is a reflection on one or more of the cases that I read where it looked to me like what the Special Master in that case was doing was saying, well, there are these other contemporaneous events that occurred, and those could be the cause.

Well, it seems to me that that does the same thing as ruling out without ruling in. That is, these other contemporaneous events, if the burden of proof is on the government to show an alternative cause that is responsible, it ought to be the government's burden to show those contemporaneous events are capable of causing the outcome involved rather than making the plaintiff do that.

That is, the petitioner ought to show among the known causes, do a differential diagnosis, but ought not have to show every possible event that occurred unless we know that it is a cause of the outcome. And I think there was some ruling out on the other side in that respect that doesn't seem to me to be correct or at least hasn't placed the burden of proof properly.

I think it's the Court of Federal Claims's

concern that petitioner shouldn't have to rule out everything in the world is right. That's why the burden of proof is on the government to show what these other causes are and that --

JUDGE VOWELL: After you get over the prima facie.

MR. GREEN: That's right. That's right. And that seemed to me to be unfortunate.

JUDGE VOWELL: Okay. Let's go back a little bit in dealing with the treating doctors and dealing with the rule of coincidence since that's a factor that was addressed in Pafford and in Capizzano. Both of those cases touched on the role of coincidence in the development of a medical problem postvaccination. In more traditional tort law, does a petitioner have a burden to eliminate alternate causes?

MR. GREEN: Sure. Sure. There's no question about that. Coincidence simply means that there was another cause that was responsible there in that event rather than the suspected agent or vaccine or whatever. And it's really a question of whether the array of competing causes that exist that might have been responsible, and also, is the vaccine involved capable of causing this outcome?

Assuming that exists, you're going to have a

population in which some will be caused by the vaccine, and some will be coincidental because it was caused by something else. The key there is is, can we figure out a way in which to say that the vaccine is responsible for more cases among that group than the competing causes which are the coincidences?

JUDGE VOWELL: So you would tell a Special Master to analyze the case in terms of can it and then did it?

MR. GREEN: We've got to first figure out -- and I see the special masters trying to do this in the opinions that I read -- trying to figure out the general causation question. It's got to be capable of doing it under certain boundaries, right? What's the disease that it's capable of causing? Within what time framework? What chronology?

Somebody who said that exposure to asbestos yesterday caused mesothelioma today would laugh at it. That doesn't happen. We know that from the studies that have been done. It takes 20, 30, 40 years of latency from first exposure until the disease occurs.

So, yes, within that framework, if it exists, we've got to figure out that it's capable of doing it because if it's not capable of doing it, we can go home. There's no need to go further.

JUDGE VOWELL: Well, let's go back to some of the tensions between our program, and this program was designed to be an alternative to the traditional tort litigation. It's set up as a no-fault system. Special masters control discovery. And traditionally, we don't have witnesses deposed.

If a Special Master is being urged to rule upon a record as it stands and the basis of causation is that treating doctor's opinion, TM secondary to hepatitis B vaccine, how would you advise a Special Master to proceed? Let's assume there's no question about the diagnosis. Everybody agrees it's TM. Nobody said it's anything else.

MS. GREY: So the only evidence you have is the treating physician's testimony?

JUDGE VOWELL: I don't even have his testimony. I have a medical record.

MS. GREY: From what I said before, I don't think that's sufficient. I don't think that would be enough to make out a prima facie case without anything else.

MR. GREEN: I guess I'd be concerned about the Capizzano opinion and whether I might get reversed by the Court of Appeals. It does seem to me that simply an attribution of causation in medical records

is very problematic without understanding what the basis of it is.

I guess if I were a Special Master, I'd say, no, I'm not going to resolve this case on this evidence. I want to hold a hearing, and I want to see the treating physician.

Or maybe, we're trying to keep costs down. We don't want to impose a lot of expense on the petitioner. You know, there are questions that I need addressed by the treating physician. Right? We can do it written. We can do it in affidavit. We can do it in a telephone hearing. Let's try not to impose greater costs on petitioners here.

JUDGE VOWELL: Let me ask you to speculate then. Let's suppose the doctor who's offering that opinion is an ENT, an ears, nose, and throat physician, as opposed to a neurologist. And let's say the doctor is going to come and testify. Post-Althen, would you care to predict what the Federal Circuit might do if I said, I don't find the ENT's testimony on neurologic complication sufficiently reliable?

MR. GREEN: Is there some reason why this ENT thinks she can opine about this? This is a treating ENT?

JUDGE VOWELL: There are two case reports

that she's read of TM following vaccination.

MR. GREEN: Yes. And that's all?

JUDGE VOWELL: That's it.

MR. GREEN: It doesn't matter the doctor's specialty. I would say that's not sufficient. It could be a neurologist who says that and bases it on two case reports.

So really, for me, what it comes down to is, what's the basis here? And as soon as you say "two case reports," I'm prepared to sort of talk about that. ENT, family practice -- really, that's not so significant as what's the underlying reason why.

MS. GREY: And just to add to that, I mean, just a basic rule of thumb is an expert, no matter how expert they are in some field, they're not qualified to testify in a civil court outside their area of expertise. So that would be the question.

JUDGE VOWELL: Well, let's make it a neurologist now who says, I base this on my training and medical experience.

MS. GREY: Right. Well, then again it depends on how much he has available to him, and I agree with what Michael just said that it might not be sufficient in that area, but I'm feeling better than the ENT, I suppose.

MR. GREEN: If I'm Judge for a minute, Special Master here, you can't hide behind education and experience. That just won't do. Tell me what in that education or experience supports this. I think experts often hide behind that. How do you know what the standard of practice is in a medical practice case? Well, I know from my education and experience. No, no, no. Tell me what the basis is here for that more specifically. And often you discover when you insist on that that the emperor has no clothes. So I want to know what it is, not just some general statement like that.

JUDGE VOWELL: In Althen and earlier vaccine cases, our Courts have used such terms as "medical theory," "causally connecting," "logical sequence of cause and effect," "but for" and substantial factor, "proximate temporal relationship between vaccine and injury," and "medical plausibility." If these are terms that are used in more mainstream tort litigations such as perhaps toxic torts, are they used with different meanings in the vaccine cases? Is there something we could learn from more mainstream tort litigation in our terminology?

MR. GREEN: I'm glad you asked that, Denise. I have to say I think in reading the trilogy that

there is a lot of mumbo-jumbo language going on. Now, the Federal Circuit doesn't have a monopoly on such language. We see it in other cases.

But terms such as "logical sequence of cause and effect" and "proximate temporal relationship," they're not helpful. Look, can there be an illogical sequence of cause and effect? I don't think so. A cause is simply a necessary condition for an outcome; "but for" expresses that idea. There may be logical reasoning about whether some causal explanation supports that conclusion. That's very different from describing the causal chain as logical.

Conditions like a vaccine don't think or reason. They can't be logical or illogical. A temporal relationship is required. A cause can't by definition produce something before the cause exists. In other words, you can't murder a corpse.

It may also be the case that the evidence about general causation limits the timeframe in which the outcome occurs. We know that exposure to some agent -- it takes 20 years at a minimum before that disease can occur, or the disease has to occur within some other window. That makes sense to me. That's really a consequence of what the evidence is about general causation.

But a cause doesn't have to be proximate in time or space. Asbestos has a latency period of somewhere between 20 and 40 years. That's not proximate in time. And Osama bin Laden wreaked havoc on the World Trade Centers from half a world away. He was a cause of the destruction of the World Trade Centers. There was no proximity in terms of geography. So "proximate temporal relationship" I just don't think is a helpful term to describe this.

The two terms that have come into use on the tort side that I do think are helpful, and it's a consequence of the sort of evidence that we need in these cases, is the idea of general causation and specific causation, which I see in some of the special masters' opinions, but I don't see the Court of Appeals adopting that language. That's language that's all over in other Court of Appeals decisions, in the FJC's Reference Manual on Scientific Evidence, in the Third Restatement of Torts, and I think it captures an important idea that is generally understood.

JUDGE VOWELL: Betsy, could you suggest some language that might make more sense in terms of analyzing cause in the context of vaccine cases?

MS. GREY: Well, other than what Michael

just said, I mean, agreed, general causation, specific causation, that would be much more useful if you just bar from what the civil --

JUDGE VOWELL: And to rephrase, general causation -- can a specific causation did it in this case?

MS. GREY: Right.

MR. GREEN: Now we need exposure, but that's usually not an issue in vaccine cases. It can be.

JUDGE VOWELL: Now we're usually not arguing about whether the vaccine happened. Sometimes we are, but --

MS. GREY: Right. Maybe I'm anticipating another question --

JUDGE VOWELL: Sure.

MS. GREY: -- but along that line, the Courts here are using circumstantial evidence and direct evidence differently than you would find in a normal tort setting, I think.

JUDGE VOWELL: Well, could you expand on that?

MS. GREY: Yes. I mean, it's just along the same lines. Usually when you talk about direct evidence in the evidentiary sense it's used in a civil court, you're talking about something that if it's

believed, then that establishes a fact. So in other words, an eyewitness says that Betsy robbed a bank. If you believe that, if it's credible, then that would establish the fact.

Circumstantial evidence, what you're getting out of that is an inference. It won't be conclusive even if you believe it. The eyewitness says, I saw somebody with dark hair and a brown sweater rob a bank. You would make the inference that Betsy robbed a bank, but it wouldn't be direct evidence.

So when the Courts talk about the difference between direct evidence and circumstantial evidence, in a lot of ways I think that most everything that's coming into the Court here is really what we would think of in a civil court as circumstantial evidence. That goes back to what I was saying before. Some of it's obviously much, much stronger than other evidence.

