Department of Health and Human Services
Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

September 1, 2011

Parklawn Building
5600 Fishers Lane
Rockville, MD

Proceedings by:

CASET Associates, Ltd.
Fairfax, Virginia 22030
(703) 266-8402

TABLE OF CONTENTS

P R O C E E D I N G S (8:15 a.m.)

Agenda Item: Welcome and Approval of June 2011 Minutes, Ms. Sherry Drew, Chair ACCV

MS. DREW: Good afternoon, everybody. This is our 80th meeting. All of our Commissioners are present in person in a different and rather small room with Michelle Williams participating by telephone. We don't take questions; we only take comments. Those will be at the very end from the public. We have only Ms. Williams, who's connected to speak to us right now, I believe.

Thank you all for being here. As I said, this is a small room, and we have a different speaker system. There are only three speakers on our desks, so if you have any comment to make, would you please make them into one of the speakers connected to this big phone here. I think our first item of business here is the approval of the June 2011 meetings. Do I have any comments on those?

DR. HERR: I approve the minutes of the meeting.

MS. DREW: The minutes are approved. We have a guest visiting us today. She's not on the agenda, but it is our new Chief Special Master, Patricia Campbell-Smith. She's going to address us briefly. Ms. Campbell-Smith was appointed a Special Master in the Court of Federal Claims in December of 2005, and she became the Chief Special Master on April 7th, 2011. She has an impressive history,

and what she wants to share with you, I'll let her do that.

She's a graduate at Tulane Law School with honors in 1992. She has an undergraduate degree in electrical engineering from Duke with honors also, and she's a member of the bars of the States of Louisiana and Maryland. She's going to say hello to the Commission at this point.

MS. CAMPBELL-SMITH: Absolutely. I bring greetings from the Office of Special Masters on behalf of my colleagues and the staff there, a component of the United States Court of Federal Claims. Accompanying me today is Ms. Jocelyn Macintosh, who is one of our staff attorneys and has been instrumental in the coordination from the office's standpoint with the OAP proceedings. We still use that term, although those proceedings have officially ended and those cases are proceeding individually, but it's sort of a catch phrase that we continue to use.

I've had the opportunity to look at the agenda. There are some exciting things happening in the vaccine program right now. This has been quite a summer, quite a calendar and fiscal year for us, so to speak, however you measure your year. It's been an exciting year for us, which means that we are particularly excited about our upcoming judicial conference, which is to be held in Claremont, California on October 18th and 19th.

We have some topical issues that we'll speak to, matters about the recently issued IOM report and the successes that have occurred in the vaccine program with being able to resolve and move along quite a number of cases through alternative dispute resolution and how that has been accomplished and certainly an update on where we are with the autism matters and how those cases have proceeded.

We're quite excited. Registration is open and available on the court's website. For those who are unable to travel it is an expectation that all of the sessions from the entire conference, particularly the vaccine component, will be digitally recorded and will be available to be heard after the conference on the court's website. Thank you very much for you time. I'm happy to be here.

MS. DREW: Thank you. The next item of agenda is the report from the Division of Vaccine Injury Compensation by Dr. Geoffrey Evans, the Director of DVIC.

Agenda Item: Report from the Division of Vaccine Injury Compensation, Dr. Geoffrey Evans, Director

DR. EVANS: First I'm going to start with meeting highlights for those who are listening on the phone following my update of the Division of Vaccine Injury Compensation. You'll be hearing from the Department of Justice Vaccine Litigation Office from Vincent Matanoski.

Then you'll have a report of the Institute of Medicine on their Committee for Vaccines and Adverse Events. Dr. Ellen Wright Clayton will be leading that presentation.

Later on there will be a review of vaccine information statements by Jennifer Hamborsky from CDC. That will end this afternoon's session. Then tomorrow morning we'll begin with a clinical update from Dr. Rosemary Johann-Liang and Candice Smith. Then there will be updates from the ex officio members from FDA, CDC, NIH, and the National Vaccine Program Office. Dan Salmon, by the way, from NVPO will be joining us by phone during both days.

Starting with the claims file you can see that the trend with non-autism filing continues, a significant portion being flu claims or half being claims alleging injury in adults. The pace is still remaining quite brisk and probably will top off again close to 400 claims at the end of the fiscal year in another couple months. Again, the trend is continuing this way.

I believe it was just this week that CDC published in the MMWR the universal flu recommendation that was approved by ACIP earlier this year. It promises certainly for more and more influenza vaccines to be given, over 100 million annually, and we're sure this will be a prominent part of the program for certain in the future.

In terms of adjudications, again a very busy

year. Not quite the pace of last year, but very close to it for both compensable non-autism claims, as well as dismissals during the autism proceeding from the autism proceeding that the chief special master just alluded to. The numbers are represented as you can see here.

Moving onto a further breakdown, the Commission has asked in the past to get a better idea of the kinds of activity that surrounds the adjudications for compensable claims. As you can see, concessions represent around five or six percent of the grouping, and about one out of every five claims that are compensated are on the basis of a court decision after a claim's gone to a hearing. Otherwise, settlements continue to represent the predominant manner in which claims receive compensation in the program. You can see this trend has remained steady over at least the past three fiscal years.

In terms of the kinds of conditions that are in the settlement category, for example, if you look at the Department of Justice handout today, the last three pages or so list the stipulations and the kinds of injuries that are documented in the stipulations. That'll give you the idea. Plus, the turnaround time for the stipulations for when the claim was filed. You'll see that there are a number of claims that were compensated that were filed within eight months, ten months, twelve months, fifteen

months, and went from filing to compensation.

Even though the overall average from a filed claim to a compensated claim for the entire program is close to four years, you can see that over the past several fiscal years with settlements becoming a much more predominant way of claims being compensated the pace of compensation, the adjudication turnaround timeframes have gotten quite shorter to where the average for claims that were filed in fiscal year ’08 is now actually one and a half years versus the average overall of four years. These claims are being processed on a reasonable and fast time basis for those that are being compensated.

In terms of petitioners’ awards, this year is on track for right now we’re up to about $145 million. Last year it was $189 million altogether. Based on just what has been paid in the last couple weeks, I would expect that we will go over $200 million this fiscal year.

The balance in the trust fund. Despite these continued outlays, there’s still plenty of reserve in the trust fund, and not only that. With the increased numbers of vaccines that are covered by the program, the trust fund still managed to even have a positive balance. It now has gone over $3.3 billion.

In terms of significant activities, there are two meetings coming up in the next two months. Dr. Charlene

Douglas and I will be attending the National Vaccine Advisory Committee meeting in Washington on September 13 and 14, and I will be the HRSA ex officio representative attending the Advisory Committee on Immunization Practices meeting in Atlanta on October 25 and 26.

For those on the phone who wish to write the program, the point of contact is the National Vaccine Injury Compensation Program. The address is 5600 Fishers Lane, Parklawn Building, Room 11c-26, Rockville, Maryland, 20857. The toll-free number is 1-800-338-2382. The website for the HRSA program is www.hrsa.gov/vaccinecompensation.

Those wishing to provide public comment or participate in the committee meeting should write Andrea Herzog at the address that I gave earlier. Her email address is aherzog@hrsa.gov. With that, I will finish my presentation and be open for any questions. Thank you.

MS. DREW: Thank you, Geoff. We will move onto now to the report from the Department of Justice. Our agenda shows Mark Rogers, but I understand Vince Matanoski will be taking his place.

Agenda Item: Report from the Department of Justice, Vincent Matanoski, Acting Deputy Director, Torts Branch

MR. MATANOSKI: Thank you, Sherry. My name is Vince Matanoski. I'm very pleased to be here again,

especially to be here in person. Last time I spoke to you was by phone. Mark Rogers sends his regrets. He's unavailable today. I know he did want to be here and present this, but I'll do my best in his stead to present our slides and our information for you. I welcome any questions. To the extent that I can answer them, I certainly will try to impart that.

Our first slide, total petitions filed during this period. We look at our information in slices of time, usually about three-month periods, to reflect the time from really the last time we reported to you to now. Then I try to look back and see if there are any kind of trends that I can see from that overall development.

We had 83 cases filed, as you can see from the slide. I would have expected maybe we would have had a little bit more during this period. Overall, I thought earlier this year we might have been on track to be about where we were in total number of petitions filed as to where we were last year around 400. We may actually be a little shy of that this year.

Typically in litigation there seems to be an ebb and flow as the year goes on. It isn't constant. Actually, in the summer we do see a little bit of a downtrend has been my experience, around the summer and around the holiday period in December and January. But come September

we see it pick up again and go through the fall after that summer lag.

I think for the fiscal year there's really just not that much time, even if we do have a pick-up, to see it meet the level of last year. I can't tell you whether that's going to be a continuing trend or whether last year represented some sort of watershed in terms of number of claims filed. It's too soon to tell, but I do think we're going to be a little shy this year of where we were last year. Again, the trend is mostly adult cases. I think we spoke about that last time.

I think Geoff might have gone over some of this. Compensated cases, 66. By far and away, most of those cases are compensated through settlement. Most of the cases are not conceded cases initially. Most of those cases are settled by the parties. You'll see decision adopting stipulation. Fifty-three of the 66 compensated cases were by settlement.

A lot of not compensated cases. Most of those were autism cases coming out of the OAP. We've had a bugbear. I know we talked about this last time about the statistics that Geoff put out in terms of his slides and the statistics we've been putting out in our slides.

When I spoke with you last time, we talked about meeting HHS folks and DOJ folks to try to work out where

that difference is coming from. We did have that meeting, and we actually did find one thing in our process of Department of Justice reporting to HHS that might have explained some of the difference that we were seeing. We addressed that.

