DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

March 5, 2010

Parklawn Building
5600 Fishers Lane
Rockville, Maryland

Proceedings by:

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

Table of Contents

P R O C E E D I N G S

Agenda Item: Welcome and Unfinished Business from Day 1

MS. CASTRO-LEWIS: Good morning. Tawny, are you there?

MS. BUCK: Yes, I am.

MS. CASTRO-LEWIS: Good morning.

MS. BUCK: Good morning.

MS. CASTRO-LEWIS: It must be so early for you. We appreciate that get up so early to be with us.

MS. BUCK: Thanks.

MS. CASTRO-LEWIS: I actually don't have any unfinished business from yesterday, just to announce one more time that the public comment will be as soon as we finish our discussions, regardless of the time that we finish the meeting. Other than that, if anybody has anything to add proceedings from yesterday or any other new comments, et cetera?

(No response)

MS. CASTRO-LEWIS: Nothing. Okay. Then we are going start with Dr. Salmon, who is going to give us an update from the National Vaccine Program Office on H1N1.

Agenda Item: Update from the National Vaccine Program Office/H1N1 Safety Working Group Update

DR. SALMON: Thank you very much. The approach that I am going to take to this is to kind of go through the NVAC agenda. This was our meeting last month. Then certain aspects I will highlight more than others, which those that I think might be of greater interest to you. But if you have other questions or you would like more information I am happy to get it for you.

So the first topic that was focused on was the National Vaccine Plan. I understand that you had a brief review with Ray yesterday, so I think you are pretty good up to speed on what is going on with the National Vaccine Plan. There was also a report of the NVAC Vaccine Safety Risk Assessment Working Group which focused on H1N1 vaccines. I am trying to recall whether I discussed this with the Commission before. Are you folks familiar with what this working group does? No.

So this was a working group that was established specific to the H1N1 Vaccine Program. It is the H1N1 Vaccine Safety Risk Assessment Working Group. Their charge is to look at all of the safety data on H1N1 vaccine as it accumulates, and to provide a rapid, independent review of those data and to help us in the overall safety assessment.

So they are focused on safety of the H1N1 vaccine. They are not considering the benefits of vaccination or the burden disease – so they are not giving us any recommendations on how to use the vaccine. They are focused on based on everything we know, what is the safety profile of the H1N1 vaccine.

So they get their information from – let me tell you who is on the group; it includes the representatives from the five federally FACA commission advisory committees that work on H1N1 vaccines. So that is NVAC, ACIP, VRBPAC, and the Department of Defense Health Board. Then there are some additional members that provide expertise specific to H1N1 safety monitoring.

So they are getting all the data that is coming in through the federal vaccine safety system for H1N1. That includes a lot of what we normally do, and then a lot of enhancements that were made for H1N1 safety monitoring. There is a report on flu.gov which describes what this all looks like. I am not going to get into a lot of detail with that, but it includes things like VAERS and VSD, which are things that are used routinely in vaccine safety. It includes accelerated development for enhancements to other systems that have been used or pilot tested in vaccine safety. That would include things like the CMS Medicare

Database R10, which is a Johns Hopkins system of actively following people who the vaccine, through text mails and that sort of thing. The Department of Defense and the VA have work they have done in vaccines safety. Those were all accelerated and enhanced for H1N1.

Then there were several systems that were put together specifically for H1N1. For example, the PRISM system links health plan data from the five large health plans with immunization registries in eight states and New York City. This is something that built on earlier work but was really set up specifically for H1N1 safety monitoring. Indian Health Services also is providing data for H1N1 safety monitoring. Then there is a project that CDC put together, which is Active Surveillance for GBS in eight-nine different states. So there is a lot of components to this and it is kind of a lot of information coming in from different sources. Each have their own strengths and their limitations, and collectively this is a very robust monitoring system than we have ever had in the past for this sort of mass vaccination campaign.

All of these data are coming to this group, the Vaccine Safety Risk Assessment Working Group. They meet every two weeks, and every other meeting they draft a report that then gets delivered to the pond(?) by the NVAC,

then once they approve it – if they approve it – it then goes to the Assistant Secretary for Health. Then once he signs off on it within a couple of days, basically once he is back in his office and he receives it, it then gets posted online. In fact, the third report just got posted today.

The idea of this is that it provides an independent group ongoing review of the data so that we can get feedback on the Safety Monitoring Program. So far, there are several steps in this, the first thing they are looking for is any signals. Any indications that maybe there is something going on that deserves further investigation. If there were any signals like this, it would then be investigated through the systems, depending on what the issue was, and what system part could really address it most effectively, could tell you what part of the system. Then they could provide us feedback on whether their associations or causations.

In this case, they have looked at all the data now, issued three reports, and there has not been any indication of any signals at all. So what their reports have basically said is we have looked at all these data, we feel there is enough information to determine if there were a signal and so far no signals have been detected.

So the group continues to meet. A lot of the data is already in basically, if you look at vaccine distribution there is not nearly as much vaccine being used as there was in the months past. So many of these systems like VAERS and VSD will continue to get a little more information but probably not that much more.

But there is still refinement, for example, serious reports to VAERS go through an adjudication process where they try and get more information and apply standardized case definition, and kind of investigate what is going on. Some of that adjudication takes time. For example, if there is a death, they will get autopsy reports – that takes time. There are other systems like PRISM that are still really coming online and they getting larger even though there is not a lot more vaccine being distributed but because they are capturing more of that vaccine that was already delivered.

There are also some systems like VAMPS(?) that are looking at pregnancy outcomes. Some of those may take years to really get answers because if you are talking about the outcome of a child that the mother got pregnant when she pregnant, obviously that child has to be born and has to get old enough for certain outcomes to either develop or not develop.

That is a brief review of what this group has been doing. If you are interested in looking at their reports they are online. As I mentioned, the third report was posted today.

Before I go on, maybe I will just stop because I know I just covered a lot of information pretty briefly. Does anybody have any questions?

MS. HOIBERG: This is Sarah Hoiberg. Where would you find that report? Is it on NVAC's website?

DR. SALMON: It is. It is on NVPO/NVAC website. I would be happy to share that with you.

MR. SCONYERS: This is Jeff. There has been a lot of surveillance set up for H1N1 and I don't understand why. To what extent do you see this as becoming more standard surveillance for potential injuries or do you think this is just ad hoc response to this event?

DR. SALMON: That is kind of the million dollar question. In more of my report it is going to transition but before I take that opportunity I would like to make sure that there are not any other questions.

We are asking those questions and we have a working group of the NVAC that is asking those questions. Some of it we need to get more data to inform that question. So for example, for PRISM, which is a new

system, we are looking at how many doses were captured through registries versus health plans. And then looking at other childhood vaccines, how many would be captured in registries versus health plans and how complete those immunization records are. That information is really important to help to make that decision, right, because we have to assess its performance. We recognize that it was set up under a short notice. There are a total of 26 million people in the health plan data. Of them 14 million are potentially captured in immunization registries.

So putting this together in a matter of months, as you can imagine, was an enormous task. In fact, the data from PRISM really just started to come in in January. It is challenging to put something together so quickly. Had there been a huge vaccine safety issue in November, PRISM would not have been helpful at all because there would not be any data. But the question you are asking is could it be helpful for routine surveillance? I think that some of the information we get on how well a captured vaccine exposures and how well it would form for routine vaccinations, would really help inform that.

As I will talk about in a minute, we have a working group at NVAC that is looking at the safety system

more broadly and should provide us some guidance on that question.

MR. SCONYERS: If I understand the systems, even a little bit, the delay in setting up was due to the complexity. Had they been in place would there have been closer to real time surveillance? Is it just an artifact of the complexity of establishing the systems that means that we are just now getting data from them?

DR. SALMON: That is a great question. I would agree with your point except that I would not call it a delay in setting it up. It was remarkable how quickly this was put together.

MR. SCONYERS: I did not mean to imply anything by that other than it takes time.

DR. SALMON: It takes time – it does. I think that yes, the short answer to your question is yes. Had there been these connections between registries and health plans had been up and running and functioning previously, the capacity of the system is really quite quick. Like the VSD, it relies on claims data. In this case their claims go into the health plans and there are some delays in some claims – it depends a lot on what outcome you are interested in and then how that outcome is actually diagnosed and going to the health plan. It is very rapid.

In fact, the name PRISM has rapid in it, however there are some delays nonetheless.

If it were set up in advance then certainly it would have had the potential to have data - . Unfortunately there were no major issues in October and November. In the end it will probably be quite informative in terms of how we understand the safety of the vaccine in the long run because it is capturing a lot of doses. In fact, it is capturing more doses than any of our other systems except for CMS at this point.

DR. FISHER: This is Meg Fisher. I think one of the things that this points out is how the potential value of immunization registries – and we have been talking about them in children for years and years, but I think that especially as we move to more recommended adult vaccines, we really need to think about registries for adults as part of the safety monitoring system. Now with the recommendation that every adult in the country be immunized against influenza, it would be really nice to have some kind of – as pharmacists do it, as they are given at airports or wherever else, it is going to be very difficult to have that information without something like a registry.

DR. SALMON: I think it really shows the potential for registries to make an enormous contribution

to vaccine safety monitoring. Historically, some registries might include passive reporting like VAERS to a limited extent, but in this case they are providing the exposure data for other systems that have great outcome data. So the potential there is enormous.

It is especially true for, as you suggest, vaccines that are delivered outside of the medical home, which would not otherwise perhaps end up in a child's medical record or in a BSD data base. Whether or not it has accomplished that task, I think we will know more when we look at how well PRISM functioned. Ultimately it is dependent on the registry. States were under tremendous pressure to vaccinate a lot of people with limited resources and well the data got into the registry and how quickly it got in, I think is still an unanswered question.