JUDGE VOWELL: Rechallenge, for example.

MS. GREY: Rechallenge or footprints. That's a very strong piece of evidence there, right? But, again, you're making an inference. You don't necessarily have direct evidence that proves the causation.

JUDGE VOWELL: Wild virus can cause this

disease --

MS. GREY: Right.

JUDGE VOWELL: -- attenuated virus maybe --

MS. GREY: Maybe doesn't. Right. Exactly. So it's just another way that this Court is using terms that you don't see normally present in other areas that maybe would be better to kind of align that, also.

JUDGE VOWELL: Can you speculate as to why? Is it something unique to the vaccine program, or is it unique to the structure of our appellate review with first the Court of Federal Claims and the Federal Circuit?

MR. GREEN: For the different terminology?

JUDGE VOWELL: For the different terminology.

MR. GREEN: I really can't. I don't know why the Court of Appeals has adopted this language. I guess -- no. Here I'm speculating it would not be reasonable language.

JUDGE VOWELL: Fair enough. You mentioned, Professor Green, the Third Restatement of Torts, Shyface and Pafford both refer to the Second Restatement. I know Shyface did; I'm speculating that Pafford did. Can you comment on the difference

between the two, the Second Restatement and the Third Restatement, specifically with regard to the substantial factor test?

MR. GREEN: I can, but first a disclosure here that's necessary.

JUDGE VOWELL: Okay.

MR. GREEN: And that is that I had substantial involvement in the Third Restatement's treatment of causation. I was Co-Reporter on that work.

The Second Restatement of Torts was a magnificent work, but, in my opinion, its treatment of causation -- and here I would include both the idea of cause-in-fact and also proximate cause or scope of liability -- were really among its weakest sections.

And so if you'll forgive some immodesty, I think that the Institute has done a much better job in the Third Restatement with causation, both with factual causation and with proximate cause, which has actually now been renamed as scope of liability. I'm skeptical that that will make any difference in the actual practice.

One of the things that the Third Restatement does is it does away with the idea of substantial factor. Substantial factor serves some utility when

we have two conditions that I don't think are ever involved in vaccine cases, or at least I haven't seen any case that actually needed substantial factor.

Substantial factor is useful when we have two fires. You remember this maybe from law school, and you probably haven't seen it since. Two law schools, each of which is sufficient --

JUDGE VOWELL: Fires.

MR. GREEN: I'm sorry. What did I say?

JUDGE VOWELL: Law schools.

MR. GREEN: No, not two law schools. Two law schools, they just cause psychiatric disorder independently. These are two fires that burnt down a house. Each one is sufficient to burn down the house. Because of the other one, neither one is a but-for cause. That was the genesis of substantial factor in the Second Restatement.

And, yes, when we have two independent, sufficient causes of an outcome, this would be a situation where the vaccine and some other condition simultaneously would have produced the neurological problem. Yes, the vaccine is a cause, and it should be treated as a cause even though it's not a but-for cause.

And then the Second Restatement has some

notion about trivial causes that we need not concern ourselves with here. With the vaccine, if the vaccine is a cause, it's more than a trivial cause, or it's not. So substantial factor really is not very helpful, and the Third Restatement does away with it notwithstanding its adoption in Althen as something that plays a role along with but-for cause.

I hope the Federal Circuit will get to the Third Restatement. Although it's not published yet, it's been finally approved. It's available on Westlaw and Lexis. It also has a long comment that addresses proof in this toxic causation context.

It was the most controversial aspect of the Third Restatement. It addresses what, in my view, is the most important development in causation in tort law since the Second Restatement, and it attempts to address the issues that need to be thought about in attempting to prove causation in a vaccine case or a drug case or a chemical case where it causes disease.

JUDGE VOWELL: Do you want to comment, Professor Grey?

MS. GREY: No, he's definitely the expert.

JUDGE VOWELL: He's the expert in that area. Well, let me hit you with this question. Some petitioners have suggested that if they put on a case

that establishes, in their view, a prima facie case; that is, they prove the vaccination; they prove it happened in the United States; they satisfy all the statutory factors and produce some evidence of, can it, and, did it; that if respondents do not offer evidence of an alternate cause, petitioners should be entitled to an inference from their failure.

MR. GREEN: Let me ask just ask a question. Why does the petitioner need a negative inference if the petitioner has already made out a prima facie case?

JUDGE VOWELL: Well, let's say the prima facie case is simply those medical records.

MR. GREEN: But it makes out a prima facie case.

JUDGE VOWELL: The medical records are the doctors saying, TM secondary to hepatitis B vaccine. That's it.

MR. GREEN: And the Special Master decides that makes out a prima facie case?

JUDGE VOWELL: Well, petitioner is arguing that it makes out a prima facie case, and that now because respondent is saying, no, you haven't given us enough reliable evidence, petitioner says, but I'm entitled to an inference because you haven't shown

that something else caused it or could have caused it.

MR. GREEN: I'm entitled to a favorable inference in establishing my prima facie case?

JUDGE VOWELL: That seems to be the argument.

MR. GREEN: I don't understand it. You may want to speak to this.

MS. GREY: Well, someone is going to illuminate us, but before you do, the problem is of course in the theory there's so much that's unknown that to draw an inference from that for the failure of the government to come up with a known cause means just that, nothing more than that.

There may still be an unknown cause out there. Of course, that's the heart of the dispute, but I don't know whether you can draw an inference that there is no other cause if they don't come up with a cause. I guess I would say, no; that there isn't.

MR. GREEN: But that's the key. Who is the burden of proof on, right, with regard to this? If the petitioner has made out a prima facie case, fine, they don't need anything more. If on the other hand, they haven't yet, then you don't get inferences from a failure of the government.

JUDGE VOWELL: And perhaps that's the argument about what constitutes the prima facie case.

MS. GREY: Exactly.

MR. GREEN: I think so.

JUDGE VOWELL: Well, we've got a question here and I think it's a good time to take the questions and I have a mic that will move.

MALE VOICE: I confess that this isn't going to be a question. I think the answer to this question that you've been trying to field is the problem with this program, why these cases take six or seven years, that there is no burden of pleading or proof on the government. The petitioner is still placed into the crucible, and the heat is turned onto the petitioner whether there is a defense or not.

Prima facie cases are ignored, and the government's defense in half of these cases is to question everything and answer nothing. And it gets back to the policy thrust of Althen. You know, I think, Professor Green, maybe you're kind of shrugging that off.

When this program was started and the fact finders were intended to be special masters appointed by district courts in your own district, I mean, the word "Special Master" to us before this Act was passed

was auditor, referee. You looked for a prima facie case. If you find a prima facie case, you do a damages adjudication or a damages audit and a damages recommendation.

It has become something that it wasn't intended to be, and Althen simply finally acknowledges that what it was intended to be is important. It was intended to be a no-fault compensation program. No-fault compensation programs talk about association.

You know, the rubric of no-fault compensation programs answers your question about what is a proximate temporal relationship. The word "proximate" in the Second Restatement of Torts has to do with foreseeability. If it's something that happens in a foreseeable timeframe, that is a proximate temporal relationship, period.

JUDGE VOWELL: -- if we could actually get to a question now.

MALE VOICE: I'm getting there.

JUDGE VOWELL: Okay.

MALE VOICE: And your logical sequence of cause and effect in worker's compensation law is called a chain of causation. And if that vaccine is a link in there, if a doctor thinks it's a link in there, that petitioner has a prima facie case, and

then the burden ought to be on the government to find an alternate cause.

I mean, you pointed out that it is part of a plaintiff's burden to rule out alternate causes in an actual causation tort case. We don't dispute that, but under Althen, which properly interprets the statute, the statute says that the government has to do that. And the government doesn't do that. They just hold the petitioner's feet to the fire, and 10 years later, the case gets decided or the petitioners give up or something.

JUDGE VOWELL: Let me go ahead. We'll get to you in a minute. You can answer it.

MR. GREEN: First of all, I agree with you that in these vaccine cases, there is no proximate cause. And by proximate cause, I don't mean cause-in-fact. I'm distinguishing proximate cause as a limit on the scope of liability and foreseeability. I agree there's no issue in these cases.

If a vaccine is a but for a factual cause, that's the end of it. There's no out, if you will, on scope of liability for the government. So I agree with you with that.

You observed that this is a no-fault scheme, and it is. And that means that as a petitioner, you

don't have to prove any fault on the part of the government or the vaccine manufacturer or anybody else. But like worker's comp or any other compensation scheme, there is a causal requirement here. We have to establish that the outcome, the adverse outcome, was caused by vaccination. That's part of this scheme.

It's no fault, but it's not no cause. And so like worker's comp, there is a need to connect the outcome with some causal agent here. It's vaccine as specified in the Act. And the Act, as I understand it -- you know it better than I do -- specifies that the burden of proof on that element is on the plaintiff.

MS. GREY: Right. Let me just put in my two cents. Agreed. A no-fault system doesn't mean a no-causation system, and the statute itself, as you point out, uses the word "causation" and uses the language "preponderance of the evidence." So you're stuck with that unless it gets amended.

Now I agree with you that what really is going on here, I think, is that petitioners are showing an association plus some biologic mechanism, and that is becoming sufficient for a preponderance of the evidence standards that wouldn't be sufficient

necessarily in a civil lawsuit, but it's becoming sufficient here.

But you can't get around the fact that a petitioner has to meet a burden of preponderance on the question of causation. That never leaves. That doesn't rest. Even though the purpose of the system is to streamline a no-fault system, protect manufacturers, to compensate people who have had adverse effects from vaccines, that doesn't mean that there is no burden of proof whatsoever.

