U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

WEDNESDAY, FEBRUARY 4, 2009

The meeting came to order at 9:00 a.m. in the 8th Floor Rotunda Room of the Ronald Reagan Building, 1300 Pennsylvania Avenue, N.W., Washington, D.C. Thomas Insel, Chair, presiding.

PRESENT:

THOMAS R. INSEL, M.D., IACC Chair, National Institute of Mental Health

DELLA HANN, Ph.D., IACC Executive Secretary, Office of Autism Research Coordination, National Institute of Mental Health

DUANE F. ALEXANDER, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

JAMES F. BATTEY, M.D., Ph.D., National Institute of Deafness and Other Communication Disorders

LINDA BIRNBAUM, Ph.D., National Institute of Environmental Health Sciences

ELLEN W. BLACKWELL, M.S.W., Centers for Medicare and Medicaid Services

DAVID DeVOURSNEY, Substance Abuse and Mental Health Services Administration (For Larke N. Huang, Ph.D.)

LEE GROSSMAN, Autism Society of America

PRESENT (continued):

GAIL R. HOULE, Ph.D., Department of Education

YVETTE M. JANVIER, M.D., Children's Specialized Hospital

STORY C. LANDIS, Ph.D., National Institute of Neurological Disorders and Stroke

CHRISTINE M. McKEE, J.D.

LYN REDWOOD, R.N., M.S.N., Coalition for SafeMinds

STEPHEN M. SHORE, Ed.D., Autism Spectrum Consulting and Adelphi University

ALISON TEPPER SINGER M.B.A., Autism Science Foundation

EDWIN TREVATHAN, M.D., M.P.H., Centers for Disease Control and Prevention

PETER VAN DYCK, M.D., M.P.H., Health Resources and Services Administration

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9:02 a.m.

DR. INSEL: Good morning. We're going to get started. Welcome to what I believe is the sixth meeting of the Interagency Autism Coordinating Committee.

I'm Tom Insel, and I'm your Chair, as you know. It has only been a little more than two weeks, maybe not quite three weeks since we last met, but a remarkable number of things have happened during that time.

And I thought by way of introduction it might be good to just take you through some of the most recent developments, and then we'll go around and do our introductions here.

If I can have the first slide. This is taken from the White House website on the part of the website that talks about the President's Agenda, under the description of what the new Administration plans to do in the realm of disabilities.

And the only disorder that is mentioned is autism. In fact, almost the only disorder throughout the entire website that's mentioned, I believe, is autism. And you can see these four points that appeared within minutes of the Inauguration on January 20th.

So, it's an extraordinary statement, I think, that with a new Administration we have this increased priority and certainly increased awareness of the issues that all of us have been dealing with.

You might notice -- I'm not going to go through all four of these points, but the third one notes that President Obama and Vice President Biden support funding the Combating Autism Act, and working with Congress, parents and ASD experts to determine how to improve Federal and State programs for ASD.

So, it would be important, I think, to remember that we're now in an environment where we've got their attention,

and we now have a possibility of hopefully, as the President likes to say, it won't be business as usual.

There will be a chance to do some things that have not been done, which brings me to the second point that we do not yet have a Secretary of HHS, and we don't have a head of NIH or a head of CDC.

So, we're still a little bit in limbo in terms of the agencies, but we're moving forward at a breathtaking clip in terms of budget processes.

And, as all of you know, there's a stimulus package working its way through the Senate this week. It went through the House last week.

A stimulus package is mostly about jobs, and the President's commitment to try to reduce the increasing rate of unemployment. But one of the ways which that's been thought about is in terms of providing research funding, a sort of jump-start funding.

It's being called stimulus funding because it's only for two years. It doesn't go into the base of any of the agencies, but it is available for a couple of years to make something happen that hasn't happened.

We've been thinking about this because of the hard work that this Committee has done, and all these extra meetings, and we actually now have a strategic plan that we are saying to the Administration is shovel-ready. That is, this is a plan that we've gone through and is ready to be implemented, but it does call for large new investment. And this may be an opportunity.

This may be a moment in time, and there hasn't been one since we've been meeting, and there may not be another one in the foreseeable future, when there could be a true ramp-up of an investment to jump-start a whole series of programs.

So, we can't tell you at this point that this is going to happen because we

don't -- the Senate still needs to pass the stimulus package. It's not clear how or if that will happen.

There has to be a conference committee which will come up with a final draft for the President to sign. And we are still going through a process, at least at NIH, where we've put forward a proposal to do a very large jump-start effort in autism, and all of the NIH directors around the table have been part of that.

But we need to know that NIH will, in fact, select that and support it and it will go forward. But, it is one of those moments where you have to say that having completed this plan has really turned out to be tremendously strategically important because we wouldn't have been able, I think, to be in this effort if we were still at the point of trying to decide what should go in and what should stay out and how we wanted to develop our efforts.

So, it's quite an exciting moment, and I'm hoping that we'll have some resolution about this within -- literally, within a week, or within -- the President has said that he wants to be able to sign this budget package by President's Day, which is only about a little more than ten days away.

And the NIH process is going very quickly. So, we should have some resolution of that very, very quickly.

The last thing I wanted to mention in terms of our work here is that since our last meeting, there's really been a tremendous amount of internet chatter about the Committee, some concerns about our process, some concerns about the results, some name-calling and some simple questioning about, is this -- are we doing the right thing and how is this Committee working.

Most of the topic is about vaccines and autism, and it's probably worth recapping for a moment what actually happened,

which was that we took language on two initiatives that you had already discussed, and we moved that to the part of the plan that said, what do we need?

And we did that for several reasons, but one of the things that we talked about at the last meeting was that we wanted to get more information, and we thought one of the ways to do that would be to get information from the National Vaccine Advisory Committee, the NVAC, which is a group that had already been charged with trying to look at questions of feasibility, look at the literature that's there, and had expertise that we don't have, and that we haven't been able to make use of.

So, we're going to do that today. NVAC will be with, at least Bruce Gellin from that Committee will be with us after lunch.

Originally we had hoped to kind of take this on first thing, but the NVAC is meeting this morning, as it turns out, so they

are not going to finish until around twelve or one. So he will come over after that.

By way of just previewing this discussion, I think it's important for us to go back and think about what we're about here.

You know, I know there's real significant disagreement, and it shows up in the language in the plan about the role of vaccines as a cause of autism, and some of you think that this has already scientifically been investigated, and the science says, as you've said in the plan that it doesn't support a link and we need to move on.

Others of you think that the science is not definitive and we need more information, and that we should continue to do additional research in this area.

You know, in thinking about this, this is a problem that we cannot just avoid. I think we do need to make sure that we have an environment here where we can talk this through, and we can hear from those who are --

have the expertise.

I'd also like to suggest to you that the problem is only partially about the scientific issues. There's also, I think, a more fundamental issue, which is really why I want to bring this up at the beginning of the meeting that has to do with trust, and whether we can develop a kind of trust here or begin to support the kind of trust that's needed that seems to be missing in the public debate about this.

One of the places where, as I've listened to the comments, and we've gotten a lot of comments since the last meeting, I think the part of it that's impressed me the most is the feeling that you can't trust the Government, or in some cases you hear from members of the public that you can't trust other members of the public, that there are lots of hidden agendas, there's some conspiracy going on.

And it's ratcheted up at a very

rapid pace. I would really like to see us take a deep breath here and look at this question and ask ourselves, can we do this in a rationale, careful, scientifically-based way?

Can we identify areas where we could actually improve understanding, improve public trust so that we become part of the solution, and not part of the problem.

And I'm going to ask you, as we get into the afternoon session, to help us think about how to do that. There is no way we can just say this is going to go away as a problem. It's not going to go away.

And it's something that this Committee really could have a very important role in. So, we will revisit this in the afternoon with Bruce.

Lyn Redwood has offered to talk to us about some of the science around the vaccine issues and she's invited a guest who's going to join us this afternoon who will take

us through some pieces of that as well.

Before we get there, we've got a bunch of other things we need to do. So, I'm going to make sure we launch through some of the morning session. Let me just take you through that.

For the morning agenda, we've got our periodic updates, so we're going to take some time to hear from each of the agencies and anyone else who has a comment about updates.

It would be great to take about five minutes each. If we take much more than that, this becomes a really long process.

One of the things that's probably on the public's mind, even more than autism some days is the financial crisis, and we have been hearing about what the financial crisis might mean for States, for State budgets for services for autism.

So, Ellen Blackwell and has also brought a guest, we'll hear hopefully about

some of the details about what does this mean in 2009 and 2010, what do we need to know about in this changing financial climate, are there some things that the financial crisis is going to be doing in terms of services that we need to get ahead of so that we can preempt some of that.

And finally, and I guess the best news of all is that we have got, at the same time that the economy may be in the ditch, the science is really is in a boom phase. The science is really moving forward very rapidly, and there's lots of exciting stuff to hear about.

So, we're going to take some time, as well, to hear about some of the scientific results as we go around from the various agencies and hopefully we'll get you caught up with that.

We will take some time today to also think about how best to package these for our annual required update on scientific

advances, and we'll take a maybe half an hour or an hour to actually think with you about what the process ought to be to do that. And we'd like your input about that.

Okay. Let's go ahead and start with introductions, then. So I think many people at the table know each other, but we actually have at least one new member who we can introduce today and we'll do that when we come to Linda Birnbaum, who is the new head of the National Institute of Environmental Health Sciences.

Story, would you like to go ahead?

DR. LANDIS: Story Landis, Director, NINDS, National Institute of Neurological Disorders and Stroke, and a developmental neurobiologist by training.

DR. JANVIER: Dr. Yvette Janvier. I'm a public member. I'm a developmental behavioral pediatrician working in New Jersey, primarily with children and families with autism.

DR. TREVATHAN: Ed Trevathan, Director of the National Center on Birth Defects and Developmental Disabilities at the CDC, and I'm a pediatric neurologist.

DR. BATTEY: Good morning. I'm Jim Battey. I'm the Director of the National Institute on Deafness and Other Communication Disorders, and I'm a pediatrician and molecular biologist by training.

MS. BLACKWELL: Ellen Blackwell, Centers for Medicare and Medicaid Services. I'm a social worker. I also have a son, Robert, who's 22 years old. He has an autism spectrum disorder.

MR. DeVOURSNEY: David DeVoursney. I'm here from the Substance Abuse and Mental Health Services Administration, and I'm representing Dr. Larke Huang, who is our special advisor on children and families.

DR. VAN DYCK: Good morning. Peter Van Dyck. I'm Director of the Maternal and Child Health Bureau in HRSA and

pediatrician.

MS. SINGER: I am Alison Singer. I'm a public member. I am the mother of a beautiful eleven-year-old daughter diagnosed with autism, and I also have a 44-year-old brother diagnosed with autism spectrum disorder.

DR. BIRNBAUM: I am the new member. I'm Linda Birnbaum and I'm the Director -- the new Director, very new, two weeks, of the National Institute of Environmental Health Sciences and the National Toxicology Program. I'm a toxicologist by training and have specialized in endocrine disruption.

MS. REDWOOD: Lyn Redwood, Coalition for SafeMinds.

DR. ALEXANDER: I am Duane Alexander. I'm a pediatrician and Director of the Eunice Kennedy Shriver National Institute of Health and Human Development, NIH.

MR. GROSSMAN: I am Lee Grossman.

I'm a public member and the proud dad of a 21-year-old son with autism as well as the President and CEO of the Autism Society of America.

MS. HANN: Good morning. I'm Della Hann. I serve as the Executive Secretary for this Committee and the Designated Federal Official, and I'm also a developmental psychologist.

DR. INSEL: And we have some members joining us by phone?

MR. SHORE: Yes. I'm Stephen Shore. I am my own autistic adult. I'm a public member and professor of education at Adelphi University.

DR. INSEL: Welcome Stephen.

MR. SHORE: Thanks.

DR. INSEL: Anyone else on the phone? I think Jennifer Johnson will be joining us. Chris McKee is going to be late. She'll get here about ten.

Is there anyone else, Della, that

we're expecting?

MS. HANN: No.

DR. INSEL: Okay. Della sent out a note last night letting you know that the team from ABC News is going to be filming today.

Let me just take the temperature of the Committee. Is that -- we didn't ask for your consent, but it's a public meeting, and we need to know that this is going to be okay with you.

Issues?

Okay. Agency updates. Dr. Landis.

DR. LANDIS: Okay. So, NINDS spends about $9 million on autism research according to the new accounting system, RCDC, and we're about close to ten percent of the NIH total.

I want to talk about four different things very quickly. One of the most important studies I think we're

supporting is a neuroepidemiological study in Norway looking at mother and children cohorts.

There will be a large birth cohort with more than 100,000 enrolled mothers and their infants to explore how various genetic and environmental factors contribute to the development of autism and other neurodevelopmental disorders.

It's examining multiple potential risk factors and their interactions with genetic risk factors, infection history, low birth weight, dietary and environmental exposure, include methylmercury and vaccination history.

So far we've enrolled -- we have 20,000 mothers have filled out screening questionnaires at age 36. About one percent of the children have been positive for autism on the screening. 500 children so far have undergone a full assessment. Of those, 200 are controls and about 60 have an ASD diagnosis.

We will continue to accrue these through screening and referrals. Probably the most important part of this study is that biological samples have been obtained on all the potential cases and controls, so that we will have samples.

And there's already a lot of interest about what to do with those samples. They are blood, urine and, of course, you'd like to right away break into them and look for infectious agents and toxicants and then the issue is if you do that, you potentially have lost the samples and a year from now where you might have better screening tests you wouldn't be able to do it.

So, we are struggling with how best to use those samples.

The second piece that I think is important to mention is in -- we support the ACE Network, some of them, and one of those ACE networks is about to start a clinical trial with buspirone with the notion that that

could influence the serotonin system and could serve as a useful intervention. It's almost ready to begin enrollment. Is my time up?

We've also been looking at a number of genetic contributions and have a large program project grant that is run by Pericak-Vance, some interesting results coming out of that, consistently identified a chromosomal region, also looking at chromosomal abnormalities, an interesting publication by Christian this year, and finally working on genotype/phenotype relationships between genes' behavior, cognitive and anatomical characteristics with a new candidate gene on Chromosome 2.

Now, perhaps the most interesting thing -- and I don't know that NINDS should take credit for this -- is that one of the NIH Pioneer awards this year, these are incredibly prestigious awards selected from thousands of applications across the country went to Ricardo Dolmetsch who is at Stanford.

And we talked a little bit about the neuroepidemiology and a trial and then the genetics. And the most complicated issue is how you bridge between the behavior and the genetics to understand how, in fact, the changes we see in children with -- and adults with autism is related to changes in -- in how the genome is structured and how it can be influenced by environmental factors.

And what you'd really like to know is what the nerve cells and the supporting cells are doing, and there's no way you can take a brain biopsy of a child with autism to get a sense for that.

And that's in contrast to epilepsy where if you have temporal lobe epilepsy you actually do surgeries and intervention. You take out a piece of the temporal lobe and you can actually study the properties of the cells in the brain from that surgical piece of tissue.

So, about a year ago, three

investigators, one from Japan and two from this country figured out a way to take skin cells and actually turn back the developmental clock of those skin cells to make them very similar, if not essentially identical to human embryonic stem cells.

And the Pioneer award went to Dolmetsch who is actually taking samples from -- skin samples from patients diagnosed with autism spectrum disorder, reversing those clocks and then using those stem cells, treating them with a variety -- a cocktail of factors to turn them into nerve cells whose properties he can study and culture.

He can look at the ion channels, at the synaptic proteins, at the connections that they made, at the properties of growth, and the Review Committee was incredibly excited about the innovativeness and real opportunity to link the genetics and risk factors, genetic risk factors with the behavior of nerve cells.

And, as I said, it's not NINDS-funded. It's funded out of the Office of the Director at NIH, but this looks like a very promising new approach to begin to understand the link between cellular behavior and human behavior.

So, that's all I want to say.

DR. INSEL: Great. Thanks It would be wonderful to have ten or 50 people now doing the same thing. It's a great new technology.

DR. LANDIS: And I would just say that several of us proposed similar kinds of things as really important challenges for the autism field.

DR. INSEL: Right. Yvette, did you have anything to --

DR. JANVIER: Just a brief comment. I'm involved in two -- a project through the New Jersey Governor's Council for Autism Research and Treatment.

We're doing two things. One is a

developmental screening clinic which is run by nurse practitioners, supervised by myself who are doing the structured evaluation.

And in the first six months of the project we screened 228 children. 107 of those, so close to 50 percent were found to have an autism spectrum disorder.

So, primarily these are children between 24 and 36 months. So, you know, my message is, we are seeing new diagnoses in high numbers in, you know, a very structured assessment.

The other piece of the program that we're -- we're going out into pediatricians' offices and working with them to implement the American Academy of Pediatrics Guidelines on Universal Screening.

And about -- we don't have large numbers. We've gone into 21 medical homes or practices, primarily solo practitioners, which is interesting.

It's been very difficult to get

into the practices. We've taken letters and phone calls and faxes, et cetera, but the 21 we've gotten into, about 20 percent are -- know what the M-CHAT is, have been using the M-CHAT, but unfortunately not a single practice is using it according to its design.

So, I just thought I would share those observations from the front lines.

DR. INSEL: Very helpful. Thanks.

DR. TREVATHAN: Okay. I have -- I asked our scientists to provide me with some slides to summarize, and believe it or not I cut it back by about 70 percent, and there's still too many slides, so I've asked Della to make them available to the Committee, and I will go very quickly and just hit the high points.

But I wanted to primarily -- and this is a bit slow. Let's see. It doesn't seem to be working, so I don't know if I -- oh, that's it. Okay. Whoops. I wonder if it would be quicker if I actually -- okay.

Okay. All right. Well, in brief, we have within the National Center on Birth Defects and Developmental Disabilities three separate programs that address really three separate issues.

One is the population-based surveillance and monitoring to address the question of what -- who is affected, whether the estimated -- what's the estimate prevalence of autistic spectrum disorders in the population, epidemiologic research, and then really a focus on early diagnosis, and then now moving on to what we do after we make the diagnosis.

Who is affected is really addressed by the ADDM Project for the Autism and Developmental Disabilities Monitoring Network.

This is the group of population-based epidemiologic centers around the country seeing the darkly-shaded states that really provide the population-based estimates of how

many children are affected, with the average among these states really being one in 150 children, which is where those estimates come from.

We actually don't have the entire country covered, as you can see by the states that are not represented. And there is potential for having better representation if funding allows it.

I wonder if maybe -- I tell you what, why don't we just stay on that. Go back one. Let's just stay there and I will just -- we won't even go through the slides.

So, the epidemiologic research is really the key issue, I think, especially over the next two to four years. Our cadre sites which are research sites from around the United States that are currently conducting what's known as the SEED Study or the Study to Explore Early Development.

And SEED will enroll approximately 2,700 children into what will be at least --

well, we think it will be the largest case control study looking at potential risk factors for autism.

There are variety of different hypotheses being tested with this particular project, and the details are actually on other slides that you can take a look at, and then I'll encourage -- I encourage you to look at the website.

But we are on target with enrollment which we're happy to report, and over a thousand children have been enrolled to date and the target is to enroll 2,700 children. So we think the power will be quite significant.

The "Learn The Signs. Act Early." campaign has worked with a variety of partners, including many of you who are at the table today, both Federal partners, such as HRSA and then also ASA, Autism Speaks, and a variety of other groups.

And we have really gotten to the

point where the screening, hopefully twice by the age of two as Yvette just mentioned, is at least out there and we're working on implementing that.

But now we're really at the phase where we're having a series of regional meetings from around the country where we're bringing in stakeholders that are professionals in education, medicine, public health and a variety of community experts to bring them together at the table to look at what can be done to actually translate the early diagnosis into earlier access for services.

And so I think, as we move on and think about what we can do about applying some of our research finding to services there is an opportunity for more services-related research connected to this program and others.

With all three of our different programs there's opportunities to enhance, expand and in a variety of different areas.

For example in our surveillance activities, we not only are doing work to identify numbers of children affected, but also there are a variety of different studies that have been done -- for example, one published recently pointed out that there is a significant increased risk of having a child with autistic spectrum disorder with advancing parental age.

And there are a few other studies that are -- either impress or almost impress from that group that can really help. By increasing the number of surveillance sites, we can increase the power of those studies and also have a more representative sample of what's going on in the communities.

As early diagnosis hopefully occurs in the populations we'll be able to identify children in the general population at an earlier age and to do a better job helping states address these questions.

Our epidemiologic research would benefit also by increasing the number of sites

involved with our cadre studies. As more and more candidate susceptibility genes are identified, we need large sample sizes in order to be able to do the gene/environmental interactions which are really quite important.

The National Center for Environmental Health at CDC is also involved with autism research and I encourage you to look at the website for that.

They serve, for examples, the biomonitoring lab for the NCS, which Duane will mention, I'm sure, that has autism as a major component.

They are looking now at potential immune biomarkers for autism and have worked with the State of California to investigate a variety of potential environmental issues there.

And then our infectious disease colleagues, immunization, there have been a number of studies published on immunizations and autism which I know are familiar to those

in the group.

There's also a summary of those studies published on the web, the CDC website, and then I assume Dr. Gellin will mention some of that this afternoon.

DR. INSEL: Thank you.

Jim.

DR. BATTEY: Good morning, everybody. The National Institute on Deafness and other Communication Disorders focuses on the research areas that explore communication disorders associated with autism.

In the last fiscal year, we funded, at least in part, roughly 40 research projects in this area and invested close to $6.3 million of NIDCD's appropriated budget towards supporting these projects.

Most of them do explore language development and, in fact, perhaps one of the most noteworthy was an effort to bring together a group of researchers with a lot of interest and experience in studying language

development and disorders in very young children, who concluded that there was a need for a more standardized approach to evaluate the language skills of young children with autism spectrum disorders, and without this standardized approach it was going to be difficult to compare the efficacy and utility of various intervention strategies, and to that end there is a paper that is in press that will hopefully provide this standardization that will allow us to meaningfully evaluate whether or not intervention strategies are working or not working.

NIDCD also provides partial support in collaboration with our other NIH colleagues for three of the Autism Centers for Excellence at the University of Washington at Yale and at UCLA, as well as a number of other projects that we fund through our RO1 standard research grant mechanism. Thank you.

DR. INSEL: Thank you.

Ellen.

MS. BLACKWELL: Good morning. Today I just thought I'd focus primarily on what we call our Autism Task Order for which I am the project officer. This is a little project on services and supports that we've partnered with our NIMH partners to fund.

And it has four parts. We're actually fairly deep into the first piece which is an environmental scan of the research literature related to evidence-based services and supports available to people with autism spectrum disorders.

The second piece, which is next year's project is an assessment of the services currently being provided by nine states to people with autism spectrum disorders.

And this piece is actually something that I'm envisioning as a -- sort of a mini state-of-the-States which could sort of jump-start a project that is not an approved

strategic plan.

