U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

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Agenda Item: Welcome and Chair Report

MS. DREW: Good afternoon. Welcome to our 82nd meeting. I thought we would start by going around the room and announcing who is sitting here at our table.

(Introductions around the table)

MS. DREW: Michelle Williams is here but has left the desk briefly. She is also present here. I would also like to welcome and mention that we have two new board members who will be joining us, and replacing Tom Herr, Sara Hoiberg and myself on the panel as of the next meeting.

Present with us today is Ed Kraus, an attorney for vaccine injured individuals who is also an Associate Professor at Chicago Kent College of Law. We have Luisita dela Rosa, who is the parent of a vaccine-injured child. And not present but who will be replacing Dr. Herr, we have Sylvia Fernandez Villarreal, a medical doctor who is a general pediatric practitioner at the Taos Clinic for Children and Youth in New Mexico.

Welcome, everybody, to our meeting. We will now take any comments that anyone may have on the September, 2011 minutes for the meeting.

Agenda Item: Approval of September 2011 minutes

MS. DREW: Are there any corrections or

additions, deletions?

DR. HERR: As sort of a part of unfinished or old business, on day two of our meeting as we were talking about the meningococcal vaccine and the components thereof and discussions of possible allergies and reactions to the components of the vaccine, the packaging of the vaccine. While it was not mentioned at the minutes because there is another body that supervises the packaging of the vaccine and those regulations, I would like to put another push in that the vaccines start to become labeled as to whether they contain latex anywhere.

Because some do and some don't. Some of it is in the package insert, some of it is not. But it should be more obvious. The practitioners, whether they be pharmacists, pediatricians, nurse practitioners, who is going to be providing the vaccines, that the bottle or the package is labeled that the stopper may contain latex or does contain latex. So that that can be acknowledgeable to the practitioner for any patient who is allergic to latex.

MS. DREW: Was that mentioned at the meeting?

DR. HERR: We did mention the packaging at the meeting. But it was mentioned that it is not our place to look on the packaging of a vaccine rather than the vaccine itself and the components. But I would just like to say that we really need to make sure that gets followed and

passed along, because I think it is important.

MS. DREW: Okay. Should the minutes reflect that?

DR. HERR: No. I was raising that as sort of like an old business rather than --

DR. J. SMITH: Sherry, this is Jason. I think to Tom's point, under the future agenda items, one of the few items that were listed was a presentation or some topic related to labeling of latex components and vaccines. And maybe Tom, to your point, it could be something the Agenda Committee could take a look at for future meetings.

MS. DREW: Thank you. With respect to the motion that is pending now, it has been seconded.

(On motion made and duly seconded, the minutes of the September meeting were unanimously approved.)

And getting back to Tom's issue, again, as a future agenda item I think the future Agenda Committee should talk about that. Our next item is a report from the Division of Vaccine Injury Compensation from Dr. Evans.

Agenda Item: Report from the Division of Vaccine Injury Compensation – Geoffrey Evans

DR. EVANS: I would be happy to start. Good afternoon, welcome. Since we last met, I believe there has been at least one earthquake. The Parklawn Building survived in good order. And there have also been some

significant changes and construction around here, but despite that fact we got you all in safely. So the construction will be continued for the next couple of years. We will see some dramatic changes around here.

Plus, the NIAID will be in the process of building a family complex right across the street from this building, so there are a lot of changes afoot. With that, let me begin by starting with the highlights over the next two days. Following my update of the office, you will hear from the Department of Justice Litigation office, and then a report by our chair, Sherry Drew, on the 2011 judicial conference that just took place.

Then there will be a review of vaccine information statements. Following that, we will have updates from ex officio members of our Commission, the FDA, CDC, NIAID, and the National Vaccine Program office. And finally, and this will be tomorrow, updates, as well as this next item will take place tomorrow.

That will be a combined clinical update and presentation of a proposal to change the vaccine injury table by adding the injury of intussusception for the two currently licensed rotavirus vaccines that are being distributed and used in this country. Those are the highlights for the meeting on the agenda.

Continuing on, the first slide in terms of the

statistics is always claims filed. You'll see that there still remains quite a number of non-autism claims involved, almost half of them being for influenza vaccine. And the average over the past three years has been 366 per year, which contrasts to what used to be 150 to 170 per year of claims altogether.

You see also that there has been a dramatic decrease in autism claims, and none filed this current fiscal year. And this past fiscal year the petitioner's steering committee notified the court that it was no longer working together. So not surprising, the Omnibus Autism Proceeding is no longer accepting cases. So that is now zero. And as you can see, the totals are still remaining high in terms of total numbers of claims.

The next slide, adjudications. There is quite a bit of activity under the adjudications side, particularly in the Omnibus Proceeding where the court is going through and finalizing decisions on working with the Justice Department and the petitioners' bar on the attorney fees and costs for many, many claims filed under the Autism Proceeding. That is reflected in the jump of adjudications that you see over the past year or so.

And then continuing on, as a further breakdown of adjudication categories, which really reflects on the entitlement side how the program goes about its business,

you'll see that over the past two years, fiscal year '10 and fiscal year 2011, you'll see that the majority of cases resulted in settlement, litigated risk settlements or defensive cost settlements, in the 79 percent, 75 percent range.

In the breakdown of those, other than those that are compensated you will see that there has been an uptick in terms of the percentage of cases that are being defended. There's more that are now going for hearing, and less on the concession side. So there is a little bit of a change.

And that could be reflective of some of the Appeal Court's decisions that have been handed down and which have perhaps given more of an incentive to defend cases based on the science as well as the legal interpretation of the causation standard. Overall there continues to be quite a bit of activity, as reflected by the overall numbers of adjudicated claims.

And turning to awards paid this past fiscal year, 2011, again you'll notice that over $200 million was awarded total, a petitioner's award as well as attorney fees and costs, for a total of $228 million altogether. That's our highest award amount in the history of the program. It has been over the past several years consistently high, higher than it had been the previous 10

years. And this trend is likely to continue.

But the good news is that in terms of the Vaccine Injury Trust Fund, with the more than 100 million doses of influenza vaccine that are distributed annually, I think this year CDC reported something in the order of 160 or 170 million that were distributed, there is a significant amount of money going into the trust fund.

So even though the program spent $220 million, it actually netted over $100 million above that. So the trust fund continues to grow and is able to absorb the increased compensation outlays that we have been seeing on a fairly regular basis, a sign of real health for the future of the program.

In terms of activities, this past year, or since the last meeting I should say, I attended the annual meeting of the American Academy of Pediatrics in Boston. And shortly thereafter I also attended the University of Pennsylvania, Center for Bioethics, Workshop on Vaccine Ethics and Legal Issues.

That has to do both with state mandates in school entry, but also focused significantly on health care workers and current laws and issues, like in New York State where that was an issue this past year or two as far as the ability for hospitals to require health care workers to have flu vaccine, or other vaccines, such as rubella

vaccine. So that was a very interesting workshop that was held there.

And of course I went to the usual October meeting of the Advisory Committee on Immunization Practices. And the big news that came out of that was, there was a vote to recommend use of HPV vaccine in boys, which made national news. That was important, and will certainly, I am sure, lead to more claims being filed with that program too.

That's it in terms of the significant activities in the program. The points of contact, and public comment participation Commission names are on the last two slides for your referral. And I will stop there and ask if there are any questions.

MS. DREW: Do you want to give the points of contact for people who are listening in?

DR. EVANS: Sarah has asked me if I would read these over the phone. I can do that again. We find that most are using the website to contact us, but I will do that for those that are on the phone once again. I am always afraid that I speak so quickly that you can't write it down.

The points of contact for the program are -- the address is 5600 Fishers Lane, Parklawn Building, Room 11c-26, Rockville, Maryland 20857. And the telephone, the toll free line is 1-800-338-2382. And our internet address for

the program, which has been recently revamped and is much more user friendly, is www.hrsa.gov/vaccinecompensation.

And for those who are interested in public comment and participating in Commission meetings, write to Andrea Herzog at the address that I mentioned above, Parklawn Building, Room 11c-26, 5600 Fishers Lane, Rockville, Maryland 20857. And Ms. Herzog's phone number is 301-443-6634. And she can be reached through e-mail at aherzog@hrsa.gov.

MS. DREW: Thank you, Geoff. We also have public comment available at the end of this day's session, at the end of our meeting tomorrow. I can't make an actual time but it will be at the end of the meeting somewhere around 4:00 to 5:00 tonight, and somewhere tomorrow 11:00 to noon-ish. We take public comment but we don't take questions.

Next we will have a report from Mr. Mark Rogers, the Deputy Director of the Torts Branch of the Department of Justice.

Agenda Item: Report from Department of Justice

MR. ROGERS: Good afternoon. I am glad to be here. Welcome to the new members and farewell to those who are leaving, and thank you for your service. Greetings to those who are returning and sticking it out with us here. I am Mark Rogers. I am the Acting Director of Specialized Torts in the Torts Branch. And I will be reverting back to

Deputy Director, probably the beginning of the year when we hire a replacement director.

You have had the last two meetings, Vince Matanoski. He will be reverting to Assistant Director. It's all transparent to you. It's all going to continue as it has, but that's just some internal moving around. Also on the personnel side, we have hired two new attorneys, Tara Kilfoyle and Gordon Schieman (?).

And we have authority to hire two additional paralegals, who really are the core of the office when it comes to moving the cases through the process. They are incredibly invaluable to us and account for a lot of the speed of processing these cases, which is going to be illustrated in a couple of slides toward the end.

On the statistics side, again, it is important to emphasize that our reporting period is a three-month snapshot. It is very recent. It is virtually real time. We track the incoming petitions on a database and we pull that information a couple of weeks before these meetings. And then it represents the prior three months, and bringing it to you.

What HHS presents is more of a year over year fiscal snapshot of the program, and so for what it's worth this gives you an idea of what has happened very recently in our litigation. We have seen one new autism case filed

and 120 non-autism cases filed. You'll see the 33 and 87 breakdown between adults and members, 87 adults. This is representative of a trend we have seen toward more adult cases.

These are the adjudications over the last three months. The big number is 920. We have been moving through the autism cases in light of the resolutions of the test cases, those cases coming back out of the program. And it has moved us into another phase, the last phase of the cases, and that is attorney's fees. And we are working those for the autism cases.

As Geoff mentioned, we have quite a few compensated cases. We had 61 of those. One was conceded by HHS. There were none where there is a decision by the Special Master awarding damages, and we will talk a little bit more about this a slide or two down the road, on how we get to a decision in these cases.

We had one proffer and no stipulations. The proffer would have been in a conceded case, or a resolved case for the petitioner. Of those cases not conceded by HHS, no decisions on damages, eight proffers and 52 stipulations. Now that's the big number in the compensated cases, that the cases resolve by a stipulation. That is a handshake between the two parties as to what the award should be.

Of those that were not compensated, the big number are the autism cases that are coming back out of the program based on those resolution of the test cases. The non-autism cases, there were 64 that were not compensated. Now this ratio of 61 compensated to 64 not compensated is a little closer to even than it has been over the last few years. I wouldn't take much away from that because we are only looking at a three-month period.

I think the year over year data is more indicative of what is happening. But it would be interesting to see, and we will be back at the next meeting to see if that is episodic or a trend. I tend to think it is the former, that this is just a three-month blip.

These are withdrawn cases. Under the program there are certain triggering timetables that allow a petitioner to leave the program without a judgment, if they want to go. That is, if the case is not resolved within a certain time period they have the option of withdrawing their case. They also will withdraw it for other reasons, sometimes because they are satisfied that the case doesn't have any merit. But in any event, we had 14 of those, most of them autism cases.

