DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEVENTY-THIRD MEETING OF THE

ADVISORY COMMISSION ON

CHILDHOOD VACCINES

September 17, 2009

Parklawn Building
5600 Fishers Lane
Rockville, Maryland

CONTENTS

P R O C E E D I N G S

Agenda Item: Welcome and Chair Report

Ms. CASTRO-LEWIS: Let's start with introductions.

MS. SAINDON: Elizabeth Saindon with the Office of the General Council.

DR. HERR: Tom Herr, pediatrician, member of the Commission.

MS. HOIBERG: Sarah Hoiberg, parent advocate.

MS. BUCK: Tawny Buck. I am with the National Vaccine Information Center and a parent advocate.

MS. GALLAGHER: Charlene Gallagher. I am the industry representative.

DR. FISHER: Mike Fisher, pediatrician.

MS. GRAY: I am Becky Gray, Arizona State University.

MS. TEMPFER: Tamara Tempfer, pediatric nurse practitioner.

MR. SCONYERS: Jeff Sconyers. I am an unaffiliated attorney.

MS. DREW: Sherry Drew. I am the representative of the petitioner's attorneys.

MS. CASTRO-LEWIS: I am co-chair. I am Magadalena Castro-Lewis. Why don't we go around the room because actually we have a new person I am still helping with the program and why don't you introduce yourself too.

(Introductions around room)

MS. CASTRO-LEWIS: Thank you. In terms of my report I have a very short report. I would just like first to mention the fact that Tawny, I am going to start with that announcement, you know that she was appointed today to the NVAC. Yesterday was her first meeting and she as usual, had an incredible participation in the meeting. I just would like to congratulate you on this appointment. It is a really nice thing and well deserved too. Congratulations.

Moving on. The outreach committee had some action but I am going to

let Sarah do the report tomorrow on what was done during this period. Then Dr. Evans and Tawny and myself, attended the NVAC meeting yesterday and the day before yesterday. I suspected all of them they do show to committee and work group supports the focus of the meeting was on the H1N1. Anything from the development of the vaccine, the clinical trials, the finance, the compensation in case of vaccine adverse effects, et cetera was discussed during the second day of the meeting. I don't know if a webcast is going to be available later on but in case you want to be updated probably on all this, you can do it.

Agenda Item: Approval of March 2009 Minutes

Really there is nothing more to report at this point. What I am going to do is move on into the approval of the minutes.

MR. HERR: Question. At the announcement of our meeting - the announcement said it was our 74th meeting. Minutes say the last meeting was 72nd. Where are we?

MS. CASTRO-LEWIS: I think it is the 73rd because I had the 73rd and I just scratched thinking that oh how I was wrong. But it is the 73rd. Thank you, Tom.

MR. SCONYERS: I move approval.

DR. FISHER: Second.

MS. CASTRO-LEWIS: Okay. Wonderful so the minutes are approved.

Agenda Item: Report from the Division of Vaccine Injury Compensation

DR. EVANS: Good afternoon everyone. Can you hear me okay? Good afternoon and welcome to the 73rd quarterly meeting of the Advisory Commission on Childhood Vaccines. We are going to start first with just –- and I cannot see the slides here so you will see me going back and forth looking - following the program update from our office, Mark Rogers from the vaccine litigation group, Department of Justice will give us an update as per usual, and then will be followed by a discussion of the Federal

Circuit decision in Andreu v. the Secretary of HHS by Commission and Petition Attorney Representative, Sherry Drew, Professor Betsy Grey from the Arizona State University and then Petition Attorney Clifford Shoemaker. Following that there will be the ex officio member updates from the Immunization Safety Office of CDC, FDA, and NIH, and the one from Dan Salmon, from the National Vaccine Program Office, will be tomorrow morning due to a conflict he had this afternoon. He will be joining us then.

Tomorrow's agenda includes a report from ACCV Outreach Workgroup, the workgroup chair Sarah Hoiberg, and then an update on the Institute of Medicine Committee Project on Vaccines and Adverse Events by Drs. Rosemary Johann-Liang the HRSA Project Officer and Kathleen Stratton, the Study Director. That will be followed by a presentation by the Program Director for HRSA's new Countermeasures Injury Compensation Program, Dr. Vito Caserta.

In the blue folders that you have today, the presentations for today are on the right side along with the amended agenda reflecting Dr. Salmon's presentation tomorrow, and then the ones for tomorrow on the left side.

Turning to a bit of good news, we have some personnel changes. You already have a little bit of insight into one of them. We decided to stay with the Herzog family and Michelle has past the baton onto her sister Andrea otherwise known as Annie and Annie has joined us and she is going to be the principle staff liaison for the ACCV and she brings years of experience working with the Federal Government and has been in the last six years HHS' Program Support Center where she has been working on logistical projects. I know everyone will give her lots of support as she transitions into her new role.

We also have a couple new docs on board in the Medical Analysis Branch. First we have Dr. Barbara Shoback who is double board certified internist and also in rheumatology and close to 20 years in clinical practice and enjoying the FDA's Center for Devices and Radiological Health and then the Centers for Biologics

Evaluation and Research Notice Achiever and she brings a wealth of clinical and regulatory experience to the branch.

In our audience here we have Dr. Marco Melo, who also has extensive training and previous clinical experience in internal medicine and laboratory research experience in rheumatology, neurology, psychiatry, and immunology. He recently completed an occupational and environmental medicine residency and comes to us with fresh clinical experience as a chief medical officer. We are very pleased to add these fine folks to our medical staff.

Turning to the numbers starting with claims filed; you will see that for fiscal year 2009 we have exceeded the average of 168 by a fair amount. We now have 260 claims nearing the end of the fiscal year, and that is something as a surprise to us. Probably it shouldn't be. But you will see as you look down that column for non-autism thimerosal column, that except for fiscal year 2007, the numbers of claims filed have been fairly steady. The surge in 2007 as you may recall, was because we had added influenza vaccines in 2005 and whenever you add in a new vaccine to the program there is a two-year window for adding claims back eight years with retroactive coverage. That is the 242 that appeared in fiscal year 2007, but the fact that we now are covering 16 vaccines is beginning to be reflected in numbers of claims being filed. I did a break down of this 263, and 60 percent of them were filed on behalf of adults and the top four vaccines are in the influenza is 40 percent of them, then that was followed by DtaP 10 percent, and then both TD and HPV were 7 percent. This was the top four by percenters.

Clearly there has been a swing from predominantly pediatric filings to now more than half are adult filings. We see no reason why this trend will not continue. Thus we need to hire additional staff for this workload.

In terms of the autism thimerosal filings, you will see that for fiscal years 2007-2008 where there was a reverse of a general downward trend. We believe that is

because of the publicity surrounding the hearings that took place during that time period, there seems now to be a trend again downward and how much the decisions in February and the first theory have to do with that we don't know but that is the trend that we see now.

The next slide has to do with the adjudications and as we discussed extensively at the June meeting there has been a change also starting in 2008 where you will see that up to that time that dismissed claims outnumbered compensable claims on a year basis and then it became the opposite, and then at your request we began to do a break down of that for closer examination. These are the adjudication categories broken down in the past three fiscal years. You will see that in 2007, roughly it was half/half compensable/noncompensable. Then that trend -– the settlements doubled from '07 to '08, and have continued to the point now where compensable versus noncompensable was somewhere in the order of about 70 percent compensable.

MR. SCONYERS: The numbers just don't look like they are the same. In the preceding table, 185 cases concluded in FY09 and this table 147 is -

DR. EVANS: I am not following you.

MR. SCONYERS: FY09 total cases in the preceding slide 185 in –-

DR. EVANS: We may not have had the total breakdown for 185, but for the 147, so far that is what we are able to give you. We weren't able to get the additional data for the difference between 147 and 185. I have no reason to believe that the trend would be any different as it finishes out the fiscal year.

Moving on to the award amounts for fiscal years 2009 you can see the petitioners' award are close to the average over the past six years of $69 million and now it is nearly $72 million. Attorneys' fees overall have been $5 million but you can see in the right column under attorneys' fees and costs that there has been a significant increase this fiscal year from $7.9 million a previous fiscal year to $12.6 now and that represents $4 million that that represents autism fees. The other increase also

represents some of the interim fees that have started just in the past year or two. So you can see activity in that area.

Overall though the highest amount of outlays was in fiscal year 2007. It actually has gone down in '08-'09 somewhat paradoxically you would think even though we are settling more and more claims but it turns out that the average amount award for settlement is less than what it would be a case that goes to a full decision and work out damages. That is the reasons why you see those kinds of changes too, more activity but the overall average amount has decreased.

Everyone's favorite slide in terms of the trust fund. Those are the numbers. With two more months to go you can extrapolate and project that at the end probably about $270 million or $275 million in receipts will come in and if you balance that out against outlays of about $85 million to $95 million it would mean that the program is netting bringing in actually altogether about $185 million to $190 million this fiscal year.

In terms of activities, starting out with the ACIP Advisory Committee on June 24th to 26th, Dr. Vito Caserta, Kathryn, Sherry and I attended the ACIP meeting and that meeting also was extended a third day for discussion of issues surrounding the novel H1N1 influenza virus vaccine - soon to be available. There was a special session also on July 29th to consider who should receive the novel H1N1 vaccine when it becomes available and which groups of the population should be prioritized.

Next Dr. Vito Caserta attended a special meeting of the FDA's Vaccines and Related Biological Products Advisory Committee, also devoted to the pending licensure of multiple H1N1 vaccine products.

On July 29 to 31, Kay Cook, our Branch Chief, staffed the HRSA VICP exhibit booth, the National Association of County and City Health Officials, at their conference in Orlando, which was attended by 840 individuals and 69 exhibiting companies. Kay estimates about 30 brochures were handed out and those who stopped

by were primarily interested in the H1N1 vaccine and whether the VICP would be covering it. But this was our first outreach trip in a good while, as you all know.

It was followed in August on 23rd and 24th, by Jean Southard and Carol Marks, who attended the National Association of Community Health Centers in Chicago at their Annual Meeting, which was attended by about 2300 people and about 60 brochures were handed out. Again, a lot of interest about the H1N1 vaccine and questions about VICP coverage. There was also some interest in the program developing brochures in languages other than English and Spanish.

Following that there was the Institute of Medicine Committee Public Scientific Workshops that will be discussed much more in detail at the presentation tomorrow morning during that session.

Finally, the ACCV chair to my left, and I spent the last two days attending the National Vaccine Advisory Committee in Washington along with Tawny, who is now an official member of NVAC. There is extensive discussion of influenza mostly on the second day, and pandemic influenza planning and Dr. Caserta also gave the same presentation. He is going to be with you tomorrow and the CICP, the Countermeasures Injury Compensation Program.

For telephone audience just to review the point of contact, if you wish to write the program you should write to the address 5600 Fishers Lane, Parklawn Building, Room 11C-26, Rockville, Maryland 20857. The toll free number to obtain packets of the program and other information is 1-800-338-2382 and the Internet address is http://www.hrsa.gov/vaccinecompensation, one word. If you wish to arrange for public comment at these meetings, please contact Andrea Herzog and her direct line number is 301-443-6634. Her email address is aherzog@hrsa.gov. That ends my update. Thank you.

MS. CASTRO-LEWIS: Thank you. I do actually have a question with something that you didn't mention. Would you please let us know what is the status of

getting new members for the ACCV?

DR. EVANS: Actually I was going to put that as number one and number two down here, but I forgot to. Good question. I wish I could tell you when to expect that the package will be approved and when we will receive word. I do not as yet have any additional information other than it is still being reviewed within the Department and even beyond the Department in the Executive Branch of government. Of course we know that the National Vaccine Advisory Committee was able to have their package approved ahead of time, but that is a downtown departmental committee so maybe it starts centrally and goes out. Hopefully we will have some news. But if I were to predict, I would say that if the current members around the table are amenable to it, we would like to see them back in December.

MS. CASTRO-LEWIS: Is that a possibility for you, Tawny?

MS. BUCK: I don't know.

DR. EVANS: Let's talk about in first in terms of procedures and rules. In terms of procedures and rules, we have been advised by our esteemed counsel, Elizabeth Saindon, that there is no reason why you, Tawny, even though you are serving on another departmental committee not within the agency, that you cannot continue on the ACCV, and the same is true for the other two members, Tammy and Jeff. I, again, apologize for the uncertainty and the delay but I understand that the ACCV is in good company.

MS. BUCK: You do have three names this time around pending approval and in understanding that actually, this is bumping up to the next three and how are you doing with nominees for those and do you have gaps do you need assistance with? Isn't it correct Magda, that your term and those that rolled on with you are -– that is for one up too, isn't it?

DR. EVANS: Yes, Tawny. You always ask these really good questions. No, this is a very good point. As I said to Jeff on the way today as far as we are

concerned, you are continuing on the ACCV until notified further, which made him happy to no extent. We certainly would be interested in any nomination. We have received some nominations and we certainly would be interested in any others you or anyone else would have in mind. The process I can say is still open to the extent that we would continue to accept them, but we certainly have to get this first one so we can get the second one.

MS. BUCK: And you do have three. They are just going through the process of being approved but you do expect one for each position rolling on to replace Jeff, myself, and Tammy.

DR. EVANS: To be clear we are the next set of members to be replaced, are comprised of the pediatrician and a member of the general public member, which would be Magda, and a member of the legal representative industry. Did I get something wrong?

MS. BUCK: I wanted to make sure you have three coming in to –

DR. EVANS: Yes, I am saying that is the next set. I thought I made that clear previously. Yes, we have had a nomination package pending for some time. Yes, we have three excellent candidates and we hope that they will be approved soon.

MS. CASTRO-LEWIS: Any other questions?

MR. SCONYERS: I have a couple of questions, Geoff, back on your slide of filing. There was this uptick in FY09. Can you remind me of what the two-year period for HPV - when is that up?

DR. EVANS: The two-year period for HPV that February 1, 2007 when it was added officially. So it would February 1, 2009.

MR. SCONYERS: So we are past that.

DR. EVANS: We are past that.

MR. SCONYERS: Whatever surge it was going to be associated with.

DR. EVANS: Exactly. So we received a couple of dozen HPD claims, a

little bit under two dozen.

MR. SCONYERS: The uptick here from what I got from your analysis, doesn't seem to be attributable to HPV.

DR. EVANS: No, and the difference is as you know influenza vaccine has been given for decades versus HPV, which is in clinical trials during this eight-year period.

MR. SCONYERS: I am trying to understand and I am sure you are too, where the substantial increase in FY09 can –

DR. EVANS: I would hazard a guess that with the publicity surrounding the program over the past three years, that the United States has become much more aware of our presence and the availability of the program and, again, more than a hundred million doses of influenza vaccines are administered annually.

MR. SCONYERS: The other question that I have had to do with the adjudications, compensable and dismissed, your next two slides. Just looking at it the pace for '09 seems to be –- I am pleased with the number of determinations that there were in '08. One of my concerns consistently has been a long time that cases wait to be resolved whether they are going to be compensated or not. I would think for petitioners it is important to reach a decision. That was good in '08. '09 looks like not as many cases were resolved and I wonder if you have any idea why that might be? I would not see that as a favorable trend.

DR. EVANS: No, I don't but maybe it's something that Mark can also address during his update.

DR. HERR: I guess my only comment on the question of the increase in claims in influenza have we seen a significant increase in the number of doses of influenza given over the past two or three years? Just saying over a hundred million doesn't –

DR. EVANS: Of course I am going to get a little confused in terms of

years, but there was the year not too long ago, three or four years ago, which one of the companies was unable to provide product and then that particular year I believe that the numbers had dropped down to 60 or 70 million doses and then now it has gone up to above –-

DR. HERR: I would like to think at least in my little part of the pie out there is that there is more influenza vaccine being given. If there is more vaccine being given there is another reason to expect that there is liable to be a little bit more claims.

DR. EVANS: Absolutely. That is roughly a third of the numbers of vaccines given annually overall. Influenza represents a significant portion.

DR. EVANS: It doesn't have to necessarily be a change in what was going on other than the fact that more doses are being given.

MS. HOIBERG: This is Sarah Hoiberg. As we are talking about the Commission, I would just like to stress again, that I would very much like to meet the Secretary of Human Services, seeing as we report directly to her. I know that she is a very busy woman but this is her Commission. I really feel that she needs to come in and sit. If the Assistant Secretary can sit in on the NVAC meeting then I think she needs to at least call in and grace us with her presence on the phone for at least a few minutes to say hello and I hear you. We deserve much more than a form letter saying thank you for your concern.

DR. EVANS: I appreciate the comment, Sarah. That was actually number two on my list that I did not write down, is that we did not receive as yet any response from the Secretary in terms of the letter that was sent up earlier in the spring.

MR. SCONYERS: Maybe she is not grateful --

MS. CASTRO-LEWIS: Any other questions? Report from the Department of Justice. Mark Rogers please.

Agenda Item: Report from the Department of Justice

MR. ROGERS: Good afternoon Chairman and members. Hopefully I

too, will keep us ahead of schedule. As far as personnel are concerned we have had four paralegals move on to better things and we have had two paralegals join us, so we are still down two paralegals. For all who are attorneys you understand how important that is, our paralegals are a crucial part of our office. We are missing the two and hopefully by the next meeting we will have announced that we have found two more. The attorneys are all that they were the last time that we met.