I still notice the fairly large difference in the slides in terms of the numbers we presented. I think it may be that the slide that you saw previously was not updated because when I spoke with HHS earlier in the this week, I saw larger numbers than that. We're confident in these numbers. This is the slice for that period of May 16th to August 15th of the cases that we saw adjudicated. Again, a lot of those cases were OAP cases.

MS. HOIBERG: You changed the word to "stipulation." I don't remember seeing "stipulation." Is that the same as settlement?

MR. MATANOVSKI: It isn't necessarily the same as settlement, and we may want to go back to using the term "settlement," but we can always add to the glossary. We did this time. Pretty soon we're going to have a dictionary there. Stipulation isn't necessarily restricted to a case that's settled. Parties stipulate to facts. They can stipulate to various things.

You might even have a case that wasn't settled, but there was a stipulation of some sort in the case. We

have a number of cases that go through where there may not be a settlement of the matter, but perhaps it will come to attorney's fees, and the parties will stipulate as a factual matter as to the amount that they agree represents a reasonable amount for attorneys' fees in that case. Then it's up to the court to adopt that stipulation or not.

In settling a case we do use stipulations as well. We use a stipulation that sets out all the matters that are being settled. When that term "stipulation" was used there, it was meaning the narrower sense of those stipulations that actually settled the case.

MS. HOIBERG: None of them were settled by stipulation. I was just wondering what that meant because down here on the ones that were not conceded you have 53 that were decisions adopting stipulation.

MR. MATANOVSKI: What we're trying to distinguish there are three kinds of decisions coming out of the court. These are in the damages areas. The first is where the court actually determines all the measures of damages. They've issued a decision, and it's their decision as to what the injured party is going to receive.

The second category—and that's proffer—is where the parties have come forward and one of the parties is setting forth this is what we say. We're proferring to the

special master. This is what we say the damages are in this case. It's not a settlement; we're saying as a matter of fact, we believe these are the damages. Then generally the other party is saying we agree with what that party is saying as a factual matter of the damages.

The final category—and that's by stipulation—would be what we are traditionally calling a settlement. This is where there has been a meeting of minds between the parties as to what they think the terms are they can agree upon to settle a case. It may not represent the full measure of damages that person was seeking, but for the various reasons, the parties have agreed that they believe it's in their interest to adopt those terms.

They set the terms down on a piece of paper called a stipulation. It's presented to the court. The parties aren't free to just make the case go away on their own by their own decision. The court has to look at that and enter a decision about whether they're going to adopt that stipulation.

Most of these cases that we saw were not compensated. We had 587. Most of those cases, as I reported last time, were cases where the petitioners decided they were going to dismiss their case because they felt that they did not have the evidence to continue on it.

I guess it was back in about January where there

was a big up-tick in these cases being dismissed in that fashion. It started doing a very orderly process that the court was overseeing where they went to the petitioner's council, who had the majority of cases, and they came to responding to and laid out a process for trying to work through those to determine which cases are going to continue on and which cases are going to drop out of the litigation. You can see in a three-month period almost 600 cases being dismissed.

Voluntary withdrawals. Still just a small number of cases are voluntarily withdrawing from that. I know we've been tracking that for a while. My recollection is early on in the autism litigation there was some concern about whether folks would be just coming into the program briefly and then moving out because they wanted to file civilly. We really didn't see that develop historically. You can see still folks who come in pretty much stay in until they get a decision.

Glossary of terms. Some of these you've seen from before, but we did add four new ones. I believe these were requested the last time. I think some of them were. I know we've talked about them before. I think they're pretty well defined here, but if there are any questions about what we've put down here, I'll be happy to answer them.

Tom Herr was talking to me before the meeting,

and he said that the definition of proffer came in handy when he was listening to a news report. He understood what it meant when he heard this news report. I felt like we've actually accomplished something greater now. We've expanded your knowledge, not that we want to make a bunch of you attorneys. I'm sure you've seen this slide before, the wire diagram.

Last time we spoke Cloer was pending en banc. It's been decided. I think you probably have all heard that. In my recollection this is the first en banc vaccine case that the Federal Circuit has heard. They don't hear very much en banc cases, period, so all eyes were on the Federal Circuit on this one. Cloer doesn't disappoint, the decision that comes out, because I think there's something for everybody in there to look at and ponder.

MS. HOIBERG: We do have some new members here and definitely in the next meeting we'll probably have more, so we may want to go back and go over the petition processing and the Office of the Special Masters unless you guys are okay with not going through it. I'm just wondering if anybody wanted to go through it.

MR. MATANOVSKI: Cloer didn't disappoint. There's a lot in that decision to look at. On the narrower question of statute of limitations the court in Cloer really

reaffirmed where they had been in their prior decisions, like Markovic(?), for example. The panel decision had already been vacated, and they came down fairly clearly saying there's no discovery rule under the Vaccine Act. You can't impute one to the Vaccine Act. It's going to be a strict three years from the occurrence or the first symptom or manifestation of the onset of an injury, so it's an objective standard. It's not when you realize that you have a vaccine claim.

The court went through pretty exhaustively its rationale on that. Really I don't think there was much new in that rationale. I've seen that before. It just brought it all together in one decision. When you have a decision en banc, that's pretty much going to be the law.

There is a chance that this case could go to the Supreme Court. That would be the next step. There's a period of time for the parties to decide whether or not they're going to seek certiorari, but for right now that's the Court of Appeals for the Federal Circuit's decision en banc, so it's going to carry quite a bit of force.

The court went further because it had actually certified a couple of other questions that I wanted to look at. One of them was equitable tolling. The court actually reversed two previous decisions that it had.

DR. HERR: Could you define equitable tolling?

MR. MATANOVSKI: Tolling essentially means the running statute of limitations--if you think of it like a clock, you're stopping this clock at a certain point and it's not running anymore. So if you had 36 months and we stopped it at 35 because something came up, then it's not running from that point on. The equitable part is talking about what it is that comes up to stop the running of that clock. Equitable tolling is actually a very narrow exception to the running of the statute of limitations, so it's only going to apply in a very limited set of circumstances.

In these types of statutes like we're dealing with in the Vaccine Act where you're putting an equitable tolling in a federal claim scenario what you're going to have to show is that somehow you were misled or you were suffering from duress, and that's the reason why you couldn't file your claim. You were deceived in some way. There was some fraud upon you or that you had suffered from duress and could not follow your claim for that reason.

What it won't encompass is I didn't know I had a claim. The court was very clear here that that is not an equitable grounds for stopping the running of the statute of limitations. Although they said equitable tolling is available, you can't bring that discovery rule that they were talking about back in through equitable tolling.

They’re going to use the traditional view of equitable tolling, which is a very narrow one.

We had a number of cases under the Act before the equitable tolling, before the Bryce decision came out, which they overturned. Those cases, I think we had about 60, to my recollection, where equitable tolling was alleged.

Generally what I saw in that was I didn’t know I had a claim or I gave it to my attorney and the attorney didn’t file it in time. Those were generally the categories of claims that were coming up in claiming equitable tolling. What you didn’t see was a ground which could have been considered equitable tolling. I was trying to think of that on the way over. What might be equitable tolling? What might make that out? I’ll take a stab at a scenario that might make out equitable tolling.

Let’s say you had a veteran who went to the VA hospital and he said I believe I’m having this problem and laid out some of the symptoms that he was suffering, and the VA doctor, a government doctor, says no, you’re fine, you don’t have anything wrong with you. That action of that doctor, that might not even be enough if that doctor wasn’t trying to delude that person. But you would get closer to it, I think, in that kind of scenario where the doctor was a government employee, especially if that doctor was trying

to willfully mislead someone into believing they did not have a claim.

I'd have to review the law, but I think that actually might be how far you'd have to go. You'd have to show that that doctor was actually trying to mislead you into not filing a claim. That might be the kind of scenario that would be equitable tolling. I'm taking a stab there because we just really haven't seen them come up.

Generally the cases that we saw come up before were scenarios where somebody said it was their attorney who didn't get it filed on time. The good news in that situation for the claimant, maybe bad news for the attorney, is that there may be a malpractice action available to that person if they didn't file a claim.

MS. HOIBERG: What did you mean when you said that there were cases that were overturned? Were those cases that were kind of in the process or they were actually ones that had been compensated or not compensated?

MR. MATANOVSKI: It was former decision by the Federal Circuit. It was a case called Bryce. Bryce said equitable tolling is not available under the Vaccine Act. The way it had been looked at before Bryce was claims for equitable tolling were entertained. About 60 of them were entertained in that period up to Bryce. None of those were found to meet the standard for equitable tolling. Bryce

comes along and says there is no equitable tolling. At that point people were bringing time bar claims, but they weren't saying they were equitably tolled and that's why they should be considered.

This decision in Cloer says specifically Bryce is overturned. It's not longer the law. Equitable tolling is available. But then they said it is very narrow. It's the traditional understanding of equitable tolling. So it's a very narrow set of circumstances under which the statute of limitations will be tolled.

The kind of thing we need to watch in the future is equitable tolling cases, while none of them were found to meet the standard to go forward, they did take a lot of litigation resources. There was a lot of time by the court, by the party litigating those cases ultimately to no end that helped any petitioner that came in because of the legal standard that's imposed.

This could end up meaning there are going to be a bit more litigation resources used to look at equitable tolling claims. If our previous history is any guide here, we're not really going to see cases that meet the standard. But again, we'll have to see how this develops. I think we're all interested in seeing how this starts playing out.