Here are some terms we use, some jargon. And I try very hard not to use jargon so stick your hands up or call me on it if I do. I want to be clear in everything we

communicate here. But I will run through these for the benefit of the new members.

An adjudication of a petition is final judgment. Judgment, only the court enters it and it is an indication by the court that the case is over. There is a whole body of law applying to the finality of the judgment, the case is over. Of course, there are some exceptions but they are very narrow. One of our cases on appeal deals with an exception to the rule about finality of a judgment. Once it's over, it's over. Final judgment, same thing.

Compensable. That's a case where a petitioner is left with an award. One way or another, is left with the program with compensation. We can get there in a number of different ways, but that's the bottom line. Conceded by HHS. That means that they have conceded that the injury or death is vaccine related. And we don't have many of those cases, as the stats illustrated.

A settlement. That is when the case has been filed, it has been reviewed, HHS has determined not to concede the case and it has gone to the parties for litigation. An alternative to litigation is the parties sit down at a table and discuss the case and its relative merits and agree to a resolution of the case that involves settlement to petitioner, and the case is over. It's the party shaking hands on what the award should be.

A decision is when the parties can't agree and the Special Master has to decide the case. Non-compensable/dismissed is when HHS has not conceded the case, petitioner still believes that there is merit to the case, and the Special Master has agreed with the respondent, HHS, that the case should be dismissed. It has no merit. And that's a dismissal.

A proffer is very much like a settlement, for all intents and purposes, and the difference is mostly internal to DOJ. I'll explain it as succinctly as I can. A settlement is where one party thinks the award should be this amount -- I'm gesturing up high -- and the other party thinks the award should be this amount -- and I'm gesturing down low. And they shake hands on some amount in between.

Conceptually, neither party has gotten all that they want. That's a settlement. It's a negotiated middle ground. A proffer is when both parties agree that a particular award is supported by all the evidence in the case. And then that proffer is filed before the Special Master, and the Special Master agrees.

But you see the distinction. It's where the parties agree as to what is appropriate. A settlement, there is a disagreement lying behind it, with a handshake on some middle amount. So that's the difference. It may sound like a distinction without a difference to you,

because both are amicable in the sense that there has been an agreement on some level. It's important internally to the Department of Justice, because a settlement has to be approved by certain authorities.

When the Department of Justice believes that a particular award is not appropriate but agrees that the case should be settled, it has to go up to an appropriate settlement authority. The trial attorney can file a proffer. The obvious benefit is, a proffer is much faster.

MS. HOIBERG: When you say stipulation, does that mean settlement?

MR. ROGERS: That means settlement, yes. A stipulation -- I think we have been through this before, and maybe we even promised to clarify it in our documents, our slides. Yes, they are both the same thing. The stipulation is a stipulation of settlement. They are the same thing.

Affirmed. This is appeal language. When one side or the other disagrees with the Special Master's decision, they can appeal. And if the case, if the Special Master's decision is affirmed, that means the Appellate Court agreed with it. That means whoever brought the appeal lost.

Reversed is when the court on appeal reverses the decision. That is, they disagree with the decision and

they reverse it. There is usually an explanation and a new decision in the case, with a reversal. A Special Master may have decided to award compensation, and on appeal the Court of Appeals said no, you should not have awarded compensation, that's reversed, and here is why.

Remanded is when the case goes up on appeal and the Appellate Court goes, you know, there are some problems with this decision. I am not going to fix them. I am going to send it back to the Special Master to fix it. That's a remand. You've got a do-over here. You improperly weighed the evidence. You used an inappropriate legal standard, or whatever your mistake was. I am not going to do it over. You do it.

This is a little arcane, but in our program the Court of Federal Claims has authority to do it over itself. If they find a problem with the Special Master's decision, they have statutory to enter their own decision, the reversal. But many times they will remand it and tell the Special Master to do it over.

Vacated is when the court on appeal says your lower decision has got a problem with it. I'm vacating it, that is, eliminating it, and sending it back to you to do it again. It is very closely related to a remand. A remand may be to fix some minor part of the decision. But a vacation of the decision means that the decision is gone

completely.

Now here is a chart we prepared on how cases move through the program. From the filing of a petition the first step is HHS takes a look at it, and either concedes it or doesn't concede it. If they do not concede it, and that is where most of the cases go, down the left side of this chart, it either goes to the Special Master for a decision or it goes down the settlement route.

By far, most cases go down the settlement route. And once there is a handshake and a filing of a stipulation of settlement, there is a final decision and an award of compensation. That pink or mauve or salmon block there, however it appears, on the far left bottom, final decision, award of compensation, under settlement, when we finally look at some of the statistics, those are the rocket docket cases. They get through the program the very fastest.

If there is a not conceded and it goes to the Special Master and they do not compensate it, that's a final decision of the Special Master, no award of compensation. That is the kind of yellowish box there. If the Special Master disagrees with the respondent and finds that the injury or death is vaccine related, compensable, it moves over to damages.

And once over at damages, for damages, that issue can be settled. And by far, in fact in the last few years,

there have not been any decisions by the Special Master on damages, other than there have been a few decisions on limited issues, but there has been a settlement in every single case on the issue of damages. And there we have the proffer over there, which is the other possibility we already discussed.

Now on the appeals of the court, at the Federal Circuit, I wanted to mention -- we don't have a slide for it -- at the Supreme Court, Cloer is still pending before the Supreme Court only in the sense that the time has not yet expired for petitioners to seek certiorari. And that is, an appeal to the Supreme Court.

The Supreme Court doesn't have to grant it, but petitioners have a right to seek it. Their time limit hasn't expired. It would have expired, but they asked for an extension to January 2nd, and the Supreme Court has granted that extension.

So petitioners in the Cloer case have until January 2nd to file for certiorari, for appeal before the Supreme Court. That is where Cloer is right now. I understand that you discussed the substance of the case at the last meeting. Just a quick snapshot. Cloer was a decision of the Federal Circuit en banc, which is very unusual. That means that the Federal Circuit, all the judges sat and heard the argument.

And what they decided was, in a nutshell, the Vaccine Act statute of limitations is not subject to a discovery rule. That is, the deadline for filing a petition for compensation under the program, the deadline runs, the statute of limitations runs from the date of the first sign or symptom of manifestation of onset of the vaccine injury, for 36 months.

What petitioners had argued was, it doesn't start to run until they have reason to believe that the symptoms were vaccine-related. The Federal Circuit en banc agreed with HHS that the discovery rule, which is what that is called, did not apply.

They also ruled that the doctrine of equitable tolling applies. That is, the running of the deadline might be delayed for those reasons that merit equitable tolling. And there is a body of law about what those reasons might be that has developed under the Supreme Court case of Irwin versus Department of Veterans Affairs, as I recall. That's where that is.

We have the decisions of Rickett and Lombardi. Both of those are cases where the Special Master ruled that the injury was not vaccine related. The Court of Federal Claims agreed, and the Federal Circuit in each of these cases affirmed. That is, they agreed with the courts below.

One case was decided that had been filed by Respondent, and that is Rotoli Knight and Porter. There are actually two cases. In both of those cases, the Special Master had held that the injury was not vaccine related. The Court of Federal Claims had reversed that decision, finding that the Special Master had applied an improper standard. And HHS appealed to the Court of Appeals for the Federal Circuit, and the Court of Appeals for the Federal Circuit agreed with HHS that the Special Master had gotten it right and the Special Master's decision should have been affirmed.

These are the pending cases now before the Federal Circuit. Three are new. Hibbard and Locane involve basic entitlement decision. A typical case brought by a petitioner is where the Special Master has found that the injury is not vaccine related, and petitioner has appealed to the Court of Federal Claims and lost, and then brought the case to the Federal Circuit to get review of that Court of Federal Claims decision. So that would be Hibbard and Locane.

Now Griglock is a statute of limitations case. And as I recall, it's one of those cases where we are trying to figure out the metes and bounds of Cloer and Zitugnick(?). And I don't want to get too much into the details, but the gist of it is the Special Master had

agreed with HHS that the statue of limitations had run on a vaccine injury case, but had not run for the death case.

This was a case in which petitioner received a vaccine, allegedly suffered an injury, and then died, and then filed a petition. But the petition was more than three years after the vaccine injury, so that statute of limitation had expired, but within two years of the death. So that statute of limitations had not expired.

So the Special Master dismissed the injury claim and proceeded with the death claim. Those are the kinds of jurisdictional statutory issues that the court is trying to resolve under the Vaccine Act. There is one appeal filed by a respondent. That was in Heinzelman, and at this point it is a Notice of Appeal. A brief has not been filed.

These are appeals at the Court of Federal Claims, which is the first stop after the Special Masters decision. These are appeals filed by petitioner, and there was one filed by respondent. These decisions have been entered since our last meeting, and they are annotated there with how they were resolved.

Again, reversed and remanded means that the Court agreed with petitioner. For an appeal filed by Petitioner, if the case was reversed and remanded, that means the Court found merit to the appeal. And the same holds true for the appeal by respondent in McKellar. It was reversed and

remanded, meaning the Court agreed that there were problems with the case.

These cases are pending. There are three new ones. And I mentioned earlier relief from judgments. This is one of those cases. Goetz involves the issue of finality of judgment. In this case the petitioner has come back to the Court saying, you know, my case was dismissed for exceeding the statute of limitations. And now Cloer has come out, and I would like the Cloer decision applied to my case, even though it's over.

So the issue there is how final was the judgment that they received, in light of new case law. We don't have any Federal Circuit oral arguments. The Court of Federal Claims has a scheduled argument in that case I just talked about, Geotz, on the 15th.

Here are the settlement stats I promised. What we have done at your request is, we are clocking the time it takes from the Petition filing to filing of the Stipulation of Settlement. The case beginning, the case virtually over but for the processing of the judgment.

And we are going from the longest to the shortest. So we have some there are four, four, three, two, three, down to three years on the first page. Many more at the two year mark on the second page. Then we have a lot here just over a year on the third page and fourth

page. Self-explanatory. A lot hovering right around a year.

I would suggest that is about normative for the program, with everything going right, to get from petition filing to a settlement. If it is a well documented case there is general agreement that it is worth discussing settlement, and there is no litigation involved, this is the time it takes to process a case. The four-year ones, there are a number of issues that go into that.

The most typical are that petitioner has asked for more time to document their case, to complete filing their medical records, and to find an expert. By far, those are the reasons that a case will sit for even a couple of years before it can be processed towards a settlement or a dismissal, as the case might be.

The last page, we've got six months. And there is one at four months. I am not remembering that one specifically, but that is extraordinary. That is an attorney who had nothing else to do but work on that case. I would like to know who it was, and give him some more work, slow this down a little bit.

That is all I have. If you have any questions I would be happy to entertain them.

MS. DREW: Mark, this is Sherry Drew. I am really embarrassed to ask this. But when we call these

adjudicated stipulations are we also including proffers?

MR. ROGERS: No. That is actually a good question. Andrea, is that right? We are not including a proffer here. These are stipulations of settlement. And the reason for that is that they have to move -- what we were trying to clock here, it stemmed from a concern that the Justice Department was taking too long internally to get approval on those settlements. They don't need approval for a proffer.

A proffer can be filed the next day after the attorneys shake hands. For a settlement, we have to process it through HHS for their approval. They look at proffers generally before we file them.

But with a settlement they have to move it through their approval process. Then it has to come back to justice and go through its approval process, which can go as high as the Assistant Attorney General, depending on the amount involved. So these are the ones that are going to be dragging behind. The proffer is quick.