In with the statistics, and I know Geoff goes through these statistics mostly from an annual basis and gives you a big picture. We have focused on what has happened from a litigation standpoint since the last time we met, but we are looking at the same numbers just sifted a different way. We had 15 autism cases filed that are down from the 24 last time. We don't see anything significant with that decrease. We know we are running further and further from the time that thimerosal was removed from the vaccines.

The non-autism cases we had 88. That is the slide uptick from last time where we reported 75, and then as Geoff mentioned the breakdown between adult cases and cases with children are slightly favoring the adult cases, slightly up from the last time we reported. The children's cases are about the same.

The adjudication side we have 21 compensable cases. None of these had been conceded by HHS. Seventeen were settled and four were resolved by proffer. We didn't have any proffers last time. Conceptually they are very close. As we mentioned last time a proffer is where both petitioner's counsel and respondent DOJ sit down and jointly produce a recommended award to the special master. It has the advantage of – it is a little faster because a special master embraces the proffer almost a hundred percent of the cases and it is reduced to judgment very quickly.

Not compensable that includes 162. That is up dramatically from the 33 we had last time. As I mentioned at the last meeting we expected this. It is attributable to the autism cases. You see 139 where the petitioners have voluntarily dismissed their

cases following the decisions in the theory one test cases. We didn't know whether that would be a long-term trend or what would become of that last time. What we are seeing now is that it is returning to a baseline. That those decisions prompted these petitioners to leave the program but now those that were going to leave have left based on those decisions. The non-autism cases are about comparable to what we reported last time.

Now we went through these terms last term and maybe we will keep them there through the next meeting if we have the new members.

DR. FISHER: Keep them there forever.

MR. ROGERS: Okay. You have had time to digest them. Do you have any additional questions about what we mean by what we say? We also have our chart. Now, again, and we had much discussion last time about how we get to the end of the case and where the numbers are. They continue to be hard to the left, if you will. The petition is filed. It is reviewed by HHS. It is generally not conceded and then we go down that settlement track and we either settle or we don't. The cases that are falling on the right side are decisions by the special master. They tend to be dismissals for jurisdictional reasons or a finding that the injuries are not vaccine related. The case processing is running down the left side of this chart and of course both sides are open. Any further questions about that?

MS. DREW: When we talked about a petitioner who received an award of compensation, are we talking about a decision by the special master and not the day that the check arrives?

MR. ROGERS: We pivot off of the decision. It can be an approval of a settlement. It can be an award of compensation but it is the special master's decision.

MS. DREW: And then there is a lag from this until the time the money arrives.

MR. ROGERS: Yes. With regard to the autism cases there hasn't been a great deal of activity aside from those – we had the trials completed in theory one. I

reported that last time. We had the three decisions from the Court of Federal Claims affirming those three test case decisions by the special masters that they occurred in late July, early August. The next step will be the running of the appeal period before the Court of Appeals for the Federal Circuit. That will run for Hazlehurst next week. We haven't gotten the notice of appeal in any of these, but again we won't know whether they are going to be appealed until those deadlines run. We will know by the next meeting.

On theory two the briefing, the trial was completed. I reported that last time. The post-hearing briefing is also completed so the cases are now before the special masters. I have heard that we could expect decisions late this year, early next year but that is to be determined.

On the appeal front we have four new cases. These are new filed appeals. You will notice that all were filed by petitioners. We have annotated one of them as an interim fees and cost appeal so it is raising issues with regard to an interim fee decision by the special master. Hocraffer and Doe 11 are burden of proof type cases where the petitioner did not prevail before the special master but believes that the special master imposed two rigorous burdens of proof under federal circuit law. Wilkerson was a statute of limitations case. These are cases that are pending. These are all new and I am not going to go through them all individually, but we had tried to annotate them enough to give you a flavor of what kind of cases there are. The takeaway here is that we have a substantial number of appeals that deal with the issue of attorney's fees and costs. We have the one Doe 11 pertaining to interim fees and costs.

MS. CASTRO-LEWIS: Can I ask a question? In these two cases the Hocraffer and Doe 11, the burden of proof was that depending on the burden of proof. It seemed like the standard should be a standard for this case. They should be -- so the people wouldn't have to bring more and more or how does it work? I don't understand

why they have to appeal a decision in something that should be more clear.

MR. ROGERS: What generally happens is that the petitioner presents their evidence, their scientific expert, and HHS presents their expert. The special master hears both. He looks at a large number of medical articles. Hears the testimony. There is a lot of questioning of both experts then the special master comes to a conclusion and writes the decision. The special master in these cases said the petitioner's expert was not very convincing to me for the following reasons and entered a decision denying compensation. The special master will conclude by saying I can't find based on this evidence that petitioners have carried their burden approving that the vaccine caused the injury.

Now on appeal in these cases, the petitioner says special master you did not apply federal circuit law correctly in making your judgment. You should have given more weight to the medical articles or you were unfair in how you have characterized our expert's testimony. You have been too rigorous, too searching in examining our evidence. Then they will cite federal circuit cases that support their views. They are saying that the special master was too hard on us in analyzing their case. I think that is the best way to summarize it.

MS. CASTRO-LEWIS: Thank you.

MS. BUCK: I have a couple of questions. Did you want to finish or can I do it now?

MR. ROGERS: You can do it now.

MS. BUCK: Are DOJ's litigation fees and costs is that anything that is available to the public on any of these cases?

MR. ROGERS: Not on an individual case because we can't break – you are welcome to our budget. I think that is what is releasable under the Freedom of Information Act, but as far as how we allocate who worked on what and for how long on individual cases, I don't think we could provide it and even if we could I think we would

be disinclined to provide it because it shows the litigative strategy of the Department whether we focus on particular kinds of cases. We would argue that that is privileged. But our total budget I believe is releasable.

MS. BUCK: Are all payments that are made to petitioners is that public?

MR. ROGERS: The award to an individual petitioner is not unless it is in a published decision. If it is not published then we have had requests for petitioners' applications for fees. Our response to that would be that under the Act we couldn't release that because it is based on information that was submitted by petitioners and we have a provision in the Act that precludes us from releasing such information without their consent. If a petitioner were to consent to that release we could.

MS. BUCK: And that partly has to do with close to 85 percent of cases that are going into settlement or a proffer, correct, because those are not considered published decisions, which aren't on the website and aren't public? Am I right?

MR. ROGERS: That is correct. If it is an unpublished decision resolution then it is not available except with the consent of petitioners.

DR. HERR: Tawny, did you try to look at the total cost of all this program, whether it is the awards, whether it is the defense, even the cost of the special master's time when it comes to looking what is the cost of the whole program period?

MS. BUCK: Well, also because it seems like fees and costs are clearly out of appeal a lot for these cases. I think it does beg the real obvious question, which is how do those compare to the fees and costs that were spent by DOJ on those cases? Whether or not that is information that can be shared I understand. It does bring up the question of how do they compare?

MR. ROGERS: It is a fair question. What would be releasable and I have seen it reported here before. I don't think you got to it this time, but we could release the total of all the fees and costs awards to petitioners in any given period and you could juxtapose that with DOJ's budget during any given period and that would probably make

sense to compare them on a fiscal year basis because that is how we operate under our budget.

MS. BUCK: This might be a really dumb question. Are these related to autism cases? It just seems to be a whole lot of cases all of a sudden on fees and costs and I am wondering what is driving that trend.

DR. FISHER: Can you give us an example of what the issue is in these appeal cases?

MR. ROGERS: The hourly rate that the special master awards petitioner's counsel has been the subject of some litigation. Occasionally there is litigation over certain categories to compensation. I think that is where most of the litigation is. It is in the hourly rate. And some cases have been appealed based on the total amount that it is inadequate. You do have the statistic here. For FY09 you have in contemptible cases $4.8 million almost $5 million. In dismissed cases $7.7 million. You have a total there of approximately twelve and a half million dollars. Our budget this past year was $7.7. If you want to compare that on a macro basis, DOJ's litigation's budget is $7.7 million and the awards to petitioner's counsel were about $12.5 million.

MS. HOIBERG: The Department of Justice's budget – you guys don't pay the attorneys. That comes out of the fund, doesn't it?

MR. ROGERS: No, we pay the attorneys. The source of the budget comes out of the fund, but we pay our attorneys from our budget.

MS. HOIBERG: Well, you pay your attorney. You don't pay petitioner's attorney.

MR. ROGERS: They are paid out of a fund. The 7.7 million is for our expenses.

MS. HOIBERG: The $7.7 million is yours. That's not the petitioner's? I thought that is what you paid to the –

MR. ROGERS: That is not on this chart. What is on this chart is the

awards to petitioner's counsel. You will see the bottom numbers under the column of attorney's fees, $4.875 million plus $7.752 million. That is a total of about $12.5 million. The $12.5 million has come out of the fund in awards to petitioner's counsel. During the same period, and we're not quite at the end of the fiscal year, you got to make sure you are not comparing apples with oranges. For this fiscal year of course we haven't completed the fiscal year and we don't know exactly how much of our budget we are going to spend. Just as the extent you want to compare those two, our budget for this year is $7.7 million.

MS. DREW: And where do your experts' fees --

MR. ROGERS: DOJ pays some of those fees, but HHS also pays some of those fees.

MS. BUCK: I appreciate you this information on the report. You have put a lot more information and it is helpful and I am sorry that we are grilling you on a lot of questions because you have provided us a lot more additional information but I really do appreciate it. It is good to see a snapshot of what kind of cases are on appeal and what the issues are around them. I appreciate that.

MR. ROGERS: If I seem somewhat hesitant I am working from a document that HHS produced here. I am fully confident the numbers are right but I am kind of working through the sheet here and squinting at it.

MR. SCONYERS: I may be wrong but would interim fees in that table.

MR. ROGERS: It would. These are attorney fee awards.

DR. HERR: But if you are looking at operational budget or operational expenses, the idea of DOJ's expenses go on all the time. They are not related to each particular case to how much more to this case and how much more to that case so that those are your interim fees so to speak. If there is a decision on a case and there is attorney compensation to compensate them for everything that they have done over X number of years. You are really mixing apples and oranges when you are trying to

figure what somebody's total cost versus what somebody's operating budget and the closest thing to DOJ's expenses are the interim and when you are comparing from the private counsel, additional of counsel.

MS. HOIBERG: DOJ continues and the attorneys continue to get a paycheck throughout their time in fighting these different cases. The petitioners' attorneys, you have to wait until the case is settled and hope to God that you get interim fees and then like I said before, mortgage your house. These petitioners' attorneys are running a business. The DOJ attorneys really –- it is a job to them. They go to this case this time and work on that case this time. They don't have to worry about taking care of family or anything like that and hoping that the case gets finished faster.

Like I said before, I think that the playing field should be leveled. I think that the DOJ attorneys should have to pay for their own experts and I think that they should have to go without pay or until the case is over. I think that the cases would be settled much faster because you guys have nothing to lose. You have nothing to lose. These petitioners' attorneys have everything to lose and they have clients. These children are dying because they can't afford to get the care that they need. It is ridiculous. They actually make it to the court and to have a special master who doesn't care about anything but to protect the vaccines. The fact that you have only compensated a little over 2,000 people in 20 years is disgusting where it is way more that could have been injured. The fact that you guys are so proud that there is $3 billion sitting in the fund - it should be going down not up.

MR. ROGERS: To your comments, I agree that it is somewhat problematic to try and compare the total awards to petitioners' counsel with our budget. It is just one point of comparison. We operate as you pointed out, under very different rules. Petitioners' counsel tends to get there - up until recently got their awards for attorneys' fees at the end of the case. And now we have a significant number of interim fee awards, which there is no rule yet developed under the case law for how many of

those there can be whether there is one or when it might occur. All of that is a work in progress.

What you do with the differences between how DOJ attorneys – back to your point, how DOJ attorneys are paid and how petitioners are paid under the program, the bottom line on that is that it is all determined by statute. Those are legislative prerogatives. They are resolved through the legislative process, through majoritarian processes, and we at DOJ have no option whatever, other than to operate under the law as it is. We can't operate under what we think the law should be. That is very much a prerogative for the Commission. I don't think you will get so far. I think your chances of changing the laws that determine how DOJ attorneys are paid I don't think that is within the prerogative of the vaccine program.

How attorneys are paid and when and how much, is very much a matter covered by the Vaccine Act and this Commission can recommend whatever it determines to be fair and appropriate. Amongst your options would be to recommend that a certain hourly rate be approved for all attorneys or a schedule, which would remove those items from litigation. Right now the standard is reasonable. A reasonable standard is an invitation to litigation and that has been a continuing source of litigation to determine what is reasonable with the special master having to finally decide it.

The Vaccine Act could prescribe it, remove it from litigation and we would smartly salute and enforce that law. I hear your concerns. I would commend you to consider what solutions might be appropriate and work towards a legislative fix.

MS. BUCK: This is Tawny. I have a question on interim fees because I understand we have made that recommendation. Now you guys are working on doing that for attorneys, which is I think very helpful in this process. I had a family ask me this question about the possibility of interim payments to families. I totally understand the process with the life care plan and the long-term expenses. It takes a lot of work but there are some costs or some payments - maybe payment suffering or loss wages, that

potentially could be hammered out fairly quickly and those payments be made as you are going through the process of determining that the long-term annuity payments for the trust funds – it is the life care plan process that often takes up quite a bit of time. I know it hasn't come up before but it was something that was suggested to me to sort of ease the burden not only on these attorneys, but more importantly I think we have to think of it using the burden on the families.

MR. ROGERS: Yes that is another fair point. I am recalling and feel free to correct me if I am wrong, but there were proposals such as this, legislative proposals that were developed five or six years ago, along the exact lines that you speak, that is, interim medical costs by petitioners to be awarded. The conclusion then and I believe the conclusion now would be that that requires a legislative change that the statute doesn't provide for.

MS. BUCK: Maybe this isn't as cut dry as I think it is. But you know once you have gone to compensation and you are hammering that out with families and so you are at that stage in the process, and you do have as far as I understand, some formulas for determining like pain and suffering, caps on those and even lost wages. It seems like speaking from experience and it has been a long time because my daughter is 14 now, those figures were fairly quickly hammered out and agreed upon. It was the life care plan and the long-term expenses for her care that took a while. As I reflect back on that I wonder if there isn't some and I don't if that is legislative or not, because I'm not talking about interim medical expenses. I think that falls under more of the life care plan and those issues that you are hammering out but I am just talking about you have these categories of payments that you make, some of them being pretty clear cut.

MS. HOIBERG: Pain and suffering should be something that could be giving like that. Just since our pain and suffering was just decided a few years ago, it is still fresh in my mind, it took them forever to hammer out and they went back and forth to the table. It takes a long time. Once something is determined, such as, pain and

suffering as Tawny said, that should be awarded to the parents because once you win like in our case, they proved liability or admitted to the fact that the vaccine caused my daughter's injury and then it was a year and a half, almost two years, before we won before they decided how much they were going to compensate and then it was another couple of months before we saw anything. It is just such a long drawn out process and you have families like I said before, that are suffering greatly and children that are deteriorating because they are not getting the care that they need.

My concern is that once it is determined that a vaccine has caused an injury then there needs to be some sort of quick compensation. I feel like it is stop trying to cheat these children. Their lives have been destroyed and you are going to sit there and nickel and dime and try to give the cheapest thing you possibly can.

I don't understand the $3 billion sitting in there. Why it is such a hard thing to decide to give these people their care.

MS. CASTRO-LEWIS: The question is in terms of if we want to influence legislation is that something that this committee is able to do for some kind of recommendations? Our previous letters are not even being read. Is that something that this committee could recommend a change?

MR. ROGERS: I would defer to HHS, which has responsibility for the Commission.

DR. EVANS: The answer is yes.

MS. BUCK: But a payment, an interim payment, a suffering payment that is not legislative because when we make the recommendation to do interim attorney – but when we make a recommendation to interim the attorneys' fees payment, we were able to find a way to do that. I know you have benchmarks. There are certain points where you make those payments and that didn't require a legislative change, correct?

MR. ROGERS: What you had with the interim that was litigated. You had the Federal Circuit determining looking at this statute they are available. That would

have to happen. We would have to have a legal determination that it could happen. Under our reading of the Act it is not there.

MR. SCONYERS: Our recommendation letter to the Secretary was to put that explicitly in the statute as opposed to relying on the Federal Circuit decision, which could be reversed or changed by a later panel. Yes, it is the case now because the Federal Circuit has decided it but on the right case it would come up that it was clarified and limited. Our recommendation was to put it clearly into the statutes so that it guides future Federal Circuit cases.

DR. HERR: But we didn't put anything in that letter that talked about sort of an upfront as soon as the case is decided. An upfront award saying, okay, pending all of the other decisions – here is $50,000 to $100,000. It sort of comes off of the total later. Here is a little money to kind of get you going. Since we have already decided we are going to award the family –

MR. SCONYERS: We dealt with attorneys' fees not awards.

DR. FISHER: It seems like a no brainer. Right now we are talking about a case that is settled or is decided, and there is money to be awarded to not only attorneys but people. Surely that should be done as quickly as possible. Is what we need to do suggest ways that it could be done more quickly like saying, okay, we understand maybe the life plans can't be taken care of in a rapid manner because there is so much decision and discussion there, but there may be some point that we would like expedited. I can't imagine anybody who doesn't agree with this.