The third and fourth pieces of this project are not funded yet, but I have high hopes, so the third piece is the design of model programs of services and supports for children, transitioning youth and adults with autism, including methods for measuring related processes and outcomes, and the fourth piece is an HHS web-based ASD information portal.

So, that is the core of our autism research right now at CMS.

DR. INSEL: Thank you.

David.

MR. DeVOURSNEY: SAMHSA is happy to support two programs which could help children with autism spectrum disorders. The first is called the Children's Mental Health Initiative which focuses on creating local systems of care to support children with identified mental health issues. And those activities do support some children with

autism spectrum disorders.

The second is a new project in fiscal year 2008 called Linking Actions for Unmet Needs in Children's Health, or Project LAUNCH. And it's focused on supporting wellness for children zero to eight.

A major part of that is increased developmental assessments for young children, and in that we hope to play a role in early identification of autism spectrum disorders.

DR. INSEL: Thank you.

Peter.

DR. VAN DYCK: Good morning. I'm going to report on -- briefly on $15- to $16 million worth of new money that's come to the Bureau in the Combating Autism Act, some related to research, but some related to treatment and services as well.

Starting with the research, we have two autism intervention research networks trying to build on the power of multiple centers to get enough numbers to determine if

certain treatments are effective.

One of those intervention networks is for physical health, and the original grant is awarded to Massachusetts General Hospital, and one of the subs is the Autism Treatment Network Sites around the country.

And those happen to be in Arkansas, California, Colorado, Maryland, Massachusetts, Montana, two in New York, Ohio, Oregon, Pennsylvania, Texas, Tennessee and Washington.

And the second intervention network is for behavioral health, and that is awarded to UCLA, and the coordinating research entities around the country for that are in California, Florida, Michigan and Washington.

The Physical Health Intervention Network is around $4 million a year for the next three to four years, and the behavioral health is $2 million a year.

We fund what we call LEND Grants which are training programs for neurological

or neurodevelopmental disorders where they train physicians, nurses, developmental specialists, nutritionists, social workers.

And we have 35 LEND networks around the country, almost all associated with major universities. We have funded four new LEND Grants at the University of Arkansas, University of Colorado, University of Connecticut and the University of Illinois at Chicago, places or states that did not previously have these training programs for people who take care of children with neurodevelopmental disorders.

And we expanded specifically in the field of autism, 18 or half of the existing LEND programs around the country to be more attentive to the issues of autism in that training of the folks who come through the centers.

We also have ten developmental behavioral pediatric training programs around the country and six of those receive specific

money for autism activities as well.

And then we fund a coordinating center, and it's an interdisciplinary training resource center to try to coordinate, facilitate all of these activities in these training centers, develop best practices, those kinds of things.

That handles the training piece. So, the research network, then the training piece, and then we have a State piece as well, and we funded State -- six State demonstration grants in Alaska, Illinois, Missouri, Utah, Washington and Wisconsin.

And those are funded at the State level, usually to the MCH unit which has broad responsibilities statewide for coordinating and collaborating and trying to develop a statewide coordinated system for early identification and treatment for children with autism, and to come up with State plans that could then be used as best practice models and marketed to other States.

And then there's a coordinating center funded to help the State grantees, those six, but also to translate what's being done in those six with the additional money to other states as they become more interested in dealing with autism statewide efforts.

And then I think, interestingly, at the beginning of the beginning of the program we've also funded a national evaluation to bring together all of these activities, the State grants, the training grants and the research grants and to make sure there's coordination among them, but also to evaluate the activity of those different families of grants.

And in order to make sure that people are working together, the grants were just awarded about six to eight months ago. We've had our first national grantee meeting very early in the process. These are -- many of these grantees don't know one another and have not worked with one another.

We had 130 people from all the different families of grants, the training, the research, the State demonstration and the resource center, and again, the idea to getting them together so early was to emphasize the expectation that these grantees do need to collaborate among themselves and to define what the logic model would be for the research questions for the national evaluators and to encourage development of new collaborative efforts and to learn about shared activities that are already underway by the Federal Interagency Autism Coordinating Committee, which is you folks here.

And in order to do that, we tried to model working together by using speakers from the Interagency Coordinating Committee to show how public and private people can work together in collaboration.

And speakers included Della, who spoke to the group and Denise Juliano-Bult from NICHD, Gail Houle from Education, Ellen

Blackwell from CMS, Dr. Georgina Peacock from CDC, and Lee Grossman from the Autism Society as well as Alison.

And these people gave discussions of what their organizations did and their interest in autism, but also talked about how they would like to collaborate and see collaboration occur among these sets of grantees.

And one other brief thing. Ed at CDC mentioned "Learn the Signs. Act Early." program, and just to show that Federal Agencies occasionally collaborate -- you'll have to take my word for this, but it's true.

We have been working together since these grants have been announced, and our staffs have regular phone calls. We have combined our activities on meetings around the country on "Learn the Signs. Act Early." and have worked together on the regional summits and now have quarterly coordination meetings between our two staffs, which have been really

wonderful.

Ed and I have sat in on one of them just recently and I think are surprised at the -- I should say surprised at the level of collaboration, but pleasantly pleased that the level of collaboration is good.

So, that's my update.

DR. INSEL: Thanks, Peter. Could I follow up on the question of collaboration, because you mentioned these research networks.

And how are those integrated with the research networks like the ACE Networks and a range of other things that are happening through NIH, for instance?

DR. VAN DYCK: Well, I think this is one of the things that the coordinating center is going to have to investigate, is what is the best way.

These are -- I wouldn't call these basic research networks. They are service treatment networks -- service treatment service research type things, and I think once

there's a plan developed, or as the plan is developing, one of the responsibilities of the coordinating center which has been hired to, quote, help this collaboration, will have to explore these avenues, because I think there is some potential for learning from one another.

DR. INSEL: I think one of the real values of having this strategic plan now is we should be able to look at how that's going to be implemented across all these agencies.

And, since you've got -- and you describe it as a kind of service research network, but there's plenty of really good service research in that plan.

We want to make sure that in some way we're aligned, and that the work that the Committee felt was the most important work to be done in that area is something that is going forward from each of the agencies.

So, at some point we -- I don't

think we're going to be able to have time to do it right now, but we will need to sit down and look at both what's going on and how it's integrated across the agencies so that it's aligned with the plan.

DR. VAN DYCK: And to see if in the strategic plan there really are things that could be looked at within a research treatment network.

DR. INSEL: One would hope so.

DR. VAN DYKE: Right.

DR. INSEL: Absolutely.

DR. LANDIS: I mean, it's an extraordinary benefit that the research treatment networks are already -- you're setting them up, so they should be a very fertile place for new treatments that come out of other parts of the plan.

I'm a little envious of the fact that they exist. We wish we had them for some of our other diseases.

DR. VAN DYCK: And many of them

are at the LEND or coincide in universities where the LEND training programs are, so there's collaboration between those networks.

DR. INSEL: Great. Thank you.

Alison.

MS. SINGER: I really have nothing to add at this point because I -- unfortunately, I'm not currently funding any major programs.

DR. INSEL: But one will only hope in the future.

Linda, welcome. And get us up to date on NIEHS from your two weeks' experience.

DR. BIRNBAUM: My two weeks. Well, first of all, I really need to thank Dr. Cindy Lawler who is sitting behind me who has ably filled this seat for NIEHS for quite a number of years.

And I would suggest that there are specific questions, at least at this point, Cindy's going to be the one to answer them, not me.

But NIEHS supports approximately $5 million in autism-related research. We do this largely through a large number of studies to investigate the effects of environmental stressors on children's health, including studies of basic biological processes which are central to brain development.

And we also have epidemiology studies to identify environmental risk factors for altered neurodevelopment.

Much of our -- the way that we're funding this work is through a joint program with the United States Environmental Protection Agency Centers for Children's Environmental Health and Disease Prevention.

On the 21st of January we announced two new funding -- or new funding opportunity announcements to represent the latest round in competition for these children's centers.

So, these centers combine research and outreach. We work with communities,

health care providers, researchers and government officials to conduct research with the goal to prevent and reduce environmentally-mediated childhood diseases.

Now, this broad program covers a range of childhood diseases and disorders. Previous awards have been made to centers that focus on the role of the environment in the etiology of autism.

One is the ongoing CHARGE Program which is the Childhood Risk from Genetics and the Environment was launched as part of the center's program.

So, in addition to soliciting applications for centers that are fully-developed, the recent announcement also features a companion initiative to support the formation of new centers, and these planning grants will allow development of new research teams connections with communities and other stakeholders, and will obtain preliminary data on childhood diseases and disorders where the

evidence of an environmental role has yet to be fully established.

We are encouraging autism researchers to apply to either initiative. In other words, if they're within the established centers or the development of new centers, and details of these initiatives can be found on the NIH Guide Notice and links can also be found if people go to the NIEHS website.

Now, in addition to these efforts with EPA, the NIEHS participates in and provides some funding for many joint activities with many other NIH Institute, including management of the Autism Centers for Excellence Program, and the National Database for Autism Research.

DR. INSEL: Thank you.

Lyn.

MS. REDWOOD: Just to share briefly, SafeMinds is a somewhat small, nonprofit organization that focuses specifically on mercury-induced neurological

disorders.

Over the years we've funded several small grants to investigators to provide preliminary data so they could move on to larger grants.

We've been funding sort of a phase 2 of a study that was initially funded, I believe, by NIEHS, to look at the differences between methylmercury and ethylmercury in infant primate Macaques.

What was sort of interesting with that study is that the ethylmercury had a lower level found in the blood after exposures of equal amount of ethylmercury and methylmercury, which was modeled for the vaccine schedule, but that the blood-brain ratio for the ethylmercury as actually higher than methylmercury, and when the ethylmercury did get into the brain it resulted in twice the amount of deposition of inorganic mercury in the brain than methylmercury.

So, sort of the outcome of that is

that you could not use methylmercury as a way to look at how ethylmercury might respond in the body.

We're funding the phase 2 of that study to look at the other hemispheres of those brains. We're going autometallography which will tell us where the mercury localized in the brain.

We're doing unbiased stereology which is a cell-counting technique that will tell us what type of effect both methylmercury and ethylmercury had in the brains of the primates when it deposited in those areas.

And we're also doing some of the neuroimmune studies that were done in the Vargas Research in children with autism.

So, we're real excited about that. That study will be finished in June of this year and unblinded. We're also funding another primate study in infant Macaques as well. So, those are two big research projects for this year.

DR. INSEL: Great. Thank you.

Duane.

DR. ALEXANDER: There is a lot going on, but I'm going to focus on just one topic that I think is of special interest to this group. It's been discussed during the formation of the strategic plan and so forth, and that's the brain and tissue bank resource for neurodevelopmental disorders.

This is research resource that NICHD has funded for about two decades, and it's up for competitive renewal in 2009, and we've been working on getting ready to do that with -- including discussions with this group and with the research community.

That was done very formally with a request for information that we released in November of 2008, notifying the community that we planned to release this request for proposals in the spring, and it -- we invited interested parties to comment on what they thought it should provide and so forth.

We got over a hundred responses from that RFI which we thought was more than we expected. These were very helpful to us in our plans for preparation for the RFP.

We asked for information about the activities of the current bank. Most of the comments were very positive about the -- from the investigators who had received tissues.

They had some suggestions for improvement, but unanimously they affirmed the importance of this bank and the contribution, the valuable contributions it provided for their research.

We also asked for information from interested parties that wanted to comment on mechanisms for extending and enhancing the bank's roles or supporting its ability to leverage its resources, including some of the things that are called for in that research plan.

Our goal continues to be advancement of research in a wide range of

neurodevelopmental disorders, and that's one of the values, I think, of this bank, and it's not just an autism bank, but it's a bank for neurodevelopmental disorders in general, as well as including normal tissue samples as well.

So, we've got comments about expanding it to include a greater number of foreign sources beyond what's already done, including live tissue specimens for storage and maintenance and other ways of collaboration.

So, we are incorporating those into the RFP. It's about ready to release. We hope to get it out by the end of the month so that it will be computed and completed during this fiscal year.

Pretty much it is consistent with the IACC's Autism Research Plan. We won't be able to do everything in one year with the expansion activities, but we will make a start and try to grow it over the course of time.

So, that's the story on the brain tissue bank. We're also involved with lead funding activities in four of the ACE's centers and in one of the networks, and that keeps us busy. Thank you.

DR. INSEL: Thank you, Duane. A quick follow-up question going back to Story's comment about the project at Stanford.

Are we -- and, Story, this may be a question for you, rather that Duane. Are we ready to begin putting stem cells into a repository like this? Is the technology there? Should we be --

DR. LANDIS: For those of you who are stem cells junkies, one of the promises that was made in Obama's campaign is that the Bush policies for human embryonic stem cells which limited the use of Federal funds to stem cell lines generated before August 9th, 9:00 p.m., 2001, would be done away with, and lines generated in an appropriate fashion since then would become available for Federal funding.

And one of the issues that that presents to us is how do you appropriately bank and make available those lines. The estimate is there may be as many as 600 new lines that would qualify. So, that's one issue.

Second -- I know. I'm getting to it.

DR. INSEL: Okay.

DR. LANDIS: A second issue is we now can turn skin cells into pluripotent stem cells which can then be differentiated to form a whole series of differentiated kinds of neurons and are incredibly useful.

And so the question for NIH is, do we want to add iPS cells like the ones that Dolmetsch is creating to the stem cell bank and if so, how do we control the number?

I don't think that the brain bank, as constituted presently, would have the ability to maintain pluripotent stem cells from any source because it's a pretty tricky

operation.

But that's something that maybe the Neuroscience Institute should think about, having a stem cell bank for induced pluripotent stem cells that are of interest for studying neurological and psychiatric disorders.

DR. INSEL: So, can this -- I think in the strategic plan it says that we would collect skin fibroblasts, not stem cells.

DR. LANDIS: ATCC does that extremely well, and in fact, some of the first induced pluripotent stem cell lines were created from cell lines that came from ATCC.

DR. INSEL: So, does that mean -- this is a science question. Does that mean that if you -- so, if it's a postmortem collection and you collect skin fibroblasts within 24 hours of someone's death, can those then be stored in such a way that the could be later be taken out of the freezer and used for

iPS cell generation?

DR. LANDIS: I don't think anyone has generated iPS cells from postmortem skin samples, but that's a really interesting question.

DR. INSEL: All right. Jim, is this -- do you know?

DR. BATTEY: There is no reason, in principle, why that couldn't be done. You can -- you can establish a fibroblast cell line, freeze the cells away and then at any point in time thaw the cells and then treat them with the factors needed to create induced pluripotent stem cells.

DR. INSEL: So, just a thought. I mean, if the RFP isn't out yet and we're trying to think about how to make sure we're consistent with what's in the strategic plan, this may be an opportunity. It's something to think about.

Lee

MR. GROSSMAN: You'll have to

excuse me. I'm just getting my voice back after spending the last four days in my place of birth rooting for the Pittsburgh Steelers, which was a marvelous weekend and a lot of fun.

I guess I'll limit my comments to what we're seeing at the Autism Society of America, and what we're noticing is that the prevalence and incidence of autism continues to climb unabated throughout the US, if not the world.

In the various school districts, State agencies and health plans that we've been in communication with, it appears as though almost all of them consistently are reporting incidents of a minimum of one in 100 of their constituents being classified with an autism spectrum disorder.

And this is pretty consistent with our call center and our contact center and the information that they're gathering as well. The increase in calls continues to go forward.

Interestingly enough, through that contact center where we monitor closely what is the pulse of the community and what they're interested in and what is really driving them, it's an interesting contrast to what we've experienced in the last few weeks since the last IACC meeting.

And I say that because the issues that many of us have been dealing with here, which shows a great disconnect within the community aren't reflective in the types of calls that we're getting, which is a good thing on one side, is that the community is fairly united and -- but it's bad in the sense of what they're asking for.

And there is certainly a united cry from the community, not only from parents and individuals, but also from professionals for increase in services.

It is kind of the unifying factor that the community all can rally behind, and what they are all in need of. And as a result

we've come out fairly strongly with our public policy initiative and have been working with the Administration to that effect to design relative comprehensive legislation that will deal with service delivery in this new Congress.

And we've modeled legislation for states, which we've recently introduced. Unfortunately, Oklahoma and Virginia that were considering autism insurance legislation yesterday both failed to pass those legislation through committee and those bills apparently are dead for the year, which is, again, reflective of the dire straits that families and individuals and professionals are continually facing in the US today in trying to serve the autism community.

Our model legislation is designed around three key aspects. The first one is quality of life across the lifespan. The second one is systems change and the need for that, because the current system, particularly

in the adult sector is ineffective, inefficient and not coordinated, and certainly not only for autism, but across the whole disability community that needs to change so that we can best serve all those that are in need of these services.

And lastly, our public policy and advocacy is based upon global human rights because parents and individuals with autism, and certainly professionals around the world are facing increasingly high levels of discrimination, lack of lifespan services and the interaction that we're seeing in a negative way with the criminal justice system for individuals with autism has certainly reached an alarming height.

On our research end, we will be discussing and having a series of keynotes and sessions in our conference in July which will introduce the concept of marrying the biomedical, behavioral and educational aspects of autism together in a manner that seems to

best address what we feel is a way to address or to solve problems of autism today and to get services and to improve people's lives.

There's much more I can go into what our activities are, but I'll limit it to that. Thank you.

DR. INSEL: Thank you. And that would be a perfect segue into the next session, but I want to, before going into the services, say a little bit about NIMH.

So the National Institute of Mental Health is $55 million in '08, out of the $118 million at NIH. I think we're the largest investor in autism research.

I should mention a story very quickly, that we have recoded our portfolio at NIH, and so the numbers have shifted a little bit, so when you look at these you have to recognize that they are not truly comparable to the '07, '06 numbers because, in the new coding system we've taken out some of the basic science that may be highly relevant, but

we didn't include.

Actually, we have slides up, so I'll quickly take you through these. In terms of where the NIMH is, what I thought I would do is, just to tell you about recent funding.

So new grants that have been funded in the last few months, we have two big arms to our autism portfolio. One part is on the extramural side. That's the kind of research project grants and centers that you've been hearing about.

We also run an intramural autism research program which is in Bethesda at our large hospital with multiple clinics and multiple laboratories associated.

That's kind of the -- we think of it as our kind of rapid response team or the place where we can do highly innovative high-risk projects and things that may not work, but are worth doing, and doing quickly. So, it's also a place for response to public health emerging challenges.

Quickly, just to tell you what's going on in the extramural side and try to line it up a little bit with what's in the strategic plan. Lots of work in the biomarker space. Everything from brain imaging studies looking at new technology for looking at brain connections or for the development of cortical maturation, to studies of peripheral cells and looking at patterns of RNA expression, that really wonderful new project at Harvard that's breaking that down.

And some work that's mentioned there at Stanford from Allan Reiss that's going after the whole question of how does the cortex develop in children at risk for autism.

We don't do a lot on environmental factors, but we have a new project out of David Amaral's program at U.C. Davis working with Melissa Bauman on -- really expanding a previous study that was done and on human primates where they showed the importance of maternal antibodies to fetal brain proteins as

a risk factor for autism.

They want to expand that to look more carefully at a new cohort and we think it's a very interesting new approach to the question of cause and mechanism.

We have several things going on in the early detection realm. A lot of this is the baby sibs work which you've heard about before, but these are all new studies.

There's one rather amazing study of looking at fetal behavior, fetal movement in the younger sibs, so following from the second trimester on, which we think is a little bit of a stretch, but we'll see how that goes.

There's also a lot of work going on now in older children looking at not the development of autism, but the development of predictors of outcome. And those studies are happening at the University of Michigan with Cathy Lord.

One other extramural effort which,

among many -- so this is just really a sampling of the kinds of things that are happening, but this really deals more with the latter parts of the strategic plan around trying to do trials that are much more community-based.

And this is the work of David Mandell at the University of Pennsylvania who's doing this very interesting, very large-scale trial in the Philadelphia School District.

It's really a randomized controlled trial that looks at two different school-based interventions that are delivered by teachers over, I think, it's a six-month period, and then looks at the outcomes and the kids.

So, this is a different kind of research, but one that we think could have an important impact on practice.

I'll just say a little bit about our intramural effort. It's relatively new.

It actually only got its first dollar less than three years ago, and it's grown very quickly. It's a large group.

They've screened over 300 children in this period and they've got about -- well, about 110 or something like that in -- who have been through protocols.

There are several protocols that are being run. One is to do an effort to really -- we call it sometimes phenomics. It's looking at the different subtypes of autism spectrum disorder.

They've got there 72 children with autism who are part of this and about half the group has a clear history of progression, and we're trying to understand in this study what's different about those children who regress from those who don't.

We've got control groups that include children without autism, but with developmental delay, as well as 40 or so typically-developing children.

So, this is a work-in-progress. It's not finished. A range of studies that are done besides very careful clinical evaluation, very careful physical exam, looking at dysmorphology and all that.

Every child, or almost every child gets an EEG, there are MRI's, and when it's possible we collect cerebrospinal fluid as well for proteomic analysis and a range of other tests.

So, this is a fairly exploratory descriptive study to try to understand something about the subtypes. The same program in intramural has a range of clinical trials.

We were sensitive to comments that we've heard over and over again about the lack of intervention studies, and so they have moved very quickly. They completed a phase one trial with minocycline, using that as an anti-inflammatory medication.

The results are not fully

analyzed, but I don't see a lot of enthusiasm from the pilot data that they did look at, Riluzole which has been used in the ALS as part of a double-blind trial now.

They've got 38 children with autism spectrum disorder enrolled in that. Donepezil is an interesting new trial that they've just begun, and it came out of an observation that the children with autism had very markedly reduced levels of REM sleep, and so Donepezil pushes REM, and they thought maybe that would be one way of seeing if you could get a change in behavior.

So, they've only done two children so far. They've been able to show that Donepezil really does completely normalize REM sleep in these kids, but we need to know much more about whether that's going to have the behavioral effects that we're hoping for.

I think you get the sense here this is, you know, a chance to try to do some early phase trials on innovative interventions

to see whether we can get something that hasn't yet been showing up in the literature or from what we're hearing in the community.

The other place that they've gone, which is the last bullet on here is a new study which has not begun recruitment. It will begin recruitment in about a month and that's to begin to study those children who have been diagnosed with autism and lost the diagnosis. So we call this recovered autism.

This was a project that was designed in collaboration with DAN Doctors and many others who helped us to think about, well, how this would be most informative.

It's now been approved by the IRB, and the hope is that this will become a big focus for the next six months, and certainly, if you know children who would fit into this definition we need them, because we want to be able to move very quickly to take a look at this. It's something that we think could be very, very informative. And that's it.

Real quickly, I should just say there is one other thing, and that is NDAR the National Database for Autism Research is moving forward. I think they have 400 -- we call them GUIDs. These are the unique identifiers that are currently entered into the database from the ACE sites and they will be expanding that.

