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

Agenda Item: Welcome and Unfinished Business from Day 1

MS. DREW: Good morning everybody. Welcome to the second half or second portion of our 79th ACCV meeting. It takes place today, June 10th, 2011 via telephone.

I believe the first item on our agenda is unfinished business. I wonder if anybody has any unfinished business to bring up to the Committee.

MS. HOIBERG: Yes, Sherry, this is Sarah Hoiberg. I wanted to address the Pace article that was mentioned at the end of our meeting yesterday. I just want to preface it by saying that I am coming to the Commission as a parent. My comments in no way reflect the opinion of HRSA or of this Commission.

My child was injured by the DTaP shot at 18 months of age. Her life was tragically altered due to an encephalopathy, which resulted in a severe seizure disorder. Through her care before even attempting to file with the vaccine injury compensation program, we were directed by her neurocognitive doctor to seek ABA therapy for her. At the time, that was not a financial possibility and so when we went before the Department of Justice and

the court our attorney did ask for ABA therapy to be included in Kate’s plan.

A lot of the other things that were addressed in the Pace report that stated that they had asked for -- you know, they saw that there was ABA compensated and that there were gates for flight risks, saying that those all were purportedly, you know, things for us and the children and in that way the government had compensated for autism.

I just felt like it needed to be addressed that when a child suffers a brain injury they become unable to focus. They need special care. They need the ABA therapy. ABA therapy is a therapy that benefits any child, typical or non-typical.

I would really like to know what all was done to find out that it was autism -- that all of these children had autism that were in this report. Did they only interview just a few people or did they just look at the life care plans? Looking at a life care plan, my child looks like she was compensated for autism.

Unfortunately, when a child -- when the brain is traumatized in such a way, it could very well lead into autism somewhere on the spectrum. Some type of autistic tendencies could develop. Because of that, my daughter is

screened every other year for that just to make sure that we nip it in the bud if it happens.

I guess another issue that I had with this report and then alongside of that with the press conference that followed was that these families, who had been compensated and generously compensated, seemed to be ungrateful. I believe that instead of helping their cause, the community that brought this forward has hurt their cause.

The omnibus proceedings were a very hot topic. There were, you know, people that felt there was a conspiracy and that because it was autism they just weren't even looked at. The Special Masters then gave the opportunity to these families to come in under a different injury, not alleging autism, but possibly an encephalopathy, if it did, in fact, happen -- that they did have a seizure disorder or what not.

I feel that in these cases the government did not compensate autism. They compensated the injuries that were alleged, which was seizure disorders or an encephalopathy. The fact that this was brought to the attention -- and the program looking at -- I guess the program was supposed to -- I can't even think. They tried to make the program look bad and make the program look like they had been lying

about compensating autism. They were not compensating autism. They were compensating a brain injury.

I just wanted to put that forward and just say that the program, as a whole, is compensating people. They are helping people. Those families that were compensated, whose children ended up with autism, now have the financial means to take care of these children in a way that will possibly help them to recover, but at least they have an avenue to help their children.

My heart goes out to those families who have not been compensated and maybe at this point now do not have a chance to be compensated because of what has happened, but I do feel very strongly that this community needs to kind of take a step back and realize that they are hurting more people than they are helping. Thank you.

MS. DREW: Thank you Sarah. Does anyone else have any comments about the article?

MR. KING: I don’t know whether it is so much of a comment as on the case review, but rather our public comment yesterday, I believe that the speaker called us to take action and that he asked us to say something along the lines of because of the level of confusion, I guess -- that may be my word -- around this that we should be asking a

hold be put on the disposition of all these types of cases. His argument was that it costs no one anything to do that, but gives everyone more time to look at and research the information.

I guess my question is should we or do we want to respond in any way to this individual's, on behalf of the people that he was speaking for's, request without making a case either way as to whether or not we agree or not agree because that is not what he asked us to do. What he asked us to do was to request a hold until more information could be uncovered.

I throw that out there -- did I misinterpret what this man said?

MS. DREW: No, I think that is exactly what he said. Thank you. I guess I would say to that if we are going to do something, it probably should be done pretty quickly because the cases are in the process of being dismissed and probably will not be around in another year or even, potentially at our next meeting. I do not know.

Again, I will throw this out to the Commission. Is there anything that you think that we can do? I think we would have to do it very quickly.

DR. HERR: Not being an attorney, is there a

legal procedure such that if any of the petitioners' attorneys feel that this is an adequate reason to forestall the completion of the closing of many of these cases -- isn't that something that there would be a normal procedure for them to present to the Special Masters or the court to stay any kind of change or any kind of closure? I mean, isn't there a legal procedure for this?

MS. DREW: I don't think I personally can address that, but maybe somebody from the Department of Justice or HHS would make some comment on that?

DR. EVANS: Julia, I would like you to take this.

Julia: I really can't comment on that. I am not a part of the OAP proceedings. I would be confident in saying that there is some sort of procedure in place that the petitioners' attorneys are aware of, but I cannot speak to that. I can certainly check with folks who would know the answer and get back to you.

DR. HERR: Even in cases, if there is new evidence that is introduced, doesn't that have some sort of weight, at least for a judge to decide on the merit of that potentially new evidence to sort of put a stay -- I mean, they can decide yea or nay, but does this fall into something like that?

MS. WILLIAMS: This is Michelle Williams. I am a little reluctant as a Commissioner to be discussing a report that I have not read and I am not sure other Commissioners have read or considered or prepared to discuss at this meeting. I am a little uncomfortable making any kind of recommendation without understanding exactly what is in a report.

Maybe all of us should have read it, but I can say that I have not. I am a little uncomfortable. I would ask the Chair is this a question that is appropriate to forward to the Special Master for their consideration.

MS. DREW: Again, I don't know if Elizabeth is there, I believe that our job is to advise the Secretary, not to advise the Special Master or the court. I am not sure that this is really something that we can address other than to advise the Secretary, who might then do some other procedure.

On the other hand, one understands that cases have to be finished at some point. If the position of the court is these cases are done with based on the current evidence, I do not know that it is our job as Commissioners to comment on that.

DR. HERR: My point, Sherry, is that if there is

a procedure out there to deal with this, we do not need to get involved at all because there is already something that if the petitioners' bar thought there was enough to relook at it -- I don't know what the term is -- then we do not have to do anything. It is up to -- the ball is still in their court to do something about it.

My point would be I do not think it is appropriate for us to do that, especially if there are legal procedures that would allow somebody to do something if there was enough there.

MS. HOIBERG: This is Sarah Hoiberg again. The title of the article was Unanswered Questions in the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury. It was a very easy to read article and I really, really, really would stress that every one of you read it. In the end, my personal opinion is that it just reiterates that vaccines do cause brain injury in some cases and that in the end that brain injury can lead in to and, you know, could possibly lead into autism.

The program has done their job in compensating a brain-injured child. Really, there is no unanswered question. The fact is that they have a bone to pick and

that is that these cases that were brought before the court, alleging autism being caused by the MMR or by thimerisol or by both were not compensated.

I have spoken at length with Geoff because I, personally, had questions. When I came in onto the Commission, I was raging mad. You look at the past notes and you will see that I was. I fought and fought and fought. I spun my wheels. But I have grown up a lot since being on the Commission and I have learned so much.

Are there still things that I am angry about? Absolutely. Do I feel that we are giving our children way too many vaccines? Absolutely. Do I feel that they could be safer? Yes. Would I like to see research into safer vaccines and for it to actually come into fruition and for them to really, actually do something and vaccinate due to size and weight, not just one size fits all? Yes. That is what I want to see.

That, I am still upset about -- that vaccines are not treated with the respect that they deserve. I feel that they are given out with really no consideration, especially the flu vaccine.

This article brings to light the fact that the program is actually compensating cases, which, for me, was

very important because I felt they did not compensate enough cases. Since being on the Commission, the rate of cases compensated has gone way up. I am super pleased with that.

My biggest thing in bringing this before the Commission today was that I was upset that it showed -- that it tried to muddy the waters of the program that, in the end, the people that it helped, it helped a great deal. I do not know for a fact what they are trying to accomplish with this article.