So I agree with your point very much that the potential contribution especially for adults and alternative vaccination sites is enormous.

Without any other questions, perhaps I will move on. Maybe I can go back to your question. It did offer me transition about the long term implications of this. I mentioned to this group before that we have a Vaccine Safety Working Group, which Tawny is the co-chair of, and they first looked at the CDC ISO research agenda and now

they have moved onto their task. They issued a report on their first task.

Their second task is to look at the Vaccine Safety System and to write white paper on what the optimal safety system would look like to prevent adverse events, to detect them in a timely manner when they do exist, and quickly identify the safety profile of the vaccine and to maintain and improve public confidence in vaccine safety. So it is a high level look at the safety system, and asking the question how can it be really enhanced or improved? How can we take advantage of new technology and new science to really have as robust a system as we can?

This is their charge. They had their first meeting in July of 2009. They brought in a really broad range of people that came in as panels and kind of shared their thinking on this. This was really very much informational gathering. There were a series of questions the panelists were asked to respond to – how could this system be improved? What do you think are our deficiencies? We heard from people from other safety arenas like drug safety and transportation safety. It was a very interesting meeting.

They then kind of broke into subgroups. So there are five subgroups; three are content focused and two are

processed focused. The content subgroups are structuring governance, biological mechanisms, and then at the end surveillance. So these are really kind of the three content areas.

Then there are two process subgroups; one is focused on stakeholder engagement and the other on implementation. I think most of those are pretty self-evident what they entail. The implementation group is really trying to think through early on how do you make sure that the end result isn't just a bunch of white papers or a white paper, but actually something that actually results in positive change.

This came from a recent Rand review of NVAC, that really emphasized the importance of thinking early on about how your recommendations can turn into actions and not simply recommendations. So they are thinking about how to really get the ball moving early on, understandably not knowing what the final report is going to be but how do you set the stage for that report to be well received and impact practice and policy.

There is also a process that they are going through to engage stakeholders. This is challenging because there are so many stakeholders to vaccine safety. If you think about the groups and the individuals, it is a

very large number. They both want to make sure that everyone gets a chance to share their views, but also have more than just a one-day meeting of testimony. Because if you had all the stakeholders in a room and you had a day, we would get 30 seconds. That is probably not the most informative way of getting input.

So they are following an approach that they took on their first task which is they are having a small writing group meeting in Salt Lake City next month. That is going to be a range of stakeholders that focus on several issues, which I will talk about, and help prepare documents that go to a larger stakeholder meeting. That larger meeting will be June 1st, the day before the NVAC in D.C. At that second meeting it is open to anyone and everyone, but hopefully they will have some things to respond to so that the input that they are providing is more focused.

If you look at the Salt Lake City meeting and the content, what the working group has done is they have developed several documents and several approaches that they want feedback from stakeholders on. They have developed a document that is looking at potential gaps to the current system. They are looking at what are the functions of the Vaccine Safety System. So functions would

be things like accountability and coordination, surveillance, research, licensing. What is a vaccine safety system – accountability, I did not mean to say – coordination and oversight, surveillance, research, licensing. The different things that one would want a safety system to do.

So what are the functions? They are looking at what they call “key attributes” or functions of big governance. Things like being efficient, being effective, being transparent, being evidenced based. Then they are looking at different options to accomplish these and the different approaches one might take to enhance our ability to meet these functions in ways that further good governance.

I know that that sounds a little bit complicated but this is what is being refined at this meeting. It will first be discussed among the smaller stakeholder group and then it will be discussed at a larger stakeholder meeting. Ultimately the group wants to have - the NVAC wants to have their report completed in September. It is a big task. It will give them about a year and a few months to do this.

The timing is really quite good because as you heard from Ray yesterday, the National Vaccine Plan, one of those goals is safety. In September, October, November, we

will be finishing the implementation plan for that safety goal as well as the rest of the National Vaccine Plan. So by us receiving this report from the NVAC in September, it allows us the opportunity to really consider it as we write our implementation plan for the National Vaccine Plan.

MS. CASTRO-LEWIS: I was just thinking, what are the mechanisms of methodology to coordinate that all of the old entities including the government offices, private operations, or whoever is interested in vaccine safety – they all coordinate their activities. How are they going to do this?

DR. SALMON: This is really the responsibility of NVPO. Our job is to coordinate HHS federal activities – that would be the different agencies within HHS, with other federal safety assets or other federal efforts such as VA and DOD. Then with non-federal partners that would include all the groups that you have just mentioned and a lot more. So that is really what the task of NVPO is. We are focused on doing this coordination both for prevention of disease through vaccines, as well as prevention of adverse events from vaccines.

So that is the responsibility that we have and we are advised by the NVAC in how we do that. If you look at the NVAC, its membership by charter, includes that broad

range of stakeholders who are really a part of the vaccine system. Many of whom are also part of the Vaccine Safety System.

Before I go on are there any other questions?

MR. SCONYERS: I want to go back and ask about the international aspects of H1N1 group. We had a little bit of a discussion about that yesterday, but what has been the interaction around surveillance systems based in the U.S. with other surveillance systems to – especially around vaccine safety –

DR. SALMON: That is a great question. There are weekly morning meetings – well in the U.S. they are pretty early, but in other places they are probably late in the day, that are really sponsored by WHO, and FDA has been the lead in those discussions. That is an opportunity for these sorts of data sharing to occur, if in fact there were a signal or a problem in one place, it would allow hopefully, other places to know before we saw it on CNN or through other media that really had a quick response so we know what is going on.

The effort is also included – I have talked a lot about different data systems and projects, but an international study to look at H1N1 and Guillain-Barre syndrome. This is doing a study that would be done in many

countries both developed and middle income countries, and trying to take advantage of the increased power one would have from doing such a large study internationally. That is something that is being led by WHO and FDA has made a huge contribution to that study.

DR. FISHER: Just a comment. Jane mentioned yesterday the Brighton collaboration. The Brighton collaboration is an international group of about – oh, I think it is up to about 10,000 scientists throughout the world now, whose task is to develop definitions of adverse events following vaccination so that you can actually do things like this. You can compare what happens in parts of the world because you are using the same definition.

It turns out that that is not an easy task to get people to agree on – even simple things like fever after immunizations, but when you get to Guillain-Barre there was a lot of discussion on developing and getting that definition out in time for this kind of surveillance.

I think the Centers for Disease Control has been part of the Brighton collaboration, and I happen to be part of it as well, it is really a very interesting way to try to get the kinds of things – it was one of the reasons I was interested in asking Jane about that yesterday. I think it will be very interesting to see what kinds of

safety information we get from other countries using different vaccines, using the different adjuvants, and really make sure that – that is kind of a quick way to ensure that those things are safe.

DR. SALMON: That is an incredibly important point. It is true when doing different studies in different countries, but it is also been tremendously helpful – you know we have all these different surveillance systems and mechanisms of monitoring safety in the U.S., one wants then to be as synchronized as possible.

So for example, GBS is a great example by having its standardized case definition, so when VAERS gets a report, there is a standardized way of looking at that and saying is this really Guillain-Barre syndrome or something else? It has helped synchronize those systems domestically, as well as worked internationally.

I did not mention this and I don’t want to get into too much detail here, I am happy to share a document describing it, but one of the approaches that was taken was a number of pre-specified outcomes were determined – things like GBS, where historically in 1976, Guillain-Barre syndrome was associated with the vaccine. According to the IOM, since then, there really has not been a clear association. The best estimate is that if there is any

relationship it is at a rate of one in a million or less. Which becomes exceedingly difficult in science to quantify a risk that is that rare. So that is an example of a pre-specified outcome where many of these systems like the VSD, like PRISM, like the Department of Defense, is looking at this every week and they are saying, okay, based on the number of vaccine dosages distributed, how many cases of GBS would we expect to see and how many do we actually see.

A lot of this is based on the Brighton collaboration definition, although it has turned into ICD-9 codes. And then having each of these systems do this, it allows very rapid monitoring so if a problem were to occur you would know quickly. You would not wait six months until a study was done. These are some of the data that the Vaccine Safety Risk Assessment Working Grouping – perhaps the worst named working group ever put together, the VSRAWG, is looking at on a bi-weekly basis.

MS. BUCK: This is Tawny. I just think it is important to point out again, that so many of these systems that Dan is talking about were sort of developed in response to the pandemic. A lot of the data that we were getting and that is coming in and is even expected to come in at this point, has not even started yet. In terms of this pandemic, it seems late. Had there actually been a

signal – it is very good that there wasn't. I think that my wish maybe is that if we do an overall assessment of H1N1 and how it was responded to, that some of these systems in place can remain in place.

Dan, I know that that is the million dollar question, which we are finding in the infrastructure, can it be able to be maintained so that if it happens again we have got the systems in place to immediately start working and getting answers right out of the gate. Instead of putting systems together and then waiting for answers and fingers crossed during that time as data comes in and we are able to process it. There has not been something out there.

Obviously, that is the big question and the big concern and fingers crossed that we can see some of this stuff be maintained.

DR. FISHER: Tawny, I think that is true. Some of these are new but a lot of them have actually been in place for some time. I don't think – it is not as if we started with nothing. We enhanced what was already a pretty robust system as we saw Jane's information yesterday.

DR. SALMON: That is completely the case. And even things that one might consider new, in fact really

come from the lessons learned from other work that has been done in vaccine safety. So you can say that PRISM is a new system, but in fact it is really built on A, to be a distributed data model, and then there was a follow up study done recently, where some process was being done looking at Menactra and a small signal that occurred with GBS. The VSD simply was not big enough for that.