MR. KING: Just a question on the equitable tolling. You've given an example of the kind of fraud type

of component, and even that was questionable if it wasn't attempted. You've also mentioned duress.

MR. MATAOVSKI: I am trying to think of a situation where somebody could have been said that they were threatened or something not to bring a claim.

MR. KING: I guess it really boils down to what does duress mean.

MR. MATANOVSKI: I have seen more cases that said what it isn't than what it is. We know more what isn't equitable tolling than what is. What's come up before that they've said is not equitable tolling are what they describe as neglect of your claim, your attorney's neglect of the matter. The other thing about tolling is you have to show that the impediment was in place during the entire period that you're trying to have tolled.

MR. KING: Is emotional stress duress?

MR. MATANOVSKI: You might see somebody bring that. I'd have to look at that law, which I stopped looking at after Bryce. The cases that were coming in before Bryce weren't alleging those sorts of things. As I said, they usually were I didn't know I had a claim, which is more what we're seeing in Cloer. Or they were I gave it to someone and they didn't file it.

We were talking in the office about a case where FedEx didn't file it in time, and how would that fare under

equitable tolling. Just to give you a little background, there was a case that was filed where it was filed a day late, but the attorney had given it to FedEx. I hope I'm not going to get myself in trouble by saying bad things about FedEx. Anyway, FedEx did not get it there the next day. It did not make it that time.

MS. LEVINE: Two times.

MR. MATANOVSKI: That's right. Lightning did strike twice in that case. But they didn't get it filed on time. We were thinking about that, and I'm not even sure that makes the strict definition of equitable tolling, even though you've got to say that that person had done what you would think was reasonable, they had taken reasonable steps.

DR. HERR: Were they turned down?

DR. MATANOVSKI: I think they were ultimately. I think that's right that the court did say it's too bad, you should have filed it sooner. The cases that I saw before aren't going to make the equitable tolling standard

DR. HERR: They didn't give easy-to-understand examples.

MR. MATANOVSKI: They didn't. I was trying to think of one that would because I know that one of the cases, I think it was Kubrick(?), which was a discovery

rule case, was a person who actually was a veteran who had seen a doctor for treatment and he was getting treated.

They were using some antibiotics to treat a leg wound and he started losing his hearing. Never put the treatment together with the loss of hearing. Ultimately filed a claim too late. As I recall, it was found to be too late. That was on a discovery rule kind of basis, but there was not equitable tolling imputed there in that instance to find that the claim was timely filed. Again, I'm a little foggy on that because we haven't looked at equitable tolling in a number of years, but we will be again soon.

The other issue in Cloer is what effect will this have on attorney's fees? I think that is what we're all going to be looking at with the court. It's a little soon to say how that's going to affect it, but that might actually have a bigger impact on equitable tolling being used to allow claims that are otherwise time barred to be filed. I appreciate the chance to speak with you. Again, it's been a pleasure to be here. I think that's it for me.

MS. DREW: Thank you, Vince. Does anybody have any questions before we let him go?

MR. MATANOVSKI: I actually have more time, and I will go through a couple of other cases. We've got some appeals pending at the Court of Appeals for the Federal Circuit. The ones in yellow are the new ones. The others I

think we probably spoke about last time.

Hammitt and Stone are kind of considered companion cases because they deal with the same medical issue, Dravet's syndrome. Both those cases there was genetic testing, and there was a certain gene mutation that was found as a result of genetic testing. That gene mutation is known to cause severe myoclonic epilepsy of infancy, which these children had.

On the strength of that genetic testing that was found to be a factor unrelated. Respondent who was putting on this genetic evidence was found to be a factor unrelated. That is, something other than the vaccine is responsible for the condition that's being attributed to the vaccine.

An aside from that was the case went up to the Court of Federal Claims. It was remanded back to the special master because there were some questions about whether the evidence met the standards for finding a factor unrelated. The special master looked at it again and said yes, it did. It went back to the Court of Federal Claims. Stone and Hammitt had different judges in each case. Those judges then affirmed, and now we're on appeal to the Federal Circuit.

MS. HOIBERG: Does that not have the same things that deal with, say, like a mitochondrial disorder like an

another case where the vaccine actually aggravated the condition? Could the vaccine not have aggravated Hammitt and Stone's condition?

MR. MATANOVSKI: I don't believe there was an aggravation claim. Could there be an earlier triggering? That, I think, was one of the questions in those cases. I'd have to go back and look at them. I know when I was thinking about it, I was wondering about that issue, but my recollection is that the evidence was that the conditions remained unchanged.

They were not anything different than what they would have expected, and I don't think there was a question that the timing was altered because of the introduction of the vaccine. I think that was looked at in those cases. Again, it was not a significant aggravation issue being alleged, but was it triggered at a time different because of the introduction of the vaccine? I think the finding was that the vaccine didn't alter the outcome.

The interesting thing also about factor unrelated here in the way the court looks at this--I kind of think about these things as we're a little caught up in the burdenship thing when we're looking at these actual causation cases. Who's got the burden? When really in an actual causation case it's really looking at the totality of the evidence.

The special master's finding is going to have to be that more likely than not the vaccine was the cause. It really doesn't matter who is bringing in evidence of a vaccine causation or of other factors being involved. The special master's going to have to sort through that and only has to answer one question. Is the injury more likely than not caused by the vaccine?

It seems like in some ways this focus on prima facie case and burden-shifting gets away from the ultimate question the special master has to decide. Having worked in this program for a long time, I think maybe some of that is an offshoot of the table entry because in the table entry it makes sense to talk about burdens and burdens being shifted because there's a presumption. If it meets the table, it's presumptively caused. Now the petitioner has met the burden.

You've got the benefit of that presumption, but the presumption can be rebutted. Now the respondent is the burdened party to try to rebut that presumption. So in that kind of legal framework this idea of prima facie case makes a little more sense to me. To me, the ultimate question in an actual causation case is, is a vaccine more likely or not the cause? It doesn't really matter where that evidence is coming from. The special master can't really find the vaccine is the most likely cause if there's evidence that

there’s another cause that’s equally likely or more likely.

MS. HOIBERG: Was the genetic testing something that was ordered by the court or was that something that had happened before they even looked into filing a claim?

MR. MATANOVSKI: I am not certain in those cases. I don’t think in any of the cases that I can think of with Dravet’s the court ordered the testing. But I’m not certain in Stone and Hammitt, and there are two more that I’m going to talk about, Snyder and Harris, about whether the testing was done during the litigation or before.

I think, frankly, parents want to know if there’s a genetic reason for their child’s condition. Actually, this is a developing area of science, from what I understand, this testing in these gene mutations because they’re actually discovering new gene mutations that can explain some of the conditions that they’re seeing all the time.

My recollection in looking at some of the information on Dravet’s is if you had been looking at these cases medically a couple of years ago, you wouldn’t have had the benefit of these genetic tests to try to find the cause. In the longer-term sense we may see more of this in the future where there’s actually a better idea of what’s going on as medical science advances.

MS. HOIBERG: My question is introducing the

vaccine again, you said that it didn't cause the condition to worsen.

MR. MATANOVSKI: That is my recollection in those cases. I apologize. I looked at my summary of the cases to try to remember what the issues were. I try to get the broad sense of where the litigation is going, but I don't really remember the facts, per se, as to those cases. My recollection was that they weren't involving a significant aggravation claim.

Caves, another petitioner filed appeal, and Hager--I'm going to deal with those two together because they have similar kinds of issues. To me, those are cases where the special master has made some factual findings or some findings that are entitled to deference. The court on review has looked at that and either affirmed those deferential findings or reversed them.

In Caves they affirmed them. They said we're not here to retry these cases. If the decision was arbitrary and capricious, we'll overturn it or if there was an error of law so that there should be a very deferential view at that point in the Court of Federal Claims.

In Caves the Court of Federal Claims said we defer to the special master on these findings. In Hager they overturned them. The judge at Federal Claims overturned the findings. So you see in Caves the petitioner

taking up the claim. We're taking up Hager because we think that those findings of the special master we're entitled to deference and should not have been overturned. To me Caves and Hager are a little bit similar in the looking at it broadly in terms of the issues involved.

Kennedy is a very unusual case. It was one where it was filed in 1990, I believe. The child at that time was represented by their parents, turned 18 before the case was dismissed. The case was dismissed by the court. Here we are 11 years later. The child has now come back as an adult saying that his case shouldn't have been dismissed because his parents didn't accurately represent his interest and he was over 18 at the time.

The special master heard that claim under a Rule 60, where they can essentially go in for matters of justice and look at a judgment that had previously been entered and determine whether or not they should vacate that judgment. The special master decided no. The judge at Federal Claims also decided that there weren't grounds to vacate the judgment, so now we're at the Federal Circuit. I only mention it because it's a Federal Circuit case. It's not going to have any kind of broad impact.

In the Federal Claims Appeals we see a couple of the same issues coming up. Snyder and Harris are also Dravet's cases. They're SCN1A gene mutation cases. They're

being appealed by the petitioners. I believe they're now both in front of Judge Braden(?) at the Court of Federal Claims. I imagine the decision will be the same in each since she's hearing both those cases.

Argueta was a pro se appeal of entitlement, fact determination. Figueroa was a case that was filed after the petitioner had died. It was filed by his estate. There's a claim of vaccine injury, but the death is not related. There's an acknowledgement that the death itself is not at all related to the vaccine injuries, so the question there is, is there jurisdiction to hear that claim?

Broekelschen is an attorneys' fee case, just a disagreement with the amount the special master awarded. Ricci is similar to the other cases that I was talking about where there's been a determination by the special master that should be accorded some deference that's being appealed now. It's kind of in that same category we were talking about of those previous cases at the Federal Circuit.