MALE VOICE: You know, there's tort language, though, in Section 33 of the definition statute where you can find that -- and it says "association."

MS. GREY: And that's what's happened.

MALE VOICE: And to me years ago, I thought that that was something that should dilute the notion of absolute causation. I still think it, but I may be a voice in the wilderness.

JUDGE VOWELL: Mr. Conway?

MR. CONWAY: Thank you, Special Master. My name is Kevin Conway. My firm actually represented both Mrs. Althen and Mrs. Capizzano. I wrote the briefs. I argued the cases in front of the Federal Circuit, and I'm proud to be able to defend the

Federal Circuit today. I never thought I'd have that opportunity.

(Laughter.)

MR. CONWAY: But let me ask you a couple of questions.

MR. GREEN: If you can do it in a logical sequence.

MR. CONWAY: I'll try, and I'll try and ask questions. First of all, did you have an opportunity to read our briefs in those cases?

MS. GREY: No.

MR. GREEN: No.

MR. CONWAY: Did you have an opportunity to read the legislative history of the Vaccine Act?

MR. GREEN: I'm beginning to feel like I often feel when I consult, and my deposition is being taken by the opposing side.

MR. CONWAY: The purposes of the Vaccine Act, if you had read it, which the Federal Circuit certainly looked at very closely -- but before I ask that, let me ask you, are you familiar with today's vaccine program, in the cases in today's vaccine program, in the pressures in today's vaccine program?

MS. GREY: What do you mean by that?

MR. CONWAY: I mean 5,000 autism cases,

which are on the verge of going civilly unless they can be resolved in the vaccine program, which might create another crisis as the crisis in 1986 started this vaccine program. Do you think Congress made a scientific decision here, or you think this was a policy and political decision? If you had read the legislative history, it's clearly policy. It's clearly political. It's nothing but that.

You made the comment, Professor Green, that these cases wouldn't win in Federal District Court. That is not an issue. The issue is, will plaintiffs bring lawsuits against vaccine manufacturers because if they will bring cases, whether they win or lose, then these cases will create another crisis for these pharmaceuticals, and they will not make these vaccines. They will not make new vaccines. Our health policy will be undermined, and our national defense policy will be undermined.

And if you had been sitting on that Court with the judges on the Federal Circuit, you'd have had the opportunity to look at these policy considerations and their effect on what causation in fact should be in the program.

I have disagreed with you in the past, but I would ask you to go back and look at those policy

considerations because I think that you will have a whole different opinion as to what causation -- and it's not causation-in-fact, by the way. It's causation. There's no such thing as causation-in-fact or actual causation. It's causation by a preponderance of the evidence.

This was a very carefully crafted statute. The decisions by the Federal Circuit are courageous and bold, and they support our national defense and health policies. And to look at the vaccine program in the very narrow slice of what scientific evidence supports a claim totally misses the purpose of the statute.

(Applause.)

MR. GREEN: Can I just --

JUDGE VOWELL: Sure. Please. Please, go ahead.

MR. GREEN: Kevin, you're right. As Betsy said, she -- and I should have joined in to her disclaimer, neither of us are experts on the Vaccine Act or the vaccine program. We come here as knowing something about causation in the toxic substances area.

I will say that I'm fairly confident that if I were a petitioner or a plaintiff's attorney, I would

much rather bring my case with difficult causation issues to the Compensation Act than I would be to go into a Federal District Court. Now, I didn't say State Court because the State Courts are quite variable on that, but Federal District Court, as opposed to Vaccine Act, I know I'd want to be under the Vaccine Act.

To the extent that you say that there are political issues, and I understand you'd be saying we should be getting these cases resolved under the Vaccine Compensation Act rather than permitting them to be unsuccessful and go out into the Courts, that is a policy determination that Congress may have made or may need to make in the future. There's a lot of issues, I think, policy issues with regard to the Vaccine Act as it exists now that could be improved.

I think the difficulty here is how to get that onto the legislative agenda and to think about how the Act might be improved. You and I might disagree about what those improvements are, but there's a lot that might be done on the legislative front.

JUDGE VOWELL: Professor Grey, anything to add on the general issue of what cause in the statute means versus the public policy arguments?

MS. GREY: I have no problem with having a policy-based compensation system, and if that's the route that this should go, then so be it. That's fine. There are very strong arguments in favor of that. But it hasn't been made explicit. It needs to be made explicit. The decisions need to make it explicit.

If they want to do that, they have to say, we're no longer following a tort-based system; we're following a policy-based system. We're going to come out with a different conclusion. If that's the conclusion that needs to be reached, so be it. But right now, it's a muddle, I guess is the way I'd put it.

JUDGE VOWELL: So you're contrasting the earlier Federal Circuit decisions that said this is a tort-based compensation system with Mr. Conway's position?

MS. GREY: Right. Right. And it's a perfectly valid position, but let's make it clear.

JUDGE VOWELL: Okay.

MALE VOICE: Let me just say I also support what Mr. Conway said, but I do have a question.

I'm a little concerned about the issue of burden of proof and what role the government plays and

what role the Special General Master plays in the evidence, and that is this: the hypothetical where the petitioner puts on evidence that they have a reaction to a vaccine. There's a temporal relationship and the treating physician, be it a pediatrician or whatever, writes an opinion relating the illness to the vaccine. End of case. The government does nothing.

Now, I'm a little confused about what role the Special Master has. Does the Special Master then look at the report of the physician and say, well, I don't know what qualifications this doctor has, and therefore, I am not going to accept it? I kind of get the impression that that may be happening when the government sits there and does nothing. It would seem to me that if the government is going to challenge the doctor's opinion, then it's the government's duty to go in and find out the basis of the doctor's opinion, not the Special General Master's.

JUDGE VOWELL: Do you want to respond? I mean, that focuses on the role of the Special Master in the program.

MR. GREEN: I suppose that we could say that the petitioner has made out a prima facie case, that in the absence of some contrary evidence from the

government would be sufficient if simply a physician renders an opinion. If the evidence is that a physician has rendered an opinion that this outcome is a result of the vaccination, we could have such a system.

I think Betsy gave to me a persuasive account why that would not be a very good system if we require causation. But we could have that, and I think that's really what you're suggesting the system should be. That looks to me like it may be close to what Althen and Capizzano stand for, at least if it's a treating physician, I think. Pafford seems to either retrench or, without saying so, be concerned that it wasn't a treating physician.

And frankly, there's reason for limiting it to treating physician. As everybody who practices law knows, the hired expert that comes in may not be the first one or the second one or the third one. The parties get to pick their expert, but treating physicians, you don't get to pick. And so there's some better reason to rely on a treating physician.

We could rationally do that. I am not entirely comfortable with it for reasons that Betsy has expressed.

JUDGE VOWELL: Betsy, go ahead and finish

up.

MS. GREY: I just want to use --

JUDGE VOWELL: We're going to break it after this, and if you have questions, you may be able to ask them during the break, but we're going to need to take our break. Go ahead, Betsy.

MS. GREY: Okay. I guess I'll end with a hypothetical thought. I think the real question here is, how much uncertainty do you want to tolerate as a policy matter? I think that's really the heart of the question here.

You know, as we talk about a tort-based system or a policy-based system, but let's just make up that after a certain vaccine is given, one percent of the population of all vaccinees will develop rheumatoid arthritis within two weeks. Now, that's too big. Obviously, that's an exaggeration. That's too high. But within that one percent, we don't know how many of those people developed rheumatoid arthritis because of the vaccine and how many of those people developed it for other reasons. We just don't know that.

So, let me just hypothesize that 99 percent of those one percent of the people who suffered this adverse effect got it for other reasons, not because

of the vaccine. Are you willing to compensate those 99 percent of the other people because of the one percent of the people that did develop this as a result of the vaccine? And maybe that's fine. But do you want to say that you're willing to compensate, I'll say, the wrong people that "don't deserve compensation" in that situation?

If that's too high, then what isn't too high? How much do you want to tolerate that uncertainty of compensating undeserving "petitioners"? And I think that's really the heart of the dispute here. How much uncertainty does the system want to tolerate in order to compensate the right victims of the vaccination?

So with that note, I will end. I'm sure Michael has a --

JUDGE VOWELL: One wrap-up, Mike.

MR. GREEN: The gentleman here has a question.

JUDGE VOWELL: We're at a quarter after. So, a very quick wrap-up, and then we'll try to address those. And by the way, if you all could be back here at 25 after so we can start the next session promptly so we can get you out of here on time. Go ahead.

MR. GREEN: I'd just say this is very tough stuff. You are dealing in an area where you just have inklings and this and that and lots of mechanism evidence, which is very hard to sort out and to understand.

I don't envy the job of both the lawyers and the special masters in these cases. To borrow from John Milton in *Paradise Lost*, "This may not be hell, but better you than I."

(Laughter.)

JUDGE VOWELL: Thank you very much.

(Applause.)

(Whereupon, a short recess was taken.)

MS. GREY: You've already been introduced so I won't do that again, but I just wanted to give you the opportunity, if you would like, to comment on the previous discussion by two other panelists, if you want to, but you cannot, if you'd like. It's totally up to you. Anybody want to add anything? No?

JUDGE BLOCK: I'd like to.

MS. GREY: Okay.

JUDGE BLOCK: I have -- comments into three parts. The first is a comment overall with the three speakers is the Vaccine Act is the primary tool and the primary cause of the Circuit's and the Court of

Federal Claims's opinions. It's not tort law in general. It's not causation in general. It's the wording of the statute, which is a primary function of the Court.