So there was a study done that captured a quarter of the adolescent population in the U.S. through a number of large health plans. That is really remarkable. Think about that - a quarter of adolescents in the U.S. Those two pieces are really what allowed PRISM to come together. So even if you take a system which one might say is new, in fact your point is absolutely correct, Meg, which is that it is really built on the very robust infrastructure like VSD, that has been around for a very long time.

If there are no other questions then I can just provide a little bit more information on the NVAC meeting. I think those are probably the areas that this group are most interested in, but I can just kind of run through the rest of the agenda. ISO provided an update on their thinking in response to the NVAC report on their agenda. They went through a number of the recommendations that came to them in that report and what they were doing to respond

to those recommendations. I think that was very nice for the committee to hear that a report that they had completed less than a year ago, to get some feedback on kind of what is being done about it.

There was some presentations on financing and first dollar coverage for the policy brief on the issue. I don't think that is probably a big issue to this group, but I just mention it. There was a report on the Adult Working Group. Stephanie Marshall, from NVPO, provided a briefing on NVPO's communication plan and the approaches that NVPO is trying to take to coordinate communication across the different agencies and across the federal government. There was also an update on the vaccine stockpile, as well as seasonal and H1N1 updates.

That was pretty much the agenda. So if there are other areas that you would like me to address I am happy to do so, but I think that probably covers much of what has been at NVPO and the NVAC since the last meeting.

MS. CASTRO-LEWIS: Any other questions? Thank you, Dan. You always leave us thinking more.

Sarah, would you please give us a report from the Outreach Working Group and tell us what is ahead of us with the working group and the progress.

Agenda Item: ACCV Outreach Workgroup Report & Other Outreach Activities

MS. HOIBERG: We are waiting for Kay to provide you all with the Banyan report that we all had the privilege of seeing at our last work group meeting. She will be bringing that for you all to see because it is not in our folders.

Just a little background on why outreach was so important to me. When I first came to ACCV I was on a mission and it was outreach, and as you all know I have harped on it ever since. When we were presented with the Banyan project I was thrilled. I was going to accomplish that mission and the program was going to be more visible. But then came my bitter disappointment, this was not going to happen right away, it was going to take a year to do the research and then more time to create the actual campaign. Lastly, we would have to make sure that we could afford what was offered.

We met with Banyan as a workgroup last week, and we learned from them what we already know; who our target audience is and that the program has no visibility. I do not wish to devalue the hard work that was put into this and we appreciate the fact that we now have documentation from a reliable source that there is need for outreach.

In your blue folders, well, you will receive it now, is the report that we received from Banyan. Over the next few months they will be conducting focus groups in both Chicago and Charlotte. We were assured by Banyan that the goal of the outreach project was that it is going to bring the VICP into public awareness. Three of us were a bit confused by some of the language – it looked like they were promoting vaccine safety and the need for them, instead of the program.

So as Chair of the work group, I am beginning to get excited again. I wish that it would be done sooner, but good things come to those that wait, or so I have been told.

I made a phone call to Annie early last week, and asked that if we could reword research question five, to be "the awareness of the program" instead of "the vaccine awareness and availability". So when we get our project in front of us – the overview, I would like to go over it and see if any of you have questions or again, Banyan is looking for input from us and I would like to be able to take that back to them in our next work group meeting. Once we get that in our hands we can look over it.

MS. TEMPFER: I have a question. Sarah, you were saying that we do know what the target group is?

MS. HOIBERG: We do know who the target group is which is doctors and then parents. That is who our target audience is for outreach.

MS. CASTRO-LEWIS: I think actually, I don't remember if they called doctors or health care providers because there are nurses and other professionals that provide vaccines. So we should kind of expand our reach to health care providers than doctors.

MS. HOIBERG: Thank doctors, right.

DR. HERR: Their technical terms were parents, parents to be, health care professionals, older adults, including all of those who are going to be immunized at various points in time in their lives, as well as those that may be responsible in their care taking as well those who are going to be providing –

DR. FISHER: So I guess – I think increasingly with the increased number of adults being included in the program, that we don't want to at all limit our target audience to just parents and would-be parents. But we really now are talking as the general population as our target audience, and health care providers are part of the general population, but then of course, I think that they do need to be almost a separate group.

It should include – I like the term “health care professionals” because that does include pharmacist and other people who might in fact be administering vaccines. I think we can no longer, although the name of this Commission is Childhood Vaccines – especially with the recent report that 60 percent are adults now filing claims, that we really need to make sure that we are broadening our target audience appropriately.

MS. DREW: This is Sherry. I actually think that after the recommendations, that all adults receive influenza vaccine, maybe we should not limit the adult population to older adults.

MS. HOIBERG: Correct – to all adults.

MS. TEMPFER: Sounds like to me it is including everyone. Who are we leaving out? There is no one left out at this point.

MR. SCONYERS: This is Jeff. This makes me to back to the question that I asked Dr. Strikas yesterday, which is why increasing awareness to the general population about the program is going to achieve any useful outcome from the point of view of the program? It seems to me that we need to make sure that people who might reasonably have opportunity to make a claim know about the program. But the vast majority of people receiving vaccinations – I have

to tell you, when you overload people with information they don't retain any of it.

It is not necessarily a good communication strategy to try to saturate the population. I think it needs to be fairly targeted towards the people who will actually benefit from knowledge and the program. Which to me suggests an awareness of potential injury symptoms among the population and an awareness of the program on vaccination. I don't know, I haven't looked at the question. We don't have it.

MS. HOIBERG: That is to me, what I have always wanted was for – you know like in our personal story when we took Kate into the hospital, the EMT's totally disregarded me handing them the list and saying, it says that she could have seizures. They were like, no, there is no way. The treating physicians in the ER did not recognize that as a possibility.

It wasn't until a month later, after millions of tests and poking and prodding her, that the treating neurologist came in and said, you know what, I think you need to file a VAERS. He knew about it, it was like after all this time had gone by and all of these tests and possibly unnecessary medicines given to my daughter, that

even an adverse event even came up into their minds that this possibly could be the question.

I feel that in today's time, they want to rule out – they don't want it to be a vaccine injury. They don't want to admit to the fact that they cause injury. For me, I think that it is so very important that possibly when you have – in the ER when you go in, they ask you if your child is up to date on their vaccinations. That is one of their first questions. If so, then I think their next question should be when did they receive the last vaccine? Then that would at least give you the opportunity to say, okay, well, maybe it is this if they are presenting with those symptoms.

The thing is none of the health care providers that I have been in contact with in the ER, which I have been in there probably twice in the past couple of months, they don't know anything about it. So I think that training health care providers, all of them, especially the emergency room physicians and then like the walk-in clinics. We have so many walk-in clinics that people with low income or don't want to wait in a waiting room, will go. I think that we do need to narrow it down and really focus educating on vaccine injury, but that is not our place.

MS. BUCK: I was going to ask that. Is the purpose of this outreach to educate people about the program and the nuances of the program about a claim or is it to educate health care providers how to identify an adverse event, what a standard of care would be for certain types of adverse events and all of that?

MS. HOIBERG: Tawny, we could not hear that question. I am sorry.

MS. BUCK: Is the purpose of this outreach to let people know about the program and how to file in the program and what it does, or is the purpose of this outreach to educate health care providers and others, about adverse events; how to identify them, how to treat them, what the course of care is after you have seen one, and all of that. I am a little confused.

MS. HOIBERG: I believe that at this point Tawny, all we really know is that they are looking to find out how much people know about the program. I may know what my goal for the program is, for the outreach program, but I don’t know what Banyan is going to come up with, to be honest with you, and maybe I can hand that over to Geoff, he could probably better explain it.

DR. EVANS: To me from the start, this whole question has been to try to amplify the efforts at

educating the public and providers about the availability of the National Vaccine Injury Compensation Program. As we are doing that to the extent that we are able to, depending on education level and interest and circumstances, we try to tell them some basic facts about the program, as Tawny alluded to.

Clearly, in terms of Tawny question just then, it is the former. We are not in the business of trying to educate the public about vaccine adverse events, nor as we discussed on the call with Banyan a couple of weeks ago, does our purpose have anything to do with vaccine promotion. It is simply – it starts and finishes with the fact that we have an important responsibility to make everyone in the public and health care community, aware of the program and then beyond that, whatever kinds of reasonable and helpful aspects of the program that can be passed along at the same time, communicated to the extent that it is understood and retained. We would certainly like to do that.

That is something that hopefully Banyan can help us put together.

MR. SCONYERS: Maybe I misunderstood with talking about who the target audience were. Looking at the research questions, the first one is understanding the

target audience. I thought the conversation was that the target audience was everybody who receives vaccines and I guess I am disagreeing with that, that that is not the target audience. We need communication about the program because I think that communication is unlikely to be effective if the target audience is so broad. I thought that was what we were talking about.

DR. FISHER: I guess I will disagree with you, Jeff. But I think the target audience is the entire population – everybody who is going to receive vaccines. But I think the timing of the message is very important because I totally agree with you, at the time you are getting the vaccine you should know about the program, but you also have to know about all the other things that go into yes, you are an appropriate candidate; yes, this is the right time for you get this vaccine, you have no contraindications, here is what to expect. There is a lot of other counseling that is essential.

What I would suggest is the timing of educating the public about this is not when they are getting vaccines, it is on an ongoing basis. So I heard a woman from Canada give a wonder talk about vaccine safety, and in Canada every school child knows what the vaccine safety mechanisms are in Canada. In this country, not only do the

school kids not know, there are very few adults who know, there are very few physicians who know, all of the systems that are already in place.

