

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEVENTY-FOURTH MEETING OF  
ADVISORY COMMISSION  
ON CHILDHOOD VACCINES

DECEMBER 4, 2009

Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland

Proceedings By:

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

TABLE OF CONTENTS

|   | <u>Page</u> |
|---|-------------|
| Welcome and Unfinished Business from Day One<br>Magdalena Castro-Lewis  | 1           |
| ACCV Outreach Work Group Report - Sarah Hoiberg and<br>Report on the VICP Outreach Contract<br>Banyan Communications  | 4           |
| Adding Hepatitis A, Trivalent Influenza, Meningococcal and<br>Human Papillomavirus Vaccines as Separate Categories<br>In the Vaccine Injury Table<br>Geoffrey Evans, M.D. | 63          |
| Public Comment  | 71          |
| Future Agenda Items   | 79          |

P R O C E E D I N G S

OPERATOR: This is a meeting of the Advisory Commission on Childhood Vaccines. I am going to turn the meeting over to the ACCV chair, Miss Magdalena Castro-Lewis, who will convene the meeting.

**Agenda Item: Welcome and Unfinished Business from Day One, Including Public Comment**

MS. CASTRO-LEWIS: Thank you. Good morning everybody. Welcome to our second day of the 74th meeting of the ACCV. We are going to start with unfinished business from yesterday. We ended the meeting a little earlier, not that we wanted to but it just happened. We probably had all the speakers and people commenting, providing comments so we are going to start with that. Operator, would you please announce that this is the moment for public comments for those that are on the line.

**Agenda Item: Public Comment**

OPERATOR: If you would like to make a public comment on this time, you may press star 1, to withdraw your comment you may press star 2. Once again any public comments please press star 1 at this time. The first comment comes from James Moody.

MR. JAMES MOODY: Thank you and good morning and thank you for the comment opportunity and I apologize that I was not able to stay past four o'clock yesterday. I

would like to talk briefly on the discussion regarding transparency of the data. I was somewhat surprised at the lack of enthusiasm for transparency. I understand there is a tension between those who believe that disclosure of data regarding vaccine injury will scare parents and those who believe the disclosure of adverse injury is essential to protect confidence in a safety net upholding the vaccine program. I would suggest that the data is irrelevant because the program itself, and the general policy of the Justice Department favoring disclosure of all settlements require disclosure. In non-vaccine cases I tried for years to negotiate secret settlements and they just laughed. There is a DOJ policy that the business of the government is always conducted in the public. Indeed they typically issue press releases even in very small cases to announce settlements.

PR under the vaccine program Section 25, speaks of public disclosure of all adverse event data, which for appropriate protection of patient privacy. Section 27 speaks of a commitment to the powers secretaries have to reduce childhood adverse events and that really can't be done properly without disclosure of all of the data again with appropriate protection for privacy surrounding adverse events. Secrecy by its very nature throws gasoline on what is already brewing as a brush fire building against vaccine

and we have seen that most recently this season with the 40 to 60 percent of poll responders saying they are not going to take H1N1 for them or their children. As more vaccines are added to the schedule that situation is only going to get worse.

The highest public confidence is required in this program because parents want healthy children and are as much worried about adverse events as they are about avoiding serious risk from infectious disease. I would urge the committee, in order to protect the confidence that the program does in fact have a safety net underneath it, I would suggest the committee take the strongest possible position favoring full disclosure of settlements, whether they are litigated risk settlements, concessions, proffers, or whatever nature but full disclosure of all data regarding adverse events including vaccine manufacturer lot number and a brief rationale, et cetera, again only with appropriate protection for patient confidentiality. Thank you very much.

MS. CASTRO-LEWIS: Thank you so much for your comment. Any other comments, operator, from people on line?

OPERATOR: Once again if you would like to make a public comment please press star 1. One moment please. At this time there are no further comments.

MS. CASTRO-LEWIS: Thank you so much. The outreach work group met during the last quarter and Sarah did a great job leading the discussion. I am going to invite her to provide us with a report and lead us also into the presentations that are in the agenda for this portion of the work group.

**Agenda Item: ACCV Outreach Work Group Report and Report of the VICP Outreach Contract**

MS. HOIBERG: Good morning, everybody. I wish I was there with you but unfortunately I am not. We did have a wonderful discussion on the phone and were very pleased to have Banyan on line with us, and thank you once again for giving us your time and your expertise. We are in the process of actually as a work group, just sitting back and letting Banyan do their job and doing some research on finding out who our target groups are and then how best to communicate the message of our program.

I did just have actually not even a presentation but just maybe some questions and this presentation I believe, will open up the floor to a very interesting conversation because I think that once again, once we put our heads together and are able to really brainstorm I think we are going to come up with some wonderful ideas in order to help Banyan go along in this process. However, as

far as trying to find out who our target audience, I think we all know who the target audience is and that is the medical community first and then the public. I am very interested to hear what Banyan has discovered in their short time of research and so I am going to go ahead and hand over the floor to them.

MS. HANSEN: If I can introduce myself, I am Merrell Hanson and I am one of the owners of Banyan Communications, the firm that is leading this effort. Today with me, I have two colleagues, Kathleen Souder who is our Project Manager, and Namratha Swamy, Nami Swamy who is a part of Altarum Institute, with whom many of you are already familiar, and she is leading the research part of this.

Let's talk about first what we hope to do today. We wanted to introduce ourselves and let you get a look at the firm. Am I out of order?

MR. SCONYERS: Before we get started, I just want to ask, we had made a request for the contract between the program and Banyan and I wonder if the staff can give us an update on the status of that FOI request.

MS. COOK: This is Kay Cook and since the request was contract oriented, the request did not come to our office DVIC, it went directly to contracts. Contracts is responding to it. I did check on Wednesday with the FOIA

office, and they are going through the process of taking out what they need to take out before they send it to you guys. That was what I got.

MR. SCONYERS: This seems like a fairly predictable request from the Commission. Understanding that it was likely to come, it would have been nice to know that this was an agenda item before we got the agenda because I think both Sherry and I made the request as soon as we saw the item on the agenda. Here we are without the contract. It is difficult for us to relate to this presentation very much without understanding what the scope of the engagement is between the program and Banyan.

My request is that the Commission be given further advance notice than happened in this case, when a situation like this comes up in the future so we can make a request. I think it could have been anticipated that we should have been provided the contract. If you feel like you can't do that then at least give us enough notice so that we can make the request so that we can have it in time for the meeting.

MS. COOK: Understood. We did give a copy of the contract. What we weren't able to release was the response of Banyan on the proposal and that is what the FOIA office is currently looking at.

MS. BUCK: I am sorry. I cannot hear. I don't

even understand what is going on.

MS. COOK: Basically what I was saying was the request did not come to DVIC since it was contract oriented. It went directly to the HRSA contracts office and following up on a telephone call with the HRSA FOIA office on Wednesday, they had gotten the response from the HRSA contracts office and was going through what they could or could not send out on the request. The request was received on November 24<sup>th</sup>, and the FOIA office told me they had 20 days to respond. They were working on it diligently. I expressed that we needed it as soon as possible, but they informed me that they had 20 days to respond.

MS. BUCK: Apparently we have contracted with Banyan to do something but I don't know until now, I have hardly heard anything about this. I am unclear as to why we have hired a contractor at all because I thought the outreach group was still working on some recommendations, but apparently the program has moved forward with doing something and then again, somehow the Commission isn't privy to the contract. Is that what I am understanding?

MS. COOK: No, Tawny. I actually sent out a copy of the contract to those that asked for it. What was not given was a copy of the response that Banyan gave to the proposal request. That I could not give out without going

through FOIA.

DR. EVANS: You say contract. You gave out the RFP but you didn't give out the contract.

MS. COOK: I did. I gave out both. It is the same.

MS. BUCK: Jeff Sconyers, did you receive a copy of the contract because I know that I was on that call and as chair I should have received a copy of the contract.

MS. COOK: Yes. I sent it out to all you guys that were on that email that requested a copy of it. I know I sent it to Magda. Tom had a copy of it here yesterday so I know it went out.

MR. SCONYERS: I don't recall getting it.

MS. BUCK: Is there some reason why the full commission did not get that contract?

MS. CASTRO-LEWIS: I think it started at the outreach working group with that request and probably the good thing would have been to send it to everybody especially when Jeff requested the response to the RFP. It would have been easy to send that too.

MS. COOK: If I didn't send it out to everybody it is my mistake and I apologize. I just sent it to those that asked for it.

MS. HOIBERG: And I didn't receive it. It is difficult to know what is happening. I am still confused

about that.

MS. CASTRO-LEWIS: I think there is also terminology. I don't know if you are calling this a contract. I don't see it as a contract. It is a request for proposal. I think we should name it request for proposal because a contract comes after that. Once the two parties have agreed on something then you have a contract. At this point it was a request for proposal. There was a response. After that there was a contract. We don't have the response and we don't have the contract.

MS. COOK: You don't have the response. The contract I did send out. We did not change anything.

MS. HOIBERG: With the proposal for work or whatever you call it -- I don't even know what the current terminology is but you did not send us a contract.

MS. COOK: What it is the scope of work that you guys received is the same thing that is attached to the task order. The only things you don't see are how they proceed with payments, how they send in the requests for payments. That is the only difference.

MS. HOIBERG: We should know how much it cost to do this so that we can then know - again, it is the IOM contract all over again.

MS. BUCK: My question here is that I thought we formed a work group to discuss outreach and it seems to me

like somewhere along that process that has been a decision made to move forward on something with outreach and that expenditure of money, which is all a big unknown, and I am still a little confused as to why that sort of happened out of the process. The work group hasn't even given a recommendation to the full Commission yet. I guess, Geoff, you can do whatever you want, but again it feels to me as if you are making decisions and moves and expenditure of money before waiting for the Commission to weigh in on anything.