So this debate between policy and tort law is a bit misleading because as Chief Justice John Marshall, paraphrasing his Fisher case, said, we're talking about congressional tenants' really sloppy language. We're talking about the meaning of the statute. And that's what the Courts try to do for good or bad.

The second problem that arises, the second factor, is once Congress has adopted a causation test, preponderance of evidence, and we equate it to but-for causation, that creates its own set of problems. How do you interact the wording of the statute with the but-for standard, which is a tort standard, of course?

And the third problem is the reliability, Daubert problem. How do you apply or select reliable evidence? And those are three things that the courts, and especially special masters, are struggling with for right or wrong.

Now, having spent some time on The Hill, I can tell you that no statute is written to be a model of absolute rationale and clarity. There are choices,

interpretative choices, that have to be made and how you apply it. There needs to be a distinction between interpretation and construction. Construction was the application. So how you construe it is a problem, but I think that the courts have and the special masters have strived to come to the rational solution.

Take the Stevens seven-part test. The Act -- forgive me if I misquote it -- the Act has a disjunctive provision saying it's a medical examination or medical opinion and record, but it says "or." It's disjunctive. So if you require, for instance, a showing of biological certainty or biological mechanism or you don't allow one or the other, then the Circuit is correct in applying its law that way.

So that, I think, is what's missing from the discussion this morning or the prior discussion is those three factors. And it's not one or the other. It's not causation in general. It's not an esoteric, theoretical debate.

JUDGE CLEVENGER: I'd like to just comment on one point that Michael Green made at the beginning of his talk. He said that he was impressed with the opinions that are written by the special masters.

I can't speak for any other of my colleagues

on my Court, but I'm impressed, too. I find in the vaccine cases that I review, I'm enormously benefitted by the hard work and the careful analysis that the Special Master has provided.

Secondly, although the Professor didn't mention this, I'm impressed with the quality of opinions that we get from the Court of the Federal Claims when they review the work of the special masters. Those two factors make life a lot easier for us when what we are trying to do is to comprehend what's going on in the medicine, what's going on in the scientific fact in the case.

I just wanted to emphasize that I certainly agree with him that the quality of the written work of both of the levels that come up to us is superb.

MS. GREY: Just building on that, in addition to the special masters' decisions and to the Federal Court of Claims's decisions, what features of the briefs that you're getting from the petitioners and the respondents are in a larger part most helpful to you, of particular use to you? Judge Bryson, I guess.

JUDGE BRYSON: Okay. Well, can you hear me well enough, or shall I try to magnify myself? If you can't hear back there, let me know by signaling that

you can't hear.

I think one thing you have to keep in mind in thinking about briefing a case in the Circuit is particularly if this is the kind of thing you do a lot, if you're doing vaccine work quite a lot whether on the government side or on the private side, it's easy to fall into the assumption that everybody else spends the same amount of time doing this kind of work and, therefore, is as familiar as you are with all the ins and outs of the statute and all the back cases and so forth.

Now, of course that is true with the special masters. To a lesser extent, but still to some extent, it's true in the Court of Federal Claims because they see a fair number of these cases. We see very few of these cases, and if I were going to tell you one thing to keep in mind, every page you write of a brief that goes to the Court of Appeals is that we see these cases; each Judge will see one of these cases maybe one every six months. I may have been a year since I saw a vaccine case.

So whatever we may have learned from a time that we got into the last vaccine case we may have sat on, we've probably forgot. So it is very helpful if you will give us some kind of background. It sounds

like it may be tedious and rather elementary, but bring us up to speed. There's nothing wrong with spending a couple of pages saying, here's the way the Act operates. Here's the problem with the causation provision of one section and the burden on the government with respect of alternative causation in another section. Lay it out for us because do not assume that we are conversant with all the opinions of our Court or of the Lower Court.

I find the briefs that give us a background, lay things out for us in a simple way -- you don't have to do it in a complex way, going into the legislative history and so forth -- just simply laying out what the background is are very useful. And then, get to the legal issue in the case.

We come to these cases looking for a legal issue which is within what we perceive is our competence to adjudicate. We are inclined, despite what you may think from the assumption that the Court of Appeals wants to retry everything, to approach these cases and many other kinds of cases in which we are generalists and we are reviewing people who are specialists -- we are inclined to be deferential and we are looking for those issues which are essentially barred from our review to be distinguished from those

issues which are appropriate for our review and you have to tease them apart and tee them up for us.

So I think one of the things I see in briefs that we get is people who are basically recycling their briefs from either whatever was submitted to the Special Master, whatever was submitted to the Court of Federal Claims. They send it on up to us without saying, this is a very different tribunal. This is a tribunal which is looking for legal error.

Present us with strictly legal claims, and to the extent that your claim is factually embroiled with the legal issues, make sure we understand where the legal hook is that you want us to grab hold of and say, this is the reversible error, purely legal reversible error. If you can't do that, as appellant, you're liable to call out all of our defer instincts, and those are pretty strong in an area like this because we are dealing with people who know a lot about this area, and we don't. And I hope that most of the time at least we recognize that we don't.

MS. GREY: Along the same lines, what do you find unhelpful? What's the least helpful part of the briefs that you get?

JUDGE BRYSON: Me again?

MS. GREY: Sure.

JUDGE BRYSON: All right. Well, as I suggested, we don't find a long exegesis of the facts that is designed to create sympathy. I mean, some of these cases obviously are very sympathetic. I hardly know any that aren't. But you do see briefs which are designed presumably to try to put us in a mind to try to find some way to reverse a disposition previously entered against the petitioner.

I don't want to say that it falls entirely on deaf ears. We are human, but it is our perception of our role not to second guess the factual findings that have been made. And if those factual findings are adverse to your position, then there isn't very much likelihood that we're going to say, well, that can't be right.

I mean, to some extent, the Federal Court of Claims has the authority to substitute findings of fact. In fact, they have explicit statutory authority to substitute factual findings for those of the special masters, but we don't. And yet I get the feeling frequently that people either feel they must either urge us to make factually-based dispositions or that they have to color the case with a factual presentation that somehow is designed to get us into a reversing mode, so to speak.

I don't think that works effectively. Simplicity of presentation, going to the language of the statute, as I think Judge Block mentioned, we look at these things as, what does the statute tell us to do? An argument based on language in the statute is going to be greeted, I think, much more warmly than an argument about general principles of fairness, you know, this just shouldn't have been allowed to happen, that sort of thing. And yet, we see a lot of that kind of language in briefs. That just doesn't cut much mustard in an appellate Court.

MS. GREY: Judge Clevenger, you have the briefs, as he just described, but you also have a 15-minute appellate argument. What would be useful to you in those 15 minutes in the presentation when you're talking about these very complex medical issues in these cases?

JUDGE CLEVENGER: Well, the problem for most lawyers who are presenting an oral argument is that they have put more in their brief than they have time to talk about in the 15 minutes in their oral argument. For example, it takes longer than 15 minutes to read the brief orally. And some lawyers have a lot of trouble figuring out which arguments they want to present at the oral argument.

I prefer the kind of oral argument where the appellant in particular is trying to figure out what problems the Court has with the appellant's position. For example, if a person can get up in oral argument and just spend 15 minutes and leave 3 minutes for rebuttal so 12 minutes they talk, they never get any questions, they probably ought to go home worried that they're not going to win because the Court wasn't very interested to push it around much.

I mean, for me, the skill of appellate advocate is trying to appreciate or should be able to appreciate where the weaker points are in the case and decide whether those weak points are so weak they're going to destroy the case. If so, they have to address those points, come to grips with them.

As Judge Bryson said, I think you'd be hard pressed to find a case or certainly a line of cases in which the Federal Circuit has critiqued the quality of the evidence that was brought forth in the case. A record gets made below. We're not doctors. We don't know the answer. The record is well massaged in the Court of Federal Claims. We by and large accept that the scuffle that's been going on over the years is over the law and how the law is interpreted and with the statute that Block was talking about.

So sometimes we've had both in the briefs as well as in the oral arguments a lawyer who's been close to the family maybe from day one who does write a brief that is extremely sympathetic, but it isn't very effective when it comes to statutory analysis and coming to grips with those issues. When that's what's at stake, then that's what you need to address yourself to.

MR. GREEN: Judge Clevenger, if I could just jump in and follow up. You suggested that a good oral advocate is going to get to what's bothering the Court and address that. On a scale of 1 to 10, how hot is the Court of Appeals in oral argument? And by "hot" I mean --

JUDGE CLEVENGER: I think if you asked our Federal Circuit Bar conferences or whatnot from a cross section of people who come, how aggressive is our bench, they would say, very aggressive. I mean, I have to be constrained from time to time to allow the lawyer to identify himself.

(Laughter.)

JUDGE CLEVENGER: I like to start, well, do you mind if I ask you a question? I actually had one litigant say, yes, I'd rather you wouldn't.

(Laughter.)

JUDGE CLEVENGER: I mean, I'm not bragging, but the bench is well prepared. If you have issues, for example, like Judge Bryson mentioned ago, the statute cries out to have an argument about alternative causation and substantial contribution and that sort of thing. So someone that gets up right away and leads right into that is prepared, wants to talk about that, wants to try to help us understand what the interrelationship is between a restatement but-for test and a statutory defense on the hand of the government, that's what we need. I don't think there's any lack of aggressiveness by our bench in wanting to get to the bottom of it.

MR. GREEN: So you're helping attorneys get to what concerns you.

JUDGE CLEVENGER: Well, sure. I read a brief two or three times. I know what the people have said. I have some questions frequently about the reasons why some issues weren't addressed in a brief, and I want to talk about that.