I think if we really want to make people aware, we don't want to hit them just when they are getting – yes, it is important that that reminders are on the VIS statement, but the real reach has to be way ahead of time so that really people have a chance to think about it. At the time you are getting the vaccine the timing is not right. You just get overloaded and it won't be as useful as if this is an on-going mission that people are aware of, not after the fact but before the fact.

MS. BUCK: Actually, I really agree strongly with what Meg just said. I think if you look at other products in this country, that people use them with confidence because they already understand to some degree, that there is a safety system in place. They don't jump in their car and start driving without having some sort of basic sense of how they are being protected.

I think that you really have done a good job of explaining the difference between separating this from promotion or bringing this up at the time of decision of vaccinating, but instead sort of making it a different conversation at a different time is just really key.

MS. GALLAGHER: This is Charlene Gallagher. Jeff I respectfully disagree with your analysis and I have to say that I do think that the general population is the target of this message. I agree with Meg that timing is everything. We don't necessarily time it to when they are getting the vaccines. You never know in advance who is going to have a reaction, but the potential is always there.

I think that it is really important to have everybody aware of the program, whether or not they get a reaction. Then if there are a few people who slip through the cracks, their children, their neighbors, everyone will know and they will be directed in the right place.

So I do think the reach has to be extremely broad if it is going to be effective.

MS. HOIBERG: I agree with both Meg and Charlene and Tawny. And again, I am just going to bring it back to personal experience. When you are going through such a traumatic situation as what we were, when your child is at death's door, you are not thinking straight. All you are thinking about is how can I help my child? How can I save my child? And to have somebody else come to you and say, you know what, it could be this so why don't we look into it further?

In another case, someone's relative came and began the filing for them because they just were not in a place to do it. So I think that as we all now pretty much agree, it is everybody that needs to know about it. I also think – it is not the education on vaccine injury is not going to come from this Commission, it is not going to come from this program. That is what NVAC's, I believe, job is. Whose job is it to educate people on adverse events and how to recognize them and what not?

DR. SALMON: If I could add a little bit of comment to this. Primarily it is CDC that does the communication from the government. But health care providers have such an important role in this. Every study that I have read, and there are dozens of them, show that the health care provider is who the parent turns to for information about vaccines. The most used source and it is the most trusted source. Even among people that don't ultimately vaccinate their children according to the immunization schedule, they still find health care providers to be the most trust source.

I can add a little piece to this. We are getting ready to submit a supplement to Pediatrics in the next couple of weeks, that is intended to help providers, pediatricians and other physicians, work with parents on

vaccine issues. It includes a number of papers that describe the vaccine safety system from VAERS to VSD to other components, what FDA does, what NIH does. And VAERS is really important there especially because it is the pediatrician or physician that is often making VAERS reports.

There is also an article written by Geoff's group that describes the injury compensation program. So I think that is a small step, because clearly a single supplement to a journal isn't going to address all of what you are working for but it is an effort to try to better educate and provide readily available information to pediatricians and other physicians, because it is not just pediatricians that read Pediatrics. Hopefully it will give them the sense that you all have been talking about, what the system looks like because much of it is invisible. It happens, it goes on, people that do it work very hard, but it is not something that is visible to the public or even to providers.

It will also provide information on the program, so presumably if a situation were to arise where it would be appropriate, we would increase the likelihood that that person would file a VAERS report and then refer the parent to the Injury Compensation Program.

MS. HOIBERG: As you said, it is the health care provider that we turn to and when you sit there and as a parent you bring up – you are sitting there and you are reading the VIS and you bring up an adverse event and they laugh it off as, oh, it is so rare in my 35 years, I have never seen a case. Then you go, oh, okay.

It is total trust that you have in your pediatrician. It is not that they lead you down the wrong path but because it is so rare, I think it would help if they were like, you know what, yes, it could happen. Probably is not going to, but it could and this is what you need to do.

As a parent, when you have a young child and you are holding down a screaming baby to get a shot, the last thing you do is really read everything that is handed to you. You shove it in your bag and you are out the door. So it is going to have to be an education that is just an on going education. Just something that is on every website for the parents and parents magazines. It just needs to be this constant every once in a while it comes out and educates.

MR. SCONYERS: I appreciate the thoughts. I guess I want to say three things in response. First I am not hearing any of you describe any particular advantage in

actual knowledge about the program. I am hearing you all describe the advantage in knowing about potential adverse effects of vaccination. I agree that that is a matter of communication, but I am not hearing any particular advantage in educating the general public.

Second I would say that educational time is a scarce resource. I am not sure I would be interested to understand better why it is that Canadian school children are better off knowing about the vaccine safety systems in Canada – why that is an appropriate investment of scarce educational resources. I would like to see that associated with an outcome that has been official.

The third thing I would say is I would like to understand or I would like to have Banyan, I guess, as the contractor, really understand how adults learn. Whether they actually learn in the way that you are talking about in more of a communication strategy. In our experience at my institution, our people learn on a just in time basis. They learn when they need to know something and not in advance in general. That kind of learning doesn't typically work.

I come back to saying, it seems to me that the people who really need to know about programs are the folks who are going to be evaluating potential adverse events

because they are in a care relationship with the person who has received the vaccination and are able to incorporate into their thinking what Sarah is saying, that there needs to be an understanding of potential of a vaccine injury, and if there is that potential then the person who has the potential injury needs to know about the program.

DR. FISHER: This is Meg Fisher. I guess the one thing you could say about the need to know about the program is at least if you are aware that there is a program that provides potential compensation, you might be more likely to report the adverse events that then get us to study the information to figure out what the adverse events are.

So while I think you are right, the actual knowing about this compensation program may not be as important as knowing about what adverse events are and what could potentially happen. I think there is some reassurance that at least knowing about that there is a program and that there are people interested in trying to compensate people who do have events following vaccination, would be an incentive to insure that those events got reported.

Now is that worth this kind of investment? I think that you are right, resources are scarce. I think

education is a wonderful thing. I think you are right that people do just in time education. On the other hand, a lot of people get educated or mis-educated, by things on television, on talk shows, on other media, that has nothing to do with gaps in their knowledge, it just happens to interest them. So I think there are other ways that adults get hooked into learning about things.

MR. SCONYERS: Whether information about the program would reach the potential concerns of people who might get a vaccination is a hypothesis that will be interesting to test.

MS. DREW: I have actually talked to Sarah and she mentioned to me that her neurologist came to her after her child was injured and said, you should file a VAERS report. Sarah found out subsequently, that her pediatrician had already filed a VAERS report. However, neither of them had told her anything about the compensation program.

I know the Act provides that attorneys have an ethical duty if they are confronted with a potential client who has a potential vaccine injury, to inform the potential client that the Vaccine Act exists. I don’t think doctors or medical care providers have such an ethical duty but perhaps they kind of have a moral duty. I kind of see the

providers being a bigger target for outreach than individuals in the general public who may be getting a vaccination in the future.

So in some ways I agree with Jeff. I think that this is kind of a retrospective outreach. If there has been an injury people are much more interested to find out about the Act. On the other hand, I kind of liken it to my homeowner insurance policy, which I know I have, but I don't go look at it until my basement floods.

DR. EVANS: A quick reminder that whenever anyone files a serious adverse event report with VAERS, that they receive correspondence back from VAERS at two months and I believe at 12 months. That letter that comes back does contain a sentence or two about the availability of the compensation program.

MS. DREW: Is that a letter that goes to the providers or just the individuals?

DR. EVANS: That is a good question. It goes to the reporter. We would hope that the reporter would trigger the idea that they should tell the patient because most of the reporters are physicians, as we know. At least there is that back-up in terms of trying to get the information about the program.

MS. DREW: I would be interested in seeing what the wording is to the provider.

DR. EVANS: To the reporter.

MS. DREW: To the reporter, excuse me.

DR. EVANS: We have shared these before with the Commission. We would be glad to do it again.

DR. GIDUDU: Most of the CDC focus is on largely the provider -

MS. CASTRO-LEWIS: A little louder so that Tawny can hear you.

DR. GIDUDU: Okay. I was saying that CDC is focusing a lot on educating the providers. We have a very big – not very big but small, but effective communication group that are evaluating effective strategies on communicating back to the providers on how to even file adverse events. We are struggling with quality. It is not just filing VAERS reports, we would like to get some sort of good information that we can draw conclusions on. So that is one thing I wanted to follow up on Dan's comment.

I had a question for you, Sarah, whether you have done a pilot on this before or if you plan to do a pilot before you roll out your evaluation and communication?

MS. HOIBERG: You mean the outreach program. It is not going to be me or the Commission. Banyan will

create a – they will create a program. They will create a campaign and then we will look at – is that what you are asking me?

MS. CASTRO-LEWIS: They are going to do some kind of testing of the messages in focus groups. But after that they would provide Geoff's office with a report. I think that that is the extent of the piloting that they are doing. After that the contract doesn't really call for doing – I think I am misspeaking – letting you talk about it. The plan that I read, there is nothing after that. They are just going to give a report telling us who the target audience is after their research. They are going to pilot some messages with focus groups actually with some consumers. And they are going to do interviews with health care professionals and stakeholders, but after that, there is not from what I saw, anything else.

DR. GIDUDU: I was asking because how generalizable will your findings be since that audience is really broad? It would be really helpful to see –

DR. EVANS: That remains to be seen. Certainly the report will contain ideas for further research. This is our first stab at doing this and hopefully it will lead to even more kinds of efforts. But this will get us at

least off the ground and get us much more involved in terms of targeted communication.