We've given them an expectation of 10,000 by the end of the year, so we'll see how they do. I don't know that they'll hit that, but they certainly will hit a thousand, and probably many more than that.

So, that's ramping up as they get more ACE centers on board.

Now, there are a couple of people of people on the phone. I don't want to exclude you from entering into this if you have updates.

I think, Stephen.

MR. SHORE: Yes. I see some very exciting things happening. Good to see some

emphasis on services and, as Lee suggested a little bit earlier, adults on the autism spectrum.

We have this increased incidence and prevalence and what are we going to do, as they continue to age out at a faster and faster rate of public education. So, it is good to see some of that being discussed.

DR. INSEL: Thank you. Is Jennifer Johnson on the phone with us yet?

Maybe not. Anyone else on the phone?

Okay. Any other points of discussion before we move on?

Very good. Let's begin talking, then, following up on Stephen's comment about the services issues.

And, Ellen, you were going to take us through what we need to hear about. Service -- we'll call this services in the financial crisis era.

MS. BLACKWELL: Hi, Stephen.

MR. SHORE: Hi.

MS. BLACKWELL: I hope I'm not going to be throwing a bucket of cold water on everybody today, but I decided last week, after we -- CMS periodically meets with a group that we call The Associations, and this meeting includes State Medicaid directors, the Association that represents all the State Directors of Developmental disabilities, the State units on aging, the State head injury administrators, the State mental health program directors, and other individuals.

And listening to folks at this meeting was just overwhelming for me. You know, it's a great opportunity for us to dialogue with them to talk about what's happening in the states, and what's happening to these very vulnerable people that have disabilities.

And after I listened to them, I thought, gosh, you know, this would be a great topic for us to talk about at the IACC because

certainly the economy is having an impact on people with autism.

In fact, Nancy Thaler, who represents all of the State developmental disabilities directors, told me that she thinks an analogy can be drawn between Hurricane Katrina and that this economic situation is akin to Hurricane Katrina for people with disabilities in this country.

So, you know, I think it is important to talk about, and so that's what we're going to be doing today, and with me is Ann Kohler, who is the -- represents all the State Medicaid directors, so Ann will be talking after I give my remarks to sort of give us the Medicaid directors' perspective.

Okay. So, we're going to -- okay. So, CMS, we now administer some very large programs, Medicaid, Medicare and also the Children's Health Insurance Program, which is not Medicaid. It is a separate grant program that the President is expected to sign into

law this afternoon, in fact.

It presently covers about seven million kids. This new bill will significantly increase enrollment and the interesting thing about CHIP is that some states use it to expand Medicaid programs. They can operate it separate from Medicaid, or they can use a combined approach. So, I'm sure we'll be hearing more today about CHIP.

Okay. So, really, I wanted to focus today on some provisions in Medicaid that I think really impact people with ASD.

The first one is probably the most important. It is the home and community-based services waivers that you folks have heard me talk about a lot, State-planned services that come through the Medicaid program, and also we have some demonstration programs that can impact people with autism.

Home and community-based waivers are really the bread and butter of services for children and especially for adults in this

country.

You know, I can't stress enough that these are optional programs for adults. Most children in the United States are supported through the education system.

Presently CMS has approved about 350 waivers. We don't know exactly how many people they serve, but we're guessing over a million people, and we think about have have.

You know, our statute says mental retardation, developmental disabilities, and that includes people with autism. Every single State in the United States has a waiver, an HCBS waiver that serves people with MRDD.

A few states, I want to say about six or eight, have a waiver that exclusively serves children with ASD and, as you heard in our November meeting, one State, Pennsylvania, has an approved waiver that serves 200 adults with autism.

CMS recently approved a separate

managed care contract. It's kind of interesting. The State is going to be experimenting with managed care. They have a provider that's very interested in providing adult services.

So, we'll see how that measures up against their fee-for-service product. But that is the only waiver that serves adults.

So, I thought I'd do sort of like a little basic refresher on what the State plan is. This is the -- the State plan is what the states submits to CMS, that talks about how it's going to serve these very, very vulnerable people.

States decide who they are going to serve, what the services are, who the providers are. States decide how much of a service a person can get. Services must be medically-necessary and CMS doesn't decide what that means. States do.

Generally speaking, if you're in Medicaid, services have to be available

throughout the State, and most importantly, State plans are living documents.

And what I mean by that is that states can come to CMS at any time and file an amendment to make changes to their State plans, and that is exactly what we see happening now.

DR. INSEL: Ellen, excuse me. On that slide, who determines whether the services are medically-necessary?

MS. BLACKWELL: States do. States decide. CMS, as the federal government pretty much stays out of medical necessity. It's a concept that is, you know, embedded in our statute, but states decide medical necessity.

DR. INSEL: So, what's medically-necessary in Maryland might not be medically necessary in Virginia?

MS. BLACKWELL: Exactly.

DR. INSEL: Okay.

MS. BLACKWELL: So we also have a couple demonstration projects that I think are

of note.

The first is one that the Congress put in the Deficit Reduction Act, and this is a demo that is looking to help 30 states transition about 35,000 people out of institutions, all kinds of institutions that Medicaid covers, ICF's, nursing homes, hospitals.

That includes what we estimate to be about seven thousand people with mental retardation and developmental disabilities, including autism.

The second demo is one that these PRTF facilities are not presently in the Medicaid statute as institutions, so this demo is to look at helping children with mental disorders, including autism, transition from institutional to home and community-based settings.

And both of these demos are underway. The second one is actually further underway than the first.

Okay. So, what's happening out in the states? Well, as we know, the national budget situation is pretty serious. State budget constraints are severe, and I can't stress that enough.

Unlike the federal government, states must operate with balanced budgets. Medicaid is about 21 percent of every State's budget.

Typically Medicaid is number two. Education is number one, but I need to tell you that they are pretty close.

The other thing we know is that Medicaid rolls are growing. State officials, as I said earlier, are taking very quick action to make amendments to their State Medicaid programs in response to the problems they are facing in their budgets.

And the other thing that's really plaguing the states is that they -- their State staff have really decreased. Not just through attrition but, you know, in one of my

states, California, folks are being furloughed for two days a month.

There are layoff's, there are hiring freezes. So, there's more work in the states and in the federal government, and fewer people to do the work, which is a problem.

So, what's happening in home and community-based services? These are really the backbone of Medicaid for adults in this country. They are optional services. As everybody knows, there are waiting lists for home and community-based services in most states and waivers have caps on enrollment.

We are already processing amendments in CMS to reflect these dire economic conditions in the states, and my last point is that once these changes go into place, it's kind of hard to put this stuff back.

So, I think that's something to bear in mind. You know, new people coming in

and changes being made to these -- to the waiver.

So, what kind of changes are being made? These are the sorts of things that we're seeing and I'm going to try to explain them. Reductions in the amount of services. What does that mean?

That means a person who might be getting a day program, say, a person with autism five days a week, now this person might be able to go to their day program two days a week.

Or, the second bullet, maybe that adults program day program is eliminated completely from a waiver. One of the folks at The Association meeting is the example of a person who's been going to a day program and a person with autism for 20 years.

So, that's the adult's routine. Now, no more day programs. This person who is an adult is now going to be home with his or her parents or parent, and that's going to

make a big difference in everyone's lives.

It's also going to change the service mix because, you know, now the parents are probably going to want some respite care and one of them may even have to quit their job because now they've got to stay home with their adult child.

So, that was an example that was used that I thought was, you know, very dramatic at The Association meeting. States can reduce the frequency of services.

Another thing that they can do is, these waivers are based on a cost comparison between institutional costs and home and community-based costs.

Typically, states take the aggregate amount so a person with autism, say, you might cost more than someone who needs, you know, less services, could actually get those because they are not going over the institutional cost limit.

But states an use individual cost

caps on these waivers. So, that could really impact someone who needs more services and who is a more costly user.

States are also putting freezes on their waiver enrollments. So, in addition to waiting lists, we are talking about freezes. You take a waiver that -- I'm just going to use the example that serves 2000 people and we do have some waivers that aren't at the cap.

That means that if there are 200 slots unfilled, that means that 1,800 people are going to be served, period, because states are only obligated to provide CMS with guesses, estimates about how many people that they serve.

So, a lot of states put freezes on waiver enrollment, which means that waiting lists that are already long are probably going to get longer.

Another thing we see -- already, these amendments are being filed for provider rate reductions. So, you heard one of our

providers talk in November about, you know, she pays her personal care workers $8 an hour, so in one state, Oregon, they're talking about 30 percent cuts.

So, you know, we're talking about people who are already very low-paid workers making even less money.

Another step states may take is to eliminate waivers entirely, or combine waivers with fewer services in them. So, an additional way states can, you know, change a waiver would be to narrow the targeted criteria regarding who gets waiver services to make it harder to get into a home and community-based waiver.

And the last bullet is they can make it -- states can make it harder to get into an institution which is the measurement criteria against which home and community-based services are based.

So, these are the sorts of changes that states are contemplating, or already

taking. And what that basically means is that it is going to be even more difficult to get home and community-based services in this country.

What are states doing to state plans? It's happening. I see. Okay. State plans are a little different from waivers. These are the services that states have either elected to provide or are obligated to provide.

We're seeing some services, including mental health services, dental services, speech, vision, personal care and pharmacy services. They can be changed or they can be reduced or eliminated altogether.

I heard one individual at The Association meeting talking about caseload management, workload ratios. Well, say, in a state like Maryland where the caseload ratio is one case manager to 50 people, now we could see one case manager, 60, 70, 100 people.

We don't really know. States are

obligated to provide services that maintain health and welfare but, you know, they're doing the best they can.

Again, on the state plan side, we're seeing provider rate reductions. In some arenas states can increase cost-sharing or premiums. You know, let me remind you that we're talking about people who receive SSDI in many cases that's -- in 2009, $674 a month to live on.

So, they have to pay room, board, everything. That's their income $674 a month. Kind of hard to increase cost-sharing and premiums on that population.

And we're also seeing some states delve further into using managed care delivery services which can be cost-savers for them, and managed care demonstrations. Vermont, Hawaii. Arizona's always been a managed care demonstration. And Rhode Island has delved deep into this recently.

So, there are changes happening on

the regular state plan side as well.

The other place where states can make changes that will have a dramatic impact, or they can make it more difficult to get into the Medicaid program. As I just said, you have to be pretty poor to qualify for Medicaid.

You have to have less than -- a single individual, generally speaking, an SSI person, less than $2000 in assets, and you also may be aged, blind or disabled, a child or a pregnant woman.

I think we might see states drop some optional eligibility groups. States can also start to count income and resources that they didn't previously consider. All of these things make it much harder to qualify for Medicaid.

So, in addition to having to face these budget cuts, states are also facing a big influx of people who are going to be poor enough to qualify for Medicaid.

As far as the demonstrations go, we had one State, South Carolina, which recently recused itself from the children's demonstration because it didn't have enough money to implement the demonstration.

We really don't know how the money follows the person demonstration will be impacted by the fiscal climate. It's quite possible that these reductions in state staff will make it much harder for states to implement these really great programs.

So, Congress is talking about the -- you know, the fiscal stimulus. It includes $87 billion to supplement state Medicaid programs, and I'm going to let Ann talk about what that might mean and what it might not mean.

It does propose to increase the match that the states receive from the federal government. As you know, states get a minimum of a 50 percent match from the Government. CMS is sort of the -- we oversee these

programs, and we really do consider the states are our partners.

We are here to enforce the rules and make sure that everyone is treated fairly, but states are in the driver's seat as far as Medicaid goes.

And this last slide is the same one that Tom put up before. It's very difficult to read, but when I looked at this earlier this week, I thought, wow, there's a lot in here about services and supports. And I thought that was very interesting.

It actually spurred me to take a look at the Combating Autism Act, and when I was looking through it last night I counted -- and my count might not be perfect, but in the CAA, Services Supports and Interventions are mentioned twelve times.

So, I think it really is important that we continue to talk about these issues.

And with that, I am going to turn this over to Ann Kohler, who is representing

our State Medicaid directors and herself, was a state Medicaid director in the state of New Jersey, so she knows first-hand how these very brave people are tackling these very, very difficult issues.

MS. KOHLER: Good morning. My name is Ann Kohler. As Ellen said, I was the Medicaid director in New Jersey but I was also, before that, the Medicaid director in New York.

And immediately before joining the National Association of State Medicaid Directors, I was the Chief Fiscal Officer for the New Jersey Department of Human Services, which is a very large umbrella organization that includes not only Medicaid and TANF, but DD, mental health and substance abuse.

So, I have a great deal of experience on both Medicaid and State budgets. And I've got to be honest, I have never seen things quite as awful and dire per State as they are today.

Okay. So, first, as Ellen said, Medicaid is a Federal and State partnership. Each put up money to run the programs and we work together to accomplish the goals that make sure that our clients are receiving needed services.

But the current economy and the budget constraints that are facing all the states, combined with the President's commitment to health care reform are causing some very, very fiscal challenges for the states.

Okay. Perfect. When I did this last week, there were 41 states who had said that they are experiencing some very severe fiscal constraints. When I started last July, a little over six months ago, it was 29.

Yesterday I heard the number is up to 47 states. 47 states that are experiencing some severe crisis with their 2009 and their 2010 budgets. 31 states have already made cuts during the middle of their budget year.

New Jersey's fiscal year starts July 1st. The Governor has already had to cut a few billion dollars out of the approved spending because the revenues are so much lower than what had been anticipated.

In New Jersey, that 30 percent of the money comes from the financial markets in one way or another corporate taxes, income taxes, et cetera, and we know that the bottom has fallen out of them, so also the bottom has fallen out of New Jersey's budget.

And I think the same -- I've heard the same from Connecticut, New York, the Northeast where the count quite a bit on the financial market for revenues.

Over half of the states have cut spending. They have spent down their rainy day fund. Some of them have had to raise fees and revenues to balance their budgets, and we think that their problems are going to continue for quite some time, and only get worse.

Right now, the only states I know of that are talking about a balanced budget are ones that are oil-producing and they are also beginning to experience some issues.

As Ellen mentioned, the stimulus package does include additional money for Medicaid. Both the House and the Senate version include money.

They distribute it differently, but they both -- the concept is that the will have the federal government pay a bigger percentage of the Medicaid budget.

We call that increased Federal medical assistance percentage. FMAP you may hear, sort of the jargon. But, as I said, the enormous losses and the economic downturn has really strained the State budgets.

As Ellen mentioned also, the states can't deficit spend. Therefore, if their revenues go down, they must cut. They are looking to Medicaid, and many states are making some significant cuts in Medicaid.

Again, as Ellen mentioned, education and Medicaid are really the two big ticket items in any state's budget. So, to balance the budget you have to look at the two of them, because other programs are not big enough to be able to absorb the needed reductions.

This -- both the House and the Senate Bill include a maintenance of effort provision so that if states get this additional Federal match they must maintain their eligibility, so they can cut services. They can cut provider rates, but they must maintain their eligibility levels in order to receive it.

And there's been a lot of research that shows that these additional Medicaid dollars help families to spend money on other things and it stimulates the economy because of the spending and it trickles down to health care workers, such as orderlies in hospitals and nursing homes.

So, what are they doing now? Because they are all faced with the need to reduce costs, a lot of effort is going into ways to prevent fraud, waste and abuse, implementing a lot of computerized models that can drill down in the claims.

They are looking at technology to reduce cost. A lot of states are looking into electronic health records and e-Prescribing. Many states were fortunate enough to get some grants from CMS to transform their Medicaid programs and most of these have gone into using technology in one way or another.

They are expanding the use of evidence-based treatment to determine medical necessity. As Ellen mentioned, each state can define medical necessity differently, and then they are using this evidence-based treatment to determine their coverage and they are looking at their coverage plans to make sure that they are effective in reducing anything that has not been determined to be effective.

Okay. So, let me talk a little bit about the stimulus package, because states are really counting on this stimulus package to save them this year. The increase in Medicaid is critical. We need it to happen and we need it quickly.

It extends until 2009, six regulations that had been implemented by CMS that would reduce, significantly reduce cost to the state and it also adds an outpatient regulation to the moratorium.

We are very concerned about that regulation because it would significantly reduce Medicaid's ability to pay hospitals, which we think when you're trying to stimulate the economy, cutting rates to hospitals is not very helpful and should only be done as a last resort.

It extends transitional Medicaid. That's Medicaid coverage for people who go to work to give them a little more transitional time before they lose their Medicaid.

A significant amount of money for health information technology which, again, we think is really a great way to reduce medical costs and it provides the temporary health insurance, either through a Medicaid expansion or through funding of COBRA.

COBRA, when you lose your job you are allowed to buy your employer's sponsored insurance for a period of time. So, it would give the states the option to either do a temporary Medicaid program funded entirely with Federal money or to reimburse workers for their COBRA coverage.

So, just in summary, states are in a terrible fiscal condition. They are going to be making some significant cuts. They've already started to make them.

This does have some pretty significant implications for people with autism, and as Ellen said, these community-based program are optional. States don't have to do them.

And so, when forced with significant budget cuts, some of the first things they do is look at things that are, quote, optional under Federal law, and reduce them.

I know from my experience in New Jersey, the waiting list for people with developmental disabilities is long. States -- and I think this is pretty common, most states don't have enough money to meet the total demand for these services, even during good times.

And so, there are waiting lists, and they are going to get longer. So, we're hoping that the stimulus bill does get through Congress and does get signed very quickly by the President because as Ellen said, once you make these cuts it's very hard to restore them.

So, thank you for listening to us.

DR. INSEL: Thank you both. I'm just coming back from a meeting with

economists, which I thought was the most depressing meeting I had ever been to, but this actually surpasses that level of misery.

Alison.

MS. SINGER: I just -- I want to add to what you said. When you talked about the fact that the two biggest components of state budgets are Medicaid and education, we also need to look that within the educational realm, there appears to be at the state level a disproportionate amount of the cuts within the education budgets in the states falling on special education programs, because those programs tend to be more expensive to implement than general education programs.

So, our families are really going to be facing a double whammy here, in that the cuts are going to hit from all sides, and I think we also, in addition to looking at Medicaid, also need to keep an eye on the educational budgets to make sure that our families are -- are not receiving a

disproportionate -- disproportionate cut.

MS. BLACKWELL: And the interesting thing, many of the children that receive special education are also receiving Medicaid-funded services in the schools, and one of the regulations that are under moratorium is a change that would have reduced Medicaid's ability to pay for those therapies in schools. So, you're right.

DR. INSEL: In a previous meeting we heard about the CBO, the Congressional Budget Office report on the cost of education to the states. It's very interesting, because you've mentioned this was second only to education.

But within the education budget for the IDEA piece of that, which has expanded hugely in the last ten or fifteen years, autism was the number one source of the budget items that they were looking at.

So, on both sides, as you say, it's a double whammy. Let me just ask you if

there's a triple whammy here that you didn't mention.

Looking at the increasing unemployment, which is starting to really skyrocket beyond six percent, we have been hearing about how for many families with young children with autism, they become, rather than two working parents, one working parent outside the home and one working parent inside the home.

What happens as unemployment kicks in? I don't know what extent autism costs per health care and services are covered by insurance, health insurance typically, but is that going to be a third whammy?

MS. KOHLER: I think so. Let me start by saying for every one percent increase in the unemployment you have about a million more people on Medicaid, so that's another strain that state budgets are facing.

The number of people on Medicaid is going up, and yes, I think outside of

Medicaid, I can't think of a single private commercial insurance plan that would be able to cover the cost of an autistic child without hitting its cap, because almost every one has yearly caps and lifetime caps.

So, you know, you lose your health insurance or you lose your ability to have two coverages. You lose your income. You go on Medicaid, but there may not be enough services out there to help you.

MS. BLACKWELL: And I would add -- I pointed this out in November, but in this country, children have an entitlement to services generally through age 21. So, even in Medicaid, children can receive a wide array of services. Children who qualify for Medicaid.

It's the adult population that is really kind of shut out because they are dependent upon these optional programs. To some degree institutional care might, you know, be an option but I don't know too many

people that are eager to go into an institution. Most people want to live in a community-based setting.

So, I think that's where the real -- the real trouble could lie.

DR. INSEL: Could you just clarify one thing? You both mentioned that the recovery package that is sometimes called the stimulus package includes an increase in the match. To what extent? How much does it look --

MS. KOHLER: Yes. And of course, each one is different. So the House version has $87 billion. The Senate, I believe, $89 billion. It's broken into two parts. Both Houses break the increase into two parts.

One is an across-the-board flat rate. I think the House's 4.6 percent bump up's, Senate 5.9 percent bump up. And then the other piece is an additional bump up, according to your unemployment.

Of course, both Houses did that

differently, too. In the House it's split 50-50. Fifty percent of the 87 goes to that first bump up and 50 percent varies by unemployment. And in the Senate, 80 percent goes to the first bump up and 20 percent, based on your unemployment rate.

MS. BLACKWELL: So, Ann, you know, each State -- most states get about 50 percent to 50 percent. Fifty percent federal, 50 percent state dollars. But it's based on a rather complicated formula.

Some states can get as much as, I want to say 78, 79 percent. So, it really depends on the state. But like what would be the average percent that a state could expect to receive? Say, a 50-50 State?

MS. KOHLER: Well, it start with the 54 percent or the 55.9 percent depending on, you know, what their -- which bill passes. And then it just keeps adding up.

So, it would get -- you know, if you were in a very, very low -- there's three

tiers of unemployment, so depending on what tier you fell into it would vary.

DR. INSEL: But you're saying that basically, at least for this first year it's a five percent increase over what --

MS. KOHLER: About that, yes. And it actually goes from October 2008, it would go back until December 31st, 2010 that states receive that extra funding.

I probably should also mention -- you know, Ellen mentioned that eligibility varies state-to-state, and it can be based on different levels of the Federal poverty level.

For families -- not disabled children or people getting SSI, the Federal poverty level for a family of four is about $20,000, and most states cover maybe 50 percent of that.

So, imagine a family of four on $10,000, and trying to buy services for their child. It's very difficult.

MS. BLACKWELL: Ann just said

something really significant here. I'm sorry. Which is that the stimulus bill, correct me if I'm wrong, will go towards paying unpaid bills as well as future bills.

MS. KOHLER: And we'll let Medicaid stay at least at the eligibility levels that they're in and not have to drop that down further, the financial eligibility bar, which some states are facing right now.

MR. GROSSMAN: Ann, in response to a request yesterday morning that we got from the Administration, we supplied them late yesterday afternoon with a listing of issues that are already in the stimulus bill that relate to autism, and I thought I had it on my computer.

So, if any of my staff is listening in, which I know a few of them are, if you could email that to me I can go over it.

But there's about eight points that are actually covered in the stimulus bill

that will affect the disability community and specifically autism.