I wish that everybody had read it because we could have had a very rich discussion about it, but I feel that if we could at some point bring this up again or have a workgroup meeting on it or this actually could be something that could go into the future science -- that we could maybe review in the future science work group.

For me, the vaccine injury compensation program has, in a way, given life back to my daughter. I have been able to get her therapy that I never would have been able to afford on my own. For these people to stand up and say and pretty much throw it in the face of the government that they messed up, that ha, ha, ha, you compensated an autistic child is just wrong. That is why I am angry

because I feel like the program did something good in compensating these people.

They compensated an injury that is a tabled injury and yet these people are turning it around and making it a bad thing. I really encourage you to read the article. I would love you feedback on it, especially as an attorney, Michelle.

MS. DREW: Okay, my comment here again, what David King, our Commissioner, interpreted as being Jim Moody's comment was there are cases that are sort of waiting for the science to show up. He, Mr. Moody, thought that the cases should be stayed until such time as the science shows up. Mr. Moody has requested that we do something to make that happen.

I am not sure that it is our position to make that happen since we are advising the Secretary, not the court. However, the court is part of the program. I am no entirely sure of what we can do. It strikes me as being something that if these cases are dismissed and the science should change drastically in another 10 or 12 or 18 years, Congress could come back and say the cases that were dismissed for failure of proof can now come back into the system. I am not sure that there is anything that we, as

Commissioners can do. I do not know if anyone has comments on that or not.

MS. HOIBERG: I think just like when the program was introduced and all of those cases that were the pre-Act cases were able to come in -- it was years and years and years and years and years. Some of those cases, some of those people were old before they had their day in court. I do not see why Congress would not do that again, but that is just my opinion. It may totally be off-base, but just Elizabeth or anyone want to comment on that? Would that be a possibility that if the science were to all of a sudden show up and they recognized or whatever that it could be caused by a vaccine, would these families then have a case?

DR. EVANS: As you know Sarah -- this is Geoff -- as you know, once an injury is added to the table, there is an eight year look back period, but if this were to be, in the case of autism, something that was extraordinary in scope obviously it would be very limiting if it just went back eight years. Congress could certainly pass legislation that would significantly open up the retroactive period. That is within their authority to do that.

MR. KING: This is Dave King, again. I am always

reluctant to ignore the public because it just seems like it is not a good thing to do, in general. I am wondering if part of the charter that we have is that we can recommend to the Director of the National Vaccine Program research related to vaccine injuries, which should be conducted to carry out the program.

Perhaps we could -- this is open for discussion. I haven't really put a motion here. Perhaps we could recommend that there is the potential that might warrant further research in this area and that we could just recommend that to the Director of the National Vaccine Program.

DR. EVANS: Maybe this is something that could be addressed by the Future Science Workgroup, as they begin to take on the issue of research in our program -- what other research either in or out of our program might be appropriate.

MS. HOIBERG: I think that is a good idea. I think that it gives us something to discuss in our Future Science Workgroup this afternoon.

MR. KING: I would make a motion to that effect.

MS. HOIBERG: Okay. I second the motion.

MS. DREW: Anybody opposed?

Motion passes. We will address that at the Future Science Workgroup at the meeting this afternoon.

CHARLENE: This is Charlene. I did read the article. It was interesting for me to read such an article, written by lawyers, as opposed to scientists. I must admit that jaded my reading a bit. No offense to lawyers listening.

As you consider the research, something that is overlooked and should be considered is that the mercury, the thimerosal was pinpointed as probably the problematic area, when it was removed in both the US and -- this is just the compelling piece for me -- that as it was removed in both the US and in Europe, not only did cases of autism not go up --

MS. HOIBERG: You mean did not go down.

CHARLENE: They continued to skyrocket. When I was in nursing school 32 years ago, I never heard the word. Now, it is around in my life space, as it is in everyone else's life space. That cannot be discounted. That research, which is a compelling quasi-experimental design that it was taken out and children do not have the option to get these mercury injection anymore, the disease continued to skyrocket. That piece is compelling.

MS. HOIBERG: I felt that it was compelling, too. I felt like they didn't -- like I said, I believe the article hurt the autism community more than it helped them. That was not at all their intention, but that, I think, is what has happened. I am glad that someone else has read it. I know Sherry read it. We had an at-length discussion about it.

That is why I wanted to bring it up today because I feel like it does -- as Dave said, we cannot ignore the public. The public has presented us with something. We do need to address it. I feel that once we are able to really sit down and digest it and really talk about it then we will be able to address the public and their concern.

MS. DREW: All right. Again, I think the issue that Dave brought up from Mr. Moody, really was sort of separate and apart from what was said in the article. Again, we will discuss that further at a workgroup meeting and see if any recommendations need to be made to anybody. If so, we will decide how to format that and who will do it and when it will be done.

Now, if there is no further discussion on this, I think we are only a few minutes late and we can move onto Dr. Rosemary Johann-Liang's clinical update from the DVIC.

Agenda Item: DVIC Clinical Update, Dr. Rosemary Johann-Liang, Chief Medical Officer, DVIC

DR. JOAHANN-LIANG: Good morning everyone. I wish I could see all of you, but, oh well, this will have to do.

Yesterday, there was some discussion about how the different sort of update -- the numbers do not match. I just want to tell you that for the purposes of the clinical updates, we sort of follow our overall HRSA calendar, which is really by fiscal year. We think of fiscal year sort of in a quarterly format.

Usually, the clinical updates are provided for the previous completed quarterly fiscal time. I can see how this can be confusing for everyone because the numbers do change. If you kind of look at it as -- what Jeff usually presents is sort of more of the final statistics of when judgments and everything has sort of been entered. We are able to log all of that into the database.

What Vince or Mark from DOJ usually presents from the DOJ perspective -- I do not exactly know how they do their reporting cutoff time, but it looks like Vince's report yesterday was from February to May, which is now off from what I am presenting, which is -- I am doing the

second quarter of the fiscal year 2011, which is January to March. You see?

He is looking at information from the Court's perspective and I am presenting from our medical group's work product from the second quarter of fiscal year 2011. Next slide. Again, as usual, we will just go over some of the numbers and demographics, what vaccines were alleged, and what sort of average events that the medical reviewers reviewed during this quarter of the fiscal year 2011.

I am going to follow that up with talking, again, about all of us preparing to receive the Institute of Medicine full report, which we are hoping will be -- well, we have always said that it would be in on the third quarter of fiscal year 2011. That is almost upon us. So we will talk some more about that.

What the program, at least from the medical perspective -- everything I will be talking about really is the clinical, the medical part. I will leave the legal stuff to our legal counsel. We will talk a little bit about what we have been doing for our program's experience from the perspective of the clinical and medical issues that we need to address as we go to update the vaccine injury table, following the full report from the IOM.

So the next slide. This is fine. Again, you heard from yesterday that we are now -- we seem to have sort of settled in the 400 plus range of reports coming in, non-autism, per year. That is up from somewhere mid-hundreds not that long ago, several years ago. There is a lot more medical review to be done and, therefore -- you see that for fiscal year 2011, the current projections are that it would be about the same as last year.

Next slide.

MR. KING: Question. May I ask a question?

DR. JOHANN-LIANG: Sure, Dave.

MR. KING: Thank you. It is Dave King. With the increasing number of petitions, where we now seem to have settled on this 400 or more roughly, has the staff increased for that medical review or does it remain as it was?

DR. JOHANN-LIANG: We have been trying to staff up so that we can address all of those reports in a timely manner. Actually, I think, from the medical reviewers perspective, our rate of review once the records are complete is very fast. We are a hundred percent in exceeding our timelines from our perspective.

I can just tell you -- I do not have the numbers

here, but I know it is confusing why the numbers are different, but just from our perspective, when I get a list of cases that need to be assigned, for example, I was looking at bill express sheets for this reporting period, the second period of fiscal year 2011, and it is really -- well, that is kind of what we know -- two thirds of the cases that I assign during this time period were not cases that just came in to the program.