The reason to have an oral argument, in my judgment, is not to give the thespian a chance to practice in front of us. It's to help the Court resolve issues that the Court has having read the briefs. In some cases, you don't need to have oral

argument. In most of the vaccine cases recently, you need to have that because serious questions of law are being debated.

MS. GREY: Judge Bruggink, we've heard how respondents and petitioners can help the appellate courts, but what can the special masters do to help the appellate review process? What can they do in their findings of fact and their conclusions of law that would facilitate the appellate review?

JUDGE BRUGGINK: Get the parties to settle. That would help. I have to begin by echoing what Judge Bryson said, and I think he credits our Court perhaps with more expertise in these cases than we have or at least than I have.

They come through, at least on my docket, very infrequently about like the comet Kohoutek, and I have to sort of reeducate myself every time to the issues. So I sometimes ponder what value-added I can contribute.

That's a long way around saying I pay a whole lot attention to what the Special Master has done because, number one, as Judge Clevenger says, the opinions are uniformly well presented. The cases are well handled. The issues are ventilated. They're very professionally handled in terms of the findings

of fact and dealing with the legal issues. I have very little to contribute.

As a critique, I will just sort of emphasize something that Judge Bryson said. The assumption is sometimes made that we are attuned to the issues a little bit more than we are. And so the use of -- citations and sort of conclusory Hornbook language assuming that we're tuned in to the prior development of an issue is probably not a safe assumption, at least in my case. So flagging, this is a novel issue and there's been conflict in the decision making and here's where I'm coming out, is useful to me. But other than that, I have very little critique. I think they do a good job.

MS. GREY: Judge Block, are there concerns that you would share about how the special masters performed in terms of getting the case to the hearing; the written decisions, how they weigh and evaluate testimony, how they summarize evidence, the quality of the record, or any other areas? Would you like to comment on that?

JUDGE BLOCK: By and large, as the facts can be extraordinarily difficult, the evidence can be extraordinarily difficult, and sometimes the Act itself is not a matter of clarity and I think that the

courts and the special masters are doing the best they can, and I think the program has been something of a success.

I will add something a little bit different, but it does touch on this; in that, why in the world in the vaccine program would Congress -- an intermediary court? I mean, why would you have a trial court in the middle of this process?

MS. GREY: I have asked myself that question so many times.

JUDGE BLOCK: And I'm going to answer.

MS. GREY: Good.

JUDGE BLOCK: The role of our Court, the Trial Court, the Court of Federal Claims, is not really, really second-guess the fact determinations of the Master. It's really to prevent arbitrary behavior. And so what we have is arbitrary and capricious review, which our Court has in bid protest in contract cases. So we're quite used to that. It's like an APA review. And then it goes to the Circuit. So you have a level of protection, and it's rational.

JUDGE BRUGGINK: I've puzzled over this structure a good bit as well, trying to figure out where the value-added is in our Court because the standard of reviews are fundamentally the same,

arbitrary and capricious not in accordance with law.

And I've come to the conclusion -- I haven't looked at the statistics -- but that even though we fundamentally approach cases the same way the Federal Circuit does, we do act as something of a filter that certainly on procedural issues and on legal matters we have a tendency to remand and to allow the record to be cleaned up before they go to the Federal Circuit.

So I think there is some value-added in that, and perhaps I guess we do ultimately see a few more. So we see which cases are appropriate for remand.

If I can jump ahead to a related but different point, I know that we have the right to find facts, and in that sense we do serve a different potential function. I've never in a case that I decided to remand seriously contemplated the possibility of refinding the facts because I didn't hear the expert witnesses, and I would prefer to have that done by the special masters. So I think that possibility exists. It's just that I would be very reluctant to exercise it.

MS. GREY: Returning to the previous panel a little bit -- and Judge Clevenger, you've already spoken to this, but I'll ask if you want to elaborate

-- tort cases, as you've all said, form a very small proportion of the opinions of the Federal Circuit. To what extent does the Federal Circuit rely on opinions from the other Circuit Courts of Appeals in deciding issues that are related to this enormous question of causation in this field?

JUDGE CLEVENGER: I don't think I've ever seen a brief where usually the appellant person has lost, the petitioner cites law from other areas, tort law. I mean, you'll recall that in Shyface, which was an earlier on case, came out of Montana. The injury to the child had been in Montana, and that was the case in which the Federal Circuit was required to sort of try to decide what the fundamental test would be for the off-table causation in that case.

And that's when we embraced the Second Restatement, and we did that in rejecting the Shyface's argument that we should rely on the law of the State of Montana to decide what constituted a no-fault tort.

And the rationale of our Court was that this was a nationwide program, and it called for a nationwide legal standard for a no-fault tort as opposed to a state driven. And so I think it is perhaps for that reason that we're dealing with a

nationwide standard bred from the Second Restatement that we don't see a lot of recitation to law in other Circuits.

I would not be at all adverse to a brief that presented to me a fact circumstance that would say, you know, an illness or a disease or something that said, for example, to go to a state or federal court that had actually adjudicated a causation vaccine injury and to say, you know, here are the facts that were laid out; here was the evidence laid out and that was deemed sufficient to show that there was a victorious case there for the applicant. But I've never seen that either.

MS. GREY: Yes, please.

JUDGE BRYSON: I think it will be interesting. I think the Third Restatement was mentioned earlier, and as Judge Clevenger says, effectively by saying we're looking at a nationwide standard, we're not looking at particular state laws as the regional circuits would do in diversity cases, which is where most of the federal tort law gets made outside of the Federal Tort Claims Act.

An interesting prospect on the horizon, having said in Shyface that we take it that Congress had in mind a national tort law and we will interpret

the national tort law they had in mind as being the Second Restatement, the acute task to try to figure out whether suddenly Congress retroactively has decided that the Third Restatement is actually a better standard to apply. So I look forward to some briefs in which that issue will be presented.

I have no idea what we'll do with it, but I anticipate that as things change, I think despite the respect that everybody holds the ALI in, that it's going to be a little difficult to say that Congress had in mind that whatever the ALI said is law. We shall see, though.

MS. GREY: I guess you'd have the same question with regard to Daubert, too, in some ways.

JUDGE BRYSON: Sure.

MS. GREY: All right. Going to more specifically Capizzano, Althen, some read those decisions and other Federal Circuit decisions as a message to the special masters that they should be more liberal in granting the petitions for compensation. Judge Block, do you think that's a fair reading of these decisions?

JUDGE BLOCK: No comment.

(Laughter.)

JUDGE BLOCK: I guess Judges have to cut a

fine line because litigants do appear in front of us, but I will say this as a general matter. It's like using an ink blot; you read things into it. Sometimes you should take things at face value.

MS. GREY: Okay. Anybody else want to comment? No? No comments.

JUDGE CLEVENGER: Well, the notion that the Federal Circuit judges sit around and compose some policy of their own and then figure out how to effect the policy by telling other tribunals how to do things, I don't buy that notion for a second. We get paid to analyze legal issues, to interpret statutes.

To the extent that there was a disagreement, if you will, between the special masters and the judges on the Federal Circuit as to how to interpret the statute in terms of setting a test for deciding how a causation-in-fact case could be delivered, I don't think you'd get much argument with people saying, well, yes, there was a disagreement.

Now, was that disagreement born from a notion that more petitioners should be victorious in the program than have previously been the case? As I say, I think that's nonsense. That's not how judges get at their work. And I don't think for a moment that the enterprise, the engagement, the process over

the last two or three years has been anything but healthy. It has been driven by right-thinking people who were trying to get at what they thought the law requires.

The buck stops with, well, the Supreme Court if they take these cases, but the buck stops with us in this case with the help and aid of the judges on the Court of Federal Claims. This interaction, as I've described it, over the last two or three years has not been a two-party debate between the special masters, on the one hand, and judges on the Federal Circuit, on the other. The judges of the Court of Federal Claims who have a great deal of experience with these cases have been useful, helpful, and willing participants in trying to get sorted out what we think the right answer is.

JUDGE BLOCK: I remember when I was growing up -- I grew up in the New York metropolitan area in New York City -- there was a front page article in the *New York Times* about the last Justice Frankfurter and how he completely switched his political ideology. You can tell from the opinions on the bench. He went from being an FDR liberal to some sort of reactionary according to the *New York Times*. And I don't think he changed at all. It's what people read into it. This

is the editorial board of the *New York Times* at that time.

And I just think that these opinions should be taken -- when I said "at face value," it's interpretation of the statute. It's a statutory case of controversy.

JUDGE BRUGGINK: It's been very helpful to sit in on the first panel because as judges deciding isolated cases, we don't see the big picture the way you do, and I think it's been a helpful exercise for us. But what I perceive -- and this is certainly an understandable reaction -- is that there's a desire on the part of the Bar and the special masters, no doubt, and I guess in our judges as well, for a certain global coherence in an approach to all cases.

And I think perhaps what Judge Clevenger was hinting at is that we take cases one at a time. Our Court does, and certainly the Appellate Court does. And one of the frustrations I've had, since this tension in approaching these cases myself -- one of the frustrations is that the structure calls for the special masters to sit individually, calls for our judges to sit individually. And a program like this in some respects calls for perhaps a more global approach to what amounts to not a class action

exactly, but certainly common causation kind of questions, and yet the system doesn't permit that.

And one of the issues that we talked about in Vance was the extent to which it's appropriate for special masters to reach outside really from their own expertise. And I'm sort of conflicted on that subject myself because, on the one hand, I'm used to sort of putting on my normal litigator's hat. I don't want to get blindsided by something that wasn't part of the record, and yet in some respects in the Court of Federal Claims, I expect the special masters to bring additional value to the process just by their own experience about what they've seen in other cases.