MS. BUCK: It seems to me that this conversation brings up the fact that there are a lot of gaps in what communication about vaccines and vaccine safety, which I think we are aware of and is actually a piece of what the Vaccine Safety Working Group white paper will include a section on that.

I hear what Jeff Sconyers is saying. I think you have to be careful to try to not address all the problems of the messaging with this project because it may not really be an appropriate place, but we are certainly identifying that a lot more messaging I think, needs to occur to providers and parents about the whole issue of vaccines and vaccine safety.

In terms of this particular project, this seems to be quite specific in terms of just the program and the availability of the program in determining at what point that message and to whom that is given to, is a little bit different.

DR. EVANS: The availability of the program, in my opinion, is the place to start. We have received over the years, I don’t know the number, easily hundreds of either congressional letters or letters from parents,

saying they had no idea that the program existed and the statute had long past. I have always likened this to when you go into a bank you know that there is a federal program that protects you. I would like to think that we get to the point that if you receive a vaccine, because after all we do cover 95 percent or more of vaccine distributed and given in this country, that you know that somewhere in the back of your mind there is a federal program.

If that can be achieved after this effort in the next couple of years, I think we have achieved something important.

DR. SALMON: Sherry asked the question if there is an obligation, ethical or otherwise, upon providers to inform people about the program. One could argue that there is actually a legal approach to this because public health law 99660 that created the program in NVPO, requires CDC to develop vaccine information statements. It requires anybody administering a vaccine to give the person that VIS.

I think Geoff, please correct me if I am wrong, but I think all of the VIS's make specific mention of the injury compensation program, presuming that it is a vaccine that is covered by the program. Is that a correct statement, Geoff?

DR. EVANS: That is correct. That is also presuming that the VIS's are handed out to the recipient of the vaccination.

DR. SALMON: And if they are handed out that the person reads them because you get lots of paper that you don't read. So I am not saying that that accomplishes your task, but I think it does somewhat address Sherry's question about whether there is an obligation. I don't think it says in a law that VBIS has to discuss the program, but in fact it does.

MS. GALLAGHER: I would just like to comment on the scope of the outreach. I still think that it should be very broad. I agree that adults do a lot of just in time learning, and I am not suggesting that the outreach be to describe the program and describe all the parameters. But Sherry when you were talking about your homeowner's policy, you said you don't pull it out until the basement floods. But in the back of your mind you know you have one.

That is the level I would like us to get to. That in the back of their minds, they know there is this program and when the need arises, then they will go and learn about it.

MS. CASTRO-LEWIS: It seems to me like there are so many issues on the table and I think Tawny expressed it

really well, the one thing that we have on hand is this particular contract with Banyan to identify our target population and to create some messages and test them with focus groups and then give us a report. That to me is the summary of this. But there are many other issues there like the education of the community or the public in general. Although the issues that you mentioned, how could we – it is really not the mission ACCV but it is kind of related.

What can we do other than this? This is only one piece of what we would like to see out there. So how can we really get some good outcomes in terms of what we are discussing here?

DR. HERR: This kind of hits on some of the other discussions a little bit previously on target and what information to get across and what kind of information do we want to convey. It has been my impression over the years being here that there has been a lot of concern that there are a number of patients out there who may have been injured by vaccines but have not come to the forefront because they haven't become aware of the program.

So one of the concerns is to try and bring those people out to make sure that we are taking care of people of all the people that we are suppose to. But I think the

education of the public, and I am talking about everybody, is going to vary depending upon the importance of what they know. Like the FDIC, it is nice that everybody knows that their bank accounts are insured, however the information that is given by that program to the individual banks is much more detailed of what is involved in their process of protecting their savers or their clients.

I think that when we start looking at providers and health professionals there is going to be a little bit more information that is going to be provided to them to make sure that they are aware of the conditions. I think we need to work with the CDC and the National Vaccine Program Office to ensure that the information that is conveyed is going to bring that attention to the proper level in the minds of the providers at the appropriate time.

Whether we are actually in charge of that provider or professional education, I think that it is reasonable that we are at least aware of what is being done. I think that it is an obligation that we have of what is being done by the CDC to provide that information.

So it may not be in the purview of this program in the awareness of the Vaccine Compensation Program, but I think it is our responsibility because we are responsible

for looking over and reviewing the table of injuries what those conditions are that health care professionals should be aware of, and most of them are not.

DR. GIDUDU: Can I just mention, at least during this H1N1 season, we have Webinars with states. This way people are able to join us and maybe one area to begin is to have a session during one of these webinars, that a presentation gets given during this session. We train, we have communications with the states.

MS. HOIBERG: That is a great idea.

MS. BUCK: It almost sounds to me like you need to identify either from what Tom was just saying, that there needs to be a better outreach to care providers of all types at some basic education level like MR training that is about the program. The analogy that you draw, the insurance or FDIC, I understand why you all are doing it but it is very different because the existence of the program is not an assurance that if your child has suffered a vaccine injury that they are going to be compensated. It is just a program there that you may or may not have the opportunity to be a part of but you do need to know are the statute of limitations and timeframes and requirements like that.

But if the problem is that if health care providers and practitioners are not aware of it then we may need to think about targeting that. Additionally, I think if you look at H1N1 and you see some unique points of distribution on vaccines that I think sort of affects the process even more and that should be of concern because when you have school located vaccine clinics or drive-through vaccine clinics, I think there is a very strong concern that this piece of the message is getting lost even more.

I am not a real expert, I am glad that Banyan is doing it, because trying to identify the target audience is I think a lot more complex than just saying that it is everybody. I think Tom makes a really valid point.

DR. EVANS: I guess what I am hearing is that – and we have talked about this before, is what is going on in training programs, both medical school programs, residency programs, that deal with vaccine safety and as part of vaccine safety, does our program ever come up. That has been something that we have talked about in terms of the project that we had in the 90's, the materials we put together.

But that is primarily CDC's mission – part of their vaccine effort, and so perhaps we could hear from CDC

at a future meeting about what is going on in terms of the kinds of materials and efforts on the education level of health care professional, both physicians and otherwise.

DR. FISHER: This is Meg Fisher. Geoff, I think that is a great point and I think the timing may be just right because I think there has now been a new shift to something that in the past was kind of totally ignored, which is adult immunizations.

The reason that shift matters is that there are a heck of a lot more internists than there are pediatricians. And if you think the pediatricians don't know anything – the internists are not always thinking about the preventive illnesses either. So this is actually a very good time to broach the whole subject of vaccine as part of preventative care and the whole move to the medical home and the whole idea of healthy choices, healthy living, as a different way to look at health.

Instead of just intervening when you are sick, preventing illness and preserving health is a whole different way to look at things that gives you the opportunity to bring this information to literally anybody in medicine, as opposed to just the small group of people going to pediatrics, which is less than 20 percent of people who graduate from medical school. Remember most

medical students get six weeks of pediatrics total, in the four years of their training.

If you look at this instead of just a childhood issue, I think it gives us an opportunity not to lose the childhood issues because clearly they are important and we are giving a lot more vaccines so it is obviously important, but it also gives us a way to wedge into that curriculum, which is already overloaded.

DR. EVANS: Let's not forget the OBGYN community, too, because they are giving a lot of post-partum rubella vaccinations.

DR. FISHER: And family medicine.

DR. EVANS: and family medicine.

MS. CASTRO-LEWIS: I have a question regarding this paper that we have just here, and the testing of the messages in the focus groups. Would it be possible to request to Banyan Communications to share with us those messages also, before they get to the focus groups? Maybe we have some ideas here also, and some input to offer.

MS. HOIBERG: Maybe I am not understanding the question because we have – I guess you are wanting to know – these are the research questions I believe, that they are going to be asking.

MS. CASTRO-LEWIS: Yes, but they are going to test messages with focus groups and I think it would be valuable for this group, for the ACCV, to look at those messages before they go to the focus groups.

MS. HOIBERG: Okay.

MS. CASTRO-LEWIS: Messages, I assume, messages regarding the – what they want to tell the community about it. I think it would be a good idea for us to look at it too.

MS. DREW: We might not have time.

MS. HOIBERG: They are doing it now aren't they? Mid-March.

DR. HERR: We are going to have minutes of our discussion. If we assure that they get copies of the discussion with a direct comment from Geoff or someone, to please take these into account. That may speed that process rather than trying to set up a whole new –

MS. GALLAGHER: I would like to also comment on their target groups as listed here. They have older adults only. I think there has been some discussion here that maybe the target differs from what they say. I would hate for them to spend time testing messages that are not going to be within the scope of what we have been discussing and

thinking about. Then they would have to go and test them again and that just sort of wastes money.

If there is any way that we can intervene before they go to focus groups. Even if we don't have it at meeting and it just gets distributed and people can send comments back. Of course Geoff, you have heard the full discussion and certainly would be capable of discerning whether you think that the way that they are going seems to be consistent with the way we are all thinking.

MS. HOIBERG: Right here it says, like the number one research question, understanding the target audience. What is the perception and understanding of vaccination, vaccine risk, and VICP among different demographic groups in the U.S.? Who are the potential target audiences for vaccination outreach and why?

MS. BUCK: Those are the questions.

MS. HOIBERG: Those are the questions that they are going to ask.

MS. BUCK: It seems to me like we have hired a contractor to do this – I don't know a heck of a lot, but usually when somebody is doing focus groups for you, you have some development in the message. It should not be a big secret to us what messages are floating before a focus group. Somebody must have seen them.

MS. CASTRO-LEWIS: No, we have not seen them.

MS. HOIBERG: And Geoff is shaking his head, he has not seen them either.

DR. EVANS: This is still a work in progress and we will communicate back to Banyan and we will certainly give them this feedback and we will see what the progress is at this point.