In other words, something was filed to the program saying we are alleging this vaccine injury, but the records followed later. We, as medical reviewers, actually cannot review anything unless we have some records available. Two-thirds of the cases that I ended up assigning during this quarter were cases that were actually filed in 2010, for example, mostly, but there were not enough records for it to be assigned to anybody for review.

Once we do have enough records for a physician to actually go through the review, our rate of turnaround is really fast, within the month. Not even. Two weeks, maybe, even a week. We really do try to turn it around and get that to our initial recommendation.

These recommendations do change because supplemental records keep trickling in and we write

addendums to the records. There is a lot of case management that goes on. There is a lot of dialogue with DOJ. Then, also, there is settlement discussions that come up.

The initial, you know, review of the records, you kind of get a sense of where we are, what is this case about. That happens very timely and on target with everybody. Take my word for it. Everybody will tell you that that is done. Dave, does that answer your question?

MR. KING: I guess the question was I am going to run under the assumption that what you are really saying here is that you have adequate staff to handle the workload. Is that correct?

DR. JOHANN-LIANG: Well, right now, we have staffed up to meet the needs of the increasing number of claims. As you know in the government, we have fiscal challenges. One can never say that we have adequate resources at any time. We are always struggling with inadequate resources, both in people and in funds. Does that answer your question.

MR. KING: Yes, it answers my question and I will reserve comment.

DR. JOHANN-LIAN: Very wise man. Next slide. So

that is what we are going to be talking about. You have seen this slide before.

Remember last time, three months ago, my slides had a lot of graphics because I was trying to show you the denominator, the distribution data, which really sort of dovetails the number of claims that have increased in the last several years and really had to do with, actually, the flu vaccine distribution and how that has gotten to the whole community, et cetera.

Those kinds of distribution data are lagged in time. We are not going to be able to get updated numbers for a while. All of that stuff that was presented last quarter still applies. What you saw in this graphic from the last time is just the first bars, the lighter peach bars, that was the first quarter of the age-band, and then the darker peach here is the second quarter.

You can see things are about the same. Basically, we are now at, of the cases reviewed in this quarter, 62 percent were 18 an above. 38 percent were less than 18. Things have not changed there either. They are not going to change very much, based on what we have been seeing lately, I think. We are no longer really just a children’s program.

Next slide is what kind of vaccines were alleged. Again, things have not changed very much proportionally from the last quarter. Influenza still leads the list as the vaccine that is coming in with the most allegations, followed now by HPV, which is the same as what we saw last time. We have a lot of adolescent and young women claims now. Then the whole slew of the rest followed by tetanus and then infant series, which is really the babies and the two months, four months, which is multiple vaccines. They just kind of allege the whole gamut. They don't say the tetanus or the it is the flu.

MS. HOIBERG: This is Sarah Hoiberg. I am going to get back up on my soap box a little bit. When we are seeing -- yes, they are allegations so we do not know for a fact. They have not gone to trial or whatnot. You are seeing these cases that are coming in from the flu -- so many of them that are coming in with injuries and what not, as well as the HPV. These are the newest vaccines that have come out.

What kind of feedback are you giving CDC and FDA on -- maybe that is not even the right people to give the information to, but what is happening with this information, when you are seeing so many claims coming in.

Yes, I know millions and millions and millions of flu shots are given out, but, for me, 400 cases -- that is a lot of people who are being injured.

I know that it is a small percentage compared to the millions that are vaccinated, but, I guess, is industry taking into consideration how many people are being injured by this and trying to do better and make them safer?

DR. JOHANN-LIANG: Well, okay, so the 400 that is coming in now per year, Sarah, remember these are -- they are claims. Claims do not equal an actual injury causal to vaccines. We have to remember that.

As far as CDC and FDA are concerned, I mean, they can speak for themselves, as well, but they are continuously monitoring average events associated with vaccines. Particularly since FDA has the purview of looking through all of the -- they investigate new drug applications -- well, I am from the drug side so I am still kind of -- the BLA -- so there are Biologic License Applications. They are the ones that go to approve vaccines or other projects, biologics, right off the bat.

They know the premarketing data and then the post-marketing data that follows. Usually, there is a very high level of scrutiny for new products. It is not that

our information is sort of in isolation. These are people who actually alleged that they were injured by the vaccine and want compensation, but there are so many more people who actually report average events to VAERS, for example.

CDC and FDA co-administer theirs. There are continuous conferences, monitoring presentations, and discussions about average events being reported to VAERS. Also, CDC has several networks out there, including the vaccine safety data link, which do more of the active surveillance. Remember, VAERS is more of a passive surveillance in the sense that people just report in, but CDC also has many sites where they actively go seeking, looking for average events following vaccination.

There is the CISA Network, which is the Clinical Immunization Safety Assessment group. Those are more people, throughout the country, academicians, who are working with CDC to look for clinical information regarding average events.

I just want to reassure you, Sarah, that this information is really not in isolation. It is a cohort of folks, who are coming in and asking for compensation. Again, the reviews need to be done to see if there really is an association to vaccines. As you know, by looking at

all of the slides that Vince presented yesterday, our program really, as Congress intended -- you know, we are as compassionate as can be.

There is this scientific part, but then there is the policy and other aspects. When in doubt, we do the presumption of causation through the table. Our attempt, in the recent years, has really been to look for possibly other things that we can, you know, modify to the table to make that process even more smooth, quicker, and, you know, helpful to people who may have been injured by the vaccination. Any medical intervention -- you know, there is a potential for harm. We know that as the public and as a scientific group. That is what we are here for.

Yes, we do talk to our colleagues. Yes, we understand where the program is in conjunction to all of the other surveillance for vaccine adverse events that are going on. The fact that the flu, in this table, is the number one vaccine that is alleged to the program is really not surprising at all from a demographic perspective because it is the vaccine that is more than half of what is distributed in total of all of the vaccinations throughout the country.

Aside from the fact that it is one of the newer

vaccines, its pure numbers alone will say that that really should be the proportion that should be the highest being alleged to the program. I do not think there is any mystery or anything strange here.

Dr. Douglas: This is Charlene. I would like to -- we are talking about vaccine injury. If you go back to our last meeting, but also as I check with my clinician peers, the word on adolescents is that they drop like stones. The primary injury -- what they do is they faint and the injury occurs when the adolescent faints and falls and hits something or the terrible situation where they got into a car and fainted. When you are looking at something like HPV, the primary injury is not a brain injury, it is what happens after you go down.

MS. HOIBERG: I understand that, Charlene. I have certain questions that I have to ask.

Dr. Douglas: I just want to keep it all in context. They just faint, get up, and go home.

Dr. HERR: Rosemary, this is Tom Herr. I have two questions. On the tetanus, on the vaccines' alleged injury, is that tetanus toxoid?

DR. JOHANN-LIANG: You know, this is tetanus-containing vaccines.

Dr. HERR: Okay. So it is tetanus in any vaccine. Okay. Do we also have a breakdown of the influenza whether it is TIV or LAIV?

DR. JOHANN-LIANG: I don't have that for you right now, but that is something, if you are interested, I can certainly do that for the next update.

DR. HERR: That would be great.

DR. JOHANN-LIANG: I can tell you just by looking at these things day in and day out that the LAIV, the live vaccine, is a very, very small minority of our overall claims. The vast majority is the injectable. Is that helpful?

DR. HERR: Yes.

MS. PRON: This is Ann Pron. I have another question, although it is not on the table. The CDAP is another new vaccine, I think administered to folks over the age of ten. It is hitting a lot of adults, who are getting that, who have not had pertussis in years. I am wondering will that -- do you expect that might be on the table the next time?

DR. JOHANN-LIANG: Anything that is tetanus-containing is covered. That is a good question. We actually do have some claims coming in now with TDAP. That

is what you are asking about, right?

MS. PRON: Yes.

DR. JOHANN-LIANG: We do have some claims coming in with that being alleged, in particular. For the next time, I can also break it down, if you like. Yes?

MS. PRON: I think that would be interesting to see because it is another new vaccine and it is a new age group, although it is a smaller dosing than is given to the infants.