And so this is merely an observation that there's an inherent tension in this process of the desire for some coherent approach and the obvious impulse in a lot of the special masters to create numerical standards. This is the way you treat cases like this, one, two, three, four, five. Yet they don't bind each other, and our judges don't bind each other. That's that desire for a sense of coherence.

And yet on the other hand, the litigating model, which is you look at the four corners of the record in front of you. And I'm reluctant. If I get some sense that the special master is bringing things

into the case that they may well be familiar with that aren't apparent to me from the record, I get a little nervous.

MS. GREY: Well, then let me ask. How does the reviewing function of the Federal Circuit, in your mind, differ from the reviewing function of the Court of Claims?

JUDGE BRUGGINK: I think the answer is, we both approach it the same way. The only difference is that if we find that the decision was arbitrary and capricious, that we potentially can become fact finders -- I think Althen makes that pretty clear, and the statute does.

As I said, I'd be a little bit nervous about doing that rather than remanding it, but fundamentally that's the only difference that I see other than our decisions aren't binding on anybody other than the litigants.

JUDGE CLEVENGER: The role that's played by the Court of Federal Claims in assessing the quality of the evidence is quite useful to us. For example, if the Court of Federal Claims examines, as they do in their opinion, the evidence that was presented that was deemed to be sufficient to defeat the petitioner's case and the Court of Federal Claims judge explains

why he or she feels that that evidence was worthy of defeating the case, it comes as a second layer of strength of the quality of the case as I'm citing it against the petitioner. It could equally be in favor of a petitioner.

The other thing that happens from time to time is that the judge of the Court of Federal Claims, while not entering fresh fact findings of their own, they will comment with some criticism on a piece of the evidence that's in the case. And so then the case comes to us, and another set of eyes has been on this evidence to help us more understand what the true character of the evidence that was in front of the special master is. It's a useful process.

Also, you have to remember that this whole program was driven by policy interest in the Congress to try to make certain that there would be effective relief for people that were injured by vaccines. The idea was to keep vaccine manufacturers in business because they were threatening to leave.

And so the fact that Congress gave, if you want to see it that way, a double-dipping review for someone who's lost in one of these cases, the consequences to the child, or to the recipient of the vaccine, whatever age, and to the family members is

just excruciatingly horrible. And so the notion that the Congress said, well, we're going to give the loser two bites of the apple, I think probably wasn't a bad idea given the policy that was driving the program.

MR. GREEN: Judge Bruggink, I wasn't sure if this would be a fair question, but your answer to Betsy's prior question suggests that you thought about it, so let me put it out not just for you but for anybody else. If you were up on The Hill before the appropriate committee and you were asked a question, what are the three most important things we could do to change the statutory arrangement to improve the process -- and you averted to some things, I think, that might be employed here -- what would your answer be? You're not limited to three, but a minimum of three.

JUDGE BRUGGINK: You're not going to get any, so that's not a problem. I'm not competent to answer that question. As little as I know about the day-to-day application of it, I'm guessing that something of the process of putting vaccines on the table would expedite the review process.

Other than that, there have been so many improvements statutorily over the last I don't know how many years, that I think a lot of the bugs have

already been eliminated, and the special masters seem to be quite good at getting Congress to assist on occasion. So the short answer is, I don't know, but I'm guessing that a tidier way of expediting the process of putting vaccines on the table is the only one that comes to mind, but perhaps these other folks know more about the subject.

JUDGE CLEVENGER: Professor, given your interest in the causation-in-fact, the tort aspect of the recovery of the case, don't you think that the first person testifying in front of the requisite committee would want to ask the Congress, what on earth did they intend?

What sort of causation-in-fact remedy did they want to have? Did they want to have a remedy that was an absolute carbon copy of what would go off in a state tort case or federal tort case, or did they want something that was more user friendly to the applicant, because the Congress would have to decide as a matter of policy what they wanted.

And once they answered that question, I think the chips would fall fairly quickly in the hands of whoever was revising the statute.

MR. GREEN: So some clarification of the causation standard that's in the statute is what

you're asking for.

JUDGE BRYSON: Well, I think along the same line if you want to get specific, you can just go to the opinion in Pafford. And you look at the dissent, you look at the majority, and you have a disagreement on the Court of Appeals about what the statute means.

It would certainly be within Congress's power, and it would seem to me it's a good place to start simply to clarify the two points that were the points of disagreement: One, the role of temporal relationship to the extent that you can give it some kind of substance; and two, what in the world you meant, dear friends up on The Hill, by starting off by saying that there was a requirement that the petitioner prove by a preponderance of causation, but on the other hand, that the government has the obligation by a preponderance to prove alternative causes when alternative causes certainly arguably can be said to be part of --

MR. GREEN: Part of a prima facie case.

JUDGE BRYSON: And causation in the first place. Those are two points that we've struggled with, the Court of Federal Claims has struggled with, and, as far as I know, the special masters have struggled with. And those are the kinds of things

that could be presumably addressed fairly readily, but those are the kinds of things that never seem to get fixed.

There are, I'm sure, others, but you could just pick up a handful of opinions and look at the kinds of issues that the Courts are struggling with and just fix those, and presumably the system would be smoother.

MR. GREEN: Are there procedural changes that might be helpful to this system? I heard one of you comment on the Court of Federal Claims reviewing with one judge. Should there be panels of judges in the Court of Federal Claims?

Are there other changes that the special masters aren't sure whether they can employ the Federal Rules of Civil Procedure as a matter of their inherent authority? There's nothing that says that they can't. Are there other aspects? And maybe this is a question that we should be asking the special masters in addition to you.

JUDGE BRUGGINK: I'll be speaking out of ignorance to some extent, but it seems to me that at the special masters level, some sort of consolidation process and perhaps panel review at that level would be useful. I think if you instituted a panel level

review at our Court, then you're making moot the use of the Federal Circuit to some extent.

So I think the idea of involuntary groupings of cases with binding results at the special masters level might be one solution. The special masters have taken informal steps to do this, and I think it's been very useful perhaps putting a hammer behind it.

MR. GREEN: So this would give the special masters the authority that exists for federal district judges under Rule 42 of the Federal Rules of Civil Procedure to order consolidation even of issues that are common to cases that are before them?

JUDGE CLEVENGER: Maybe we're just talking in an utter vacuum about whether or not congressional attention to or reform of the program is anything possible. I have no idea whether there's any constituency to make anything happen.

If you want to see a real constituency at work, the veterans, the various veterans organizations. Our Court reviews the veterans benefits cases that come out of the Veterans Court. And from time to time, we'll produce an opinion that is unfavorable to the veteran and the veterans organizations don't like it and they are very quick to get our opinions overruled.

But I don't know whether there's any constituency. As I mentioned earlier, I think this vaccine program was driven in the beginning by the desire of the pharmaceutical companies, some that wanted to stay in the business of making vaccines although it wasn't making a lot of money for them and they needed some protection.

I don't know that it was the people that had been injured by vaccines have as much of a constituency, but I think if you're going to get any reform, you need to have a strong tailwind pushing you towards Congress.

JUDGE BLOCK: I second that comment. The program tried to balance, as I see it, two interests. On the one hand, if you make liability and judgments too easy, then vaccine makers, who make in economic terms a public good, won't make that public good. On the other hard, if you make it too harm, then the innocent won't recover or will be stuck in certain state tort systems, which is, you pointed out, not necessarily coherent. There is a concern with judiciary committees about the state tort system as a whole.

So, any reform has to take that consideration. First of all, I think Judge Clevenger

is right. There doesn't seem to be a built-in constituent. For instance, it's going to be hard to get it changed.

But I would say the one change that I think is possible is to look at streamlining the table situation, putting more things on the table, because that's what the program was designed to do. Chief Master Golkiewicz told me when I first came on the Court of Federal Claims -- and we were discussing that program in general -- that originally about 95 percent -- and I'm maybe misquoting him -- up until about five years ago or four years ago of the cases that he had were table cases, and now it's reversed.

And Congress didn't foresee it. So you have a lot of provisions -- we were discussing this before -- alternative causation provisions, that may have been originally designed to address the presumption of the table issue. But I think that needs to be looked at. And that's one area of reform that may be bipartisan and might be able to get fixed.

MR. GREEN: One of the means to that end, I think, would be more research being done on these common outcomes that are occurring for a variety of the vaccines. Just in conversations, I've heard that there's not a lot of research that is being

commissioned to be done in this area. That would remove some of the uncertainty that we were all bemoaning in the earlier panel.

We might add that to the list of what we put on our Christmas list for Congress would be to get a mechanism to get research done on the issues that are coming up that we're asking the special masters to decide.

JUDGE CLEVENGER: Maybe we need to bring back Lyndon Johnson's way of doing things. I remember so clearly in the Johnson Administration when there was a social problem of some order that either Joe Califano or someone like that convinced Johnson needed attending to, they would appoint a Blue Ribbon Panel.

And they would have distinguished participants. I worked for many years for Lloyd Cutler in private law practice, and Cutler was a great believer in Blue Ribbon Panels. And so they would gin up a panel, and you'd have in a nine-month period a very careful analysis of a program. Whether it was working or not, suggestions for change, and that was then, if you will, the sort of the calling card that began the drive to try to initiate some change.

It seems to me the Blue Ribbon Panel analysis of programs has either fallen out of favor or

people forgot how to do it, but it's not happening anymore.