MS. DREW: Thank you for this. This is very valuable to the Commission here. Thank you.

MR. ROGERS: You are very welcome. As long as I am giving caveats here, the alleged injury there, I have to emphasize, is alleged. Where we draw that information is from the petition. It may be that the injury morphed into

something else as additional medical records came in. so I wouldn't put too much stock in that, other than it is what was originally alleged.

DR. HERR: It was not the final diagnosis for settlement?

MR. ROGERS: It is not. The reason for the settlement may be something completely different from what is listed on this chart. But generally it is pretty accurate. Anything else?

MS. DREW: I think that is all. Thank you very much.

MR. ROGERS: Thank you very much.

Agenda Item: Report from the 2011 Judicial Conference.

MS. DREW: I guess now I get to turn this over to myself, because I am going to be giving a brief report on the Judicial Conference, the Court of Federal Claims Judicial Conference that took place back in October. Every year the Bar Association of the United States Court of Federal Claims, with the cooperation of the Court itself, hosts a conference that includes practitioners before the Court, the judges, the Special Masters, and other interested parties.

The Court of Federal Claims hears vaccine cases, but also has a fairly wide jurisdiction that isn't really

important to us here. But a portion of its cases are Vaccine Act cases. The vaccine attorneys have a real specific agenda that is almost totally different than the other attorneys who may practice contract cases or Indian jurisdiction cases before the Court.

Anyway, there is a judicial conference every year. I believe in alternate years it is held here in DC where the Court is located, and then on the opposite year the Court tries to travel to places where people practice before it. And I think they try to be -- it used to be mainly East Coast places. Now they are trying to travel throughout the country. This year the conference was held in Berkeley, California.

I was fortunate enough to attend last year when the conference was held in DC. The entire Commission, all of the members, were able to attend the conference, which I think everybody found to be very valuable. Today, for this past one in California, obviously, it would have been quite a burden for everybody to have to travel. Anyway, I was appointed, or allowed to attend on behalf of our Commission.

Ed Kraus, who is a future Commissioner, who is here with us today, was also present, as was Elizabeth Saindon and Vince Matanoski and some others from the Justice Department. The attorneys who represent vaccine

petitioners had their own program that ran in conjunction with the other programs that were run on behalf of the people who practice different sorts of law before the Court.

There was some overlap. There were some areas that were of general interest to everybody there. And there was also some socialization, which actually can be very helpful in achieving a collegial attitude such as this court has, which is really quite unlike the kind of practice that I have ever had in other courts, which can really kind of help your cases along.

Anyway, the conference had a specific vaccine program this year that was really quite extensive. And I think that every year as more vaccine practitioners attend the programs get better and more pointed towards our practice. And there were the general areas of interest. The crossover subjects were helpful as well.

It had to do with evidence. It had to do with ethics. It had to do with peer review of scientific evidence. That was a particularly interesting panel where the folks who gave the presentation were talking about scientific evidence and how sometimes even the best or what appears to be the best peer reviewed evidence may not in fact be that good.

They mentioned some cases where it had actually

been faked, it had been made up. But as a general rule, as I think we all know, peer reviewed evidence is generally viewed favorably by the Court, and sometimes actually required by the Court.

The first day of programs for vaccine petitioners was probably the most relevant to our panel here, and fortunately it was recorded, and the recordings turned out, unlike some of the ones from the second day. They are available on the Court of Federal Claims website, and I would really hope that the Commissioners here can find a few hours to go to the Court's website, the Court of Federal Claims' website.

I don't have the location before me, but you can just Google it. It's no problem, just put in US Court of Federal Claims. You will get to the website, and there on the home page you can click on information on the conference, and get audio versions of the presentations made by Dr. Claiborne Johnston on the IOM report, and Dr. Clayton, who spoke to us at our last meeting.

I thought that the presentation that Dr. Clayton gave at the Judicial Conference was really amazing. I was speaking to Sarah on our Commission here about one of the graphics from her PowerPoint presentation. I have asked that the PowerPoint presentations be distributed to the Commissioners here, but those also are available on the

website, the Court's website.

And I think she really kind of simplified things with a graphic that has five circles intersecting, with a very small area of overlap in the very middle. And she talked about how a vaccine reaction can only happen if many things come together at the same time, including personal behavior, your own genes, the microbiome, environmental exposures past and present, and that would include the vaccine, and intercurrent illness.

So I really hope that you can all take a look at the PowerPoint presentations, and then hopefully listen to what was said, because I think this is relevant to what you are going to be doing as we get more discussion of the IOM report and potential table changes.

And the same is true for Dr. Johnston, who gave quite a lengthy report. Again, this was more of a review of how the IOM was put together, than comments on vaccine injuries. But I think that he explained the process that the Commission went through very well, and his PowerPoint presentation is a nice little review of how the IOM report was put together.

I know that our new Commissioners are going to have a job looking at the IOM report, and I hope they are all provided with a copy of it, as we were. Unfortunately, as I said, the second day's meeting was recorded but

somehow the recordings didn't turn out, so those are not posted. Those included presentations by the Special Masters on settlements and process. And as we have all heard, the Court is encouraging settlements.

We talked about various ways that settlements are encouraged through alternative dispute resolution, both by Special Masters acting in other Special Masters cases, and by private mediators. The Special Master session was interesting, as it always is. I don't mean to put Ward Sorenson on the spot here, but one thing that was brought up was, an attorney who said her client had a judgment that didn't get paid before the end of last fiscal year, and she was told that the program had run out of money.

I don't really know how that happened. I spoke to her two days ago. She did ask that I bring it up and see if anything could be done so that didn't happen again. I haven't heard of it before. It may have been some weird anomaly that happened this past fiscal year, and I see that it was an expensive year for HHS for the program. I don't know, and maybe at some point that could be addressed, if that is something that occurs more than once or twice.

Other than that, the judicial conference gave the Petitioners Bar Association, which is now called the VIP Bar, the Vaccine Interpetitioners Bar, an opportunity to meet. This is separate from the Court of Federal Claims

Bar Association. This is an association just for the attorneys who do this particular practice. We had a full half-day meeting, perhaps longer, as well as our own social events.

It is valuable for us to get together. The Department of Justice is one department in one place. Their attorneys are aware of what is happening with each other's cases, and this is something that the VIP Bar is hoping that we can encourage with our practitioners as well.

I think that pretty much covers the Judicial Conference. I hope that you folks will all be able to attend a future conference.

MS. WILLIAMS: This is Michelle. Did they put the dates out?

MS. DREW: The dates are out, I think, a few months beforehand, and you have to follow the Court's website or the Bar Association's websites. Ed Kraus will be aware of the dates and he can obviously report that to the rest of the Commission, if you folks are interested in attending. Thank you. Does anyone have any questions?

It's 2:00. Our schedule calls for a break now. Our next speaker is going to be a call-in, so why don't we take a break for awhile and then hopefully Miss Hamborsky will be able to call in.

(Brief recess)

Agenda Item: Review of Vaccine Information Statements

MS. DREW: Welcome back, everybody. I have just been informed that Jennifer Hamborsky and Skip Wolfe are on the line. We will be looking at the Vaccine Information Statements, the VISs that are in your meeting book. Skip? Jennifer? Hello.

MS. HAMBORSKY: Do you have a preference of which one you want to start with?

MS. DREW: Td first.

MS. HAMBORSKY: Why don't we just start with Section One.

DR. FEEMSTER: This is Kristen Feemster. I have one comment about pertussis. One of the biggest reasons for the adolescent and adult recommendation is for protection of infants. I thought it would be good to include some information. There is mention of the risk in adolescents regarding hospitalization and complications. But the highest degree of morbidity is in young infants.

I thought especially since the goal of the recommendation is to encourage adult vaccinations, to also protect infants, that we could maybe include a statement regarding infants.

MR. WOLFE: In section one?

DR. FEEMSTER: Yes.

MR. WOLFE: Okay.

DR. HERR: This is Tom Herr. I would agree with that. I also have that little mortality and morbidity to infants, because that is the biggest problem. But my other question was, just a couple lines further up on disturbed sleep, what does that mean?

MR. WOLFE: It came from our pertussis subject matter experts. I'm not sure. I guess just waking up coughing, I suppose.

DR. HERR: I would probably say something like that rather than disturbed sleep, because there are all sorts of reasons why kids won't sleep well. So I would look on coughing, difficulty breathing, vomiting. I think that's enough. I think if you open it up to disturbed sleep, there are all sorts of things.

MS. HAMBORSKY: I think they are saying that the coughing spells can cause disturbed sleep.

MS. HOIBERG: Maybe mention it that way. Maybe you could say resulting in disturbed sleep?

MR. WOLFE: It says which can lead to --

DR. HERR: We already have difficulty breathing. Isn't that enough? Or is it disturbed sleep on whose part? Parent? (laughter)

MS. HAMBORSKY: What if we just said, pertussis

can cause severe coughing spells, which can lead to difficulty breathing, vomiting, and sleeping?

MS. HOIBERG: No. You're going to have difficulty vomiting? That could lead to vomiting, difficulty breathing and disturbed sleep. I would just take out the disturbed sleep. That's not a good enough reason. I mean, it's not necessary.

DR. DOUGLAS: This is Charlene Douglas. Are you trying to capture the fact that children get into mortal difficulty, it's during the night when no one --

MR. WOLFE: This isn't children. This is Td and Tdap, so this is adolescents and adults. Well, children older than seven, at least.

DR. HERR: Asthma can do that, too.

MR. WOLFE: It doesn't seem like a particularly important item. I don't think we would have any objection if we left it out.

MS. HOIBERG: I think that's a good idea.

MS. HAMBORSKY: Any other problems in one?

DR. FEEMSTER: This is Kristen Feemster again. Along the same line, in the last paragraph about children six years of age and younger get DTaP, et cetera, et cetera, could we also maybe add a line saying protecting adults and adolescents also helps prevent transmission to infants who are too young to be vaccinated? Newborns?

MR. WOLFE: If we are going to put a statement about protecting infants in there, that would be as good a place as any to put it. The point there is that we are leading into the discussion of the vaccines, the adolescent and adult vaccines that contain pertussis.

DR. HERR: I agree, but what I would do is, again, we are focusing ultimately on protecting infants and newborns. And I would put the mortality and morbidity first, rather than talking about adolescents and adults. And then move on to them. Because we are trying to protect the infant who is at the greatest risk.

MR. WOLFE: Okay, so we need to point out that by making older children, adolescents and adults, in their immunity we are also protecting infants.

MS. PRON: This is Ann Pron. Infants who are the ones at most risk of mortality from pertussis.

MS. DREW: This is Sherry Drew. In describing pertussis, do you want to say that it can last for months?

DR. EVANS: It is true.

MR. WOLFE: We could.

MS. HAMBORSKY: I think that's when we will have to add some subject matter I heard about.

DR. EVANS: It is true, Sherry.

MS. DREW: What bothers me about the whole thing is, we talk about how they are caused by bacteria. And in

general, people think that if you have a bacterial disease they give you a shot of penicillin and then you are over it. And they don't really know that it is the toxins here that are causing the problem and that no matter what you do to treat it, you are not going to really get rid of it timely, ever.

That's just my comment. I am not necessarily suggesting that you include that.

MR. WOLFE: Yes, that is pretty nuanced for DIF, I think.

MS. HAMBORSKY: Is that everything for Section one?

MS. DREW: It looks like it.

MS. HAMBORSKY: And then Section Two, vaccines for adolescents and adults?

