DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

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P R O C E E D I N G S

Welcome and Approval of Minutes

MS. GALLAGHER: Welcome everybody to the 77th quarterly meeting of the ACCV. I apologize for the delay. We did not have a transcriptionist in the room, but we have made arrangements to have the meeting recorded so that we can comply with regulations. Thank you very much for your patience.

The first thing that I would like to do is turn to the approval of the minutes from June and July. Let's start first with the June minutes. I am assuming all of the commissioners have reviewed the minutes and I would like to ask if anyone has additions, revisions or adjustments to the minutes.

MR. SCONYERS: Move approval.

MS. HOIBERG: Second.

(On motion duly made and seconded, the minutes of the June 9-10, 2010 meeting were unanimously approved.)

Now, the July minutes. Some people only got them this morning; others have looked at them before that time. If anybody needs a little bit of time just let me know. I am now calling for any changes, additions for the July meeting that was held via teleconference in connection with the vaccine information statements. Does anybody have any comments?

DR. HERR: Move we approve.

MR. SCONYERS: Second.

(On motion duly made and seconded, the minutes of the July 29, 2010 teleconference meeting were unanimously approved.)

So the minutes are approved. Thank you very much.

MS. BUCK: I am sorry but I am just getting up to speed here. On the

June minutes, I know we have approved them, but there are a couple of spots where I am referred to as Mr. Buck instead of Ms. Buck – I don't think my husband would appreciate that so can they just be edited in that manner?

MS. GALLAGHER: Absolutely. Every time there is a Mr. Buck in the minutes it will be changed to Ms. Buck. How about the July minutes? Did you fare better in those?

MS. BUCK: I am still trying to find them. Just make sure that everybody's title is right in these. I don't have them. I am looking on the captions Annie sent me but I don't see July minutes.

MR. SCONYERS: They were e-mailed out a couple of days ago, Tawny.

MS. GALLAGHER: The copy we received, they are fairly short compared to the others and it seems to always be Ms. Buck.

MS. BUCK: Okay, I am fine with you guys reviewing them. I have a million e-mails to wade through and I can't find them. So that is fine.

MS. GALLAGHER: Thank you very much. Now I would like to turn to a report from the Division of Vaccine Injury Compensation. Dr. Geoffrey Evans will be delivering that.

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

DR. EVANS: Thank you and good afternoon. Again my apologies for not starting right on time. We try to get everything liens up and there is always that little complication.

Let's begin with the slide presentation. First of all, the meeting highlights.

Today we are going to be hearing from Mark Rogers, a report from the Department of Justice. And then we will be hearing from Sarah Hoiberg, chair of the ACCV Communications and Outreach Work Group. Updates from various members of the Commission and tomorrow morning we have Dr. Rosemary Johann-Liang to provide an update of clinical cases, highlighting a clinical issue on shoulder injuries, and that will be by Sarah Atanasoff. Then we will follow that with an update by Marie McCormick, who is the chair of the National Vaccine Advisory Committee work group looking at the H1N1 vaccine. She will provide an update that she gave recently at an NVAC meeting.

Moving on, turning to claims filed you will see that there is still a large number of claims filed that are not part of the omnibus autism proceeding. There are over 400 this year and they are predominantly adult claims, perhaps half if not more influenza and we will know more about that with Rosemarie Johann-Liang's update tomorrow.

MS. BUCK: Geoff, I am sorry to interrupt but it is really hard to hear you.

DR. EVANS: Can you hear me better?

MS. BUCK: A little, but there is a ton of background noise. Whatever you can do I would appreciate.

DR. EVANS: Can you hear me better now?

MS. BUCK: Yes, that is better. Thank you.

DR. EVANS: Moving on, we are now turning to adjudication and in your blue folders you will find there is a report dated September 2nd, different from the one that was mailed out dated August 23rd. You will see that the rate of adjudication is fairly consistent, another busy year in terms of that. You will note that the program had compensated first claim under the Omnibus Autism Proceeding. In order to keep things clear we have actually put the headers on the Omnibus Autism Proceeding and Non-

Omnibus Proceeding claims on the other.

So claims that are filed that allege autism are part of the OAP, and the ones that did not allege autism become part of the non-OAP claims. Because of confusion in the past, previous autism claims being compensated sometimes have appeared in the media and so on – I want to be clear that in the case you see compensated HHS has never concluded in any case that autism is caused by vaccination. The footnote that was added there hopefully will provide that kind of clarification because obviously these documents go beyond our meeting here. They will be on the Internet and our web site and so on, so this makes it clear that this was a case that was compensated and it was not compensated on the basis of autism, but yet was filed in the Omnibus Autism Proceeding.

MR. SCONYERS: Can I just ask a couple of questions here. There is a footnote 2 under the caption of adjudications but I don't see a footnote. And then there is an asterisk down below, but I don't see what it is an asterisk to.

DR. EVANS: The first asterisk is under the –

MR. SCONTERS: Sorry, I see it now. It is compensable.

DR. EVANS: Is that clear to everybody? The asterisk starts with the footnote "May include cases that were originally filed and proceeded as OAP cases, but in which the final adjudication did not include a finding of vaccine-related autism." That asterisk is with the compensable under the Omnibus Autism Proceeding column. Then the double asterisk is by the number showing the compensated claim.

MR. SCONYERS: Then the footnote – is it just a straight footnote? Does it go to anything else?

DR. EVANS: Yes.

SPEAKER: Can I just interrupt for one second? People in the back are

having difficulty hearing anyone who is not talking directly into a microphone. I know it is cumbersome, but it would help.

MR. SCONYERS: We have two microphones that we need to talk to, one for the people on the phone to hear and one so that people here can hear.

DR. HERR: On that – is that a settlement or proffer or what?

DR. EVANS: Tom, because of various restrictions that are part of the program, part of the Act, I really at this point cannot say anything further other than the fact that it was compensated.

DR. HERR: If it is settled doesn't that mean that that information could be released? Haven't we discussed that in the past?

SPEAKER: We have discussed that and the case either is or will shortly be on the court's web site. So the decision will be publicly available. It is possible that it isn't within the ethics of the Department to discuss it right now. But it will be available on the courts web site.

DR. HERR: I am just curious why there was a lot of talk about making information known about cases that were settled or otherwise adjudicated and this one is not?

MS. GALLAGHER: That was Sherrie's comment and I think, Tom, you have to understand that there is some time lag in some of the proceedings and some of the postings and ACTB(?) is not permitted to jumpstart what has been put out by the court. So if you are patient you will get all that information eventually.

MS. BUCK: I would just like to make a comment about the same thing that has been brought up here by Dr. Herr and Mr. Sconyers, which is that I find the footnote to be kind of confusing. I don't know that it actually presents very well, so maybe for the record I would kind of like to state my objection to the footnote. I think

when you show that you compensated a case in the OAP but then you footnote it saying that you haven't, I think that mixed message is very confusing to people and I think it would be interpreted suspiciously. So it is just a comment. I think I am going to get questions, and you will, too, about what you are doing there and why.

DR. EVANS: Thank you, Tawny, for that comment. Moving on to – assuming no one else has any questions – to categories of adjudication. Again, the breakdown that we have been providing over the past year, really not much in the way of any change. There was a slight decrease in the cases settled, for example, and by concessions and court decisions, and you will note based on the questions and the discussion from the previous meeting that we now put a parenthetical "proffered" under court decisions. We clarified that. As an additional parenthetical I would say that our office is involved in the entitlement side of things and therefore whether entitlement has been granted or not conceded and so on, whereas the Department of Justice of course is charged with the responsibility of taking it from that point and then either settling cases or going to a court hearing and so on. So we have a basis for them to delve more into the technical and the procedural aspects of what goes on, whereas we are more concerned about whether a case is entitled to compensation or not. So our figures rather reflect those basic distinctions, whereas Mark and his colleagues are much more concerned about how their process works and the variations on how they approach cases and have an outcome.

MR. SCONYERS: So we are continuing to get educated about what the terms mean. I think I understood what Mr. Rogers said last time about the proffer process. Court decision here -- can we reach conclusions about whether entitlement was conceded or whether it was contested and adjudicated? I think we are all trying to understand how cases move through the system and to characterize something as a

court decision as if it were an adversarial proceeding is different than to understand it to be an entitlement with damages determined by proffer.

DR. EVANS: And I did not ask you to ask that question – I'll state for the record. No, absolutely. Our office is concerned about entitlement. Court decisions actually means this was a case we did not concede. This was a case that we did not defend. We did not in the end. This is a case we didn't settle. This is a case where we went to court and defended and the court decided not to agree with our view of the case and they decided to compensate the case. So that is what a court decision means.

MR. SCONYERS: And concessions are where the program has conceded entitlement and the issue remains about compensation?

DR. EVANS: Yes.

MR. SCONYERS: Thank you.

DR. EVANS: One day before you leave the Commission you may understand it –

MR. SCONYERS: Promises, promises.

DR. EVANS: All right, under awards – this year we are on track for the highest amount of compensation outlays, approaching numbers we had back ten years ago when we were doing both the pre- and post-'99 cases. Now we are at $153 million awarded through the beginning of September. Again, just as a reminder, the $15 million that jumps out on the attorney fees side for '09 involved interim payments.

DR. HERR: That is why the attorney's fees are actually lower?

DR. EVANS: Correct. Moving on to the Trust Fund at about $3.2 billion or a little over that and receipts are on track for being about $250 million.