MS. HOIBERG: Geoff told us at the last meeting that they were looking to go into contract, to hire a contractor and we were all excited, at least myself I thought it was this huge step forward, but it turns out as you will hear that it is really not a step forward in any way but to spend money and the same thing that we would be doing then it wouldn't cost you anything for us to give you our ideas. I still appreciate Banyan, and please don't take this personally Banyan, but the turn around and be -- you are going to hand us some information that is going to take you over a year to do.

MS. BUCK: What is the amount? Is this a big secret? Can somebody tell us what the amount of the contract is?

MS. COOK: It was \$297,585.

MS. CASTRO-LEWIS: I think in addition to that what I am most interested in is in seeing what was the response of Banyan and any other companies that responded to these requests for proposal, that made it suitable to meet the goals of this RFP. I guess you are going to talk about that but it would have been very helpful for us to see that ahead of time. I think that is what Jeff and all of us are referring to.

MS. COOK: I agree but that is the piece that has held up in the FOIA office.

MS. CASTRO-LEWIS: How many people have applied for this?

MS. COOK: Two.

MS. CASTRO-LEWIS: Only two.

MS. BUCK: I think that the two doesn't indicate a lack of interest from the rest. I think the two just indicates that the assumption is that they got information they would again distribute it to those of us who need to see it.

DR. EVANS: This is Geoff, Tawny. I apologize for the confusion. I think we tried to do the best we could to get this information out focusing primarily on the work group to begin with, because they were the ones that were charged with advising the Commission on the outreach activities. During the summer, which was the previous

fiscal year, there was a request for proposal sent out. There were some replies to that, and a selection was made and the response from the contractor Banyan, was something that requires FOIA clearance in order to be released.

We were able to provide the request for proposal, which is a public document. We provided that to the work group members at the September meeting because again that was what the primary interest was at the time. You were more aware of the outreach issues; therefore, we had more relevance. We certainly could have provided it for the entire Commission at that time. That was the first thing that we did.

And we then began to set sights early on having Banyan come not only -- excuse me, we had Banyan first of all have a telephone conference call with the work group to advise them on what was going on, and then with the idea that there would be a formal presentation in December. Had we thought there would be interest in seeing the contract and all the releasable information at the time in October, November, certainly we would have instigated if we had asked you to do that. We did not realize or anticipate that. We thought simply by having Banyan inform the work group and later inform the full Commission that that would suffice.

I understand Jeff is expressing some frustration

over not having it available, but once we realize that this was something that was a document that they wanted to have we moved as quickly as possible to have you request it and our understanding is that this should be available later this month and we will make sure it is given to all of you and anyone else that is interested, as soon as it is available. And should there be questions or follow up at that point, that can always be handled either through email or even a telephone conference call.

I want to make clear this is not in any way trying to limit information or not have transparency, this is just trying to go forward in a deliberate logical fashion to put together what are the first steps of a year-long project.

MS. BUCK: Geoff, I appreciate that but we only meet quarterly in terms of a public phone call where people can give public comments so I think the logical thing to do would have to have this information be available to make our public meetings sort of your timeline for releasing information that you know that the public is going to want to look at and comment on. You have set up the separate timeline and that is great, but you really sort of pulled the rug out from under anybody outside of the Commission or even the work group, to give comment on what appears to be a \$300,000 contract to a company to possibly research how

to do outreach with maybe an answer from them in a year. I just think that is the kind of thing that you would probably get some public comment on and I believe that the roadmap that you have laid out for handling this sort of details that opportunity and that course causes me great concern.

MS. HOIBERG: This is Sarah Hoiberg. Geoff, I expressed to you last night in an email how I feel about this contract and what is in my eyes is a huge waste of money. We don't need any research to tell us who are target audience is. You don't need to spend \$200,000 to get an idea of how to go about doing it. We know what we want to do. We want to find out how much it costs to do it. We used to have only \$10,000 for outreach. Well, now we have just spent \$300,000 to pay somebody else to come up with ideas. To me it is just another way to procrastinate, not get the program out there.

DR. EVANS: I think that is a fairly broad oversimplification of what Banyan is going to be undertaking and I would like to give them the opportunity since they are here with smiling faces intermittently, to inform the Commission on what their task is at hand and certainly it is something that is still in a work in progress in terms of being put together and that is why they are here to receive input and make some further

changes and provide this kind of thinking.

MS. BUCK: Before they get started, my real simple question would be for \$300,000 in the next year will we see any change in what is happening or is this a process that is going to wait to hear from them and their ideas before we get going.

MS. HOIBERG: They will have nothing but ideas. There will no hard copy product of anything that we can purchase from them. It is just ideas, Tawny.

MS. CASTRO-LEWIS: I think Jeff would like to hop in.

MR. SCONYERS: Just on the process side just one more time. I think it is easy to anticipate when there is an agenda item that says report on the VICP outreach contract that the outreach contract would be a matter of interest to the Commission. To time the agenda that came to us in a way that it was impossible to get a request in 20 days in advance so that the contract that is the topic of this discussion, this hour long presentation, the biggest item we have on our agenda in two days can't be provided shows at least a failure to anticipate the role of this Commission.

The only thing that I would request is that we have pages and pages of slides here. It is clear that these have been prepared in advance, but we are handed them

this morning. There is a lot of meat here. We are going to be unable to interact with you in any meaningful way. We are going to be talked to, not with. It would have been a courtesy to all of us to receive this ahead of time so that we could have read and digested it and be somewhat intelligent about the presentation we are about to hear rather than being passive recipients of it. Another thing that I think could have been anticipated.

DR. EVANS: We apologize for not being able to get it to you sooner. I think that based on this past year and contracts, I should anticipate that any future contracts we will make sure that the proper FOIA requests are put into place ahead of time.

MS. CASTRO-LEWIS: I understand it is a HRSA contract but it is something that has to do with the ACCV. To what extent the ACCV should have had or at least the outreach work group has some input in the decision of who will get the contract revision stated.

DR. EVANS: Magda, we have explained this and we will explain it again. That is not appropriate. That is not the way HRSA contract systems work. You advise the Secretary, but in terms that we certainly understood your interest and priorities, but the decision making in terms of putting an RFP out and the decisions that flow around that are internal.

MS. CASTRO-LEWIS: There is a straight line but I think there are points that could have been clear. Sarah or Tawny, anybody had any other comments before we proceed with the presentation?

MS. BUCK: No, I am done.

MS. CASTRO-LEWIS: Okay. Thank you.

MS. HANSEN: I would tell you that we appreciate your comments Magda, Sarah and Jeff. As we go through this one of the things that we are going to propose to you, you guys are going to be a good resource for us. As we put information together, we are going to call on you for advice throughout this. We planned a time when we can talk on a quarterly basis and on an as needed basis beyond that. What we don't want is a tell discussion to what Jeff saying we do. We would like to interact with you guys very much. So whatever we can do to facilitate that please know that we are very open and would like to do that.

The other thing, what we are presenting today is sort of a top line of what we submitted and that you would read in our proposal back to these guys. Hopefully that will give you a good idea of that as well. We encourage your questions along the way and let's just jump in.

What we are going to try to do today is first give you an idea of a little bit about who we are, who the people with whom you are working are. Then we are going to

talk through what we will be doing over the next several months. We are going to present a timeline sort of what we are all about. And again like I say we are looking forward to an open dialogue as we go.

MS. SOUDER: I just want to jump in here. I know the people on the phone have the print outs of this presentation. If at any point you are confused about where we are, we will try to direct you to which page we are on but please jump in and let us know.

MS. HANSEN: We moving from the agenda, the project team slide here connotes that there are two firms represented: Banyan Communications and the Altarum Institute. The Altarum Institute we love partnering with them on this and brought them into our program because they are familiar with. Namratha is going to talk more about that in a little bit.

The next slide has the names of the three people who are with you here today. Myself. I am Merrell Hansen. I am the Project Director. Kathleen is our Project Manager and Namratha who we call Nami. She is our evaluation director for research. That might help you direct questions as we go.

Now we are on to a really simple -- and I'm going to skip through the slides that are sort of what I would call just outline. This is just a structural vision of how

our team will be working together. I also want you to know that we are truly working as a team. There is no one person who will have a heavier footprint in our recommendations or the research that we do and I think you should be pleased about that because it will allow our ultimate recommendations to be much more robust, rich, and not aligned from one person's point of view. The thing that we want to be careful throughout this is each of us has a passion and is deeply interested about the work that you are doing. What we can't come back is with recommendations that are from the perception of my point of view or Kathleen's point of view. We have to make sure that what we pull back is a representation of the people with whom we are going to speak and we can't operate under the presumption that we know what they think or what will create the most meaningful response to what we are going to give to them. I think that is the very helpful voice in the research.

Banyan as you can see from our slide we are 15 years old. We are a firm that has come from three partners who previously worked in the private sector. We came together for the express purpose of working on government and nonprofit projects, those that have more meaning to them. We are going to talk about those in just a second to give you several examples because I think what we have been

able to do for the past 15 years is take some really complex and sensitive issues and deliver those messages to the general public and specific population groups and really gotten good results from that. One of those actually happens out of DHHS from HRSA itself on organ donation. Kathleen is involved with that project right now so I am going to have her take just a couple of seconds to describe to what we are doing.

MS. SOUDER: Just to reiterate what Merrell said. A quick little walk through the projects that we work on currently might help you guys just understand our perspective and how we approach projects that involve messaging to large groups of the public. It involves some sensitive issues. This organ donation project we work with the Department of Transplantation out of the Department of Health and Human Services, specifically to Health Resources and Services Administration. I serve as the project manager on this contract as well and we are tasked, Banyan, with communicating with the general public, specific groups, some older generations, younger generations, and then people of multi-cultural backgrounds about the importance of organ donation. Our goal is to increase the awareness and to hopefully increase registration as organ donors. We are taking some potentially controversial issues at least issues that are certainly misunderstood

within the general public at certain times regarding the organ donation and translating that into really meaningful impactful outreach in a variety of ways.