I guess Magdalena, I would say let's do whatever someone thinks is the right thing to do whether it is write a letter or –

DR. EVANS: A little institutional history. The major package of recommendations that went from the Department based on unanimous votes by the Commission in the 1990s, a package went up in the Shalala administration and one of those amendments did include interim cost and that appeared in a number of bills over

the next decade, none of which ever we passed into laws. This has been the subject of interest both in terms of the Department as well as Congress for a while. There is no harm in duplicating and going back and reminding and maybe refining, but that's been the approach. If you do it through the Commission the Commission then advises the Secretary. The legislative proposal is put together within the Department and that is sent over to Congress to see if it is approved within the Department.

DR. FISHER: Does it still count as interim when you are saying it is already – because it is not finally decided. Okay I get it.

DR. EVANS: It is pre-judgment. Again, as Jeff pointed out what was sent up this past year had to do with both interim fees and costs, I believe.

MS. GALLAGHER: This is Charlene Gallagher. I think that this is a really interesting topic. I think we really should pursue what is available to us, but I personally don't feel that I am familiar enough with the Act and I am going to ask Geoff. Are we allowed to consult with the HHS attorney about what lies in the Act, what decisions there have been about it, what the sense is around it so that when we write our recommendation it is on really firm ground and we understand the legal implications because I am an attorney and I am telling you I am not sure I have a grasp of them.

MS. BUCK: I would like to add to that. The RAND Report that is coming up for NVAC, was helpful in giving the NVAC guidance on how to write recommendations that could actually be implemented. You know the kind of language that we use and the kind of things we addressed. I don't know if it would be helpful for us to see that because I agree with Charlene that we need to make sure that we are writing viable recommendations that are even worded properly, and even on the NVAC we had to make changes to the kind of wording to show that we understood who we were reporting to and what our goals were. I don't know if the RAND Report would be helpful. I think it might but I agree that that is something we need to be educated on here.

MS. CASTRO-LEWIS: I think it would be worth it to if somebody for the next meeting to have somebody come from that report and talk to us about it. Meanwhile also we probably could – issues here – a committee or a working group or what is the working group to start looking into institutional looking at that report and the possibilities. What do you think of that?

DR. FISHER: I would like to do it sooner as opposed to later. I would hate to wait until the next meeting because it just seems like such a – I am looking at our legal brains there. Is there something we are missing? What stands in the way to getting the money to the families?

MS. SAINDON: Right now the statute would have to be amended in order to permit for more than one payment to the petitioners.

DR. FISHER: That is a big deal.

DR. EVANS: And again, I would like to point out that no one was arguing with the wording or the spirit or the specifics of the language in this proposal of that 10 years ago, and since then it is difficult to get legislative packages approved in Congress and get them through. This requires a legislative passage of these proposals.

MR. SCONYERS: Two things. The first is as the chair of the last work group, I will tell you that Elizabeth was invaluable in keeping us on the rails and focused on what the right things to say were and kept us away to Tawny's point, from language that was going to counterproductive. Second, I would like to move a creation of a small work group to prepare a recommendation letter for approval by the Commission of this next meeting to address the issue.

MS. HOIBERG: Second.

MS. CASTRO-LEWIS: Any volunteers who would like to be in this work group? Sarah. I think we need more than one person. Sherry and Meg. Wonderful. We have a working group to start.

MS. GALLAGHER: Do you need an attorney on this group because I am

an attorney, as well? -- highly legal issue but I don't think the Commission is divided on the result that they would like to see but I think we are exploring what would be necessary to get there. There may be more than one way. I haven't thought about it enough. I think we really need to have a group that systematically works through it and if there are alternatives, let's offer alternatives. I think there is a really hard legal analysis that has to be done and I would appreciate Elizabeth's help because I get the impression she is really much more expert on this than anybody else.

DR. FISHER: I guess that is why I was slow to volunteer. It is not that I don't want it done. It is just that it is clearly a legal deal and my mind and the legal mind don't match.

MS. BUCK: I do just want to say that it is always important for us to go on the record and even if it is a mountain that we may never get over, there is always great value in putting out a statement and having it on the record and standing behind it as a Commission. I don't think it is futile.

MS. CASTRO-LEWIS: Wonderful. I guess the one thing that we can do to support this would be to provide this report. I guess we can get the report from the NVAC for the working group and we go from there.

I think we need to continue the presentation.

MR. ROGERS: Actually we are on the last slide and that is the cases that were recently decided. The most significant here are the autism cases. Shaw was an attorneys' fees case. That concludes my presentation. Thank you for your questions and comments.

MS. CASTRO-LEWIS: Thank you very much. Any additional questions?

DR. FISHER: Can you go back just one slide to where we stopped and the recently decided ones? I just need a little help with all that means.

MR. ROGERS: They are largely grouped under one case. I believe Hager, Porter, and Rotoli are companion cases that – Hep D as I recall that were

remanded for further proceedings before the special master and there was a finding – the special master found not vaccine related. The injuries were not vaccine related and the Court of Federal Claim's Judge Firestone found – she reversed that finding and remanded for determination on damages and as I recall the other two cases were also related that Judge Firestone affirmed them. They were all the same fact patterns, basic same fact patterns, same vaccine and same injury. It was a group of cases all related.

DR. FISHER: Thank you.

MR. SCONYERS: I would like to go back to the slide upon Theory Two under autism and just note that there is about or more than a year between the conclusion of the trial and the filing of the petitioner's post-hearing. Is that the end of the briefing?

MR. ROGERS: That is the end of the briefing. Yes sir.

MR. SCONYERS: That is a long time. And again my interest is in moving cases forward. The autism cases have been pending a long time. I know that you work on this but I think in fairness to petitioners my recommendation, my desire is for the Department and for petitioner's counsel to move these cases for that. I understand that there are often considerations that cause that delay but petitioners rarely benefit from that –

MS. BUCK: You have to talk into your mikes. People on the phone can't hear. I just wanted to let you know. I am hearing messages from the people on the phone and they can't hear.

MR. SCONYERS: My point to Mr. Rogers is that these cases have been pending a long time. There is a long time between the close of the trial and the conclusion of the briefing and the trial. I would simply encourage everyone who participates in litigation around this to move the cases forward expeditiously to conclusion because I think that is what petitioners need is a resolution to their cases.

MR. ROGERS: The point is well taking. My understanding is in this case

the briefing schedule was agreed to by petitioners, but the point is well taken. Nobody involved in the process should become too relaxed about it. There is a premium in the Act on making processing expeditious. The point is well taken.

MR. SCONYERS: That is really my only point. Thank you.

MR. ROGERS: Thank you very much.

MS. CASTRO-LEWIS: Thank you so much. We have –- let's take our 15-minute break. We will convene at 2:35.

(Break)

MS. CASTRO-LEWIS: Just a reminder to everybody that will be speaking, please use the microphones because people on the phones cannot hear and also for recording purposes.

Our next item on the agenda is going to be a very exciting subject. For that I am going to let Sherry introduce our speakers on the issue that we are going to discuss in these sessions.

Agenda Item: Andreu v. Secretary of Health and Human Services

MR. DREW: I believe that Chief Special Master Golkiewicz who is here in our audience today, told me that he believed that the biggest challenge to the parties and to the court in vaccine cases was the issue of burden of proof or causation. Several of our commissioners here have asked me what the words burden of proof mean and of course the words mean different things in different courts and at different times in the evolution of the interpretation of laws.

We are fortunate here today to have Professor Betsy Grey from Arizona State University who has done something of a study of our vaccine cases and Clifford Shoemaker who is a long-term petitioner's attorney and an Adjunct Professor of Law at George Washington University here to talk to us today about burden of proof and causation in vaccine cases. They haven't worked together on their presentations but hopefully they will be able to work together to explain it and then to answer any

questions that you may have. Right now I will turn this over to Professor Grey and she will turn it over to Mr. Shoemaker when she has completed her portion.

MS. GREY: Thank you. I just want to tell you that Clifford and I disagree that Clifford would answer all the questions. Thanks for inviting me. I am very honored that you have asked me to attend. I come to you as an academic who has been studying the system along with two of my colleagues, Michael Saks and Roselle Wissler, and we are looking at various issues affiliated with a program including causation in this no-fault system. I look at causation in toxic tort cases and I also look at other no fault systems, but I acknowledge and appreciate that you are the experts on this program and your knowledge of this system, the problems, and the injuries in the vaccines is deeper and broader than mine.

What I am going to try to do is offer the perspective of an outsider who can compare what has happened in the toxic tort area to what has gone on in this particular specialized field. As Sherry just said, I have been asked to give a survey of the development of the jurisprudence in this area with regard to proving causation and fact.

I am going to speak for about 45 minutes, which isn't really enough but I am sure it is going to be plenty for you. There are many people in this room who have been with this program since the inception or shortly thereafter and you certainly have them to turn to for further insight.

Before I talk about the development of jurisprudence under this program of causation and fact, I am going to try to explain quickly how this type of claim would be pursued as a toxic tort claim in a regular tort civil litigation setting. My goal is to try comparing how the two approaches are similar and have diverged and maybe help move the conversation along among the policymakers in this. But I want to say as Michael Vick might say that I don't have a dog I this fight.

This is a very complex area, one that I find very challenging. I have great

respect for the efforts of the Federal Circuit and the Court of Claims of the special masters here. I must say that in some ways this is like a law professor's dream because it is really a conversation among the decision makers and the special masters in the trenches are dealing with these very complicated issues and they are trying so hard to come up with innovative ways to work through these cases and the appellate court's respond to that and sometimes they agree and sometimes they don't agree but it is nice conversation to look at.

Say you have a tort lawsuit. You can take your pick: a simple car accident or a complicated toxic tort case. What I want to do is try to explain how the burden of proof would work there. At a trial the plaintiff has the burden of proving the essential elements of her case and there are two components to what we think of as burden of proof.

First the plaintiff has to introduce enough evidence to show that a jury could rationally find on her behalf. If, for example, the plaintiff doesn't get any evidence on what the defendant did wrong then the plaintiff would have failed to satisfy her burden of production. Another way of putting this is that she has failed to make out her prima facie case. You will hear that language in all of the decisions in this area. In other words, if you haven't put enough evidence we are not going to waste everybody's time with a full hearing. You need to show enough of your hand to give you the right to a hearing and make the defendant answer to your charges.

The second requirement in addition to that burden of production or prima facie case is what we call the burden of persuasion. This burden of persuasion never leaves the plaintiff in a regular tort suit. After having introduced enough evidence to get a hearing then the plaintiff still has to persuade the decision maker that her version of the case of the facts are correct. After the plaintiff makes out that prima facie case the defendant can then try to persuade the decision maker that the plaintiff version is wrong and the defendant's version is right.

In torts we call this burden of persuasion preponderance of the evidence and that means something more likely than that it means something like 50.0001 percent. It is something that puts you over that line. Here of course we are not going to have the identical issue because the special master is the only decision maker. He can hear everything, lets everything in. There is no inadmissible evidence, but he still has to make a determination about whether the petitioner has made out her burden of production or prima facie case and her burden of persuasion.

Why? Why is that? Why do we have burdens of proof? The answer is basically we have to determine who wins if the evidence is in equipoise, if the evidence is equal. If the decision maker, which in the tort case is usually a jury, can't decide which side presented the stronger case then the decision makers returns a verdict against the party who had the burden of persuasion, usually the plaintiff if it is equipoise.

These burdens of persuasion apply to each element of the plaintiff's case due to breach causation and damages. We are focused on one element of that case and that is causation. The question is whether the agent at issue caused the injury alleged to the petitioner.

In tort law when we are talking about a complicated toxic tort case we usually divide the question for causation into two parts, what we call general causation: can the exposure to the toxin cause the claimed effect; and specific causation: did the exposure to the toxin cause the effect in this particular case? Again, the plaintiff in the toxic tort case has to show those two elements of causation by a preponderance of the evidence. It is more likely than not that this exposure can cause the effect and it is more likely than not that it did cause the effect of this particular plaintiff.

When we talk about proving the first part of causation, that general causation, we break it down into two parts when we talk about a toxic tort case. Is this a feasible effect from the exposure? Does it make sense to us from a biology point of view or organic chemistry point of view from science from a science point of view? In other

words, is it plausible to argue that exposure to power lines in a playground outside of a school causes cancer? That was a claim. Does that make sense? Ultimately we decided that no. It doesn't really make sense from a science point of view.

The second question that we want to look at is whether there is any association seen between the exposure to the toxin and the claim effect. If there is some association the big question is how strong did that association have to be to move beyond the realm of correlation and get into the realm of causation.

Assuming that the plaintiff can show that it is a feasible relationship and that -– in the Virea(?) the question was –- the DPT vaccine is it capable of permeating the blood brain barrier quickly so that it could over stimulate the nerves and cause a seizure. From a science point of view is that plausible?

The next question is if we can show that it is plausible the next question again if whether there is an association between the exposure and the claimed effect and how strong that association is.

Now in tort law we like lots of big studies. We like lots of big numbers. We like epidemiological studies. We like controlled clinical studies. We like controlled observational studies. We even like uncontrolled data from case reports because we like information that others can review and test and test for validity.

In a toxic court case what we are usually asking for is an association that is fairly strong. If there is an epidemiological study we are usually trying to calculate a relative risk between the exposed group and the unexposed group. For example, if a scientist is studying whether a group of workers are looking to see whether lung cancer in that group that has been exposed to some certain substance in the work place for over five years, we are looking to see what the relative risk is of developing one cancer in the exposed population to the unexposed population. If we find that there is twice the risk of developing lung cancer for the workers who have been exposed to those who haven't been exposed, in tort law we use that as a substitute for the question of

association and how strong it has to be. We look for at least a relative risk of two to one.

Again, we are looking to see whether the incidence of the disease is twice as likely as those who were exposed but did not suffer the adverse event. Now if the toxic substance caused the incidence of the injury to ride more than a hundred percent above the background risk of the disease then we are in that realm of legal causation. If it rises less than a hundred percent beyond the background risk then that doesn't show that question of general causation and a plaintiff couldn't recover based on that amount of evidence.

Now with the same data we are looking at another question. In addition to that risk ratio we have to look at one other thing and that is what we call the P value, which is the frequency with which a given exposure would also be associated with the disease process solely as a matter of chance. Think about flipping those coins. It should be 50/50, heads or tails – we are looking at how much is chance. The threshold statistical significance is customarily set at a P value of .05.

Again, a study could show that a certain substance doubles the risk of getting lung cancer but that study is only statistically significant if the P value generated by the study is less than .05. That means that the association would be observed as a matter of chance only five out of a hundred times.

Under traditional application of the preponderance rule whether the individuals will recover depends on these probabilities and where we are going to draw the probability percentage line.

I will give you one more example. Suppose that a plaintiff's expert testifies that he has done this study showing that 51 percent of those that were exposed to the toxins got thyroid cancer within a year after exposure to the toxin. Assume that the study was well done, does that make it a prima facie case? Does that get you to the decision making? Does the meet the burden of persuasion on the question of causation? Generally, this wouldn't be sufficient in the toxic tort case to meet

preponderance of the evidence standards. Let me try to explain why.

First, we don't have that control group. We don't have the comparison group. We really want to know about everybody who wasn't exposed to that toxin. What percentage of the population under similar conditions would get this type of cancer anyway? We want that relative risk otherwise we are just showing a correlation. We are just showing that people's hair continues to grow after they are exposed to the toxins. That happens anyway. We want to look at who wasn't exposed.

Let's say out of that similar population but who weren't exposed to the toxin 1 percent of that population gets the thyroid cancer anyway. Then you have a pretty good case about causation because you are looking at 50 or of 51 percent of the people who get thyroid cancer. It looks like they get it from exposure to the toxin. We are getting closer to what we think of as a signature disease. This is what happened in the DES cases. Adenoma carcinoma started showing up, which most people have never even heard of the disease previously. It started showing up in large numbers and they were able to trace it back to exposure to DES.

Moving on to the second question. Even if you could say this showed general causation this could happen, it doesn't necessarily show what we think of as specific causation that the toxin caused the claimed effect in this particular case. We don't know which people fall into the 50 percent group and which people fall into the 1 percent group and that is when we asked a lot of other questions. We are going to ask about genetics. We are going to ask about lifestyle. We are going to ask about age, health, gender, and exposure to other environmental factors. What was the level of exposure? Was it the same for everybody in the study? Even if you could use the data to show general causation, it doesn't necessarily mean that it would be enough for specific causation and we are looking for some more information to put you into the right group.

I'm not going to go through these. Don't worry. But in a toxic tort case

when you are trying to figure out whether an association is causal, these are some of the criteria that courts sometimes use. They were developed by Sir Austin Bradford Hill and a lot of courts have adopted them. Some of these will look familiar to you for those of you that are familiar with the vaccine cases, but temporal relationship, experimenting humans, catch on as the association study, the study, so forth and so on just to give you an idea.

There is one other point that we need to keep in mind before we turn to the vaccine cases. In terms of what's happened in the toxic tort area when we are trying to prove causation and that is this. Since the early '90s courts and the law have moved toward applying a heightened standard of scrutiny for expert testimony in both the civil and the criminal area. Courts are attempting to insure that all expert testimony relies on reliable grounds before the testimony is admitted into court. The evolving standard is talked about in terms of reliability rather than general acceptance, but this is the critical point that the test for admissibility of expert testimony has moved from expert testimony alone to credentials plus some adherence to some appropriate professional or technical standards. The watershed case out of the United States Supreme Court is called Daubert 1993. Daubert comes out of a toxic tort case. Daubert comes out of the Benedectin cases. The Supreme Court in that case was concerned with the admission of what was called junk science to prove causation in toxic tort cases.