DR. JOHANN-LIANG: It is very interesting. There is an interesting story behind that, too, because there is the issue of the herd immunity and how the recommendations to vaccinate older folks to protect the little babies, et cetera. I got you. We could do that. I can definitely -- I did not want to make the whole table broken down so much.

Remember, I always stress that this whole presentation, the clinical presentation, we are very sensitive to patient confidentiality. I want to try to present information as de-identified and as sort of grouped as possible. Certainly, the requests that you have right now, those are very reasonable. That is very helpful to me to know what your interests are. Let me know and I can certainly modify presentations to include your requests,

okay?

MS. PRON: Yes.

MR. KING: Rosemary, Dave King here. Just to go back to Tom's question on the flu vaccine, the live is a much smaller proportion of the alleged injuries. Is that correlated to that is given out significantly less than the injection?

DR. JOHANN-LIANG: Yes. Okay. I do want to say that I, personally, for the time that I have been with the program, the first case of that -- the polio case -- was the vaccine-associated polio case. This is a case of a lady who died, but she had an underlying immune deficiency.

It appears, based on this incredible typing that they can do in CDC -- they can actually type the enterovirus. Polio is an enterovirus. They type it and actually know, based upon their analysis, how far back that particular strain infected the person. It is like CSI stuff.

It is a sad case. The mother died. But she probably was exposed and was infected with a polio -- a live polio back in the 1990's from her daughter receiving oral polio virus. Ten plus years later, she comes down with sort of a paralytic illness. It is not your usual

clinical presentation, per se, but after many sort of investigations, they were actually able to drill down with an isolate, which they found that it was molecularly traced back to the daughter's oral polio.

That was a very unusual case and something that I, generally, have not seen in the program. I guess these cases were much more frequent many, many years ago in the program, but we certainly do not see them anymore because, as you know, in this country everything is inactivated polio vaccine now. Any questions?

Next slide is just some acronym explanation. I hope I spelled them correctly. I think I spell checked, finally, but it is just for your reference.

Next slide. Again, GBS is our leading diagnosis. This is giving you not what came in alleged because the GBS being alleged was a little more than what is being reported here. This was actually what was reviewed and determined as what diagnostically meets GBS. A whole slew of other neurologic comes next -- Brachial Neuritis, the Complex Regional Pain Syndrome.

I just want to point out that Dr. Shaer is going to discuss this illness with you, but this is a very, very uncommon illness. It is the kind of thing that we actually

had a couple cases that we were aware about and we put it as one of the average events for the IOM to look at. Even at that time they were like what is that. It is that type of rare.

We just want to assure that no matter how rare, how whatever, that is what we are here for. Our medical staff is here to figure out, even if there is something really rare, could that be something that goes back to the actual vaccination.

CRPS, we have a number of seizure disorders -- encephalitis, encephalopathy. There, again, several here or there. They all come under this other neurologic category. Then, aside from Guillain Barre Syndrome, as you guys are so aware by now, which is what we call a monophasic, meaning it comes -- the illness comes and then it goes away for the most part. A peripheral, meaning this is in the nervous system, outside of your brain and spinal cord, in the sense of your symptoms.

GBS is a demyelinating disease, but there are other demyelinating diseases like Transverse Myelitis, Acute Disseminated Encephalomyelitis -- you know, the other things with the acronyms. We had a case here and there, several for this and that that contribute to the group of

demyelinating cases.

Again, we do have a subgroup of cases that we viewed that there is clearly some type of genetic and underlying disorder. We had a case of mitochondrial case again this quarter. We had a couple of cases of the Dravet's Syndrome, which is the severe myoclonic epileptic infancy. We had patients, who have neuropathy, but they also have diabetes and some of them put diabetes as an underlying disorder. There is always a discussion about the interplay of someone who has that.

This MTHFR, this is Methylenetetrahydrofolate Reductase. This is an enzyme in our body that you need to sort of convert your homocysteine into a methionine. Basically, if people have a genetic disorder, then we have a couple of cases of Varicella vaccine and patients alleging stroke. It comes into being. That is another one that we have asked IOM to take a look at -- Varicella and stroke. There are some cases that have been reported in the literature and our medical staff has had journal clubs on this. That is another one that we are keeping an eye on.

Short QT Syndrome -- that is an underlying cardiac disorder. We do have a lot of very interesting,

very sad cases that we review. A significant proportion of our cases actually have patients with different kinds of affective disorders, psychiatric disorders. In particular, someone had talked about HPV to adolescent group.

In adolescents, we do get claims for syncope. That is for sure -- syncope resulting in long-term illness from fall and all that. But a lot of the adolescents who claim injury with vaccination, they have a huge affective underlying disorder, other psychiatric -- you know, conversion disorders. They have depression. That is very interesting as well.

Then there is a whole slew of -- again, here is this newly filed autism. These are cases that are outside of the Autism Omnibus proceedings. I think Vince reported that we had no cases of autism being filed in his reporting period, but we actually did review some because, remember, I told you for our medical staff, we are reviewing stuff as the records come in and it is from January to March. We did have some cases of newly filed autism and then a whole slew of other things.

I just wanted to tell you that for -- Vince also said that in his reporting period I think there were four concessions from HHS. In fact, in my tally, we had seven

concessions right off the bat. Five of those seven were table injuries. One was Brachial Neuritis. Two were MMR, table encephalopathy. One was DTAP encephalopathy. Then we also had an off-table for the SIRVA we are actually -- you know, we talked about SIRVA previously -- and also for our vaccine associative paralytic polio.

You can see, again, the numbers are all -- but I think as long as you understand what we are all doing and that all of the different pieces sort of fit together in this program, it makes things a little bit more digestible. I am going to move on. Next slide.

This is about the IOM study. The way we kind of look at how we are going to go about taking the IOM study and then updating the table, we look at it in the terms of injuries related to vaccine administration. We talked about the SIRVA, shoulder injury related to vaccine administration, that was published in Vaccine last year.

I forgot to include the syncope presentation that was presented by Dr. Ryan, our last ACCV. Syncope also really has to do with the vaccine administration, itself, not necessarily with any sort of antigen going into the body, but just the needling. That would go under there. Dr. Shaer is also going to talk about CRP today. That

really falls under the vaccine administration -- you know, the logic scheme.

Analysis by adverse events and that is the anaphylaxis case series that I presented to you the last time, which has now been published in May. Then, you know, we have a number of other, sort of looking at things in a group format projects ongoing because these are going to be important as we go to update the table and in dovetailing with the IOM report, what is the programs experience. I do think that is a little bit different than what VAERS does or BSC does and all the other types of surveillances going on.

Lastly, we looked at it in terms of analysis by vaccines. In the last ACCV, we sort of did this a little bit, too. Dr. Schobeck(?) presented HPV claims in total, what came in alleging HPV and then Dr. Ryan presented what came in alleging meningococcal vaccines. That is kind of how we, the medical staff, are looking at things.

In regard to H1N1, that was not scope of the charge to the IOM Committee. That charge was prior -- it was 2008, prior to the whole pandemic happening. We are waiting -- our program is waiting for the National Vaccine Advisory Subgroup on H1N1 to publish their findings and

then we will be using that, along with our IOM report about other influenza vaccines, in general, obviously, as we go to update the table.

Okay. I think that is it from my end. Are there any questions before I turn it over to Dr. Shaer, who is going to present the Complex Regional Pain Syndrome? Okay.

Agenda Item: Complex Regional Pain Syndrome, Dr. Catherine Shaer, Medical Officer

DR. SHAER: As Rosemary has said, I am Catherine Shaer, one of the Medical Officers with the Department of Vaccine Injury Compensation. I am going to talk a little bit about Complex Regional Pain Syndrome, which is a quite odd and interesting condition.

On the next slide, you can see that it has been recognized as an entity for about 150 years. It was first described during the American Civil War. I am assuming because of all of those terrible extremity injuries that we have all learned about in history that happened during the Civil War with the mini balls and all of that.

Multiple names have been used over time: Reflex Sympathetic Dystrophy (RSD), Causalgia, which means hot pain, Algodystrophy, Sympathetic Overdrive Syndrome. I think this is partly because it is so unusual and so

difficult to get a handle on this condition that people were looking for ways to describe it and understand it.