MS. CASTRO-LEWIS: Most definitely the working group to have a good discussion of those messages before then, but I think the entire group, we will be valuable - you know to hear from everybody. Given the discussion that we have had today, I think it would be good to have everybody's input.

MS. HOIBERG: Charlene and Meg, you are now on the communication group, right?

Meg is, you are not?

DR. FISHER: I am not, do you want me to be?

MS. HOIBERG: The more the merrier. We just have to have one less person, right. That way we can get together and get some ideas out there.

MS. TEMPFER: I just have one question. On the focus group, is the point to gather information, to see what their knowledge base is? Or are you saying that they

are actually going to be doing some teaching and giving out information?

DR. EVANS: I believe they are testing instruments that they are going to be developing to try to –

MS. TEMPFER: To get the information out there.

DR. EVANS: I believe that the focus groups are also in terms of eliciting viewpoints, perspectives, too. I think it is going to have a dual purpose.

DR. FISHER: On the formative research activities, about half way down the page, focus groups with target audiences; Research plan focus: Understand the audience, trusted sources of information, effective communication strategies.

MS. HOIBERG: They did not specify.

MS. CASTRO-LEWIS: They did not specify the testing of the messages. Which is something that I saw when looking at the proposal that they submitted, they say there the testing of the messages. So this probably should be added here.

DR. EVANS: It is not clear. Actually as I look at this, it is not clear they will be doing the testing with the focus groups but certainly they will be eliciting

perspectives and information on focus group understanding of the program.

DR. FISHER: Actually on the next page you get to the messaging. On the second page of this they talk about messaging at some point.

MS. GALLAGHER: It says, using a discussion guide, focus group participants will be asked about the following topics: familiarity with and perception of the VICP, trusted sources for vaccine-related information, opinions on messaging and communication strategies that resonate with them.

DR. EVANS: That is not necessarily – that may be various kinds of messages, phraseology, and those kinds of things, rather than any kind of a semi-finished product that they would be ending up with. It is a little bit of both as I read it.

MS. GALLAGHER: It is unclear to me whether they are going with a message or not.

DR. EVANS: This is something that again, the work group – that is why we have been having these conference calls. So this is something that we will discuss at the next conference call. Again, it is a work in progress.

MS. HOIBERG: Right, we have made it very clear to them that we want to make sure that it is everything to do with the program and nothing to do with the promotion of vaccine – we were very clear about that. We of course seconded and thirded it and driven it home.

Like you said, we don't have a lot of answers. They really have not given us a lot to work with at this point, but we just know that they are working and we will keep you informed as far as what their progress is.

MS. BUCK: You say that they are working – I guess I would make a request as a Commissioner that we don't wait until the June meeting to get another update. Maybe the work group can send out periodic updates to all of us on what they are doing. They are working but what are they doing? I am very confused.

Is it a reasonable request to ask the work group to send out updates on this particular project in where it is at and what is going on that answers some of the questions, instead of waiting another couple of months for another meeting

DR. EVANS: Tawny, this is Geoff. This is a contractor who has a specific set of deliverables and I think right now there has been an extraordinary amount of

transparency of what they have been doing in efforts to try to apprise the Commission as to what has been happening.

This is really something that is their responsibility to carry out and they will inform us to the extent that they can. Your comments are appreciated and they will be communicated to Banyan, but I cannot guarantee or promise that they will be able to give you the kinds of feedback and specific information that you are talking about at this point.

There will be a final report. The report will be reviewed with the Commission later this year, but this is again, a contractor that is working under the guidelines of a contract from the government and they will be assisting to the extent that they can in trying to make things available and keep us up to date.

MS. BUCK: Kind of this whole conversation that we just had then is like a day late and dollar short. Should have happened before the contract to Banyan was sent out and this kind of input should have gone – Geoff, what I am hearing you say is they have their marching orders, they know their job requirement and they are doing it. That is pretty much what is happening.

DR. EVANS: I don’t know that that is fair. They have started with an environmental scan of the literature,

which they have carried out. They are speaking with subject matter experts to get at their understanding of the program and their perspectives. They will have focus groups that will go over the kinds of things that Charlene read just a few minutes ago.

They certainly have been kept informed and have had discussions with workgroup members about their concerns about the kinds of individuals – demographics information are important to understanding the program and so on. I think that they have made every effort to adjust what they are doing with those kinds of concerns and questions in mind. It is not a done deal in that respect but it is not clear to me that they are going to be able to share every draft document and every procedural step with the kinds of transparency that you all are suggesting you would like to have. That is all I am saying.

MS. HOIBERG: Tawny, this is Sarah. We were informed that they were going to have reports but we were not going to be privy to those reports. I did raise the question of why not, but was told we would get the final report at the end and that was really pretty much it.

They have been cooperative as far as changing research question number five to reflect the knowledge of the VICP instead of vaccine. They are working with us.

They are accepting our input. I am with you that I would like to see everything, but we are not privy to it unfortunately.

MS. BUCK: I think some of the questions that will come up at some point they may, depending on the outcome of this, be open to criticism are things we can't control. Like when they are doing literature reviews or they are pulling together expert information, and people to participate in focus groups. I think the obvious questions are we are identifying people that we think need this messaging and should have input in the process.

Wanting to know the criteria for selecting people, what they are looking at, who they are using as a resource for literature and information to review. Are they operating independently and neutrally, are they reviewing stuff that has been given to them by HRSA and the government? Who are they picking for focus groups? We all know you are going to have to have a very random selection of people from all points of view to get valid information. That is the kind of stuff that I think would be looked at in terms the overall results.

But if the work group is feeling like they have a handle on a process and are getting what they need, then that is fine with me. I just felt like this conversation

this morning was raising all kinds of questions and concerns and that there were questions being asked that answers were not being given to. I guess I was just hoping for a little more.

MS. HOIBERG: Unfortunately we don't have those answers. We have asked, Magda and I both, were concerned about how they went about choosing the focus group participants. They said that they went through some sort of a process – an agency that chose through phone calls and phone surveys, or something like that, is how they chose their participants.

I really don't know. There are a lot of questions. Like I said, I wanted to get the input from the Commission and hopefully we will be able to have a phone call with Banyan before they actually do the focus groups, to possibly have input on what questions they are going ask or what the messaging is.

DR. EVANS: This is Geoff, again. Some of the concerns on the last call just a couple of weeks ago, were why aren't you including members of this demographic group, that demographic group? Why are you not going to more cities and so on? There is criticism about the cost of this contract that was voiced previously. I will tell you to be able to do the kinds of things that were suggested on

this call, you would have a contract that would be two to three times more expensive.

I think we have to be realistic about what this is and what this is not, and keep in perspective that this is a good faith effort to try to put together as best we can with the resources available, a reasonably complete communications plan for the program for the next couple of years. Hopefully there will be additional research suggestions that will be a part of this so that if money is available, to continue to do further research and try and create additional materials for our program.

But I think this is a good start and I would like to again, look at this as half glass full instead of half glass empty and let us go forward.

MS. TEMPFER: Sarah, how often do you have contact with Banyan – the teleconferencing and everything?

MS. HOIBERG: We met with them twice – once.

DR. EVANS: Twice. We have had conference calls before each of the last two advisory commission meetings so the work group would be informed about what was going on so Sarah could report back to the Commission. We are trying – and I think that that in itself is unusual that a contractor would be doing that and that is because we are trying to keep you informed to the best extent that we can.

MS. TEMPFER: So there is not another scheduled at this point?

MS. HOIBERG: Not at this moment, no.

MS. TEMPFER: Since I kind of heard Tawny asking for interim reports –

MS. HOIBERG: We would like that. We would like them to report but we were informed that they are paid every time they come so there is not the resources. The resources are very limited and so they are unable to come and give a presentation every time.

MS. BUCK: I was actually asking for interim reports from the work group?

MS. HOIBERG: Right, and Tawny we can only give you what we are given.

MS. BUCK: I just want to say to Geoff Evans, I am not necessarily looking at this in a negative way or as the glass half empty, as you suggested. But I think that this is an important task and I think that that the kinds of questions and dialog that has happened today is relevant. It is not really negative or glass half empty conversation, it is trying to get the best product from this contract that we possibly can.

It is what it is, as you said, but I am not sure everybody is totally clear on what it is.

MS. CASTRO-LEWIS: Was this given to everybody put in the packet?

DR. EVANS: What is this?

MS. CASTRO-LEWIS: I'm sorry. This is the response.

DR. EVANS: Yes.

MS. CASTRO-LEWIS: So everybody should have that and if you look at it before the meeting, you can tell the kind of responses that they gave on the plan to eventually to give us a report on our types of population and messages, et cetera.

MR. SCONYERS: This is Jeff Sconyers. The reason that this is important to me is not from a glass half empty or a glass half full perspective, but because I assume that the results of this work are going to drive activities by the program and by the Department in the future. I want to make sure that those are going to be as effective as they possibly can be. That is why I am making the comments that I am making.

I want to make sure that we don't ask a series of questions developed and worked through a series of assumptions that are going to result in a plan that is unachievable.

MS. CASTRO-LEWIS: I think we can all agree with that. We want the best out of this. Sarah, do you have anything else?

MS. HOIBERG: That concludes my presentation. If anybody else has anything? Hopefully we will be able to get in contact with Banyan. We can always send them an e mail with our suggestions, right?

DR. EVANS: Yes.

MS. CASTRO-LEWIS: Thank you so much. We are 25 minutes ahead of the schedule so let’s take a 10 minute stretch before we move into the election of the chair and the vice-chair. We will reconvene at quarter of.