The Boys Town National Hotline just to kind of quickly run through this. It is a nonprofit organization. I am sure a lot of you are already familiar with if you watched Boys Town, an old movie. This is one and the same. We work with the national hotline, which is their call center for teens and for children and for parents and for families. They deal with a number of very sensitive issues from family violence to depression. We get calls for suicides. We get calls from parents for crises and children in crises. What our job is and has been for the past 15 years is they are one of our oldest clients is to promote hotline to make people across the United States aware of it so that they will use it in a time of need.

MS. HANSEN: I would add to that that we worked as a strategic partner with them and really grown their impact into the American public. We have watched them evolve in messaging for the general public. The fact is it is an evolving sort of iterative process to be effective and it starts at a place and then it moves forward and you evaluate what messages and the mediums for the message, which are impactful and make a difference. That is what we have been able to do with Boys Town.

I would also move forward to the next slide, which is a project we are doing for CDC. We have created a training website where people can go who need accreditation or not but we are dealing with areas of child maltreatment, intimate partner violence, domestic violence, youth violence within this. It is from a very different perspective. It is all about violent prevention, which may sound very obvious but it is something sort of new to the general public and to the people who work in these fields. Our point in bringing these up would just be to give you an idea that we want you to be very comfortable that we are a vendor that understands reaching out to people with sensitive messaging. This is one that will be a tricky message to get out into the public and having the right impact that we want to have.

MS. SOUDER: I will just one other because I think it is especially relevant. The next slide, the National Cancer Institute, we were tasked with conducting outreach to a specific target audience. Like this project we know the target audience but what we were tasked with is finding out more of their information gathering behavior so that we could construct strategies and messaging that reach them where they were. Reach them where they were looking for information and reach them at the point in which they decided to look for information. There is a little more

background on that slide if you wish to look at that but not to belabor the point, we can move on.

MS. HANSEN: I am going to let Nami talk for a minute about the Altarum Institute.

MS. SWAMY: Hi everyone. It is really great to see all of you again. I appreciate the opportunity to be working with Banyan and with all of you again. I am just going to remind you about a little about Altarum Institute. We are a nonprofit health systems research and consulting organization. We have done research whether it is conducting needs assessments, formative research involving focus groups, and literature of views, and environmental scans, survey research for just a broad range of clients at the federal level, the state level, and at the local level. What we value and what we are committed to is providing a sound foundation of knowledge in order to effectively inform decision making whether it be program development, health communications campaigns, policy, and policy change. For several divisions within HRSA, NIH, CDC, and SAMHSA we have extensive experience doing this type of research. We are really looking forward to working with you, again, basically building on the petitioner satisfaction survey report that we work with you on. And if you recall one of the recommendations was to further the outreach efforts for VICP. We are so excited to be working with you and moving

that recommendation forward.

MS. HANSEN: Now we are going to take a look at the project. I think the genesis of all this ties back to the legislative mandate specifically the National Childhood Vaccine Injury Act states that the Secretary shall undertake reasonable efforts to inform the public of the availability of the program.

The goal of this contract was ultimately the creation of a comprehensive outreach and marketing plan for the public and healthcare providers. That is the basis for all of our recommendations.

Whenever we work with a project we want to make sure that our teams and everybody that we are all on the same page and one of the things that we look to is to say at the end of the day how will we know that we have delivered what you all need and were said to make the next steps.

In this slide, the slide that we are on now is one that we have titled measurements of success. We have narrowed those to three points. One is that the plan that we make a recommendation about will it accomplish the goals of that legislative mandate that certainly DVIC is satisfied with the scoping content of the research plan and that the marketing and outreach plan at least exceeds the expectations of what they had hoped to do.

Let's move on to the next page. The other thing that we try and very carefully take a look at whenever we work on a project like this we try to immerse ourselves in the issue so deeply that we could say golly we can just jump into this, move forward, do our research, but first let's think along the way what are the unique propositions, what are the areas that we need to be carefully mindful of so that we can uncover everything that we need to make the right kinds of recommendations. A lot of people jump into research or marketing and outreach efforts without doing that and sometimes that just doesn't work. We recognize that ultimately once we need to be -- once this effort goes out into the field and starts to touch the target audiences that we all know exists it needs to be right on. It needs to be using words that resonate with those audiences. It needs to accomplish the goals that we are after.

This slide where it talks about the challenges we really wanted to focus on that. One of the big things that we know in messaging we have to be sure that whatever message goes out to the population that it doesn't discourage people from vaccinations. That is a big issue. We have to be sure that we are just telling them about the availability of the program. In order for us to accomplish that we have to learn a lot about how our audiences perceive messages, where they are, how to reach them the

best to be efficient with the taxpayer's dollars.

I am going to move on. The marketing and outreach vision slide that we have in front of you while it takes a pretty top line approach about what we are all about, I think it really hones in on our approach to this. Our experience, which is pretty deep in these areas, has shown us that again research plays an absolutely invaluable part as much as you can know about any issue. If you don't step back and look out and reach to the people that you are trying to talk and reach to have the best impact using the right words that you can take a step off the wrong way. The research that Nami and that we will be partnering on will tell us a lot about our population and health care groups, what they know so far about vaccinations, what motivates them to get vaccinations, the barriers, where we can reach them. Are we going to go through the Internet to get them most efficiently? Will they be using blogs? We will be using conventional television. It will help us derive to those ultimate answers so that when we create this recommendation, it will be really efficient. It will use dollars effectively and there will be no waste in that.

We also -- our experience shows us that to be really effective in any sort of an outreach and marketing campaign, you have to touch people on a lot of different layers. Ideally you talk to them one on one as the

individual that they are through the people that influence them, their parents, their other parents, their health care providers and what not, through media messaging. This slide sort of gives that imagery. They call this a Social Ecological Model. It is a very interesting approach and it is most effective to have a good, long-term and ultimately iterative way to speaking out to people.

Again, the next slide, which is marketing and outreach, the vision. These were sort of our top line goals with this campaign. We want to make sure ultimately that we recommend messages that inform that don't deter that will include consideration for the tone of voice we use, the content and the messages. It will have to be -- the message will be able to be adaptive. It will evolve. It will be used in traditional media, television, radio, outdoor boards and the like as well as in new and emerging media. It's not out of the question to think part of the recommendation might even be the use of cell phones. A chunk of the population base now that it would probably be served by this is going to be best reached through their cell phone. It will be a unique proposition in the way that we recommend --

We believe it has to have a long shelf that is practical because we are using taxpayer's dollars and also that just needs to be the way it is.

Again the communication channels that we recommend to you will be born of what we learn about where our target audiences are, what they watch, what they view, with whom they speak, who influences them. And again this consideration for evolving the message as conditions alter even -- gosh I think if we went back three or four years ago there wasn't such a thing as H1N1. Clearly all these issues change as we move forward.

Now we are going to jump into the project plan. I am going to hand this over to Kathleen so that it's not just my voice.

MS. SOUDER: A lot of this once the solicitation or the response to the solicitation is in your hands. I think you will see a lot of our presentation today will echo that very closely, obviously this being a very top line version of that. Our overarching approach to this project as Merrell has said. Our first phase is to really live in the information gathering stage to identify research outlets, to gather the resulting research and then synthesize it into a really comprehensive report. Not so much -- obviously we will be responding to the contract as far as knowing our target audiences have been already outlined but looking into the what, the where, the why, and the how that they seek and how they gather information and how they I guess wish to find out about this program.

Our second phase will be to actually will be taking that research base and moving that into a strategic point will be identifying all of the optimum strategies, outreach, communication tactics that will achieve the overall project goals.

And then the third phase is a reporting phase. We will be bringing that back to DVIC and giving them our recommendations providing hopefully if we have done our job well a really solid and effective blueprint that can be used in future years for that actual outreach piece.

MR. SCONYERS: A couple of questions on timing. It looks like your final report is next September after this Commission's meeting in September. Is there going to be any opportunity for this Commission to have any interaction around that report since it won't be presented until September?

MS. HANSEN: That is a great question Jeff. When we get down here a little bit later you see that minimally we have called out four times that we would talk together. Certainly there would be events beyond that that we hope to be able to engaging folks through conference calls. I don't think it is practical that we will all fly in together but certainly do that. What we have done is taken your regular quarterly meetings and we have backed up a week or so before that and called out dates where we hope

to get everybody on the phone. What we would share with you at that point is say here's where we are now, here's what we have uncovered. We get your feedback and you would be able to inform where we are at that point. We look forward to continuing to communicate not just at the end of this but minimally those four times throughout.

MS. SWAMY: I would like just to clarify. At a minimum I think we would like to engage with outreach, which we have agreed to quarterly several weeks before each quarterly meeting for the ACCV. I don't know if it is possible for all of us to convene.

DR. HERR: I guess my question, this is Tom Herr, is on the final presentation where you are going to present your final planning of DVICs. Is it possible to move your timetable up a couple of weeks so that you can make the presentation and then you can come to this Commission with what the proposal is and then we can make some comments on it? I know it is DVIC's decision of what they are going to do on the contract but whether we can get a final response or make some comments on the final product rather than gee okay you had some thoughts and now there is a final product and now it has been given to DVIC and now you get often rolling but just a chance for input and higher implementation.

MS. HANSEN: Absolutely. In fact what we do

we'll first put together what we will label as a draft report and I think it would be great to get that out in your hands specifically the work group and everybody whatever Kay and Geoff direct and then we would love your feedback on that. Absolutely. That would be several weeks prior to the final meeting. I'm not going to go to the detail of the schedule now because my eyes aren't that good.