It is thought to affect about 1 in 20,000 individuals. I can occur at any age. The mean age at diagnosis is 42, but many people have this condition for years before they are actually diagnosed. It is three times more frequently diagnosed in women than in men. In recent years, the number of cases among adolescents and young adults is increasing for reasons that I have not been able to find in any of the readings that I have done.

Many people believe there is a genetic predisposition to develop this condition, but the mechanism is really not understood. More current thinking is that it involves some sort of an interrelationship between the immune system and the neurologic system, but, again, why this happens or how this happens is not understood.

Chronic Regional Pain Syndrome has received more attention in recent years. Now, we have a current nomenclature and a differentiation of types that began in 1994 with the International Association for the Study of Pain, which met to better define the condition so it could be more consistently diagnosed across the various practitioners.

They replaced the term Reflex Sympathetic Dystrophy, RFD, with Chronic Regional Pain Syndrome I and Causalgia was replaced with Chronic Regional Pain Syndrome type II. The type I is pain that develops after injury to an arm or a leg. We will talk a little bit more about the injury, but it can be very minor. It can be more severe. There are various injuries or antecedent events reported. Trauma is most frequently a fracture, surgery, just inflammation or infection in the superficial part of the body, in the skin, various medical procedures, including injections, IV lines, and also stoke and actually even heart attack.

CRPS II is exactly the same, except the pain can be traced to an identifiable injury to a specific nerve or nerves. With type I, there is an injury, but not an actual injury to a structure large enough to be called an actual nerve. There are obviously nerve fibers involved in CRPS type I. Again, it is exactly the same, but you differentiate the two by being able to tie it to a specific nerve injury in type II.

In 10-20 percent of the cases, no cause is found. The injury that precedes the onset of the symptoms may not be significant or even in retrospect, looking back and

asking the patient did you injure yourself, what happened, what happened in your life before this happened. They cannot even think back and identify an injury that might have -- or other thing that might have precipitated the symptoms.

The next slide is the fruit of the work of the IASP. They came up with four diagnostic criteria for Chronic Regional Pain Syndrome. Number one, there has to be an initiating noxious event or cause for immobilization of the extremity. Sometimes the only injury is prolonged immobilization. The noxious event could be fracture, surgery, heart attack. It can just be a bump. It can be an injection of any type, IVs, whatever.

The second criteria is that there has to be continuing pain that is disproportionate to any known inciting event. Once they have an onset of this symptom, if they have pain in the area that is affected, just brushing up gently against something or coming in contact with very minor changes in temperature in their environment can make the pain worse, very worse, disproportionate to what you would expect from that stimulus.

The third criteria is evidence that some type of edema, which is swelling, or changes in the skin, such as

color or temperature, from blood flow to the skin, which can lead to changes in color or temperature of the skin, or abnormal sweating in the area in the region of the pain. Some of these things can be met, especially the evidence, maybe not so much the edema, but some of the other things by the patient reporting to their doctor that they have experienced them because they come and go.

If one of the main things they have is abnormal sweating, they may never actually have it at the time they see the physician. Patient report is also accepted for that criteria number three.

Then there should be no other conditions present that would otherwise account for the degree of pain or dysfunction. So they cannot have some other diagnosis like Brachial Neuritis or Diabetic Neuropathy or anything else that could explain why they are having the neurologic symptoms that they are having.

MS. HOIBERG: This is Sarah Hoiberg. I just had a real quick question. Maybe you are going to go over it, but what are some -- when you talk about this Chronic Regional Pain Syndrome, could it be just like an underlying pain that feels like it is in your bones and your muscles

all over? Or is it just in a particular -- like specific to an arm or a leg?

DR. SHAER: I was going to get there. It is regional. It is not as specific -- that is why it is different from some of these other things where it follows a nerve -- the part of the body that a specific nerve serves.

A neurologist or a good general doctor can look at an injury that someone has and see if it seems to be the ulna nerve in the arm or the radial nerve in the arm. Those are the two main nerves that serve your arm and your hand. They are very discreet in terms of where they lead to sensation and so forth. With Chronic Regional Pain Syndrome, it is more diffuse. It is not confined to the exact path that a nerve follows. It is regional. It is an arm or a leg or a part of an arm or part of a leg.

MS. HOIBERG: So it would not be like the whole body?

DR. SHAER: No, no, no, no. It is regional. We will get to that a little bit more. Also, it can move around. The pain is not always in the same place. Once you get it, it can change from day to day, week to week. It can move around. Where the area of maximum pain is is

not always the same. But it is regional, not total body. It is not a muscle ache. It is not a bone ache. It is a tremendous pain in the extremity and burning like in the skin and that sort of thing.

MS. HOIBERG: Oh, okay.

DR. HERR: Catherine, this is Tom Herr. Does it have to be an extremity?

DR. SHAER: Yes. As far as I can tell, it has never been in the trunk.

DR. HERR: So there has never been like a facial neuritis or something like that?

DR. SHAER: I didn't find that. I always found extremity. More common, some people say, in the legs than the arms, but reading across studies I am not sure that is even true, but in extremity is all I could find.

DR. HERR: Okay.

MR. KING: Question, Dave King here. That is also true then -- you had mentioned heart attack.

DR. SHAER: Yes, actually. In the heart attack ones, it is in the arm and it is in a specific distribution in the arm for some reason.

MR. KING: Great. Thank you.

DR. SHAER: I do not know if it follows what you feel when you may be getting a heart attack or experiencing, but it can follow just an MI, yes. As I said, in 10-20 percent of the cases, there is no identifiable precipitating event or interesting event.

The symptoms that you get -- now, I am going to focus this now on type I. Type II is very similar. They have the same four criteria, but it is not as much of a mysterious black box. You can find and identifiable injury to a nerve. Type I is a lot more mysterious as it is. It is not measurable. It doesn't make a lot of sense medically as to without a nerve injury how this whole thing would happen.

You have extreme sensitivity to stimuli out of proportion to whatever the stimulus is. You get this burning or electrical tingling. Shooting pains. You can get some muscle spasms and movement of the extremity can be very painful.

There are early and late signs. The early signs that can begin within minutes to months after the injury, most often within hours or very few days, are extreme sensitivity to stimuli, local swelling -- that is the edema we were talking about -- a change in skin temperature

and/or color of the skin like it might get blue or mottled looking, joint tenderness and stiffness, and abnormally increased sweating. Again, they can be intermittent and the area of maximum pain can change from day to day.

The later signs take weeks to months to occur because these are things that affect really the underlying structure of the effective extremity. It may become smaller like apathy. As you can imagine, that can take time. The color can change. It can become darker. Pigment can increase. There can be more hair over that area. The skin can look shinier and tauter, even when it is not swollen, it will look like shiny, swollen kind of skin. The texture can change. It can become more coarse. You can get softening or thinning of the bone due to osteopenia or osteoporosis, which are varying degrees of loss of bone density, and change, actually, in the nails of that extremity.

The diagnosis is really clinical. There are no specific laboratory or imaging studies that will do diagnosis or even help to make a diagnosis of Chronic Regional Pain Syndrome. Blood count, tests for markers of inflammation -- in Type I, nerve conduction studies are normal. If you do nerve conduction studies in Type II,

they would be abnormal, but you can usually tell in physical exams if a specific nerve area is involved.

Since these people have severe pain anyway -- to do nerve conduction studies you stick needles where the nerves are, it would be extremely painful to do that. It is not fun. They usually just rely on clinical findings. So if they meet these four criteria that would be the way the diagnosis would be made. In a way, it is a diagnosis of exclusion because the fourth one is no other condition account for the illness of the person who is suffering.

The treatment is not really satisfactory, but this is the best that can be offered at this time, try to give medications that will relax the muscles enough to not exacerbate the pain, physical therapy, because of the painful use, you can get disuse injuries and lack of a range of motion in joints, nerve blocks, which can be successful, especially in Type II, to block the feedback from the nerve -- in some severe cases, they actually try to cut specific nerve tracks to interrupt that feedback loop of pain --, nerve stimulators, which give a constant stimulus to the nerve with the hope that it can kind of drown out or overcome, overwhelm those background signals

that are causing the pain that we don't really understand, and psychological support.