In terms of significant activities, Dr. Rosemary Johann-Liang attended the Advisory Committee on Immunization Practices in Atlanta last June and then as far as

our outreach efforts staff attended two medical conferences and in both instances they report that they were well received and there was a lot of activity. For example, on June 16-19, Annie Herzog and Kay Cook staffed the booth at the 26th Pediatric Nursing Annual Conference in Philadelphia, which was attended by toe 400 pediatric nurse practitioners, clinical nurse specialists, pediatric nurse managers and staff pediatric nurses. They handed out over a hundred information packets and most expressed interest at that time in the influenza vaccines and the H1N1 vaccine. A little bit later that month they also went to the American Academy of Family Physicians annual conference in Kansas City, where they had nearly a thousand family physicians, residents and medical students. They handed out over 150 information packets. There was interest in the influenza vaccine and in the meningococcal vaccine.

DR. HERR: At these conferences, people who come up to the booth are they surprised about the practice or the activity of the program? Is it new to them? Is it getting on to the outreach idea – we are talking about medical personnel.

DR. EVANS: I am advised, since we are doing this via telephone, again it is difficult for people to hear so I encourage everyone to really speak into the microphones.

MS. COOK: This is Kay Cook and the individuals who came to the actual booth, a lot of them did not know about the program at all. They had no clue that it was even in place. They knew a lot about CDC, but not so much our program.

DR. HERR: Thank you.

DR. EVANS: I would also add, Tom, to that that the Academy of Pediatrics has done surveys of fellows in which a significant percentage, more than two-thirds, were aware fo the availability of the VICP.

Just touching on some communication activities, in terms of the different

kinds of things that we receive in the office, in terms of a breakdown by topic, most of the inquiries, either by phone or e-mail, have to do with how to file a claim, and then there are also questions about medical advice, sometimes vaccine mandate issues, the autism claims, and as far as the breakdown by vaccine, the tall blue line, like the various categories in the previous slide, but for vaccines it is the meningococcal vaccine, influenza vaccine seem to generate the most interest.

That is the end of my formal presentation. Those who wishing to contact the program should write the National Vaccine Compensation Program at 5600 Fishers Lane, Parklawn Building, Room 11c-26, in Rockville, Maryland 20857. The toll free line for information is 1-800-338-2382 and those who have Internet access, the information can be gleaned through our web site at www.hrsa.gov/vaccinecompensation -- that is one word.

With that I will end my remarks and I would be happy to answer any questions.

MS. GALLAGHER: Hearing no questions I would like to continue on with the report from the Department of Justice. I was hoping that Mark Rogers can come up here and speak very loudly into both microphones as we are having some technical difficulties today.

Agenda Item: Report from the Department of Justice, Mark Rogers, Deputy Director.

MR. ROGERS: Good afternoon. I am Mark Rogers. I will be reporting for the Justice Department. We hired one new attorney since we last met. We are now up to our full complement of 18. That was Justine Danielle. She was a paralegal with us a number of years ago and has come back. Great attorney.

From the statistics side the big takeaways are that the autism filings are ramping down, that our cases are, as has been mentioned, mostly adult cases, and that our non-autism cases are kicking upward towards about 400 a year.

For some more detailed statistics, and we have tried to respond to some of the comments in the last meeting – the first thing you will see, decision as, I guess I should emphasize this is Sheri's comment, that every case spins with a decision of some sort or another. The Special Master is in charge of the proceeding from start to finish. And, at the end of the case, no matter how it ends, it ends with the Special Master's decision.

Now, we've broken down the cases by the types of decisions. And, we've broken these down by whether the case was conceded or not conceded by HHS. Another data point is that we take the cases, and we've mentioned this before, off an assembly line before they get to HHS, and it's an important point.

For cases that are compensated, there's a final decision, and then judgment is entered by the court. That's our stepping off point to execute that judgment and pay the case for a compensated case. Now, we at Justice receive it first. And we perform the very important role of ensuring that everything is done that's necessary for payment before we send it to HHS to actually pay it. It's a very good system. HHS does not see the judgment until it's ready to be paid.

The most important block that needs to be checked off is an election to accept the judgment. It's a statutory requirement. We cannot pay the judgment until petitioner has elected to accept it. They have 90 days to do that. We can't hurry them up. We can remind them about the requirement, but they've got 90 days to think about it, and some of them take it.

So HHS does not see that judgment until we get a properly filed election

to accept the judgment. The other thing that has to be done is that we need in place an appropriate legal vehicle to receive the judgment. Most commonly that's a court-approved guardianship. It's up to the state, the relevant state, to decide what's required, but we've got to have a legal vehicle to play catch to the money. That has to be done.

And, so to ensure that there's no slip-up, there's no check going out to an improper recipient, we do not send that judgment to HHS until the trial attorney has checked all the blocks. And one of them is to carefully review that judgment and that decision one last time because once judgment is entered it's one of those firm and fixed rule of our judicial system that judgments are hard to change. There has to be an extraordinary reason to change that judgment. And the longer after the judgment, the harder it is to get it modified.

So, we make very sure that the judgment is ready to be paid before we send it to HHS. Well, you can see, like with the election to accept judgment that can be a 90-day process. So, well, it wasn't a short way of saying it. It was a long way of saying it.

We see the judgment sometimes months before HHS sees it. So when you look at these statistics, you're looking at judgments that are hot off the press. They may not be ready to be paid yet, but you're looking at a snapshot of the program as fresh and hot as it can be.

What you see on the HHS side are the judgments after they've come to them, and that's when they start ticking and counting. That's why you'll see, occasionally, a case here that doesn't appear on HHS's desk. I just wanted to explain that. Are there any questions about that? Okay.

Our numbers. For cases conceded by HHS, we counted three. And, you'll see, they were resolved by either the proffer or the stipulation. Again, a refresher.

A proffer is where the parties have agreed what the evidence shows on damages. And, normally when the parties have agreed, there will be one life care planner that they both trust.

The life care planner files the life care plan. That's the only evidence in the case. We submit it to the Special Master. The Special Master looks at it, and virtually all the time, I think all the time in my recollection, the Special Master blesses it with a decision. I approve. The case is over.

Decisions adopting a stipulation. That's where the parties couldn't quite come to a -- well they did come to an agreement, but in the first place, they agreed over what the evidence showed. Generally, there are two life care planners: ours and theirs. And, the two life care planners had some disagreement. The parties sit down together and say, hey, let's resolve it in this way.

Now, sometimes it will be to pay everything the petitioner has requested and to lay on a requirement, an agreement, that it will be administered through a trust. Respondent says that's a good deal. We know it's going to be used for what it's intended. We have some assurance that it's going to be managed well in this case we think it will be for whatever reason.

That may be what's bargained for, not an amount of the award, but how it's going to be administered. Those kinds of things, it's very, very flexible as we've mentioned many times. So, we think it's good because it's resolved by handshake. Both sides agree. Proffer, even a little faster and maybe even a little better because the parties are agreeing on what the evidence shows so there's even less controversy.

So we break them out just to show you how this program is working. Both of those are good things in our view. Both of those are efficient, amicable to the extent they can be. The decision option up here at the top, that's where the parties go,

we can't agree, and we can't come to an agreement on the amount of damages, we have two different life care plans. You're going to have to decide this. And a Special Master would convene a trial and both life care planners would testify. And, it's a challenge in that setting to call it amicable. Everybody's professional and we work through it, but it's a greater challenge. It also, it takes longer. Yes?

MR. HERR: Just to clarify things in this feeble, non-legal mind, the stipulation here is what you discussed last meeting as a settlement?

MR. ROGERS: Yes. Stipulation and settlement are the same thing.

MR. HERR: Okay.

MR. ROGERS: A proffer is not technically a settlement, but it comes awful close. It is where the parties agree what the evidence shows, they haven't settled the case which is what you do when you disagree and you kind of shake your hands on a middle point.

So settlement and stipulation, in fact, the stipulation is a stipulation of settlement. We can put that in there, kind of shove that one a little further to the right, but we want clarity. We welcome these questions.

MS. BUCK: Hey, Mark, I have just a tiny quick question. Do proffers end up on the court's website? Can you tell us which of these are available publically once they're finished?

MR. ROGERS: The answer is sometimes. We have seen them sometimes, and we have not seen them sometimes. I can't answer why. That is a question for the courts. We're kind of, they file them, and they've put like head note denominators on them, and we really have no control over that process.

MS. BUCK: Okay. I'm not sure what to do with that, but the other question is, where would you put something that was settled but the liability evidence be

disputed? I mean, where does that fall in these categories?

MR. ROGERS: Okay. Very good question. That would be in the second category here: cases not conceded by HHS. And, we're going to get to the wire diagram, and I hope to kind of reinforce this by taking it down through the wire diagram on, again I won't belabor it, but if you take cases not conceded by HHS, 50 of them, of those cases, some will be immediately settled. It's called a "litigated risk settlement". That is, where the settlement wraps up both issues whether causation has been proved and the amount of the damages. In that case, there would be no decision by the Special Master deciding whether the case is vaccine related or not. The settlement embraces all of the issues of the case, and when we get to the stats and start looking at the data on these settlements you'll be able to figure out which one is which. Not in every case, but you'll see some trends. So we'll get to that.

Now, if the case is not conceded by HHS, and it is not settled, the parties can't reach a litigated risk settlement, then it moves down to a resolution by the court. The court has to decide the case. Once the court decides the case, if it dismisses the case, it's dismissed and then it goes, maybe, maybe not, on an appeal track. If the case is, if the Special Master, contrary to respondent's position, finds that vaccine causation has been shown, then you'll see on our wire diagram, you move over to the damage processing. And, once you get to damage processing, then we decide anew whether we can settle that or proffer it or have to have the Special Master decide it.