Again, what the courts are looking for following Daubert and this has happened since '93 and it has been extremely persuasive is we are looking for whether there are others in the relevant scientific community who have had the opportunity to test the conclusions reached by the experts. That is why it is important for the conclusions to be published or publishable so we can subject them to peer review and see what kind of reactions we get about the conclusions that have been reached by these scientists.

If this rigorous testing hasn't or can't occur there won't be the scientists available to testify to the limits of the risks of errors in the scientific analysis at issue.

Because of this the usual safeguards of the trial process, cross-examination, oppose and testimony may be limited. It may be unavailable. It may be ineffective.

One other point. A temporal relationship alone no matter how strong wouldn't usually be sufficient in a regular toxic tort case to move beyond correlations into causation.

Let's turn to the vaccine fund program with that background. If I were to try to focus a single question for us to grapple with when we look at proof of causation in a cause-in-fact case for these off table claims this is what I would ask. What do we do when we have claims for injury in the absence of strong evidence for data on causation? How do we handle that? You could do it through a tort spaced lens or you could do it through a different policy based lens. If we go through the jurisprudence in this area we are going to see that there are strains of both approaches.

Going back over the statute and the legislative history and remarks by Congressman Waxman, our primary architect of the program, we know that the primary goal of the vaccine program is to promote the receipt of and production of vaccines. The concern of the legislation was how to balance the needs of the vaccine-injured individuals, the interest of the vaccine manufacturers, the public health interests, and maintain the vaccine supply as well as the public confidence in mass childhood immunizations. They try to accomplish this in several ways. This is all very familiar to you so first try to protect the manufacturer and administrators from widespread liability. We do this by shielding them from the cost of defending the traditional lawsuit and also creating this fund through this tax-generated fund shifting the cause of compensation over to the fund away from the manufacturer. We want to try to make it easier for the plaintiffs to recover in some expeditious manner allowing them to avoid the proof requirements that you would find in that traditional toxic tort case that we just talked about, file it under an informal, flexible administrative program and here is a quote from the house reporter at the time. Awards were to be made to vaccine-injured persons

quickly, easily, and with certainty and generosity.

Finally, we want to protect the integrity of the childhood vaccines. How do we do that? By not allowing compensation for every single claim, but only for certain injuries and those are the ones that are recognized is what we call table injuries and these off-table injuries where the petitioners have proved cause-in-fact.

We also know that science, public policy concerns are interwoven through the Act. We see this most keenly in the direction to create the table injuries with the statute directing that input begins from the Institute of Medicine from this commission, CDC to HHS. The goal with regard to the table presumably is to have the table reflect current scientific knowledge with regard to what adverse effects are caused by childhood vaccines.

When a petitioner proves that he has an injury in accordance with those listed on the table he creates a presumption that the vaccine caused the injury. This is the way he establishes his prima facie case. In other words, this isn't a conclusion. It is just a presumption. We presume this is true unless somebody tells us otherwise. This is a huge help to the petitioner because proving causation is a substantial hurdle in a traditional toxic tort case. After the petitioner has established his prima facie case this way, the respondent, HHS, may try to defeat the claim. In one major way that the respondent can do this is to show an alternative cause. I call this ruling in the vaccine as well as the cause, as well as ruling out other causes, ruling in and ruling out.

Again, what we are worried about is coincidence. We are worried that there is some other – that some effect happened after the vaccination but there is no causal effect. We are worried about coincidence.

If the petitioner can't satisfy these table requirements he still has another shot under the statute and so he can try to receive compensation through proving what we call a cause-in-fact case. The major difference is that the petitioner is now entitled to the presumption of causation. He has to earn it. He has to make out his prima facie

case. He buries the burden of persuading us that this vaccine caused the claimed effect.

The big question again is how much evidence is enough. What is sufficient to rule in the vaccine as the cause and what is sufficient to rule out of the causes who has to rule the in and who has to rule them out. Let's take a look at the language of the statute here. This is a big slide. Presumably most of you have seen this already. The provisions of section 300 says that you can through affidavits and supporting documentation show that the vaccine cause or significantly aggravated an injury not listed on the table or showed that it is a listed injury but it is outside the time period for the onset.

Also, it says in second part B that there is not a preponderance of the evidence that the illness, et cetera was due to factors unrelated to the administration of the vaccine – by the way this is why I only tell my students never write in the passive voice because that there is not a preponderance doesn't say well who should tell you which is the preponderance. It leaves us two big questions.

Petitioner needs to rule in the vaccine that how much evidence is enough and how to do that, what's sufficient, and also again at part B who has to rule it out. It doesn't really tell us. Unfortunately the statute doesn't give us a whole lot of guidance on these questions. It says that the special master can consider a whole lot of stuff, anything, diagnosis, conclusion, medical judgment, autopsy's report, diagnostic evaluative tests, summary, conclusions, and all other relevant medical and scientific evidence.

None of this is binding on a special master. The special master can determine the way to give each bit of this evidence. It can consider the entire records. The act is written to give the special master great control over what evidence to accept and how much weight to accord it in this administrative proceeding.

When we examine the legislative history, when you turn and look at the

legislative history to this statute, you will see there is a lot of discussion that is focused on the creation of the table, on the revision of the vaccine injury table, bringing claims under the table but there is not a whole lot of discussion about these off table claims. It kind of gives you the idea of how much this mechanism was an afterthought. Most of the misgivings in the legislation was about how to prove actual, how to design the table, what would the breadth of it be to show what actual injuries would show up there.

We do have just a tiny bit; some of you have seen this already too I'm sure. This is section 908 out of the House report that was quoted. You see it in a lot of the early cases and the briefs there but it doesn't tell you a whole lot. This is literally basically all we have on what we mean by proving causation and what the burdens are. Here you see that under this House report that simple similarity to conditions or time periods listed in the table is not sufficient evidence in causation in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. And also the committee does not intend to suggest that variance from the table should act as a presumption against the petitioner but only that such a petitioner is not deemed to be entitled to be eligible for compensation without further showings of caution. It doesn't tell you a whole lot other than what is insufficient there.

The House committee at the time recognized the need either as a practicality or as policy matter to err on the side of over inclusion for compensation at least with regard to table cases. Here you can see that until such time the committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the table and his injuries cannot be demonstrated to be caused by other factors because we anticipate that there will be ongoing studies and we will continue to modify the table. This same scene of the need to err on the side of over compensation was repeated by again Representative Waxman. In the 1999 oversight hearings he said –- now this again in the context of table injuries. He talks about the need to balance being erring on the side of compensation and the need to comport with

medical and scientific facts.

We have always erred on the side of compensating children if there was a scientific argument that injuries were vaccine related. At least that was always our intent. We have tried to rely on the best scientific evidence available when revising the vaccine injury table.

This discussion wasn't directly specifically to the question of what should constitute sufficient proof of an off-table claim, but it captures the tension at the heart of the program between the intent to compensate and the need for sufficient proof of that causal connection.

There have been several oversight hearings since the initial act was written and passed, but it has never changed the Act's initial approach to proving causation.

The original legislation clearly anticipated the greater use of the table for claims. But over time the mix of table cases and off-table cases has changed in a much greater significant number of non-table claims have been brought. Probably the watershed moment for that or time periods for that is when the table itself has changed in 1995 and the cases started changing that. But as a result of that the special masters with this lack of information from the statute itself and from the legislative history they struggled with the issues of how much evidence is enough, who should have to prove ruling in and ruling out the vaccine, and underlying that struggle was the question of how much we should follow traditional tort standards when deciding these causation and fact cases.

Let's turned to how the courts have decided these questions under cause-in-fact cases. But before I do that I want to bring up one underlying premise, which we will need to remind ourselves of. Constantly I will bring this up a little bit later in the talk too and that is this. This comes from the Austin case. We lack significant scientific evidence on general causation for off-table claims. Quoting Althen, this is a

field bereft of complete and direct proof of how vaccines affect the human body. Given that dearth of scientific evidence with regard to general causation, specific causation if these were straight tort cases, you would predict generally that the decisions would be against the petitioners, yet, the decisions don't reflect that result. Other standards are in play and what might be considered insufficient in a common law toxic tort case is sometimes considered sufficient in the vaccine program.

Let's take a look at some of the cases and try to figure this out. Early in the program, 1992. The statute takes a couple years for the program to get off the ground and then for cases that work themselves up to the Federal Circuit. Early case 1992 is Grant. I am going to try to look at a couple of early cases and then the Steven's case and then the trilogy of cases after Stevens.

Grant, the Federal Circuit comes out with a three-part test to prove causation in fact. Here you see the three-part test. You have to show a medical theory causally connecting the vaccine and the injury. You have to show some logical sequence of cause and effect showing that the vaccine was the reason for the injury. And finally you have to show this was reputable medical or scientific explanation. And then the case said if the petitioner satisfies these elements a special master must evaluate whether factors not related to the vaccine caused the injury. It didn't really talk about who had to prove that but we will leave that aside for a minute.

Grant becomes a significant case and later cases rely on this framework. The case itself though has shades of tort law like we talked about before. The first factor is really general causation. Can this happen? Is this a plausible theory from a science medical point of view? The second factor really is what we talked about specific causation. Does it show that the vaccine was the cause of the injury in this particular case? The third factor asked for reputable explanation doesn't really tell us what it means by reputable. It is obviously asking for reliable evidence but doesn't really explain what this means. In this case, '92, coming down the year before Daubert. So

we don't really have the benefit of Daubert yet.

It is telling us you don't need those big studies that we like. The tort cases you don't need epidemiological studies. You need something less than that. It is giving us signals here that may be it is not going to be identical to what you are looking for in the tort context.

Another what I will call early case was Shyface. Shyface involved a DPT vaccine and then there was an unrelated factor, which was an E. coli pneumonia. The petitioner's expert claimed that both were causes of the injury and the government's expert said no. It is really just the E. coli alone that caused the death but we don't really care about that right now. For our purposes this is what we want to focus on the language that they ended up using. They said that we have held that causation in fact in the Vaccine Act context is the same as legal cause in the general torts context. It ends up adopting a test from the restatement second. That restatement is a compendium of views of prominent jurists and academics and lawyers in the field. Each common law area has a restatement. It is run by the American Law Institute. It is periodically reviewed. It is very influential. Courts rely on it for guidance all the time. Here they take a test from the Restatement Second of Torts, which we call the substantial factor test, and they said in adopting it. You see it there. The vaccine is a cause-in-fact when it is substantial factor. In other words, it follows tort law.

These two cases out of many, I just took them on my own judgment, showed these signals from the Federal Circuit. Tort principles could be at play and I don't like these cases.

There were a lot of cases being decided by the special masters, by the Court of Claims, by the Federal Circuit. Twelve years into the program the special masters were still reaching inconsistent results regarding the claims involving similar vaccines and similar injuries. Litigation on cause-in-fact cases was getting costlier. They were getting lengthier. Faced with these problems Chief Special Master Gary

Golkiewicz commendably undertook to clarify the standards for deciding cause-in-fact cases. He came out with a five-part test to show how much evidence the petitioner would need to produce to meet that preponderance test of causation.

Here you have the five-part test: medical plausibility and confirmation of the medical plausibility from the academics community or science community and temporal relationship, elimination of other causes. This is obviously an expansion of the Grant test but it is the same basic principle. The petitioner must show that the vaccine can cause the alleged injury and that the medical and scientific community is linking the vaccine to the injury and that the petitioner must prove that he actually did suffer the injury here. But the test is more demanding than Grant and closer to what was going on in the toxic tort litigation area in this way. It required proof of published or publishable studies in literature following that Daubert line of cases so that the science community could test the hypothesis on both the plausibility of the theory, the expected time period of the onset, and so forth. Also, the last part he suggested is that the petitioner needs to in addition to ruling in the vaccine has to rule out the elimination -– eliminate other causes.

Well Stevens sparked quite a reaction from the Federal Circuit. It used its review of the next trilogy of cases. Althen kept his eye on password to say that the Steven's test was too demanding. There was another issue but that's not important here.

The Federal Circuit says this first. The petitioner doesn't need to supply peer review literature to make out of case. He doesn't need to show epidemiological studies. He doesn't need to show necessarily rechallenged evidence, presence of pathological markers, and general acceptance in the scientific community. Instead the court says he can use reputable medical or scientific explanation. It says that medical opinion alone can be used to satisfy his evidentiary burden. Thus parts 2 and 3 of the Steven's test were too demanding because that asked for that medical literature. Maybe

you need this in other fields but the Federal Circuit says you don't need it here.

Here is a quote from the case. This prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress in which close calls regarding causation are resolved in favor of injured claimants. That last quote close calls are resolved in favor of injured claimants regarding causation. That language whether it is binding or not binding is basically apathetical to the traditional toxic tort approach. Close calls in the tort case are resolved in favor of a descendent. If you can't get over that 50 percent burden, that hurdle, you lose.

Althen resurrects and polishes the test from Grant to require again three elements, in the petitioner's case the chief. Medical theory causing – general causation, specific causation, logical sequence of cause and effect, and temporal relationship between the vaccine and the injury. The Federal Circuit said and often that the petitioner's burden is limited to ruling in the vaccine by meeting these three tests and after meeting these tests the burden shift to the government to HHS to the respondent to rule out other causes by establishing an alternative cause of injury otherwise petitioner entitled compensation.

Meeting this three-part test under Althen gets the petitioner pretty much to the same place as somebody relying on the table in the sense that it established the prima facie case for the petitioner. It will at least give you an inference of causation.

Here is that Althen quote once more that I already raised as the court explained. While this case involves the possible link between a TT vaccination and central nervous system injury, a sequence hitherto unproven in medicine the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body. That is the courts telling us the intent of the Vaccine Act wasn't to make this harder for table versus off-table cases. It was to get them to the same point meeting these standards.

Capizzano, second case in the trilogy comes down just about the same time and it has similar conclusions. It continues to break away from traditional toxic tort litigation approaches. It again emphasizes that the petitioner isn't required to show peer review literature. And importantly it says the following. It says that medical opinion testimony is quite probative since treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccine was the reason for the injury. That quote again is a break away from traditional toxic tort principles in this sense. The Federal Circuit is signaling that it is willing to put tremendous weight on the treating physicians' testimony. In the toxic tort area that wouldn't necessarily be the result.

The problem is just because the clinician has examined the plaintiff tort courts don't necessarily assume that the treating physician has special insight into the relationship between particular toxins and disease. In other words, when treating physicians engage in the differential diagnoses we usually think about them in terms of eliminating other diseases. But we don't necessarily think about them in terms of eliminating causes external to the patient like drugs, like toxins, like chemicals. In a traditional toxic tort case the court would likely qualify the treating physician as an expert in this sense. They would look to see whether that doctor had a background in genetics, had a background in epidemiology, and had a background in keratology, whether he has received formal training in those areas since medical school. In other words, in the toxic tort case just because the treating physician gave a clinical recommendation to discontinue the use of a drug say that wouldn't be sufficient to establish specific causation in the tort lawsuit because we are looking again for expertise on toxic chemicals and on drugs.

The third case in that trilogy was Pafford 2006. It basically reaffirms the same principles, the same tests. In that case it was the opposite results, however. They said the petitioner didn't sufficiently rule in the vaccine as a cause of the juvenile

rheumatoid arthritis that was alleged there. There were multiple potential causes.

But basically these three cases, these trilogy cases, outline what constitutes sufficiency of the evidence in making out that prima facie case; in other words, how to rule in the vaccine as the cause. This still left one other big question and that is ruling out other causes. The Federal Circuits have two other cases in to answer that. That is Walther in 2007 and De Bazan was in 2008. In this the Federal Circuit is really turning to the fifth part of the Steven's test from special master Golkiewicz. And the question was again who has to rule out the vaccine once the petitioner has ruled in the vaccine.

These cases tell us two things. One is that to meet that Althen test to rule in the vaccine as the cause you can do it by meeting the three-part Althen test or if you can't do that, you can basically rule out other possible alternative causes, plausible causes to prove cause-in fact. This is very similar to what would happen in a tort lawsuit. You don't have to rule out every possible cause that could have caused the injury in order to meet your burden of proof, but you again just have to prove that this cause is more likely than not why you suffered an adverse effect. But you can do that by ruling out other obvious known causes of the effect.

I will just give you one example, a tort's case that is a classic case that we teach in tort law called Stubbs v. City of Rochester. In that case the plaintiff was alleging that the City of Rochester had mixed potable water and nonpotable water together by negligence and then the plaintiff is claiming that is why he got typhoid. Now he had to prove that that's what caused his typhoid. The way he did that was by eliminating other probable known causes, not every cause, but the most likely causes of typhoid. In that case the court that was sufficient for him to show that it was the mixing of the water that caused his typhoid.

In other words, if the petitioner receives several vaccines at the same time, yellow fever, typhoid, rabies at the same time she got her Td vaccine that she

claimed caused her ADM, she can demonstrate her prima facie case by eliminating the other causes to show that the one vaccine was the most likely cause. It followed the restatement again of showing burdens of proof and production. Now De Bazan gives us a slightly different lesson. It says to us that once the petitioner makes out her prima facie case the burden formally shifts to the government, the respondent to prove that the petitioner's injury is due to factors unrelated to the vaccine. This is exactly what would happen in the traditional talks of tort case also.