(Break)

Agenda Item: Nomination/Election of New Chair and Co-Chair

MS. CASTRO-LEWIS: We are ready to start again. Our next item in the agenda is the nomination and election of the new chair and co-chair. I am glad pass the baton to Tammy who is the chair of the nominating committee. She is going to lead us through the process of elections. You have seen your tab number three has the process that the committee has developed for the election itself.

So, Tammy, all yours.

MS. TEMPFER: Thank you, Magda. I know you are anxious to pass on the gavel, but I just want to thank you and Sherry for doing an outstanding job. You have really done a great job this year.

MS. CASTRO-LEWIS: Thank you.

MS. TEMPFER: Everyone should have received the material and reviewed it. I was able to contact everyone because I wanted to make sure that anyone who had any interest in running for any of the offices that there names would go into consideration.

We have three people actually, for the position of chair and vice-chair, which is how it is written in the charter, the chair and vice-chair. If you look down to five, it actually has a process in place that I just want to open to the Commission for discussion to make sure that that is acceptable to everyone to go forward that way.

DR. FISHER: This is Meg. I was just surprised that it was kind of a complex process as opposed to just having a vote and whoever gets the vote, gets the position.

MR. SCONYERS: It is what happens when you have a lawyer working on it. To some extent pretty much anything in there reflects some experience that one of the three of us, Tammy, Tawny or I, had since we have been on the

Commission in connection with these votes. Like I usually say, experience is a hard teacher.

It will probably go just fine but in anticipating how to deal with some of the things that have come up in the past, that is what a lot of that is there for. If they don't come up then they don't come up.

MS. CASTRO-LEWIS: I also think that last election we kind of followed this process a little bit, it is just that it was not in writing either. There was the secret ballot, there was the speeches, there was – everything that is outlined here. We decided in the nominating committee to make it a little more formal, which is the opposite of what you are saying, Meg, just transparency also.

DR. HERR: I don't remember. Did we have multiple ballots last time?

MR. SCONYERS: We did not need to.

DR. HERR: Because we had three people running at various times for each thing. We would have had to have had multiple ballots last time and we did not.

MR. SCONYERS: We did not need to.

DR. HERR: We did not know that.

MR. SCONYERS: I knew that. The candidates who were elected got a majority on the first ballot.

DR. HERR: But it wasn't public. Was the number of votes tallied?

MS. HOIBERG: Yes, we sat over there and tallied them.

DR. HERR: The number of votes per person, okay.

MS. TEMPFER: Okay, so the question is do you want to go forward with doing it this way, if there are three to drop the bottom candidate and then have another election.

MS. GALLAGHER: I would like to go back to the simplistic way that we did it before and you just have a vote and the person with the greatest number of votes gets the position. If there is a tie, then of course you would have to have another vote. I could not see the need to get so complicated. I understand that it is a secret ballot. We have always done that. I thought that Annie could tally it just as well as the nominating committee, so I did not know why we changed that.

I did not see the purpose of having number five be so lawyer like.

MR. SCONYERS: That is my thought, because I think the chair ought to be elected by a majority and not by a plurality. If you don't go through that process and

you have more than two candidates, then you won't necessarily have a majority voting for the chair.

MS. GALLAGHER: I did not really see anywhere in the charter that that is required. In fact it just says that we select a chair. We could do it by just agreeing, which we have done in the past as well. I just felt that we were getting a bit bureaucratic and I did not think it was required. So those are just my thoughts on it.

DR. HERR: Has there been an instance in the past where there has been a minority elected person and there has been discord because of that?

MS. TEMPFER: Not that I know of.

MR. SCONYERS: Not in my experience.

MS. TEMPFER: I am not sure on how to come to an agreement on how we are going to do the process.

MR. SCONYERS: I will just move that we follow the process that is outlined in the report from the committee.

MS. SAINDON: In that case, I would just add – this is Elizabeth Saindon from the Office of the General Counsel, the process as I reviewed it did not exactly reflect the position of the charter, which only permits present members to vote. So I had submitted some redline comments to just clarify that only those members that were

present at the meeting, if not in person but still present, would be eligible for this process. Those are also included in your packet.

MR. SCONYERS: I think we are all present.

MS. SAINDON: I recognize that we are all present.

MS. TEMPFER: And Tawny has designated a proxy?

MS. BUCK: I haven't yet but I intend to.

MS. SAINDON: I was just saying that as you move to adopt this process, I would ask that you would move to adopt the process as edited to reflect the condition of the charter – the conditions of the charter, as opposed to the one that was submitted. That was my purpose for raising my comment.

MS. GALLAGHER: I think Jeff, she is asking you to revise your motion because it would be inappropriate to pass rules that are not in compliance with the charter.

MS. BUCK: I am having a terrible time hearing anybody.

MR. SCONYERS: Tawny, Charlene's comment was that – did you hear Elizabeth's comments about the –

MS. BUCK: Yes, but I can't hear the Commissioners though.

MS. SCONYERS: So Charlene's comment was that she is interpreting Elizabeth's comments as inviting an amendment to the motion.

MS. TEMPFER: Elizabeth, could you clarify that. Is that what you added on the next page – parts that are underlined, right?

MS. SAINDON: Yes. That's correct and they were just merely technical edits to reflect that only – they are really merely technical edits so that the proposal conforms with the requirement of the charter that present members be allowed to vote. But all of the edits are technical in nature.

MR. SCONYERS: Since we are all present, I really don't feel the need for the amendment but –

MS. SAINDON: Presumably Jeff, this would then be adopted for all future ACCVs, and that is not guaranteed that all members would be present at the time that the vote was taken.

MR. SCONYERS: I don't think that is necessarily a valid assumption. I think this is a report from this year's committee. I don't think anyone disagrees with you about what the charter requires. I don't have a strong feeling about it so if someone –

MS. HOIBERG: This is Sarah Hoiberg. When you say present, does that mean present here or present on the phone?

MS. SAINDON: Present in any capacity at the time of the meeting.

MR. SCONYERS: So unlike a stock owner, it is not possible to designate a proxy and not be at the meeting. You can't just tell somebody vote for me, hope that works out. You have to participate in the meeting.

MS. SAINDON: There are members who have been unable to attend meetings on some occasions, certainly within this Commission and in others. That does happen and it is fine for that to happen because the charter permits a majority of the members present to vote. I think that it would be appropriate as a document that would be binding on future commissions to have it conform with the existing charter.

MS. CASTRO-LEWIS: Given the time that the nominating committee put in preparing this, should we think about adopting this just for today or like Elizabeth is proposing – suggesting saying that this will be adopted for future elections, too, since there is a process here. That is another question.

MR. SCONYERS: This is a report from this year's nominating committee.

MS. HOIBERG: I move that it be just for this time.

MR. SCONYERS: I moved that but you could second.

MS. HOIBERG: Second it, then.

MR. SCONYERS: If someone would like to amend it to reflect Elizabeth's suggestion, that is fine too, but it is a report from this year's nominating committee.

MS. TEMPFER: Is there suppose to be a vote then to accept it? I am not sure about the rules.

MR. SCONYERS: There is a motion on the floor.

MS. TEMPFER: There is a motion, there is a second.

MR. SCONYERS: This is the part where we discuss.

MS. CASTRO-LEWIS: Are there any other discussion to Elizabeth's addition? Here is the technical question, it is you as the committee leading the vote here or is it a matter of the chair? That is another question.

MS. TEMPFER: Doesn't matter.

MS. CASTRO-LEWIS: Tammy, go.

MS. TEMPFER: Those in favor of supporting this report this year, raise your hand.

MS. BUCK: My hand is raised.

MS. TEMPFER: There are five votes in favor.

We will proceed with this process in place.

The three going forward then for the nominations for the chair this year were Charlene Gallagher, Sarah Hoiberg and Sherry Drew. We also outlined, each person is going to be able to speak for not more than five minutes, on why they should be considered for these positions. The only way I could think to do it in order was to pass out – just pick a number. Is that okay?

MS. BUCK: At this point, I just want to identify Jeff Sconyers as my proxy and I will just text him my vote.

MS. GALLAGHER: This is Charlene Gallagher and I have received number one, so I believe that I am to proceed first.

I have been on this committee for a number of years now. I come to this committee as a health care professional, a lawyer and a mother. I feel that I should also mention that as of this week, I am now a retiree. That aspect of my life leads me to have a bit more time to devote to this committee than I have had in the past. I feel that I would be able to take on the responsibilities I have learned from Magda and other past chairs, can be quite extensive at times. There is an ebb and flow, but there can be days or weeks when it is quite intensive.

I have also during the time that I have been on this commission, listened and learned quite a bit. I have learned to appreciate that there are many different points of view for almost every issue and I have appreciated that there are different ways to solve just any problem. I feel that I have become even more open minded since listening and learning here.

I think that there are a lot of areas on which the entire commission agrees. I think that the individual health of children or adults, who are getting vaccines and the public health impact of vaccines, are overriding concerns for all of us. I also think that we agree that there should be a way to insure safety and the efficacy of all the vaccines that are distributed in the United States. This commission I think also agrees, that all individuals who have suffered injuries due to vaccines deserve fair compensation and they deserve an affective, fair, and efficient process for compensating them.

MR. SCONYERS: Tawny is not connected.

MS. CASTRO-LEWIS: Tawny is not connected. Sorry Charlene.

MS. BUCK: After I gave my proxy to Jeff, I did not hear anything after that. Sorry.

MS. GALLAGHER: Okay, Tawny, I will start again. I drew number one. This is Charlene Gallagher and I am going first.