MS. HOIBERG: I had issues with that section where it talks about the Tdap vaccine. It is mentioned over and over again that it should only be given once, the Tdap. My concern is, A, what happens if a person were to get Tdap more than once? And second of all, should we just not recommend it at all to be given after a wound?

Because in many cases you are just going to be going into an urgent care facility to get a booster shot for Td if you have a cut, or the hospital. And for the most part I think you are not going to remember if you got

a Tdap, and there may not be sufficient records. So maybe in the event of a wound, maybe they should just be recommending the Td, just for safety prevention.

It has got to be important that it only be given once, or you guys wouldn't have said it in all three different -- it is mentioned quite a few times that you can only get it once.

DR. FEEMSTER: This is Kristen Feemster. If you happen to get it twice, it's not going to -- I think that you could potentially have a little more of a local reaction if it is within a short period of time. But there is no significant untoward events that would happen if you happen to get Tdap more than once.

I don't know what led to the decision regarding just saying that you only get it once. Maybe having a statement that says, it is recommended that you receive it once after a certain age. But if you happen to get it more than once, there is no specific action required. Would that be okay? So that if there are questions, if there is a risk associated with getting it more than once that would answer that question.

MR. WOLFE: We can check and see if people will go along with that. And remember, the patients getting the VIS are not going to be making the decisions on which vaccine to get. This is just to inform them, it's going to

be the provider who decides what vaccine to give them.

DR. HERR: This is Tom Herr again. I think the other thing to recognize when we are talking about non children getting the vaccine, whatever the opportunity, is most adults haven't a clue what their immunization history is. The other part is, for most adult practices, they don't really keep very good immunization records. And so this is relatively new for internal medicine, et cetera.

So I think the idea of only getting Tdap once at some time, it is going to happen a lot. And so we need to be prepared for that and have some sort of a statement.

DR. FEEMSTER: You mean potentially getting it more than once?

DR. HERR: Yes.

MR. WOLFE: That's about all we can do on the VIS.

MS. HAMBORSKY: As the person said before, it's not necessarily a safety issue. If you happen to get a Tdap and then 10 years later you get another Tdap instead of just your regular Td, it more has to do with the intervals in which you are getting additional pertussis protection.

DR. HERR: But it could be two years later, three years later.

MS. HAMBORSKY: That's the subject matter, the

specific pertussis subject matter. But I have not seen any safety data showing that anything needs to be done if you get more than one Tdap. It's just that it's not recommended.

MR. WOLFE: In the clinical trials, they probably didn't test multiple doses.

DR. HERR: Is it licensed only to be given once?

MR. WOLFE: Yes.

MS. PRON: This is Ann Pron. When you read it, it does make it sound as if you only get it once. If you read the statements where they occur in this VIS it does kind of maybe get folks a little fearful. Oh, maybe I had it already and now I got the second one. Now what's going to happen?

MR. WOLFE: Yes, so putting in a mollifying statement in there is probably a good idea.

MS. HOIBERG: The pertussis antigen is really kind of the problem causing part of the DTaP, the acellular pertussis and the pertussis. That seems to be the problem child when it comes to adverse events.

MR. WOLFE: The tetanus is the one that gives you a reaction if you get them too close together.

DR. HERR: This is Tom Herr again. In an article that was distributed to the Commissioners along with our packet form the Academy policy statement and the October

pediatrics, it does mention that the Tdap vaccines are not licensed for multiple doses. So is that the permanent, or is that the baseline of why it's only recommended to be given once? Simply because of the licensure?

MR. WOLFE: Yes.

DR. HERR: Then we still need to look into that, because it is going to happen more often.

MR. WOLFE: Yes, you are right. It will happen. And you are right that I think we probably need to reassure people that if it does they don't need to panic.

MS. HAMBORSKY: Anything else in two?

MS. DREW: No. We're done with two.

MS. HAMBORSKY: Okay, number three, which vaccine and when?

DR. FEEMSTER: This is Kristen Feemster again. I thought that maybe this could be reorganized just a little bit, because I thought it was just a little bit confusing. Perhaps either just starting with a statement saying a single Tdap dose is recommended for all 11 to 18 year olds, and 19 to 64 year olds. Or to start with Tdap and talk about the recommendations for Tdap, and then talk about Td, just so everybody knows for sure that we all need to get one Tdap dose, starting at the age of 11.

And also, of course, including the statement that you can get it for a catch-up vaccination starting at the

age of seven. But just to have Tdap first and then Td next, and just emphasize the new recommendation for adolescents and adults.

And to also perhaps mention that the most recent recommendations also, while it is recommended for every 10 years that there is no minimum interval really for receipt of a tetanus booster. If you happen to come in for a wound, for example.

MR. WOLFE: Maybe the place to mention that would be in the section where it says protection after a wound. Maybe add a phrase that says, if this happens to be prior to your 10 year booster, that's okay.

MS. HAMBORSKY: Any more?

MS. DREW: Anything else? No.

MS. HAMBORSKY: Okay, number four. Some people should not be vaccinated, or should wait.

MR. KING: It's Dave King speaking. The last paragraph before five, it says anyone who has a moderate or severe illness on the day the shot is scheduled, should usually wait until they recover before getting -- and then it says a person with a mild illness or low fever can usually be vaccinated. So a moderate, mild -- those are kind of pretty close. So which is it?

MR. WOLFE: The reason we are vague on that, and we have talked about this many times, is that we like to

leave that up to the -- make that a clinical decision on the part of the person who is giving the shot. So we don't want to be too directive. There are many factors, how high is the fever, and what other symptoms there are, that might provide a lead one way or the other.

MR. KING: So here is my concern with that. If I say the word tree, everyone in this room and on the phone conjures up a different image. Some think of Christmas, some think of elm, some think of sycamore, some think of pine, some think of apple, some think of willow, some think of cherry. Mild, moderate, conjures up different things in people's minds. You are leaving it wide, wide open.

MS. HAMBORSKY: That is just standard language that we kind of say for everything. We have had multiple discussions with multiple people. It's true what you are saying, that it is open to interpretation. But that is the point of it. They want the clinician to make a clinical judgment of how ill the person is or is not. So they don't want to get locked into, well, if you have an ear infection you definitely can't.

MR. WOLFE: Partly it would be the patient reading but the IOM making the decision, either.

MS. HOIBERG: But the patient is the one that actually receives the VIS. But that's beside the point. My thing is, I have always had an issue with the whole idea

of being sick and it being okay to get the vaccine. And now you are adding in that even with a mild fever or a low fever that they could usually be vaccinated?

I don't understand why you are making it okay for someone who has an already compromised immune system. I don't care how little compromised it is, but I've seen really in the end it couldn't be effective, or they could have an adverse event because their body is already attacking whatever, trying to fight off the illness that they have. So why is it okay for them to get a shot, if they are sick?

MR. WOLFE: Well it may or may not be. That would be up to the Commission to make that decision.

MS. PRON: This is Ann Pron. I don't want to speak for the CDC, but having read a lot of their materials over the years they speak of what they call precautions, and they speak of contraindications for administering the vaccine. And there are really not very many contraindications, meaning you never should get the vaccine, regardless. And that's like severe allergy and there's a few other things that are on there.

But things that are considered precautions are, like you are saying on the phone here, a mild illness, a low grade fever, even a moderate fever, if there is a reason that child is going to be in danger if they don't

get that vaccine, they can still be vaccinated. And that is most likely why these statements are separated into those categories here, because severe illness isn't exactly a contraindication but is sort of a high precaution.

MR. WOLFE: This is language directly from the general recommendations, too, which are paraphrased from the general recommendations, which we can't really do much about. But sometimes it's a risk benefit issue, too, that even a very strong risk, the fact that they are getting the vaccine might outweigh it, or vice versa.

And again, that's got to be a decision made individually, case by case.

DR. HERR: This is Tom Herr. I would like to go a little bit along with what Ann was saying. When we see children in the office, there are competing factors going on. Obviously most children aren't going to come in even with the thought of a vaccine, if it's not thought that they were probably well to begin with. Or relatively well.

So the idea of trying to immunize children as often as we can, because there has for years been a push up, or push, to make sure that you adequately immunize and take every opportunity to immunize children, to keep them and prevent illness.

Now when they come in, there can be all sorts of things that can make a child ill. They can have a cold,

they can have a stuffy nose and a little cough. But that child is technically ill. They could come in and be acting great and have an ear infection, or they can have strep. But they are not really all that sick. You can have a child who comes in and has 104 and has an ear infection. They are not critically ill, but they have got a bad ear infection.

And so in the competition, or the competing desires of immunizing the child to keep them from getting a very serious illness, as opposed to not pushing things when they are significantly ill, it really comes down to a clinical picture of how sick is the child.

And that really ends up being something that the clinician has to decide at that time.

MS. HAMBORSKY: Wait. Other things that we have heard are things like if they have got an established patient and they bring the child in and they have an ear infection. And they know that after 10 days of antibiotics that mom will be back and make sure that the kid is in to get their shots, that's one thing.

Versus maybe being in the urgent care center where the kid doesn't have a medical home, and may not get back to see a doctor for another year. So it's also the clinical picture of the child, but also the insurance data and the medical home and the risk for missed opportunities.

DR. HERR: Precisely.

MR. WOLFE: And then all of that is true, but the other thing that I want to stress again is that since it appears on the VIS, which is for the benefit of the parents, nobody is going to make decisions based on that. It's just telling the person getting the shot what might happen. They might get the shot if they are a little bit sick, or they might not. But that is going to be the clinician's decision.

MR. KING: Dave King here again. I think parents make decisions based upon what they read, regardless of what the doctor thinks. That's why we have problems with people not being vaccinated. People are making decisions. What I am saying here is that I don't know whether a person should be vaccinated with a mild illness or not. Maybe they should, maybe they shouldn't, and yes, that should be decided in a conversation around.

What I am saying is that this isn't clear. This is to me, when I read it, it's like it's one sentence contradicts the following sentence to some degree. That's all. I view it as an unclear component. I am not objecting to, if it's someone is mild that they should get a vaccine. If that's what everybody agrees that they ought to, then let's do it.

DR. HERR: I think it is meant to stimulate the

conversation. So that if you read this and you have a question about it, then when you bring your child in, you are going to talk to them. Is this a serious enough illness? Can my child still get this safely? Or should we come back and get it another time?

This is the incentive to talk about it, not to solve all the answers, but just to stimulate the conversation.

MR. KING: And in your practice that's how it has basically been used?

DR. HERR: Absolutely.

DR. EVANS: Those are the purposes of visits, to facilitate discussion, not to be the end all, but so that there are questions asked and there is dialog.

MS. HAMBORSKY: And then number five, what are the risks?

MS. WILLIAMS: This is Michelle Williams. After the mild problems, in the mild problems section, there are ratios three and four adolescents, two and three adults. Some of those parentheses have adolescents and adults, some of them don't.

MR. WOLFE: Yes, if there is no difference between the rates in adults and adolescents, then we just have the one.

DR. HERR: Redness and swelling, I guess it is

one in five of every --

MS. HOIBERG: One in five persons?

DR. FEEMSTER: Adolescent and adult. I guess you could say one in five adolescents and adults, just to be consistent.

MR. WOLFE: We could. We are trying to keep them as brief as we can. I don't know, I think that should be understood, if you say one in five they were talking about people.

MR. KING: It can't be understood if the question got asked.

MR. WOLFE: We're trying to keep it as succinct as we can without making it unclear.