MS. SOUDER: Phase III is extended. It says July 3rd through September 14th and I think the reason that is so long is to walk through a draft phase so we won't be just presenting the final one. We are not going to be in a corner doing our work and then it is the final presentation. It will be definitely an iterative process with feedback along the way.

MS. HANSEN: And not just iterative but I would say this is a very collaborative effort. We do all this homework and we present our recommendations. Our recommendations will be based on our findings but also our experience over these last oh so many years and what we have seen to be successful in marketing and outreach. We will look to you to advise us all along the way certainly as Kathleen has just said particularly in phase III when it sort of not just stuff it's all come together.

MS. DREW: This is Sherry and you just said that

you are going to present to the work group several weeks before each meeting. I am just wondering if it would be possible for you to present to the work group and then also make a brief presentation to the ACCV via telephone at each of our meetings because I think there is very broad interest in this.

MS. HANSEN: Absolutely. If you have room on your agenda we would love to.

DR. EVANS: We will do our best to squeeze you in.

MR. SCONYERS: My other question has to do -- I see that the final plan as presented in September of next year, which I have to assume misses the federal budget guide deadlines for FY11. This means as I assume it that there is going to be assuming and this is a huge assumption that the program accepts the plan. There won't be any funding for it for another year.

DR. EVANS: Glad you asked. Now while I'm not at liberty to talk about the president's budget, the fiscal year 2011, I can say I think I can say this. HRSA has shown that this is a priority by making available \$300,000 for this contract and others have pointed out far lower sums of money have been utilized over the years for outreach but I think that this represents new thinking in terms of the kinds of activities we want to put forward and

the reason that such a generous contract is being put together with this kind of expertise is because we want to do it right and we want to begin to expand the nature and the kinds of activities we have and have some science and evidence based approaches is part of that. I don't have figures I can share. I can certainly say that I expect that there will be a much more generous allocation of funds in the new upcoming budget and we will certainly be able to do portions of this outreach plan utilizing the additional monies.

MS. BUCK: This is Tawny. Just to clarify. The deliverable on this contract, this \$300,000, is just a plan in a year from now on what to do. We are still a year out from actually implementing any kind of outreach and for that investment and money the deliverables is a year out and it is just that the plan. Is that correct? And then we are supposed to take your assurance there in your last little statement that there will be funding to back it and implement it and that is about what we are getting this morning.

DR. EVANS: I am hopeful with the superlative product that I am expecting out of this, that we will be able to justify greatly expanded activities for the years to come.

MS. BUCK: You have to understand that from just

a regular person perspective, Geoff, this seems outrageous. This is an extraordinary amount of money to a contractor that quite frankly, we have used before and no offense to the contractor but the customer satisfaction survey was at a 100k that went out the door that didn't give us anything to work with. I realize that I'm not involved in the federal system and that you have a lot of things you got to do and hoops you got to jump through and all this, but just from waking up at 4:45 in the morning and toss this at me perspective, this is just craziness. On the record as the Commissioner I am just having so much trouble - compared to the kind of money that you have prioritized for outreach in the four years I have been on this Commission this is a mountain of money to just deliverable a year out which we may or may not make that deadline, but up to this point we have never actually made a deadline, to just put a plan in place that we hope there will be a financial climate within the administration that may or may not give you funding to implement it.

A person who is just your regular old taxpayer who is struggling with all kinds of issues, I'm just sitting here just stunned at this process. I appreciate what the motive behind it is. I appreciate that you are finally giving some acknowledgement to the importance of outreach, but perhaps it's just a federal bureaucracy back

there but the way to go about it to me is just mind blowing. I don't see that this allocation of funds to this process being efficient or useful. If it is just what you got to do to do it then that's not your fault. That is just the fault of the way system runs. As one voice out there I am just really rather stunned at what is going on this morning.

MS. HOIBERG: Tawny, this is Sarah. I have been dealing with this for I guess the past two months now, that I have this sitting on my desk and looking at it and not understanding. So much money is being spent. I am just going to echo what Tawny said and I said it before Geoff, I want to see something at the end of this next year that we can say okay, we'll buy it. We'll do it. It is absolutely astounding amount of money to end up with really just an idea. Three hundred thousand dollars, we could do a lot with \$300,000.

MS. BUCK: Previously our line item for outreach has been 10 grand. So anybody who is listening on the that hasn't walked the path with us for a while, the \$300,000 to a contractor to study outreach when 10 grand has been your line item for years on outreach, that is a significant shift towards making an importance here with outreach, which I think things could be a meeting's worth of questions as to why this significant change in priority on

funding for outreach, what your intended vision is for this. Like Jeff Sconyers alluded to earlier, this is our biggest item on our agenda on the second day, which typically is very poorly attended, with no meeting materials prior to it. I think quite frankly, we could have a full meeting about the change in priorities and the significant change in priority on this topic on your expenditures on this topic and sort of the vision for where to go. So it frustrates me to have it being put at this point. I just feel like this train has already left the station and this work will go on clearly without us with maybe a few opportunities of input probably not during our public meetings, for a deliverable that may or may not be met in a year out. As an outgoing Commissioner I have a lot of difficulty with all of that and the way that is being presented.

MS. TEMPFER: This is Tammy Tempfer, another one of the Commissioners. I just have a couple of comments I would like to make. First of all, I think the addition that Tawny brought up the point about the petitioner's satisfaction survey. That was something that we asked for a couple of years ago. That was really the Commission's idea and I think the program was very helpful in going forward with it and I know it cost a lot of money but that is the nature of the beast, and I think we did it the best

way we possibly could and did not get as much information back as we would have liked. My understanding was because we didn't get their response we would have liked from its many petitioners as it was sent to. I think it was a good process and unfortunately we didn't get the results that we had wanted. I think that should go on record that that was something the Commission asked for and we got.

MS. BUCK: To counter that, the Commission asked for some sort of a tool to gauge customer satisfaction. My understanding was that the General Accounting Office required the program to expend a certain amount of money because they were failing on that point. I believe those two pieces came together conveniently at the same time, but in terms of the tool that this body that I was on was asking for and what we got as a deliverable were very different. I believe that is because the decision to spend a hundred grand was being driven from a requirement from an audit and not because these Commissioners here on the ACCV made the recommendation.

I believe if the audit had not happened and required this program to gauge customer satisfaction, I would question whether or not \$100,000 would have been spent on that contract based on just Commissioner recommendation.

DR. EVANS: I just think it is more useful to

look forward and we are undertaking a project for very appropriate reasons to try to come up with a series of evidence-based activities because it doesn't make sense to spend \$10,000 if it's not effective. It's not the amount of money we have been spending, although I certainly would have liked to have spent more. But we are in a situation where the budget as you understand as the Commissioners know now, has been significantly increased over the past two fiscal years. We are in a much better position to go forward with an ambitious communication plan. But to do so and to have HRSA's communication office approve these kinds of activities, we need to show them that there is scientific validity to a whole series of approaches and that includes validity of the kinds of instruments that are used to communicate information. And in terms of target groups, yes, the big picture target group or health care providers in the public, but there are dozens and dozens of interplays below that in subgroups and frankly there is a lot more information that we need to understand about how best to provide vaccine risk communication as an activity going forward.

In my view this money is very well spent and I think that it behooves us all to take a deep breath and let's see what kind of process and what kind of input and activities that go on over the next nine months, as we try

to make the most of this opportunity.

MS. CASTRO-LEWIS: Tammy, did you have another point?

MS. TEMPFER: I wanted to actually finish the presentation but it is kind of the same thing I guess that Geoff just said. I am really glad - we made this a priority in our Commission and I am really glad that now we are seeing this kind of presentation with this depth because I think it is going to be a very rewarding expenditure.

MS. CASTRO-LEWIS: I do have one more question in terms of the process in the next couple of years. Let's say in September we have a report from you with ideas on how to proceed. After that we cannot do this before because we don't have your ideas, there will be another RFP out there for how to implement these ideas. How long do those take? How long is this process? Are we talking about another year, two years into this Geoff? What do you see ahead?

DR. EVANS: Can I postpone answering that question? I would like for time to pass and see how things play out. I don't know the answer of that right at the moment.

MS. CASTRO-LEWIS: We are going to have the report that we don't know what we are going to do with it?

DR. EVANS: No, I am saying that I don't know in terms of the budget and in terms of planning and putting together another contract or amending a contract, I don't have insight into those kinds of answers at this particular point.

MS. CASTRO-LEWIS: At this point we will have the report in September and that is about it. Okay, so please continue.

DR. EVANS: That's not what I am saying and would you like me to repeat what I just said a minute ago and that is that this is a wide range of evaluations and research is going to be part of this, and we will be following this along and we will be planning for the next fiscal year as we are doing it and the kinds of activities we can do. I'm not saying that nothing begins prior to the final report. Obviously we will be having drafts and we will be thinking about the activities that we can begin to put together. It's not all or none Magda, but I just can't give any more specifics than that at this point.

MS. CASTRO-LEWIS: Thank you, Geoff.

DR. EVANS: You are welcome.

MS. HANSEN: If we move ahead, the next slide that we have included mentions exactly what we have been talking about, the advisory panel and this includes and is headlined by the work group from within ACCV. We have

called out the dates here where we minimally hope to get together February 24th, June 2nd, August 24th, and November 23rd. We will rely on Kay to help us facilitate those conversations. Along the way in between those times I am sure we will be calling you guys out for additional information and advice and guidance as well.

I think it would be a really good time to take a look at what exactly we are doing inside the research part of this. Sort of what Geoff was alluding to a minute ago. The task of this is reaching this sort of ginormous hunk of people in our country, the general population as well as health care providers and our country and the people that we want to talk to with these messages. We are a lot of different kind of people types. I don't doubt that this is parent, grandparent, and people of different ethnicities. It is just a very diverse group of people that we will be reaching. It is imperative that the information that we get from the research really guides us in the right kinds of recommendations so that we don't waste the money once we all move forward.