There's a case pending at the Federal Circuit for decision, Knight (Rotoli), Porter. I think we've talked about them in our previous meetings. Those cases are ones we appealed where the Federal Claims judge overturned fact finding by the special master. We though the decision was entitled to deference. We didn't believe that that

deference was appropriately accorded by the Court of Federal Claims judge, so we appealed it. We'll be interested in seeing what happens in that case because it may affect cases like Hager that we have pending, Caves, or Ricci here.

McKellar is one we took, the respondent took. It's an attorneys' fees case, interim fees. There was an interim fee decision. We maintain that the statute doesn't permit the payment of interim fees, except in cases where judgment has already been entered, the narrow case that Avera(?) presented. We've rooted our interpretation in the statute. But the special masters have unanimously disagreed with us on that.

McKellar presented a little bit different twist on this because we thought there was some concern about whether there was a reasonable basis to bring the claim or to get attorneys' fees. In McKellar it was filed pro se, I believe, initially.

An attorney intervened later on, collecting medical records, then withdrew from the case after collecting the medical records. The medical records in our view didn't support any vaccine connection. The attorney withdrew and then sought interim fees. We opposed it for a statutory reason, but we also opposed it because we didn't think there was really a reasonable basis to bring a claim.

When we were thinking about this, we were thinking about what the statutes say. The statue says file the claim with all the records in the beginning. So it kind of supposes that you're actually looking into the claim before you're filing it. This attorney coming in later, collecting the records, and then dropping out of the case because apparently they didn't see any reason for them to continue on with it to us was kind of close to the margin on reasonable basis.

Rickett is a case that we've talked about before that's going to be argued September 7th. We don't know of any Court of Federal Claims arguments coming up.

On adjudicated stipulations, these would be the settlements. I went back last time and I gave you a sense of how many cases we had and what the timeframes were. We had 74 cases adjudicated last time by stipulation or settlement. We had 53 this time. A little bit down. I would look longer-term to see if there's a trend in that. I don't really think that there is a trend away from settlements. I certainly haven't seen any lessening of the pace, myself. I think we're probably somewhere around there, on pace for somewhere around 60 or 70.

What I did notice last time we looked we took the average of how long is it taking to get these cases from filing to adjudication. Last time after dropping out a

couple of the outliers that were coming out of the hepatitis B omnibus proceeding, we came up with 19.2 months. This time dropping out the two outliers from the hepatitis B we came up with 21.1 months. We're right about at the same pace.

I want to keep an eye on that because we want to monitor that trend, especially as we head into a time of tightened resources, including manpower resources, because we are very concerned. We want to make sure that we have the manpower and the resources to continue to move cases as efficiently as possible consistent with the law and the interest of justice. It's something that we're really aware of and keeping track of. But nothing here that surprised me when we looked at it this time.

MS. HOIBERG: So the case that took eight years and four months?

MR. MATANOVSKI: That case that took eight years and four months, I took a look at that one too. That one was one that had been filed. Just as an aside, a lot of times some of the time between filing and the case actually moving is while records and information is being collected. I wanted to take a look at that one.

What happened with that case was it did need some documentation, but it also entered the OAP in 2003. It entered the OAP, and then in 2006 it left the OAP by their

own desire. That case had three years where it was sitting, trying to see what was going on in the OAP. I was looking at these too.

Then when you got to the two 12-year ones, and those were both the hep B omnibus. They were fought in ’99 as part of the hep b. Then they went into the hep B omnibus and stayed in the hep B omnibus for a long time and then eventually came out and were adjudicated.

I look at those and I want to know what the reasons are in those, including the five years. Looking back at five years ones there was time spent collecting information and records. I think one of the five-year ones actually went to a hearing. So it was going the full litigation route, and then after the hearing, it went into a settlement track.

Are there any other questions? Thank you a lot. I really appreciate being able to speak to you. It’s always a pleasure. I imagine you’ll probably have Mark Rogers, and it’ll be a much smoother presentation. Again, it’s been a pleasure. Thank you.

MS. DREW: Thank you. Now we will have a short break before we hear from Dr. Clayton.

(Brief recess)

Agenda Item: Report on the Institute of Medicine Project on Vaccines and Adverse Events, Dr. Ellen Clayton,

Chair IOM Committee on Vaccines and Adverse Events

MS. DREW: Our next speaker today is Dr. Ellen Wright Clayton, who is the chair of the committee on adverse effects of vaccine evidence and causality. Her committee of 13 individual medical folks reviewed essentially all of the literature involving adverse reactions to vaccines and has come up with a report. She will give us a briefing on the report today.

DR. CLAYTON: It is a real pleasure to be here with you to discuss the committee's work. This is a declaration against interest, but if you want to interrupt me and ask me questions, that's fine. I'm ready to go with that.

I want to begin by discussing what we did and what we found and our ultimate conclusions. I want to be clear what the charge of the committee was. We were charged with looking at the scientific literature regarding the adverse health events associated with eight specific vaccines covered by the VICP. We just looked at risk, period. That's all we did. That's what we were charged to do. HRSA presented us a list of specific adverse events to look at, and we added a few more, but we were not asked to assess efficacy or benefits of vaccines to individuals or the population at large.

Let me talk about who the members were. As is

mentioned, I had the privilege of chairing this committee. This was an awesome committee who worked incredibly well together bringing together an amazing array of skills from immunology, neurology, genetics, other things, all the way to serious epidemiology and study design. So really a diverse group of skill sets that we brought together into a united whole to address this question.

Immaculada Aban, actually called “ChiChi,” is from the UAB. Doug Barrett is from the University of Florida. Martina Bebin is a child neurologist from the University of Alabama at Birmingham. Kirsten Bibbings-Domingo is an epidemiologist from UCSF. Martha Constantine-Paton is a basic scientist in neurologic development from MIT. Deb del Junco is an epidemiologist from University of Texas Health Science Center at Houston.

Betty Diamond is a rheumatologist from the Feinstein Institute for Medical Research in New York City. Claiborne Johnston is an epidemiologist and neurologist from UCSF. Tony Komaroff is from the Brigham and Women’s Hospital at Harvard, and he is an internist and epidemiologist.

Paige Lawrence is a basic scientist from the University of Rochester School of Medicine and Dentistry. Louise Markert is a pediatric immunologist who takes care of children with severe immunodeficiency at Duke

University. Mark Patterson is a pediatric neurologist from the Mayo Clinic. You can see this is really quite a diverse group.

We looked not at all vaccines but at eight of them. The measles, mumps, rubella vaccine. The varicella zoster vaccine, and this one is the chicken pox vaccine. There is a higher dose one that is given to adults called the zoster vaccine. We did not look at that. Flu vaccine except for the H1N1 in 2009. Hepatitis A, hepatitis B. human papillomavirus. Any tetanus-containing vaccine except the old wholesale DTP because we don't do that anymore. And meningococcal vaccine, which is a vaccine that we have largely until recently given adolescents.

Here's the committee membership. We met eight times, including three open sessions. As I mentioned, we added 10 vaccine-adverse events to the list that we studied.

In terms of the evidence review, I'm going to make a number of points here, but I think these are quite important. We had a medical librarian do three comprehensive searches, as well as spot searches. We initially looked at more than 12,000 articles. We focused on the articles that address new evidence, and that number is slightly more than 1,000. So 1,000 articles with primary research that we examined in depth.

In addition, the bibliography or our list of things that we looked at was made available to the public about halfway through this process so that they had the opportunity to identify to us whether there were articles that we should have been looking at that we missed.

We looked at peer-reviewed literature. This is really important. We looked at a broad variety of data from the peer-reviewed literature, but it had to be published in the peer-reviewed literature. I will mention that all of them had to have at least three attributes.

They had to have documentation. We didn't necessarily have to see it, but they had to have documentation that the actual vaccine was administered. The adverse effect that it was concerning had to have been diagnosed by a healthcare provider. I want to be clear here that that includes nurses and other providers, not just docs. And it had to have an appropriate timeframe because some adverse events occur right away, some occur on a somewhat longer phase, and some may take years to appear. So we needed to look at the appropriate timeframe. As I said, we looked at original literature only.

Our general framework for causation was pretty complex, so therefore I'm going to spend a little bit of time talking about it. We looked at two bodies of research and then put those together to reach our ultimate

conclusion. The first body of research was epidemiologic research, so that's research done in populations comparing people who are vaccinated with those who aren't and then seeing whether an adverse event was more likely, less likely, or no different between the two groups.

The second is mechanistic evidence. The IOM in all of its reviews has looked at this, but what we were specifically looking at were reports where we had not only those three attributes that I already talked about, but where there was additional biological evidence that really went to the issue of proving causation. I'll say more about that in just a minute, but this was really important.

One thing about mechanistic evidence or biological evidence is it only helps support causation. There is no biological evidence that can say that some adverse event didn't happen. The only kind of evidence that's probative of the question about whether there is no link between a vaccine and an adverse event is epidemiologic data. Finally, we reached causality conclusions.

Looking at how we weighed epidemiologic evidence, we set a high bar. We required that the studies have an a prior definition of exposure. They had to know before they started what they were going to count as a vaccine exposure

or not. They had to verify that the vaccine was given and they had to verify the adverse event.

They had to control for confounding and bias. What do I mean by this? There are some kinds of adverse effects that we look at that lots of different things can cause. A good example of that is Guillain-Barré, which can be caused by a number of things. If those confounders weren't controlled for, then that went to the weight of the evidence.