The sad fact here, and as you were saying, Tom, his goes beyond a triple whammy, this is really an infinitesimal whammy on families.

The stimulus bill will have little impact on retaining most of the services that are about to be cut. It will take years to catch up, unfortunately, and this is falling heavily on the families that can least afford it and the adults that have been denied adequate services to this point.

I hope that in future, as we move forward, the IACC, that this will become an extremely high, our highest priority on how we can go back and, as our role to advise the Secretary, whoever that might be at this point, on ways that we can devise systems that will address this population.

The systems that are here now have been ineffective, and we're pumping money into

systems that will remain that way. There are solutions out there, and they're not -- they're not hard solutions, they're just different, and people are resistant to change, but we need to change it to fully address the needs of this community because they are not being met now, and they won't be in the near future.

With that said also, I think that we can't afford on this Committee to let another generation go by without getting the actual improvement that we can provide to them today. And I hope that will be our emphasis going forward.

DR. INSEL: Yes, I think if you could make a motion about this, Lee -- what I, if we are going to make this an action item, what I would like to recommend is that we bring the Secretary, whoever that's going to be here to the next meeting to get a sense of what this really means, and how this -- yes, I have to say, I thought these were great

presentations, but whenever I see that the plan to save money is to invest in information technology, I get really worried because I've never seen that actually work, in reality.

MS. KOHLER: Well, I can tell you in Alabama, it will save Alabama, using this transformation fund money that they received -- I think it was about $16 million, they've created an electronic health record for 97 percent of the people in Alabama. It's up and it's live.

DR. INSEL: It may be a great way to improve efficiency, but I've never seen it save money. I keep hoping that it might, but we all -- we get pulled into all kinds of great ideas with IT, and I'm always amazed at the hidden cost that you don't expect to keep something like that up to date and all that.

But, anyway, that's a bit of an aside. I think the bigger message for the group here is that you've laid out sort of the brutal facts, and it's clearly -- it's

evolving and it doesn't sound like it's getting better, although perhaps the Recovery and Reinvestment Act, if it passes, which is still not clear, but that would provide at least a two-year partial solution.

There's a lot we haven't talked about around this, both the education cost and the costs that come around from other parts of the service sector, which I think need to be formulated and laid out or whoever's going to be the Secretary of HHS to hear about.

And then to think about -- so, you know, it's true that this really rests at the level of the states, but it's hard to believe that there isn't more that we can do.

I mean, if this group collectively, with all of the HHS and even the Department of Education person on it, can't come up with something that will be addressing this, it's a very sad statement indeed.

MS. KOHLER: I think there is.

DR. INSEL: I think we ought to

talk about how we can actually come forward with a plan.

MS. KOHLER: I think there's a couple of areas that I would sort of suggest that you look at.

The first is one that all Medicaid directors will tell you about. Medicare and Medicaid don't talk to each other. And the most expensive people are folks that have both.

So, you have two big health care programs that are covering the same person, and they don't even talk to each other. So, that needs -- that improvement, I think, if you could somehow get those two programs to be more coordinated could lead, I really do believe, to some significant savings.

The other area I think that we certainly talked about at The Association meeting, in depth, is institutionalization is the norm. Community services are optional and the exception.

So, you have to provide nursing homes and ICF/MR services you don't have to provide care in the community to aged or developmentally disabled.

We have to flip that. We have to change that, and make it be hard to get into an institution and much easier to get your services in the community.

MS. BLACKWELL: And the reason, for the most part, that our statute is rooted in this institutional bias is because it was written in 1965, you know, and revised -- home and community-based services were only added in 1981.

So, you know, if the growth in home community-based services since 1981 is staggering, and if you look at the charts you can see institutions down, home and community-based services up, but nevertheless we are still, you know, operating based on a law that was written decades ago.

MS. KOHLER: Yes. And if you

think that one person can't make a difference, let me tell you about a woman named Julie Beckett.

Nobody had -- the were no community services covered under Medicaid until she hounded Ronald Reagan to change the rules so she could bring her little girl home.

And you have an entire industry now that came out of one woman's fight for her child. It's an amazing thing.

DR. INSEL: These are complex issues, but -- and we'll have to stop here for the break, but I appreciate both of you getting us up to date with, as you said at the beginning, it's the equivalent of Katrina, but it affects everyone in the nation and even outside of the US, increasingly.

Let's take a ten-minute break, and we'll be back at ten after -- I'm sorry. Five after the hour.

(Whereupon, the above-entitled matter went off the record at 10:57 a.m., and

resumed at 10:08 a.m.)

DR. INSEL: It's time for us to begin the last agenda item for the morning. If I can have the Committee return to the table. Thank you.

We have one more piece of business this morning. Okay. Welcome back. We are going to talk about what is really truly just a process issue here that is in the Combating Autism Act, a requirement to provide an annual summary of advances in research.

We already did this last year, and you saw the advances and you voted on them and they were submitted. The question is: Looking at the process for doing this in the coming year and how you want to engage that.

We've asked Diane Buckley, who is part of the Office of Autism Research Coordination, to give us some ideas about how to do this.

And, Diane, I'm going to turn this over to you.

MS. BUCKLEY: Thank you, Tom. Good morning, everyone.

So, to kick off the discussion, I'd like to take a few minutes to just tell you about the information that we've gathered to date to outline a few possible next steps and to pose a few discussion questions about how to proceed.

And following those remarks, I'll turn it over to the Committee and it will be time for all of you to discuss and define the process that will be used to prepare this year's report.

As Tom mentioned, the Combating Autism Act did require -- does require the IACC to develop and annually update a summary of advances in autism spectrum disorder research related to a range of topics.

The Committee approved the first annual report at its public meeting on July 15th, 2008. That report highlighted ten key scientific advances that were identified in

peer-reviewed literature in calendar year 2007. And that report is available on the IACC website also.

So, to lay the groundwork for the 2008 report, our office, the Office of Autism Research Coordination, asked the NIH Library to conduct a literature search to identify original scientific findings, published again in peer review journals in calendar year 2008, using the primary search terms autism and autistic so a very broad approach, using those terms to search more than a dozen sources.

The search yielded more than 120 peer-reviewed publications from over 80 journals. In an attempt to focus the search on the most significant or noteworthy publications, the search focused on identifying scientific findings that were highlighted in major science news or databases that provide ratings or reviews of scientific publications.

So this resulting list are not the

news articles, of course, but they are the base science that those articles were about and that they were highlighting.

We have begun to do an initial sorting of those publications into six broad topic areas. You can see from the list that those topic areas encompass the range of topics that are required in the Combating Autism Act and they should also look very familiar to you because, in content, they really correspond to the six-question framework of the strategic plan.

So, that's where things stand. That's how far we've gotten in terms of initial groundwork. And so the question is for discussion today is, how would the Committee like to proceed in going from that beginning work to producing your next annual report summary of advances.

One approach would be to undertake these proposed next steps which would be to first finalize this list of publications.

Again, the search strategy, it was an objective strategy, but in terms of finding those articles, if things were highlighted in the news it may be because they were highlighting a criticism or a flaw or a controversial issue or for a variety of reasons.

So, I think we really view that that publication list is a first step, and that list needs finalization. A second step would be to identify among that final list what's most significant, and then ultimately to translate that into a concise report that is very lay friendly.

In each step, the IACC members, all of you, could really play a critical role so that in finalizing the list of publications, as members, you could review what we identify to date, and then identify publications for addition, possibly deletion or resorting.

In terms of identifying the

significant publications, that would, of course, be a critical role in pointing it and kind of working through this long list of really what is the most important thing, and what do we want to highlight.

And then finally, our office could incorporate all of that input that the Committee provides and develop a draft report for your review with revisions and ultimately get to a final report to vote upon.

So, questions, to start the discussion, what do you think of those steps? Are those steps okay? Are they acceptable? If not, would you like to modify them in some way?

Once you define what the basic steps are, how would you like to complete those steps? There's a variety of approaches that could be used. Perhaps each member would want to review the listing individually and work through just email and electronic means to indicate your additions, deletions and even

what you think is significant per topic area.

Or, perhaps you would view this as more of a collaborative effort where you would want to have OARC organize for you a teleconference or webinar. Well, teleconference and webinar, we do them at the same time, so that you can talk with each other as you -- as you determine what is significant.

And then finally, once all of that -- those process steps are agreed upon, to lay out at least some major milestones in terms of the time table, to think about if you'd like us to organize a meeting, when would it make sense to do that or, if you wanted to do the individual reviews, what kind of timeline would that require, and when would you be looking to us to provide you with a draft report as kind of a target date.

DR. INSEL: A point of clarification here. In terms of the timetable, the previous report was July 15th.

MS. BUCKLEY: Yes.

DR. INSEL: Of '08, and it covered all of calendar '07.

MS. BUCKLEY: Correct.

DR. INSEL: So we're talking about a July submission to cover all of calendar '08 at this point, right?

MS. BUCKLEY: Yes.

DR. INSEL: Okay. And that means published in '08 or --

MS. BUCKLEY: Published, including e-published, is how we handled that last year.

DR. INSEL: Okay.

MS. BUCKLEY: And then once we identified an area that we wanted to discuss based on things that came out in 2007, if there were follow-up publications that had come out early in the next year, we did sometimes include those in the write-up to, kind of, you know, flesh out the whole picture.

But it was based on -- that the

initial discoveries were coming out in the defined calendar year.

DR. INSEL: And in terms of -- how are we defining publication? Does that mean in a peer-reviewed journal or are we including abstracts at meetings, those kinds of issues?

MS. BUCKLEY: No, definitely in peer-reviewed journals, just as last year, and we omitted things like review articles and editorials or abstracts or anything like that.

DR. INSEL: And what about books?

MS. BUCKLEY: No. I don't believe that they are in there, no.

DR. INSEL: Because they wouldn't be peer-reviewed. Okay.

MS. BUCKLEY: Right.

DR. LANDIS: So, is there a requirement that the advances have been funded by federal agencies or not?

MS. BUCKLEY: No. There's nothing in the law about that, which is really our only formal guidance. And the precedent that

we use in terms of just our first report, last year was we did not look to funding source.

We looked to this issue of quality based on using peer-reviewed -- the peer-reviewed literature.

DR. LANDIS: Great.

DR. INSEL: Jim.

DR. BATTEY: Would it make sense to use a criteria such as citation index to determine which of the articles, perhaps, had the greatest impact?

DR. INSEL: I think the problem, we talked about this before, last year, but it's so recent that you won't have a chance to collect the citations.

That's why the group was looking at, kind of, popular, you know, like newspaper articles that would have picked up the story.

But that, as Diane mentioned, is a flawed approach, because they may not be identifying the most high-impact science.

MS. BUCKLEY: We also did use

Scopus, and we only included from that particular search of using Scopus, included articles that had been cited five or more times. So, that was one piece of the dozen sources and search IDs that were employed.

DR. INSEL: Five or more times not by the original author.

MS. BUCKLEY: I don't know. So that would be something for sorting and cleaning of the list.

DR. INSEL: Linda.

DR. BIRNBAUM: This may be a naive question, but I was wondering why reviews are excluded. They are peer-reviewed and very often, in fact, someone who pulls it all together also can sometimes provide insight into where the field should be or is going. So, I would urge that reviews should be included.

MS. BUCKLEY: I think that's an issue for the Committee to discuss and agree upon.

DR. INSEL: As an example, there were three reviewed papers on autism in Cell in September or October, which would be, you know, pretty high-impact for the field.

MS. BUCKLEY: And I think that is the critical question, at least that we tried to focus on again, and the only report we did so far was: was it really indicative of an advance?

Where, often times, review articles don't do that. Don't push it forward. But if they do, and if that were a criteria, I don't -- I don't think it would be a problem.

DR. JANVIER: I just had a comment also. I know last year Dr. Insel presented at IMFAR and I would assume there will be representation this year that, you know, sometimes, whether it's a poster or an oral presentation, you know, it takes a long time to get from data collection to submission to publication that, you know, I would recommend

that anything that was published there would also be considered as an advance but, again, based on scientific criteria.

DR. INSEL: So, that's an important issue, I think to have in the discussion because, if you draw the line at peer-reviewed publication, then you wouldn't include what's presented or abstracts at IMFAR.

You know, they may ultimately show up, but probably in the following year, and I think it's something the group should grapple with if that's worth doing or whether that makes this vulnerable to having research that might not be the quality you want.

Jim.

DR. BATTEY: No, I would encourage sticking with peer-reviewed publications and reviews that advance the field. I think that's a defendable criteria for inclusion, and if you slip to anything less than that, I do believe you leave yourself with some

vulnerability that's -- for which I see no major upside, since if, in fact, those IMFAR items do evolve into peer-reviewed publications, you'll capture them the subsequent year.

DR. INSEL: Linda.

DR. BIRNBAUM: I just want to support that. I think that all too often abstracts end up with serious mistakes and the more flaws, not because they were intended that way.

And I think, given that you include the e-pubs, that really does enhance the rate of stuff appearing in the available peer-reviewed literature.

MS. REDWOOD: Dr. Buckley, I'm wondering whether or not we might should try the search again and broaden it some to include Asperger's Syndrome or Rett.

I just am sort of disappointed to see only 120 articles that came up, so I'd like to maybe try to broaden the scope a

little bit, and I do think it would be important to look at funding source.

Personally, I would like to get a little bit better feel for who is providing a lot of the cutting edge research this year. How much is coming from our federal agencies and how much is coming from private funding institutes, and to have this somehow broken out -- and you may have already mentioned this -- into sort of our subcategories from our workshops, like Biology Treatment Risk Factors, so we can see if our research portfolio that's coming in is somewhat balanced, and then also to look at the research that NIH has funded to do some type of portfolio analysis to see whether or not we really got a bang for our buck for what we funded.

And this may come into this afternoon's discussion when we talk about how we actually look at the strategic plan and evaluate and update it annually, but I think

building in some type of mechanisms to do a research portfolio analysis would be real important, too.

DR. INSEL: So, before you answer, if I could follow up on that. These six categories were created before there was a strategic plan. And, as you said, there's some match-up. It's actually not a perfect match.

MS. BUCKLEY: Back up to that slide, Azik, please, the sorting slide. Thank you.

DR. INSEL: Would it make sense, along with Lyn's recommendation, if this -- if this exercise is going to become one of the ways in which we can actually look at progress, and that's, I think, what the Combating Autism Act was asking for, should we make these six categories match precisely with what's in the strategic plan and then we could use this exercise as one of the ways in which we monitor progress on the plan?

MS. BUCKLEY: We had a similar discussion last year and there was really some interesting perspectives, I think, across the community about what it meant, especially when we came out with the report, and we would -- we used the -- the question header from the strategic plan and then we had the advances.

And so then the immediate question is: ss this a report on progress from the plan? Well, of course, last year it wasn't. We didn't even have the plan. We had the new framework, but we didn't even have the plan.

And so there was some concern that it might be a bit confusing to link it that specifically to the framework in the plan.

And that, really, the whole purpose of our afternoon discussion is going to be to determine how we will monitor progress in the plan.

And so, these categories that you see before you, they do reflect the ones that we started with. They are close to the ones

we started with before the six-question framework, but really we only started with four topic areas then.

Right, we had diagnosis, risk factors, biology risk factors and treatment. So what you see here is actually a new list that we created in anticipation of this meeting drawing on all of that.

So, trying to make it parallel in content area to the plan's framework, but not use those specific questions, so as to minimize confusion, it's not a reporting on the objectives of the plan.

But to make it meaningful -- really what it fits for, Tom, is, and for the Committee, the what do we know section of the plan.

So, when you go into the updating of the plan in a few months, perhaps, and we're looking at the first question about when should I be concerned, the one thing we may want to be sure of is that in the what do we

know section, that it is informed by what we identified and highlighted as advances in the prior calendar year.

MR. GROSSMAN: I'm going to respectfully disagree with many of the colleagues here. I think that we need to liberalize the information that comes into this type of database for us.

There is much -- I think if we limit it strictly to those that are only peer-reviewed publications, that we are really going to miss a lot of wonderful, innovative research and thought that is being promoted out into the community.

I've seen incredible presentations at various conferences that will never make it to publication just because of the limited resources of the person that is presenting this.

And I think, with the technology that exists today, that we should make as much available to the world as possible in terms of

what is being done to further advance the science.

To not take advantage of and to look at this as being like a knowledge base type of platform I think would be doing us a disservice and truly not responding to the urgency of the matter.

DR. INSEL: Linda.

DR. BIRNBAUM: I'm sorry, I don't want to respond to Lee's comment. I wanted to respond to Lyn's, actually. Which is, I would support the suggestion that we include funding information. I think, in order to enhance transparency, I think it's very important that disclosure always is easily and readily available.

DR. LANDIS: One of the things that has changed with the new disease code reporting, is that it's entirely possible to go online now and find all the grants and, I think, contracts and intramural programs that are included as that support this as a new

facet of the disease reporting, and I think that some of the issues that you're addressing, Lyn, and will be answered in that list of what our funded projects are.

DR. INSEL: So, let me follow up on this, because I think it's a very interesting idea. One of the concerns I often have in looking in other areas that we fund is I'll see papers that I think are of the highest impact that are coming from places that we don't fund. They're in Japan or maybe it's in the UK.

And I think it would be really interesting to know, if you did this sort of screen and you came up with, let's say, 30 of what the Committee decides are high-impact papers, how many of those 30 papers were supported by NIH or by Autism Speaks, or by the Japanese government or by somebody who has funded by a foundation out of Australia.

It would be really telling to know where the investments are having the greatest

return. And I don't know how else you'd get that, except to -- because I think if we left it to RCDC, it wouldn't show up in our own coding.

DR. BIRNBAUM: I was not saying that we shouldn't have a funding source in the report, but that in addition, if you wanted to know what NIH in particular was doing, RCDC now provides that.

So, I didn't mean to say we shouldn't include the funding source. I think having the funding source would be a very interesting and informative additional piece of information.

DR. INSEL: Alison.

MS. SINGER: I would just add that I think the decisions on what were the highest-impact studies should be made independently of the funding source, and then the funding source information be added.

DR. LANDIS: Absolutely.

MS. SINGER: I would also suggest

that we include a section in this report that focuses on, after we choose the highest-impact studies, that really focuses on the impact and the relevance to families of those particular studies, so that we're translating it into, really, information that's focused on stakeholders.

MS. BUCKLEY: And if I may respond just to one other piece of Lyn's comments about the breadth of the topics covered in the list, I would suggest that the Committee take a look at what came out of this first attempt before you decide on that because many -- I mean, really, topics across the board, including related disorders like Fragile X and RAD came in and work on co-occurring medical symptoms and sleep and all kinds of treatment, pharmacology, behavioral alternative medicine.

I mean, because we drew just on the term autism and autistic, it really, I think, picked up a really broad range.

MS. REDWOOD: I'm sorry. I was

just hoping there would be more.

Can you send that to us, Diane?

MS. BUCKLEY: I think that's part of the process that we're -- that you all are talking through and trying to decide.

DR. INSEL: So that got you to 120 publications?

MS. BUCKLEY: Yes.

DR. INSEL: Because I would have thought it would be five or ten times that many.

MS. BUCKLEY: Again, I think the, you know, the limiting factors -- can you go back to the search. Yes.

For example, the PubMed search was not a full PubMed search. It was searching in clinical trials, reviews, meta-analyses, practice guidelines, randomized control trials. So, it was focused in certain areas.

Again, going to the things that were cited at least five times in Scopus -- and these are things that had just been

published in 2008, so there may be things that hadn't been cited yet or that came out at the end of the calendar year that, you know, we wouldn't have picked up.

And again, things that made the news, there could be wonderful science that didn't make the news. So, --

MS. HANN: Just to add -- this is Della. Just to add, I think last year's efforts to do this report resulted in identifying about 60 to 70 articles that ended up in the final summary of advances. Just to help in terms of contextualizing this discussion.

MS. BUCKLEY: I think the starting point was similar to this number last year of the -- in the 120s or so, but we cited, I think, 54. Right. So, right on that part of --

DR. INSEL: So, just to clarify, so the 120 represents, out of the tens of thousands of articles --

MS. BUCKLEY: Thousands.

DR. INSEL: -- that came up on PubMed --

MS. BUCKLEY: Exactly.

DR. INSEL: They were the ones that ended up being identified through your secondary search as having impact through Scopus or through newspaper articles.

MS. BUCKLEY: In conjunctions. It didn't have to be cited in PubMed. Something could have come just from being in a Science News article about autism and then we would take that.

I mean, I guess, it speaks to the comprehensiveness of PubMed, but we didn't start with a PubMed list is what I'm saying, of everything published in the world about autism.

So again, it's -- it was targeted to try to not hand you a thousand, actually, to try to hand you a more manageable number.

DR. LANDIS: But I think that

knowing what the number is from a PubMed search would be helpful, that there were a thousand, two thousand, three thousand articles that came up in the PubMed search with this, here is what we picked from the secondary screen, because I think if you say there are only 120 papers published on autism, it's pretty --

MS. BUCKLEY: Oh, no. Oh, no. That's --

DR. LANDIS: So, I think having the gross, the big number from a PubMed search would be much more informative, although if it's 12,000 and only 120 of them of significance level then we can also worry about that.

MS. BUCKLEY: I think we have the number about to be reported.

MS. BLACKWELL: Diane, I was just going to mention that our autism research project at CMS starts with the environmental scan piece and we've already settled on some

health keywords.

The lead researchers are David Mandell and Brenda Miles, and we might want to -- as I look at the keywords, I mean, Lyn's suggestions are incorporated in the ones we've been using.

You might want to even take a look at what we've got here and mirror that.

MS. BUCKLEY: The search came back with --

MR. SCHWECHTER: 14,000 articles were selected when you searched PubMed using the word autism.

MS. BLACKWELL: For 2008?

MR. SCHWECHTER: For -- oh. Sorry.

DR. LANDIS: So, I think that's a very important number that actually could be included in an introductory paragraph to the report, which is then winnowed down by the secondary.

MS. BUCKLEY: And we did start

with that. I don't recall what it was, but we looked at that very large number and discussed different ideas about how to narrow it.

DR. INSEL: So, in addition to funding source, could we add in the PubMed Central Citation, so that if somebody was reading the report and they were doing it online, they could just hit that and then they could actually see the original article?

MS. BUCKLEY: Sure.

MS. BLACKWELL: And reviews?

DR. INSEL: And reviews, yes.

MS. BUCKLEY: A revised number.

MR. SCHWECHTER: I'm sorry. The revised 2008 autism numbers for PubMed search was 1,564.

DR. INSEL: That's falling faster than the stock market. So, we haven't had a discussion of Lee's concern about broadening the input here so that we get additional articles that may not be in the peer-reviewed population.

What's your sense?

MS. REDWOOD: I think it's an important consideration, but I'm almost wondering if we could do that in sort of a separate area to say, also, in addition to these peer-reviewed science -- there were these other, you know, articles that would be incorporated as well, but in some way separated from the peer-reviewed science.