JUDGE BLOCK: I think it's a great, great idea, and I'll tell you why. Because if the Judiciary Committee, as an example -- and I'll only say that because I was senior counsel of one of them for a while -- has a jurisdiction over this, they're going to look at it very narrowly and look at certain fixes. And if there's no constituent; there's not an interesting topic to the members of the committee, then it gets dropped. But having sort of these universal Blue Ribbon Panels is certainly a way to build bipartisan support, I think. That's a great idea.

MR. GREEN: Something the British have been using for a long time with their Law Reform Commission, what we might take a look at. There is a standing Law Reform Commission that examines various issues that are thought to be of importance with regard to public policy in Great Britain.

MS. GREY: Getting back to the appellate review process. Let's say, Judge Block, a special master rules in favor of a respondent after they have a hearing, and the special master finds that the respondent's experts are more credible or persuasive

and better qualified than the petitioner's experts. On what basis can the Court of Federal Claims reverse that finding?

JUDGE BLOCK: Well, it's not quite a bonkers test. Okay. No, seriously. I mean, there has to be substantial evidence on the record to support the special master. Are they acting arbitrarily? It's not a de novo review of the facts, pure and simple.

MS. GREY: So giving some weight to that finding.

JUDGE BLOCK: It's a built-in deferential system.

MS. GREY: Right. Right. Anybody else want to comment?

JUDGE BRUGGINK: I don't recall a case in which that's come up, but I've seen our judges wrestling with this issue, and I wonder what I would do if I wasn't persuaded by the special master's analysis when they've seen the witnesses. As I suggested earlier, I'm reluctant to weigh into that.

But as one of the two professors said, when I have experts in front of me on a case of my own, their opinion is useful. It's interesting, but I don't take it as obiter dictum that somebody says something. I want to know what's behind the expert's

opinion and specifically what it's based on. So I guess between us and the special masters, if I wasn't persuaded by the special master's treatment of an expert, I think I would probably send it back for another explanation.

MS. GREY: Okay. Assuming that the Court of Federal Claims reverses, then what happens with the Federal Circuit? What weight does the Federal Circuit -- you'd send that back --

JUDGE BRUGGINK: What's happened in the meantime hopefully is that the special master has had another opportunity to explain why they thought one expert was more --

MS. GREY: I see. So you're assuming that the Court of Claims is going to remand and then it works it's way up.

JUDGE BRUGGINK: Right. So hopefully that wouldn't be the problem.

JUDGE BLOCK: Let me jump in and clarify what I said. It's incumbent on our Court to search the record. So you're looking at all the evidence -- I know Judge Bruggink didn't mean that -- not just one or two experts, but search the entire record --

MS. GREY: Right. Right.

JUDGE BLOCK: -- which leads me to one of my

favorite topics, and that's the growing relevance of Daubert and of what is reliability.

MS. GREY: Please.

JUDGE BLOCK: What would happen if, for instance, the Tenth Circuit said, we have the exact same -- I can never pronounce this -- epidemiological study in front of us. And they say, well, based on the facts, we're reversing the Trial Court, District Court in Utah, for instance, because it's just narrowly unreliable or because the association but for its cause, and you have the same study in front of the special master, and we have that. I can see this is becoming an issue.

Now I'm not talking about particular cases. I have nothing in mind, but I can see this becoming more and more of an issue. Now, the special masters don't necessarily have to follow the Rules of Evidence, and the statute itself, the Act, at times diverges, I think, from the strictness of Daubert. So you have all these issues that are going to come to fore that is going to make this even more interesting.

MS. GREY: You know, honestly, I'm surprised it hasn't come up more than it has so far because Daubert was decided in '93, so it's really been around a long time.

JUDGE BLOCK: What was the last of the trilogy cases?

MS. GREY: Kumho Tire, GE, Joiner --

MR. GREEN: Daubert is the relevant one here, I think. Maybe Joiner because of its views of discretion with regard to reviewing a trial court's determination.

My guess is the reason it hasn't come up is because -- the audience can probably help us on this -- how many Vaccine Act cases are actually litigated in federal court to an appellate court? Does that happen? That's why we haven't confronted it, federal courts dealing with the same kinds of evidence in a Vaccine Act case that you're contemplating would be before a special master, I think. It may happen in the future, but I think that's the incidence of these cases getting out
into --

JUDGE BLOCK: Well, I know we've addressed issues of differential diagnosis.

MR. GREEN: Sure. Sure.

JUDGE BLOCK: It does come up.

MS. GREY: Somebody mentioned earlier -- and excuse me, I can't remember who -- that the Court of Claims has the ability under the statute to enter in

their own findings of fact and substitute it for -- if they're overturning what the special master found, they have the ability under the statute to enter their own findings of fact and conclusions of law.

Now, from the Federal Circuit's point of view, are there any concerns about that happening when in fact you're not seeing the witnesses and you don't have the live testimony that you would have as a fact finder? Judge Bryson, if you care to talk about that.

JUDGE BRYSON: Well, this is getting into the realm of the pretty hypothetical because as Judge Bruggink pointed out, I think it's very seldom that the Court of Federal Claims seems to overturn purely factual determinations, especially when they are credibility based.

I mean, I suppose if one of the special masters -- and this is really hypothetical -- but if one of the special masters were to say, for example, well, the petitioner's expert had an M.A., but the respondent's expert had a PhD. PhDs trump M.A.s always, no matter what. Therefore, and solely for that reason, I believe the PhD. If that were to happen, I suppose the CFC would probably, very possibly, say, no, you can't do that.

Now, that's not to say that the Court of

Federal Claims would substitute the conclusion at that point of saying, well, instead, you should have believed the M.A. Instead, they would probably do what Judge Bruggink said, which is to send it back.

But on the assumption that there was something in the record that just compellingly cried out for believing the M.A. instead of the PhD and the Court of Federal Claims adopted that, it's the kind of thing that, as a second-level reviewing Court, I would think we would be very reluctant to get into. That's sort of between the special master and its immediate reviewing Court, which has the specific authority to make those determinations.

I suspect, without having thought it entirely through, but I suspect we would view that as the finding in the case, which is as binding on us, coming from the Court of Federal Claims, as it would be if it had been the finding of the special master approved by the Court of Federal Claims.

MS. GREY: Right. Someone's going to correct me, but isn't that what happened, though, in either Althen or --

JUDGE BRYSON: Althen was a substitution. That's right.

MS. GREY: Right.

JUDGE BRYSON: I think on the basis, if I recall the case correctly, it's essentially a legal-type determination. It was not a credibility because of, I-looked-at-this-person-on-the-stand-and-I-could-see-that-this-person-was-a-lying-dog-type determination.

MS. GREY: Right. Right, right.

JUDGE CLEVENGER: Well, the Daubert issue will continue to be present in all of these cases, but in the last two or three iterations that we've seen, it wasn't so much a question of, how good is your evidence; it's, what evidence do you have, because the first question is, what do you got?

Like playing poker, you put your hand down; that's the evidence. Daubert says, whether you had a flush, whether you had a royal flush, or just one of a kind. And so the issue in the cases that have been discussed here today didn't turn on Daubert. In fact, they turned on, what'd you have? And there seemed not to be much debate, at least when the cases came to us, that the evidence that was in the record was okay evidence. It satisfied the test.

MS. GREY: Right. Right.

JUDGE CLEVENGER: I think it's not at all odd that that happens because if you have a vaccine

that's administered that didn't qualify for table status at all -- two classes of cases come, and as I understand it in the causation-in-fact world, one will be a table case where the table says, well, the onset has to be more than 24 hours of the first manifestation. It turns out that in the case in front of you the first manifestation was 25 hours. So, it fell off the table; it becomes a causation-in-fact.

The second class are administrations of vaccines for which there is no table at all, and the question is, well, in this world that we live in, has the petitioner made out a non-fault causation case? And in those cases, the real question is, what do you got? What's your hand look like? What evidence do you have at all to be able to fit into these tests?

I think maybe as you see more incidents of an administration of a particular vaccine that produces a particular form of illness, disease, or adverse effect, and you have a second case and a third case and a fourth case that comes through the system, you'll begin to see more of the Daubert analysis being applied to the evidence that's being brought forward.

JUDGE BLOCK: I think the Daubert problem, if you can call it a problem, will be almost entirely at the special master and maybe at the Court of

Federal Claims, though. The time you get to the Circuit, I mean, you already have a record, and so you're looking at the entire record. It's going to be more of a problem with the special master in front.

MR. GREEN: Can I just --

MS. GREY: Please.

MR. GREEN: Judge Clevenger, your comment about lay your hand down and the special masters looking at that and the appellate courts looking at whether that is enough, it seems to me that that's the standard sufficiency of the evidence review that's used by all courts, which is a pure question of law and is reviewable de novo. It's a legal question whether there was sufficient evidence to meet a party's burden of production.

The interesting thing here is is that under Daubert, which is doing the same thing, the standard of review is not de novo and a question of law, but because it's the admissibility of a witness, it involves a standard of review which is abuse of discretion. That may be another question that comes up in vaccine cases. What should be the standard of review on those questions?

JUDGE CLEVENGER: I think Judge Block is right that appellate courts when they get Daubert-type

issues filtering up to them are going to be questions where the issue will be, did the record support the fact finding made by the trier of fact as to the quality of this evidence?

What I see happening, not right away, but my guess is that as more and more litigation in America is driven and is governed by complicated scientific issues, we will see the Supreme Court returning to Daubert, returning to fine-tune the legal test at that stage in what qualifies as competent medical evidence or scientific evidence.

At that stage, you'll then see the courts of appeals getting back in the game by saying, well, there's been a revised legal standard, and the question then is whether or not the evidence meets the legal standard.