As you can imagine, if you have chronic severe pain that goes on for months or years, it would be surprising if people did not develop psychological problems, including depression, anxiety. In one of the studies we will talk about in a minute, they had 656 patients that they looked at. Not one of them had spontaneous remission of their symptoms over the course of the follow-up, which was up to 46 years that they followed these people.

Here is one of the first epidemiologic references for Chronic Regional Pain Syndrome. I am going to talk about this and then the references we have in relation to vaccine. The Veldman article focuses on the signs and symptoms of Reflex Sympathetic Dystrophy. They call it that, but it was written in 1993, which was before the IASP working group. They used different terms and their inclusion criteria was not the same for diagnosis because they did not have those four criteria to go by.

75 percent of the people had pain within one day of whatever their event was. One percent of the people -- I think it was seven people -- it was more than a year,

which raises some question as to why they even would think it might be related to that stimulus more than a year later. 24 percent they did not report the interval between the injury and the onset of symptoms.

As you can imagine, we are very interested in if that can be worked out what the timeframe would be if we are going to look at the issue of whether vaccines or administration of vaccines could be a precipitating event for this type of injury. They did not report on it for almost a quarter of their patients.

The antecedent event, you can see, 65 percent of them were trauma, most of them were fractures, 19 percent had an operation, 2.7 percent were just various other precipitants, 2 percent were after an inflammatory process, and 1.3 percent, which is about 11 patients, was after injection or intravenous infusion. They did not specify vaccines, but I imagine some of those injections could have been or probably were vaccines. I do not know. In 10 percent there was no antecedent event identified.

This did have more female -- it was 75 percent female. The average age of diagnosis was 42. 12 of the 829 patients were younger than 14. They did not report it by 18 or 21, which we may look at.

Another large epidemiologic study, this one focused on the natural history. They did not have the same data in that paper as the one that talked about signs and symptoms. They were looking at what happened to people over time. They had 656 patients. Again, most of them were female, 80 percent. The average age was about the same, 37.8. The paper did not address the interval at all between antecedent event and onset of symptoms. They were concentrating on the natural history, as I said.

The inciting events were very similar. They had 1.6 percent were medical procedures. They did not specify it. They did not even say injection. I do not know what the medical procedures were because they were not surgery, obviously, because 11.5 percent were surgery.

I realize that these numbers do not add up, but this is the way they reported. All of the inciting events only add up to about 98.9 percent. Under the types of injuries, it only adds up to 48.6 percent, but that is all they reported. Again, we do not know how many of those medical procedures were needlings of any type.

This last reference, here, this is a reference for vaccines as possible antecedent events. This is the sum total of what I could find in looking through the

literature and coming at it from all different ways to try to find everything that was there.

I do not know how to pronounce this, but the Jastaniah article, this came out of British Columbia and they looked at, once they instituted the Hepatitis B vaccine, they had four patients identified, all female, all in sixth grade. I do not understand where this group came from, but they were all very similar. They all received the Hepatitis B vaccine and they all met all four criteria.

During the time that they found these four patients, they gave over a million doses of the Hepatitis B vaccine. They all onset within an hour of injection, two within 15 minutes, one within 30 minutes, and one within an hour. This was so rare that the authors could not attribute causation to vaccine administration.

It was interesting that of the four patients, as a contrast to that large study where none of them got better simultaneously, three of them recovered pretty quickly. The fourth one had four episodes over time, two in relation to two doses of Hepatitis B vaccine and two of them that they never identified an antecedent event. At the time the paper was written, the girl had recovered from that fourth occurrence and it hadn’t returned. I do not

know if they followed her long enough if she would have more recurrences or not.

The second one, the Genc, I guess you would say, that one is one case report after a rubella vaccine. This was written -- came out of Turkey. Then the last one that is in a different color is because it was in French and I did not read it. We have a total of six cases, none of them in the United States. That is the sum total of all that I could find in the literature to date on this condition, specifically related to vaccines.

The next slide shows our experience, here, in the Vaccine Injury Compensation Program. This is the history of the program, from the beginning. There were eight claims filed where they alleged either Complex Regional Pain Syndrome or Reflex Sympathetic Dystrophy. However, there are limits to our ability to tease this out, especially as we go back further. We are now tracking and keeping tabs on all kinds of things in much more specific fashions.

Going back, looking through out database, this was all we could find. There may be cases that came in that were classified as neurologic injuries only or Brachial Plexus injury, which may not have been a Brachial

Plexus injury. Of these eight claims that were filed, the age range was 8-54. There were four children and four adults. They were girls. You can see the vaccines that were listed. Three of them involved Hepatitis B, one of them in combination with tetanus.

In the thing from British Columbia with those four girls who developed it after the Hepatitis B vaccine, they do comment in that paper that they were non-related to any other vaccine during the time period that they followed that, which was a ten year time period. It was very interesting. Less than half of ours were Hepatitis B and all of theirs were Hepatitis B.

In our eight cases, the onset between the vaccination and -- the interval between the vaccination and onset of pain was just five -- it was almost immediate in one case, less than 24 hours in one, one to seven days in five, and two months in one person. Seven out of the eight met the pain criteria. Five out of the eight met the physical findings criteria -- the edema, some evidence of temperature change or sweating change, those sorts of things. And the criteria for no other criteria or diagnoses, five out of the eight met that.

The same three that did not meet the physical findings criteria are the same three that did not meet the other -- not having other conditions. The one that did not meet the pain criteria is also mixed in there as well.

We had several that we felt met all of the criteria, but there were five of them that did and three of them that we do not think would have met the criteria. The other diagnoses that they had were very curious because they did not really seem to meet all the criteria. They did not have the edema. It was not that they just did not complain in the right way or whatever. There were really no objective physical findings.

But they really believed that they had pain. They did not think they were malingering. They didn't think it was theatrics. They called it things like idiopathic chronic pain syndrome. I looked into that. That is not a well defined term. Different people use it differently. They did not really have another good diagnosis. They were just not diagnosed with Chronic Regional Pain Syndrome.

In summary, you can see there is a paucity of literature, in terms of vaccinations being associated with this type of injury. There are only six that I could find.

The VICP claims information is going to be added to the current knowledge and plans to publish our series of eight. We are looking at vaccine administration, itself, or a local injection reaction, not necessarily the needle as it goes in, but possibly as it sets off inflammation. That could be a trigger as the antecedent injury.

As Rosemary said, the Institute of Medicine was asked to look at this when they were given their charge. We will use the information that comes in when we receive their review along with our experience when we consider updates to the table. That concludes my presentation. Any further questions?

MS. PRON: I have a question. This is Ann Pron. The last slide that you showed us with the data for your eight claims, do you have any idea what the denominate is for that?

DR. SHAER: How many claims were filed since the start of the program?

DR. PRON: Yes, I can’t remember. I am sure I was told at some point.

PARTICIPANT: 13,000 or so.

DR. PRON: Not counting the autism.

DR. JOHANN-LIANG: This is really looking for the -- if this is actually something that could be attributed to vaccines that is why we are here. We are trying to find the very rare cases where there actually is vaccine injury happening.

As you can see from Catherine's presentation, we were very surprised when going to the literature and looking for this information of vaccination or any kind of needling as an antecedent, how little there is out there. I do think that we do have important information to add from our experience here. We will see. This is very, very early. We are sharing information with you as we are trying to understand the scope of what is going on.

It will be interesting to see how the IOM pulls together all of the literature on this. Not just the way of the vaccine, per se, but the whole epidemiology of what this illness is about to put that into perspective.

MR. KING: Hi, this is Dave King. You know I have questions. One of the slides we talked about that it is estimated to affect one in 20,000 people. In a population of 300 million that would be 15,000 people. What I am trying to understand -- or I am beginning to try to narrow this down. If we were to look at one of your

slides where it talks about 1.3 percent after injection or intravenous infusion, that number comes out to just under 200.

DR. SHAER: Okay. This is over many, many years.

MR. KING: Understood. I am thinking, though that many people probably do not even think in terms of Complex Regional Pain Syndrome as something that might be -- hello?