Because, parents, you know -- I agree with Lee -- get information from everywhere, so I think it's important to consider some of the other sources, but make sure that they're categorized appropriately so parents aren't thinking those are from peer-reviewed scientific journals.

DR. LANDIS: But if you want to pick up on that, does that give an imprimatur to small studies which might lead parents to think about treatment paradigms which we don't know work or are even safe?

MS. REDWOOD: They are doing that

now.

DR. LANDIS: I know they're doing that now, but if it's included in a DHHS-sponsored publication, then it actually ratchets up, I think, the apparent validity it would have in parents' eyes. And I'm -

MS. HANN: I would just like to add a practical piece to this discussion. Whichever you decide is fine, but I think it's going to be locating these abstracts and having them available in an electronic format that we're able to capture them.

So, at some of the meetings they do that, some of the meetings they don't. And also, it would be helpful and instructive to my staff and I for you to identify which meetings it is that you're thinking of to be looking for these kinds of abstracts.

So, I just -- I'm throwing in the practical piece of this as well.

MR. GROSSMAN: I would advocate that the more knowledge, the better. And

again, with the technologies that are out there to create knowledge bases and which are fairly easy to monitor and add to, I think that, again, to address the urgency, we need to present as much as possible.

In response to what Lyn was saying now, I think that when people look at this type of knowledge base, they would easily identify something as being peer-reviewed or not. And so they could self-select.

Again, trying to get this out of what we need to do versus what has typically been done, which is, you know, to follow certain procedures based on what HHS might want to do, we've got a crisis on our hands. Let's get as much information out to as many people as possible.

If we only limit it to peer-reviewed journals, I just don't see a lot of-- a lot of people that, perhaps, could take advantage of this information and really utilize it.

DR. LANDIS: So one question is, if we're talking about -- I think you're talking about a knowledge base where there is a catalogue of information, and I think what this is, is a report on scientific advances, and you could potentially argue that both things are important and that they should be distinguished.

MR. GROSSMAN: How we do it is not as important to me as just getting as much out there as possible.

DR. LANDIS: So then one question that the IACC might consider in our next plan generation is: is there a need for an integrated database knowledge base that wouldn't correspond to the advances, but would represent an additional tool or facet.

DR. INSEL: I sounds to me, as I listen to this that we're kind of talking about two very different animals. The way that we had interpreted the language was, show us where there's the most important advance

that's got the highest impact and very high, kind of, threshold in terms of quality control.

There's another piece of this, which is to show us, as in the term that you used, Story, where the knowledge base is going and where the interest base is going, which may be driven much more by the web and may be driven by lots of other kinds of information technology.

I'm not sure that they're the same thing. And I think you're right in saying that many members of the public are going to respond more to the latter rather than the former.

I think the question for the Committee is, at least for this piece, for what Combating Autism Act wants, how much you want to strike this balance.

Do you want to set a high bar here to provide the absolutely most carefully vetted information, or do you want to open

this up with the possibility that you'll be putting in some stuff that would be in 2008 a science advance, and in 2009 would be totally disproven and look ridiculous.

And I don't know that there's a right answer. I think it's up to you how you want to -- what the right balance is going to be as you go forward.

Jim.

DR. BATTEY: Yes. In my opinion, science advance isn't a science advance until it's peer-reviewed.

MS. BLACKWELL: Well, and I think we should also harken back to the Act which I referred to earlier. I mean, I read through this thing last night and throughout the Combating Autism Act, the term evidence-based is used.

So, maybe we need to come to some agreement about what does that mean. Is the baseline that the articles are peer-reviewed? Is that, you know, the first step for

evidence, because that seems to be where this Act is directing us.

DR. INSEL: Ed, do you have --

DR. TREVATHAN: I would say I tend to agree with -- with Jim in that -- but as I listen to Lee and Lyn talk, I mean, one thing that does come up quite a bit, and I'm sure many of us deal with this, is that we're having this conversation right now about peer review, and we know what that means, and the value of that in terms of being one of the metrics we use to determine whether science is really science as opposed to someone just throwing out an opinion, you know, in an abstract.

And I think one of the -- one of the things that this Committee could do, perhaps with this process, would be really valuable regardless of exactly how this handled, is to use this as an opportunity to perhaps provide some education for the public as to what peer review is, how it does benefit

science to have peer-review, and distinguishing peer-reviewed science from other types of communication.

I think that would be very useful because I think we have that understanding at the table, but I think some of the public that we're -- that is dependent and really is hungry -- dependent upon much of this information and really hungry for more information doesn't really necessarily see that as an issue.

MR. GROSSMAN: Yes, I fully support peer review. I mean, that's something that's critical and that we have to have.

I would argue, though, that we, again, should not look -- limit ourselves to only that and I would also argue the fact that, at least from the vast majority of the families that I know that have found improvement in their children, the information that they garnered for those improvements did not come from peer-reviewed articles.

MS. REDWOOD: And I think what Lee may be getting at is that there are topics, let's say gluten-free, casein-free diet, that hasn't really been studied. It's not in the peer-reviewed literature, but parents are trying that.

I think there is one study out now funded. It may be something like vitamin supplementation, giving CoQ10 or a central fatty acid. That, you know, sounds like an okay thing to do when parents are doing it without, you know, having it be reviewed in the peer-reviewed literature, although there is a lot of literature regarding giving, say, central fatty acids in terms of learning disabilities, but I think those are the types of things that Lee's capturing, and I think that those also -- those anecdotal reports offer us some opportunity for scientific investigation.

I think that's included in the plan where we try to pick out some of these

treatment strategies that parents are using now and reporting success and actually subject them to peer review -- I mean, not peer review, but double-blind placebo controlled studies so we can get answers.

So, I'm still -- I'm grappling with how we present both of those sides, and I understand, Lee, the passion for wanting to get as much information as we can in the hands of parents, because they're short of shooting in a black box right now, when they only thing they have is Risperdal and, you know, educational and behavioral therapies.

DR. INSEL: Della just whispered to me, and it just seems very appropriate. It says, if we're talking about what do we know versus what do we need in the plan, I mean, these are really -- in a way they are two separate entities here, and they're both important, and the question is what is this one going to do, and how it would be used.

Linda.

DR. BIRNBAUM: I guess what I'm hearing again is what Story suggested before is that maybe, in fact, there needs to be a second part for, you know -- so you have the part that focuses on what we are fairly confident about knowing from the peer-reviewed literature, and the high-impact work that's coming out there.

And then there is the second part which talks about emerging ideas, which might come -- some of that might come out of the nonpeer-reviewed as well. So, it would be a second -- potentially a second part to the report, and that might --

DR. LANDIS: Or be in a separate place.

DR. BIRNBAUM: Absolutely. It could be in a separate place.

DR. LANDIS: And I would just say as a cautionary note, there's a new director of NCCAM, Josie Briggs who, for her maiden speech in the ACD, Advisory Committee of the

Director --

DR. INSEL: Can you say what NCCAM is?

DR. LANDIS: National Center for Complementary and Alternative Medicine, and that was a new center which was commissioned to look at complementary and alternative strategies.

And they've run a series of very well-controlled trials on echinacea, glucosamine for joints and St. John's Wort for depression, and while there's not uniform acceptance of the way those trials were done, in each of those cases there was no compelling evidence for the efficacy of any of those treatments.

So, I think it raises the issue of bringing forward for controlled trials, and since autism is very complex, it's hard to know exactly how you do that.

If you have the approval or inclusion in this report of things which are

anecdotal it raises the question.

So, I would argue, if we were going to have things that might or could be considered as treatments that that should be in a separate document or website or whatever, than from the report.

But I agree with making that information available.

MS. BUCKLEY: And if I could just note, I just -- I had a -- just a handful of the ones from the treatment category with me today, and there was one study that the search produced on gluten and casein-free diets for autistic spectrum disorder, and there was another on behavioral effects of omega-3 fatty acid supplementation in young adults with severe autism.

DR. VAN DYCK: Were those both from the peer-reviewed literature?

MS. BUCKLEY: Yes.

DR. INSEL: Okay. Alison.

MS. SINGER: I was just going to

say that there are different communication vehicles for different communications, and that the statute is relatively clear here, that this communication is intended to be a summary of advances in research.

So, I think it really needs to stick to the statute and focus specifically on the peer-reviewed research.

MR. DeVOURSNEY: One of the things we focus on in SAMHSA very much is implementing evidence-based practices and services and interventions and supports, and one thing that we've found through our work is that having broader sets of input about how you implement this evidence-based practices and taking into account a wider range of views towards adapting those practices to specialized settings and to different kinds of populations can be very helpful.

So, I wonder if there is a place for a broader set of information about that type of work from other sources.

DR. INSEL: Anything else here that we want to put into this mix? We do -- we'll need a proposal and then we'll need to vote on how we're going to take this going forward.

But before we do that, I just want to make sure that this document will have the greatest utility. For instance, I wonder whether anybody has used the 2008 report from July on the 2007 advances, or whether that's just something that we put together because the statute requires it and we send it off, and then forget about it.

Is that -- has it had any value to the Committee at all?

It has?

DR. TREVATHAN: Well, we've referred to it and I think it's helpful because you look at the list and you see something you didn't know about, you know, and it's very helpful. So, I would say it was helpful. It wasn't a waste of you all's time.

DR. INSEL: Good. Thank you.

MS. BUCKLEY: Thank you.

DR. INSEL: That's what I was fishing for.

Jim.

DR. BATTEY: I'm going to suggest that we vote on a motion because there's clearly a difference of opinion here about what the bar ought to be for inclusion in the report, and I'm going to move that we restrict it to peer-reviewed articles and reviews.

DR. INSEL: Is there a second for that? Okay.

In favor of accepting Jim's motion that this would be restricted to peer-reviewed articles and reviews, hands up.

MS. HANN: Okay. One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen.

DR. INSEL: On the phone?

MS. HANN: Stephen?

DR. INSEL: Stephen?

MR. SHORE: Barely. The audio is cutting in and out and I'm -- it's almost not enough information for me to make a decision, because I'm not getting enough audio.

DR. INSEL: We're told there's not much we can do to fix this, but we'll be breaking soon, and maybe during the break we can try to figure out what the problem is.

I apologize for the bad reception. Here we are trying to make all these high-tech breakthroughs in science, and we can't even get a phone call to work, we have a problem.

So, do you want to abstain or do you want to vote one way or the other?

MR. SHORE: I guess if you could just quickly review for me what we're voting on and I'll -- sorry, I'm just -- I heard something about peer review and that's all I got.

DR. INSEL: Okay. Dr. Batty, would you like to restate the motion.

DR. BATTEY: Yes, that the items

to be included on the list be restricted to peer-reviewed, original research articles and reviews.

DR. INSEL: So we need to know whether you want to abstain, vote for or vote against.

MR. SHORE: Oh, okay. I'm going to vote against because there's a lot of stuff out there that hasn't quite reached peer review yet, but it's still important.

DR. INSEL: Okay. Thank you.

So, the motion carries, but the sense still from this discussion is that there's a need to capture that other stuff out there that Stephen was just talking about, and that Lee has brought to us.

And I'd be really interested in how you think we might do that, and are we the best place for that and, if so, what would be the right way to try to capture that whole realm of information that may not be in the peer-reviewed literature.

DR. TREVATHAN: I think this discussion, at least, has convinced me that this is an important issue, and I think probably a lot of us that voted for Jim's motion feel that way.

So, I wonder if there's -- I don't even know that we understand what it is we're all feeling that we need to do, but I wonder if there's an agreement that this does open up an important issue that maybe we ought to have some subcommittee or group look at.

So, how can we really do a better job of making available information that is not peer-reviewed without giving the impression that we're -- we're -- yes, that we're actually endorsing it necessarily as science, but at the same time, actually providing information, because some of that information could have within it a hypotheses that would be worth looking at, perhaps.

And I don't really even feel comfortable making a motion on it, because I

don't know that I know exactly what I'm suggesting, but I wonder if we could have a subgroup come together and then report back to the IACC on that.

DR. INSEL: Yvette.

DR. JANVIER: I have a comment. I know that the agency or group or whatever they are, the Complementary and Alternative Medicine Group at the NIH, I know I had gone to them looking for information on many of the treatments that the families are using, and this was -- could have been two or three years ago, and I found nothing.

But, maybe we could, just like we're doing with the vaccine group, you know, invite them in or collaborate with them, because I do have concerns if we do put information out on a website saying, "People, use B-12 injections and gluten and casein-free diets or whatever," it is going to be an endorsement. But, you know, there is an agency at the NIH that focuses on that, and

I think it will be very important for us to work with them on this issue.

DR. BATTEY: Yes, I think inviting Josie to come to one of our meetings and acquainting her with some of the issues revolving around alternative treatments for autism.

Just sensitizing her to the importance of the problem would be productive and might lead to increased interest on the part of NCCAM and exploring the scientific validity of these issues.

DR. INSEL: Is there someone here from NCCAM here in the room?

They have attended some of the other meetings. I don't -- I don't see any hands going up.

DR. LANDIS: And it's interesting right now what they're focusing their attention on potentially is the next initiative they would consider is chronic back pain. A huge issue.

Many, many people use complementary and alternative strategies to treat back pain, but you could argue that autism and the use of complementary and alternative strategies for autism is an even bigger issue.

So, I think having her come and meet with the group would be great.

MS. REDWOOD: Tom, I think also the Autism Research Institute has been collecting for decades now these parent surveys with regard to all sorts of different types of treatments, and then they score them, if they've been helpful or not helpful, and it goes anywhere from ADD/ADHD drugs to Ritalin, to, as you say, B-12 injections, and some of those things may be considered complementary and alternative medicine, but if indeed there is, say, a functional B-12 deficiency, then it really is a standard of care to treat with B-12 injections.

So, even though they may fall into

that realm, oftentimes their children have these actual medical conditions, that it may look crazy that you're doing that in autism, but when you really look at the child and you see that they have these abnormalities, then it makes perfect sense.

So, I would like to suggest that someone from the Autism Research Institute present some of that data, along with NCCAM, I think that would be a nice, a mix to sort of get a feel for what parents are doing.

DR. INSEL: That's a great idea. We've actually done this with Josie already. We've gone through the ARI compilation, which is very thorough and it involves a huge number of individuals with some interesting information in it.

It would not be that difficult, I think, to build on that to create something and Peter Bell's idea was to create a category like emerging trends or find a way to capture a lot of what's going on that people are

telling us about far short of the evidence base.

It wouldn't be considered part of the evidence base yet, but it would be a way of tapping into a kind of on-ramp for the next part of a strategic plan.

I think Josie could be very helpful to us because she does this in other areas, like Story mentioned, back pain is one.

And we have not had anybody from that part of the NIH really helping to carry the water in this area. It would be great to bring her to this discussion.

Alison.

MS. SINGER: I was going to add that the Interactive Autism Network at the Kennedy Krieger Center also has a lot of parent-collected data on treatments. So, that would be another source, I think, to go to for this information.

DR. INSEL: So, I think we're not going to resolve this completely, but I do

sense that the group wants to have some vehicle for doing this, and maybe we can bring this up, Della, at the next meeting as a follow up with Dr. Briggs here and figure out how best to try to pull all of this together from all these sources.

There were a couple of other things that came up, so before we close out this discussion, we need to get your input about these. One was including the financial support in each of the final items that are sent forward as peer-reviewed publications, including something that would allow a link to PubMed Central so that if it's available someone could actually get the article online.

And I think those were the two main changes. Is there anything else that I'm --

MS. HANN: Also need to clarify the steps by which you wish to do this. So, that's the other part of it.

DR. BIRNBAUM: I would move that

the financial information be included in this after the decisions are made which papers to focus on.

DR. INSEL: Thank you for that clarification. I'll take that as a motion.

MS. SINGER: Second.

DR. INSEL: In favor of including the financial information after the quality is determined.

MS. HANN: Okay. One, two, three -- apparently it is unanimous in the room.

DR. INSEL: And, Stephen, are you still able to hear us?

We missed you partially. We only got --

MR. SHORE: I was just telling a joke, all three of me. I'll vote yes.

DR. INSEL: Okay. Thank you very much.

MR. SHORE: Sure.

DR. INSEL: And PubMed Central, can we add that into this as well?

All in favor?

(Show of hands.)

DR. INSEL: Anyone opposed?

(No response.)

DR. INSEL: I think that's unanimous.

Stephen, you're okay with including --

MR. SHORE: Yes, yes.

DR. INSEL: All right. So, Della, about the process.

MS. HANN: So one way by which we can accomplish this is to send you electronically the listing that we have garnered using the strategy that we have discussed already, and send that to you.

I believe we an flip to that slide about process. Are you going to get that? Okay.

For you to review the list and to tell us if there are any additional articles that you want to have added, if there are some

articles that you feel --

MS. SINGER: Propose next steps.

MS. HANN: Yes. Propose next steps. There you go.

Anything to add, anything to delete, or also we've begun the sorting, as Diane already indicated to you across those different six areas, and if you feel an article doesn't belong in that particular bin, it should go to a different bin.

We can do that electronically, or we can do that vis-a-vis a conference call, teleconference. Whatever your pleasure is to do that -- to do that part.

And then, once we have that, that will then give us the final listing of all of the publications, which we can then send back out to you for you to then tell us which ones you think are the most important to include.

But we want to make sure we start with the universe, essentially, of what you want, and then narrow it down from that --

from that way.

DR. BATTEY: I think that first step, the vetting list can be done electronically.

MS. SINGER: I second.

DR. INSEL: In favor?

(Show of hands.)

MS. HANN: It appears to be unanimous.

DR. INSEL: Stephen?

MR. SHORE: Same here on the phone.

DR. INSEL: Okay. I got hung up on something. Excuse me for a moment, but I want to go back to a point that Lyn raised at the beginning about the categories that you've recommended, the six broad topics, because, as I looked at the key advances in ASD research in 2007, they track exactly with the strategic plan items.

So, maybe I've misunderstood something, but why not just continue to do

that?

MS. BUCKLEY: Because of the confusion that people had, really, when the report came out. Even the Committee, the initial reaction was, so I was reporting on the plan, but really the plan and the defined research objections hadn't even been defined yet.

So, in terms -- again, we're thinking about this as possibly feeding into the "What do we know?" section of the strategic plan, but we don't want it to be, you know, -- anyway, we heard your concern about it being misinterpreted as a reporting of progress on the plan.

And so, that's why you have this. And just -- I would say it's not even defined that, even though we provide the publications to you in this manner, those wouldn't need to be even headlines in the report. It wouldn't have to be, anyway.

But, think of having a list of 120

or more, once we add in the reviews, how would you like them sorted? Do you really want to read through a list that is just alphabetical where you see a study about treatment and then one about diagnosis and then one about something else?

We were just offering kind of an initial first cut, and then really I think it would be through the deliberations of the Committee in whatever way you choose to say "What do we really want to say about this pool?" Possibly under these headings, but maybe not.

DR. INSEL: So I understand that they would have to be sorted into categories. It looks like five of the six categories already track what the plan --

MS. BUCKLEY: The sixth one is an attempt to sort of address the "What does the future hold?" issue, which is very broad, but we interpret it as mostly focused on issues related to adolescents and adults.

DR. INSEL: Okay. I think I'm finally catching up. So what you're saying is the last conversation that we had last summer, the group was unhappy with the idea that this was exactly mapping on the plan, so you're actually doing it, but you're using different words to try to --

MS. BUCKLEY: To minimize confusion.

DR. INSEL: Okay.

MS. BUCKLEY: Which, based on this discussion, I'm not sure it was successful in that.

MS. BLACKWELL: It actually looks -- when I look at what the law says and your listing it, I think it's kind of a nice mesh of what ICCA says, and, you know, what our strategic plan says. It's just a little bit broader.

DR. INSEL: Okay. Is there -- so, in terms of this process that Della has recommended, any additional discussion about

that or is this what we want to follow as a group? Are you okay with that?

MS. HANN: So we'll vet them with you electronically, so you'll see it one time -- okay. We'll send it out first and you'll tell us deletions, additions, et cetera.

We will take your feedback, clean up the list, send it back to you for you to then identify the ones that you consider to be the keepers, I mean, the ones that we really absolutely have to talk about.

We thought about combining it in both -- in one step, but we figured that would be a little confusing.

DR. INSEL: Jim.

DR. BATTEY: So, would we be selecting a specific number to be included?

MS. HANN: What we had suggested, but it's up for your discussion, is we would say to you with the second list that we send to you, choose the three per topic that you think are the most -- have the greatest

impact.

DR. BATTEY: Thank you for the clarification.

MS. REDWOOD: Della, do we have a timeline for this?

MS. HANN: Well, I do believe that the first listing is almost ready to go out the door.

MS. BUCKLEY: We have to finish sorting and also we need to now incorporate reviews.

MS. HANN: Right.

MS. BUCKLEY: So we would have deal with some additional searching to make sure we capture that.

DR. INSEL: Right.

MS. HANN: So we would probably be able to have that ready within the next two weeks to send to you. And my guess is that you would like to have an opportunity to review that for a minimum of two weeks. My guess is.

And then that would come back to us and we would need a week or so of cleaning it back out to you. So we can --

MS. BUCKLEY: So that's mid-March.

MS. HANN: So that takes us into March, towards the end of March. And then once we -- once we get all of your feedback about what to include, then we can begin the process of trying to distill those keepers, essentially, into nuggets that can -- we're very fortunate, we have a science writer with us now who will be able to help us translate the information into something that the general public can understand.

So, our goal would be to be able -- I don't think we'll make it in time for the May meeting in terms of having a draft for you, but it may be a draft that we can circulate to you electronically.

DR. INSEL: Lyn.

MS. REDWOOD: I was just going to say I'd be somewhat not inclined to set an

arbitrary number on how many, because we may have a real bumper crop one year in scientific advances and have 20 or 30, and the next year only ten rise to the top.

So, I think we should look at them first before we decide what's important.

DR. INSEL: Jim.

DR. BATTEY: After the list has been cleaned up on the first round, will your staff bin them for us in the six categories so we'll be choosing within a category?

MS. HANN: You will get the bin the first time through, too.

DR. BATTEY: Okay, in terms of --

MS. HANN: We are already doing a preliminary bin, but you can tell us, oh, it doesn't belong in that bin.

DR. BATTEY: Thank you.

MS. HANN: It should go into a different bin.

DR. INSEL: And then the -- in terms of timeline, the final required time to

get this in, because it says annually would be July 15th, is that correct?

MS. BUCKLEY: You could interpret it that way. July.

DR. INSEL: July. Anything else to discuss here?

Diane, do you have what you need from the Committee? Are there any -- any other questions that you have for us?

Della, are you okay?

MS. BUCKLEY: I think we have everything.

MS. HANN: I think we are ready to start marching it out to you all and if we have questions, I'm sure you'll hear from us.

DR. INSEL: Yvette?