So, this number 42 encompasses, and you can add in the eight as well, the eight and the 42 will encompass cases where the Special Master has decided that the case was vaccine-related contrary to respondent's position.

Now, what you'll never have, hate to say it, never say never they say, but I can't recall any case in which you have a proffer of a case in which, well you can't have

a proffer of a case without a decision on entitlement. Proffer cases will always be after the issue of entitlement is resolved because that's just a life care plan that both parties agree is good evidence. I mean that's virtually all of those cases. Does that make sense?

Okay. Non-compensated cases, and I'll show you the block on the wire diagram, there are 125, and you'll see most of them were autism cases. Non-autism, 31. Voluntarily withdrawn, very few. We had one non-autism and two autism cases.

There's a new statutory right of the petitioner to pull the case. Yes, sir?

MR. SCONYERS: I know that you've been activating the autism cases sort of on a cycling basis. Will you talk some about what the status of those activated cases is? Do these statistics, some autism cases dismissed and a few withdrawn, do they represent activated cases? I just am unclear about how that activation process is working.

MR. ROGERS: Yes. Some of those, they are being activated on a schedule by the court. We start looking through them, we start assessing, we file a response. We first look at jurisdictional issues. Those issues have become a little problematic because of the core decision. So we're working through that, and we'll get to that. We'll talk about the core decision. But yes, the answer's yes. As they come out of the program, those are generally activated cases. Not all, some are voluntarily dismissing prior to activation.

Okay. Oh, our definitions. I hope that through this process these terms are getting more familiar to you. You see this "final judgment". That's what we pivot off of. These stats, all the cases represented by these statistics have a final judgment entered by the court. Our job is to execute that judgment.

Okay. The wire diagram – I've really covered this, but I'd just like to go

through it one more time. Most cases come down the left side of this chart. The petition is filed, HHS reviews it, they don't concede it, we settle. Down into the red box which is a litigated risk settlement. Okay? It encompasses the decision on the merit, whether it's vaccine-related, and the amount of damages. That's how cases are generally -- most of the cases are compensated in this program through that process. It is one in which both sides are shaking hands and agreeing that this is appropriate, culminated by a Special Master who says, I agree, too -- decision entered.

Some cases are being, well, there were three that were conceded. This is down the right side. That's three of the decisions, three of the judgments. They move right to damages. They keep going down through either the middle or over here to proffer on the right. We'll resolve the issue of damages, and you get into the green box. That's where the conceded cases that were compensated, they end up there.

Now the litigated cases come down from petition, HHS review, not conceded, and they go over here under this right box. And what decision embraces is a trial proceeding, generally. Under this program, you don't necessarily have to have a trial. Special Masters can decide the case based on a written record. They have to have authority, and sometimes the parties both ask them to do that. They say, you know, the issues here are pretty clear. You can decide this case based on the paper record which is much faster. That happens.

Now, the decision is either that it's not compensable and dismissed, goes straight to the yellow box, or Special Master says I think this is a compensable case, in which case it would go over to damages and then down to either a settlement or a proffer, green box. The big numbers are coming down and over to the left for compensated cases. The non-compensated cases are coming down, going over to the left, going back to the right to decision, and then down through that yellow box.

Autism. Theory one, the big news is Cedillo was affirmed by the Federal Circuit just a few days ago, on the 27th. That was a big decision. The Federal Circuit speaks in very sweeping terms. They cover the big issues in the program. What is the causation standard? What is the role of Daubert, the Supreme Court case that says you need to use good science in federal courtrooms? And how much we should defer to the Special Masters.

These are big issues in this program. The Cedillo court addressed them, and now it's in the, we stand by to see if there's going to be a request for either rehearing or to seek certiorari to the Supreme Court. And I mention the word "certiorari", what that is is they request that the Supreme Court review it, and it's not a matter of right. The Supreme Court can say, no, we're not going to do that. So, it's elective by the Supreme Court.

Yes, sir?

MR. SCONYERS: I read the Cedillo case, and I read the portion dealing with Daubert, and I couldn't tell from the Court's opinion what the petitioner's argument had been on the application of Daubert standards or not. Can you just say a little bit about that?

MR. ROGERS: Well, not yet. I think when we know whether rehearing is going to be sought or certiorari. And the reason is, at this point, my office does not speak for the Department of Justice. If rehearing is sought or certiorari, that is the Solicitor General will speak with authority on what, I know, on what they argued. I believe that the briefs are on the website, and I think the thing for me is to refer you to them.

Okay, theory two. Those cases, really no change. Those are long past their time for appeal now, so those decisions are final.

Before the Federal Circuit, we have two new cases, or wait a second. I have some notes here. Okay, never mind. Okay. Federal Circuit, we have two new appeals: Davis and Hall. Davis was a statute of limitations case, and it might be affected by Cloer. That's the most I can say about that. Hall was an hourly rate case where petitioners were not satisfied with the hourly rate that was approved by the Special Master for the petitioner's counsel.

We've talked about Cedillo. These were recently decided cases. We also had Shaw. The Federal Circuit decided in Shaw that there is jurisdiction to hear an appeal of an interim fee decision. The arguments there were, no, there's not by respondent, and yes, there is, by petitioner. The Federal Circuit ruled that that jurisdiction exists meaning that when an interim fee decision is entered by the Special Master, that's a separate decision for purposes of appeal.

Cloer, that's within this period for seeking rehearing, so it's not a common case. But Cloer, we talked about that at the last meeting, and you'll recall that a petitioner's counsel, I believe it was Kevin Conway, expressed some frustration that Cloer seemed to be inconsistent with Wilkerson, as I recall.

Cloer, in that case, they petitioned for rehearing en banc, rehearing and rehearing en banc is in a trial by the Department of Justice.

SPEAKER: What is rehearing en banc?

MR. ROGERS: Rehearing en banc means a hearing in front of the full Federal Circuit, all the judges. The process there is that it first goes back to the panel that decided the case, and they are asked to reconsider. Are you sure? That panel either says, oh, no, we're not sure, we'd like to have another argument. Or, they say, no, we're sure. If they're sure, it goes to the full panel for the Federal Circuit, and they have a process for deciding whether they want to hear it sitting en banc. Very unusual.

Very unusual for the full Circuit to sit and hear a case en banc.

DR. HERR: But, this is also an unusual situation with the Department of Justice. Is that true?

MR. ROGERS: Yes. It is unusual in this program for us to be the appellant.

Okay, these are two new cases appealed to the Court of Federal Claims, and both involved where the Special Master has decided that petitioners have not proved facts in causation and both appellants are arguing that the Special Master used the wrong standard, and they're pending before the Court of Federal Claims.

Okay. Appeals at the Court of Federal Claims; these are recently decided cases. We have parenthetically the issues involved. Scheduled oral arguments, none at the Federal Circuit, and Simanski, we talked about before and Stone are upcoming.

Now, we're continuing to lay out for you in tabular form here what those stipulations of settlement look like. And, there they are. Now, I mentioned before, I can look at these, and without even knowing, I can make a good guess of how they came down that chart.

For those cases that are in the one year, year and a half, year and three months, year and one month, and I'll go further, and especially those that are less than a year, almost certainly came down the hard left side of the chart. These are litigated risk settlements. By and large, they are the high speed, low drive way to resolve a case.

Now, some of these kind of balloon out six years, three years. In my experience, generally, I'm speaking generally and not about any of these cases individually, generally what happens is, and let me run back up to the chart, between the time the petition is filed and either before HHS review or after HHS review, petitioner has asked for more time to collect records or to get an expert. And, it can happen under the

not conceded. Just conceded, no, we would have moved on.

But, if it's not conceded, the next step there is the Special Master turns to the petitioner and says, well, you're going to have to prove the case here. And a lot of these cases get stuck right there with petitioner looking for an expert.

Sometimes petitioner will say, you know, we'd just like to kind of move off and park here until the science develops. We occasionally hear that. Normally, we will object to that. We'll say this program is not a place to stop while the science develops. But, petitioners will say, well, instead, we're looking for an expert and the fact is, I can't find an expert because the science hasn't developed.

We generally don't object to a petitioner who's asking for more time to look for an expert. We generally do not object to a petitioner who's asking for more time to find additional medical records. Many cases stay in that status for a very long time.

Now for all the cases, it's important to emphasize the Special Master is not a potted plant. The Special Master is periodically checking in. What's going on here? How can we help? You need a subpoena? Respondent could help with that? And, generally we do for medical records.

You need an expert? Well, you've got to have one you know. I'm still looking. Well, how much time do you need? The schedule says six months. That's too long. Let's have a status conference in three months for you to explain your efforts.

That's generally how those go. So, they don't just disappear off the radar screen. If the Special Master were ever unhappy with what respondent is doing, believe me, they'll say so. And if they're really unhappy, they'll say so in a written decision, and you'd see it. So that's kind of speaking generally just based on the big picture, what's going on here as I quickly run back forward to these cases.

MR. SCONYERS: Outside of the omnibus group that has been sitting

around for a while, what's the longest one that you know that sat around there in that holding position?

MR. ROGERS: Well, we've got, we had the Rubella, this is going way back, arthritis cases. Cases that are handled in omnibus fashion tend to experience the greatest delays because it's public record, we say what we did in the Omnibus Autism Proceedings. We thought trying to handle all of these cases in omnibus fashion does not speed them up. So, we had Rubella Arthritis cases, and we had the Hep B cases, and they went on for years.