But the government can also try to defeat the petitioner's case in chief, that first prima facie burden, that first part of the case by suggesting that it hasn't addressed these other obvious known causes. It can attack the petitioner's prima facie case by saying you haven't made out your case. If that happened in a regulatory suit we would dismiss it on summary judgment or a motion to dismiss at that point.

Now if the respondent doesn't offer any alternative cause that doesn't mean that there is no alternative cause. You are not entitled to an inference from that failure. The government has the same problem as the petitioner and that is that there may be some unknown cause out. In this area there is just simply so much that is unknown and that is the heart of the problem here.

One last case and that is Andreu. Now -- June 2009, so a couple of months ago. Now Andreu it follows this line of thinking pretty closely but it is interesting from one other point of view. It talks about what you mean by reliable scientific or medical evidence in this context. It says petitioner again quoting that same language from Capizzano and Austin that a sequence hitherto and proven in medicine can be acceptable here. It just needs to be well grounded. But what if scientific evidence is submitted. What if you do submit literature? What if you do submit it an epidemiological study? How trustworthy does that evidence have to be? Andreu quotes the gold standard and toxic tort cases quotes that Daubert standard and says it must be reputable, but here is the language. It says they are not going to look at it through the

same lens as that of a scientist but will examine that evidence with the policies of the program in mind. It says that in contrast to medical research which quoting attribution of causation is typically not made into a level of very near certainty. Perhaps 95 percent probability is achieved. Determination of causation-in-fact under the Vaccine Act involves ascertaining whether a sequence of cause-in-fact is logical and legally probable not medically or scientifically certain. So the shift is now becoming explicit.

The court says that it doesn't have to demand a significance level as strong as that in standard science. They don't have to require confidence level that is statistically significant relationship of a P value of .05 between the vaccine and the suspected category of injuries. That is the standard science approach but they are saying it doesn't have to be the right approach for this program. They are saying that is a policy decision. I could set the P level at .15 rather than .05 and that would be enough to show causation in a prima facie case.

What does this all boil down to? You see threads of a tort-based program and a policy-based approach in all the cases. We see the migration from the tort-based orientation to a policy-based system. What do I mean? I mean as just summarizing we don't need to supply extensive proof of a biological mechanism to test to be plausible. The petitioner doesn't have to supply published literature to support its claim. Often there isn't any. This means that a finding of general causation can be based on reliable medical opinion alone even when there are not supporting studies and medical literature isn't required, but if it is submitted we are going to test it for trustworthiness but not to the same level that a science approach would do or courts would do under traditional toxic tort setting. Treating physician testimony is weighed extremely heavily. Close calls regarding compensation are resolved in favor of the injured claimants.

In conclusion try to demonstrate the threads of both the tort based and the policy-based approaches in the vaccine compensation program. This is a no fault system. But it's not intended to be a no causation system. How far can we go? How

much uncertainty with regard to causation can the system tolerate? In tort law, again, if there is not enough evidence to persuade the plaintiff loses. There are no notions of close calls being made in favor of the plaintiff. There is no notion of generosity in the tort system. Here the problem is that the petitioners are forced to litigate long before the epidemiologic or other research is available. The compensation system must necessarily lag science and it is doing the best to reach the correct results based on the available information. There is nothing wrong with the flexible approach to sufficiency, a proof of causation in the face of this lack of exonerative body of epidemiological evidence.

In the vaccine cases the Federal Circuit seems to be saying that it would be inconsistent with the nature and the purpose of the vaccine program to require the injured claimants to lose every case where it is a close call where there is no direct evidence or strong evidence of general or specific causation.

We are really looking for some possible association rather than causation in the regular legal sense. The theory or the sad fact is that simply often just no evidence and to deal with that and still promote the other policies of the program the Federal Circuit tells us that we should lower the standard for sufficiency. It seems to me that the standard is closer to the preponderance of the available evidence. It is not demanding the same level of science acceptance and certainty you find in the tort system to determine the link between the vaccination and the claimed effects.

The clinical picture is critical evidence. Going back to Congress' desire to be generous as generosity can mean, that we will compensate some people whose injuries may not be caused by the vaccine. Thank you.

MR. SHOEMAKER: That was an excellent presentation. I thank you very much for that. Let me back up just a moment to the beginning when we talk about burden of proof. There are reasons why we have different burdens of proof. You all know the burden of proof in a criminal case. You have to prove someone guilty beyond

a reasonable doubt. There is a reason for that. The reason is we are trying to protect people from being convicted even though it means some people may go free who committed a crime. So I understand why that burden of proof is there.

There are varying burdens of proof. When we have a system in our country where one person is suing another person because they are claiming that they have caused an injury to them like an auto accident case, there is a very good reason why we should have 50 percent plus a feather as a burden of proof. We want to be fair. These two people weigh the same on the scale of justice.

If we could say one thing and if Congress had said one thing that would have helped us in this program it would have been to say this is not a waiver of sovereign immunity. It is a remedial compensation program. Now if you understand what that means, let me explain that. The waiver of sovereign immunity goes back to the king. It means that the king allowed himself to be sued but when he allowed himself to be sued, it was only the restrictive rules that he gave allowing for that suit. In this country our government can only be sued by a statute like the Federal Tort Claims Act that allows the government to be sued. Whenever there is a case under the Federal Tort Claims Act it is always strictly construed against the petitioner or against the plaintiff because you assume that if a government didn't say it they didn't waive it.

This is a program where the funds that go into this program come from all the people who get their children vaccinated or get vaccines. A little piece, a little amount of that money goes into this fund. You have talked about it today how much is in the fund. It's not coming out of the general treasury. It's not coming out of the taxpayers' pocket. It is coming from the people who get the vaccines. The fund is created to do what? It is created to compensate victims.

Maybe a little history might be important to you. Go back with the history of litigation. I recognize that vaccines were important from the day I was born or as soon as I remembered when I was born. My sister had polio the day I was born in 1948

because there was no polio vaccine back then. I know how important vaccines are. When I first got the first swine flu vaccine, it was in 1976 while I was in the Marine Corps and of course if 200 cc's is good enough for the civilians, the military got 400. We got 400 cc's that year of swine flu, A, Victorian and B, Hong Kong, 1200 cc as a flu vaccine.

When I got out of the Marine Corps one of the first things I got involved in was the swine flu litigation. I worked for the firm that became liaison counsel for the multi-district litigation in front of Judge Gazelle involving swine flu cases that a lot of people have made claims that their Guillain-Barre or encephalitis have been caused by swine flu vaccine. I think that probably what happened at that time is a lot of what Professor Grey was talking about in that the courts got to enjoy epidemiology. Why did they like epidemiology so much? Because during the swine flu program one of the government studies showed that if you got swine flu vaccine and developed Guillain-Barre Syndrome within two to three weeks thereafter there was a 10-fold relative risk. That meant there was a 90 percent chance that your case was caused by the vaccine. If you line 10 people up in a room that got Guillain-Barre Syndrome after swine flue vaccine, you could say 9 of you got it from the vaccine, 1 of you got it by chance alone. I don't know which one is the one that got it by chance alone, but for every single one of you there is a 90 percent likelihood that the vaccine caused the injury. That was the P value of .05 or less. That was tremendous epidemiology. It was amazing.

It is very easy to have the kind of evidence that we talk about in those cases. But that epidemiology as Professor Grey has pointed out is not always available and there are many reasons why it's not and we will get into that.

We talked a little bit about -– I am going to go through your presentation because I made some comments to myself as I went through. One of the things Professor Grey talked about was the difference between a jury and what we have in these cases. There are a lot more differences. If you had a jury in one of these cases and you voir dired the jury and found out that one of them had sat on a case a week ago

or a month ago involving a similar issue, you would challenge them for cause. They wouldn't sit on your jury. Jury would be people that don't have any prior experience with this subject. It is a jury of peers who are hearing the evidence for the first time.

It is a little different in this program because I have no idea what experts have told the special master I am in front of last week or last month or last year. These special masters here multiple experts day in and day out for years and I have no idea what they have heard or what they haven't heard from other people, but they become very educated. They become to the point where they are able to cross-examine the experts with the kind of flavor that is normally reserved to seasoned trial attorneys who have really prepared a lot for doing so. It is a totally different situation.

The interesting thing about that, the thing that I would like to point out is that while you would think that might provide an advantage, the disadvantage is that in the program one special master is not bound by the decision of any other special master. If one special master makes a decision that a particular vaccine can cause a particular injury that is not binding on any other special master in the program. Each case has to be proven over and over again, which is one of the things that I think is a criticism of the program but we can't come up with a way to make finding precedents.

Typically, if you were looking at what's called res judicata. If you were looking at a situation where what should I be bound by as a plaintiff. If I come in with a single plaintiff, it shouldn't matter that there is some case that has been decided by a special master adverse to my plaintiff in another case because my plaintiff wasn't a party to that case. He didn't get a chance to cross-examine. He didn't get a chance to participate in that other case so it shouldn't be binding on my client. On the other hand, the Department of Justice is the party in every other case where a petitioner has prevailed. By that logic every single case where a special master decides that a particular vaccine can cause a particular injury should become binding and should be something that every petitioner thereafter can rely upon.

You talked a little bit about the necessity of epidemiology in the toxic tort system. Toxic tort system does like epidemiology but it's not the only way to prove causation. Obviously causation can be proved with other methods like positive rechallenge. What does that mean? Positive rechallenge means if you receive a vaccine like the Hepatitis B vaccine is a perfect example of this because multiple vaccines are given over a period of time. Someone gets the first vaccine and has a reaction then they start getting better. They have the next vaccine. They have another reaction. That is what we call positive rechallenge.

As a matter of fact, the chief special master in the Capizzano case pointed out the fact that this evidence -– the chief special master stated the evidence of rechallenge. This was a case of rheumatoid arthritis after Hepatitis B vaccine. They are quoting the chief special master stated, "this evidence of rechallenge constituted such strong proof of causality that it is unnecessary to determine the mechanism of cause. It is understood to be occurring." There is no reason to prove any medical, biological plausibility. There is not reason to prove a theory. We know it is occurring because of something like positive rechallenge.

Other ways to prove causation include animal studies. Sometimes you have situations where there are biological markers. For instance, the best example of that were the children that developed paralytic polio from the oral polio vaccine before we stopped using it. There they could actually test to see that the particular strain of polio the child was suffering from was the strain being used in the vaccine as opposed to some wild strain. There are many other ways of proving causation besides the use of epidemiology and as Professor Grey pointed out the court has made it quite clear that epidemiology is not required.

Why is epidemiology important and why do we need to consider the difference between vaccines and other things? Vaccine is not like tobacco. It's not something that is unpopular. Vaccines are popular. It is like motherhood and apple pie.

You are not going to get a lot of people to go out and do research to try to prove adverse reactions from vaccines and that is for very good reason. If we didn't have the measles vaccine, for instance, we would have thousands of cases of measles and out of all those kids developing measles a percentage of them would develop post-infectious encephalitis. We know that. We would have lots of case post-infectious encephalitis.

When we have a measles vaccine, we don't have all those thousands of cases of measles, but we have rare cases of post-vaccinal encephalitis from the vaccine itself. It is a trade off we are willing to take in the society and it is certainly a fair trade off because while we would like to eliminate all those cases of post-vaccinal encephalitis, we would rather have a small number of those then have thousands and thousands of children coming down with encephalitis because of the naturally occurring measles virus.

This is why vaccines are important, but you are not going to be able to do a lot of epidemiological tests where you test kids that get the vaccine versus kids that don't get the vaccine because the goal is to give everybody the vaccine. You don't run epidemiological studies where the whole vaccine from kids to see if they have different rates of disease.

The other reason we have problems with the epidemiology in vaccines is because typically vaccines are causing conditions that are caused by other things besides vaccine. There are multiple causes, for instance, Guillain-Barre Syndrome is caused by a lot more things than swine flu vaccine. Obviously that is not the only thing that caused it because we continue to have Guillain-Barre Syndrome day in and day out without swine flu vaccine. It can be caused by a variety of infections or vaccinations or other things. We are dealing with situations where a vaccine is only one of the causes.

If you think of this big tent of multiple sclerosis that is a large number of cases caused by many different factors, many different things can cause it, and now you are trying to prove that by giving Hepatitis B vaccine you are going to produce a relative risk rate of it too. Even if you did it's not going to increase that big pot of multiple

sclerosis. It is going to cause a little bump on it. You may or may not be able to see it. But epidemiology is very difficult to use in these cases.

We actually are going to be doing a study in epidemiology involving vaccines coming up very shortly. We are already doing it because we are vaccinating pregnant women and children with influenza vaccine both mercury containing and vaccine that does not contain mercury. This year pregnant women and children are being recommended to receive influenza vaccine regardless of whether or not it contains mercury. That is a perfect epidemiological study. If we analyze those women and look forward we are going to be able to see whether or not they have more birth defects because they get mercury. We are going to be able to see if the kids who are born have more neurodevelopmental problems. The only reason that study may not take place is because the form that I have seen that is being used for the flue vaccine does not indicate the manufacturer or the lot number. If you are not collecting that information there is going to be no way you can do the study.

I think one thing this committee ought to be looking at is why are we giving this to pregnant women and children in the first place and if we are doing it let's at least make it a good epidemiological study and collect the information necessary.

I agree that temporal association alone is not enough to prove causation. Obviously if I get a vaccine and walk out and get in a car accident, I can't claim that the vaccine caused my car accident unless I pass out or faint from the vaccine or something.

I think we are dealing with the difference between tort based and policy based. Obviously the program initially was a policy-based program. That is what it was designed for. It was to be quick, easy, generous, certain all those things. The table initially, as the chief special master will tell you, resolved over 90 percent of the cases. When the first table came out roughly 90 percent of the cases worked on table cases. After 1995, as Professor Grey pointed out, the tables changed. It was eviscerated. A lot of the stuff was taken out. After that you can probably say that over 90 percent of the

cases are off table cases. The table has become a meaningless thing.

For many, many years back in '97 they added Hepatitis B vaccine to the program. We filed many cases in 1999 before the deadline for the eight-year look back and for many, many years I went to the Hill and lobbied Congress trying to change the burden of proof in this program. I kept my telling my clients if you want to lose your case we can go to hearing as fast as you want, but when we go to hearing you are going to lose. Let me keep trying to lobby Congress to get them to change the burden of proof. Well, Congress didn't change the burden of proof but Professor Grey has pointed out the trilogy of cases that did change the burden of proof and today we have been able to prevail many of our Hepatitis B cases that we kept alive for many, many years.

One thing I would like to point out and I think you made the point, which is an excellent point and I think you made the point as well. One of the problems of this program is we have a statute of limitations of three years. If you don't file within three years, you can't be in the program. Typically in a state tort or tort litigation these children would have time for the science to develop. They would have until they are 18 before the statute of limitations even starts running. Many of these cases would not even be filed by the tort's attorney. A toxic tort's attorney would wait on the science. We can't do that in this program. We can't wait for the science because we have to file so quickly. There are thousands and thousands of cases out there of children who are not able to file in the program because their parents didn't even know they had an injury caused by a vaccine within three years.

I have a mother that called me. I filed a case for a mother that I know I will lose and won't get any attorney's fees on it, but I don't care because this poor woman had a son who received a Hepatitis B vaccines, two or three of them, had reactions after each one, but because they were on Medicaid they kept going to the doctor and they kept saying the child was having psychiatric problems, kept saying he had to go to counseling and this sort of thing. It was not until more than three years later

that the poor mother implored the doctor please do an MRI. Did an MRI. Oh well he may have MS. It is too late. The onset of symptoms occurred more than three years ago. I know I am going to lose the case but it is a case I want to Congress and say this is what you have done. This is one of the recommendations you need to make. If you can't have the time to delay – and I was interested.

I went back and looked at one of the presentations that were made to the ACCV committee back on December 5th, 2001. It was made by a representative from the American Academy of Pediatrics. He recommended at that time a lower burden of proof and he also recommended that petitioners be allowed to stay their proceedings to allow science to catch up. One of the problems we have that – you mentioned that we want this program to be quick to give them their day in court to be expeditious to move quickly. Yes, that is true if we are ready to move expeditiously, but we as petitioners aren't always ready to move expeditiously. We shouldn't be forced to move forward on proving that mercury causes autism too quickly. How many years did it take to prove what Agent Orange caused? How many years did it take to prove that there is a Gulf War Syndrome? How many years did it take to prove that tobacco causes lung cancer? And today you will have people say well tobacco doesn't cause lung cancer. It increases the risk.

We know it takes a long time to establish these things. We need to have a system where if the petitioner wants a delay, it's not going to be held against the special masters or the court. It is kind of like the speedy trial system. We have the criminal law. You are entitled to a speedy trial but if you don't want a speedy trial you can take your time. The petitioners need to have that same option because I have never found anything in the canon of ethics that say that I owe an obligation to my client to be quick. I do owe an obligation to my client to be thorough, to tell them exactly what the situation is, to do the best I can to prevail for them and if that means wait for the science, if that means take a little longer to get your case to court then fine. That's what it means.

Quick is not in the professional ethics anywhere.