DR. JANVIER: Not directly related, but I was thinking about when you were asking what are people doing with this information, I keep thinking back to 2003 when there was a National Autism Meeting organized by the NIH and I know for myself, personally,

I was able to interact with folks that were working on projects that may or may not have gotten published or, you know, -- Lovas was there, you know, et cetera.

It was really an amazing experience for myself and, you know, I was one that spoke up to Secretary Leavitt. I didn't realize the rules were we weren't supposed to say anything to him last -- two years ago when he was here.

But, you know, I think that that could be a vehicle for us to share this information and share other information about best practices, complementary treatments and so on.

But, you know, I just again -- just came into my mind. I thought I'd throw it out there. It's not exactly on topic but, you know, the organization of a National Autism Meeting may be in conjunction with ASA or Autism Speaks, or however -- but I think it would be very important and very helpful to

the children and families struggling with this.

DR. INSEL: And one of the hopes is that in the new Administration, there may be some opportunities to get either a White House meeting or some other kind of secretarial-level meeting to really get this focus.

We're already working on that at this point, but nothing specific that we can say.

Okay. Thanks, everybody, for getting us through this process issue. Let's break for lunch. We will return promptly at one o'clock because we have a lot to do in the afternoon.

(Whereupon, the above-entitled matter went off the record at 12:11 p.m. and resumed at 1:03 p.m.)

DR. INSEL: Okay. We are back at the table.

Stephen, are you still with us?

(No response.)

DR. INSEL: Anyone else on the phone? I don't know if that means you're not there or if our audio problems are continuing.

TECHNICIAN: We don't have any audio problems, but there's no one on the phone.

DR. INSEL: Thank you very much. So, we'll expect that Stephen and possible Jennifer will be joining us by phone momentarily, but to stay on schedule I'd like to invite Lyn Redwood to open up the next session on -- the title on this agenda item is "Vaccine Studies Considerations."

MS. REDWOOD: Thank you, Tom. I just found out Friday afternoon that I would be presenting today, and I know at our last meeting there was quite a bit of difference of opinions regarding whether or not we should include vaccine-related research in the strategic plan.

And the e-mail that you sent us

this weekend, you said that you had hoped that our meeting today, we would be able to discuss ways to bridge these gaps and opinions and that you were looking to the Committee to bring some collective understanding to this national debate.

I know we've invited Dr. Gellin to speak today from the National Vaccine Program Office in terms of what they're doing with regard to vaccine safety research.

And there's also a handful of scientists who also have been looking at this issue very closely and trying to think of what information do we have now, what information do we need, what does the information tell us.

And Dr. Noble is one of those scientists. So, I thought it would be nice for him to come here today and share with us some of his ideas and opinions with regard to vaccine safety research. So, I thank you for allowing him to do that.

And I might add that he's

completely rearranged his schedule to be here today, so we really appreciate this.

DR. NOBLE: Okay. Well, thank you. It's great to see all the good things that are being done here. It's -- I must say I'm very nervous about giving this kind of talk, aside from the fact that we're only sending the relevant papers out now, this is an emotionally-rich area.

And it's -- those of us who work in science know that we're charged to approach things without emotion, and ironically the best way to approach science is as though we had at least a mild Asperger's syndrome.

Well, I guess if mild Asberger's syndrome was good enough for Thomas Jefferson, then it's good enough for me. So, I will try and approach this.

Scientists disagree. For those of you who are not scientists, scientists disagree. That is essential to the scientific process. That is how we move forward. If

scientists didn't disagree we wouldn't accomplish anything.

So, I'm now going to talk about an area of disagreement which is about thimerosal. Some of you know me. Most of you don't. So, I'll do something that I've never done before which is to start off by telling you just a little bit about who I am.

So, I'm one of the founders of stem cell biology in the central nervous system. My laboratory was the first to figure out methods of carrying out repairing the central nervous system and the damaged spinal cord with purified progenitor cells while we were working out the growth conditions.

Our team has been responsible for purifying, characterizing most of the progenitor cells that we know about. We are among the first groups to recognize that dysfunction of these cells was important in developmental maladies.

We have made pioneering

discoveries on oxidated regulation of cell function on the effects of chemotherapy on the central nervous system, on developing ester site transplantation therapy for repair of spinal cord injury.

So, I'm not coming to you as a member of the DAN community. All right. I'm coming to you as someone deep in the scientific mainstream.

I'm also unusual in that I have a strong math's experience. I've had the honor of working for more than a decade with one of leading people in biostatistics, the late Andre Yakovlev.

We have more than a dozen papers together. We have -- I'm a collaborator or co-I on two mathematical grants in biology and that has perhaps given me a particular perspective regarding what I'm going to talk about.

I also want to make it clear, because it has come up when I've discussed

this before. No one in my family has autism. No one in the families of my friends of many years has autism. I have no patents in the field. I don't make money from vaccines and I don't testify at trials.

I work in this area because it's a convergence of a lot of our interests, scientifically, and because of the importance of this extraordinarily prevalent condition among the pediatric population.

Okay. What I want to discuss here is our work related to thimerosal, and I'm going to isolate thimerosal for a very specific reason. In many ways, thimerosal is almost the perfect toxicology experiment.

I know there's a lot of people who feel that, come on, it's out of vaccines now. Why would we even worry about it.

But, we have so few agents that we know when they were applied, the age of the children, the dosage that they received where the agent come out in vaccines in different

parts of the world in different times, and it has so many of the characteristics that we need to study a toxicological problem, that if we cannot make sense out of this, it's going to be very hard to make sense out of anything.

Also, were it the case that thimerosal were interesting, then that may give us a clue as to other environmental risk factors that we need to be paying attention to.

We started this work because -- now, how do I move this forward. Oh, I'm sorry.

Because of our work in signaling biology, that we have been trying to figure out how changes in oxidative statement cells become more oxidized, how that changes the function of the cells that build the nervous system.

And we were very, very grateful to be funded by the National Institutes of Environmental Health Sciences for our work on

environmental toxicants, working on substances like methylmercury and lead and paraquat.

And we discovered an entirely new regulatory pathway that takes any kind of oxidative stressor and it activates a new pathway that we discovered that causes receptors, shown here, that are involved in cell division and cell survival to be degraded more rapidly.

And when they are degraded, you have cell death, premature differentiation, increased vulnerability to other stressors, losses of progenitor cell division.

And because we had studied methylmercury, we thought, well, let's look at thimerosal and we found that at clinically relevant exposure levels it was just as toxic as methylmercury.

That put me into a dilemma because if it has been shown convincingly that thimerosal was not a risk factor for autism, who cares. It's a biological artifact that

you study in the laboratory.

So, I was driven to go back to the epidemiology literature, and that is what I am going to address now. There's a real problem in studying the epidemiology of autism and related disorders.

And I'm going to approach this by first talking about two of the most famous graphs in all of autism research. One is from a paper by Madsen, et al., "An Analysis of the Danish Registries."

Many of you, all of you have probably seen this, and it shows that for the period from 1971 to 1990 the prevalence of autism in Denmark was pretty well flat.

And then, there was an explosive increase. This graph is interpreted by the authors as saying they had incidence increase and continued to rise after the removal of thimerosal from vaccines.

Now, why did autism increase at this time? You could hypothesize local

environmental factors, but you could also hypothesize that the changes in diagnosis had something to do with this. If that was the case, you would expect to see similar increases in other countries at the same time.

So, this is one of the other most famous graphs that, from Eric Fombonne's laboratory, study in the Montreal School Board, where do you make the claim that on average the prevalence rate increased by ten percent annually over the 12 years of study and continued to increase after thimerosal was removed from vaccines.

But this increase is about at the same time. So there are IPB intervening factors and one sees similar increases at this time in the United States and Sweden. So, that creates a real problem.

We're trying to ask a biological question. Is there an influence of thimerosal exposure as a risk factor for autism? That is a biological question.

The increase in prevalence of autism due to nonbiological factors creates a confounding variable. How much did autism increase because of changes in diagnosis, because, you have to compare like with like if you want to study biology.

You can't do an experiment where I say I'm going to do an analysis on whether there are more males on the left side of the room or the right side of the room and then say, by the way, on the right side of the room I'm going to include everybody wearing slacks as a male.

That's not good science. And that's the heart of the problem. So, how do you get at this information? People have been trying to understand this. And, you know, I guess before I show the next slide, let me just ask you to help me here with the data here.

We have two extreme hypotheses. One is that the increase in autism and related

disorders is entirely diagnostic. All these kids really are already. We're just now calling them autism.

Do any of you believe that that's true? It doesn't look like it. Too much buy-in to that.

There's also the hypothesis that the increase is entirely biological. This is a true epidemic explosion in cases that just didn't exist before. A hundred percent.

Does anybody think that that's true?

(No response.)

DR. NOBLE: Right. Nobody buys-in to that. So, the answer is somewhere in the middle and where in the middle is it?

Okay. Now, I'm not getting full -- I want to go back one. People have tried to approach this in a number of different ways, and if I can get the slide that I want we can discuss that.

Here we are. Okay. So, these are

the ways that people have tried to calculate the contribution of nonbiological factors to increases in prevalence of autism disorders.

One method is to just assume it's not biological at all. Assume that the change is entirely diagnostic. There was a study from Finland and they came up with an answer that there's a 3.4-fold increase due to changes in diagnosis.

Another approach is to see if people have been swapped out of different diagnostic categories. As autism went up, did mental retardation and language disorders go down?

Some studies say yes. Some studies say no. There's one study by Paul Shaddock which gives an average value of about a fivefold change in prevalence because of diagnostic substitution.

There is only study that I can find in the entire world that has gone back and reanalyzed earlier records and said, how

many cases would we now classify as autism, and that was a study published by Heisler, et al., from England on a 1970 database that they had on children who were analyzed.

It's coded on a questionnaire for the disorders. And, what they did is, they took all that information. They were able to get all that information and they'll give it to autism doctors. Nowadays autism doctors and say, "How many kids would we now call autistic?" And the answer from that was that there were 8.4 times as many cases that they now picked up and called autism that previously we had not called autism.

And then there's folks who do metanalyses of all these studies and they come up with correction factors ranging depending on the age group from about two to over 28.

So, as you can see, you have a wide variety of choices. That makes it hard to go in and do these analyses but this is the data we have.

Okay. So, let's look at the Madsen studies. Remember, this is the initial Madsen graph. We have this increase. But we know that during this period here there were kids who were called something else.

So, if we're going to compare these kids with these kids, we've got to try and figure out what was the real prevalence of autism in this period. So, I'm going to use an intermediate correction factor.

I'm going to use the one of Paul Shaddock of a fivefold increase. That's shown in the green line here. All I've done is, I've taken these values, multiplied them by five to try and estimate what is the real prevalence of autism at this time. All right.

Simple mathematical correction. And what you find is that now we're about at the levels that were seen in 1995 to 1993 in different populations, but there's still these increases afterwards.

What caused those increases? When

you go to the materials and methods of this paper, you find that in 1995 the way the work was done was changed. Prior to 1995 the only kids who were on the Danish registry were children who were diagnosed as inpatients.

And, in fact, in 1995 onwards, the Danish registry included all outpatient medical data. Not just for autism, but for everything. That was four to six times as many people.

So they added four to six times as many people to the pool from which they're going to get out, but they didn't change the denominator, that they still scored at per ten thousand people in Denmark.

Well, that's not scientifically valid. So you have to try and correct for it. So what I've done in the next slide is I've said, okay, they added six times as many people. Let's say that added six times as many cases. What's the outcome of that?

Well, the outcome is that now the

estimate of original prevalence is up here, and from 1995 when thimerosal came out vaccines, or early 1990's when it came out of vaccines in Denmark to the 2000 values, there's quite a significant fall.

Now, I've used a very conservative estimate for that analysis because if you go to another paper from this same research group, what you learn is that in Denmark, 93 percent of the cases of autism are diagnosed as outpatients. So, the real correction factor should be much higher.

Let's turn to the Montreal studies where it's the same story. So what Fombonne says is that prevalence rate increased by ten percent annually over the twelve years of the study, and there's a statistically-significant linear increase.

Well, when I look at this graph I thought that's an odd way to describe this graph. The lines interconnecting these different points are imaginary. This is not

a dose response curve.

These are isolated points, and what's the case is that there's no increase here and then there's this big jump.

So, let's graph it differently, and what you see is this big jump. No increase here, and this claim of a ten percent linear increase per year, it's a way you can describe the data. It's not a statistical lie, but it's not the only way that you can describe the data.

Now, according to Fombonne, all of these kids received thimerosal in the 1987 to 1990 group. And, in Canada, thimerosal came out in '95. So, these kids got no thimerosal. And for the purpose of trying to even work with this data, let's make the assumption that these kids were diagnosed all under the new system, under the new diagnostic system.

So, we're going to say that these are real values. Maybe too low, but it's the best we have. What's the effect of correcting

these values?

If we use a low end correction factor of about threefold, then the estimated prevalence of, in this case, pervasive developmental disorders in this population is already above what is found in 1998.

If we use a moderate correction factor of fivefold, the difference is even greater. And if we use the only correction factor obtained by direct analysis, then the fall from those early years of the estimated real prevalence of pervasive developmental disorders to nowadays is even larger.

Now, this is not a matter of interpretation. This is a matter of taking an analysis and applying the correct mathematics to it so that you correct -- so that you can compare like against like.

That creates a real problem, and it creates a real problem, particularly, I believe, because in both of these studies the authors tell you in the discussion of their

papers that these are problems, and they never asked about what this means in terms of the data.

Now, what about other studies that have been used to claim that thimerosal is safe? One of the famous studies is that of Andrews, et al., conducted in England. And we're going to get to that in a moment, but first I want to make a point about what this data shows, and maybe I need to go back here to do this right.

The larger the correction factor, the bigger the fall after thimerosal comes out of vaccines. What that means is that if you believe that the increase in autism is due to changes in diagnosis, largely due to changes in diagnosis, thimerosal was a disaster.

And if you believe that the increase in cases is biological, a biological explosion, then thimerosal was totally safe. You can't have it both ways.

If thimerosal exposure doesn't

contribute to increases in prevalence, then the increases in prevalence are less biologically-based. If thimerosal does not contribute, then the increases are biologically-based. That's just the maths.

Now, I'd like to have more data to analyze, but this is the best you can pull out of literature, and the reason for that is, is that most of the literature has problems like in the Andrew's study.

So, here the problem is very different. They've taken data on a large number of children. It was about 100,000 kids, as I recall, and what they did is they coded according to different neurological categories, including autism.

You see, go to the materials and methods. And you read that they tried to confirm their diagnosis. They sent out 166 questionnaires. 162 people responded. Okay. So, that reduces the data set to that much.

Of those in 19 percent of the

cases the diagnosis was wrong. So, that comes out of the data. In another 35 percent or so the problems were transient. That does not describe autism. That comes out of the data.

And another 35 percent or so of the cases they could not confirm continued problems. So that comes out of the data.

To me, this is analogous to having a student come to me and say, "Mark, I'm going to write this really exciting paper but I've only been able to confirm 20 percent of my data points and I'm not going to tell you which ones they are," because that's what they do in a study.

And I have gone through every single published paper on autism prevalence and thimerosal and there's not a one that doesn't have problems like this.

The latest study from Italy that got a lot of press, 1400 kids examined. In those 1400 kids there was one case of autism. We're talking about a prevalence for these

disorders of one in 150.

If this was a statistically-valid sample, there should have been eight or so cases. There was one. There's a statistical problem with the data.

The same is true for studies out of Johns Hopkins, and I can go through study-by-study sharing with you the flaws in them. So, the conclusion that I come to is that the safety of thimerosal has not been proven.

This is a mythology. It is not supported by the data. And what worries me, particularly, is that we know more about thimerosal than we do about anything else related to the vaccines.

The data on aluminum salts is much, much less, for example. Now, we can't approach this problem with data of this nature, so the question is: What are we going to do next?

And that's what I'm going to close on, what I think should happen next, because

this is a frightening problem.

Vaccination dropout is something that terrifies, I think, all of us, but it's going on, and it's increasing. And I think we've got to do a better job.

And where we are now is that I think that this lack of data is like having this discussion, it's like trying to hit a nail with an imaginary hammer. And from my perspective, there's many people arguing about the virtues of their imaginary hammers, but the nail's not moved.

The hammer that we need is better data. And I don't think this is going to go away. I've had advanced looks on primate studies on vaccines. They have data that is disturbing. I know what's going on in various laboratories. The studies are going on around the world. The data is going to come out.

So, I want to not suggest to you, I want to plead to you that we've got to change the way we're doing this, that it

reduces confidence in the scientific enterprise when the CDC had information on early versions of the study that indicated a linkage between thimerosal exposure and autism, and people only got access to that information by filing a Freedom of Information Act.

It reduces confidence in the scientific enterprise when someone like Paul Offit states, as he has, that it would be fine to administer 100,000 vaccines to a child in one day.

To a parent who is concerned about additives in vaccines, they are not interested in his calculations on how many lymphocytes there are and what they can do.

What they hear him saying is that he thinks it's okay to inject five grams of thimerosal, which is 50 percent ethylmercury and maybe 20 grams or more of an aluminum salt into a child in a single injection.

And we know he wouldn't do that to

his own kids. He wouldn't do it to himself. So, people dismiss him.

Drama can make you feel good, but it doesn't help in building bridges, and I am becoming increasingly concerned about this as I travel between the different autism communities trying to understand the concerns of the parents.

Let me try and help you understand it. For many of you, I don't know how many, but I'm sure for some of you, when Jenny McCarthy comes on the television, you cringe. You don't believe anything she says. You have an emotional reaction and it forces you to lose faith and interest in the people with whom she's associated.

Take that emotional reaction and understand that when Paul Offit goes on the television and says the things that he's saying an equal or larger number of people are having precisely the same emotional reaction to him, but in the other direction.

It's not the way to do this. I happen to believe that people can make intelligent decisions about relative risks if given the information to do so. One of the reasons I believe that is because one of our areas of research is on the effects of systemic chemotherapy on the central nervous system.

We are the group that has been pulling apart the underlying biology of chemo break, and I get calls and emails from around the world of people who want to know whether they should do chemotherapy, whether they should go through this course.

And there's no black-and-white answer, but I talk to all of them, and I tell them about relative risks and, you know, they're happy with that. They just don't want to be ignored.

Because, when their doctor tells them, "Oh, there's no problem. Don't even worry about it," paradoxically what happens is

that they become more worried, and that's not what we want.

So, I would like to suggest to you that the data on safety is not good, that it's deserving of a sum of less than three percent of the proposed budget for autism research.

If the studies are done well, and if it turns out that they provide good evidence of safety -- not the easily-dismissed information that I've discussed here, but good evidence for safety, and this helps us turn the tide against opting out of vaccination, that's money very, very well-spent.

And if it turns out that there's a problem, we're scientists. We can't be afraid to find out data. Now, there's various ways to go about this, and each has different merits.

Epidemiology studies are useful, but not if they suffer from the same kind of problems I talked about. I favor cellular molecular studies because I'm very driven to

mechanism.

I'm also interested in environmental contributions to disease, in general, growing worldwide problem, so I'm very much in favor of environmental studies, but that's me.

I think what's needed is to bring together a working group. You all are good at doing that. 25, 30 people. Some people from the advocacy community, some people from different parts of the scientific community to try and design studies that people are going to have buy-in on.

And for that working group I would have a primary strait. If someone is of the opinion that there is no study that would convince them vaccines are safe they can't be on the group. And if there's no study that would convince them that vaccines are harmful they can't be on the group.

This is not a place for idealogues. This is not a place for people in

conflict of interest. This is a place for people to come together and try and define studies that are getting -- going to get buy-in because I am deeply afraid that if we do not do this, if we do not embrace the problem and get the data, we're going to lose more and more people in this opting out of vaccination.

And as you all know, we're seeing this opt-out in some of the communities in the United States that are great focuses of higher education, people who, you know, who have advanced degrees, you know, in places like Boulder where you're getting these drop-out's.

We're not doing it right, and I hope that we can do it better and it's true that autism research represents maybe 15, 20 percent of what we do, but I can tell you that I and people like me will do anything that you need to help make this happen.

DR. INSEL: Thank you, Dr. Noble.

We can take about a little less than five minutes for questions, because we're

a little bit over schedule, but I want to open this up, especially if there are questions for clarification.

I have one, maybe just to -- because I want to make sure people don't misunderstand the data you showed --

DR. NOBLE: Yes.

DR. INSEL: -- because one interpretation of what you demonstrate is that there has been either a 30 or 80 percent decrease in prevalence in the last ten years, rather than there being an epidemic, actually autism looks like it's going away.

DR. NOBLE: Right.

DR. INSEL: And I think -- I'm not sure if that's what you're implying, but that's certainly the message that you send.

DR. NOBLE: No. Tom, thank you for asking that. And it brings up one of the challenges in this whole arena and why I've been so reticent about talking about these issues.

I'm not taking a stance on that. What I'm saying is that the data cannot enable us to take a firm stance. Whatever you want to believe, I can find you a study to support it.

So, what I'm interested in is the mathematical consequences of accepting the data in the literature as correct. It's very important. I accept every data point in the Madsen studies, in the Fombonne studies, everybody else's studies.

I accept them as they are report in their papers. I accept all the data on changes in prevalence as report in the papers, and the only thing they do is say what is the mathematical consequence of analyzing it all at one time.

I don't know what the right answer is. We don't know what the right answer is because we don't have enough data yet.

DR. INSEL: So again, just to clarify, the examples you used were examples

that span the period --

DR. NOBLE: Yes.

DR. INSEL: -- the diagnostic criteria were changed.

There have been studies done, for instance in California --

DR. NOBLE: Absolutely.

DR. INSEL: -- tracking the prevalence --

DR. NOBLE: The Scheckter and Grier studies.

DR. INSEL: -- all much later at a time when the diagnostic criteria were stable.

DR. NOBLE: Yes. And the problem is that we have had contributions of increasing support for these disorders in school systems and health care systems in increasing a probability of a doctor choosing this diagnosis over another diagnosis that's continuing to penetrate the population.

The problem is so severe that my colleague, Pat Levitt was telling me about

studies that they had done where they got very, very excited because they had a county or school district where autism was here and one right next door to it where it was here, and they thought, my goodness, we've got an environmental cluster.

And after six months of study what they finally figured out was that this school system reimbursed for autism and this school system reimbursed for something else.

And it's continuing to change. So, to go in and say that we have a definitive answer, as a -- for me as a scientist, I could never take that stance, that I -- we don't know.

The data is not there on how much the prevalence is continuing to change biologically and is continuing to change because your kids are more likely to get this diagnosis.

DR. INSEL: Alison.

MS. SINGER: I want to thank you

for your presentation for coming today. I also want to ask if you have a hypothesis as to what might lead to eleven different studies or multiple studies all done on different databases by different laboratories and different countries around the world all misinterpreting their data.