We had to look at the adequacy of follow-up. Did they follow the individuals for an appropriate period of time? If it is an adverse effect that we expect to take some time to occur after an immunization, a one-week follow-up is not enough. Did they develop and use appropriate eligibility criteria?

Other things that we looked at were things like precision. What this means is if you have a study that's adequately powered, then you can get a really pretty narrow range about what the risk is. If it is adequately powered so that you can get a more narrow risk range, that is more helpful than if you have a very small study that has a huge risk range.

We also looked at the validity of the study. Was it appropriately conducted, et cetera? We also looked at consistency. In the context of some studies all the studies

went the same direction. That was helpful either for or against causation. So those things all went to the weight of the evidence and led us to come up with a score for our confidence in the conclusion from the epidemiologic studies.

We then assigned a weight to the epidemiologic studies. If there were two or more studies that were really great and were consistent, then we had high confidence in the results of the epidemiologic studies. If there was only one study that was great or a collection of studies that were generally consistent, then ours was somewhat lower, and we viewed that as having moderate weight.

If there was one study that actually wasn’t very precise or the studies weren’t consistent, they really gave us very limited confidence. Of course, if there were no good epidemiologic studies, then we simply said there were insufficient epidemiologic studies. That’s how we categorized the epidemiologic or population-based research.

Biologic mechanisms. This is where we have differed from previous studies, not that the other studies didn’t look at biologic mechanisms, but we worried about it a lot. If you look in chapter three, we go through an exhaustive review of the various ways that we thought that vaccines could cause bad things to happen. We listed these at some length, some as direct infection. You’ll see that

in just a minute. Some being immune-mediated, some being tissue responses, some being related to the shot itself. You'll see shortly that we actually made some findings based on the shot itself.

And some that may be based on changes in total body coagulation, either too much or too little. We actually know that this is really like Goldilocks and the Three Bears with regard to coagulation. You don't want too much or too little; you want it just right. So this was another possible mechanism that we could be talking about.

We discussed this at some length, in part because we wanted to sort of suggest things that people might want to impart because we would think that the readers might then think of things that they want to be looking at in the future as they work up future adverse events. We tried to be exquisitely careful about how we did this.

As I mentioned, with regard to the case reports, I've said what's necessary and not sufficient; that we know that the vaccine was given. It says physician here. That's not right. It has to be a healthcare provider who diagnosed the adverse outcome, and that the timeframe was correct.

There was other information that we looked for and that we found very helpful in terms of trying to decide whether there could be a causal relationship here. Rechallenge. If somebody got given the same vaccine twice

and the same bad thing happened to them, that was helpful.

Also efforts to exclude other causes. For instance, in the case of Guillain-Barré we know, for instance, that there are other infections that cause this. Ruling those other infections out would be very helpful in deciding whether a case would be Guillain-Barré.

Some of the workups provided clinical information that was quite helpful in looking at issues of causation. Of course, one of the things that was quite helpful as you're going to see shortly is if you got the vaccine strain virus out of a place that it's not supposed to be, that is pretty helpful information.

We did look at animal and in vitro studies. These we viewed with some caution in terms of saying that they supported causation in humans. On the other hand, these are studies that may give signals of things that might be more profitably studied in the future in humans. We talked about them and that's the weight we gave to them, but we thought they had something to say.

Interestingly, one of the things that we looked at was that some of the adverse effects that we looked at are ones that the natural infection can cause. This is most true in the case of live virus vaccines. But where that happens it's helpful to is in our analysis and did contribute to the weight of the evidence.

Here again we assigned weights to the mechanistic evidence. We found strong evidence where there are one or more cases in the literature for which the committee concluded that the vaccine was a contributing cause of the adverse event based on an overall assessment of attribution in the cases and clinical and diagnostic or experimental evidence. I'll come back to this in a minute.

An example of this is the chicken pox vaccine in children who have serious immune problems or adults who have serious immune problems--if you can get overwhelming chicken pox infection, if you look at that infection and what you find is the vaccine virus, that's pretty strong. That gets us to strong. We had a number of strong mechanisms cases here that I'll go to.

Intermediate weight of the evidence was at least two cases taken together where the vaccine may be a contributing factor, but it wasn't enough to be conclusive. Here I want to make a point that we did pursue. There were some cases that weren't strong enough to get us into intermediate but where there was enough there to say there may be a signal here. Those we deemed as low intermediate weight.

I'm going to back up here and make a point that if you've not had a chance to look at the report, I really want to point out for you. The staff did an amazing job of

organizing this report. What it did that is really important besides the fact that we lay out our approach in exquisite detail is that if you are concerned about a particular vaccine and a particular adverse event, you can find where we discussed it.

Each one gets somewhere between two and five or six pages. In each one we talk about every single study that we looked at and if we rejected some, why we rejected them. If there were ones that we thought contributed to the weight of the evidence, we discussed them at some length, both their strengths and weaknesses. Then same for the mechanisms evidence. If you have a particular concern about a particular vaccine and a particular adverse event, you can go right to it in the book and look at four, five, or six pages that will tell you what our thinking was.

MS. HOIBERG: Your conclusion says can either reject or accept the causality--inadequate. You have that as a lot of your findings.

DR. CLAYTON: I'm going to hold that for a second because I'm going to get there. Of course, it's the question that you're most concerned about. Is yours on target with that?

DR. HERR: It's a little bit different, still a little more of what you're talking about here. When you're making these decisions of intermediate or strong or weak

even though there are some objective ideas in the literature review that you're basing your opinion on, the opinions are still subjective. How much agreement or disagreement was there amongst the panel on the various decisions of strong, intermediate, weak?

DR. CLAYTON: This study is a complete consensus. Everybody on the committee agreed about everything. We worked really hard to achieve that. We had no dissent at all. It was hard work, and where there were issues we did a lot of talking back and forth until we came to a conclusion that the committee was completely comfortable with.

MS. HOIBERG: Can you give me an example of a case, DTAP, say, encephalopathy, and seizure disorder? How many cases did you look at in that? It says one or more cases in the literature. How many cases did you go over, and when you say cases, were they specific children that it happened to that had been written up? Was it research done by neurologists or the pharmaceutical companies? What kind of cases were you looking at?

DR. CLAYTON: When you read that section, it will tell you exactly how many cases that we looked at. Obviously we had 150 pairs, so I can't remember all the data exactly right off the top of my head.

Every bit of data that we looked at was from the peer-reviewed literature, so somebody wrote it up. Some

were from the VAERS, which was then written up, and if they had adequate detail, then we could use them. Others were written by physicians who ran into these cases in their own practices. Some of them were written up by pharmaceutical companies. Actually, Merck published the articles about chicken pox vaccine. They identified it and they reported it.

We looked at everything that was in the peer-reviewed literature that had enough clinical information for us to make a judgment about. When you read it, it'll tell you exactly how many cases we looked at for each specific thing.

We also said that some evidence was weak. Either there was insufficient evidence from cases in the literature. These included, by the way, ones where the natural infection caused the thing we were worried about. In some we just said there was no biologic evidence at all.

Here's where I'm going to come to your question about inadequate to accept or reject. Basically what this does is it says that we took evidence from the epidemiologic literature. We took evidence from the mechanisms literature. We came up with an independent weight of evidence for both of them. Then we brought them together to decide whether we could make a conclusion about whether the vaccine caused that particular adverse effect.

We had four causality conclusions. One is that the evidence convincingly supports a causal relationship. The poster child for this is oral polio vaccine causing vaccine causing vaccine-associated paralytic polio. We know for sure that oral polio vaccine does that.

Evidence supports acceptance of a causal relationship. We're not quite so sure, but it's certainly strongly suggestive. This is the measles, mumps rubella vaccine and temporary joint aches and pains.

The evidence is inadequate to accept or reject a causal relationship. I promise you I'm coming to this soon to discuss this at some length. Then we had that the evidence favors rejection of a causal relationship, where we say that the epidemiologic evidence shows no evidence of a link between the MMR or between the vaccine and the particular adverse event.

This graphic, which is in your program brief handout, actually shows how we combined epidemiologic evidence and mechanisms evidence. Here are some really important things. Epidemiologic evidence could be strong enough to do convincingly supports. Mechanistic evidence could be strong enough to do convincingly supports.

The epidemiologic and the mechanisms evidence could each bear the weight on their own. If they were inconsistent, that was more problematic. But they could

each bear the weight on their own. Then, as I mentioned, only epidemiologic data can lead us to a conclusion that favors rejection of the idea of causation.

Let me say something about inadequate to accept or reject. We were very careful in terms of how we assessed the literature. We discussed it in length so that people could look at what we did and see how we approached it.

What ends up inadequate to accept or reject is a mixed bag, and the mixed bag looks like this. There are some for which we just have no evidence at all. That's just inadequate. For others we have a little bit of evidence, but not enough to lead us one way or the other. Those are also inadequate.

For some if you look at the actual write-ups, there's some signal from either the epidemiologic data or from the mechanisms data that goes one way or the other, but it isn't enough to really address the issue. The poster child for this is flu vaccine in GBS. Here's what we've found. There have actually been a number of studies that look at whether influenza vaccine causes Guillain-Barré syndrome, but there are a couple of issues with these studies.

One is that there are a lot of things that confound this. One is that you give the flu vaccine at the same time that GBS occurs during the year. GBS is a winter

disease. Flu shots are a winter thing. So that's a little hard to figure out. Another thing is that we know there are a lot of other things that cause Guillain-Barré syndrome, and if those things aren't ruled out, then that weakens our confidence in the literature.

The third thing that's really important is the flu vaccine is different every single year. It's not the same vaccine. The vaccine that I got last year is not the same vaccine I'm going to get this year and it's not the vaccine that I got 10 years ago. So because actually the vaccine's different every single year, it's hard to come up with a big enough body of literature to reach a conclusion.