The table I think did cause us some problems early on. I remember a case one time that they found that seizures started 76 hours after the vaccination so the child didn't prevail. Early on the table was almost a burden to us because if you didn't come within the table it was almost like you had this bigger burden of proof. I think today we have a system where even though Congress hasn't done anything to change it, I think it has been properly addressed by the court of appeals and I think the court of appeals is right to say that close call should go.

I know in reading your paper about the Homeland Security and looking at some of the other examples of other programs. There are many reasons why programs whether it is Veterans Affairs or whatever should have a different burden of proof. I actually like the veteran's analogy.

We started a clinic at GW Law School last year representing injured veterans who were going through the disability evaluation system, separation process, and facing problems with the Veterans Affairs Administration. One of the reasons I like the analogy so much goes back to what happened after the swine flu program back in the late '70s. At that time the government stepped on the shoes of the manufacturers and the administrators. You had to bring a claim under the Federal Tort Claims Act on behalf of your plaintiff and the cases were all tried before federal judges and federal district courts all over the country. Just to make sure I'm not picking on special masters let me just say this. Every single case I won involving swine flu could have lost in front of a different federal judge and vice versa. There is a lot of discrepancy among federal judges all over this country in terms of which ones rule for and against us. A lot of it has to do with the jury or judge receives it.

The point I am trying to make is that back at that time we were – I forgot what I was trying to make. That is called halfzheimer's. The reason I like the analogy is because after the swine flu program there was a conference held over at Georgetown

University. Dr. Blonk(?), he organized the conference on the public policy issues involving vaccinations, he brought in a lot of speakers from around the country trying to figure out a better way to handle litigation involving vaccine victims. That conference I think went a long way even though it wasn't until almost a decade later that we actually got this program up and running and funded and going. I think that conference was an important step in the right direction.

One of the speakers of that conference Dr. Leroy Walters analogized the pediatric warriors. He said our children are like pediatric warriors in the war against infectious diseases and like all wars some people are injured. Some of the soldiers get injured. He said with this war even though it is mandatory conscription because you had to get the vaccines to go to school. He said even though a lot of the reason you are getting the vaccine is to protect yourself, you are also doing it to protect other around you. When people say people are vaccinated shouldn't be worried about somebody who is unvaccinated, I don't agree with that because there are a lot of people who have immune conditions where they can't be protected by vaccines so it is important to be vaccinated. It is important to protect other people. The point he was saying was that as in all was some of these children were injured; however, unlike the veterans system back at that time what we were doing is telling these children thanks for your contribution to the war effort and best of luck with your disability. That is really not what this program is all about.

This program is about compensating children. It is about compensating children even if we get it wrong sometimes and even if some of the kids who get compensation maybe if you put a red dot on their forehead to say this was caused, that wasn't, this was, that wasn't. Maybe you compensate some that you shouldn't. Would that be such a terrible thing to have happened? I think the goal of this program should be to over compensate not to under compensate and it should be to make the system move smoothly and move quickly. It should allow petitioners the time to wait for the

science when they need to but when they are ready to go forward we shouldn't be involved in four pieces of litigation, one involving the onset, one involving the experts, one involving the damages, and then the final involving fees. It shouldn't be that tough. It should be much simpler, much more streamlined system. I would be glad to come back and talk to you about the fee's issue that you are going to be addressing in the future because I think that is an important issue.

The reason that issue is important goes back to the toxic tort issue. You can't afford to do epidemiology. You can't afford to hire the experts that you need to hire. You can't afford to do the job you would do in toxic tort litigation in this program. It is simply not in the cards. You are not getting contingent fees. You don't even know if you are going to get all your fees compensated. You don't know if your experts are going to be paid. You don't know if you are going to get paid for all this stuff until the end and you are not going to get paid everything you have asked for. It is not like toxic torts where the MDL committee for swine flu, for instance, went out and spent a lot of money doing studies, hiring experts to look at things to do epidemiology, to do analyses and so forth. We don't get compensated for that in the program.

It is interesting to me that this program pays for studies of the VAERS database, the VSD database, and the other things that get published and are used against us. But we as petitioners don't have the right to even look at the data. We don't have the right to have our experts go in and analyze it. We are not going to get compensated or paid for our consultants or experts working on this data or doing studies. If they do the studies and publish them, that is not something that is compensated under the program. That is very different than toxic torts believe me. In toxic torts you make plenty of money to cover all of those expenses in most cases. That is the situation.

The Andreu case let me just finish with that because I think Andreu stood for a couple of things. A lot of people think it didn't mean anything. I think it does mean

a couple of things. One is it means that if you have reputable doctors testifying, you cannot reintroduce the Stevens' test by challenging their credibility. So that you can't challenge that by saying well you weren't credible because you didn't provide epidemiology or you didn't provide medical evidence. You didn't provide this or that therefore you are not credible. Credibility determinations are reserved for fact witnesses not experts, not qualified experts. Daubert should not be applied to the extent that it is in civil arena in these cases, but a doctor should be a respected doctor. They should provide the evidence, the basis for their opinions. In most cases they do.

You have to understand the difference between a petitioner in this program getting an expert and a respondent getting an expert. A petitioner in this program is asking someone to wait to be paid to testify against the government and to run the risk they are going to have their character impugned. That is a pretty tough road to put somebody down. On the other hand, if you were asked to testify on behalf of the government that is a job that I think anyone would take. Any chairman of any department anywhere is going to take that job on.

The other thing that Andreu stood for was the fact that yes Capizzano did say that treating doctors are important but we really shouldn't be going out and taking the testimony and challenging the opinions of treating doctors that they have written in the medical records. That is what happened in that case. We had treating doctors who had written enough in the medical records that we should have been able to rely upon that and that should have been important enough to say okay. We can take that. Because believe me when a treating doctor writes something in the record against your client, nobody wants to go out and take their challenge them on that. They just accept that. But here we had enough. But the court said you really shouldn't go out and interfere with that patient, doctor privilege. You shouldn't be interfering with these doctor relationships and threatening them with testimony and so forth. Don't go overboard Capizzano. Don't go out because some doctor wrote in the record I think it was caused

by the record. Don't go out and challenge them and try to find the basis for their opinion and try to put them down. That is not what treating doctors are normally for. As Professor Grey pointed out, one of the reasons we rarely use treating doctors as experts in cases is because that's not what they do. They don't sit around studying vaccine reactions. They treat patients for conditions. I think that is what the Andreu case stands for. If there are any questions we would be happy to answer them.

Agenda Item: Questions and Answers

MR. SCONYERS: Thank you. This was an interesting presentation. Especially Professor Grey, thank you for bringing things together. The question that occurred to me is one that I really want to address to Dr. Evans, which is in light of Althen, Capizzano, and Andreu how has the program altered its approach to cases in order to resolve close calls in favor of injury claimants?

DR. EVANS: I will defer the question to Mr. Rogers because that has to do with the way that the program is litigated in the cases both in terms of litigated settlements and so on. We have discussed this at length. We are faced with a situation in which we think science says one thing but the courts and the special masters are interpreting the law differently and we have to face the reality that we are not going to if we were to pursue a defense in the case. It is not a case that is likely to be successful so litigated settlements have become the predominant way in terms of management of our program.

MR. SCONYERS: I don't want to take away from Mark if he wants to address it. Another approach to the program could take it seems to me -– cases in light of the three cases that we have been talking about rather than to refer them to litigation. That has always been the prerogative of the program, as I understand it. These are not complete -– of the courts. This is the controlling law for this program.

DR. EVANS: Mark could probably say this much more eloquently in terms of the legal aspects of this. But in terms of the medicine our role as we have

viewed it over the years has been to defend the Secretary's decision with regard to science as well as some policy considerations. And the science as it stands today is that many of the conditions that are being litigated, resettled in this program are conditions in which there is really very little indication or any credible proof that the vaccines have any role whatsoever in causation.

MR. SCONYERS: So this is basically a dispute between the executive and the judiciary in which the executive doesn't accept the results of the courts.

DR. EVANS: I think that answer should come from someone whose paycheck is a little bit above mine. I guess in some sense you could reduce it to that, but again we have what we believe is our role. We have put a great deal of time in trying to put together the information and recommendations of the court that reflects our best understanding of where the current science of understanding vaccine causation is right now. The Congress in its wisdom made this – the only federal compensation program that I am aware of that has a judicial component to it. They did that for a reason. We view our role in the terms of the science and then the way that this plays out is the way that it plays out.

MR. SCONYERS: I understand what you are saying about your view about the science, but the courts have instructed you to the contrary. The courts have instructed you that closed policy. The courts have instructed you that rather than scientific proof these cases are to be resolved on the basis of the decisions in – they weren't appealed to the Supreme Court that I know of. They may have been but they haven't been overturned by the Supreme Court. They are the controlling law for the program. You don't get to choose. You don't get to say just the statute is controlling. You have to say the statute and the case law.

MS. GREY: I just want to say this. This isn't a no causation program. This is a no fault. There is some notion of causation for when you say that these courts have instructed special masters. You have these statistics better than I do but it seems

like a lot more cases are going in favor of petitioners than it used to be. I think that that shift has actually occurred. You all know this information a lot better.

DR. EVANS: I believe that Jeff understands that quite well. Jeff, your point has been made previously and again it is certainly a valid point. It is one that we will take under consideration.

MS. BUCK: I wanted to draw another element into that and this is Tawny and everybody knows that I said this before. I believe that this is why I have such a difficult time with HRSA funding, the IOM contract to look at these vaccines and establish a table based on a scientific certainty. That does not mean that I don't think that perhaps that needs to be done, but I have a problem with it coming from this program because of the things that I am hearing today about this conflict or this push between science and policy. That is where I want to make my comments about that contract and its purpose and what it is doing. They are about funding of it and whom that contract is being paid for. My comments in the past just to clarify for the Commission are based from this conversation that we are having not on the necessity perhaps for that to be done.

MR. SHOEMAKER: Can I just add one thing about the reason why it is important to resolve cases short of protracted litigation. It goes to a public policy consideration. It goes to one of the reasons for this program and that is that you want to develop public confidence in vaccination programs. You want to prevent future civil litigation. If you want to prevent future civil litigation, you can say well if the burden of proof is the same for causation but you don't have to prove a theory of liability then anyone who loses in the program should never file civil case. Okay you can say that, but if you reduce the burden of proof in the program so that it is lower than the civil arena and now a case loses in the program with a lower burden of proof there is no lawyer in this country that is going to take that case on a contingent fee and go sue a manufacturer or administrator where he has a higher burden of proof plus he has to

prove a theory of liability. It's not going to happen. One of the ways you keep cases out of the civil arena is by having a lower burden of proof and yes not having to prove liability. Those are important things.

The other reason why it is important not to litigate is because when you litigate you draw attention to something. You put it on every blog out there. You put it all over the Internet. You create this tremendous diversion and you actually reduce the vaccination rates. If after the swine flu drug in '76, if they had gone out and said look we're not sure if your case was caused by the swine flu or not but its close enough. We are going to compensate you but we also want you to participate in this study. We are doing a definitive study of Guillain-Barre Syndrome. We want to periodically take a blood sample. We want to look at your medical records. You are going to become a big study. We are sorry this happened. We don't know if the vaccine caused it or not but we are going to bend over backwards to compensate you and help you out here. If they had done that and if they had used an insurance adjustment firm to do it, cases would have been resolved in six months. We would have had the definitive study on Guillain-Barre Syndrome and I wouldn't have spent two years going all over the country trying cases and making contingent fees. It just makes sense to do things that way. That is the way it should be done. Yes, if it means over compensating. Somebody one time suggested if a child dies within a day or two of a vaccination, should they just be automatically compensated? Yes, why not? Because then you can step forward and you tell the public we don't think it is caused by it but we are going to bend over backwards to compensate anyway and therefore you should have confidence in the vaccines. There should be no problem with the vaccines, but if you make the litigation go on and on and protract it, that puts it on the blogs and that's what ends up causing a lack of public confidence.

DR. EVANS: I would like to respond to Tawny's point. Tawny, we discussed this at the June meeting. Unfortunately we did not in terms of conflict of

interest and HRSA monies unfortunately we ran out of time and did not have the opportunity for Dr. Stratton to go over the project and also explain a little bit about the background of what she has been doing in these projects over the years. I would like to defer that criticism and concern to Dr. Stratton's presentation tomorrow. I think that perhaps when you understand it's not so much the source of the monies but really the fact that the Institute of Medicine, a chartered body by Congress, is doing this is really a very important determinant in terms of the quality of the outcome.

DR. HERR: This is Tom Herr. I appreciate the presentations today. It has been very helpful as far as I'm not an attorney trying to understand these things and on the idea of the program I can't agree with you more on the idea is that these kids are soldiers. The problem is that with the decrease of what I see burden of proof or responsibility of burden of proof with the recent decision I think it has an incredible amount to undermine public's confidence in vaccines because the blogs are all there. The newspapers are all there. The government doesn't have or isn't having the option of saying we don't think this caused anything. We are going to compensate you anyway because the allegations are that vaccines did cause it because that is what information is put out there. The idea of the practicing physician, the attending physician, the primary care provider, which I am, being knowledgeable enough to say that it caused the injury, I think it is actually putting too much credit on that particular person. I know I don't have the training. I may suspect things, which is why I fill out forms and why I might talk to the families and say we need to look into this. When I counsel somebody who comes into my office and gets a vaccine and say if anything happens that makes you nervous after this vaccine in the next number of days or weeks, I want you to tell me. I am not smart enough to say that this particular incident caused that outcome. That is why I rely on what I consider true scientists to help and come up with that decision. I am concerned that the level of expertise has been significantly lowered.

MR. SHOEMAKER: Let me respond to that. You read a package insert I

assume lately? Okay. And that package insert says this, this, and this have been reported. We are the only country in the world that allows prescription drug advertising but what do you hear at the very end of every one that can cause this, this, and this. I don't think that cases that are settled get any publicity at all anywhere. I don't think anybody looks at those and says that's a reason not to get vaccinated. I think on the contrary the ones that go to the court of appeals and get into the National Law Journal and things like that those do create the problems. We are never going to be able to have doctors who are going to say definitively – you might be able to look and say well there is a 1 percent chance of this. All you can say about the other things is it has been reported. That is just the way medicine is. That is the way the package insert looks.

One of the things we did wittingly or unwittingly with the VAERS database is we stopped doctors from sending in case reports. Before the VAERS database if a doctor had something that occurred after a vaccine, what would they do? They would write a case report. They would submit it to a medical journal. Some other doctor would see it and he would write a case report and then somebody would write a series and then this is how things would grow in the medical literature and pretty soon they would be epidemiological studies. The VAERS database has changed all that because as a doctor you don't write a case report. What do you do? You send a report to VAERS. That is the way you do it.

We changed the way we look at vaccines from the traditional way the products are looked at in medicine. It is just a different way of doing business.

MS. HOIBERG: This is Sarah Hoiberg. It is really just kind of a statement. As a parent of a vaccine-injured child I do have a vested interest. You may all think that I am crazy and what not. I agree with the fact that vaccines are important and that I desperately need everyone around me to vaccinate their child so that my kids can be safe. If the parents had the guarantee from the government that you were there for us if our kids got hurt and that we weren't going to be treated pretty much as

criminals or money grubbing greedy people then it would be so much better. No one knows about vaccine injuries. That is the whole thing. No one really knows about vaccine injuries. All they know is what they hear and now with the whole thing with autism and like Cliff said. If these things were compensated and taken care of quietly you wouldn't have the scares that you have. But because it has been made such a huge deal and you have these parents that are just out there pretty much rioting because they need help for their kids and the government is not listening and they are being treated as – and the experts being defamed and all that kind of stuff. You have made it an issue. You know what. I will take my chances with the disease.

I guess what we are asking as parents is compensate our kids. Take care of those who have been injured. If your goal and our goal is to protect the vaccine and to make that decision to vaccinate their children then compensate the people who have been injured so that they don't get out there and start talking about how horrible the vaccines are and it can kill your kid and you could have this and you could have that. If you are compensated you tend to be a little bit quieter. I am not out there screaming about how terrible the vaccines are in public. I'm not. The government took my child and she is taken care of for the rest of her life and for that I am eternally grateful. But there are other children out there with worst-case scenarios than Katelyn and they have no recourse whatsoever and that is what we are asking for. That is what Mr. Shoemaker fights for everyday is to compensate those poor families that don't two dimes to rub together to help their kids. Thank you.

DR. EVANS: Mine was just for clarification.

MR. BUCK: I just wanted to respond back to your comment to me about the IOM because I'm not going to be here tomorrow and I will miss the presentation. I wanted to be clear. I actually do pretty well understand what's going on with the IOM contract. My concerns are not something that Dr. Stratton would even address. My concerns are about what I believe to be a conflict of interest in terms of who is holding

the contract and who is funding the work not the work itself. I always feel like that part of my message isn't heard, which is I understand that this work will probably be done and it should be done. IOM does quality work on a lot of this. My little piece of it is just what I believe is an inappropriate – I don't think HRSA should be the contractor and I don't think this funding should come from the program or the administrative costs or however you want to define it and that is just my piece because I am not going to be here tomorrow and I actually wouldn't address with Dr. Stratton anyway because I think Dr. Stratton is going to be talking about the work she is doing and I don't think that is my issue.