I am a health care professional, an attorney, and a mother, now I am also a retiree. I feel that I will have the time to devote to the many hours that chair is called upon for not just the meetings but the business of the Commission.

I have been on the committee for a while, and I have had the opportunity to both listen and learn and I believe that I have appreciated the many perspectives that have been presented from the many diverse groups and individuals who have presented to the committee. I have learned that not only are there different perspective on what the issues are, but there are different perspectives on how to address solutions of the issues.

I have also found that I think there are areas on which we all agree and those would start out to be the individual health of children and adults who get vaccinations, and the public health impact. I believe those are overriding concerns for all of us. I think we also are definitely involved in ensuring the safety and effectiveness of all vaccines that are put on the market in

the United States. We want to ensure that there is a supply of vaccines in the future.

Lastly and more importantly for this commission, we share the view that the vaccine injured individuals deserve fair compensation and there should be a system that is effective, efficient, and provides this compensation in a timely manner.

I tend to be an optimist by nature, most of you hopefully have noticed that, and so I tend to see the glass has half full. I have the opinion that this committee can continue to do good work and I think we have done good work while I was on the Commission.

The diversity of the group and the diversity of the individuals who present to us, brings us a diversity of good ideas. I think working together we can accomplish a lot of goals that we share and we can also outline areas of disagreement so we can have further discussion of those.

I think the chair of the Commission is in many respects, an administrative and a leadership position. I feel prepared to assume those duties if the Commission feels fit to elect me chair.

Thank you very much.

MS. HOIBERG: This is Sarah Hoiberg and I drew number two, so I get to go next. When I took this seat on

the Commission two years ago, I was so excited and proud to be the parents/petitioners voice in Washington. I really want to take this opportunity to say that I am not anti-vaccine. I really wish that I could continue to vaccinate my children, but our personal trauma was so great that I simply cannot.

I would also like to remind everyone sitting in this room today, of what we are here for. It has nothing to do with the promotion of vaccines or even their safety. There are other commissions and forums for that. We are here to advise the Secretary of Health and Human Services on the Vaccine Injury Compensation Program. My goal is to make this program more effective. Find ways to get information to those who need it so that they have all the tools they need to expedite their cases.

I have learned so much from my time here and I really feel that I would like to take it to the next level. I value the opinions and experiences that others bring to our discussions. I have served as chair on the outreach committee and participated on various others.

We are always talking about regaining the public's trust, so by having me as your chair it would make this high profile commission, as Geoff calls it, trustworthy. My experience going through the program

brings with it valuable insight on how to make this commission and program the most effective that it can be. VICP was created to compensate families such as mine, so who better to serve you than me.

MS. DREW: Hi, this is Sherry. This commission has been to advise the Secretary as to the running of the program. I have had 20 years continuing direct experience with the program. My constituency is the attorney's who work in the program, many of whom earn their livings that way, and who are also very familiar with the program. I am in contact with those people almost every day.

I believe that I am qualified to be the chair of this program. I have worked on work groups, but all that said, I would like to withdraw my name from consideration as the chair. I would like to run as co-chair. But I believe that we have two qualified candidates here for chair, and I will defer to them. And there is no scandal. (Laughter)

MS. TEMPFER: Everyone should have received a small piece of paper to write their vote and I will collect those.

(Vote taken)

MS. TEMPFER: Charlene Gallagher is the new chair. We will now have a vote for the vice chair.

The people who are interested in voting for the vice chair are Sarah Hoiberg, Tom Herr, and Sherry Drew. Now two of you have already spoken, would you like to speak again?

MS. HOIBERG: No.

MS. TEMPFER: Sherry, did you have more to say?

MS. DREW: No.

MS. TEMPFER: I wanted to give you every opportunity to speak. So Tom, would you like to speak?

DR. HERR: I'm happy to serve if the Commission decides they would like me to serve.

MS. TEMPFER: Short and to the point, thank you.

Everyone should have another small piece of paper.

(Vote taken)

MS. TEMPFER: Our new vice chair is Sherry Drew. That will conclude our report.

MS. CASTRO-LEWIS: Thank you very much and congratulations to the new chair and vice-chair.

(Applause)

MS. DREW: I think Charlene and I can work together very well.

Agenda Item: Public Comment

MS. CASTRO-LEWIS: Okay, after this we move to the public comment.

Operator, is there anybody on the line that would like to make a comment.

OPERATOR: If you have a comment or a question you may press star one on your touchtone phone. We will give it one moment. Excuse me, we do have a question. Paul King, your line is open.

MS. CASTRO-LEWIS: Operator, could you please rephrase that this is a time for public comment and not for questions, please.

OPERATOR: Okay, thank you.

MS. CASTRO-LEWIS: We are waiting for any public comments.

Are you there operator?

OPERATOR: Yes, I am. Did you want to take questions from the phone at this time?

MS. CASTRO-LEWIS: Comments.

OPERATOR: One moment. Paul King, your line is open.

DR. KING: This is Paul T. King. I have only one comment. There is one critical issue that you keep overlooking and that is the fact that there should only be

vaccination programs that are cost effective. That is no longer the case.

You are placing the vaccine compensation program in an awkward position when you continue to do this because you are wasting health care dollars that don't need to be wasted on programs that are not cost effective. If you would like an example, chicken pox; it was approved only marginally, socially, cost effective for one dose. Now you are giving essentially three doses. The last time I read the literature, the excess cost from the excess cases alone is $700 million a year. We know that because we are filing vaccine compensation claims.

Thank you. That is all I had to say.

MS. CASTRO-LEWIS: Operator, are there any more comments?

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

MS. CASTRO-LEWIS: Okay, thank you so much.

Agenda Item: Future Agenda Items

MS. CASTRO-LEWIS: Future agenda items – does anybody have any recommendations for the next meeting.

DR. FISHER: I think we talked about it at length, and I think we definitely want to keep the Banyan efforts on our radar screen and also the outreach group and

any other things that the outreach group is working on. This kind of should be a standing agenda item, at least for the next year.

MS. DREW: I believe it includes a report from the CDC. I believe that Dr. Gidudu mentioned that she would –

MS. CASTRO-LEWIS: Yes, that was a very specific recommendation to have somebody from CDC to talk about what are the efforts to educate the public and the health professionals.

Any other items.

MS. BUCK: Are the June meeting dates right? I am actually back for NVAC the first part of June, but it looks like the ACCV meeting has been pushed to the following week. Apparently my term continues for a while so are the 10th and 11th correct?

DR. EVANS: Yes it is Tawny.

MS. BUCK: I apologize then I probably won't be tripping it back again for that.

DR. EVANS: I understand. I don't know off hand why it could not have been the 4th and 5th but it was probably because of a meeting. The 3rd and 4th, I should say. The Thursday and Friday of that week.

MS. BUCK: It is nice when it backs up to NVAC because then I can stay. If I am going to keep doing this for a while that is going to be the thing that allows me to continue to attend in person I guess. I did not pay attention to the dates because I did not think it was going to affect me. I did not mean to bring it up late but apparently it does affect me now.

DR. EVANS: I agree with you. I saw that there was a week difference and I knew what that would mean in terms of your traveling that huge distance. We normally have it the first week of June, so my hunch is that we could not get the room those two days. We will check again, and we will let you know if it is possible to adjust it.

MS. BUCK: Okay, it is okay if it is not. I just wanted to bring that up. I am doing my best to keep both my commitments on both commissions.

MR. SCONYERS: If you are going to change it, please let us know ASAP.

MS. CASTRO-LEWIS: Any other items for the agenda or anything? Well, I would like to say a very simple, thank you so much to all of you for your support. I really needed it and I appreciate it.

I am just going to pass it on to Charlene to adjourn the meeting.

DR. EVANS: Charlene, before you adjourn I want to thank – maybe a round of applause is in order for Annie and Kay, for the excellent job of putting this meeting together.

(Applause)

DR. HERR: Thanks for the new furniture.

DR. EVANS: The wonderful new furniture, which was not taken out of the trust fund.

(Laughter)

MS. CASTRO-LEWIS: Transparency.

DR. EVANS: In terms of transparency – I am glad you used that word, I spoke with Rosemary Johann-Liang, the chief medical officer, and we are going to put together – she is going to put together, maybe one of her staff, some data on some of the cases and the reviews and some conditions that we are seeing from our vantage point. So we can put that as an agenda item for the June meeting if you are interested.

MS. HOIBERG: I would just like to say that I still have that pipe dream of wanting to meet the Secretary of Health and Human Services and have her grace us with her presence.

MS. GALLAGHER: Can I make one more comment on the agenda? Is the working group going to take care of reporting on the areas where we feel that we can internally improve either the website or other spots that would give better information for outreach or should that be a separate agenda item? I am not clear.

DR. EVANS: Well, the workgroup report can as today's workgroup report was quite expansive, the workgroup is certainly taking this on, they have these two major areas of interest. I would suggest that we see what they come up with and I think that that can certainly be the starting point.

MS. GALLAGHER: And we need an agenda committee to work on the agenda for next time. I can't remember who all volunteered the last time.

MS. CASTRO-LEWIS: The last meeting there was Tom and Meg.

MS. BUCK: You guys have got to keep speaking up.

MS. GALLAGHER: I was wondering if there are volunteers for the agenda committee?

Tom has volunteered and Magda has volunteered. We now have an agenda committee for the next agenda. Thank you very much.

At this point I would entertain a motion.

DR. FISHER: This is Meg Fisher, so moved.

MS. TEMPFER: Second.

MS. GALLAGHER: Okay, all in favor of adjourning.

(Chorus of “ayes”)

MS. GALLAGHER: This meeting is adjourned.

(Whereupon, the meeting adjourned at 11:30 a.m.)