There are a number of studies that have looked at flu and GBS. They all tend to show, not strongly enough, that flu doesn't cause GBS, but the literature just isn't there to support our reaching a causal conclusion. That's indicated in our discussion.

On the other hand, there are concerns that the measles, mumps rubella vaccine can cause chronic arthritis. But when we look at the data, there have been a couple studies from more than 20 years ago that came from the same group. They didn't actually look at whether you could get the vaccine virus out of the joint. There have been no studies since then showing that the MMR vaccine can cause arthritis. That made us less confident. We weren't able to

say that MMR can cause this chronic arthritis.

Let me just put it this way. Inadequate to accept or reject means just that. It means that we just don't have enough data to make a decision. In a few cases we have some signal, but for the most part we just don't have any data one way or the other to answer the question about whether the vaccine causes the risk.

MS. HOIBERG: So you may have a certain number of cases that say it does and a certain number of cases that says that it doesn't, and it kind of weighs 30 on this side and 29 on this side, so you kind of have to say it could or it couldn't.

DR. CLAYTON: You can't tell. But the thing that I want to emphasize is that in every single one of those inadequate to accept or reject we say what the data does or doesn't show and why we reached the conclusion that we did. I know it's unsatisfying. I can imagine that it would feel unsatisfying if we have those results, but I think if you read the discussions, you'll see what the data really looks like.

One thing about science is we'll have more of it, so some things that are unresolved now will be resolved in the future, and some things just probably aren't knowable. I really wanted to drive home that issue about the

inadequate to accept or reject. It's a big group. They're not all the same. In the absence of adequate data we just weren't going to make a conclusion one way or the other. We wanted to stand firmly on science.

If there's one you're concerned about that's listed as inadequate to accept or reject, read the report. It'll give you some idea. It will give you an idea about whether there's any data at all, what it looks like, if it's just a total mess, whatever it looks like. We didn't want to just say we conclude inadequate to accept or reject. We wanted to give the current state of the science as best we could, and that's what we tried to do.

The ones that we say convincingly supports, this is the chicken pox vaccine. We know that some group of people, mostly with really severe immune problems, who get this vaccine can get more widespread infections. The issue of MMR and febrile seizures has been known for decades, but only two decades.

Actually identified in the first IOM report assessing the risk of vaccines in the early 1990s that some children when they get the MMR vaccine will about a week later get a fever, and if they are prone to febrile seizures, they'll get a seizure. I'm a mom, and I understand that that's terrifying. The good news is that those seizures have no long-term consequences. But we know

this is true, and it’s been true for decades.

There’s a really rare kind of brain inflammation that’s been reported in a very few immunoincompetent people, people with really serious problems with their immune systems. We know a bunch of vaccines can cause you to have acute allergic reactions. The things that you mostly think of with regard to peanuts. Somebody will eat a peanut, and then 15 minutes later they can’t breathe. There are a number of vaccines that have been reported to do this. The great news about anaphylaxis is that if you hang around your doctors office, it’s easy to treat. But there are a number of vaccines that do this.

Then there are a couple of adverse events that are just related to getting a shot. One of them is this thing called deltoid bursitis, or frozen shoulder. If you get the shot up here, there’s a big fluid sac that goes over your shoulder. If the needle goes in there, that can be bad. That can happen from getting a shot. It can be a shot of anything, but if it’s a vaccine that’s in the shot, it can do that.

Then obviously we know that shots can cause some people to faint. We believe that shots can make some people faint and they do. I don’t mean to be silly about that; it just is true.

The ones that we have some signal for but we’re

not quite confident enough to say so. We think that probably the human papillomavirus can cause anaphylaxis, just as the other ones can. We think it’s pretty likely that the MMR vaccine can cause transient joint pains, both in women and children.

There was a version of the flu vaccine given only in some parts of Canada for only two years that causes really weird oculorespiratory syndrome. When they got a different batch of vaccine, it didn’t happen anymore.

Let me also say about this subject of anaphylaxis and flu that actually over the years that vaccine has gotten safer in terms of anaphylaxis, and the reason for that is that it was recognized in some years when they were seeing more of these acute allergic reactions it was because there was too much egg in the vaccine. So what they did was they took the egg out. In one case there was too much gelatin in the vaccine, so they took the gelatin out.

One of the pieces of good news here is that if a signal is identified and it’s rectifiable, then they fix it. That’s the reason why we give the polio shot now rather than oral polio because it turns out that—and not part of our study—we knew that the oral polio vaccine could cause paralytic polio. We know that the polio shot doesn’t. As polio became rarer and rarer, it became really clear that we needed to give the kill shot to keep people from getting

polio if ever it came around again. But we didn’t want to cause anymore vaccine-associated paralytic polio ever. That’s an offhand thing.

The committee concluded that the evidence really supports rejection of the notion that MMR causes either autism or type 1 diabetes. There have been a number of really strong epidemiologic studies of autism, understandably because of the concern that so many people have had about this. There has been a lot of research about this, and the research from the epidemiologic perspective is uniform. It all says that there’s no causal relationship.

The tetanus-containing vaccines--there is no evidence suggesting that favors rejection of a causal relationship between these vaccines and type 1 diabetes. The killed flu shot. There was concerned that the killed flu vaccine caused Bell’s palsy and that it made your asthma worse, which is kind of funny because one of the reasons we’re so eager to give flu vaccine is because people who have asthma really don’t need to get flu. It’s really bad for them. Happily, the evidence is really overwhelming that the flu vaccine neither causes Bell’s palsy and the flu shot neither causes Bell’s palsy, nor does it make your asthma worse. This is great news.

Here I want to go back to some of these ones

where we saw some signal. I've said a little bit about this, but I'll go back over it again. These are ones where the epidemiologic evidence by and large--when it says null, it means that there's no evidence of causation. That's epitalk.

These all suggest that the signal is looking like flu doesn't cause seizures, it doesn't cause GBS. The nasal flu vaccine doesn't cause increased wheezing either. This is interesting because it's contraindicated in people with asthma. And that stroke, MI, and all-cause mortality are actually decreased by the flu vaccine, either one.

It appears that the MMR vaccine doesn't caused meningitis. Again, not enough for us to reach a strong conclusion, but there's some signal in this area that may be helpful. And that the hepatitis vaccine doesn't make you have a first demyelinating event, as in the context of multiple sclerosis or type 1 diabetes.

Here are ones where it looks like there may be a causal link, but there's just not enough of evidence for us to reach that conclusion. The measles, mumps rubella, I've mentioned this already and the issue of chronic arthritis and arthalgia. This has been a long-standing concern, but nonetheless, there's some signal there, it's just not strong enough.

There's some evidence, actually I think primarily

from mouse models, that the measles vaccine may cause hearing loss. But again, really very little evidence there. Some evidence that the hepatitis B vaccine may cause a number of neurologic events, one called ADEM, first demyelinating event, and vasculitis. And some evidence that just getting a shot of whatever it is can cause something called chronic regional pain syndrome.

These are the areas where we saw some signal that may be suggestive but that just wasn't enough for us to reach a conclusion. In the first case not reach a conclusion that there's no causal link, and in this setting to say that there is causal link.

I want to say something about susceptibility as well. We certainly heard that discussed in the previous setting. One of the things that we can say looking at science going forward is that we are in an era where we can really begin to think seriously about susceptibility. That's what personalized genomics is about. That's what pharmacogenetics is. It's all about looking at susceptibility to adverse events.

The thing to say is that there are a lot of things that contribute to susceptibility, not just genetic variation in us but microbiome genetic variation. As you look at me, 95 percent of the DNA that's in the body you're

looking at is not human. It’s scary, isn’t it? Ninety-five percent of the DNA is either bacterial or viral.

There was a study that I just looked at yesterday that I think came out in Science or Nature that suggested that in some studies in mice that depending on what your gut flora looked like, it makes you happy or sad. Who knows? This is an area of biology that we’re just beginning to look at.

Past and present environmental exposures. We’re exposed to jillions of things every day. All of these need to be taken into account. Intercurrent illness. Let me give you an example of that. This is one of my favorite general pediatric stories. All of you have probably heard of mono. Probably many of you have had it. You may not have known it, but many of you have had it.

When a kid comes in with mono, they often are feeling horrible. You look in their throat and they have tonsils that are gigantic and are covered with puss. They look to all the world like they have strep and they feel terrible. But if you don’t look to see if what they actually have is strep and what they actually have is mono, if you give them amoxicillin, about 80-90 percent of those kids will get a horrendous rash from the very top of their head to the bottom of their toes that will actually make them feel worse than the mono does. It’s almost diagnostic

when we hear this.

This does not mean that the individual is allergic to amoxicillin. They're not. There's just something about being infected with mono that makes amoxicillin do that bad thing to you. We're just beginning to get a handle on that. Obviously personal behaviors have a lot to do.

The other thing that is really interesting to look at is that when you're born, your genome is what it is, your DNA that everybody is born with. But the way it comes out changes over time, and so there are some things that are harmful for you when you're little or even before you're born—think about lead, think about thalidomide—that are bad for you before you're born that once you're born, they're okay. There are some things that are bad for you if you're a little kid, but then when you get older, they're not so bad for you.

When we think about susceptibility, we have to think about genetic variation in us, genetic variation in our microbiome. That's what we call all this gut stuff and skin stuff. All these environmental exposures that make a difference over time, all these illnesses and personal behaviors, and the fact that all these things change over time and their impact changes over time. This is enormously complicated.