MR. SHOEMAKER: Let me add to what you just said. I am not speaking of just IOM studies. There are a lot of studies that get published in the literature that our studies of the VAERS database and the VSD database outside the IOM that if you look at the study it was funded by funds from this program. This program is funding those studies, which end up getting used against us. My experts don't have the right to get that kind of funding. They don't even get paid for doing studies in the program. With regard to the IOM I think we are dealing with a situation where I have never heard of an IOM meeting in 2004 saying no further research is necessary. I encourage you to look at the 2005 IOM study which said access to the VSD database should be given to petitioners, experts and outside experts.

DR. EVANS: Maybe I misheard but Mr. Shoemaker I thought you said during your remarks that program money had paid for VSD research. I am not aware of any trust fund monies for any of the entities.

MR. SHOEMAKER: I will provide the papers for you.

MS. DREW: Thank you very much Professor Grey and Mr. Shoemaker.

MS. CASTRO-LEWIS: Thank you so much. We can continue with our agenda. We are a little behind or just a few minutes late. We have next an update on the immunization safety office from the Centers for Disease Control and Prevention

Vaccine Activities. How do you say your name? Dr. Gidudu.

PARTICIPANT: Excuse me. I am sorry. I apologize for the interruption. This is the conference coordinator. If we could have our speakers get a little closer to a microphone. Participants by telephone are having a difficult time hearing questions. Thank you.

Agenda Item: Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities

DR. GIDUDU: Good afternoon everybody. I have a problem with my voice but I hope you can hear me. My name is Jane Gidudu. My presentation is an update from CDC and specifically it is from the Immunization Safety Office. I appreciate the opportunity to come here today and I wanted to give one brief update. In terms of our office we do now have a current director who is Dr. Frank Destephano. We have had over the years we have had a lot of acting directors and we now have a permanent one.

We know that vaccines to protect again it is the pandemic H1N1 vaccines have just been approved a few days ago by the FDA on September 15th and they are anticipated to become available probably in the first week of October. Coordination and communication for vaccine safety related activities at all levels are very critical for the H1N1 vaccination campaign.

Vaccine safety monitoring is a share responsibility among the Federal Government, state and local health departments, vaccine manufacturers, healthcare providers, and the general public.

I want to emphasize again the mission of our office. Our mission is to perform high quality vaccine safety research, to identify adverse events following immunization through public health surveillance, to assess causality and preventable risk factors for adverse events. We pursue our mission in order to protect the public's health and improve the safety of vaccines.

Today I am going to talk mainly about two main activities. One is monitoring the safety of influenza H1N1 2009 monovalent vaccine, which I will just refer to as 2009 H1N1 vaccine, and briefly about monitoring the safety of HPV vaccine, which was recently published in the JAMA paper, which you have in your binders.

I borrowed this slide from Anne Schuchat from her talk yesterday at NVAC. She is the Assistant Surgeon General in the U.S. Public Health Service and many of you know her. There are about over 20,000 cases that are -- confirmed cases in the U.S. and more than 70,000 cases worldwide and they are increasing daily. The majority of persons in the U.S. that have been hospitalized and some have died, due to other underlying conditions. More cases I expected and transmission will likely continue into the fall, which coincides with our annual influenza season. Young people have been disproportionately affected and socially very disruptive especially for schools. I want to thank the many healthcare workers and others who are responding to this worldwide pandemic.

The U.S. government has a four-pillar strategy to address preparations for the novel H1N1 influenza epidemic. We have surveillance. We have mitigation. We have vaccination-pillar and communication and our office falls under the vaccination-pillar.

Following a special SCI(?) committee in July, the priority age groups for receiving vaccines as you all know include pregnant women, household contacts caregivers for young children, and children who are younger than six months of age, and in healthcare workers and emergency workers and those in the six months to 24-year age group, as well as persons 25 through 64 years who have other health conditions associated with the higher risk of medical complications from influenza. This slide is a flow diagram on how vaccine safety for influenza H1N1 vaccine will be conducted in the country. It involves various personnel all listed here and our office is one of the players.

When seasonal influenza vaccines are administered as indicated they are

safe. It is our discredit that the safety profile of the H1N1 vaccine will be similar to the seasonal influenza vaccine.

Serious adverse events after vaccinations have been uncommon. Vaccine safety monitoring is a critical component of that pandemic H1N1 influenza response. The objectives of monitoring that vaccine safety are to identify the clinically significant adverse events following receipt of the H1N1 vaccine in a timely manner. Rapidly evaluate serious adverse events following receipt of the 2009 H1N1 vaccine and determine the appropriate public health importance. And evaluate if there is a risk of GBS associated with this vaccine and other specified outcomes. My previous speaker has really highlighted the importance of this -– that 1976 pandemic or the situation that was then. We would love to communicate the vaccine safety information in a clear and transparent manner to healthcare providers, public health officials, and the entire public.

We plan to use this graph here as a summary of our monitoring activities. We plan to use our established routine surveillance systems outlined here on the left. These include the various systems that my previous speaker mentioned, about that many of you might be familiar with largely for signal detection or identification of potential vaccine adverse events or concern. The Vaccine Safety Datalink or VSD and that Clinical Immunization Safety Assessment Network are used for signal verification.

On the right are the systems that have been enhanced for monitoring safety of the 2009 H1N1 vaccine. They have been enhanced to manage an increase of reports we expect a slight increase of reports predicted up to a thousand reports a day, and we also have a Real Time Immunization Monitoring System, that is, RTIMS. The Defense Surveillance System, which is DMSS, will also be used. We hope to also conduct GBS Active Case Findings as well, and use an expanded healthcare plan system to monitor the safety of this vaccine. These are all again I emphasize, collaborative efforts with various partners all listed on this slide here.

I will go ahead and just mention some of the examples of the systems

that I have already just outlined. Many of you know VAERS. They are the Vaccine Adverse Event Reporting System. It is a voluntary reporting system jointly managed by CDC and FDA. It has its advantages. It is large in scope. It is very flexible and it encourages a lot of reporting from healthcare providers as well as the vaccinnees and others.

We have planned system enhancements and communication efforts to promote timely reporting among healthcare providers and CDC is working with states and personnel organizations. We recently had with best training to the state project officers and we have a planned session with Coca Cola as well in the future. We are increasing CDC's staffing to process VAERS reports more rapidly and would like to facilitate reporting of manufacturer information including information of lot numbers and vaccination cards to persons receiving the 2009 H1N1 vaccine.

DR. HERR: The enhancement this year or this season in VAERS, is that there are more people at the CDC to process the information as opposed to the fact that physicians and distributors or whatever, have always been encouraged to report any findings. Now the problem is they are going to process this or report this as soon as it happens as soon as they remember. The enhancement is that there are more people who deal with the reports.

DR. GIDUDU: Yes. We typically get about 150 reports a day and our staff currently of less than 10 people of which about 2 medical officers, are very few to really have a good look at those reports. We have a very fast system of electing priority – but we need to – obstruction and we need additional people for that. Another angle to that is we have a contractor who actually enters, who gets the reports. It's not CDC that gets the reports. It is got by SRA, and SRA we have revamped their system to increase also and get the report into them into our systems and code them for us. It is various angles but within CDC we have increased people from other groups and hiring other people to come and help us review the reports.

The next system is Vaccine Safety Datalink, which are also monitored advances in following this new vaccine. VSD is a collaborative effort between CDC and eight managed care organizations representing approximately nine million of the US population. VSD uses rapid psychoanalysis to monitor specified adverse events in near real time using appropriate comparison groups. Adverse events of potential concerns that are identified in VAERS and other sources may be added to the specific outcomes. This provides accurate vaccination information within the managed care databases and we would be able to have outcomes linked to exposure. In this case the exposure would be the H1N1 vaccine.

Another system is the Vaccine Analytic Unit, which is a collaboration among the Department of Defense, CDC, and FDA, which is DMSS, that I mentioned earlier. This has data on about 1.5 million active US military personnel. The VAU will also monitor adverse events similar to the methodology that is used in VSD.

We have another system which is the Real Time Monitoring System, which we call abbreviated RTIMS, which is for timely identification as well and rapid evaluation of adverse events following the immunization. This is a collaboration between CDC and School of Public Health at Johns Hopkins. It is an automated web-based surveillance system for certain sub-populations of vaccinees like school-aged children, healthcare workers, and pregnant women. Enrollment will be at the time of vaccination and follow up periodically will be post-vaccination up to 42 days. I have already mentioned that it is a collaboration between the two entities.

This next slide we have another system, which is an in-house – this is a new system which is a collaboration between the FDA and CDC to increase capacity to monitor vaccine safety in real time as well. This is going to use vaccine registry data, which will be linked to outcome data as available in large healthcare plans in selected states. I don't have so many details on this system but this also is one of the ones we are going to be looking at. It is going to use the same kind of methodology like RCA.

We have these systems and we hope that they are robust enough to be able to generate for us the information that we need.

A next example here of monitoring GBS since it is a very sensitive issue since the 1976 immunization campaign, CDC will perform active Guillain-Barre surveillance(?) through the emerging infectious program, EIP, which is a population-based network with CDC in 10 states and state health departments. Working in collaboration with local states departments, public health laboratories, clinical laboratories, infection controlled practitioners, healthcare providers, academic institutions and other federal agencies. CDC has also established collaboration with American Academy of Neurology. They are reporting of neurological events and actually beyond neurological events we have a list of outcomes of concern that we will actively monitoring for.

I want to talk about one of the systems we have which is CISA, the Clinical Immunization Safety Assessment, which is a collaboration again between CDC and six academic centers, Johns Hopkins, Vanderbilt, Columbia, Boston Medical Center, Stanford, and Northern California Kaiser. These are experts. We have a lot of expertise in these individuals. They will provide clinical expertise and consultation in the evaluation of serious adverse events after the vaccine administration. We have already been working with them on various protocols and who is actually running two very complicated cases, this resource we can tap into.

We plan to rapidly communicate vaccine safety information to support informed decision makers about our chain. We want to base vaccine safety communication material on the best available science. Our Immunization Safety Office and its research and surveillance partners, would like to provide the best expertise to the CDC communications team. We want to collaborate closely with the state and local health departments and other partner organizations involved with vaccine safety communications.

I want to now turn back to the second part of my update, which is the postlicensure, a study which is the Postlicensure Safety Surveillance for Quadrivalent HPV Recombinant Vaccine by Slade and others, that was published in JAMA last month.

This is the first published comprehensive review of adverse events following HPV immunization in the U.S. to VAERS between the periods June 2006 through December 2008. This is after over about 23 million doses have been distributed. VAERS obtained over 12,000 reports of adverse events were filed to VAERS and this mainly included syncope, local reactions, dizziness, nausea and headache. About 6 percent of these reports were serious reports and we had 56 repots of venous thromboembolic events. Those who had the venous thromboembolic events had other non-risk factors. Some of them were using estrogen birth control pills and others. All the details of this are in the paper. I want to mention that VAERS reports do not establish a causal relationship between the vaccine and the adverse events.

I want to share some of the resources I have for you here on this slide and I want to again as I mentioned earlier emphasize that coordination and communications of vaccine safety related activities at all levels are very critical for the H1N1 vaccination. Vaccine safety monitoring is a shared responsibility among the Federal Government, state and local departments, vaccine manufacturers, healthcare providers and all partners including the public and I want to acknowledge all these people listed here. Thank you for listening to me. I will take a few questions.

MS. CASTRO-LEWIS: Thank you very much Dr. Gidudu. Are there any questions for her at this point? Thank you so much.

Dr. Mulach, we would like to continue with the update on the National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Agenda Item: Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities

DR. MULACH: Sure, thank you. I just wanted to briefly talk a little bit

about some of the H1N1 clinical trials that have been ongoing. We have been doing some trials in a stepwise fashion. We conducted trials at the Sanofi Pasteur and the CSL vaccine. This is in addition to some of the trials that are being sponsored directly by the manufacturers themselves. Basically we started with adults and then moved into elderly patients and we are still continuing the elderly studies and now we have started in the pediatric populations 6 months to 17 months and also recently started our first trial in pregnant women. To let everyone know the trials in the children and the pregnant women are thimerosal-free vaccines. We have some preliminary data from the adults as do some of the manufacturers that show that the 15-microgram dose seems to be given immune response and seems to be safe. We are continuing those studies. We will have more data with the second dose and we will continue to monitor those patients and then we look forward to more information on the pediatric results and the pregnant women studies.

Again, the reason we are doing these trials is because those have been identified as priority populations and we want to know as much as we can about the vaccine before we start the larger scale vaccination efforts.

DR. HERR: Has there been any studies done on the intranasal vaccine?

DR. MULACH: We are not currently doing those. I believe the manufacturer might be doing those.

DR. HERR: Do we have any information on it?

DR. GRUBER: Not yet.

MR. SCONYERS: The vaccine that is scheduled to be released is that going to be available in single dose vials or is it going to be in multi-dose vials do you know?

DR. GRUBER: Am I speaking through the microphone here? There will be single dose vials. There will be multi-dose vials and implied in your question I guess is a big question. Will there be thimerosal preservatives in these vaccines? Of course in

the single dose vials they will be thimerosal-free presentations. The multi-dose vials are the current regulations need to contain thimerosal.

MR. SCONYERS: Are they going to be released at the same time?

DR. GRUBER: They will be released at the same time. That is what I have been informed.

MS. HOIBERG: Dr. Gruber, this is Sarah Hoiberg. I was wondering why are we reintroducing vaccines with thimerosal?

DR. GRUBER: This is a decision that is being –- first of all we don't reintroduce vaccines with thimerosal, influenza vaccines, as you know, these influenza vaccines have contained thimerosal because the presentations are in multi-dose vials and in single dose vials and under current regulations as I referred to, multi-dose vials need to contain the preservative. That is the law.

With that being said, there have been tremendous efforts, especially by influenza vaccine manufacturers, to really build new plans, establish new filling lines so that you can really fill these vaccines in pre-filled syringes and single dose vials thereby obviating the need to put preservatives in these vials. It is an effort that is ongoing over the last couple of years and capacity is just not there at this point to really fill them all and to fill those vials.

The other argument is being made by policy makers are in the scenarios of a mass vaccination program. Multi-dose vials are actually a feasible and practical option because they don't require the same cold-chain capacity. In other words, you don't need that much refrigerator space. There are many reasons for that.

But again, for H1N1 and specifically I have been informed by BARDA that at the time the vaccine are being released, initially we will have about the same amount of thimerosal preservatives-free vaccines as thimerosal preservative-containing vaccines. You may know that at the time of release we are not going to have enough H1N1 vaccine to really supply and immunize everybody. Initially we will have about 45

million doses available. I have been informed about half of them are going to be thimerosal preservative-free. The other half will contain.

MS. HOIBERG: Unfortunately you are going to have people that aren't going to take it because it has the thimerosal in it. You are going to end up having more people that are not going to vaccinate against it because it has the thimerosal in it.

DR. GRUBER: I think this whole thing is a voluntary program and I think much of the recommendations that are reported – these are current recommendations. I think what is going on right now there is an intense surveillance about the epidemiology of this disease of the virus and I think we have to follow this very closely in the next couple of months to see if even recommendations will change. I'm not saying that I heard anything about that but I think this whole epidemiology of this H1N1 vials is under close surveillance.

MS. CASTRO-LEWIS: I do have a question and then I will pass on to you. I just want to question. Are there any provisions for doctors to inform or let the consumers know if the vaccine they are getting has the preservative or not or is going to be just the decision of the doctor?

DR. GRUBER: If I understand you correctly your question goes towards are there some distribution efforts that targets special subject population – are going to get thimerosal preservative free vaccines –

MS. CASTRO-LEWIS: More specifically is there information given to the consumer at the time of the vaccination? You are receiving the vaccine with thimerosal or not.

DR. GRUBER: I don't think that there is specific emphasis being made. The vaccine information sheet, as my understanding, contains that type of information and of course the consumer can ask. Am I not correct about vaccine information sheets do not contain that information? I thought that was the case.

MS. CASTRO-LEWIS: We haven't seen it yet.

DR. GRUBER: Geoff, help me out here.

DR. EVANS: I think as you heard Magda yesterday at NVAC, there is a great deal of information that is in the plans of being distributed. While it does not have this specifically there will be many other avenues of information that will be made available to practitioners and the public as this unfolds.

MS. CASTRO-LEWIS: I hear a lot of information but I also want our Commission to hear it too so that is why I asked the question.

MS. BUCK: Barbara, can you talk to me about clinical trials that may be going on for high-risk kids?

DR. MULACH: I do not have any information on specific sub-populations. I know there have been a lot of discussions about potential populations that we can test. I have heard things turn about children and other subpopulations, but I think at this point in time what we were trying to do is get the general lay of the land and those studies would be follow on studies. I would be glad to keep you informed of any follow-up studies.

MR. SCONYERS: I do have a question for Barbara and you may have said it. I just may have missed it. Do you know when the crunch studies on pregnant women and the pediatric population are going to conclude?

DR. MULACH: The question was about when we would have information about the pediatric populations and the pregnant women. I think it will be similar with the adult populations. We are trying to keep that information updated on our website. So far we have given out preliminary information that was after the first dose. I would imagine that very soon we should have information form the first dose in the pediatric populations and then again just realizing the caveat that there will be more information after the second dose we continue to follow those children and see if they get a better immune response after the second dose.

For the pregnant women we just started those studies less than a week

ago. It will be a little bit longer before we have that data.

MS. BUCK: I wanted to follow up only because I have been doing this for days and I currently have just forgot something. What was approved the other day was that for two shots? Is that still the recommendation for a two-shot series on H1N1?