I am going to hand this over to Nami and let her walk through the formative research if you will. Your voice is a little softer so you might need to --

MS. SWAMY: I actually am distributing a summary docket, eventually an overview of our research plan and I

believe it has been emailed to the folks on the phone and it is called the research plan overview. I am just going to start off what our goals are for this particular phase in. Like I said earlier and Kathleen and Merrell also have mentioned this that we really want a sound base of knowledge to build an effective communication plan off of. That is our goal. There are several components of our research strategy. First is the literature review followed by an environmental scan, a traditional environmental scan, followed by an online environmental scan that really takes a look at our user generated discussions that are web based and also primary data collection that will include focus groups and perhaps key informant interviews.

Our objectives are essentially to better understand our target audiences. We understand that the general public needs to be informed about the VICP. We understand that health care providers are also a target audience but we want the literature and our research to verify that. We want to better understand their behavior patterns. What information sources do they turn to for medical and health-related information but also who are their trusted sources for information about vaccination and vaccination injury? What are their current attitudes and perceptions about VICP, about vaccination, about vaccine injury? How can we best engage them and communication with

them and what is the most appropriate messaging? What types of language do we need to use? Depending on the specific demographic and socioeconomic groups all of that is going to be taken into account. The research is going to be very broad. It will start with our literature review, which will use sources that include peer review journal articles, technical reports that have been produced by federal agencies, state agencies, local entities, also perhaps expert panel proceedings, and maybe conference presentations as well. It is a very broad scope of research that we are looking for at this point trying to establish a sound base at this point.

We are going to use information that we get from the literature review to help inform our traditional environmental scan. The sources for that component of the research are slightly different. We are going to be looking at what news outlets are saying about VICP, about vaccination, about vaccine injury. What are advertisers saying about it? What are magazines saying about it? What types of articles are out there discussing this issue? What books and book chapters are out there talking about this? Because we want to understand what complementary messages are out to what we are trying to do but also what competing messages exist as well. We have to better understand the environment in which we are trying to

communicate.

Kathleen is actually going to be talking about our online environmental scan. This is a very exciting aspect of this work and I think it is a very nice complement to the traditional research components of environmental scan and literature review.

MS. SOUDER: We will be heading up the online environmental scan. I am working really closely with Nami to complement what we are calling the traditional environmental scan. This online environmental scan I am going to go into a little bit more depth because I think it might be something that you guys are not quite as familiar with perhaps. With the blossoming use of digital media and user-generated content in the past few years this type of research has been really helpful for the construction of very detailed and very effective outreach campaigns. If you recall the National Cancer Institute slide we have done a lot of online environmental scan for their division of tobacco cessation specifically as I said to outreach to pregnant smokers. The information that we were able to find complementing the traditional forms of research was absolutely "revelatory" and I use that word in quotations because it was the feedback that we received from a lot of behavioral scientists at NCI who had not yet looked into this area of research to inform their outreach messaging.

What we are actually doing is we're not looking at the traditional news outlet and journal articles and news items but we are looking into the user-generated response to those. While the traditional may look at as I just said all of those, we are going to be looking at the response to it.

Comments on news items. If you have looked at the New York Times you have seen often times in the hundreds of comments and really robust discussion and we feel that since our outreach at the end of this will be geared towards the general population, it is really important for us to take into consideration their feedback and the discussion past as we call it.

We will be looking on online forums and message boards. We will be looking into blogs, microblogs, and user-generated media sites. We will be looking into social networking groups and book marking sites and even into Wikis. A lot of these words I'm sure you are familiar with as some buzz words of the digital generation but I can't emphasize how important it is for us to go there because often times our target audience that is the first place they look for information especially around health decisions and even into vaccine injury or at least into making decisions about vaccine injury compensation. I just wanted to pull out a quick example. As I said I'm going

into a little bit more depth because it might not be something you are as familiar with and I think these examples really highlight what types of things we will be looking in to.

I am sure you guys are familiar with a very recent article that came out last month in the *Wired* magazine about vaccine injury and what they call the epidemic of fear. What I want to specifically point out is this piece right here, 433 comments at the time that I took this screen shot, which was I think, a few days after --

PARTICIPANT: You might reference the slide for the people --

MS. SOUDER: I am on the online environmental scan example section of the presentation, 433 comments. I think this was about three days after it had been published. This is considering that the comments would only be made by those who actually had to sign in and create an account. Just to underscore how robust and the conversation resulting from this type of publication can be. If you go a little bit deeper as many of you may have, the comments and the discussion are incredibly detailed.

MR. HERR: Just as an example on this one particular slide, there are a lot of people who will look at something but not make a comment. Do you have any idea on the ratio of hits to comments?

MS. SOUDER: We don't own the analytics for a site like Wired. There are ways to estimate it not to get maybe down into the really detailed. I am actually glad you brought that up because a lot of our environmental -- this online environmental scan will be focusing on qualitative data and quantitative data. When we go qualitative we are looking at anecdotal, that conversation, what we call conversation mapping, how perception will evolve because of what is posted online and how people interact with that. The quantitative data is really interesting and I will actually show you an example of that in a little bit. Search engines that we have access to are really robust so we can map the amount of mentions of certain key words, even the name of the division. We can map engagement. We can map perception. We can map passion. We can map influencers. We could track back to the nodes that actually are disseminating most of the information. We can do some of that quantitative stuff that you just mentioned. For this specifically I'm not sure of that ratio if we can really gather that but we can close to understand some of it.

Some search data we are privy to relative search volume for different key words within this topical area we can look a lot at what key searches are rising compared to others and get that public pull some. Even mapping to

geographical area, mapping to a certain data, tracking that against maybe a news item that was just released and seeing how the general population interacts with that.

MS. BUCK: This is Tawny. Are you just using a *Wired* article as an example of a place where there has been passionate response? That is a hot article to bring up and -- it is going to make a lot of people nervous in terms of communication reference to those articles. Even that alone is probably going to cause a whole lot of person heartburn if they don't pay careful attention to how they are using that.

MS. HANSEN: This is really a good point because we're not using the article at all. What we are doing is looking at how many people read that, how they respond. This is how we are learning about -- these are some of the people that we have to reach when we build our recommendations for the outreach and marketing plan. We want to see where they go. Like Kathleen is saying, this information from an online scan is useful because it tells us the smart way to build an online messaging campaign.

MS. BUCK: And I understand that. What I am just saying is even in your messaging -- it is a little bit like referring to the National Enquirer in terms of using a lot of gauge response. I am afraid that people listening in or -- or may look your records to the *Wired* article and start

really flipping out.

MS. HANSEN: I understand it is a really sensitive topic.

MS. BUCK: It is a sensitive topic but the article that you referenced -- it is not reflective of a lot of the conversation that goes on -- that there is going to be some push back on that. When you are talking about doing these online scans and those kinds of things, I would just request that you be really sensitive to that when you are referencing what you are looking at. I understand the context you are using because I am listening very carefully but maybe other people aren't. That may be a problem.

MS. HANSEN: Two points come to my mind. This is the kind of input that we love to get from your guys. There are other examples and I think Kathleen should move on to those so you can see the depth of what we are looking at right here. Let's proceed.

MS. SOUDER: I just want to highlight. We are at the very beginning stages of the actual research. This is more just examples I pulled in preparing for this presentation. I would say it's not at all an accurate reflection of actually where we are going and where are looking. Obviously this is being considered but the bulk of the research has yet to happen.

I just wanted to show you a quick other few

examples just to underscore how our potential target audience may interact with media in order to find information and how looking at it is definitely consideration of ours. So just a simple YouTube search into vaccine injury the top hit was the slide that you see here and then the comments below. Looking at that could give us insight into perceptions or misperceptions about this topic matter.

Twitter and I am sure you guys have heard a lot about this. Again, I did a really quick cursory key word search. This was vaccine injury compensation and the volume of discussion around this exact key word was quite robust when I pulled this information. Just took a simple screen shot just to kind of highlight that these types of discussions are occurring in great number and these types of user-generated content areas.

This is kind of a reference to the earlier comment about the actual quantitative data that we can pull. There is one mention of vaccine injury compensation program every seven hours on average. That will obviously change day to day sometimes. This is important to note that this search was done exactly as it appears. In quotations using the Boolean terms so we can really make very -- carefully see that that exact term and people are actually discussing that.

As I kind of hinted at earlier the research outcomes of this is that we can construct an online data map and see how people are discussing this and who the influencers are followed by conversation and then hopefully put a finger on the pulse of how people are gathering information about this topic and other related topics within the online digital space.

MS. SWAMY: Based on the information that we obtained from the literature review and environmental scans we are going to delve even further and get the first hand feedback from our target audiences through focus groups. What we are attempting to do is essentially verify what we have learned through our environmental scan and literature review, but also uncover any additional information nuanced to the information that will really help us hone the messaging that we will produce in the plan. It is critical. We understand how important it is to hear from our target audiences themselves. There are several focus groups that we are expecting to conduct I think in early February or March based on the information that we uncover through the environmental scan and literature review.

We also want to let you know too that we will be interacting with subject matter experts that we are in the process of identifying now with DVIC and perhaps conducting key informant interviews with them. These could be

researchers who have conducted surveys of parents about their attitudes of vaccination, vaccine injury, and VICP on a broad range of issues. They along with the work group members and all of you we are really looking forward to all of that feedback based on all of your experience, your wealth of experience with this particular topic so that we can really get it right. Get it right the first time.

MS. CASTRO-LEWIS: I have a question in terms of the focus groups. How many focus groups have you planned? Where are they going to be? How are you going to select the populations that are going to participate? What are you doing to insure that we have the diversity or diverse populations in all the groups?