MS. HOIBERG: Could you explain personal behaviors and what you mean by personal behaviors and how that makes us susceptible to certain things? What do you mean by personal behaviors?

DR. CLAYTON: Great question, and I'm not going to do it in relation to vaccines. We're having an epidemic of obesity in our country. Our genes are not accounting for this. What's accounting for it is that we have sociocultural change and people are eating more and exercising less. It's not that we had a sudden genetic shift and that all of a sudden we all have obesity genes; it's because our culture changed and it's because our personal habits changed. That's what I mean. That's a pretty simplistic example. We're going to see that a lot more as things go forward.

MS. HOIBERG: Yes, but I would like you to explain it in terms of vaccines because that is why we're here today.

DR. CLAYTON: I think we don't know yet. What we were talking about in our thing as we talked about susceptibility was we really kind of wanted to frame this up so that we could think about how to structure the research questions so that we can begin to answer what are the factors that if a vaccine is causing a particular adverse event, why is it happening in one person and not

another?

All I’m trying to say here is that there’s a lot more than just looking at individual human genetic variation. I have to say that this is an area of science that I think we’re just beginning to get involved in, but I think it’s going to be enormously helpful.

Let me follow up on another question and say I think what genetic variation is going to tell us or is going to be remarkable for is to give us tools to try to understand that biology. As we understand that biology, then we can really think about how to personalize medicine in a way that’s going to be helpful. I understand your question. I’m just being honest about what the state of the science is. I think it’s going to be enormously interesting and helpful.

Thinking about past environmental exposures. Going back to chicken pox vaccine, we looked at the risk of chicken pox vaccine and the fact that it almost all falls on people who have really serious immune disorders. One of the things that those people really benefit from is not having regular chicken pox around.

It turns out there was a study that came out last month in Pediatrics that showed that death from chicken pox have gone almost to zero since the chicken pox vaccine came into use. That’s great news. But the other news is that

kids who have an immunodeficiency or have something wrong with their immune system, if nobody around them has chicken pox, then they're less likely to get chicken pox. That's great news.

The fact that there's no native polio, there's no wild type of polio in the western hemisphere and hadn't been for two decades means that kids who have serious immune problems really benefit from the fact that other kids don't have polio and can't give it to them. That's great news.

As we think about these environmental exposures, that includes what other kids have, as well as what the particular kid who might be at risk has. Those are some of the things that I think are going to be things that we can look at in the future. A lot of people are beginning to think seriously about susceptibility. This is going to be really important for vaccines, and to make the point that it's going to be complicated to unravel, but we can make traction.

Look at what has been found out about SCN1A. The fact that we now know that there's a genetic lesion that actually was heavily involved in kids who got encephalopathy from the old DTP vaccine is really helpful information. Those are some of the things that I would bring to your attention.

MS. HOIBERG: Is there a study out about children who got acute encephalopathy from the DTAP? Is there a study out there from that? I'd be interested to read the genetic one about the DTP, but I don't think it would pertain to my case in particular. I'd like to know why it happens to my child.

That's a huge question because, as I've raised before, there are certain vaccines that I would like to vaccinate here with, for example a meningococcal, but I don't know if I can do that because I don't know what it was that caused her to have that adverse event. I don't know if I can continue to vaccinate without worsening her condition, or can I vaccinate my other child because I don't know if what happened to one couldn't happen to the other.

DR. CLAYTON: I will just be honest with you. There's still a lot of uncertainty about mechanisms. My great hope is that we understand more about biology, then we'll be able to answer your questions with greater specificity. We have addressed the existing literature in this report. It is my great hope that we will learn more. I'm sympathetic with your concerns. There are a lot of people who are studying vaccines, not only their efficacy but also their risks. One of the things that they're interested in looking at is to figure out why this happens.

MS. HOIBERG: It is so few that have the reaction that my daughter had, but it's enough to have a program to compensate those who are injured.

DR. CLAYTON: I understand that. I think we all want more answers.

Let me tell you about some of the susceptibility that we looked at. We found invasive viral disease in people who have serious problems with their immune system. That was mostly the chicken pox vaccine. We found some immune mediated. That was with all the allergic reactions. I mentioned that it turns out that egg and gelatin are a big trigger, and so it was important to remove that stuff.

There's beginning to look at some work not in the vaccines that we were looking at but for some other much more reactogenic vaccines about genetic variations that may contribute to worse outcomes. Then the rechallenge cases, cases where someone gets a vaccine and then has a bad event, and then they get the same vaccine two or three more times. Sometimes you have to wonder. In any event, those were helpful.

Issues of age and gender. The issue of febrile seizures, that's something that happens to little kids. It doesn't happen once you get to be a school-aged child, and it certainly doesn't happen to adults. It's just for real.

The issues of gender. Some of the signals with regard to MMR are seen in women and not in men. That may be some ascertainment bias that we don't tend to immunize men as much as we immunize women, but nonetheless, that was an area where we saw a signal in women and not men.

Then we worried some about the metabolically or genetically vulnerable kids. I mentioned the SCN1A. Actually, one hypothesis that I went into this with that I didn't find evidence and support was there are a number of kids with metabolic disorders who whenever they're stressed, they just get into trouble.

I was, for instance, thinking that children with a particular kind of metabolic disorder called urea cycle defects could have adverse effects with these vaccines. It turns out they do better with vaccines than without. The hypothesis is—and it's just a hypothesis, I don't know the evidence—that the vaccine actually prevents them from getting the natural infection, which would be worse.

MS. HOIBERG: What is SCN1A?

DR. CLAYTON: I am happy to answer that question. Nerves conduct by sending a signal down the arms of the nerves called axons. The way they do it is by having ions, in this case sodium but also other ions as well, go back and forth across the cell membrane. This is a sodium channel transporter in the neurons.

It turns out that having something wrong with that sodium channel transporter is really bad. It causes this severe myoclonic epilepsy of infancy, also called Dravet's. There was another article about it last month in Pediatrics, I believe. What it is is a transporter problem that makes nerves not conduct right. Again, I think that's an evidence of fragility; that these because they're not wired right, they're just going to have bad seizures. Or they're wired correctly, it's just that the signal doesn't go the right way. That's what SCN1A is.

MS. HOIBERG: And that is something you can genetically test for?

DR. CLAYTON: Yes. We don't do that routinely, but yes. You'll see from the conversation that was occurring earlier today that now in the DTP cases they're doing this routinely.

I've said this already, but I want to repeat it again. One of our goals was to be as transparent as possible about how we approached the literature with the idea that it would provide a framework for future analysis. There's going to be much more science happening, I hope, and I hope that the way we approached it will be helpful to other people of all sorts who are looking at this literature to try to figure out what it has to say about whether vaccines cause particular risks or not.

It is certainly my hope that there will be future studies that will tell us a lot more about not only whether vaccines can cause particular risks but if they do, how they happen so that we can try to understand that and others than us who make policy can make policy recommendations about what to do with this information. It is my fervent hope that this is not the final word.

MS. HOIBERG: With you just describing the SCN1A, if a child has that, do you think that that could possibly make them more susceptible to an adverse event in receiving a vaccination? Is that what you're saying? If they have that condition, that they could possibly react incorrectly to a vaccine and have an adverse event?

DR. CLAYTON: I think that the issue of causation is a little bit unclear at the moment, and I would say that there is a general consensus within the neurologic community that these kids are going to have a bad outcome regardless and that the vaccine has nothing to do with it. I don't know what the final word is.

MS. HOIBERG: When would something like this show up? When would you begin to see signs that your child has this?

DR. CLAYTON: This occurs in the first few months of life.

I want to make a note in closing that this report

would not have been possible without the collaborative work of the committee members. To get a bunch of people who do a lot of different things in a room, and to get them to work together and learn about each other's methodologies to come with a conclusion is hard work. But the committee really did that. We reached a complete consensus on this report. I can't emphasize that enough. I also can't emphasize the extraordinary efforts of the staff. They did a phenomenal amount of work working with us to get this dainty document in a form that we could do this.

Finally, I have to acknowledge the wise leadership of Kathleen Stratton, who has years of experience working on this issue and really helped us come together. This is the best report that has ever been done on these vaccines, period.

Will there be more to come? Sure, I hope so. I'm always happy to learn more. But honestly, this is the best report that's ever been done on this hands down, and it's attributable to a whole bunch of people besides me. I don't want that to go unacknowledged. I'm happy to take any more questions that you have.

MS. DREW: I wonder if you would just tell us the website that people can go to. It's in our literature, but people may not be able to have that.

DR. CLAYTON: I'm delighted to tell you about

this, and particularly in light of a new policy that the IOM has that makes me ecstatic.

www.iom.edu/vaccineadverseeffects -- if you go to that website, this is the thing I'm excited about. The IOM recently decided to make all their reports that are in PDF downloadable for free. This is awesome. You can have this for your very own. In addition, there is also a six-page report brief available at that website that is also available, and it's actually really accessible, I think. Mostly the staff wrote it, that's why it is.

Finally, we had a public briefing this morning about this report, and that public briefing is available on archive at this website. Lots and lots of information available for you. We really encourage you to look at this and learn more about it.

DR. EVANS: I want to mirror our appreciation and how impressed and pleased we are with the effort that was undertaken. Rosemary Johann-Liang, the project officer, began to talk about this years ago. Things came together, and Rosemary did a wonderful job working in the background shepherding the adverse events together working with input from the advisory Commission several different times and working with, of course, Kathleen Stratton to achieve the result that we very clearly have achieved, and that is a sentinel that will be helpful not only for our program but

to many other parts of HHS and academia that deal with vaccine safety and vaccines. We're very pleased with that.