DR. SHAER: Yes?

MR. KING: I heard a beep bonk out there. Let me back up for a second. What I am saying is that I am thinking that many people do not know or would think of Complex Regional Pain Syndrome as being possibly an injury that could occur from a vaccine. Is that possible?

DR. SHAER: Yes, and it is equally likely that they were not diagnosed with Complex Regional Pain Syndrome. Physicians are not thinking about it. The average time from onset of the pain to someone actually getting a diagnosis is anywhere in some of these from a year to 20 years.

MR. KING: Even though the symptoms might manifest themselves within minutes or an hour.

DR. SHAER: Or days. For someone to give that label to that person's complaint --

MR. KING: Without doing a – right, studying it and using the exclusion, saying, well, let's rule everything out, and then they finally set on that. That makes sense to me.

I am going to go to yesterday when we were talking about -- we had talked about the vaccine statements that we were reviewing. One of the questions I raised was should we something that relates to this on those statements. We were told that was something that the ACIP would have to look at. I do not know who is responsible for creating that type of question and bringing it to their attention if it is not already something that is under their review.

DR. SHAER: I would just add and maybe, actually, Geoff and Rosemary should be responding, but this is all very preliminary. We are really just beginning to look at this. We do not know what the IOM is going to say.

DR. JOHANN-LIANG: Well, the ACIP is the scientific advisory group to the CDC Director, right? Sort of like how you advise the Secretary. They really are looking at scientific information. Usually when scientists

look at scientific information, they really do go to peer-reviewed journal articles. That is why it is really important that we think there is something going on, we pull the information together, we share it with you because you are our Advisory Commission, but really this is at the stage where we have to put it in the context of what we know is already out there. As Catherine said, the IOM report is coming shortly.

Then we also need to contribute to the literature because you are absolutely right, how does one know if there is a problem unless somebody actually says I may have a problem here. But to go from I may have a problem here to, in fact, alerting the public that we do have a problem, there are some steps that have to happen along the way.

Part of the scientific inquiry is really once you have the information, you may think something is going on. To have it written up and let other people, who are sort of experts or people who have seen patients with this or have done research on this issue to take a look at it and comment on it. Then it becomes part of what is known. That is the type of information that bodies like IOM and ACIP and folks like that can take that information now and

then translate it to public information that can be disseminated.

I think your point is very well taken. We just think that this is a very early step in that process. You may be perfectly right. At the end of all of this, we may have information to the public that says with vaccination there may be average events that are actually the administration part -- you know, the administration, itself, could result in certain conditions.

I think ACIP has already come out with statements to that regard, regarding syncopes. But, you know, that also took some time for them to make those kinds of recommendations. You should have people sitting down, lying down -- that type of thing.

If this is something real -- we do not know if this is something real. If this is something real then that hopefully will happen in the future and not too distant future.

MR. KING: I am confused over if it is something real.

DR. JOHANN-LIANG: Related to vaccination.

DR. SHAER: You have to remember that in 10-20 percent they never find an antecedent. Let’s say someone

gave themselves their insulin injections a week before this happened. They say to the doctor I have this terrible pain and they start looking at what happened and what happened in that person's life. You cannot really say the insulin injection one week before was the inciting event, even though we think -- they report in the papers that needles can do this.

It is really a leap of logic to really attribute it to something that is distant in time. The one where they get the shot and within minutes -- that is one thing, but a lot of these have a lot more time in between. The four girls from British Columbia it was very soon. It was within an hour and in every case it was in the extremity where they got the injection. That is four cases out of all of those millions of doses. It is very hard to not keep an if in it at least right now.

MR. KING: I would agree with you on that. I am not looking to say that there is any causal relationship at all. All I am saying is that in your summary you state that the vaccine administration, itself, or the local injection reaction may serve as the antecedent injury that leads to the Chronic Regional Pain Syndrome.

All I am suggesting is since we think that it may -- we are not saying that it does, but that it may, we also state on our vaccine statements that there is really no real risk for harm when you are given a vaccine because it is so extremely small -- this would certainly qualify as something that is extremely small --, but, nevertheless, it might be something that we should be informing people about.

If it is premature to do that because we do not have the science all behind it, but what I am saying is we are beginning to see that there may be something here. Are we remised if we do not at least let people know we are not saying that there is, we are just saying that there may be, something you ought to be looking for.

DR. EVANS: Dave, this is Geoff. The remised part I think I can hopefully reassure you on. The fact that we have this presentation, the fact that one of our ex officios is Jane Gidudu, who works at the Immunization Safety Office at CDC, which is primarily responsible for writing input to ACIP, who are meeting in a couple weeks from now, that looks at safety issues with various vaccines. That type of information is incorporated into the usage recommendations as they continually get updated.

This is information that, at this stage, is preliminary, but it certainly now gets raised as a topic of interest. Just like the shoulder injury after vaccination with a paper that has raised some interest and it remains to be seen what happens. You know, it could be with the shoulder injury paper that would be something that would fall under the general use recommendations workgroup and the general use recommendations statement that is updated every couple of years.

These types of things -- the awareness of possible adverse events associated with vaccination are continuously being raised. They are in the may cause category. It remains to be seen how much additional information comes forward, the numbers, the putting it into context, keeping in mind that when it comes to vaccine information statements, there is this natural limitation of a one page, two-sided document, which has to carefully consider what is put in and what is not put in. There is a whole bunch of may cause or may be associated so you have to keep that in mind when you are trying to make this document as useful as possible.

DR. GIDUDU: Thanks, Geoff. This is Jane Gidudu. I have been listening in. My question was whether you

would be able to provide some of this information to the General Recommendations Working Group?

This is basically a very tricky subject. I have spent a lot of years reviewing block reaction. I am just made a group that is defining local immunization pain. It is definitely very subjective and a really tricky topic.

I think of the literature and as we get to understand more, we may be able to build an understanding around some of these concepts. Things that happen way after the initial insult will take a lot of time to be teased out, but definitely, like many things, there is a first time, things may be built around that.

Within CDC, at least within our group -- the group that I just told you, we are going to be publishing around the definition of pain, but this is with the international group -- we might put that in the literature. In terms of reviewing cases in VAERS, that could be something that could be considered if, indeed, this is an issue.

At this point, VAERS has not looked at this issue yet, but who know what may be down the road? So all of this effort may come to fruition many years down the road

thanks to initial efforts by others in the vaccine injury program. Those are my few comments.

DR. JOHANN-LIANG: Thank you Jane. That makes a lot of sense. Again, Jane, to go to the point of -- it is like looking at cases and reporting the experience. This is not looking at an epidemiological study or doing any kind of randomized clinical study. We really do have to put those in perspective. It has to be in conjunction with other information that we arrive at anything that goes beyond just hypothesis generating to something that may be causal.

There is a timeline that it has to sort of go through. We really need to get information of cases into the literature. That is the way people share information of what kind of issues people have experienced that we have information about. It also gives people who are putting it into literature -- the people who are reviewing it may say this is really nothing at all. We need that feedback, just like what we did with SIRVA. It is hard to talk about it too much until we have some sort of peer-reviewed assessment.

DR. GIDUDU: Absolutely. This is Jane again. Here, I think it may be at least attributed to the

technique. If it is due to administration technical issues that is very easily preventable. If it is an antigen in the vaccine that is another story, but there are things that can with very, very simple recommendations be prevented like syncope. If, indeed, some of this comes out, it is very easy to provide preventative guidelines. That might be something that is very useful.

MS. PRON: This is Ann Pron. I guess I find that is a conflict because the Vaccine Injury Compensation Program, it seemed like it was concerned about the vaccine, not the method of administration. Maybe down the line, also, needing to look at the type of needles that are used and whatnot, so many other factors that could, as well as the administration technique -- or maybe considering that all as part of the administration, itself, and not the vaccine. It really raises a lot of different issues.

MR. KING: Ann, are you saying that it is more than just the vaccine, it is about the administration as well?

MS. PRON: Yes, that is what Dr. Gidudu just mentioned, also. There are other factors involved. Seeing people give and giving myself injections, there are a lot of factors besides the actual antigen involved.