JUDGE BLOCK: That's absolutely true. I was going to also suggest, when I was talking about a Daubert problem, it's not the same problem the district courts and the court of appeals have because my understanding of the Act is that the special masters are not bound by strict rules of evidence, and the Vaccine Act itself has certain incentives to use certain evidence. So it's a little bit different.

MS. GREY: I'm wondering. Some of you

suggested consolidated cases or omnibus proceedings to facilitate the resolution of these kinds of disputes. I'm wondering what effect Daubert would have if you had a consolidated hearing or an omnibus proceeding. Maybe that would make it better or worse? I'm not sure. I don't know if you think anything about that. No? I'll leave it.

JUDGE CLEVENGER: I'm not sure that I understand the notion -- it's been mentioned earlier maybe -- of groups of these cases or groups of these judges could be put together. Except for class action cases, the way we resolve disputes in this country in the federal system is one at a time and building precedent.

But it seems to me that the most useful thing going forward in these cases as more come along, especially of the cases that are dealing not with falling off the table by an hour, in my hypothetical, but by genuine vaccine-administered ill effect that cries out for causation-in-fact analysis, is that body of law grows, then the cases will begin to look more comparable, and there'll be a better baseline of medical evidence that will either tilt in favor of the petitioner or away from him.

MS. GREY: So there'd be some maturity of

the issues in the cases. You'll see more resolution of them. You'll get a better sense of how valid the findings are.

JUDGE CLEVENGER: You have to remember there was always a first tort. I mean, I don't know exactly which one was the first tort. When I was in law school, there was a lawyer in California named Melvin Belli who was famous for delivering the first tort in the California system. He would always be the first one to win. Well, after he won 15 or 20, it was pretty easy for other lawyers to win.

And so what you're really looking at in some respects in the vaccine program with especially the nontable causation-in-fact cases, you're looking at the first tort, the first one around, maybe the second one around. And the question was, was there enough evidence there to produce a victory? If it produced a victory, it'll produce a victory on the same facts, I would assume, in the next case, the next time it comes along.

JUDGE BRUGGINK: That phenomenon of waiting for individual case dispositions, obviously that's the American litigation model. What I was suggesting is that in vaccine cases, perhaps something different ought to be tried because the consistency of results

seems to be an important end result when you're talking about causation issues and connections of various vaccines to potential injuries.

Maybe the special masters would be more appropriate to speak to this question, but it just seems to me it's inherently less efficient, even though ultimately you probably end up getting the same result by having this sort of spotty process where whoever comes in first goes through the system first.

Unless there's a process of amicus briefs or common presentation of evidence or something, the first few decisions are going to be perhaps not fully aware of all the evidence and that kind of thing. So that's why I applaud what the special masters are doing in terms of trying to group cases to the extent they can. It occurs to me that it would probably be faster to do it on a more formal basis because everybody else has to wait obviously until those first decisions come out.

MR. GREEN: You mentioned amicus briefs. What role do amicus briefs play in vaccine cases, if any? Do you get them, and are they helpful?

JUDGE BRUGGINK: I personally haven't had any. I think I asked Gary that question about some pending litigation -- what subject? What's the issue

that you -- about a month ago? And I believe he told me that they were not soliciting -- autism? Okay. That's why. It seems to me that would be an ideal setting to ask for outside briefing, although I'm not sure if it gets to the question of evidence because there's a limited role to amicus briefing.

MS. GREY: We only have about 15 minutes left, so I was wondering if anybody in the audience would like to ask any questions? Does anybody have any questions? Please. Here.

MALE VOICE: Good afternoon. I'm with the Vaccine Injury Compensation Program, and normally speaking, I would be down in Atlanta at the ACIP meeting talking about vaccine policy. So I think that I want to at least put my public health hat on for a moment and address one of the ideas that was put forward, and that was that you could just simply add injuries to the vaccine injury table.

And I think it's important to point out that there are statutory provisions tied to the table, such as the vaccine information statements and the VAERS program, the Vaccine Adverse Events Reporting System, so that if we do add lots of different injuries to them, then it's going to have some public health consequences.

This program doesn't really operate with the outside interest of what is going on in the public sector as much as one would think. It does operate in a vacuum. And I thought it was important to at least point that out.

JUDGE BLOCK: That's a fair point.

MS. GREY: Any other questions? I have a question. You were just touching on this a minute ago about the role of the special master. This is a very unique program in the sense that you have fact finders who are highly specialized, in contrast to civil court system in tort cases.

They see the same witnesses over and over again. They're seeing some of the similar evidence, and in some recent decisions, I think that some of the special masters have been taken to task for relying on matters which would be considered outside the record, although it's matters on which they have developed an expertise.

Does this signal a shift in the role of the special master? Should it, or how do you view that? I have a volunteer.

JUDGE BRYSON: I'll take that. Of course, you're right. In the civil court practice, there aren't very many specialized adjudicators, although

there are some. The Court of International Trade, of course, is a perfect example of specialists who are reviewed by us in that instance of generalists, and they come to their cases with an enormous amount of information about a very challenging and arcane area.

And, of course, outside of the court area, there are many, many administrative tribunals. We review some of them. Another Court, by the way, is the Veterans Court, which has been mentioned, and many administrative tribunals.

And I think the system of having people who are experts, whatever reservations you might have about the extent to which they allow spillover by virtue of their expertise from one case to the next and whatever reservations, which may be legitimate, that you might have about their making decisions which are not entirely predicated on the particular record in front of them, I think those kinds of risks can be guarded against by maintaining some care about making sure that anything that the decisionmaker decides is based on something in the record. But I think those risks are vastly outweighed by the benefits of coming to adjudication with a deep knowledge not only of the science but also of the law.

We take advantage of that in our deferring

to the special masters, and I assume the Court of Federal Claims does as well with a lot of confidence, and I think a great deal of more confidence than we would have if we just had eight people who were pulled in off the street even though they might be excellent lawyers but with no background in this area. They can call and pick and choose evidence based on that kind of background, which I see as an almost unalloyed benefit.

MS. GREY: Anybody else? When I first started studying this program, one thing that I found very confusing was the term "special master" because I thought of it in terms of an Article III special master, and I suspect I'm not the first person to have that kind of confusion. You know, here the special master is authorized to issue a final decision without getting the consent of all the parties, for example.

Do you think that that is a misnomer, that they shouldn't be called special masters? There's some confusion that's caused by that because people like me are associating it with an Article III special master appointment, or do you think that it doesn't add to the confusion in the area? Anybody?

JUDGE BRUGGINK: I call them "extra special masters."

(Laughter.)

JUDGE BRUGGINK: I think because the Vaccine Bar is sufficiently self-identified or expert itself, I don't think there's any confusion or need for name change. In fact, they don't operate the same way as Article III special masters do. They operate more something like a magistrate judge.

Another difference is the fact that, as you say, they can enter final decisions that are binding, which makes them very unlike the special master. But I don't think there's any confusion anymore because the Vaccine Bar knows how to operate with them.

MS. GREY: Okay.

JUDGE CLEVENGER: As Judge Bruggink suggested jokingly, the courts are not in a position to confer a grander title on the special masters --

MS. GREY: You would. I know you would.

JUDGE CLEVENGER: -- although I think we would if we could. Years ago, the administrative judges in Washington got quite upset at being called administrative judges because we used to call them AJs in our opinions. So I suppose an administrative judge would go home and his wife would say, well, AJ, what did you do today? And so they got together in their trade association and lobbied for a better name,

administrative law judge. So perhaps the special masters can get a very special masters title.

MR. GREEN: It probably depends upon where the hyphen is placed in the extra or very special master.

MS. GREY: Do you have any other questions?

MR. GREEN: Are there any more from the audience?

MS. GREY: Anybody else? Are there any further comments that anybody would like to make as a final comment, or do you feel like you've said your due here?

JUDGE CLEVENGER: Well, I mentioned, which Judge Block liked, the idea of a Blue Ribbon Panel to get engaged in this area. I'm not certain that we'll see that happen.

I'm a great believer in the power and authority of law schools and law professors, and I would think that this vaccine program would be a marvelous topic for, say, a two-unit course taught in the spring of the third year when students have got nothing to do but have fun since it's all over. They have their jobs or their clerkship.

And I would think that the magnificent collection of policy issues plus, as we've learned

today, incredibly complicated legal issues, all of which are at the forefront of where science and where law is going in so many other fields, would be a marvelous topic. And if you could generate in the law school just two students a year who cared about this, got passionate about what was going on, you'd make a bigger difference from the law schools than we're going to make from the court if you simply add two or three people every year who want to worry and care about this program.

MS. GREY: That's a wonderful suggestion.

JUDGE CLEVENGER: That's a great challenge, too.

MS. GREY: Very good. Well, I thank you so much for your time. That was very illuminating. Thank you very much.

(Applause.)

JUDGE VOWELL: I want to thank all of our panelists, again, for their efforts in this. It's not easy to be grilled by this audience.

Chief Judge Damich would be very upset with us, however, if we didn't remind you all to go to the reception after this session, and it is going to be going back downstairs. If you are facing the place where we had lunch, there's a hallway to your right.

Go all the way down that hallway and take a left at the end of it. You're going to the Franklin Pierce Room. A plaque is going to be placed in the Franklin Pierce Room today to honor the Willard Hotel's role in the history of the Court of Federal Claims and Franklin Pierce's role in signing legislation.

Thank you all again for coming, and I'm sure some of our panelists will stay by to deal with other questions.

(Whereupon, at 4:48 p.m, the conference in the above-entitled matter was concluded.)

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REPORTER'S CERTIFICATE

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CASE TITLE: 19th Judicial Conference

HEARING DATE: October 25, 2006

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: October 25, 2006

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