MS. HOIBERG: So down at the bottom where it says chills, body aches, sore joints, rash, and swollen glands, it just says uncommon. So that means that no one reported it?

MR. WOLFE: The figures come from the ACIP statement. So that was probably the term they used. And I don't know what the actual figures are.

MS. WILLIAMS: This is Michelle Williams again. On the last sentence of that section, it says a severe allergic reaction could occur after any vaccine. They are estimated to occur less than one in a million doses. Is that they, for any vaccine? Or is it for the vaccines that

are the subject of this statement?

MR. WOLFE: That's a good question. I will ask. It's probably any vaccine, but I'm not sure. Do you know?

MS. WILLIAMS: And I think the statement, a severe allergic reaction could occur after any vaccine, is fine. But isn't this -- well, I see there are problems.

MS. HAMBORSKY: I think it is for all of them, it would be something like overall they are. I think a word like overall is missing. Because I am pretty sure that in general, especially our communications people, they use that a lot. They say estimated to occur in less than one in a million, talking about across all vaccines.

MS. WILLIAMS: Okay, and I guess then my question is --

MS. HOIBERG: But really that is not a true statement. I mean, if you just look at the amount of flu vaccines that were given and the amount of cases that have come in, that is more than one in a million.

MR. WOLFE: Where is that?

MS. HOIBERG: The cases of flu vaccines, how many flu vaccines were administered and how many adverse event reports that we have received, isn't it more than one in a million?

MR. WOLFE: Anaphylaxis?

MS. HAMBORSKY: No, this is severe allergic

reaction, not all adverse events.

MS. WILLIAMS: This doesn't even say anaphylaxis.

MR. WOLFE: Because we don't want to say anaphylaxis. We call it a severe allergic reaction because, look, most people probably won't know what anaphylaxis is.

MS. WILLIAMS: So a severe allergic reaction should actually be a bullet point underneath swelling?

(overlapping voices, off microphone)

MS. WILLIAMS: That was my original question, is it Tdap or is it any vaccine?

MR. WOLFE: We think it's any vaccine, but we will check.

MS. WILLIAMS: Okay, so is there anaphylaxis after Tdap or Td? Because if there is, then there is a missing bullet under severe problems? Do you see what I am saying.

MR. WOLFE: Yes. I don't know. If it was not listed specifically in the ACIP regs, we can ask and find out if there have been reports, and if there are, if they were confirmed, and see if there were any.

MS. WILLIAMS: This would lead me to believe that the most severe thing that could happen would be, for the most part, would be swelling, severe pain, bleeding and redness. And perhaps severe allergic reaction.

MR. WOLFE: I don't know if we have to add on the frequency of anaphylaxis after any vaccine, but I can check and see. That's why we make that a general statement like that. And then that same statement occurs on just about every VIS.

MR. KING: But maybe we should be rethinking them all.

MR. WOLFE: Well, if there is actually data, then maybe so, yes.

MS. HOIBERG: And what about seizures and encephalopathy and all that kind of stuff that can happen with acellular pertussis?

MR. WOLFE: Well, if it has been reported after Tdap, presumably we would have it here.

MS. HOIBERG: Can DOJ come in and say anything about it?

MR. WOLFE: That happens in kids. I don't know if it is happening in adults or adolescents.

MS. HAMBORSKY: Even for Tdap, isn't it, even if you have had a history of a severe reaction as a child, you are still eligible to get Tdap. So I don't know if they would actually have that data.

MR. WOLFE: Some of the things that are contraindications for DTaP are not for Tdap.

MS. HOIBERG: It says anyone who has had a life

threatening allergic reaction after a dose of any Tetanus, Diphtheria or pertussis containing vaccine should not get Td or Tdap. But then it goes on to say talk to your doctor if a person getting either vaccine has epilepsy or another nervous system problem, has severe swelling or severe pain after a previous dose of Dtp, DTaP, Dt, and so on, or has Guillain-Barre syndrome.

But it says anyone who has had a coma or long or multiple seizures within seven days after a dose of Dtp or DTaP should not get Tdap, unless a cause other than the vaccine was found. These people may get Td. That kind of contraindicates the --

DR. HERR: This is Tom Herr. With the question of trying to make a statement that may specify anaphylaxis as one of the only serious reactions, or very serious, or all capital word serious, capital letter serious reactions, and leave out the others that have been noted to be associated or compensated for with the vaccine, maybe you want to change the statement to something like, very serious reactions, or more serious reactions do occur very infrequently or very rarely.

And you can leave that vague, and not specify what serious reaction you are talking about, and then leave that, have that lead into the rest of the paper here, the VIS that says what to do if you suspect something very

unusual happens.

MS. PRON: It actually does describe it -- this is Ann Pron -- under signs of severe allergic reaction, under number six in the second sentence.

DR. HERR: Without going into your transverse myelitis and Guillain-Barre and all that stuff.

MS. PRON: But maybe that could be included under -- maybe that's what people are looking for under severe, and they want to know what that might look like. I don't know if that's what the issue is that we are discussing in the first place. Because then it goes to describe it.

MS. WILLIAMS: This is Michelle. I guess what I was looking at was severe problems, unable to perform usual activities, required medical attention. And then I see there is just one bullet, and it says swelling, severe pain, bleeding, redness in the arm. That doesn't sound so severe to me.

MR. WOLFE: Well, that is not our decision. And the thing that is interesting about this, this is the only ACIP thing where they actually give criteria. And then that happened to be the only item that fell under that category, that they had data for.

And then they call it a severe problem. I'm not sure if that's R2 syndrome.

MS. HAMBORSKY: Yes, because even the ELS, limb

swelling is under moderate. So we are going to check to see if this statement that says they are estimated to occur less than once in a million, is specific to Td or Tdap or if there is an overall statement encompassing all vaccines.

MR. WOLFE: If it is, we will make sure that that is clear.

MS. WILLIAMS: And then if there is another severe problem other than swelling, severe pain, bleeding and redness, such as a severe allergic reaction. Because that phrase makes it seem as though a severe allergic reaction, you need to spread out over all vaccines, and that severe allergic reaction therefore would be less or nonexistent for Tdap or Td.

MR. WOLFE: My guess is that they don't have specific data, because they are so rare, on the rates of anaphylaxis after vaccination.

MS. WILLIAMS: But if that is true, then they could put a severe allergic reaction, rare, because that is specific to Tdap or Td. You can still have the sentence --

MR. WOLFE: Unless we don't know that there has ever been one after Tdap or Td. In that case it would be misleading.

MS. WILLIAMS: Okay, and that may very well be. And that's all we are asking.

MS. HAMBORSKY: We will have to ask Dr. Lang

about this. Okay, anything else for that section? Should we go on to six?

DR. EVANS: This is Geoff. I just think you need to make clear -- and I see where this has gotten confusing to people -- you have this transfer from the use of DTaP in seven year olds and below, and then now you have this newly licensed Tdap, which is going to be given to older, school age children and adolescents.

And the precautions and contraindications for the neurological stuff that is residual to what we used to have for Dtp and DTaP, and that is kind of getting mixed in or close to this little transition time period for Tdap. So I think you need to make clear that you are talking about severe reactions. Are you talking about allergic reactions? Are you talking about neurological reactions? Or either, or both, or what?

That is part of why it is getting confusing, because you are using some of the same language there. So I think there has to be, to the extent that you can, we know that the same precautions and contraindications continue to be used in the red book. When we went from Dtp to DTaP that didn't change, because there really wasn't data.

All I am suggesting is that as we try now to go forward with Tdap, that we make clear the demarcations

between the older language, the older precautions for the DTaP, versus the new when we use Tdap vaccine. Do you follow what I am saying? I think it is getting kind of mixed together.

MR. WOLFE: Because you believe that people will remember what we said about DTaP?

DR. EVANS: The way you are starting out by talking about severe reactions and talking about neurological symptoms, and then you are talking about severe reactions and you are listing things that are more analogous to allergic reactions. And I think you have to be clear which vaccines, and what you are talking about.

Because Tdap, you don't have your neurological disorders to worry about when you give a Tdap vaccine, whereas you do when you give a DTaP vaccine. So it's making sure where those AIDS distinctions are, and for the products.

MS. HAMBORSKY: This is just for Tdap and Td. I think most of those are on the separate DTaP VIS.

DR. EVANS: But you still have DTaP listed here.

MR. WOLFE: We mention it only -- yes.

MS. HAMBORSKY: Right here are you talking about?

DR. EVANS: Yes, anyone who has had DT or DTaP should not get Tdap. Just be clear about what you are talking about in using this language, especially for the

allergic reactions. Because as you know, for DTaP, we don't have the neurological complications and the evolving neurological disorder concerns that we have with the other vaccines that were given earlier in an infant's life.

MR. WOLFE: So you're talking about under number four, when we are talking about the multiple seizures?

DR. EVANS: I'm just suggesting that may be part of the confusion that we are bringing forward here.

MS. HAMBORSKY: So as far as number five, have we gotten all the comments?

MS. DREW: Apparently we have.

MS. HAMBORSKY: Okay. So number six.

MR. WOLFE: Now six, seven and eight are going to be the same on all of them. And to bring you up to date, last time we had a protracted discussion about number six.

MS. HAMBORSKY: Especially about calling 911. And so we have some updated information about 911.

MR. WOLFE: Yes, we haven't changed anything on any of the VISs yet. But we have been discussing it. We had some discussions with Dennis Murray from AAP about that, and he had some good ideas. So we are trying to get a consensus among some of the people here about how we can change those, especially under the second part of part six there, to make it more in light of what we talked about in the last meeting.

DR. DOUGLAS: Will that be available for our next meeting?

MR. WOLFE: I hope so. We can at least have a draft, even if it's not part of one of our public VISs, we can have a draft of that section to look at.

MS. HAMBORSKY: If we don't have 911 to talk about -- we are at that section.

MR. WOLFE: We were under some pressure -- not some pressure, but the people who conducted some focus groups on these, they wanted us to change number seven. And Jeff, I know that we spent a lot of the time trying to hammer out the wording that we had in there. So we talked them out of that. Unless there are other objections, we are going to maintain the wording that we have under number seven, since so much work went into getting that the way it is now.

MS. HOIBERG: As you see, I have given up on trying to get you guys to put in 911.

MR. WOLFE: Oh, don't give up.

MS. HAMBORSKY: It's not that we don't want to do it. It's just that the feedback and the information that we get from HCCV is only part of the feedback we get. And we can't just unilaterally make some of these changes without getting feedback from other groups. So it has to be a compromise of a whole bunch of different groups.

MR. WOLFE: Right now we are leaning toward an either/or. To call 911 or get the person to a doctor.

MS. HOIBERG: Like emergency services, or an ER. I know we discussed it at length last time.

MR. WOLFE: Although, to quote Dennis Murray, he said you will be in deep doo-doo with that if families rush patients to the doctor or ED for what they perceive is a high fever. So we need to be cautious.

DR. HERR: They do that anyway.

MS. HAMBORSKY: So what does it say about 911 there?

MR. WOLFE: You would not rush.

MS. HAMBORSKY: I would not rush to the doctor, ED, or call 911 for a fever -- he is saying a fever less than 105, unless the patient was having other problems with airway breathing or cardiac related problems.

So he is basically telling us that if we add 911 there has to be all these criteria of why you would call 911.

MR. WOLFE: So anyway, hopefully by next time we will have some briefer language for you to review.

MS. HAMBORSKY: Do we want to move onto the next one?

MS. DREW: We have hepatitis B as the next one.

MS. HAMBORSKY: Okay. So number one, what is

hepatitis B?