MR. KING: Agreed. I am confused are you thinking that we don't -- I just want to make sure, we can still be concerned, though, with the administration.

MS. PRON: Yes. I think we do need to be, but I think it just seems something that you would not routinely even think about necessarily because it seems like the antigen, itself, that we are worried about most of the time.

MS. HOIBERG: We had a presentation a couple meetings ago on the Frozen Shoulder Syndrome. I can't remember if that was you guys' first meeting.

DR. PRON: No. I don't think we were at that one. I read the article, though.

MS. HOIBERG: Okay, you were not at that one. They are being compensated for the injury because -- correct me if I am wrong -- I do believe a lot of those cases were compensated through the program because it was a vaccine injury. It was not necessarily the vaccine, itself, but it was the administration and the fact that the vaccine went into a wrong area of the body and caused the Brachial Neuritis -- is that right? And the frozen shoulder and the paralysis in the arm, is that right?

DR. HERR: That would be my thought, but you ought to ask Rosemary.

DR. JOHANN-LIANG: You guys are talking about SIRVA case we used, right?

DR. HERR: Right.

DR. JOHANN-LIANG: Shoulder injury related to vaccine administration. That really has to do with the injection going into the shoulder bursa. That is around the shoulder capsule instead of going into the muscle. That is not Brachial Neuritis, but that is what is what that series was about.

As I was talking about before in my update, this falls under the Vaccine Administration Injury. It is injury, nevertheless. We are compensating cases that we think have been -- that we have actually looked at the cases and think that it is from the vaccination administration.

Syncope, actually, falls under that --

MS. HOIBERG: Right, it is not the actual vaccine.

DR. JOHANN-LIANG: Yes. A lot of it is HPV because it is the population. Young women and young girls faint. But you can get syncope with all of the other types

of vaccinations and also from if you go to get blood drawn. Some people just faint from having blood drawn, too. It is the actual needling, itself, and not the antigen.

MR. KING: Okay, is it safe to say that there is continuing research in this area and that it is still being conducted?

DR. JOHANN-LIANG: Yes.

MR. KING: And you guys will continue to report back to us, I am sure, as new information becomes available.

DR. JOHANN-LIANG: Yes.

DR. SHAER: Thank you.

DR. DREW: Are there any more questions? If not, Dr. Rosemary and Dr. Shaer, thank you very much for your really interesting, informative presentation.

Agenda Item: Public Comment

MS. DREW: We now move onto the public comment portion of our meeting. Operator? Is the operator there? Is anyone there?

OPERATOR: I am here, madam, thank you. If you would like to make a comment please press star one and your name will cue up. I will be able to announce you in the conference at your turn. If you decide to withdraw from

the cue and no longer wish to make your comment, please press star two. Once again, press star one if you would like to make a comment.

Your first speaker is Jim Moody, National Autism Association.

MR. MOODY: Thank you and thank you members of the Commission. Thank you, especially, to Ms. Hoiberg and Dr. Tiang for your comments about the study. I would urge everyone to read it. There is another epidemiology study out this week by Dr. Delawn(?). She shows this connection between vaccine uptake and today's autism rates. That is another study on the horizon.

I just want to give a couple very, very quick comments in response to what was said before. Again, I urge ACCV to put this question of a scientific stay or a moratorium on the agenda for full review pending these are very, very important questions that need full attention.

The authority I am asking the ACCV to use is the first listed duty, which is to advise the Secretary on implementation of the program, in addition to the authority that Dr. Tiang mentioned on advising the Secretary on conducting research. I do not mean to suggest that this Commission should be telling judges what to do, but

certainly the Secretary, as the client agency, here, and the lawyers at the Department of Justice, this Commission certainly has the authority to advise the Secretary to seek a moratorium or scientific stay until the science moves along.

Regarding the question about the evidence of autism, I had no involvement in the study at all, but just looking at it quickly, they describe five categories of evidence, ranging from comments by the Special Masters to medical records to social communication questionnaires. I think that is one of the unanswered questions and one of the areas the program could be improved a great deal is much more transparency of these diagnoses and their connection to injury.

I think these 83 cases described in the paper all have either a specific autism diagnosis on the spectrum or features of autism or autism-like features -- things like that. The first autism case out of the court that I could find is the Sorenson case in 1990 where Special Master French described I think features of autism, but it describes the description of the child’s condition very much mirrors what a lot of parents are reporting today.

Part of the confusion arises from the fact that autism is a behavioral diagnosis. We sometimes use the shorthand vaccines can cause autism. More accurately, it might be better to say vaccines cause a brain injury or an immune injury leading to a diagnosis of autism or features of autism. That is a problem with the statute. The statute talks about injuries or manifestations of injuries, some of the Omnibus cases like Hepatitis B describe a vaccine. Some of the Omnibus cases, in this case the OAP, describes -- it would be fair to say a diagnosis or a symptom.

I think that controversy would be helped a great deal if the government would simply say, yes, vaccines can cause injury leading to autism in some cases. We are working hard to figure out which cases those are. The epidemiology I mentioned, VACS MVACS(?) study is finally on the horizon. That is the only way I know of, at least at a population level, to resolve the question of how much autism is being caused by vaccine. That is one of the studies that we think will lead to a resolution of this issue.

Obviously, there are two questions. One is the population level, but the ultimate question is did vaccines

cause a particular injury in an individual child's case. That is why we need this scientific stay to be able to sort out the particular injuries, as well as gaining knowledge on the population level.

There are 16 or so studies that say they have not found a link. There are three or four or five studies that say they have found a link. This controversy will rage on until we get further and more science. That is why we need this scientific stay.

The only epidemiology of unvaccinated children so far that I am aware of in the US case kids is the first couple of phases of the Verstraeten study that found a relative risk for autism ranging between seven and eleven, but these unvaccinated children were subsequently deleted prior to final publication.

Those kinds of things -- obviously there was a debate as to whether it was methodologically sound or not, but those kinds of things contribute to the unresolved controversy and the unresolved question.

The last comment is for clarification on the mercury removal. The US data, the last publication from CDC was from birth cohort 1998. That is where the one in 110 prevalence rate for autism comes from. Mercury was not

removed until the beginning of 2000 and it was still in most vaccines until 2002.

It is premature, at this point, to comment, really, on the natural experiment, which the Commissioner and I -- I apologize, I do not remember your name -- correctly noted is a good natural experiment to see what happens when most of the mercury was removed. The data for children born in 2000, which is still a heavy mercury year, will not be released until this year so it will still be some time before we can sort that all out.

One of the problems is there is a long, long delay in the counting because some kids are not diagnosed until five, six, seven, eight years old. It takes some time to assemble the data. That is a good natural experiment.

It is a good reason why the data should be made open to the public to do these kinds of studies. It is still premature to make that conclusion. Also, mercury still is in flu vaccines, mostly vaccines given to six month olds and pregnant women so it is not correct to say it is completely eliminated, but it would certainly help to resolve the mercury part of the controversy to see what happens in the data in the next few years as we start to

see birth cohorts where there was less mercury given to the children.

In short, I think the Commission's work is not done until the Commission can satisfyingly say that every child who has suffered a vaccine injury has been given appropriate compensation. Toward that end, at least for these autism cases and probably in other cases that are going to up, we need to hold them in the program until the science reaches a point of relative certainty. Thank you very much.

MS. DREW: Thank you, Mr. Moody. Do we have any more comments?

OPERATOR: One moment. We have had no one else cue up.

MS. DREW: Okay, thank you, operator. That being the case, do I hear a motion for adjournment or should I just remind everybody first that we have a workgroup meeting following this? It is a different call in number. I would suggest we take a brief break before that meeting. Call in at 11:15 AM. Does that work for everybody? If it doesn't, say so. Then the workgroup will be at 11:15 AM. I look for an adjournment motion.

DR. HERR: This is Tom Herr. I move we adjourn.

MS. PRON: This is Ann Pron. I will second it.

MS. DREW: Thank you. Any objection to the motion? Motion is passed then. We will adjourn until our September meeting. Thank you everyone.

(Whereupon, the meeting adjourned at 11:00 AM.)