DR. NOBLE: I'm not going to say thanks for putting me on the spot like that, but it's a right question, and it puzzles me.

One is that we have a history of discovery things that other people haven't discovered. That's what we do, so we're good at that.

That's not to brag. You know, some people are good at playing piano and some people are composers and some are painters. In my limited skill set that happens to be one that I have.

I have the mathematics skills, which most biologists don't have. So, I combine the worlds of the cellular biology

with the maths.

There may be another problem. You may remember the famous Uri Geller, the spoon-bender, who succeeded in fooling the scientists at the Stanford Research Institute with his parlor tricks.

And there has been great interest in discussing: How did he get away with this? How did he go and take a bunch of scientists and get them to believe that with his mind he could bend spoons?"

It turns out that scientists are among professional magicians. Scientists are something of a joke. You say that scientists are the easiest people for them to fool because we approach the world as though it were rational.

We integrate data as though it were rational and that it says exactly what we're being told that it said. That's our mind set.

And that's how we function as

human beings. All of us do that in various courses of our life.

And maybe what happened was that the combination of our toxicological studies and my mathematical training and that, in my continuing youth I've always been interested in the psychology of magic.

You know, maybe when I read the studies I was able to see them a little differently. I know that when I've talked about this data with my colleagues in the epidemiology community, the responses have been twofold.

One is that the analysis is correct. I've run this by heads of biostats departments, heads of epidemiology departments. The other is that, well, epidemiology is an imprecise science, and maybe we're a little too accepting of that.

Molecular biology tries not to be an imprecise science, so maybe there's a different mind set that's brought to the data

analysis.

In the end, though, I don't know. We have to ask the others why they did -- why they presented the data the way they did. I don't understand it. It's not how we would do it.

DR. INSEL: Mark, thanks very much for joining us. I hope you'll be able to stay around because --

DR. NOBLE: I will.

DR. INSEL: -- we can give you some additional time.

We want to move onto the next presentation, which is from Dr. Bruce Gellin who we invited to come her from just down the street from the Department of Health and Human Services to chat with us a little bit about the NVAC, the National Vaccine Advisory Committee.

And we especially appreciate Dr. Gellin coming here because this is a day of an NVAC meeting and he, I believe, is shuttling

from one committee to another.

Welcome.

DR. GELLIN: Thanks a lot, and thanks for having me here. You know, I get introduced in a lot of ways, but I've never -- when you have somebody named Gellin following a discussion of Uri Geller, it's -- I've not been in that predicament before.

I have no relationship to him. We spell our names differently, and I'm not going to talk about bending spoons.

Thanks again for having me here. I also appreciate that I understand you had to juggle your schedule around to accommodate my coming so that the vaccine discussion was pushed to this afternoon.

As Tom mentioned, we had an open session of the National Vaccine Advisory Committee's Vaccine Safety Committee this morning. They are continuing some of their discussions and some of the camp-follower or management come to these -- both these

meetings as well.

And despite what I told Tom when we were talking about preparation for this meeting that I was going to get sort of an overview of what we are doing.

I actually wanted to share with you some of the things that were going on in the meeting across town this morning, because I think a lot of it is relevant.

So it's my understanding that the National Vaccine Program Office and the National Vaccine Advisory Committee have come up in some of your discussions in your past meetings.

And so, I'm here to tell you what it is that we have been doing. There may have been some differences of the way it was -- what we are doing is portrayed, but I want to tell you what our process is, a little bit if the history and how we go forward, and then ultimately addressing the letter that came from Tom on your behalf to our advisory

committee that is one of the things they're talking about this afternoon.

I assume you all have all those. So, let me go forward. So, the National Vaccine Program Office, this is -- this is where I am, is in the Department of Health and Human Services. I report to the Assistant Secretary for Health. It's been around for 20 years.

I'm not going to read this slide to you. You will get these, and I apologize for not having these ahead of time, but you'll get all these.

But this is just to give you an overview of the scope of the many different areas of vaccine -- the vaccine policy that the Program Office is involved with in our responsibilities.

And it's really the whole range of things, from early research to financing and supply, the use of vaccines in monitoring how they do.

The National Vaccine Advisory Committee is advisory to the Assistant Secretary for Health, and in my position of the Director of the National Vaccine Program Office, I serve as the ex officio to that committee, and that's what was one of the meetings today and they will -- they are actually in town all week.

So, if you want, we can come over there for the next couple of days and see what they do.

But I want to give you a sense of the charter, again, for both the National Vaccine Program and National Vaccine Advisory Committee. Again, 20 years ago this was put into place.

The National Vaccine Program refers to all of the components of which the National Vaccine Program Office is supposed to be keeping track of all of those for the Secretary's Office.

And the National Vaccine Advisory

Committee, as a Federal Advisory Committee, is external advisors, and they make recommendations to the director of the program on matters related to the responsibilities and that was that full set of things that you had seen before.

In 2005 the Institute of Medicine had this report that many of you may be aware of and again, on the slides that you'll get, you can find your way to the links.

But it was reported on Vaccine Safety Research Data Access and Public Trust, and it was largely focused on the CDC's vaccine safety data link that had to do with how they -- how -- about access to that information, how studies were designed, what was the sequence of which the studies were recommended to use that database.

And among the recommendations that the Institute of Medicine made at that time was the idea that there should be some external -- external review of that whole

process of how decisions were made for research to be conducted using that system.

When we talked to the CDC about that, as we were going through the process of developing what has ultimately become this vaccine safety working group that I mentioned, it was clear that there's a lot more at CDC than with vaccine safety activities than the vaccine safety data link.

And I felt, as long as you're going through all of this, let's look at the entire program. So, what you'll see in subsequent slides is referring to the Immunization Safety Office, which the embodiment of where the vaccine safety is done at CDC.

So, the idea, then, is that what was in the recommendations from the Institute of Medicine, essentially morphed into a -- have an external group look at the research done at CDC.

And then, as you will now think

through and recognize, that there's more to vaccine safety than just CDC, so that's something we're taking on now.

But in looking at the broader system, and I'll show you that in a second, but the first charge based on this, of this vaccine safety working group is to take a look at the CDC's vaccine safety research and not limiting just to the vaccine safety data link.

So, the -- we established a group, and I'll show you. You won't be able to see the names, but you'll get them subsequently, or you may have seen them. I believe they may have been shared before. This is all on our website.

And there were two charges initially given to this group. The one that I just mentioned, which is to overview -- to review and provide advice for prioritization on the CDC's Immunization Safety Office to look at the content, to look at how they prioritize the research topics and to look at

some potential scientific barriers to implementing that.

The second charge which grows out of what I just mentioned before is, recognizing that there are -- there's more to vaccine safety than just CDC -- sorry, Ed -- but it's, actually, as you would imagine, there's a lot more to it, not only within HHS, but within the VA and the Defense Department, which is also part of our family with vaccines and immunizations.

So, the second charge that the working group will look at is the whole system. So, just know that that is going on, and that's what -- that's what -- this is part of what they were talking about across town this morning, mostly focused on the first part.

I will spare you this. This is, you know, under -- you need a microscope with oil immersion to read all this. The idea is that the working group is composed of people

who are formal members of the National Vaccine Advisory Committee, the parent committee, as well as others from a variety of different fields that would really spread the -- a variety of different disciplines, and two public members.

When this was discussed, there was a lot of thought about, and a lot of discussion about who should be on a working group like this. As you can imagine a lot of the interest in that.

And it was clear that, given the amount of interest, and I think you just heard from Mark about the interest in this topic overall, that there were clearly more people that were interested in this topic than you could accommodate in a working group and have it work.

So, that led to our -- and you'll hear much more about this -- our commitment to engage in the public-at-large because it was clear that you couldn't have a functioning

group with 300 million Americans on it.

So, that gets to the constitution of this group which is, again, composed of formal members of NVAC, and then people with particular expertise, but no one in here has a disease-specific expertise. So, I wanted to highlight that.

So, I'll spare you the other slides, but you'll see who's on the -- on this working group and why they are on the group.

In addition, there are liaison members from the federal government. And just to be clear, that this is -- the liaison there are mostly to make sure that the working group knows what's going on in the system.

They are not voting members, but they come and go depending on what is going on with the discussions at the working group, but that's -- I'm trying to give you the full picture of who comes to which meetings and why they're there. So, that's the working group itself.

So, the charge that they have, and this is a 60-plus page document, so I won't even try to even summarize it, but this is really the draft recommendations that the CDC put forward as the ISO, the Immunization Safety Office's draft agenda.

The whole point of this was, they put this out as a, you know, as a straw man and said, okay, here's what we think. They developed this in a number of different ways with consulting a range of people and then said, here's what we think and then said to our working group, okay, here's what we think it is. What are we missing? Tell us what you think about it?"

And then go back to the issues that were asked of them, the content, how they should begin to prioritize because they obviously couldn't do all these things simultaneously, and some were going to have to be more important than others and, within these things, to identify these barriers to

trying to address some of these questions.

So, I -- you're going to look for the word "autism" in here, so I'll show you where it is. But know that this is a broad piece about vaccine safety, and it's not on this page, so I'll keep going.

But there are a whole range of things they looked at, so this is vaccine safety questions, and I don't know what's fair to do here. I guess it's -- I wish I had given you these slides ahead of time but, again, this is a document that hopefully many of you have seen and begin to look at, because I know that we've actually been asking for lots of input about these issues from the public as well.

So, there are a number of these hypotheses. There's specific questions. There are thematic areas as they put forward -- of a range of different things. And you can see some of these.

Simultaneous vaccination, that

came up -- that's come up before. Off-label use of vaccines, vaccine interactions, as some of these thematic areas in vaccination practices.

The question of other special populations who should be studied. Again, without specificity of what to study but, again, these are the things that came forward and part of the task of this working group is to try to put some more specificity on that, and then with some prioritization.

What you'll see in here children with in-born errors in metabolism, people with immunodeficiency, autoimmune disorders and the recognition that not everybody's biology is the same, and vaccines may behave differently in them.

And on this next one, is in here, so you'll find your word in here on the fourth line, but the idea is -- again, I don't mean to be flip about this, but there's a lot -- there are a lot of interests from a lot of

communities about where is my thing in this agenda.

So, they're in this, under the "Clinical Outcomes," is the neurodevelopmental disorders, including autism spectrum disorder. Again, just to give you the feel for the range of safety issues and disease concerns that this working group is taking on as they do their work.

So, that is the -- that is the CDC's Immunization Safety Agenda that's been put forward. They're not waiting for this working group to make conclusions to start their work.

Obviously, CDC's got an Immunization Safety Office. They are busy doing a lot of things, but as they look to the next five years, they were looking for some guidance as was outlined in this IOM report about that.

So, that's what that -- what the Committee is up to now, of taking on that

report, the draft agenda, looking at what's in it, having scientific consultations and having public consultations.

So, I go back to this slide, and what's highlighted in italics at the bottom is also out of the IOM's recommendations that should meet publicly and allow interested persons to observe the process and provide input through established mechanisms.

Again, I'm going to tell you some more about that, because that's what our committee heard a lot about this morning, is some of the processes to try to get broad input.

It's always striking when you're -- the meeting that you're having makes the news -- as I look at the camera -- and I joked about this one with one of the reporters who came to the first meeting of this working group last April, and several of you were there that, you know, this is Government having a meeting, it's a public meeting and

film at eleven.

Well, there you have it, and I don't know what time this film will air, but it was a -- but you saw based on the headline and the first sentence in this article from the AP that this was the news part, that the Government was having an unprecedented effort to give vaccine critics the say in shaping how the nation researches immunization safety questions.

I thought we were doing that all along. We formalized the process so I think that that's helping us but, again, this is what got us a headline and made the New York Times. My mother always says, "Why wasn't your picture in the paper?" But you all have mothers and have to deal with that as well.

So now, this is the home page for the Advisory Committee, and you might want to be familiar with this, because this is where you'll see what is -- what we're doing in coming attractions.

And it's going to -- it gets pretty confusing because there's a lot of interest in this topic and a lot of things going on, not only that we're doing, but the Institute of Medicine is involved and your Committee is involved, so keeping track of all of this is going to be quite something.

So, part of this is trying to get people's input into this was the usual way Government does this, put out a notice in the Federal Register and tell us what you think.

So, we did that, and we asked -- we tried to help people digest this 60-plus page document from the CDC, and asked them about concerns about vaccines, including personal experiences, comments on their values, on how to consider what to prioritize, and specific comments on the agenda.

We had them -- we gave them a month for comments. We had the comments due earlier this week so that this information could be packaged to some degree and presented

this morning, which is what happened. And I'll tell you something about that.

So now, this is -- I'll describe this and you'll see this a few times, but this is the -- our process and the timelines over the coming couple of months of the various -- there are various times that our Committee's going to be working when there are the opportunity for the public to participate directly, the opportunity for written comments and other meetings.

And then at the end of this, in June, hopefully that will be the time when the working group presents its case to the full committee that has a discussion, and ultimately there will be a decision on what their initial charge was, tell the CDC's Immunization Safety Office what they think they should be doing.

So, that's in the -- that's at the end of this process which is, again, the end of this first piece of the agenda.

So, part of this was to engage the real public, not just people who write in, not people who come to your meetings, but to go outside the Beltway and talk to people who otherwise don't have a dog in the fight.

And this has been very interesting. So, starting in mid-December up until a few weeks ago, help by the Keystone Center -- and I'll talk about them in a second -- who are particularly good at this, of organizing these town hall meetings.

We went out to Birmingham, Alabama, Ashland, Oregon, and Indianapolis to meet with a small group of people, 50 to 75 people and take their pulse and these are people who, again, don't have a dog in the fight and the idea was to find out from the public-public -- and I see some of the public-public is here today, and they may want to talk about it as well, as they did this morning -- but what it is that people think is going on. And I'll share some of that with

you.

So, again, where the Keystone Center is particularly good in this, this is what -- this is from their website. This is not an advertising for them. But they have helped us quite a bit in this process of bringing groups together that don't necessarily -- aren't necessarily comfortable at the same table, and trying to see where there's some common ground and a way to move forward.

And so, with that, I have stolen several of the Keystone slides of their summaries for this. They made the important point this morning of what these meetings are.

Again, three meetings, and these three places is not a representative sample of anything but, again, it's just the idea that you're going to go outside and talk to people about what they think.

And it wasn't intended -- these weren't intended to persuade anybody of

anything. We actually tried to be quiet more than we've -- than people wanted, because they wanted to hear what was going on.

But we went out there, again, to take the pulse of the public, and so we wanted to hear lots from them. And again, there's some people from that real public who are here today that may want to something about it.

So, we went to three of these places. The only one that was intentionally picked, and I was there, and they are all intentionally picked because you had to get an airline ticket to go to these places, but was Ashland, Oregon, which has a 25 percent exemption rate in kindergarten children, I believe is the right number.

And we thought, well, we should go to a place like that and find out what's going on there. And it was quite something. And people were amazed that the Government would come to a place like Ashland where they said, you know, knowing what -- knowing the kind of

people who live here -- I'm quoting somebody -- it's amazing they'd want to come out and talk to us.

So, we learned a lot from that. I want to share part of that, and the full set of slides that were presented this morning will be available on our website.

But the community concerns -- and these were just about -- we didn't ask anybody ahead of time. There was no list of things that we wanted to hear from people.

This is -- as I mentioned this morning, I saw this as a white board experiment where you sort of -- you went out there, you told people about the vaccine system enough to make sure everybody was on the same page and what came out of it were these concerns about safety, effectiveness, special populations, trust, access and education.

So now these Keystone slides, which I'll just buzz through so you get a

flavor for what some of the concept was.

So, among safety, there were concerns about the vaccines that we currently give. Again, this was from the community. These are people who don't have websites, but came on a Saturday to spend their day with us.

They got $50 for coming and they got lunch. Not everybody took the money, but they wanted to -- they came to tell us what they had to say.

So, they're concerned about ingredients, the number of vaccines, the schedule, combinations of vaccines and ingredients, side-effects, both short- and long-term, interactions with various other things, medicines, allergies, cosmetics, environmental factors to the diseases caused, what they're supposed to target.

This is -- this flu-caused -- does the flu vaccine cause flu, our seasonal discussion with everybody, and in some places about manufacturing, security and the safety

of supply.

And I only say that because I think that some of this stuff is probably at the whim of what's going on in the news. So, when there's a story about melamine, people think, well, where do these vaccines come from.

So, that was in one place, and I think that's one of the cautions about these exercises.

So, safety -- there were safety concerns about data, the studies and the vaccination system, why hasn't there been a study about vaccinated, unvaccinated population, so there are people outside the Beltway who asked us that question, not just you.

Do the studies ask the right questions? Are they reporting the data accurately? Are there -- have people with alternative thoughts been excluded from the process somehow?

You will see these are, again, some of the highlights of very rich discussions. There were concerns about effectiveness and whether they actually work and do we -- and about, again, special populations.

Again, this is some of the way this was broken down into genetically predisposed, the elderly immunocompromized, premature babies and pregnant. Essentially every subpopulation you can imagine came up somehow.

There was this issue of trust. Who do you trust to tell the truth. And what I found particularly interesting, and I'll get to this last bullet is: Scientists and the question of are they independent.

At some of the break-out sessions, many people talked about the importance of independent research. And when you push people on it, and I'd like you to think about yourself is, you know, what is -- what

ultimately is independent research and who funds it, because no matter how far you push, if it's the Government doing it, well, that's not independent.

If the Government, NIH, is paying for it, how independent is that if people are dependent on them for the next grant? If it's the manufacturers, well, is that truly independent?

So, I think this whole notion of independent research is a complicated one. It sounds good, but how you actually do it in a way that is going to then satisfy what the idea behind it is, I think is a larger discussion.

There was -- this wasn't as relevant to what we're talking about here about safety. But people did talk about access. There was a lot of discussion in the news in December about the health care system, so it wasn't surprising that that came up.

And then about education. Where

do we get information? Who's a trusted source of information. Where do you get complete and accurate information. What do you do with competing information that both looks credible.

So, I think that's a lesson for other parts of what we're doing as well.

But I want to give you a glimpse of what, again, in those three bubbles on the left in Birmingham, Alabama in Ashland, Oregon and in Indianapolis, Indiana what people thought.

We also had -- you saw the Federal Register Notice -- written public comments. And we received, I believe, just under a hundred written comments. They are -- all the comments are on our website now so you can peruse those and see for yourself.

But again, and among these was yours, so yours counts as one of these, I guess, 91 comments we received. I'll get back to this letter, which is the letter that you

wrote to us, and I'll talk about that subsequently.

So, the summary -- I'm going to talk a little bit about the summary. There's always this disclaimer of did we summarize it right, but I just want to give you a flavor as to the high level of what came in over the transom in response to the Federal Register notice, adding to what we heard from these public engagements, recognizing this is essentially -- these are additional data points for this working group to be putting into the mix as they ultimately do their work, which is, you know, reporting out what they think this ISO research agenda should be. So, we don't want to lose track of that.

So, the comments that we got so far were -- this is -- you don't need this. We have 91 comments, ten from organizations, 81 from individuals and, again, a sense of how it was broken down.

Many were not specific to the

research agenda, per se, but showed interest in the larger system. So, when we talk about other things that this working group has to do later on, in looking at the broader system, not only the CDC's piece of this, we clearly have a lot of good information.

There were many who had concerns about vaccines, immunization safety, including their personal experiences. Many commented on -- a few commented on the values that we asked we, and a few had specificity of -- from that 60-plus-page report.

So there was somewhat, you know, it was somewhat mixed as far as what we got in You'll see the organizations that wrote to us. Many of you may be aware of this but, again these are the written comments we received and many from individuals.

Again, we had a lot of personal experiences. Every one of these identified a vaccine safety concern, and you can see the topics. So, of the 81 individuals, 60 of the

81 commented about autism, 36 of the 81 individuals commented about simultaneous vaccination and the vaccine schedule. 35 about ingredients and 32 about a study of comparing vaccinated and unvaccinated children.

So, that's what you get when you put out a Federal Register notice, and that's where we are so far on the first piece of that.

So, there's going to be -- obviously, this is one piece, and I'll get you the bubble diagram in a second to see where you are on the map, but there will be other additional opportunities for both direct input into this working group and the full committee and -- and from written comments.

So, I think I go back to the bubble here. So this is what -- we'll get to where you are on the map. There are additional things going on. The first purple box was today's meeting.

The next purple box is what we're referring to as a stakeholder meeting, which will be a public meeting in Washington in mid-March and the Committee today will tell us whether it's the 16th or the 17th of March.

Subsequently, they'll put out their draft report for public comment, so you see in the upper right-hand corner there's another opportunity for people to write in their comments.

There will be deliberations and hopefully this will come through at our June meeting of the full committee we'll have another discussion and potentially a vote to finalize this. That's, at least, the plan, and the plan timeline.

So, I'm going to stop there and just tell you one other thing that otherwise is going to confuse things, is that simultaneous with this, we are doing something which we call the National Vaccine Plan.

So, what I told you before is part

of an NVAC Vaccine Safety Working Group. The National Vaccine Plan is being updated for the first time in a long time. It was -- again, this is a 20-year program.

The first National Vaccine Plan, the first and only plan was written in 1994. A lot has happened since 1994. So, in the whole vaccine and immunization enterprise, we felt we needed a road map and a vision for the future.

So, there are five broad goals in the National Vaccine Plan. The second one you'll see here is enhancing the safety of vaccines and vaccination practices. Maybe a relevant goal is the third one about supporting informed vaccine decision-making by the public, providers and policymakers and then there are these other goals as well.

So this is going to -- this is really a simultaneous exercise of looking at all things vaccine and immunization that the Government does, and so you may hear about

things going on.

For example, on Monday this week the Institute of Medicine had a meeting related to this which talked about the communication aspects. And I know some of the people in the room participated in that.

Goal 2, again, I'll just highlight this and I won't confuse you with the rest of the plan, is about safety. And among the things that we have in this is this -- is what we're calling "indicators."

The X's and Y's here are intentional. They are not typos. We're trying to have a national discussion about this to get a sense of how achievable or aspirational a plan like this could be.

So, we've put that out there with X's and Y's in it and hopefully people will tell us you should be doing better than that or you're doing good enough, or whatever it is, on a variety of these things.

There are a number of indicators

for each of these goals. That sounds very bureaucratic, but I just want to give you a flavor for what was in it.

And again, just to make sure that if you bumped into something called the National Vaccine Plan and Vaccine Safety that you have some grounding of what this was about because these are on somewhat parallel paths.

So, with that, let me get back on track. So the -- and I mentioned the Institute of Medicine is working on this as well. There are a series of meetings, one this week on communications.

April 14th may be a date some of you may be interested in, in Washington, that the Institute of Medicine will be focusing on that second goal, the vaccine safety goal.

So now I'll get back to your letter, and then I'm now representing the folks on the other side of town who aren't watching this real time because they've got to actually have their own meeting, but they'll

see this later on or listen to it or whatever technology they have available.