Now, we have a couple in here, ten years I think, let me see, there's one. You've got a Hep B case, and I believe that was in the Hep B omnibus, the timing would be right. But these here, like at the top of the screen, one month, and in the middle, four months. That is a litigated risk settlement, and that is screaming through our program.

DR FISHER: Is Guillain-Barré a table injury?

MR. ROGERS: No. It is not.

DR. FISHER: So essentially none of these are table injuries.

MR. ROGERS: You know, I don't think so, but I can't say authoritatively. I don't know. The vast majority are not. Okay. I don't see any.

So for all of these we've got to resolve whether it's vaccine-related. Litigated risk, we're just going to agree to a certain amount. That concludes my comments. Any questions?

MS. BUCK: This is Tawny, and I have mostly just a comment to make, but first, I want to thank you for the very detailed report that you're giving. I do really appreciate all the information.

I'm a little struck, however, by in the efforts to be more transparent and to provide us with more information, it almost, it's kind of overwhelmingly confusing and

convoluted, and I guess in my mind, it seems to me that this process should just be simpler, that a claim should be filed, there should be a public decision that lists the vaccine, the injury, the liability, the compensation if there was any, and the rationale. Very straightforward, and I think -- understanding my appreciation for all the information you're giving because it has been asked for, it just really surprises me that there's so many different angles and ways to go about this that kind of muddy up the water and make it very difficult for people to really see what's happening. I thank you for the information and a general comment about the complexity of the process.

MR. ROGERS: Yes, fair comment. My response would be twofold. Most of the complexity and the friction, if you will, moving through the system, stems from two realities. One is Congress wanted the level of damages to be tailored in individual cases. They did not come at it at from a size fits all or even a schedule for particular types of cases. That would speed it up. To the extent that there's discretion, there's going to be differences of opinion and litigation.

The second thing is the cause-in-fact requirement, that there be proof of causation in fact. In those cases, the court system has said very loudly, and most recently in Cedillo, that's a heavy burden. And, that aspect of it, even though there's some accommodations that make it easier in this program, there's no rules of evidence. That's huge. You don't have to lay a foundation for each bit of evidence. That can take a lot of time. But in the end, you've got to have an expert. You've got to put on a scientific case, and that takes time. Beyond that, fair points, you're in the area of policy and what Congress might or should have done or could do, but here we are.

Any other questions?

MS. GALLAGHER: I would just like to thank you very much for all the time that has gone into this, and I think we need to see that you are clarifying further and

further each time. It's a very complicated situation, but I feel like I'm following it now.

MR. ROGERS: Good. Okay, thanks a lot. Take care.

MS. GALLAGHER: Now we have a report from Sarah Hoiberg about Communications and Outreach Workgroup, and I'm going to ask her to step up to the front here so she can shout loudly into both microphones.

Agenda Item: Communications and Outreach Workgroup Report - Sarah Hoiberg, ACCV Member

MS. HOIBERG: Good morning, everybody, and thank you so much for taking time out of your busy schedules to be here. I am the chair of our Outreach and Communications group, and I have had the privilege of sitting in on a few of the ones that I actually remembered to call in for, the calls with Banyan as they reported their findings and what they were working on.

What you have been given is an overview of what they've been doing. This is simply the phase one, the report that is in front of you is phase one of the findings. They are currently, I believe at this point, working on phase three. They will be reporting to us in October with the final product in hand, which I'm very excited about.

Does anybody have any questions for me? And, I really don't have that much more information about what it's going to entail. Yes.

SPEAKER: (Inaudible comment off mic).

MS. HOIBERG: They are finding a lot of information, and it has been very informative. As you will see on the back where it has the major themes and the areas for further research, they do agree in that the information they've obtained does agree with the fact that the healthcare providers are going to be the major focus for the program.

I also did mention that they need to include adults because when I read over this it didn't have adults as their intended audience. And because the program is now mainly adults being injured by vaccines, they do need to know about it. So we are going to hear what they have to say. Unfortunately, I've not seen or heard what the final result of the work is. So, I guess we'll all see it. Yes, Jeff?

MR. SCONYERS: Is that October?

MS. HOIBERG: Yes, October 28th. For our next meeting, they will be here. And, I just wanted to kind of get feedback from you guys, what you thought would be a good enough time for discussion. We've been planning on an hour for their presentation, and I've pushed for an hour of comments with a possible 15 to 20, 30 minute break in between so that we have time to digest what we heard because I know it's going to be a lot of information. So, I just wanted to find out from you guys what you thought. We can further discuss that in our agenda meeting.

MS. GALLAGHER: Can I just clarify whether we would be given the report in advance of the day of the 28th? Would we be able to get it like the 26th and review it, or we would not see the report until the meeting on the 28th?

MS. HOIBERG: I was told that we weren't going to see it until the day.

MS. COOK: This is Kay Cook, and I'm actually the Project Officer for the Communications Contract. The division staff has not seen it either. We are due to get a draft final at the end of September. We're going to work very, very hard to get whatever comments or revisions we need to do for the HRSA people down so we can give it to you guys before the meeting.

SPEAKER: Thank you very much. That would be very helpful.

MS. HOIBERG: That concludes my report. Anybody have any other comments on the other sections or anything? Anything that you want because I don't

think I'll be speaking with Banyan. I think we're done, aren't we? Or, are we going to have on more meeting? One more meeting with them? Okay. If anybody has any questions or can think of anything, contact me on e-mail. Thank you.

MS. GALLAGHER: Thank you very much. Now, Dan, I have some very good news for you. You just gained some extra time. So if you would be so kind as to come up to where the various microphones that we need to locate, that would make it easier. And, if you could please try to project as if you're talking to the last person in the back of the room, that would be great.

Agenda Item: Update from the National Vaccine Program Office, Dr. Dan Salmon, NVPO

DR. SALMON: There are two areas where I generally give an update to this group. One is on the work of the NVAC Vaccine Safety Working Group, and the other that I often give is on the H1N1 Vaccine Safety Risk Assessment Working Group of the NVAC. That's the group that's been looking at all the H1N1 safety data. And tomorrow, you're getting updates from Dr. McCormick, who is the Chair of that working group, so I'm not going to include any comments on that because you're going to be hearing from a much better source than I.

I'm going to spend the time I have today talking about the NVAC Vaccine Safety Working Group. I think you're all probably pretty familiar with this because I've discussed it before, but I'll give you kind of a general overview and let you know what's coming down the road because there will be some work coming from that group shortly.

This was a working group that was established several years ago. Its first task was to look at the CDC Immunization Safety Office research agenda, and they

finished a report on that about a year and a half ago. Starting in July of 2009, they started their second task which was to look at the safety system more broadly and to develop a white paper on how we can enhance the safety system and take advantage of new technologies and make the system as robust as possible. We have been working on this for a little bit over a year, a year and a few months.

The Safety Working Group is co-chaired by three people: Marie McCormick, Andy Pavia, and your own Tawny Buck. So, Andy is an infectious disease doctor in Utah, Marie is a Professor of maternal and child health at Harvard and also chaired the Immunization Safety Review Committee for many years, and I think you all know Tawny very well, so I don't need to describe her more.

It is 20 members of the Safety Working Group. It includes the public representatives from each of the four HHS vaccine advisory committees, so the public reps from ACCV, that's Tawny, NVAC, VRBPAC and ACIP, and they're not necessarily the current reps. When we had change, we tended to go with people who had tended to be on the committees for awhile or just came off the committee because we wanted people that really knew how it worked rather than the new member. It includes a broad range of scientific expertise from immunology, neurology, pediatrics, obstetrics, genetic epidemiology, biostatistics, I mean the right scientific expertise to try to address the various multidisciplinary nature of vaccine safety.

So, they had the first kick-off meeting in July of 2009, they heard from a broad range of experts and handled a variety of issues. And it was really a broad spectrum of people that came there and kind of shared their views on how the system was working, where there were areas for improvement, how do we address issues of public confidence in vaccines and vaccine safety. They broke into five groups or subgroups that I've described to you before: clear content focus, one is structure and

governance, one is epi and surveillance, and one is biological mechanisms.

Two subgroups are process focused: one is stakeholder engagement and one is implementations. And, when I say "implementation", I mean implementation of whatever comes out of this NVAC report. And this really builds on the RAND report when they made the point that the NVAC, like any advisory committees, would benefit from thinking about implementation early on. So they tried to think about. How can this report be developed in such a way that it will become more than just a lot of white paper, but actually be the guidance for future action?

So they've been working in five subgroups, they've had briefings, I think more than 30 at this point. So they've heard from a broad range of individuals and groups that have expertise in vaccine safety ranging from groups within the FDA and NIH to programs being run by CDC, like the Vaccine Safety Datalink and CESA. They've heard from individual experts, international vaccine safety issues, specific topics such as bar coding. So they've really done robust information gathering process.

They also had a small stakeholder meeting in the spring of this year, about six months ago in Salt Lake City, where they brought together a broad range of stakeholders and advocates from PVAC and came off with thinking through some of these issues.

So, at the September 15th NVAC meeting, they will be discussing the first draft of their report, and it really is a draft. I mean, they've made a tremendous amount of progress, but there's still much work to be done. And the point of bringing this to the NVAC now is to get the larger committee feedback on what they're doing, where they're headed, and where they need to go from here. I think there's a fair amount of meat in the draft, but there's still, I think, much work to be done.