MR. WOLFE: This really hasn't changed a lot from the last one.

MS. HAMBORSKY: No really, did we just add diabetes?

MR. WOLFE: Yes, it was precipitated by their recommendation to add diabetes to the indications. And there are just some other wording changes too. But nothing really, no real significant changes other than the addition of diabetes.

MS. HAMBORSKY: So we are okay with section number one?

MS. DREW: Yes.

MS. HAMBORSKY: Okay. Section number two -- why get vaccinated.

MR. WOLFE: Some of the epidemiologic figures under number one changed, too, because we have more recent data.

MS. PRON: This is Ann Pron. As I was reading number two, and then I went on to read number three, the second paragraph, it's a single sentence actually, hepatitis B vaccine may be given by itself or in the same shot with other vaccines. I was just picturing the parent thinking that you are going to have three mls or a very large amount of liquid that's put all together in a vaccine

and shoot them into your child.

Down in three it does talk about combination vaccines, and that getting an extra dose is not harmful, which is repeated in the next VIS we are going to review about polio. And I just didn't know, that sentence, in the same shot with other vaccines, I didn't know if you wanted to talk about the combination there, or just defer that whole sentence. I'm not sure why it is right there.

MR. WOLFE: You mean define it up in part two, the combination vaccine?

MS. PRON: Or else just move that whole sentence down. I'm just not sure.

MR. WOLFE: You are right. It doesn't really need to be up there.

DR. HERR: It doesn't add to number two.

MR. KING: I take a more holistic approach here. I ask why we are not consistent in the format between the vaccine information statements. So when I look at what we are on right now, which is the hepatitis B, we start with what is the hepatitis B, then we go with why get vaccinated. Then we go with who should get it.

And if I were to sneak ahead, I would find under polio that would basically follow that format. But if I go back to the one that we just closed out, and said that we were done with discussion on, I find that we don't quite

use that same type of format. Wouldn't it be best to have a similar format across all of them, in terms of a rhythm of how it flows? What, why, who?

MR. WOLFE: Yes, possibly.

MS. HAMBORSKY: I think because, if I remember correctly, because of space issues, because there were so much more space taken up with the problems, we kind of awhile ago made a decision to combine the why get vaccinated with what -- if you look in where it says tetanus, diphtheria and pertussis, and it kind of defines what it is, we kind of collapsed one and two into one for Tdap, because there was a space issue.

MR. WOLFE: In theory we agree with you. But also, depending on the vaccine, there are specific differences in what we want to say about vaccines, that sometimes may lead to differences in format.

The example I always use is, when we created the HIB CIS, nobody knew what HIB was. So we had to devote the first section to explaining, to answer the question what is HIB, whereas with some of the other ones that is not as important because people are already familiar with them.

MR. KING: Maybe. I think let's go back to the Td one, where we are saving space. Why don't we just say what is -- or on the same line put the question what, and put the question why. If you have to combine them, make it

the what is it, and why get vaccinated? You could fit it on the same line from a space perspective, and then you would be able to continue with that same type of format or cadence for how these are done.

MS. HAMBORSKY: We can do that. We are just telling you why they differ, and that was it. It was a space issue.

MR. WOLFE: Sometimes when we work with the subject matter experts, they want to do things in a certain way, too. You see that more with the travel vaccines, where they have specific ideas about how we should organizes things.

MR. KING: I think we should organize it based upon how people receive the information. And that the people who are reading it and who it matters to are more important than those who are actually giving the information. And so since parents have to read and other adults and caregivers have to read, and actually people who are adults who have to take vaccines over time have to read many of these, if they are all in a similar type of format, it's kind of like a book.

It has a cover, title, table of contents, chapters, information, index at the end, and we all get a rhythm on how we go about it. Why not the same with Vaccine Information Statements?

DR. HERR: This is Tom Herr. I am going to put a little glip in what you said.

MR. KING: A little wrinkle.

DR. HERR: Only because one of the things that I have been doing is, when I see newborns in the office for the first time I give them all of the Vaccine Information Sheets that they are going to get for as long as they are going to be in my practice. And we update them as things come.

I have found that new parents are more likely to read Vaccine Information Sheets than at any other time in the child's life. So I give them all at the same time. And if they are all the same, they might get sleepy and skip over parts. So if you make them a little bit different, it makes them a little bit more interesting. Just as a little wrinkle.

MR. KING: I would like to find out from Tom if that is best practice across his industry, and if everyone does that.

MR. WOLFE: I don't even know if people reading them, whether that matters to them or whether they would understand them more if they were consistent, or whether it doesn't make any difference at all. That would be interesting to find out.

MR. KING: It should be about the recipients of

the information, how do they best get it in a format that allows them to understand and maybe not a full understanding, but to foster, as we said, the dialog with their physician or the child's physician, to have a conversation about what is or isn't.

MR. WOLFE: And it may be that the format is really important, and it may be that it's not. We don't know.

MS. HAMBORSKY: We know a little bit.

MR. WOLFE: That's true.

MS. HAMBORSKY: And just anecdotally, I have a daughter who is three and a half now, but her pediatrician did the same thing. When I went for the very first visit I was given all of the VISs, and I was told when you come back in two months she is going to be so upset, you are going to be so upset you are not going to read this, so read them all in advance.

So it may be kind of common that a lot of pediatricians are doing that. But the focus groups told us as far as parents' ability to comprehend the information and really ask good questions, they wanted the VISs in advance so that they could read them, go in, talk to the doctor, and then get the child vaccinated. There are small samples and there are focus group data.

But it's what we have, and that's what the

parents told us. They said the paper itself didn't make as much of a difference. It was the timing in which the paper was given.

MR. WOLFE: Jennifer and I have a lot of interesting discussions on this topic too, because she is more concerned with consistency than I am. We also have internal discussions about this.

MS. HAMBORSKY: Right. But that is what the parents told us, was that it really had to do with when it was given, when they got the information. Really they wanted time to read it and internalize it so they could ask good questions.

MS. WILLIAMS: This is Michelle Williams. In section one, we talk about acute illness is more common among adults. Children who become infected usually do not have acute illness. Do adolescents fall with the adults or with the children because we usually are talking throughout about children, adolescents, and adults.

MR. WOLFE: I don't know.

MS. HAMBORSKY: So how about number three? Any comments on number three?

MS. PRON: This is Ann Pron. I want to address this issue that came up before, and I thought again we were going to have more information about what had actually been said by consultants or focus groups, et cetera. The last

paragraph on the page where number three is says your doctor can tell you about other dosing schedules.

And then again it is repeated in number four a couple of times. Your doctor can give you this and that. But in fact, many patients don't see a doctor. They see a nurse practitioner, some may see physicians assistants. And many who may go to health departments to get their immunizations will only see a nurse.

So I think that I know you said once before that there were some focus groups in the past that had said they really understood the word doctor better than any of the other wording that was used. But there are many of our citizens who never see a doctor.

MR. WOLFE: It turns out at least from the data we have got that from a readability and for an understanding doctor seems to work better than provider or doctor or nurse. And I may have mentioned before that when we tried to be more inclusive before, every time we would add a type of provider another one would call and say that they wanted to be added too.

So we finally went to provider, and then learned that people didn't like provider either.

MS. HAMBORSKY: Right. The focus groups, they told us that they interpreted provider as their insurance carrier. And they were saying things like, why would I

call Blue Cross, why would I talk to Blue Cross. So it's unfortunate, but the compromise for nurses, nurse practitioners, pharmacists, PAs, was provider. And then we find out provider means carrier.

MR. WOLFE: And interestingly, we have heard from three or four different sources that people want to hear doctor. I understand why people might object to that or not like it. But it seems that is the most understandable way to do it.

MS. PRON: Are these sources available? Are they recent? Are they across different socioeconomic groups, ethnic groups, what not?

MS. HAMBORSKY: The most recent focus groups were done in January and February of this year, of 2011. And yes, they were done in multiple cities with various socioeconomic levels. They did triads, they did regular focus groups, they did one on one interviews. Methodologically it was pretty solid.

I attended several of them, as did our attorney. So the decision was made to go back to doctor.

MR. WOLFE: We knew we were going to get a lot of flak for it, but we thought we would try it anyway.

MS. PRON: I will probably bring it up a couple more times before my term is over, so thank you.

MR. KING: Just one other comment on that,

because I think Ann may be on to something there. And that is, there are probably a lot of people without insurance at all. So if they are, it is unlikely that they would think of their provider as an insurance provider. And so we might not be capturing those folks in the focus groups.

MS. HAMBORSKY: Even the ones who were on Medicaid or various -- I can't remember exactly which ones they were, but there were several. Here in Georgia it's called Peachcare. I can't remember the one in Arizona, which was one of the places I went to. They thought that, too. That was a question that was specifically addressed.

MR. WOLFE: Also, I suspect that if somebody sees "ask your doctor," and there is only a nurse in the room, they will ask the nurse. They won't not ask because there is no doctor there, I don't think.

MS. PRON: I guess in the field of vaccinations, nurses in public health clinics have been involved for so many years in this aspect of health care that it just seems in a way a little injustice to them. But I am listening to what you say.

MR. WOLFE: We try to include different groups. I don't think there is a good solution to this, only ones that are less bad.

MS. HAMBORSKY: Right. And we have gone full circle now. We have been through all of them. That was

one thing out of the focus groups that they were very, very specific about, was just call all providers doctors.

DR. HERR: You know, if you want to just sort of avoid it, why even just not leave it in saying other dosing schedules might be used in certain circumstances. And leave off by whom altogether.

MR. WOLFE: In that one specific instance, that might work, but there are other ones where we say, talk to your doctor, where we really do need to say it.

MS. HOIBERG: This is Sarah Hoiberg. The visits are not uniform. And so if in this case where there is a dosing schedule available, so there is a different dosing schedule available like Tom said, just leave off ask your doctor. In that case, in this particular instance, just leave off ask your doctor. Just state that there is a different dosing schedule available. Ask for more information.

MR. WOLFE: In fact, I would ask about leaving that sentence out altogether, because the other dosing schedules are not very common.

MS. PRON: It gives them a chance to think they could do it a different way.

MR. WOLFE: If a patient is in a situation where the provider is going to use a different schedule, they can explain it to them. It doesn’t necessarily have to be on

the VIS anyway.

MS. HOIBERG: Are you ready to move on to number four?

DR. FEEMSTER: One quick thing on three. So under children and adolescents, it nicely lays out the dosing schedule for babies and then says that you can be vaccinated through age 18. But it doesn't give the dosing schedule. And so maybe at the end of that section we could say unvaccinated children, adolescents and adults should get three doses. And just include them, because otherwise it doesn't really indicate when they should get vaccinated.

You have babies, and then you have adults, for the dosing schedule.

MS. WILLIAMS: There is no adolescent dosing schedule.

DR. FEEMSTER: Yes, it doesn't discuss unvaccinated children or adolescents. So either make a specific statement up in the children and adolescents section, or just add children and adolescents to the statement you have about adults getting three doses. Because it is the same schedule.

MR. WOLFE: Okay, so we are going to say anyone through 18.

DR. FEEMSTER: Yes, anyone through 18, anyone who is unvaccinated, previously unvaccinated.

DR. HERR: Or anyone not immunized as an infant, as a child, this is the schedule.

DR. FEEMSTER: Exactly. Anyone who needs catch up vaccination, essentially, or who hasn't been vaccinated.

MS. WILLIAMS: This is Michelle Williams. At the risk of, I don't know what it would be called, but under adults we have got sex partners, people who inject street drugs, people with more than one sex partner. Those aren't activities that are restricted to adults -- respectfully.