MS. SWAMY: There are five focus groups that are planned at this time and depending on the locations we have estimated cost based on conducting focus groups in Atlanta, St. Louis and DC, three cities at this point. Now that is for planning purposes. That doesn't mean that those are final. Those are cities are being discussed at this point. And based on the literature the research will really help us determine which cities we should actually conduct a focus group and which target audiences we might need to spend more time with. Perhaps we conduct two focus groups with parents, two focus groups with the health care providers, and one with the general population or some

combination of that. But the environmental scan and literature review research will help us determine who we need to be communicating with during those focus groups and in which parts of the country we need to be conducting the focus groups in.

MS. HANSEN: And to some degree what will be communicating with, what we are going to seek out in every focus groups too. Each phase of the research sort of informs the next. It will also let us know where we need to pick up some of the more diverse groups of population that would be harder to just reach out more easily. That will sort of evolve from the other research that we will be doing if that makes sense.

MS. CASTRO-LEWIS: Yes. I just want to be sure that when you do the research and keep in mind all the populations. It might not be the same kind of result for the white and Hispanic whites and et cetera.

PARTICIPANT: We are very aware of that.

MS. HANSEN: The next slide that we have up is just sort of a summary that says at this point -- this is one of those benchmark points and we will be taking the literature review, the environmental scan, the online environmental scan and all those primary data collection pulling it together to create a final report. This is one that you guys will all see and we will look forward to your

comments on it and what not as well and then we will present that to Kay and Jeff and everybody and that begins to take us to the next phase, which will be the creation of the marketing outreach plan.

Now we are down to about slide 38 for those of you who are going through this in the Internet. If we look at the phase II plan goals where we start here we take a look at the research. We analyze any kind of effort that we have been able to uncover that has tried to reach out with the messaging to the general population or population groups as well. And we make sure that we align goals that are all aligned with what we have uncovered in the research. There will be a great connection from one step of this to the next. Geoffrey is mentioning that this will be evidence based. It will be very logical. We will not influence it with our own personal opinions about anything. This will be rooted in the research that we uncover so that once we finally take it to the population groups with recommendations it will be rooted in something that is very real.

The next slide talks about the marketing and outreach plans sort of what it will look like because I think this is something that you guys were asking us about in the phone call. The physical report itself there will be an executive summary will outline the goals of the

marketing efforts, which I think will be really important. It will be stated in terms of here is the problem, here is what we want to impact, and here is the one, two, three, four and five, six steps how we are going to get there. It will be tied to the formative research. It is very logical. I am on slide 40 now called marketing and outreach plan. I think this will be a really good document that you guys will be able to put your arms around. And again we will have some more interaction together at that point.

MR. SCONYERS: I meant to ask when you back on the phase I completion slide but it is timely to ask now too. The phase I completion slide I heard you say that we would receive that report. Is that in fact the case that we will receive that report or are we going to have to make a FOIA request for it? The same thing with the marketing and outreach plan of phase II. Are we going to receive that report or are we going to have to make a FOIA request for it?

MS. HANSEN: I don't know. I will have to ask.

MS. COOK: I don't know if that is releasable but I will have to ask HRSA.

MR. SCONYERS: You don't know what?

MS. COOK: If it is releasable. I will have to ask HRSA contracts.

MR. SCONYERS: The presentation that we are getting says that we are going to get it. I am questioning what is going on here.

MS. COOK: All I can do is follow up with HRSA contracts and see what is releasable.

MR. SCONYERS: So we may or may not get it.

MS. COOK: I will do my best to get it. If we can't release it then you can release it directly to you. Yes, you will get a copy of it one way or the other.

MR. HERR: Question. When we get to this marketing and the plan, will the presentation be such that there may be or recommendations of phases of how to attack the problem so that depending upon budget constraints what would we do first, what will we do second depending upon what the program can afford.

MS. HANSEN: I think that is a great question as well that it is very likely that we will say we would recommend tiers sort of how this should presented to the general population understanding that we will need to be flexible based on funding and frankly we might even find out that part of this and I look to what Kathleen is talking about in the online environmental scan that we will say let's start here and let's start presenting this sort of messaging. We can look at the feedback that we are beginning to see occur online and we might even want to

evolve a few key words, a few whatever so it will be iterative as we go. I think that it is very likely that our recommendation will be based in tiers. Like I say think back on that social ecological model we will be looking at making recommendations that target each level and layer of a community and so that could be very iterative if you will done on tiers, done on available budgets and what not. It needs to be flexible.

I think our goal also is to say at the end of this here is a plan. It can be implemented right away. It can be implemented down the road. Based on the situation it will be a document with shelf life that you guys will be able to use and move forward really nicely at the end of this.

MS. BUCK: This is Tawny. You are that your deliverable the one that will be available in September. It is going to actually -- that report that will either get from your guys or maybe if we are lucky the program will give it to the Commissioners is going to include actual messages and a marketing plan and we can look at it including budget. I think I just heard you tell Tom is that it will also perhaps have the levels of messaging and marketing plans tied to budgeting. Is that correct? That you will actually have specific messaging in that plan?

MS. HANSEN: Our document will include

recommendations on messaging what we are not producing. We're not creating a television spot after this. We're not creating a radio spot because media -- particularly these days for us to present any sort of a budget, which is not a part of the scope of this but frankly if it were we would be a little bit nervous about it because you don't know really what some of these costs will be when --

MS. BUCK: What about specific messages? Are you going to include specific messaging in your report?

MS. HANSEN: We will be making recommendations about the tones of messaging, verbiage that seems to work with the target audiences we are after. We will be making recommendations about the kinds of vehicles that will be appropriate to use. There will be specific recommendations in this. Again we're not going to hand over a 60 or a 30 or an outdoor board. We are going to hand over the kinds of recommendations that we think should occur whoever takes this on to the next phase. Yes, there will be some specific messages on what should be said and how it should be said to different population groups inside our report. Does that answer your question?

MS. BUCK: It does. But it's not going to be like you said something that we can then say oh, we'll take that and then you just hand it over. It is going to be something that you are going to have recommendations but

then you are going to have to turn around actually create the actual product.

MS. HANSEN: Yes. You will be creating the product. Now with that said technology has really taken marketing and outreach to a whole different level. You know how I am talking with some risk so I don't want to make Jeffrey and Kay crazy but the fact is that it may well be that that tier of the marketing and outreach to people that includes the Internet that that could happen really sort of instantly. I don't know that yet because we haven't gone through this whole project but it's not to say that you couldn't start a big part of this right away. I would say we would need to be flexible and make smart decisions. I think that is our responsibility together to make really smart recommendations as we go forward so that when dollars are going behind this that we have spent. I am a taxpayer too. I want to see this money spent really wisely.

MS. BUCK: I think from the concern that I will hear I suspect -- there is already rumblings going on from people trying to figure out what this presentation means is not nearly as much about the vehicle with which the messaging will be sent. The CDC has an enormous budget for communications regarding vaccines. I believe on the H1N1 alone they have pushed well over \$20 million or something.

There is going to be a lot of interest in another agency being tasked and money to spend to develop a message and what it will be. I think that for some of us we feel like the target audience is pretty straightforward -- a lot of scrutiny on the messages that you come forward with and you know if there are actually be accomplishing which they should be which is basically to create awareness about the program and I think that that is definitely an issue that either Commissioners who listen to the public or the staff themselves is going to have to work with in terms of push back on this which is CDC has a massive and aggressive communications department for messaging. This is going to be interesting to see how this is different from that.

MS. HANSEN: Again I think those are great points. One of the examinations or some of the recommendations we'll do. It could be we might uncover that it would be smart to do some partnering with some of these other agencies who knows and what not as well to take advantage together. Maybe not. Who knows? We will see as we --

MS. BUCK: It may be very wise for you to consider partnering with some of the NGOs and agencies that are not affiliated with the government. I don't know how your contract is written or how much freedom you have to partner on this project but it is going to be very

important for you to step outside of the federal realm on this topic and there are some very savvy NGOs and nonprofits that spend all of their time and energy working on this issue depending on whichever position they take would be very important partners to include in this process to make sure that -- they have already spent an enormous amount of time and money working on the messaging. I would really encourage you to step away from the established federal people who are doing this and if you are allowed to within your contract to go to some of those folks.

MS. HANSEN: Absolutely. If you don't mind I'm going to move forward on our presentation a bit. The last part of this we have talked about phase III that is again goes back to that collaborative time with the work group and you guys. It allows us to assimilate all the information that we have gathered and put it together in a document that we think speaks meaningfully for all of you taking the next step with this. I would underscore that that would be a collaborative effort. You guys will seek out your guidance on that and ultimately end up in September with a document that I hope you are proud to have been a part of you and that DVIC will also be proud of as well. That is so we can continue discussion and questions. I don't know your timeframe today.

MS. CASTRO-LEWIS: Thank you so much for the

presentation and for responding to the medium questions that we have. That is very helpful. I don't know if there are any other questions.

MS. DREW: I am just wondering about your subcontractor Altarum. Do you have a contract with them or does HHS?

MS. HANSEN: The way this works we have the contract directly with HHS and then we brought in -- we are subcontracted in -- Banyan had subcontracted to Altarum. We sought them out. We have worked together before we have -- the good news is that we have a great relationship. We are like a team already. We don't have to dance together first to get to know each other and we know their knowledge of you has elevated our understanding of this whole -- beyond our own personal experience with vaccinations. It has elevated us into what you are all about much more quickly than I think we would have any other way. They pay us. We pay them.

MS. CASTRO-LEWIS: Any other questions or any other comments regarding the presentation? Thank you so much. We are looking forward to seeing your outreach work group in the future meetings.