So, it includes three broad areas of recommendations and then action

steps under each of those recommendations, and I don't want to get into the real details because there's a call, actually tomorrow, where they're still working on this. So it's a work in progress, but I mean, I can talk about it in general terms.

So the first area that they're discussing is that of leadership oversight and coordination, and they talk about internal enhancements that can be made to improve this coordination in vaccine safety. And then they raise some various options for other types of external oversight, although they haven't yet gone beyond the options to a single recommendation in that regard, and I'll talk about that more in a few minutes.

The second area of recommendations in terms of tools and resources, how can one enhance the tools that are available in vaccine safety science. And the third area is recruitment to science and epidemiology surveillance and biological mechanisms and causality assessment and solving studies to understand risk factors in subpopulations, and protocols to avoid adverse events when possible.

So, those really make up the broad categories they're working in, and I don't really think it's appropriate for me to get into more detail because the report hasn't been presented to the NVAC or gone public, but it gives you a sense of where they're headed, and this is consistent with the three subgroups they have in these three areas.

There's still a lot of work to be done. A part of what they've worked on is developing functions and key attributes for safety, so functions of things like coordination and surveillance and research and licensure. And then, attributes are, as they've described, like good governance principles, things like being effective, being efficient, being equitable, being transparent, and they're using these as evaluation tools between the four options. But, they just started this. So, at this point, like I say, it's very much draft.

They are also planning a larger stakeholder meeting sometime in the fall

where they'll get additional feedback from stakeholders, where their thinking is and where it's going. So this is kind of where they're at and where they're going. The anticipation is at the February NVAC meeting, there will be a final report which is deliberated upon and ultimately votes upon. So, that's kind of the who the group is, what they're doing, the process by which they're doing it, and a sense of where they're going.

The discussion at the NVAC on September 15th -- that report will be public at that point, so I think it will get some wider attention. And, like I said, they're starting the process of getting broader feedback, what they're thinking is, and so, I'm going to stop there, and I'm happy to answer any questions if anyone has any.

DR. GIDUDU: (Inaudible comment off mic.)

DR. SALMON: Dr. Gidudu, thank you for mentioning that.

MS. BUCK: Can somebody quickly tell me what she just said?

MS. GALLAGHER: Just ask him to repeat it. You're going to repeat it, right?

MS. BUCK: Thank you.

DR SALMON: I will with pleasure, Tawny. So, this is Dr. Gidudu from the Immunization Safety Office, and she made the comment that the report from the Safety Working Group on the ISO agenda was very helpful to their office, and they've now incorporated that in their drafting of their final ISO agenda which should be coming out in the next month. So, she was just stressing -

DR. GIDUDU: (Inaudible comment off mic.)

DR. SALMON: Am I getting this right?

DR. GIDUDU: (Inaudible comment off mic.)

DR. SALMON: So, it's going through clearance, and it should be out in about a month. Given that its clearance, it could be a bit longer. Then, she was sharing

her gratitude for the efforts that the NVAC made. Did I get that right? Okay.

So, I'm very pleased to hear that and to share that with the working group in the NVAC. I know that a lot of effort went into it, and it's very nice to hear that both your group found it helpful and that there is a final agenda coming out. So, thank you.

Well, I didn't use up your extra time.

MS. GALLAGHER: I'm wondering if I should ask Dr. Gidudu to start now instead of after the break. At least, we will somehow capture this additional time, and perhaps this way we can get to the public comment in the adjournment of the meeting earlier. And, I would like to remind everyone that the public comments come whenever the meeting ends and not the times necessarily posted on the agenda.

Agenda Item: Update on the Immunization Safety Office Vaccine Activities, Dr. Jane Gidudu

DR. GIDUDU: All right, I'll try to speak as loudly as I can. I hope you can hear me. I am Dr. Jane Gidudu from CDC. Good afternoon to you all, and I appreciate the opportunity to be here with you again. So I'm just going to be sharing a few updates on our recent studies within our office, and they're going to be shared, much of them are already in the public domain. I'll be talking about recommendations, as well, that have been published in the MMWR on the use of CSL seasonal vaccine here in the US in the next flu season, and I will give a brief update on the measles, mumps, rubella, varicella combination and the risk of febrile seizures, a report recently published in Pediatrics. The last one is the lack of association between acellular pertussis vaccine and seizures in early childhood. And if there is a bit of time I may give you little update on the status of narcolepsy.

So this next slide here. During the 2010 influenza season in Australia

administration – they are already ahead of the season – there is an inactivated trivalent vaccine, TIV, which is Fluvax Junior and Fluvax, manufactured by CSL, and which was associated with an increase frequency of fever and febrile seizures in children aged 6 months through four years. Surveillance indicated an increased report of fever in children 5 to 8 years after vaccination with Fluvax compared to previous seasons. An antigenically equivalent vaccine for the Northern Hemisphere, a seasonal influenza TIV vaccine, Affluria, also manufactured by CSL, was approved by FDA for use in people 6 months an older. The prescribing information for Affluria currently includes a warning that administration of CSL vaccine is associated with increased fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years. So far this is not explained.

So in the US annual influenza vaccination is recommended, as you know, for all persons age 6 months and older, and in August, just last month, the ACIP recommended Affluria vaccine should not be administered to children age 6 months through 8 years. Other age-appropriate vaccines, however, could be used for prevention of influenza in these children. And if there are not age appropriate licensed vaccines available for these children aged 5 to 8 years who have medical conditions that increases risk for influenza complications then Affluria can be used. Providers should discuss with parents the benefits and risks of Affluria before use, before administering this vaccine in children 5 to 8 years.

DR. HERR: What is the penetrance of that vaccine in the Untied States?

DR. GIDUDU: Affluria? I don't know.

DR. HERR: Because I have never heard of it.

DR. GUIDUDU: It was recommended but I don't think I know the answer.

DR. GRUBER: I will be talking a little more about this in my update.

Affluria was licensed in the United States for individuals 18 years and up in 2006. I believe it has been licensed in November of 2009 for infants 6 months and up. There were predictions, if you look at about 160 million doses of inactivated influenza vaccine in total for the upcoming season, the part of the market that Aflluria would take is about 10 to 12 million, but this is further reduced because of CSL will not market the .25 milliliter formulation of this vaccine, which is really given to very young children, but as I say I can cover this in my update with a little bit more detail.

DR. GIDUDU: Thank you. Concerning safety monitoring, although CSL seasonal influenza vaccine is the only vaccine associated with increased reports of fever and febrile seizures in young children, as in previous seasons the CDC, FDA and other federal agencies will closely monitor the safety of the seasonal influenza vaccines during the next season. And CDC will rely primarily on VAERS and the Vaccine Safety Datalink to conduct this monitoring.

The goals for post-licensing monitoring of influenza vaccines each year are the same as other vaccines, except that there are additional considerations because the formulation changes each year. There are three viral strains to include the vaccines selected a few months prior to the influenza season. The next year's vaccine will include last year's pandemic strain. In the recent years recommendations have been expanded, as you know, to cover more people and especially to look at Guillain-Barré following influenza vaccine. Since 1976 they have continued to monitor GBS associated with vaccines and there have not been any major signals.

DR. FISHER: Before you go on could I ask one more question about the CSL vaccine? Dr. Gruber, maybe you are going to have this in the information you give us. But since there is no biologic explanation, I just want to make sure I am clear, there is no adjuvant in this flu vaccine, correct?

DR. GIDUDU: That is my understanding. The question is if there is one in the Southern Hemisphere vaccine.

DR. GRUBER: For the Southern Hemisphere vaccine Fluvax or Fluvax Junior that, by the way, is not licensed in the United States, there is no adjuvant. And neither is adjuvant added to the licensed vaccine made by CSL which is Afluria. We don't have any adjuvants in flu vaccines licensed in this country.

In terms of biological plausibility, what the company has done and what CDC has done, is looked into very carefully the manufacturing process. And I just looked it up, the Afluria was licensed in the United States in September of 2007, not 2006 as I stated. So we looked again at that process. We looked at whether there were manufacturing changes implemented in the last 18 month, and none of this was the case. We requested that the company submit to us a detailed report, we reviewed that and we couldn't find any evidence.

We asked the company -- the company has actually done several lots of Fluvax – that is the vaccine licensed in Australia but not in the Untied States – some testing that included testing for endotoxin, and they also did perform testing by pyrogenicity tests to see if these animals would develop fever – nothing. So, by any of the criteria that we have applied, and looking at the manufacturer's process, we haven't seen anything that would explain this. That is something that I think we need to explain is that Fluvax didn't have that much of an uptake in Australia but during the last year when there was like an immunization campaign or it came under some immunization programs. So the point is, at this point it is really not very clear whether there was something very specific to that season, the 2010 season, with that formulation. Concerning the pyrogenicity, it could be you only see it now because the uptake was more and we are going to try to find out about this and I am going to report on this in my

presentation.

DR. FISHER: Then one further question. The antigenicity – is there more antigen in the vaccine? Because last year we had trouble with the shelf life being too short.

DR. GRUBER: No, it is formulated at 15 microgram for adults and then of course the infant formulation is adjusted downward.

DR. GALLAGHER: Tawny, could you hear that?

MS. BUCK: Yes, it's tough. If I really concentrate hard I can, but if people can speak up as loudly as possible it will be really helpful.

MS. GALLAGHER: I think I will just summarize and say there is no adjuvant in licensed vaccines in the US – influenza vaccines in the US, so there is no way to attribute it to that. And they did a lot of testing. They tested for endotoxins and pyrogens and they haven't been able to come up with anything related to the manufacturing process that they can identify. And the amount of antigen that is in the influenza vaccine is about the same.