MR. WOLFE: But it is routine for people up through 18, so it doesn't matter what risk factors there are for them. The only time when risk factors become an issue is for adults over 18.

MS. HOIBERG: Assuming that the children were vaccinated.

MR. WOLFE: Yes.

MS. HOIBERG: So meaning an adolescent, no matter what they do, whether or not they engage in risk behaviors, should be vaccinated.

MR. WOLFE: Right. It's routine up through 18 years of age.

MS. HAMBORSKY: But if you were not vaccinated as a child, and say you are 30, it would only be indicated if you had one of these risk factors. It wouldn't be that just because you weren't vaccinated as a child, you

wouldn't get it. There is not a catch up, like. Do you know what I mean? It's risk based catch up. It's not just age based catch up.

DR. FEEMSTER: So you don't need to isolate adolescents doing risk factors, because they should be vaccinated, no matter what. Maybe we should just say that explicitly, like all children through age 18 need to be vaccinated. It is recommended for routine vaccination to infants. Give the schedule. Anyone who is unvaccinated gets it. Then everyone knows that it's --

MR. WOLFE: That everyone up through age 18 should be routinely vaccinated, and then go into the details. Okay.

MS. WILLIAMS: Maybe is that in section two, that it needs to be clarified?

DR. HERR: There was another article that I read recently along with this stuff, and it dealt with the question of just, I think, the 60, 65 which maybe looking into the adults. But there was some comment that, again, how people who are over 65 respond to the vaccine. They don't respond as well as younger people do.

And something about the cost benefit numbers are markedly different. So the risk benefit really changes as a person gets older. So I think when we are talking about adults with these problems, these are people that make it

more important than the average, quote unquote, healthy older person, of why they would want to get hepatitis B. As opposed to somebody who has the normal I'm getting old, high blood pressure, my cholesterol is up, that kind of stuff. Do I need to get the hepatitis B and I haven't had it yet. Maybe that's what they are talking about here.

MS. WILLIAMS: They talk about people over 60. I was talking about adolescents engaging in --

DR. HERR: The point is, they should already be getting it anyway.

MR. WOLFE: They are covered. Then there is that last bullet, the second bullet under adults, that gives anybody who wants to get the vaccine the option that if they want to, even if they don't have any of the risk factors.

MS. PRON: Are you wanting them to write adults as anyone over 18? Do you want them to spell that out, Michelle?

MS. WILLIAMS: The first issue is that the adolescent dosing schedule wasn't up there, even though they talk about adolescents. So I was just trying to figure out if -- I think my question was answered. I don't think I need to change any more.

MS. HAMBORSKY: Could it answer that question if we said anyone through 18 years of age who didn't get the

vaccine when they were younger should receive three doses, and then add zero, one, and six months, or whatever the schedule is? Would that cover the adolescents?

MS. WILLIAMS: Yes. And should it be any? When we are talking about adults, is it just residents and staff in institutions for the developmentally disabled? Or is it any institution?

MS. HAMBORSKY: We will have to check, because I think that wording comes directly out of the recommendations.

MR. WOLFE: Which presumably means that is all they have data for.

MS. WILLIAMS: I know when you donate blood for the Red Cross now, one of the new questions -- it may not be that new -- is, if you are questioned further, if you have been in jail for longer than three days. And I had always assumed that was for hepatitis.

MR. WOLFE: It may well be. I don't know.

MS. WILLIAMS: So I just don't know why it is restricted.

MR. WOLFE: I could likely say that if it is evidence based, and they have evidence for institutions for the mentally disabled but no data for prisoners, then maybe that is why.

MS. WILLIAMS: That could be.

MR. WOLFE: We will check.

MS. HAMBORSKY: We will ask.

MR. WOLFE: Just to make sure that hasn't changed.

MS. WILLIAMS: Nursing homes? I don't know, nursing homes.

MS. HOIBERG: I thought nursing homes was on the old one. Or was that for another one?

MS. PRON: I am wondering -- this is Ann Pron -- does this list refer to that the insurance companies will pay if they are on the recommended list? Is that why it is spelled out?

MR. WOLFE: Probably so. We have been getting questions about different vaccines where insurance companies refuse to pay for somebody who wants to get a vaccine and is not on the list of people for whom it is indicated.

MS. WILLIAMS: Well that is my question. It seems like there are a number of people -- children, adolescents, and adults -- that are in institutions for a long period of time. It's not just being in a hospital institution, that that would be indicated.

MS. HAMBORSKY: We are just looking, pulling out the most recent ACIP recs, and we will look and see. But we are pretty sure that's what it said.

MR. KING: Maybe it could say something, though, like residents and staff in institutions such as -- and list some. And even if you don't have a comprehensive list, you could end it with et cetera.

DR. HERR: Or more to follow.

MR. WOLFE: We copied them word for word, residents and staff at facilities for developmentally disabled persons. So if we tried to expand that, I think the -- ACIP people would slap us down.

MS. HAMBORSKY: Yes, unless they update their recommendation.

MR. WOLFE: And then ACIP is really big on making everything evidence based now, so it is going to get tighter and tighter. I anticipate that these problems are going to get worse in the future, when we can't generalize about anything.

MS. WILLIAMS: If you are going to ask about incarceration, and then what about health care workers?

MR. WOLFE: Well people with jobs that expose them to human blood. Actually, we should look at the new health care worker recommendations that just came out to see if there is something in there that would change this. for all health care workers, instead of just those that have been exposed to blood.

MS. HAMBORSKY: Yes, because this says people

with jobs that expose them, and that would include public safety. This says health care and public safety workers.

MS. WILLIAMS: Is it just human blood? Don't policemen get it because they get bit?

MS. HOIBERG: It says here bites.

MR. WOLFE: That would include them, with jobs who -- the human blood, that would include law enforcement I am sure.

MS. WILLIAMS: Where is bites?

MS. HOIBERG: It's in the first part, on the first page, it talks about hepatitis B virus can be spread easily through the contact with blood and other bodily fluids. Bites.

MS. WILLIAMS: That's not their blood. You are the biter, not the bitee.

MS. HOIBERG: No, but it says here fluids, it says contact with blood and bodily fluids, through breaks in the skin such as bites, cuts or sores.

DR. HERR: People's gums bleed.

MS. WILLIAMS: Right, that's what I am saying. It says bites, but it doesn't include bites, daycare workers.

PARTICIPANT: So this should just say body fluids, and not just human fluids?

MS. WILLIAMS: Yes, is it just human blood or is

it bodily fluids?

MS. HOIBERG: It just says, and other bodily fluids.

MS. HAMBORSKY: But blood contaminated bodily fluids, so that's why I think they came up with human blood.

MS. HOIBERG: Because this says contact with blood and body fluids through breaks in the skin. That's on the first page.

DR. HERR: Do we want to just say this includes but not limited to?

PARTICIPANT: I think that is implied, though.

DR. HERR: Yes, I know, but --

MR. WOLFE: I am kind of glancing at the new health care personnel ACIP statement. And under hepatitis B it does say, depending on the task performed, health care public safety personnel might be at risk for HPV and again it talks about possible exposure to blood.

MR. KING: So should that be inserted here?

MR. WOLFE: Well, that is really going to -- I don't think that is really different from what we already say. I'm trying to see if this says anything different.

MR. KING: Well public safety is a new word, I think.

MS. HAMBORSKY: That's why I think that this says

job. Because they didn't want to get into defining --

MR. WOLFE: Who might be exposed to blood.

MS. HAMBORSKY: Right.

MR. KING: So why not use what you just read in this statement?

MR. WOLFE: Well, there might be a reason to do that, since that is in writing in another ACIP statement. Maybe I will suggest that. And again, it would have to be included. We would still have to say people with jobs that expose them to human blood, for example --

DR. HERR: Day care workers.

MS. HOIBERG: Dental hygienists.

MR. WOLFE: I don't see how anybody could object to that.

MS. HAMBORSKY: They start putting OSHA stuff here.

MR. WOLFE: They could, yes. But our Hep B reviewer is pretty reasonable.

MS. HAMBORSKY: Yes, because they are quoting, it says here, the federal standard under OSHA made available. It says the hepatitis B vaccine should be made available at the employer's expense to all health care personnel who are exposed occupationally to blood or other potentially infectious materials. The federal standard defines occupational exposure as reasonable anticipated skin, eye,

mucous membrane, or parenteral contact with blood or other potentially infectious materials that might result from performance of an employee's duties.

Outpatient studies or those residing in long term care facilities, for example, assisted living. But there is nothing mentioned about correctional facilities.

MS. WILLIAMS: This is Michelle Williams. I just think this section probably needs more work than we are going to get to right now.

MS. DREW: Can we look at this and get back to you at some point? Or can you bring back the revisions next time and let us take a look at it?

MS. HAMBORSKY: I am just looking at the further book that it goes into. Free exposure, unvaccinated, incompletely vaccinated health care personnel exposure, unvaccinated trainees, vaccinated health care providers and trainees, health care trainees at additional risk. Yes, we will have to figure out a way that incorporates all of this.

MS. DREW: If you could incorporate what you can, and then let us see it next time, then I think we could probably make more informed comments. Can we move on to four now:

PARTICIPANT: Is that acceptable to them?

MR. WOLFE: Okay. We can't go outside of what

ACIP says, so within what their recommendations say.

MS. HOIBERG: Okay, so four, we are going on to four. My question is, it just starts with the number one bullet. Anyone with a life threatening allergy to yeast should not get the hepatitis vaccine. And this brings me back to the idea of, we don't know what our babies are allergic to.

MR. WOLFE: That is why we have that last sentence under the first bullet there. That is the best we can do, to let their doctor know if they have any severe allergies. And the provider can cross check that against the package insert.

DR. HERR: If the parent has severe allergies?

MS. HOIBERG: We don't know if the baby. So this needs to be clear a language, then, because you don't necessary inherit a specific allergy. So one, you are assuming that if the parent is allergic, that the child would be allergic. Or if the parent --

MR. WOLFE: No, that is not an assumption. An allergy in a parent is not a contraindication to any vaccine.

MS. HOIBERG: Right, so I guess that just -- when you have a vaccine that is such a life-threatening reaction, we don't know what our kids are allergic to as babies, as infants.

MR. WOLFE: That is true. That is true the first time you give them eggs, it's true the first time you give them aspirin or anything.

MS. HOIBERG: Right. But this is given to them at birth.

MS. HAMBORSKY: I think it depends on how widespread the birth dose recommendations are. If there were a lot of anaphylactic reactions to yeast that would be picked up in the birth dose we would see some safety issue.

MS. HOIBERG: Wasn't there at one point something where they had started recommending that the first dose be given at six months? But now they have brought it back to the birth dose?

MR. WOLFE: For Hep B?

MS. HOIBERG: Yes.

MR. WOLFE: Yes, at one time it was optional. You could give it at birth or you could give it at two months, I think, the first dose. And then ACIP went to recommending birth dose for everybody. I don't remember what year that was.

DR. HERR: And that is just compliance.

MS. PRON: That's because they didn't know the status of the mother. The mother may have not been treated for hepatitis B and they might not have known that. Just to catch those babies.

MS. HOIBERG: That was my only thing with that one.

MS. DREW: Five?

MS. HOIBERG: I had to laugh, because remember, we were talking about in the last one with one in a million, and this one is 1.1 million doses.

MR. WOLFE: Everybody has specific information Hep B.

MR. WOLFE: If that is a figure that is supposed to apply to all vaccines, we will make sure it's consistent.