It's going to be a lot of work for us to go through this, a little bit longer than what we originally thought was coming, but it's been a wonderful project to watch from a distance. Again, our thanks for all you've put into it. I think it shows.

DR. JOHANN-LIANG: Tomorrow I guess we'll talk about the next steps of what we're going to be doing. Now I would just thank you. It's probably a very busy time for you with all the different things. We thank you for sharing. We look forward to digesting it.

MS. DREW: I have been asked for a five-minute comfort break before we go further with public comments, so if anyone wants to get up and walk around, please take five or ten minutes.

(Brief recess)

Agenda Item: Public Comment

MS. DREW: We are going to move to the next item on our agenda, which is public comment. This was actually on the agenda at 4:30, but in previous meetings we've always had our public comment at the end of our meeting. Operator, would you call forth any public comment that may be out there?

(Operator queries)

MR. CONTE: Good afternoon, honorable Commission members. My name is Louis Conte, and I'm the father of triplet boys, age 11, two of whom have autism. Further, I'm one of four authors along with Mary Holland, Lisa Colin, and Robert Krakow, of a paper called Unanswered Question, a peer-reviewed article that was published in the Pace Environmental Law Review in May of this year.

I'm addressing your committee today because this committee discussed our article at the June meeting. I want to thank Sarah Hoiberg, the public representative, for starting that discussion at your last meeting. However, I do note that I disagree with Ms. Hoiberg in that the article and the press conference about the article that was held in Washington in May, did harm to the autism community.

As authors of Unanswered Questions, we believe that the process of questioning is, itself, positive, even when doing so invites controversy. We did not author a paper called Definitive Answers, and like many of you, we're struggling to understand what causes the behavioral disorder called autism. It is estimated that 700,000 young people under the age of 21 now have autism. We as citizens have a lot of questions, and some of them may be tough questions if we're ever going to understand how we got here and what to do to stem this tidal wave of cases.

The only way to understand autism in our opinion is get to the truth about what causes it. We are not anti-vaccine, and we must be willing to consider whether vaccine injury has played a role in the startling increase in autism. There really is no other way through this problem but to ask tough questions.

The families who spoke out in May were not being ungrateful or disrespectful to the VICP, the Department of Justice, HHS, or the special masters, as Ms. Hoiberg asserted in the comments that we read. They were appealing for justice for people who they don't know personally but who they understand have shared their struggle to raise vaccine-injured children.

These compensated families that spoke out were simply being good Americans, speaking from their hearts in the hopes that doing so will help other Americans. These families were brave and sincere, and they know that there are many other families just like them who have not been treated equally by the VICP.

Our investigation identified 21 VICP published judicial decisions or other court records where autism was clearly described as being a result of vaccine injury. Further, we found 62 cases where the federal government's federal cases in which the child was compensated for encephalopathy or seizures that came along with features of

autism.

This information was gleaned from telephone calls and interviews with caregivers. In many instances the verbal descriptions of these families was strengthened by the documents they later supplied. We believe that we only scratched the surface of the reality that autism is now a common vaccine injury. We reached only a total of 150 families or so, and we know that there are 2,500 families compensated. This is why we say this is just the tip of the iceberg.

What makes us say that autism is a common vaccine injury? The families all reported the same array of symptoms. Brain damage, seizures, all of the behaviors that are commonly identified with autism, such as impaired speech, impaired social and repetitive behaviors.

Let me be very clear. If a family member didn’t use the word “autism” in describing their child and said their child doesn’t have autism, that case was not reported in our study. In every case we reflected exactly what the families reported to our interviewers.

Several family members know that no one from the government had reached out to them since their child’s case was resolved. This led to one of our report’s conclusions that an independent clinical and medical review of all

compensated cases should be undertaken; that this population is a treasure trove of insight into the nature of vaccine injury, including autism.

Another one of our recommendations is that Congress should hold hearings to determine if the VCIP is living up to its original intent. We ask the ACCV to support this request. Why? Because we cannot determine what the real difference between a case where a child was compensated for encephalopathy and seizures and who also has autism and a case where a child suffered a vaccine-induced encephalopathy seizure and the family has not been compensated.

In fact, HRSA does not dispute that vaccine-induced encephalopathy can lead to autism. Why would this acknowledged pattern of injury never attract a study before? Vaccine-induced shoulder injury has been reported on for this committee, but not autism. Which poses a greater threat to public health?

On August 23rd Emmy Award-winning journalist Greg Dobbs covered our work in a segment of HDNet TV's World Report called Mixed Signals. This report will be on the EBCALA website within a few days. Regrettably, no one from the federal government, no one from DOJ, HHS, FDA, or the VICP would speak to Mr. Dobbs on or off camera.

Mixed Signals begins by contrasting two cases.

Kimberly Sue Leteure, who was compensated, and Michelle Cedillo, who was not compensated. It essentially asks what is the difference between cases where encephalopathy and seizures both accompany autism after vaccination. Is the difference that one family used the word “autism”? If it is, then this clearly is not the conduct the Congress envisioned when they created the VICP.

I invite all of you to watch Mixed Signals, which again should be on the EBCALA website within a few days. The authors of Unanswered Questions would be happy to discuss their findings further with your honorable Commission if you would permit us to do so. I am certainly willing to answer any questions and I invite your comments.

MS. DREW: Thank you, Mr. Conte.

OPERATOR: Our next comment comes from Jim Moody.

[Some words or phrases in Mr. Moody’s comments were not discernable or audible because of the quality of the phone transmission.]

MR. MOODY: Thank you for the opportunity to make comments. I apologize I am on a cell phone at an airport so the quality is not up to the usual standards.

I am Jim Moody. Dr. Clayton told a profound story during this morning’s briefing about the benefits of the vaccine program in eliminating pain and suffering from preventable infectious disease, yet the work of the vaccine

safety system is not finished until preventable adverse events are eliminated.

In particular, the work of this Commission is not finished until every injured child and adult has received appropriate compensation, including resolving doubt in favor of compensation as determined necessary by Congress where they could carry out this nation’s profound legal and moral duty to make sure that every veteran of the war against infectious disease is adequately taken care of and in order to protect the benefits of the overall vaccine program.

The IOM report is very helpful in explicitly discussing so many studies and by being quite honest at noting the limitations of existing epidemiological studies, the lack of definitive epidemiological evidence for so many adverse events, how little we actually know about the immune and autoimmune response to vaccines and how this might contribute to adverse events, and the growing importance of understanding the role of both genetic susceptibility and gene environment interactions.

It could have been a better report in a few respects. Number one, the report could have more expressly endorsed the need for a comprehensive program of research on vaccinated and unvaccinated humans and animals in order to get better baseline data for comparison purposes. The

committee correctly rejected a number of studies, particularly in the vaccine autism question, for example, on the lack of inadequate unvaccinated controls.

Number two, the report could have included a discussion of the research at the University of Pittsburgh looking at vaccinated versus unvaccinated attacks. There is a good discussion about the importance of animal models in the report in general.

The first two papers published found profound differences in the acquisition of survival reflexes following hepatitis B administration. The second report found changes on neuroimaging between vaccinated and unvaccinated animals. As far as I know, this is the only ongoing program of research that compares vaccinated and unvaccinated primates according to the current and recent past human schedules.

Number three, the report should have discussed the development in the scientific literature showing association between mercury and autism. I’m reading about the Immunization Safety and Review Committee six years ago. This may have been beyond the charge, so it’s not a fair criticism. So much literature has come out since then, notably the DeSoto group showed the weight of the epidemiology literature does favor association between mercury and vaccines, also know as thimerosal, and autism.

There's also the Pittman/Gallagher papers out of SUNY Buffalo showing an association between hepatitis B and autism and the Young study using BSD data showing there is a statistically significant connection between mercury and autism.

Most important, the report could have included a discussion of the cases actually being compensated in the program, especially the autism cases. As Mr. Conte noted, there were 62 such cases, going back to the Sorensen(?) case in 1990 leading up to cases, one of which was actually a test case, the Pollin(?) case, as well as cases more recently compensated in the program where vaccines caused autism.

The IOM report strongly supports recommendations I noted before. ACCV must strongly endorse, as has NVAC and the CDC, an ongoing program for research comparing vaccinated and unvaccinated humans and animals. This is absolutely necessary to obtain baseline data for comparison purposes.

Second, the ACCV must support a scientific study of the remaining LAV(?). Over 500 of these cases have now been dismissed while the science, showing a possible connection, is yet unexplored (?), as well as the science on mercury and MMR continues(?).

(Inaudible segment) This is a question for

science and medicine to inform the law that much remains to be done. The sheer number of cases in the program has probably imposed a rule of thumb on compensation for most but not all of the cases. As they go forward on a one-by-one basis, they should remain in the program until the science and medicine has sorted out with certainty which child is entitled to compensation.

(Inaudible) Indeed, the greatest threat to the benefit of vaccines comes from a lack of public confidence up front in the safest possible schedule and from growing concerns about those who are injured, quote, for the greater good unquote, will in fact receive compensation.

Parents want healthy children, but once death and disease are all but eliminated caused by infection, the emphasis must be based on science and not on rhetoric and propaganda, but on the elimination of adverse events and on compensation for all those who suffer vaccine injury. Thank you very much. And I am sorry for the cell phone.

MS. DREW: Thank you, Mr. Moody. Are there any more comments?

OPERATOR: There are no further comments.

MS. DREW: That being the case, we will end this portion of our meeting. Do I have any comments from the Commission? Do I hear any motions from the Commission? We will adjourn until tomorrow morning.

(Whereupon the meeting recessed to reconvene at 9:00 AM the following day.)