There was some discussion about whether perhaps the uptake of the vaccine initially in Australia wasn't that great and it increased substantially last year, so maybe they are seeing reactions for a large number of people they did not see before, but there is still no clarity around any biological explanation for what has been reported. Would you say that is a fair summary?

DR. GRUBER: Yes.

DR. GIDUDU: VSD and others in February 2008 have presented preliminary results to the ACIP that showed evidence of a twofold increase of risk for febrile seizures after combination MMRV vaccine, measles, mumps, rubella and varicella, when compared to the vaccines separately – measles, mumps, rubella. So the

current publication that they have used twice as much data as was presented then and their study goal was to examine the seizure risk after MMRV vaccine.

The next slide I am just showing – the publication using Vaccine Datalink data. They assessed seizures and fever risks among children 12 to 23 months after MMRV and separate MMR plus varicella vaccines. So they compared the seizure risk after MMRV vaccine to that after MMR and varicella vaccine and recipients of MMRV vaccine were over 80,000 and these were compared to the recipients of MMR plus varicella vaccine, over 350,000 people. So the excess risk of febrile seizures 7 to 10 days after MMRV compared with separate vaccines of MMR plus varicella was about 4.3 per 10,000 doses.

So in summary, among the 12 to 23 month olds who received their first dose of measles-containing vaccine, fever and seizure were elevated 7 to 10 days after vaccination. And vaccination with MMRV results in one additional febrile seizure for every 2,300 doses given instead of separate vaccines of MMR and varicella. I think similar results are also published in the MMWR that I shared last time.

The last publication is by our EIS office, that also did a study on the association between acellular pertussis vaccine and seizures in early childhood. So receipt of diphtheria-tetanus-whole-cell pertussis vaccine, or DTP, is associated with seizures. I think this was the study question. Limited population-based studies have been conducted on the risk of seizures after receipt of this vaccine. So a retrospective study done by Huan and others looked at this from 1997 through 2006 using risk-interval cohorts and self-controlled case series analysis on automated data in seven out of the eight managed care organizations in the VSD that participated in this study.

So in summary the study did not observe any increased risk of seizures after diphtheria, tetanus and acellular pertussis vaccination among children who were

aged 6 weeks to 23 months and these findings provide reassuring evidence on the safety of the vaccine with respect to seizures.

Lastly I wanted to give you an update on narcolepsy that you have seen in the media recently. CDC has been aware of recommendations made by the Finland National Institute for Health and Welfare to discontinue vaccination with Pandemrix, which was used for H1N1 vaccines during the last pandemic period. They stopped the vaccinations while the investigation was being conducted, looking into the risk of narcolepsy among children that were seen mainly in Sweden and Finland.

This vaccine was developed specifically for the last pandemic. It was not used here in the US. So a different influenza vaccine will be used in Europe, which will be made by GSK. So they are not going to use a similar vaccine. So narcolepsy, which is a chronic neurological disorder caused by the brain's inability to regulate sleep-wake patterns normally. I wanted to share this because the media sometimes affects what we do at CDC. So we are monitoring the vaccines in response to this recent issue. CDC has reviewed information with VAERS and VSD and I wanted to assure you that they are not seeing narcolepsy. You may be seeing this in the media and we are watching out for it.

Thank you.

DR. FISHER: I am actually a member of the Brighton Foundation, the Brighton Collaboration, and this was just discussed at our recent teleconference that we had. They are proposing a very large study to first of all define narcolepsy so that you can look for whether there is or isn't an increased incidence, and to study it specifically in Scandinavia and probably the rest of Europe, where there is a large collaborative that just has been functioning for the last two years. I think that these international things are important for us to consider here. This is a different vaccine than anything we have in

the US, but any adverse event that happens may make us smarter or brighter about what kinds of things to look for in our own. I am glad you brought it up.

DR. GIDUDU: I thought I might share that. Thank you.

MS. GALLAGHER: Thank you very much for your presentation and for all of the information that you provided to us. I was wondering if I would ask Dr. Mulach to begin her presentation now because we still have considerable time before our scheduled break. Would that be okay with you.

Agenda Item: Update on the National Institute of Allergy and Infectious Diseases (NIAID), NIH Vaccine Activities - Ms. Jessica Bernstein

MS. BERNSTEIN: I am Jessica Bernstein. Dr. Mulach is not here and I will be providing the information. I have a brief report from the NIH. I wanted to report on a new effort to define markers of human immune responses to infection and vaccination. This is an effort that was just recently launched to study the human – well, it is to establish the human immune phenotyping centers. These are six US-based centers and they will be researching responses to naturally acquitted infections and to vaccination. So this is funded through the Recovery Act, by the way, and we are going to be looking at gaining a better understanding of the range of responses to vaccines and natural infections in specific subpopulations. So these populations will include newborns, young children, the elderly, patients taking immunosuppressive medications and those with underlying immune diseases. So that is one thing I wanted to report on. Any questions about that?

Then there is also a newly formed autism informatics consortium, which is a combination of organizations including Autism Speaks, the Simons Foundation, the Interactive Autism Network and NDAR, the National Database for Autism Research,

which is part of NIH. Recently these groups got together to form the Autism Informatics Consortium to talk about how to harmonize the major informatics platforms in autism. So for all this information that is coming out from different sources, how to put these together to make them more useful to researchers. Just last week there was a conference on this topic. I don't have any details yet because it was just a few days ago, but I just wanted to let you know that that was held and these issues are being discussed. Hopefully we will have more to report on in the future about the results.

MS. TEMPFER: This is being funded through what?

MS. BERNSTEIN: The consortium? I am not sure. I will check on that. I don't know who funded the conference. It is a collective effort and NIH is part of it. Yes, we are contributing to it but I don't know exactly who funded it.

MS. GALLAGHER: Thank you very much for the very quick update. We are now even more ahead on time. We believe that a brief personal comfort break is n order, so if everyone will come back in about 15 minutes I will put the phone

(Break)

MS. GALLAGHER: I will again say that Dr. Marion Gruber from the FDA is here to present next. Thank you very much.

Agenda Item: Update on the Center for Biologics, Evaluation and Research (CBER) Vaccine Activities, - Dr. Marion Gruber, CBER, FDA

DR. GRUBER: Thank you very much. Actually people never really have problems hearing me but at the off chance please let me know.

I just wanted to report today that since my last update, and that is a while back because I couldn't be here in June when Dr. Cross represented me to talk about rotavirus vaccines, we haven't had any major new vaccine approvals. However, what

we have done at the end of July 2010 we did approve the so-called “stain change” supplements for the 2010-2011 influenza vaccines. We have currently seven US licensed influenza vaccines. Since Tom Herr indicated that he wasn’t aware of Afluria, maybe it doesn’t hurt to just briefly mention the US-licensed influenza vaccines.

So there is the only live attenuated influenza vaccine by Medimmune that is FluMist. Then we have Sanofi Pasteur’s product, Fluzone and also Fluzone High Dose, which is specifically indicated for the elderly. There is a vaccine called FluLaval that is ID Biomedical’s, but that is a subsidiary as I understand it of GlaxoSmithKline. We have Fluarix that is an inactivated trivalent influenza vaccine, and by the way so is Fluzone and FluLaval. Then we have Agriflu, a trivalent inactivated influenza vaccine that we recently licensed. That vaccine is made by Novartis. Novartis also makes Fluvirin. And we have Afluria, which we licensed again for adults in December 2007 and then we licensed it for use in infants six months and up in November of 2009. That vaccine is manufactured by the Australian company, CSL.

So I think you all know this, but I am just going to repeat it because I have it here in my notes. The 2010-2011 seasonal influenza vaccines include three strains, an influenza type A strain, and that happens to be the strain that was the cause of the pandemic of last year, the H1N1 strain. Then we have the H3N2 strain that is also an A strain and that is different that what was present in the last year’s seasonal vaccine. And the trivalent influenza vaccine also contains a B strain.

In contrast to last year, this year two different vaccines are not needed. During last year’s influenza season we needed two different vaccines, one to prevent the seasonal influenza, and there we had the trivalent vaccines, and the other one to prevent influenza that was the cause of the 2009 pandemic.

As we discussed a little bit about thirty minutes ago each year there are

two influenza seasons actually across the globe due to the occurrence of influenza at different times in the Northern Hemisphere, of course primarily in the winter, and in the Southern Hemisphere, where the flu season is in the summer. Some influenza vaccine manufacturers produce vaccines for use in both the Northern as well as the Southern Hemisphere. As an example, CSL, the Australian company, has a Southern Hemisphere influenza vaccine, Fluvax, an they also have the Northern Hemisphere vaccine called Afluria. So Fluvax, the Southern Hemisphere formulation of CSL vaccines was used actually not only in Australia but also in New Zealand, and there it has been seen that the vaccine has been associated with an increased incidence of fever and febrile seizures among young children, mainly those who are less than five years of age, peaking at about 12 to 24 months of age.

The data that are available to the FDA at this point suggest that the increased rate of fever and febrile seizures in these children who are les than five years of age are only associated with the Southern Hemisphere influenza vaccine formulation by CSL. The available data regarding the safety of other influenza vaccines that were used in the Southern Hemisphere did not suggest an increased rate of fever or febrile seizures.