DR. SHIMABUKURO: This is Tom Shimabukuro at CDC. So there is published data on rates of anaphylaxis, determined from epidemiologic studies for some vaccines. And I know that hepatitis B is one of the vaccines they have looked at. And from my recollection that 1.1 is about right.

Maybe for Tdap and Td they don't have any published data because Tdap is a fairly new vaccine and they haven't done the work. So maybe they had to estimate or extrapolate that number. But that appears to be, it sounds like it is probably Hep B specific from the one single study that looked at the rates of anaphylaxis. But just in general, anaphylaxis following vaccines happens. It is pretty well documented.

But it is very rare, and it is in the neighborhood, for the vaccines we studied, of one to a few per million. So I think the take home message is, it is a known, serious adverse effect but it's very rare and it is difficult to --

MS. HOIBERG: Well then shouldn't it be on here, then, under severe reaction? Instead of it just being the swelling and severe pain, shouldn't anaphylaxis be on there as a severe problem?

DR. SHIMABUKURO: I'm saying anaphylaxis, but I think Skip was saying they use severe allergic reaction and don't use the term anaphylaxis because that is more of a medical term. But most people understand severe allergic reaction.

Skip, hasn't there been some discussion about maybe saying severe life threatening allergic reaction or something like that?

MR. WOLFE: Yes, just the other day, about I can't remember what vaccine it was. We say life threatening up under the contraindications there. But probably we should say it down here, too. That's probably a good idea to always say life threatening.

DR. HERR: I like the wording on these two sentences better than what we had on the last VIS.

MS. PRON: The last paragraph or the next to

last?

DR. HERR: Running a temperature of 99 degrees, 99.9.

MS. HOIBERG: Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses. He likes that wording better than what it says in --

MS. WILLIAMS: This is Michelle. Since I brought it up before, if there is a study that says specifically of hepatitis, 1.1 million doses, then it should go on to say 1.1 million doses of hepatitis B.

MR. WOLFE: Yes.

MS. DREW: Number six?

MR. WOLFE: Again, six, seven and eight are the same as they were in the last.

MS. DREW: Actually, Skip, remember we needed to change the wording in number seven, about people who believe they may have been injured can call to file a claim? We need the new wording that we have in the other VISs. That is a cut and paste problem.

MR. WOLFE: Oh yes, you are right, okay. Yes, the second paragraph.

MS. DREW: Eight, you are using the word provider. (laughter)

MS. WILLIAMS: Ask whoever is giving you the

shot.

MS. HAMBORSKY: The shooter. Yes, ask the shooter. (laughter)

MS. HOIBERG: The injecter.

MS. HAMBORSKY: Are we going to move onto polio?

MR. WOLFE: Polio, just as an introduction, is very similar to the published one. There are a couple of changes. The reason we wanted to change it was, we got calls from the manufacturer saying that people who got combination vaccines and therefore got an extra dose, they wanted to put a statement in there about the possibility of kids getting an extra dose when they got combination vaccines like Pediarix or Pentacel, because that would give them a fifth dose.

So the main reason for changing it was to add that. We took the opportunity to make some other changes like taking out that box on OPV, which people probably don't remember any more.

MS. HOIBERG: I remember. Yes, the one that we had, had that on there, that it says it wasn't given any more but they still had the --

MR. WOLFE: I think we mention it in passing, but we don't have that big box any more.

MR. KING: So there has been no reported problems when people get a fifth dose, correct?

MR. WOLFE: Not as far as I know.

MS. HAMBORSKY: Anything in number one?

MS. WILLIAMS: Yes. This is Michelle Williams. I would prefer that we not use we had a vaccine. I'm not sure who we is.

MR. WOLFE: Before we had a vaccine.

MS. HAMBORSKY: Before there was a vaccine?

MS. WILLIAMS: I think what it's saying is, in the United States. I think the we is the United States.

MR. WOLFE: Before anybody had a vaccine, we can say.

DR. HERR: Before the use of vaccines.

(overlapping voices)

MR. WOLFE: I like before vaccine. And in fact, we said that on one VIS and somebody wanted us to change it, to make it more -- I don't know if they say we had a vaccine, but they wanted more words. I like before vaccine. I think nobody is going to misinterpret that.

MS. HAMBORSKY: Number two?

LT. MARSHALL: This is Lieutenant Valerie Marshall. There is a grammatical error in the bolded statement, polio vaccination was begun in 1955. Just say began, no was.

MS. WILLIAMS: Also, this is Michelle. I don't think there is an apostrophe after 1950s. Isn't it 1950s,

no apostrophe?

MR. WOLFE: Or use began in 1955.

MR. WOLFE: Are you suggesting changing polio vaccination was begun to polio vaccination began? It kind of makes it sound like it started on its own.

MS. PRON: Vaccination for polio began in 19 -- how about you change it that way? Vaccination for polio begin in 19 -- against polio. Was initiated.

MS. WILLIAMS: Polio vaccination program.

MS. HOIBERG: How about polio vaccine was licensed. Is it a license? Is it when it was licensed? Was that really what it is?

(overlapping voices)

MS. HOIBERG: How about vaccination against polio began in --

MS. WILLIAMS: That's what I said.

MR. KING: Vaccination use began?

MS. WILLIAMS: Polio vaccination started in 1955.

LT. MARSHALL: You could say vaccination program.

MR. KING: It still works, the way Valerie said it.

MS. DREW: The next committee has to have an English major.

(overlapping voices)

MR. KING: That's what we should do, and let them

decide. Check with a grammarian and let them decide.

MS. DREW: I actually think it is correct the way it is. I think the way it is, is correct grammar. But I am not in a position to argue about it.

DR. DOUGLAS: I think for non-English speakers that is a usage that is not common. And we are trying to make this as approachable as possible. For those of us who aren't native speakers, we are arguing about it. It's not common usage.

MS. HAMBORSKY: How about number three? Number four? Five? Okay, well, we know six, seven and eight are the standard ones.

MR. WOLFE: We hope they do. Let's check the compensation program paragraph again.

MS. HAMBORSKY: This one says ask your doctor or nurse.

MS. PRON: We changed that. We suggest that remain as is. (laughter)

MR. KING: I guess we always go back to the consistency, and that when there is certain consistent language that can be applied across the board to all of the vaccine information statements, why are we not doing that? One, it's taking up a tremendous amount of time here. It's taking up your time, it takes up a lot of people's time when we could have this uniform across the board.

Because if I go back to the -- again, that holistic approach, to Td, when we talked about anyone who has a moderate or a severe illness on the day the shot is scheduled should usually wait until they recover before getting Tdap or Td vaccine, a person with a mild illness or a low fever can usually be vaccinated.

Yet here under the polio, anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover. But then it says people with minor illnesses such as a cold may be vaccinated. That seems to be a common theme or thread that runs through the Vaccine Information Statements. It is just worded differently on each one. Why not word it the same across the board?

MR. WOLFE: We could. And the fact is, the VISs are written at different times, and maybe when one is written we come up with what we think is a better way of stating something so we change it, and then it is different than one that was written before. So that is why a lot of that emphasis is in there. And then as we update them we can --

MR. KING: Boilerplate. I understand what you are saying. If you see that something might be better worded, you make the change on one and then therefore it may not be on the older ones. But what we are looking at

are three different ones right now that are not yet done but ought to have the same type of wording across the board. If that argument is consistent.

MR. WOLFE: I think some people would argue for that. I would say that as long as people understand it, it doesn't matter. But again, I guess we don't have data to show whether that really would make any difference or not.

MR. KING: I would argue with you that you are correct, as long as people understand it, it doesn't matter. But we have already shown that we don't understand it. And so why not use something that is consistent? Since we are talking about three right now, and all three have a similar statement, why would we not incorporate that across the board on these three? And begin that process?

MS. PRON: And Dave, what you are saying is, even more accentuated because in this VIS the may is bolded, and italicized. So it seems even more like may, which means they may not, it's more strongly that they may not, too. Whereas the other one says can usually be vaccinated. It is sort of more like calm. This one sort of accentuates that point. I would question it, whether my child should get it, the way it was bolded and italicized.

MR. KING: Just keep it simple.

DR. SMITH: First a follow up on Dave's point. This is Jason Smith. I agree, and I think we spent the

last few VISs, we get to six, seven and eight and we take great pride that there is a consistency for all three of them. And we joke when there is a word change, to the extent we can.

Again, I appreciate trying to keep that consistency across all of them, to the extent we can. I think the opinion is here that it is probably beneficial to apply that to all of them.

MS. DREW: Is there anything else on the VISs? Okay, thank you.

MS. HOIBERG: Thank you. Everybody have a nice holiday and hopefully we will have 911 language next time.

Agenda Item: Public Comment

MS. DREW: Operator, we have come to the public comment portion of our meeting, and I wonder if you could see what the people on the line, if anyone has a comment.

(Operator message)

MR. MOODY: Good afternoon, ACCV. This is Jim Moody with the National Autism Association. And thank you for the opportunity, again, to provide public comment. It has recently come to my attention that the government specifically asked the IOM not to review the scientific literature relating to mercury and report its findings in the adverse event report filed last August. This explains the glaring gap in the report and the limitation in the

autism section only to a discussion of MMR and its role in causation.

This is an obvious improper censorship of scientific inquiry, especially since the directive was not disclosed in the contract to the Commission or in the IOM report itself. Indeed, IOM specifically listed a massive amount of mercury related literature in its 5,000 citation long bibliography, and specifically called for an inquiry into the cause of secondary autism, making the absence of analysis all the more suspect.

As you know, the program has been compensating dozens of autism cases since 1980, when the injuries are severe or immediate but what remains unknown is how many children have been similarly affected but not compensated is the precise mechanisms of injury.

The Masters have specifically left open the question of mercury causation on the ongoing autism proceedings. A massive amount of epidemiology and mechanism literature has been published during the last five years. And there is ongoing research that continues to implicate mercury as a cause of autism.

It is obviously unethical for a party to litigation to openly censor inquiry and input by IOM, as the designated input expert by Congress and paid for by the fund, while at the same time pushing for expedited

dismissal of the remaining autism cases.

This has prevented the petitioners, their counsel and the Masters from having the benefit of an IOM analysis. This failure is especially significant in the autism inquiry because the IOM report disavowed a large portion of the MMR literature previously relied upon by the government as not showing a connection between autism and MMR, as inherently unreliable.

The report also well illustrated how much we still need to know about adverse events in general, including mechanism evidence and epidemiology. Moreover, such back room and blatant censorship called into question the statutory role of this Commission in properly advising the program.

Why is the Commission here, if not to ensure that every person with a potential injury gets a fair hearing with unbiased scientific evidence and truly independent expertise from the IOM? Decisions must be based on evidence, and on informed opinion by independent experts, and not based on haste or deliberate ignorance.

Why the secrecy? Why was the Commission kept in the dark? Why was the public kept in the dark? It is absolutely imperative that ACCV act immediately to declare a moratorium on further dismissals of autism cases for the reasons I have previously given, basically ongoing science,

especially the need for determining the rate of autism among unvaccinated children.

But now, and most urgently, until the IOM report can be remanded to IOM with instructions to complete its review of the scientific literature relating to mercury and other censored areas, and revise its report accordingly. Thank you very much.

MS. DREW: Thank you.

OPERATOR: There are no other comments, thank you, at this time.

MS. DREW: Thank you. Unless there is any discussion of that, we will finish for the day, and be back here at 9:00 in the morning. Thank you.

(Whereupon, the meeting was recessed to convene the following day at 9:00 a.m.)