MS. HANSEN: I will say we will say we will use Kay as sort of our funnel of communication. Anytime you have a question funnel it through Kay and we will do the

same and we will all get together regularly as we go.

MS. CASTRO-LEWIS: Let's take about a 10-minute break and reconvene in 10 minutes, which is 10 till 11.

Thank you.

(Brief recess)

**Agenda Item: Adding Hepatitis A, Trivalent Influenza, Meningococcal and Human Papillomavirus Vaccines as Separate Categories In the Vaccine Injury Table**

MS. CASTRO-LEWIS: Are you ready? Dr. Evans is going to talk about adding some vaccines to the vaccine injury table and now is going to go into the details.

DR. EVANS: There is a one-page handout just this morning passed around. There is no PowerPoint presentation and I emailed that to the speakers on the line. Did you receive that? The program is seeking ACCV consultation for a proposed rule that will change the vaccine injury table to create a distinct and separate listing for the foremost recent vaccines added to the program and those are hepatitis A, trivalent influenza, meningococcal vaccines, and the human papillomavirus vaccine. These were added starting in 2004. These four vaccines are listed in the table but in a placeholder category, which is now box 13. This has sometimes led to confusion regarding their coverage status because it is more or less a footnote that

they are in this box. The problem views this proposal is a technical change only not something that will affect petitioner's rights to file or has any economic implications per se. It is something that is very straightforward and I will explain why we are coming forward and proposing this now. But I think it is first good to start with some background.

The '86 act did not include any language on adding new vaccines. This didn't come about until what is known as the Omnibus Budget Reconciliation Act of 1993. It laid out the following. That vaccines can be added for coverage under the program once some prerequisites are met and that is that an excise tax is imposed by Congress and the vaccine must be officially recommended for routine administration to children by the CDC and once those two criterions are satisfied then after a notice, a publication by the Secretary of HHS of a notice of coverage in the Federal Register then it is officially covered and it is put in this placeholder category and all four vaccines have gone through these steps.

In order to make any further changes for these vaccines and add them as separate categories there is also a step-by-step process. This begins according to section 2114 of the Public Health Service Act, which you see in front of you, saying that the Secretary to begin with must

provide a copy of a proposed regulation or revision any time the table is to be changed whether it is to add a condition or add a vaccine or both and this consultation after requesting it the Commission is afforded at least 90 days to make such a recommendation.

We are coming today and I am going to go over this proposal and then you have 90 days to come up with a recommendation for or against this. You can decide to do it today. You can decide to postpone it. You can weigh the 90 days. Whatever you want to do. But it is up to you. This is what the statutes say.

Once the Secretary publishes a notice for coverage for these four vaccines it is in this provisional category and this box 13 is for any new vaccines recommended by the CDC for routine administration of children after publication of a notice. In order to actually have separate categories a formal rule-making process is necessary and not only will it place them in a separate and distinct category it will also add any associated injuries or conditions if they are appropriate. This is actually a five-step process and begins after the consultation. There is then a notice of proposed rule making that is published in the Federal Register and that triggers a 180-day public comment period, which also must include a public hearing. Traditionally what we have done

is we have had the public hearings following an ACCV meeting. So we adjourn the ACCV meeting and then we announce that the public hearing will start and this is all announced in the Federal Register and the last two public hearings, for example, no one has actually showed up for public comment but at least it is part of the rule-making procedures. Once the public comment period has ended, the public has been held then the department publishes a final rule and these changes to the table whether it is adding vaccines or adding injuries or both is ineffective, it is usually 30 days after the final rule is published.

We have gone through this. The department has gone through this rule making three times: '95, '97, and 2002. For the most part each required three to four years to complete. It seems like a long time but there were consultations and a lot of reviews in the department and so on, even outside the department. The ones that involved IOM reports and extensive changes it was easily three to four years. Since the last 2002 rule change we have these four vaccines. Hepatitis A was added in 2004. The trivalent influenza in 2005 and then you have meningococcal and HPV vaccines added in 2007.

Except for the addition of intussusception rotavirus, which was done very quickly with case control studies by states and quick determinations by CDC and the

department as far as the association there. Except that the department has always relied on independent reviews of vaccines and adverse events by the Institute of Medicine before proposing to add or remove injuries for the table. You should know that the two major committee efforts in the 1990s each required two to three years to carry out the reviews. The current IOM contract as you know is also not supposed to have a report available for the department until mid 2011.

The department has taken the same approach with these four new vaccines in that we are waiting for the IOM reviews before we would suggest adding any injuries as well for the other vaccines that the IOM is considering and at this time there is really no injuries that the department thinks are appropriate to be added. Rather than wait for the results before initiating rule making while they are waiting for the results at the IOM report before initiating rule making, which would be more than a year from now for the IOM report and then three to four years for the rule making itself, we want to go ahead and at least for clarity purposes make it clear that these vaccines are covered by the VICP. They would be placed in each separate categories and it would also say no conditions specified in terms of any injury. Again, it is technical. We view this as a housekeeping kind of exercise but we are coming for

consultation as is required under the act.

MR. SCONYERS: This is Jeff Sconyers. Why is this a change that needs to be made? Is there confusion?

DR. EVANS: We have some reports that there is some confusion. It's not clear that it is covered because when you look at the vaccine injury table unless you take a quick look at it there is just a very small footnote at the bottom showing these four additional vaccines. We would expect that some would look at the vaccine injury table and not see it. The answer is we have anecdotal incidences, yes, but it is nothing that is major. But it does occur from time to time.

MR. SCONYERS: It is my understanding from what you said earlier that this change to the table would not in fact lead to any change in the administration of the program because the program already considers these vaccines to be covered. Is that correct?

DR. EVANS: Correct.

MR. SCONYERS: Can the Federal Register notice that establishes assuming that that is what happens. Can it be clear in filing the Federal Register notice that it's not the intention of the program to effect any change in the regulation or in the table other than to make clear what may have been ambiguous before? In other words, so that no one is going to consider within the special master,

the court of federal claims or anywhere else, that these vaccines were not covered until they were separately listed.

DR. EVANS: Based on the draft language of the regulation that I have under review. Yes. I can answer that we will make every attempt to be sure that the intent is clear and what does not change is clear, too. Yes, important point.

MR. HERR: By making a separate category for each vaccine now does it make it easier because there are multiple vaccines for each category? There are a number of influenza trivalent influenza vaccines as well as now the human papillomavirus vaccines. Does it make it easier or more obvious that the multiple examples of those vaccines are covered?

DR. EVANS: It doesn't change it all. There are two meningococcal vaccines, for example, but in the pneumococcal conjugate vaccine it is very specific that that is the only pneumococcal vaccine to cover. For trivalent influenza it is any of the trivalent products.

MS. CASTRO-LEWIS: Any questions from people on line? Tawny, Sarah, Meg?

MS. HOIBERG: I don't think so. I am okay with the vaccine being recognized on the table.

DR. HERR: Should we move to approve the

proposal?

PARTICIPANT: That would be okay with me.

DR. HERR: Then I move that the Commission approve the proposal.

MR. SCONYERS: Second.

MS. CASTRO-LEWIS: Any other discussion regarding this new proposal? No. Nobody. All those in favor? Thank you. No one opposed that? No. That was quicker than I thought.

If we don't have any other comments or questions I think I would like to again operator to move to the public comment. Do you have anybody on the line that would like to do any comment?

OPERATOR: If you would like to make a public comment, you may press start 1 on your phone. One moment please.

MS. BUCK: Magda, while we are waiting this is Tawny. At the end of our call yesterday there were people who indicated through the operator system that they wanted to make public comment and were cued up to do so and then for some reason weren't given an open line to do that. We just adjourned very quickly yesterday after public comment. I just definitely want to make sure that anybody who is on the line I would first like to apologize for those people who were on the line trying to make a comment yesterday

that couldn't and I hope that allowing for public comment this morning gave them the opportunity to do so. It would be bad for us to adjourn a meeting when people are cued up with the operator to give public comment and can't. I just wanted to acknowledge that that happened yesterday.

**Agenda Item: Public Comment**

MS. CASTRO-LEWIS: Thank you, Tawny. We apologize if anybody was on line. We were told that there was no one else to make any public comment. We will be sure to wait today a little longer and see if anybody else is available who would like to make comments.

MS. POLLING: My daughter is Hannah Polling. She recently, actually back in 2007, had a case concede in a vaccine court and I am speaking from a personal point of view specifically as an RN and as an attorney and I was listening carefully about the marketing in terms of trying to get the message out about vaccines without scaring the public. Speaking from a nurse and attorney perspective I can tell you that whatever has been used in the past is absolutely -- we must to be careful about the message that we are giving but I think our own case in point is the way to look. You are looking on the Internet and I heard something about looking at *Wired* magazine for input. You have to remember that people that go onto *Wired* magazine online and make comments have a lot of time on their hands

and that's not necessarily going to give you a good view of what the general public is thinking or what other medical professionals are thinking or what attorneys are thinking. I can tell you from my own point of view as a medical professional and as an attorney that I went to my journals to look for information of what's not there. I think it is extremely important --

MS. CASTRO-LEWIS: Operator, I think the connection is broken. Something is going on that we cannot hear her. Could you please be sure that she is reconnected or she could repeat what she just said?

MS. POLLING: I have no idea what everybody heard and I don't want to be redundant. What I was just trying to point out is as both a medical professional, a legal professional, and somebody whose child was injured by vaccines but is also interested in safe vaccination and I do realize that the message to the public needs to be carefully met.

I think that one of the key things that we are forgetting is listening and talking to people like myself. What happened when we tried to get information about this in making these decisions? While looking at *Wired* magazine I found that very offensive. I don't have time to read *Wired* magazine or make comments on *Wired* magazine and for people to look in marketing research at people who have the

kind of time to look at comments that are issued on online blogs or media outlets is not necessarily going to help the public as a whole because the public that you are trying to meet or reach out are not necessarily on it all day leaving comments like this. I certainly am not.