We of course do not have any data of this year's formulation of Afluria, which is the vaccine that is licensed here for the Northern Hemisphere in the United States, because flu season has not really started yet. But what we have done is the following. Afluria and Fluvax are both CSL-made vaccines, but they are not exactly the same. As a measure of caution actually we decided to change the prescribing information, that is, the labeling for Afluria to inform health care providers about the increased incidence of fever and febrile seizures which was seen in young children following the administration of the 2010 Southern Hemisphere Fluvax influenza vaccine.

In addition, the company will not distribute in the US market for the upcoming flu vaccine the 0.25 ml single dose vaccine that is used in small children, i.e., those six months through 36 months of age. They also have informed us, for different reasons, that they will not make available their multi-dose vials, that is, the 5 milliliter presentation of Afluria. So, all that will be available for the upcoming season is actually the 0.5 milliliter syringe, the single dose presentation.

The total number of doses projected will be 10 to 12 million for the upcoming season, but now that the 0.25 ml formulation is not being distributed and also the 0.5 ml presentation is not distributed, the numbers will be really much smaller. As part of the strain change approval this year the FDA required CSL to conduct a further study of Afluria in children to obtain additional information regarding the febrile events that have been seen in the Southern Hemisphere. Since the Australian government, if you will, the chief medical officer, has decided that the CSL flu vaccines will be used in the Southern Hemisphere in children five years of age and older in the 2011 influenza season in Australian, the company will conduct a clinical study with Afluria in children five to eight years of age. We hope that we have the data available from that study in August-September of next year so that we then can make a decision on what to do with Afluria.

In other words, will the indication remain the same? Right now we have, as I stated, included a statement in the warning and precautions section, but we have to get to the bottom of that. I described before that we looked into the manufacturing and we looked into additional testing and we cannot really get our arms around it and the company cannot get their arms around what happens, what is about the vaccine. I should also tell you that since we licensed this vaccine in November of 2009 for infants six months and up that licensure was tied to a post-marketing required study to prove

and demonstrate clinical benefit. Once we have analyzed the data we will have more information to really see what the profile is of this vaccine, of Afluria in the Northern Hemisphere.

That concluded my part of giving you an update for Afluria.

DR. HERR: I have another question. With the doses of the Afluria that will be distributed in this country, will there be anything other than the package that described the increased precaution regarding the 5 to 8, or actually three to eight age range, which will reflect different doses to call increased attention to that precaution.

DR. GRUBER: The answer to that is yes. We actually approved with the package insert what we call a patient package information or PPI, and that is actually an information sheet for the parents that describe these incidences. Also we have actually talking points that are available on the FDA web site. And there has been a press release that describes that. So there have been various communication pieces going out to explain that not only to the health care provider but also to the parents.

If there are not additional questions regarding the influenza vaccines I can move on with my second update.

MS. TEMPFER: I am just wondering – I know it is a guessing game, like how many doses of the vaccine you are going to need. I am just wondering if the universal recommendation this year for everyone, is there a number of how many million doses you are thinking we will need in the Untied States?

DR. GRUBER: ACIP has made a universal recommendation that everybody six months and up should receive influenza vaccine, right? How many people live in the United States? Three hundred million or something? Okay, so subtract the less than six months of age – it is a substantial number.

Projections that I have seen, but that is before I went on my vacation and

I haven't seen the latest number, so that was projections in July, beginning of August, and I saw numbers of availability of about 160 million doses total between the seven US licensed vaccines that we have. So it is not going to be enough if you are talking immunizing every US citizen.

I would actually like to report a little bit more on the issue of rotavirus vaccines and give you a little bit of an update on the reports of the presence of this porcine circovirus in US licensed rotavirus vaccines. I am not going to repeat lot of what you heard in June when Dr. Cross was here. I think he gave you a fairly extensive update.

I just wanted to tell you about additional steps that the Agency has taken between June of this year and now. I think Dr. Cross has informed you, and I think you all know, that we actually did convene a special meeting of our Vaccines and Related Biologics Products Advisory Committee in May where we discussed the findings of porcine circovirus and porcine circovirus DNA in the US licensed rotavirus vaccines. Our advisory committee at that time also discussed application of novel highly sensitive techniques for the detection of adventitious agents that may be present in biological products in general. As you have heard from Dr. Cross, porcine circovirus was really only found by the use of these novel highly sensitive techniques.

The Office of Vaccines within FDA has taken since then the following steps. First of all we reached out to US licensed viral vaccine manufacturers, that is, we issued letters to all these manufacturers and we requested that they provide us with their plans and programs to implement additional testing for adventitious agents as part of the manufacturing process. That would include but is not limited to screening for porcine circovirus because if you actually apply highly sensitive technology you may find other adventitious agents that you were not able to pick up with the usual technology that has

been used so far.

So we actually sent out that letter. We are awaiting their response and we will actually, based on their response, take the next steps. We also have established a research working team within the Center for Biologics to really develop highly sensitive new technologies and we are trying to standardize these and we are trying to develop reference reagent so that some of these new technologies can be applied for characterization of vaccines as they are developed.

We have been working with each of the licensed rotavirus vaccine manufacturer, GSK and Merck, to update the prescribing information for both Rotarix and Rotateq to include information about the presence of porcine circovirus and its DNA in the vaccines, and the labeling will be approved, if not today, they will be approved this week.

We continue to investigate the findings of PCV in these rotavirus vaccines. The manufacturers still look into these situations. They have set up various testing methodologies and investigation is ongoing.

As you know GSK has announced in the VRBPAC meeting of May 2007 to revive its licensed rotavirus vaccine to get ready try to deplete the vaccine of procaine circovirus, and has scheduled a meeting with the FDA to discuss further proceedings in that regard.

So that actually concludes my update on the rotavirus vaccine and the issue of porcine circovirus. If there are any questions I may be able to answer them.

DR. FISHER: The question is the letter you sent to all the pharmaceutical companies doing viral; vaccines, and I realize that is because that uses cell culture media, et cetera – but what is being done with the bacterial ones, the toxoids, just to insure there are no processing problems there.

DR. GRUBER: That is going to be the next step. We actually sent letters to all viral vaccine manufacturers, but many of those – actually there are not that many. We don't have that many US licensed vaccine manufacturers. Many of them have combination products that contain bacterial antigens – for instance, Pediarix is one of those. So we are trying to capture that information. But there are few manufacturers that make bacterial vaccines only and we are going to be addressing those as well.

DR. FISHER: And if no one else has a question may I ask one more? Moving back to the influenza, this summer there were a few case reports of H3N2 strains causing influenza outbreaks off season, summer outbreaks. Is it the same as the one that is in the vaccine? Is there a match?

DR. GRUBER: That is my understanding. I think it is the Perth strain. I will be happy to double-check for you but I think that is it, because we changed the H3N2 in this year's formulation.

MS. HOIBERG: The vaccines that are out right now, that they are giving in the Walmarts and what not, are they the old ones or are they the new ones? Are they still providing the influenza vaccine from last year's stock?

DR. GRUBER: You meant eh trivalent influenza vaccines? No, they are the new formulations because we approve them at the end of July.

MS. HOIBERG: So what happens to all of the vaccines left over from last year? Do they get destroyed?

DR. GRUBER: They expired. They get destroyed because that is why we actually assign an expiration date that is usually June 30th of the next year, to sort of prevent this overlap to have in parallel new and old formulations on the market.

MS. HOIBERG: Okay, I just wanted to make sure.

MS. GALLAGHER: Thank you very much, Dr. Gruber. We really

appreciate the updates.

Agenda Item: Public Comments

MS. GALLAGHER: Now we are going to the time for public comment. And we have a few individuals here in the room who wish to make public comment. Given the audio difficulties we are having I would like to invite each one to please come up and sit in this chair right in the middle and speak as clearly and loudly as you can so that both people in the room and people on the phone can hear you.

I have a list of three names, so I am just going to call them in the order in which I got them -- so Ms. Catherine Frompovich? While we are getting ready here may I ask the operator to see if there is anyone on the line who would like to make public comment and we can get them queued up as well after we have finished with the people who are here in person?

MS. FROMPOVICH: Thank you very much for allowing us to speak. My topic is brain swelling and damage associated with vaccines and inappropriately labeled “shaken Baby syndrome.” With all due respect to what has been presented at this meeting, the Advisory Commission on Childhood Vaccines needs to hear about the unfortunate miscarriage of justice against parents whose children suffer brain swelling vaccine damage and are legally prosecuted by authorities with such chares as shaken baby syndrome, Munchausen by proxy, fictitious induced illness, non-accidental injury, physical abuse, failure to protect and child abuse.

Numerous infants and toddlers suffer brain trauma with or without hemorrhage, brain swelling and cardiorespiratory events shortly after vaccination to which the medical profession and several authorities attribute some form of child abuse because of terrible misconceptions that vaccines are not capable of producing such health anomalies.

The Iowa District Court adjudicated just such a case June first, 2010. It is case number JVJV002265, wherein a six month old male was removed from his parents care for close to eight months because they were charged with shaken baby syndrome after the child suffered traumatic brain injury following three vaccines administered simultaneously – Pentacel, Prevnar 7 and Rotateq.

Furthermore the child had a facial hemangioma that exploded in the doctor's office immediately following the administration of the vaccines. Medical staff was witness to the event and an MRI confirmed traumatic brain injury. The Iowa court ruled that the parents were not responsible and that the problem could have resulted from vaccines. Dr. Harold Buttram, MD, was the medical expert for the parents, documented this case in his paper Subdural Hemorrhages Occurring in an Infant Immediately Following Vaccination, wherein he methodically charged the infant's anamnestic allergic responses to the vaccine at six months of age. Such responses should preclude further administration of all vaccines, but when interviewed, when I interviewed the child's father for an article I wrote about the case, and which was published on the Internet, the father told me that the day before my phone call the authorities mandated that the child receive more vaccinations to which he had a reaction.