DR. MULACH: Yes. This is a question for FDA. I am pretty sure maybe I have already this week but –-

DR. GRUBER: I think I can incorporate –- in my update.

MS. CASTRO-LEWIS: Why don't we just move to Dr. Gruber's update.

Agenda Item: Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities

DR. GRUBER: I wanted to keep my comments short after the CDC speakers and NIH speakers have talked a lot about H1N1 vaccines and have already mentioned that the FDA has approved on September 15th, vaccines to protect against the pandemic H1N1 2009 influenza virus. This is a monovalent vaccine. That means in contrast to the seasonal vaccine that some of you may receive every year, that has three different types of influenza vials and that 2A and 1 type B strain. This is a monovalent vaccine. It contains only one strain and it is a California 709 like virus. That is sort of made on the virus that circulated here in spring and fall and now and get people sick with H1N1 influenza.

There are four manufacturers, which have been approved to make this monovalent vaccine. These are actually the same manufacturers that also are licensed to make seasonal influenza vaccine in this country. These manufacturers are an Australian company named CSL. MedImmune, that is the company that makes the life attenuated influenza vaccine. Novartis and Sanofi Pasteur.

When you look at the package inserts for these four different monovalent vaccines, the age indication is all different because it is guided by the age indication that is contained or that is specific for the seasonal influenza vaccine. When you look at the

monovalent vaccine that CSL was licensed for the indication is 18 years of age and up; MedImmune, 2 years to 49 years of age; Novartis, 4 years of age and older, and Sanofi Pasteur 6 months of age and older. Why is it? Because as I stated, all these manufacturers have licensed seasonal influenza vaccines and we have approved these vaccines as we call a strange change to each manufactures FDA approved seasonal influenza vaccine. Each of the manufacturers who make these monovalent vaccines using their established age-based manufacturing process and technology that they have also used some of them for many years, to make the seasonal influenza vaccines. In other words, we have considerable experiences with that technology. As was pointed out that – and we therefore expect that the safety profile of this vaccine is going to be rather familiar to the seasonal trial influenza vaccines.

I also want to mention because there is some confusion. These vaccines that the FDA has approved do not contain adjuvant. So these are your adjuvant monovalent vaccines and there are no plans to license in the imminent future H1N1 vaccine that contains adjuvant because there is a lot of confusion. We get a lot of these inquiries so I wanted to make that clear.

As Barbara has mentioned, clinical studies are ongoing with these monovalent vaccines. The NIH is doing these studies and the vaccine manufacturers. Each of those manufacturers also perform these clinical studies to really look at the -– you know verify basically the optimal dose and dosing regimen and so far the information, the preliminary information that we receive from these clinical trials is very reassuring and that 50 micrograms of this monovalent vaccine induces a robust immune response after one dose in adults and we expect to have data from pediatric clinical trials within a couple of weeks as well.

Of course since we are using the manufacturing process for the seasonal influenza vaccine as a base to make these monovalent vaccines, these monovalent vaccines of course will undergo or do undergo the same rigorous testing in a lot of these

programs that we apply for seasonal vaccines.

As I mentioned these vaccines will be available both in thimerosal preservative and thimerosal free formulations. The MedImmune attenuated vaccine does not contain thimerosal. It is just like FluMist.

I don't really have to talk a lot about the collaborative efforts that are going to be enhanced into safety surveillance and monitoring of this vaccine. That was described by the CDC speaker.

Again, this is a standalone monovalent vaccine. It is separate from the seasonal vaccine. In other words I guess there will be recommendation to also for people to get their seasonal influenza vaccine because it is not believed that seasonal influenza vaccine will protect against the new H1N1 virus and vice versa.

That concludes my remarks regarding H1N1. I just wanted to let you know in addition to all these, how we call it flu activities that have been going this summer, we have numerous other biologic license applications under review for adults, for children, for infants. These vaccines include those that protect against human papillomavirus, prevention of neisseria meningitidis disease, and there is a pneumococcal vaccine that is also under review.

Some of you may know perhaps that on September 9th the FDA did convene our Vaccines Advisory Committee and we brought to the committee the human papillomavirus vaccine that is called Cervarix, manufactured by GSK. We asked the Committee for recommendations on the safety and effectiveness of this product in females 10 to 25 years of age.

This vaccine if approved would be indicated for prevention of cervical cancer by protecting against pre-cancerous lesions and infections that are caused by human papillomavirus serotype 16 and 18. So this vaccine will look different from the licensed vaccine Gardasil. Gardasil contains four serotypes.

The committee also discussed, however, Gardasil and made

recommendations on the safety and effectiveness of vaccinating males with Gardasil. Again, the review process of this vaccine has not been completed.

That actually concludes my update. If you want to ask me further questions, I will be happy to answer them if I can.

DR. FISHER: This is Meg Fisher. For the males and for the Cervarix, you did not license them yet? You did not approve them or you recommended approval but it's not official?

DR. GRUBER: The Advisory Committee makes recommendations and we finish up our review and determine safety and effectiveness of these products we take into consideration the recommendations made by the committee. But it is just that we have certain time windows by which we can complete our review and they are close. They are coming up but they are not there yet so we are still wrapping up.

MS. BUCK: Marion, can you tell me what you looked at or what kind of safety has been looked at with the H1N1 vaccine along with the regular kid's schedule simultaneously in addition of the H1N1?

DR. GRUBER: Let me please verify. You are talking about other vaccine other than influenza vaccine that is being given concurrently? That is a very good question. We don't have any data on that.

MS. HOIBERG: Sarah Hoiberg. At 15 and I am probably going to get the – did you say micrograms? If 15 micrograms is enough for an adult, then shouldn't be look at less for children?

DR. GRUBER: We have. The pediatric clinical trials really did look at a dose range. Right now actually the seasonal influenza vaccines, the trivalent vaccines for kids 36 months of age and younger, they actually get only half of the dose of the adult dose. This is something that we looked at it too. Yes, we do those kinds of studies too.

MR. SCONYERS: Dr. Gruber, I read in some piece of news the other day

that there is a fifth monovalent vaccine that is being considered a GSK vaccine. Is that correct?

DR. GRUBER: That is correct. GSK also has submitted what we call a supplement to the biological license application. They anticipate also approval of their monovalent H1N1 vaccine. That is also if we approve that, that would also be an unadjuvanted vaccine.

MR. SCONYERS: The other question I had. I know you have explained to us the procedure for determining the strains to be included in the seasonal vaccine. I am just wondering how that will be approached for the 2010/2011 flue season and whether you anticipate incorporating the H1N1's strain into the trivalent seasonal vaccine so that this will be the only year in which the other compensation program whose name I can't get off my tongue very readily applies as opposed to the VICP.

DR. GRUBER: That is a good question. Yes, there is a possibility that the current strain may be incorporated into next year's the 2010/2011 trivalent influenza vaccine but I think that really depends on what is happening the next couple of months. An epdiemiological survey will tell what kind of strains are endemic and what strains will need to be included in the seasonal trial data for that upcoming season. As you know it is the -– and then our advisory committee recommends the strains to be included. I wouldn't exclude that possibility.

MR. SCONYERS: About when is that recommendation made?

DR. GRUBER: Usually the WHO convenes in the middle of February. I think it always run on time. You want to try to stay around that time and then our work -- usually convenes like one or two weeks thereafter.

MS. BUCK: Quick question. I can't remember but does Cerverix have an adjuvant?

DR. GRUBER: Cerverix does have an adjuvant. It is a combination adjuvant, aluminum hydroxide plus monophospholipid A.

MS. GALLAGHER: I am Charlene Gallagher here. Can I ask you? I know you said that there hadn't been studies of concomitant vaccines in infants but has there been studies of and if there are recommendations about receipt of the seasonal flu vaccine and the H1N1 vaccine and can it be one visit or is it going to be more than one visit? It just has practical implications.

DR. GRUBER: Very good questions -– I got that question yesterday as well. We don't have any data yet to study concurrent administration of seasonal or where we studied concurrent administration of seasonal trivalents with the H1N1 monovalent. However, the NIH is conducting these studies and we hope that we will have these data available.

The problem here was this summer and I wanted to make this very clear. It was all a timing issue. You had to make what was scientifically and medically justifiable and that ideally you would want all these data, but what somebody at FDA said prepare for the worst and hope for the best and that sort of dictated how we went by in recent products.

DR. GIDUDU: I had a question for you. With a vaccine in Australia that was recently licensed compares how does it compare with – that we have in FDA that is similar?

DR. GRUBER: So the question was and I need clarification on that because the question was how the vaccine that was recently licensed in Australia compares to the vaccine here. You are talking about the seasonal trivalent influenza vaccine or the H1N1 monovalent vaccine?

DR. GIDUDU: The H1N1.

DR. GRUBER: The H1N1 monovalent vaccine that is the same product.

DR. FISHER: We have been waiting to see what H1N1 did as it went through the southern hemisphere and the only report I have seen so far isn't a very precise report, but it suggested that it was the primary strain circulating and that it had

indeed replaced other seasonal influenza in the southern hemisphere. Do you have more or better information on that?

DR. GRUBER: I really don't. I think that is more of a question also of CDC and others. I really can't speak to that. I'm sorry.

DR. GIDUDU: I am probably going to get that answer from – from another group at CDC.

DR. EVANS: I was going to say that I probably wrote on my hand out. Maybe Tawny has a clean hand out, but Dr. Ann Shook(?) yesterday passed out a very detailed –- showing the distribution cases in the southern hemisphere and the cases that occurred this past six months in the US of morbidity and mortality. I was deeply impressed with the cases in children and so on. We will see if we can get a copy of that in the Commission for tomorrow.

DR. MULACH: I believe they put the NVAC presentation on their website. There may be an easy location for you to send to the group about the whole series of flu presentations from NVAC in case you are interested.

MS. BUCK: I said this before but in a different form so it would be remiss of me not to say it here. Wear my ACCV hat. There is a pretty strong communication campaign going on for the H1N1 vaccine, seasonal flu vaccine as well, and there is also a lot of concern among the public about doing this and some of that concern lies in the fact that this is pretty fast track and that a lot of the really important clinical trials haven't even started yet and probably what you know the most about is efficacy but safety is going to take some time. As I did yesterday I would hope that practitioners and everybody else who would be really respectful of the dialogue with patients and pregnant women and parents with young children with their concerns about going forth with this vaccine based on the fact that it has come out so quickly and the safety profile in question even though I understand that we are hoping it to be very similar to the seasonal flu vaccine but that is a trust me that a lot of people may not be willing to do.

MS. CASTRO-LEWIS: Any other questions for the –-

MR. SCONYERS: Before we move to the public comment period, I think this has been an excellent afternoon and particularly Professor Grey and Mr. Shoemaker's presentation really struck me. On the basis of that I would like to put a formal motion in front of the Commission that the ACCV advise the Secretary to adopt and approach to resolution and concession of off table cases that is fully consistent with the Althen and Capizzano cases and that resolves close calls regarding causation in favor of injured claimants. I am moving that. Let me be clear to what I expect. What I would like to have happen is for this question to be referred to a work group to come back with a recommendation but we have talked about this a number of times and we have never done anything about it and I would like for us to do something about it. Annie, assuming that there is a second and we move forward on this can provide with effects that I just read. I would be happy to read it again.

MS. HOIBERG: I second.

MS. CASTRO-LEWIS: Any discussion on that?

MS. GALLAGHER: I really would not be prepared to vote on it today and I hope that it is absolutely clear that it will take everybody reading those cases and refreshing themselves on what they say and that we report to the working group, et cetera before we move to that.

MS. BUCK: How do we move from the motion to a meeting to a work group?

MR. SCONYERS: I think procedurally probably it needs to get referred to a work group. I am not suggesting that we act today. I would like for this to move forward with formal consideration –

DR. FISHER: Meg Fisher. I guess my thought as I was listening to it also was what happened to the Stevens' thing. It just sort of seemed like it got tossed and how do you know that you won't come back to that in the future. I had a little hesitancy

there.

MS. DREW: This is Sherry. Just to address that. The Stevens' case was decided by one of the special masters and it was overruled, changed, decided against by subsequent loss. The Stevens' rule is out according to the upper appeals court.

DR. EVANS: The work group is very informal and that could be – the chair. That is the next step. You don't need a vote or anything for that.

MS. CASTRO-LEWIS: What we need to do is – for the work group to look into this not necessarily to discuss this right now.

MR. SCONYERS: The question is not to be voted on – it would probably be a good thing not to call it a question at this point.

MS. GALLAGHER: We were already having a work group looking into legal aspects of causation, et cetera. Could this just be another question that is referred to the same work group – to do different work group?

DR. EVANS: That was a work group having to do with series of reforms, proposals, updating the proposals from before. This could be something that would tailor maybe just for the discussion that is here today.

MR. SCONYERS: I think the chair should appoint a –

MS. CASTRO-LEWIS: Appoint a group? What about you, Jeff?

MR. SCONYERS: I believe that I am not – I believe there is going to be a successor named at some point.

MS. CASTRO-LEWIS: According to the report of Geoff this morning it's not going to be any time soon. You still have a few months in the Commission and I think it would be a great idea for you to lead that at least in that work group.

MR. SCONYERS: This falls into the category of no good deed –

MS. CASTRO-LEWIS: It always happens. I am open to volunteers but I think I really would like you to be in there – would you like to join Jeff in this work group?

Thank you. Who else was not in that work group – for the time being to start the work. We have six people in that work group. Do we need to close on that? We have the work group to looking to the motion that Jeff presented, which I am not going –

MS. GALLAGHER: Can I just request that before we wait for formal minutes, which take a while and all that if somehow what the total words of your resolution be circulated so people can read it and consider it?

MS. CASTRO-LEWIS: And also for – if they can work on that – the one that we did this morning so we will have them tomorrow before we begin. Thank you so much. Any other comments, any other questions before we go to the public comment?

Agenda Item: Public Comment

PARTICIPANT: We have to ask the operator too.

OPERATOR: Actually this is the conference coordinator. If you have a question or a comment by phone – for questions or comments by phone please press star one. Star one for questions or comments by phone. I will announce you by name when your line is open.

MS. CASTRO-LEWIS: Okay. Meanwhile we have a comment on the floor.

MR. SHOEMAKER: I just have some questions about the flu vaccine both the seasonal and the H1N1 vaccine. This year my real concern is giving thimerosal-containing vaccines to pregnant women and children. A vaccine that has 25 micrograms of mercury you would have to weigh 550 pounds to be below the safe dose according to the EPA for that vaccine. The safe dose according to the EPA is .1 microgram per kilogram of body weight per day. If you are looking at 25 micrograms, that is 250 kilograms which times 2.2 pounds is a 550-pound child. I don't know too many 550-pound children. I don't know too many fetuses that are going to be able to withstand this. You are looking at monitoring the adverse effects for 42 days but nobody is talking about looking at the births of these children for birth defects, for

neurodevelopmental problems and that sort of thing. There has to be some way to make sure that pregnant women and children receive single dose injections thimerosal-free injections.

Secondly, in the military it is mandatory. What is being done by the military to insure that pregnant women in the military are given thimerosal-free vaccines and what is being done to insure that women in the military tested for pregnancy before they are given thimerosal-containing vaccines? I don't want any more cases. Don't send them my way.

MS. CASTRO-LEWIS: Thank you so much for the comments. Any comments from the line on the phone please? Can you hear me operator?

OPERATOR: One moment please. Jim Moody, you have an open line. Go ahead Jim Moody.

MR. MOODY: At the NVAC meeting yesterday CDC stated that there would be no safety data available as of the time of vaccine release for H1N1 on pregnant women or infants and certainly in respect to fetuses. In light of that it seems indeed cruel to force young mothers to choose between advertising based on fear mongering and the uncertain risks of catching some sort of chronic adverse event from thimerosal. Just yesterday a study came out showing that the rate of autism was three times greater based on thimerosal-containing Hepatitis B vaccines. So the scientific literature continues to mount showing there are very serious concerns here yet CDC states on its web page there is no evidence showing harm from thimerosal. It is just a blatant lie. I would urge this committee strongly to tomorrow adopt a resolution advising the Secretary to take all steps necessary to insure that pregnant women and infants are provided with thimerosal-free vaccines. CDC said there is going to be 90,000 distribution points throughout the United States and there is no steps that I am aware being taken to make sure that every distribution site has thimerosal-free vaccine available and that people would be told with information that they have the right and the

opportunity to ask for it and can ask for it and should ask for it. There is doubt and uncertainties are the enemy of public confidence. The social networks, the left and rightwing talk radio are viral with rap songs and with – of both the scare tactics as well as the vaccine program. This committee has an opportunity to take a very strong safety first stance consistent with the safety section of their governing statute to preserve some public confidence on this by making sure that pregnant women and infants are not exposed to any mercury unnecessarily. Thank you.

MS. CASTRO-LEWIS: Thank you for your comments. Any other comments?

OPERATOR: If you would like an open line by phone for questions or comment, if you would like an open line press star one. I will announce you by name when your line is open.

MS. CASTRO-LEWIS: It looks like there are no more comments. I would like to get a motion to adjourn the meeting. Anybody?

MS. TEMPFER: Motion to adjourn.

MS. CASTRO-LEWIS: See you tomorrow.

(Whereupon, at 5:15, the meeting was recessed until 9:00 a.m. the following day.)