I think when you go to looking at marketing research what that sounds to me is like you are looking at how to get a message to people not how to get the message that if you want information here is where you need to go to get that information. I would have really appreciated knowing where to turn to get the kind of information that I needed when I knew something was wrong. I found that very concerning and I did hope that you will turn to some of the parents and individuals who were injured by vaccines because I don't know that -- tended to be very helpful learning what type of information we would have liked to have had, what type of information we would like to promote because both myself and my husband are not anti-vaccine. I just wanted to put my input on that and one last thing and that is that with respect to vaccine injury "program" and my daughter.

One of the interesting things that I don't know that anyone has addressed is that my daughter will continue to be vaccinated for the rest of her life. What happens in a situation like my daughter? For example, she just got

the Gardisil vaccine. The chances of my daughter being married or having a -- of a Gardisil vaccine or -- let's just say for example that she did. What would be the ramifications of a vaccine injury in that scenario? These are the kind of things that I would like answered based on my daughter's own individual problems and nobody has those answers and I would really like for people to look into that.

MS. CASTRO-LEWIS: Thank you so much for your comment. Could you please advise the commentators to pick up their handsets so we can hear them well?

MS. WRANGHAM: I have my handset picked up. Can you hear me okay? My name is Theresa Wrangham. I am President of SafeMinds. I appreciate the opportunity to offer comments again today to the ACCV and appreciate the work that is being done. I will start off by saying it was very difficult to follow the presentation by Banyan today or understand the scope of their undertakings. The comments I am going to make in that regard I will apologize up front if I have taken an incorrect meaning and would suggest to the committee that for meaningful public participation in the future, it would be extremely helpful if all meeting materials such as the PowerPoints used yesterday in the meeting, were somehow webcast to the public or put up on the website so we can download and have

a more meaningful participation within public comment. It is very difficult to sort out what you all are doing without being able to see the materials that you are looking at.

However, as I understand it, Banyan is being contracted to look at messaging from VICP and to establish who the target audience is to better look at how to message to them. I have to say I would agree with Mrs. Polling. Even if the organization -- I have heard the *Wired* article is extremely offensive, a little more than a fan piece on Dr. Offit, which didn't cite any scientific citations or mention any of the scientific -- I'm sorry, mention the scientific limitations on some of the statements made in that article. It paints the vaccine concern community, which helps legitimate vaccine safety concerns, which have now been largely acknowledged by the recent NVAC Report on the CDC ISO, it portrays us as anti-vaccine when nothing could be further from the truth.

SafeMinds is an organization has participated for the last 10 years in pro-vaccine safety policy with federal agencies and continues to do that. I would hope that as Banyan moves forward that the outreach to the vaccine community to look at what is not being addressed and how to more effectively message.

I would say that same thing that we touched on

yesterday, lack of transparency and information available to the public in terms of awards and compensations made through the program is an area that needs to be messaged more clearly. It needs to be available to the public. There is no such thing as a perfectly safe vaccine and nobody expects that. The public needs to know how to access the program. They need to know what vaccines may be causing injury. They need to know how the state of science or the deficits in the science that were acknowledged by the NVAC Report, are being addressed so that the 1986 mandate to reduce vaccine adverse events is being addressed.

I would like to see media messaging stop neglecting the rising distress around these legitimate safety concerns held by the public and instead focus on telling us what is being done to expand the science or to close the deficit. It is clearly not acceptable to the public that these items are not being addressed publicly. The vernacular has to change around how the vaccine community is being perceived. The vaccine safety community, we want to participate in this. We want to see deficits closed.

In closing the messaging must clearly convey what vaccines cause what injury, state where the science is and what is being done to close the gaps and how to quickly

access the program and the event to the injury.

I would also comment on a statement made yesterday within the committee that I think many of the claims made or dismissed do to statute of limitations as being past. If there are so many claims being dismissed on that basis, clearly that needs to be revisited and the statute of limitations expanded. It is very difficult for a parent to sort out or go to a medical professional to sort out, if there is a possible vaccine injury and very often it goes beyond that statute of limitation. That needs to be acknowledged in the light of the lack of basic science on vaccine safety data that is not available and how that impairs a parent's ability or even a doctor's ability to report a possible injury.

Again, I would like to thank the committee for their work. I hope that we can count on Banyan to engage with the vaccine concern community around the safety issues and I appreciate your time this morning.

MS. CASTRO-LEWIS: Thank you so much for your comment. Any other comments, operator?

OPERATOR: At this time there are no further public comments.

MS. CASTRO-LEWIS: We are going to wait a couple of minutes and see if somebody else comes through just in case. We don't want to dismiss anyone too soon.

(Pause)

Anybody else at this point, operator?

MR. MOODY: One thing that was said this morning about the Banyan presentation -- stay on the line or this could be conveyed to them. I also would like to echo the comment that the fact that of all the messages that they came across on the internet, that they singled out the Wired magazine article, which is perhaps one of the most misleading, false, and frankly, libelous article on the Internet. It lists National Autism Association as an anti-vaccine organization, which again is simply not true. Starting there, if that is there starting point to look at this as a pro versus anti-vaccine communications issue, is going to take them down a dead end. I hope that they focus on the fact that the public is primarily interested in healthy children and that is a combination of safest possible vaccines, as well as worrying about stopping spread of infection and the vaccine compensation program is a critical if not a core feature of the safety net part of that.

I will just give one example of a message, which I hope the Banyan folks can come to grips with. It was from February 20th last year, issued in fact on the occasion of the polling concession. HRSA issued a statement that said the government has never compensated

nor has it ever been ordered to compensate any case based on a determination that autism was actually caused by vaccines. I understand of course the whole world of nuancing and messaging and everything, but the fact is that statement it be the essence of that message is simply false. The program has been compensating cases of vaccine-caused injury for autism since 1991. There are at least 13 published decisions and an unknown number of concessions and that is the kind of messaging that simply has to stop. The message has to come out that the program will in fact compensate a case for autism or any other injury, as long as the case for legal causation is met.

I can appreciate this is a challenging cause for Banyan to take on. But the guiding principles for this mission, this contract has to have a vision of both honesty and transparency and that is a role I think the committee can in directing Banyan, clearly send a message that will expect its communications plan to be characterized at a minimum by central core values of honesty, completeness, and transparency, as well as the importance of the Vaccine Compensation Program to an overall national vaccine strategy. Thank you.

MS. CASTRO-LEWIS: Thank you so much Mr. Moody. I guess there are no more comments. We are going to proceed.

OPERATOR: There are no further public comments.

**Agenda Item: Future Agenda Items**

MS. CASTRO-LEWIS: Thank you so much operator.

As we finish the 74th meeting, I would like to thank Sarah and Tom, who were part of the agenda work group and I would like to invite a couple more members to be part of the agenda work group so we can plan the next meeting. I am going to ask for volunteers.

DR. FISHER: This is Meg. I volunteer.

MS. CASTRO-LEWIS: Thank you, Meg. I was hoping you would.

DR. HERR: I have to admit that I was sort of on the planning committee by name only because I wasn't really able to show up on time on the call so I would be happy to serve this coming time with Meg.

MS. CASTRO-LEWIS: Thank you so much. We have Meg and Tom for the next working agenda-working group. Thank you so much again. Let's talk about future agenda items if there is anything in particular that anybody would like to -- Sherry.

MS. DREW: This is Sherry. I am hearing kind of loud and clear, both from members of our Commission and from some public comment, that people are very concerned about transparency. I am wondering if we couldn't discuss that, discuss what is possible, what could be done, what we

can do, what HHS can do, to attempt to resolve some of the transparency issues. I would really like a discussion on that at our next meeting.

MS. CASTRO-LEWIS: We will discuss how we can address that. Thank you, Sherry. Any other -- anybody on the phone any items for the next agenda?

MS. HOIBERG: I would just like to reiterate that we would like to have some representation from the Secretary to come to the meeting, especially if we are going to have new people. Now if we are not going to have new people, that is one thing.

Also if we could just discuss at length again the outreach and just continue to put our heads together so that we are ready to work with Banyan and give Banyan good feedback. Is there going to be any chance to do that? Have the meetings and then make sure that we get all the materials to the Commissioners before the next meeting so that everybody can be prepared?

MS. CASTRO-LEWIS: That would be the ideal to have the materials ahead of time and they can do interim reports probably in every meeting that we have until September. That should be the way to go at this point.

MS. HOIBERG: I think definitely outreach right now is going to be key and I think along with outreach that goes right along with what Sherry's and Tawny's issue on

transparency. I think that sounds like a good plan.  
Outreach could be an entire meeting.

MS. CASTRO-LEWIS: Thank you, Sarah. Anybody else have any other suggestions for the next meeting?

MS. BUCK: Can you check again to make sure there is no public comment because I think there must some delay. It seems to me like the operator was trying to patch in another comment.

MS. CASTRO-LEWIS: I guess we could do that except that the time is -- but we can do that. Operator, is there anybody else for a public comment?

PARTICIPANT: I don't know if you are intending the public to comment on suggestions for the meeting agenda if that would be appropriate?

MS. CASTRO-LEWIS: Do you have a comment?

PARTICIPANT: Are you asking for suggestions for the agenda?

MS. CASTRO-LEWIS: No. Not to the public, only to the Commissioned members.

PARTICIPANT: Thank you so much.

MS. CASTRO-LEWIS: Thank you.

OPERATOR: There are no further public comments.

MS. CASTRO-LEWIS: Thank you so much. With that I look forward to seeing you all in three months, and with that the meeting is adjourned. Is there a motion please?

(Whereupon, the meeting adjourned at 11:30 am)