I respectfully ask this learned committee to consider the implications of such medical and civil directives that fly in the face of medicines implications and prime objective of first do no harm. Numerous medical tests will exonerate child abuse charges against parents falsely charged. Please, I implore you, on behalf of the children who suffer brain damage, and their parents who are maliciously charged with child abuse, that you use your good offices to alert the medical profession to what is happening to these infants and children and to recognize its ethical responsibility to

identify the true offending agent toxins and adjuvants in vaccines. Thank you for listening to my appeal on behalf of those who do not seem to have a voice in this matter. I thank you kindly. Are there any questions?

MS. GALLAGHER: Thank you very much for your comments. We don't generally entertain questions to public comment, but I thank you for sharing with us.

MS. FROMPOVICH: Thank you for having me.

MS. GALLAGHER: Ms. Larraine Abbey, I have a note that says you would like to make a public comment. So would you kindly come to the front so that your voice can be heard clearly?

MS. ABBEY: I also want to thank this committee for the opportunity to make a couple of comments. Protecting our children and the vaccine program is what I titled my concept. There are some handouts that you have hopefully gotten is too long for now.

Vaccine critics are saying that we are trading vaccine preventable infectious diseases for some chronic health disorders. How can we reasonably say that vaccines don't cause or contribute to autism when we don't know what does cause autism? Vaccine concerns are no longer just about autism, they are about children's total health. Armies of parents are reporting that they took a normally developing child to the pediatrician for routine shots and the child's health or behavior changed, never to be the same as before the visit. Thousands upon thousands of parents report similar coincidental symptoms related in time to vaccinations. It behooves everyone to find out why.

We now have general agreement among many that vaccine safety studies are flawed. Short-term studies won't see possible long latency effects; older vaccines used as inert placebos are not reasonable and I am particularly concerned

about the effects of aluminum, but not only. Most vaccines and boosters contain aluminum. Aluminum exposure has risen steadily in tandem with our escalating vaccine program and we need to focus on the cumulative vaccine components, and particularly cumulative effects of aluminum.

Much of the anger focused on vaccines stems from the use of mandates which holds individuals hostage for employment, school requirements and pediatric medical care. This seems to me to be a flagrant violation of personal liberty and is now seen as a most unpopular aspect of what many are calling a socialist agenda.

The primary argument for mandates has been herd immunity, but herd immunity is failing even among highly vaccinated populations. This further challenges the use of mandates because vaccine components have been documented as health damaging in issues ranging from gut problems, brain inflammation, nervous system damage, sterility, allergic reactions, asthma and even, some of questioning diabetes. The mandating of improperly tested vaccine fuels public outrage.

The Advisory Commission on Childhood Vaccines needs to issue some strong recommendations. I urge the following. One, discontinue mandates and initiate informed consent on all vaccines. Two, gather all toxicity data on all vaccine components. Do controlled animal studies with plain saline placebos studying each component separately and in combination and address aluminum as a priority.

Three, encourage a reduced and delayed vaccine schedule until safety issues are clarified. Four, discourage or limit vaccinations in families with a history of reactions or autoimmune disease. And five, revisit the lifting of pharmaceutical company liability by government as this creates an unrestrained rush to profit. Compensations are on the rise, as victims like Polling, Hiatt and Banks have proven their cases to the satisfaction of the courts. Like the canary in the coal mine we must heed the warning

and study the situation in earnest – what is causing problems for one can be causing problems for another and another and another.

The question in my mind is no longer are vaccines causing damage, but rather what damage are vaccines causing? Let's act quickly to protect and regain our children's health. Failure to explore the associated factors given the epidemic nature of children's health problems today could really be the disaster of the age and spell the death of the vaccine program.

I just want to mention there were a couple of books that are on my bibliography as suggested reading list that I think all of you should be aware of. This new one by constitutional lawyer Jonathan Emord, Global Censorship of Health Information – very powerful, very powerful information. Andy Wakefield, who has been under attack as you all know, lost his medical license, and he put out a book called Callous Disregard. It is very impactful and powerful. And not all the information that official sources give us is correct, so we need to be aware, as Marcia Angell, the former editor of the New England Journal of Medicine published in this book, the Truth About the Drug Companies – How they Deceive Us and What to Do About it.

There are a lot of agendas here, not necessarily this committee, but a lot of powerful forces, and some of these books help you to understand what those forces are. Thank you.

MS. GALLAGHER: Thank you for your comments. I believe Dr. Harold Buttram has indicated his desire to engage in public comment. Would you kindly come up front near the microphone so everyone can hear you?

DR. BUTTRAM: I appreciate very much being here. I am a retired physician and I have the advantage over most or all of you simply in my age. I was born in 1925, went through my childhood and early teenage years in the 1930s. As a family

practitioner I retired in 2008. In the later years of my practice I saw quite a few autistic children and related disorders. My presentation today, the idea behind it, is reminiscences of children in the 1930s.

I have especially in mind a summer camp that I was very fortunate to go to in New Mexico in the mountains. The boys then, no boy was sick, no boy had allergies, no boy was on medication. How different it is today. I won't go through the statistics, but I remember a pediatric warning – that is not the word they used – several years ago that learning disability affects one out of six children.

Things have changed dramatically. If it is not vaccines, then what is causing this? There is a very profound increase in physical and mental problems, allergies, so on in children.

The other point I wanted to bring up is there was a publication from Germany, published in the New England Journal of Medicine in 1984 and in the study tetanus booster vaccines were given to eleven healthy adults. Blood tests were taken before and after the injections to test for T-helper lymphocytes. I am sure most of you know that lymphocytes are a form of white blood cell that governs the immune system. The results were there were significant drops in the T-helper cells in all of the subjects, but in four of them levels dropped to levels seen in active AIDS patients.

To the best of my knowledge this test has never been repeated, and until this one test is tested I don't think we have the right to – there is still a question about the safety of vaccines. Now if it has been repeated I would certainly like to know about it.

That is all I have.

MS. GALLAGHER: Thank you for your comments. Is there anyone else in the room who wishes to make a public comment? All right – operator could you please let us know if there is anyone on the line who wishes to make public comment.

OPERATOR: Yes, we do have someone. Jim Moody, your line is open.

MR. MOODY: Thank you, Madame Chairman and thank the committee for the opportunity to make public comment. I would like to address two topics. They both revolve around the theme of uncertainty as to safety, doubt as to safety, underlines the benefits of the vaccine program. We are seeing more and more data of that. Just to mention one thing that was in the media recently, which was a series of schools in California now have rapidly increasing exemption rates. There is a private school in San Diego where 51 percent are filing exemption applications, and these rates seem to be increasing all over California. A lot of states are seeing the same thing. This is the direct result of concerns and doubts over safety, and the only way it is going to be addressed is through science and transparency.

Regarding the reports from the DOJ and from the DVIC, it looks as if 90 percent of this element, adjudications, are the result of these litgative risk settlements, and what this does is it creates a vast body of secret laws, because there is apparently no public reporting of the vaccine, the mechanism of injury, the amount of damages, and apparently some of this ends up on the court web site by reps of the decisions, and they are just the amount, and there is an allegation of vaccine injury without really any details.

What this creates is the government may pay more compensation than it feels is owed because of uncertainty in the science. The petitioners may take less compensation than they are entitles to because of uncertainty in the science. The public, as a whole, is subjected to this growing body of secret law that does not inform the public as to what science is needed, what vaccines are safe, where the concerns are. So this is strong evidence for the need for much, much more transparency in these settlements and in full transparency of all data the government has on vaccine safety, in particular the Vaccine Safety Datalink. That is something like eight percent of American

children are part of that. There should be full transparency. So far that information has not been able to be obtained by petitioners in vaccine court, again further undermining the program.

The second aspect of public confidence regards the science. A year ago now the National Vaccine Advisory Committee made a finding and made a recommendation that there needs to be more science looking at unvaccinated children to understand what the baseline data is so that adverse events could be appropriately ascertained. This dovetails on the comments of the three people in the room there that, until we know for sure what the acute and chronic health status is of unvaccinated children, and derive useful understanding of the chronic and acute adverse events, particularly the chronic adverse events that vaccinated children are subjected to – it may be very little, it may be as many as one in six – until this is done we just won't have a good answer. There is an announcement from NIH on this hundred million dollar funding for immune markers – that is all very good – but in the listing of subpopulations there was no specific mention that unvaccinated children be looked at for the purpose of determining a baseline. Without that even that investment is useless to ascertain full confidence that the mandate in Section 27, the mandate for safer childhood vaccines, has been carried out.

ACCV has an opportunity here, indeed must take a much stronger stand in making recommendations to the Secretary on the Section 27 authority, both the address the transparency issue and to address growing gaps in the science associated with vaccine safety, with the goal of maintaining public confidence.

Thank you very much.

MS. GALLAGHER: Thank you for your comment. Is there anyone else on the line who wishes to make a public comment?

All right operator, will you please confirm that there do no seem to be any other people who have indicated a need for public comment?

OPERATOR: I am showing no further comments at this time.

MS. GALLAGHER: Thank you very much. I would like then to recess until nine a.m. tomorrow morning in this room. Thank you everybody for your participation and patience and I will see you in the morning.

(Whereupon, at 3:45 p.m., a recess was taken until 9:00 a.m. the following day.)