So, this is extracted from the letter that Tom wrote on your behalf to the working group. And I guess the question is -- I won't read this to you. The question that I'd like to maybe -- I'll end my presentation and maybe start the discussion is: What is it that you want?

So, I think that there is a question of: Does the vaccine stuff all go to this Vaccine Committee; are you looking for a consultation, somewhere in between?

When we polled the members of the working group when they saw this letter, they were enthusiastic about working with you somehow. We have to figure out how best that works out because, clearly, you have expertise that they don't have if they're going to entertain this question, and vice versa.

So, I'll -- let me stop there and then with hope that the New Yorker doesn't sue

me for a cartoon from last week's edition, but I think this is where we are.

And you can decide which tree you are and which is the seedling, but I'm hopeful that we're somewhere along the line of a process that's going to grow and make a better product in between.

So, I'll stop there again. Thank you for your time and your interest in having me come in.

DR. INSEL: Thank you, Bruce. That is very helpful.

So this presentation is open for questions, and if I can just start off, I want to go back to the work that you're involved with now, with the ISO, the Immunization Safety Office of CDC.

You are producing a document which came from their set of potential initiatives where you're helping them to establish priorities. At the end of that process, which sounds like it will be in June, what happens?

This goes back to them and then what?

DR. GELLIN: So it's -- they came to us with their draft agenda. And just think about that. If you live in Birmingham, Alabama, and somebody says, "We've come to talk to you about the ISO draft agenda. You know, what does that mean?"

So, you have to sort of get -- you know, this is what sort of the research plan is. So, they came to us with this draft agenda to say, well, what is it that you think that we should be doing.

So, now, this gets back to what an advisory committee is and does. This is a committee that has been asked by -- essentially by the Assistant Secretary for Health, given the way that works, to advise CDC on their priorities and to identify any gaps.

So, they will make a recommendation, and that is -- they will then

make a recommendation to the Assistant Secretary of Health.

It is essentially then the recommendation to the Immunization Safety Office of CDC for which time, like a lot of recommendations that come from a lot of people, it's up to the recipient to decide what they're going to do with it.

DR. INSEL: Where I was going with this, though, is that it sounds to me like that entire effort is restricted to the CDC. Is that right?

DR. GELLIN: Currently. So there was a key word in here called "initial" and this poor working group that got lured in on this IOM report that said, "We need some help on this. We're going to do something more than the Vaccine Safety Data Link, more than CDC."

Well, it's clear that there's more to the system than that. So, their second charge is to look at the system overall. So,

I think it's probably in there -- and a lot of things that they've heard already are clearly not in CDC's lane. There's stuff that that -- you know, there's a lot of different pieces of research that are related to vaccine safety.

So, exactly how they package that, I'm not clear, but it is clear that as they have looked at some of these things and some of the concepts that Mark mentioned before, in cell biology, probably it's people at CDC who do cell biology but that's not why they're paid to be at CDC.

So, I think that it's going to be -- and I can't predict what's going to come of it, but clearly the charge to them is to say, "Well, here's the CDC stuff." Then there's going to be all these other things that they're going to have to then make a comment on, and probably in the context of their larger piece.

The other thing I want to highlight is that this is an advisory

committee like many that makes advice. They are not working off of a checkbook. They don't have any authority to say, "Well, you're going to do this and here's this pot of money for it."

They are merely going to make advice to the Government, for which the Government then has to make a response.

DR. INSEL: Well, we can certainly relate to that. We know how that works.

DR. GELLIN: Well, okay. I --

DR. INSEL: So, I want to hear from other people and then maybe we can circle back around to think about what we might do with you.

Other comments or questions?

(Off-microphone comments from the floor.)

DR. NOBLE: Thank you for that. That was really interesting. And with the understanding that it's not my intention to put you on the spot, it's that you're in a

position we are getting exposed to a lot of interesting data.

What is your estimation of where we are with vaccination dropout. Are we talking about a thousand kids in the country, ten thousand kids, a hundred thousand kids? And what's the slope look like?

DR. GELLIN: It's a great question. I don't have the best access information of the number, and it's -- and what we heard actually this morning was interesting, from people in Ashland, Oregon.

As I mentioned, you know, if there's somebody here from Ashland they can probably better represent it, that a quarter of the kids in kindergarten are not vaccinated.

Well, it may be that they get an alternate vaccine schedule, and it's not entirely clear the relationship between exemption rates and the number of people in a community who are vaccinated or fully-

vaccinated.

People may pick and choose. So, it's really the -- it's the right question, but it's, as you would imagine, it's a pretty complex answer.

The other thing we know is that these vary very much by community, that like-minded people tend to live in similar places, so there's a clustering within community, and there are -- there was a presentation on Monday from San Diego County in the context of the discussion of the measles outbreak that they experienced.

I've seen similar data from Washington State that looks at exemption rates and/or coverage rates in various communities.

So, it's -- it really -- you really need to look at a community level. So, I don't mean to dodge that. We can provide you with more information.

I think it's a fair -- the fair point though is -- the question is: Are we at

a tipping point. And some of the information we get, both either from Gallop poll type surveys or other things tell us that there are a number of people -- even those who vaccinate their children who have some concerns.

And I think that trying to understand at what point concerns turn into behavior is really one of the questions because, as you suggested before, that when there is enough concern in a community so that the community immunity level drops, they are susceptible.

So, the measles outbreak in the United States last year was largely because of that, of community immunity. Some because kids were too young to be vaccinated. Some because they weren't vaccinated.

Last week there was a report of an outbreak of haemophilus influenza B meningitis, HIB meningitis. And for those of you who are old enough, which is defined as older than me, that have been in hospitals,

you knew that people trained on meningitis by taking care of kids with HIB.

That before there was a vaccine, there were 20,000 cases a year in the United States. Most of those had bad sequelae. Most of them the kind of sequelae that you're worried about in the neurosciences. And that disease essentially disappeared.

Flash forward, it is largely gone, and now out of Minnesota, in part because they have a great health department that's got a great surveillance system, identified five -- I think it was five cases of HIB meningitis in -- of HIB disease in Minnesota, including a death.

And, in part, that was because of a problem with unstable vaccine supply. So, this is part of my other part of my job, but in part, because it was an active decision by the parents that this kid didn't need it.

So, the question then is at what point the population gets, you know, swings

back to a point in time before -- when there was much more susceptibility.

So, that's a very long answer to your very good question. Are we at a tipping point? I can't say, but is there a concern that we might be approaching it? Absolutely.

MS. REDWOOD: Dr. Gellin, I just have a question. Does the National Vaccine Program Office actually have a budget to conduct research? From what I'm hearing, you don't put out RFPs. You don't have those mechanisms in place to be able to do that, and I'm just curious if that's true.

And then, from what you're saying, that this would then be advice going back to the CDC and the CDC would be responsible for doing the vaccine safety studies. Is that correct?

DR. GELLIN: Almost. So, the National Vaccine Program Office -- and this is the Wizard of Oz behind the curtain -- is ten people. That's the entirety. And we have a

small budget for those ten people. Most of that budget is to do the things that we do, largely supporting this Committee.

We have a small budget, that is dwindling, to support what's been referred to as unmet needs or emerging issues that come up in vaccines.

And it was a process, an internal process of the Government where things would come up out of the budgetary cycle and say, "Listen, here's something that we really need to look into," and we couldn't have anticipated two years ago when we did our budget.

So, we had a process that now has probably a million and a half dollars in it. Just to give you a flavor for how much we, NVPO, can control which, for all these discussions, have dedicated to vaccine safety while we have that amount of money.

So, that's -- but that's my piece of the thing. So, we have -- what you're

asking, really, is what leverage we have, and so we have that little bit and then we have this -- the National Vaccine Advisory Committee which is the nation's advisory committee on vaccines to make recommendations to the Government on what they think the needs are.

MS. REDWOOD: I guess one of the concerns I have is, from what I hear from parents they don't really trust the CDC to be doing that type of research because they have inherent conflicts of interest in that they develop vaccines, they hold patents on vaccines, and they are also responsible for monitoring vaccine safety.

So, I just wanted to point out that I don't know that research coming out of the CDC will really be broadly accepted by the community that has concerns about vaccine safety.

DR. GELLIN: I guess to the point of what's independent research. Another

piece, and I didn't get into it because I couldn't give you the whole landscape of things in vaccine safety.

Last summer NIH put out what they call a program announcement which was -- and I can get you the link to that, or maybe you've discussed that before, which was really signalling to scientists saying, "Listen, here's some things we're interested in hearing from you about."

There's no special money for that. There's no special system to evaluate those coming in. I think -- it's too early to tell how that's working. I know that there have been some academic investigators who have submitted proposals.

I don't know if you know anything about that of where they are in the process for review, but again, that's -- it's another part of the system which is signalling, "Come tell us what you think," and then -- but then they're in the pool as far as I understand it,

for the rest of science that comes to NIH in the way that it's reviewed.

DR. INSEL: So, can I follow up on that, Bruce, that increasingly we've been thinking about this issue much the way that you portrayed it and that Mark talked about it as a problem of trust.

And the question for this Committee is where we can be helpful in that, and whether there's a way in which we can either make recommendations or begin to craft the issues where there's some common ground between these various sides in this debate, so that five years from now or ten years from now we're not still having the same debate, but we're able to actually provide a better level of trust and a better level of understanding of what the issues are.

Your sense of what we ought to do there?

DR. GELLIN: I would ask Lyn, if I could, because, you know, I think if you think

that stuff that comes out of CDC is not going to be trusted, then I guess -- I mean, I'm sorry to do this, but I think to try to get -- I don't have any answer to that.

But I think we need to go to the people who are saying "I don't trust this for some reason," and figure out what it is that they would trust.

So, Lyn, would you -- sorry.

MS. REDWOOD: I think Dr. Noble touched on that at the end of his presentation to establish some type of committee that would include public members, scientists, clinician, to decide what kind of questions we need to ask, how best to ask them and to have buy-in from everybody at the table and to not have people at the table that have conflicts of interest, that develop vaccines or hold patents on vaccines and agree that these are the studies that need to be done and get them done now and get answers for our country.

DR. LANDIS: It's interesting. I

referred earlier to the studies that the National Center on Complementary and Alternative Medicine had done on echinacea, St. John's Wort, Glucosamine and I've forgotten what the fourth one was.

But it was very clear at the end of those studies, while a significant fraction -- some of the public was convinced and sales of those treatments or whatever you want to call them, biologics decreased.

There was also continued sales by a subset of the population who criticized the studies because it was the wrong preparation of St. John's Wort, it was the wrong Glucosamine, it was the wrong echinacea. They didn't get the buds. It was from the wrong country.

And I think it may be extremely difficult to come up with a set of studies that -- and the right group to do them that would actually be compelling. And I think I raised that concern before.

MS. REDWOOD: I think there's concerns about the epidemiological-based studies and that they might not be able to detect a subgroup of children that might be more genetically vulnerable to vaccine injury.

I think that some of the science studies, the primate studies -- there's a lot of wonderful things we could do mechanistically to try to answer those questions.

And you're probably right. Not everybody will agree with the science, but I think we've reached a crisis now and people who don't have children that they perceive to be injured by a vaccine are asking questions. So, I think it really behooves us to respond to that.

DR. INSEL: Duane.

DR. ALEXANDER: Bruce, one of the concerns that I think has led to people questioning the accuracy and adequacy of our data on vaccines has been the surveillance

systems.

And the questions about the adequacy of the vaccine adverse event reporting system and now the newer data link system that are legitimate, for their limitations.

One of the questions that we posed to you in the letter was whether there might not be an effort made to put together a team of epidemiologists and study design people and whatever it takes with independence to design what might be the very best surveillance system for adverse events, and put that into place and how costly that would be and how adequate it would be.

Have you given any thought to that or is this anything that's within the purview of your office?

DR. GELLIN: Well, purview -- everything's in purview. What I have control over is a lot less than that. But that's -- actually, I'm glad you raised that because,

again, that's the National Vaccine Plan piece. This is really looking at the system.

And so, there are clearly a lot -- so I would encourage -- this is my infomercial. I would encourage you to take a look at that and to see if we missed something within that.

There's a lot in there about surveillance and not -- I don't think it's addressed specifically the way you framed it, but I think that it is clear that these are in the context of a larger system and if parts of that system aren't working, then the engine is not working as well.

I won't get into the detail. I mean, theirs is a very different kind of a system. It's not going to be helpful for doing these kind of epidemiologic studies.

It's more just sort of -- it's like, you know, the alarm in your house. When it goes off, you have to figure out do you have a fire, do you need a new battery. So,

it's good for that.

Beyond that it's -- you need to do additional studies. I actually think the Vaccine Safety Datalink is an -- and that's why I believe that was the focus of the Institute of Medicine's report.

It is a national treasure. I mean, to me, it's sort of what electronic medical records hope to be. If everything was available, you knew what everybody's medical history was and what interventions were on, you just push a button and get all the answers. Wouldn't that be wonderful.

So, I think that that's -- I wouldn't put those in the same sentence of saying we've got problems with our surveillance, but they are there for different reasons.

But I think your point is an important one to look at components of the system so that when people say, well, what about -- did you look into X, Y or Z, you say,

"Well, here's what we're able to do based on the tools that we have.

DR. INSEL: So, just one second, Mark. I want to -- we don't have a lot of time, and this may be our only chance to pin you down here --

DR. NOBLE: I doubt it.

DR. INSEL: We've got a problem. This Committee does. We don't have the vaccine safety expertise, but we have lots of concerns. And as I looked at what you presented, I think you guys have got a problem, because you don't have the autism expertise that many of us are deep into.

I wonder if at least one thing we might do today, growing out of the letter we sent and the discussion we've been having is to have some sort of an agreement between the NVAC and the IACC that we will come up with a plan together about how to address the kinds of issues that you're struggling with and that we're struggling with, but that I still

haven't heard lots of answers for.

You know, what would be the science -- is there science that will help. Maybe Story's right, and you know, it's not going to be the way forward.

But it seems like we owe it to everybody around this table to dig deeper here. Mark had an interesting suggestion about maybe it would be a work group, but if it were a work group it would have to be very time-limited with a very clear charge that they're going to come up with a set of actionable targets here.

Is that something you'd be open to?

DR. GELLIN: It's not up to me. It's up to the working group who have already signaled, based on your letter, that they would be interested in that. How we structure it, we'll have to figure out.

You've seen all these bubble diagrams and this process going forward, the

degree to which you want to play into that, it's a little complicated because the train has left the station to some degree, although there is opportunity coming up that you could see, that may not be ideal.

So, I think we can work out the logistics, but from the team that I left to come over here, they clearly, after seeing the letter from the Committee, were interested in trying to figure out how to complement each other's talents that they don't have, given the common problem.

So, if you've got a suggestion as to how to structure it, maybe we don't have to get into that now, but for the commitments -- the commitment is the easy part in this one.

The details we'll have to work but I think there is interest in given what they've heard not only from you, but from -- like I said, the public outside the Beltway who, on the white board, came up with a number of the same kind of things that we hear in

your letter, and Mark's comment about what's going on out there in the communities and what's the curve look like.

I think that it's something that does need to be addressed.

DR. INSEL: What's the sense of the Committee on this? Is this something that you want to pursue? We kind of walked a little ways towards this in the letter that brought Bruce here, but how far down this path do you want to go?

Is this something we ought to develop? Should we have further discussion with the NVAC? Should we actually provide some sort of charge about getting this landscape, getting some ideas about what could be done in the next strategic plan or before, frankly?

It could probably be done very quickly right now because we may have an opportunity to move in some of these directions, and if you look in the plan that

we have in front of us, there's a lot of talk about gene by environment interactions, a lot of talk about inflammation. A lot of talk about metabolic disorders and figuring out who's vulnerable to environmental effects and all those kinds of things.

So, we may not even need to think about the plan so much as actually getting an RFA out and getting this process moving forward.

But, I throw that out there for you to chew on, and I'd love to get some input while we've got Bruce in the room about what you'd like to do going forward.

MR. GROSSMAN: I'll step into this briar patch. I guess I'll start by saying that I think what Mark had said at the end in terms of setting up some sort of independent work group is a fine idea.

It's probably something that we need to do. And it's just based on the simple premise that trust is the issue that we're

talking about here. We need to restore trust in the vaccine, in the National Vaccine Program, and right now that doesn't exist in many families' minds, particularly the ones that feel that their children have been vaccine injured.

And quite frankly, you know, I think that's -- there's legitimacy there to have their concerns, their needs, their -- what they so clearly observed ignored and not addressed has been a national crime.

And it's time that we get to the bottom of this to understand what is actually going on here so that all sides can come together so that we can minimize the potential for risk that could exist from the administering of vaccines.

It is a real issue, and whether people want to admit it or not, or people think it's bigger than it is or not, it is something that we have to do to restore the trust here.

And so, I would strongly support us setting up some sort of independent relatively -- well, not relatively. Very independent work group to evaluate how to address these concerns.

DR. LANDIS: Can I just -- I'm not sure you're -- I'd hate to be so -- continue to be negative. One question is how you get the appropriate expertise, scientific expertise on that committee without having potential conflict of interest.

So, so for example, if you wanted people who were doing -- who are knowledgeable about toxicology using molecular systems, cell culture systems, those are the very same people, if there were to be an initiative who would actually be applying for such money.

So, I think the question of how you would get an unbiased group with no conflict -- I don't mean to pick on you, Mark, but Mark is actually funded by NIEHS to do this kind of work and were he to be a part of

that committee he would have to be a saint to not advocate for an increased investment of NIH.

So, while it's not patents and royalties, it's what's the next best thing for a scientist, which is funds to do the research you think is really important.

MS. REDWOOD: But Story, we just had that when we had all these work groups. We brought in the scientists that are NIH-funded who advised us on the science we needed to do.

DR. INSEL: So we can do -- I think it's a good point. The difference is, we'll all advisory, so we're not a counsel making funding decisions. We don't have any money to spend, so we can't actually figure out how it would be spent.

And since we're FACA, that's Federal Advisory Committees -- both of us, both the NVAC and the IACC, it's maybe less of an issue to worry about that kind of a

conflict.

There are other conflicts that Mark mentioned which would be -- and it may be the most important ones are intellectual conflicts where people are so committed to an idea that it's not going to be useful for them to enter into a conversation about how to overturn that idea.

So, Bruce, I guess the question is: Is there a way to get these two groups together and --

DR. GELLIN: That's the easy part.

DR. INSEL: -- and have a joint meeting or --

DR. GELLIN: We can get the calendars going. We can -- that's the easy part, but just listening to this, I think that unless you -- unless we all have a clear sense of what is going to be on the path towards restoring trust we can do a lot of stuff that may or may not be good science and the rest of it, but at the end of the road, if it's not

addressed in the heart of that question, we may have learned some interesting science along the way, but I'm not sure it's going to do what you and I both think and what Mark suggested needs to happen.

So, I think that we -- and I punted on the question and pitched it to Lyn, but maybe we need some professional help on a better sense of what it is -- what actually would it take to get trust.

I mean, this is a bigger issue than this -- than autism and vaccines. I think it's an issue of trust in authority, trust in institutions, trust in Government.

It's a bigger -- we heard that in these communities. So, I don't mean to make this impossible, but I think that if that's the core problem we're trying to solve, we need to think through very clearly of how what we're going to do is going to help that and not just be a distraction for it and at the end of it find out that we're not any better

off.

DR. INSEL: Linda.

DR. BIRNBAUM: I would like to second Bruce's suggestion. I think this is a larger issue. I think the issue of how you develop trust and how you develop a trust in a process.

People study that all the time, and I think that there could be appropriate professionals -- another, you know, consultant or something could be brought in to provide us some guidance on that.

DR. INSEL: Now, let me challenge you a little bit, because I really think that if what we are talking about is trying to restore public trust in this arena, part of it is not going to be meetings, but actions of some sort, and I wonder if we can't get these two groups together quickly enough to come up with a set of actions that might actually start down that path.

I'm just really struck by, when I

looked at this recently, the number of IOM -- there was an NIEHS, National Academy at CDC meetings around this topic over the last four or five years. It's at least one a year.

And I don't think that the trust has gotten any greater in that -- and many of them, all of them include the public and all of them have public comments and they always have, you know, an RFI or some other approach that tries to be very inclusive, it's not going to get any better after that.

So, I guess I don't want to just see us come up for the plan for yet another meeting, unless there is some way of really thinking about how to push this forward.

Linda.

DR. BIRNBAUM: Yes. I think that's why I'm saying we -- we've tried to do kind of the obvious things of opening up the processes to a great degree.

Now, I'm not saying maybe it couldn't be done better on new, so I don't

really know, but I think that an outside, fresh look where someone comes in and says, you've done A, B, C and D, and it hasn't worked. What might be some of the other things you could consider doing?

DR. JANVIER: Just -- this is Yvette. I have a few thoughts on this, not that I have a solution, but after our last meeting I went home and I Googled, you know, Vaccines and Safety, and there was a little bit, once I got through some of the CDC pages, but there wasn't a lot there that a parent could sink their teeth into to support vaccine use.

And I happen to have spent seven years in Eastern Europe, and I've seen polio and tetanus and many of the diseases that don't exist today.

I almost feel that because autism is the number one concern of families with young children, that we're a victim of the success of the vaccine program-- that the

American public, especially families with young children, have no idea what it is to have a polio or measles or even H flu meningitis, which-- I took care of those kids, and I don't know how old I am compared to you, but I took care of those kids when I was a resident.

So, I think these families don't see those diseases as real because many -- you know, whatever, I don't know what the cutoff is of what percentage the community has to be immunized, but clearly we haven't, you know, tipped over that in many arenas.

So, the real concern is: "Is my child going to have autism?" not "Is my child going to have meningitis?"

So, you know, I think for a family -- and they're doing a lot of different things. They're not just not immunizing. They're breaking up vaccines. I mean, honestly, I'm not really sure what sense that makes at all, but I was in an 80-year-old

pediatrician's office last week, and she said, "Oh, some practices aren't seeing the children that refuse to vaccinate," so she's seeing them. And she knows what these diseases are, and she's breaking up vaccines, you know, giving you the diphtheria, the tetanus, the pertussis separately.

You know, and again, I'm not really sure what the logic to that is but, you know, she's trying to support her families.

So, you know, to me, I think we've forgotten and lost sight of what vaccines do and what their benefit has been to our culture. I mean, who do we have people living into their 80s? To me, it has to do with the fact that we have the vaccinations.

So I think a different approach, instead of -- I heard somebody from the CDC on a radio announcement saying, "Oh, we should get vaccinated," but we need to remind people, I think, of where we'd be without the vaccines.

And we get back to that problem of we still -- we don't know what the cause of this is. You know, we talk about all kinds of different growth factors and genetic factors, but until we have a cause that is not linked-- I think parents are withholding vaccines for the same reason they use alternative and complementary treatments.

Medically, I can't give them a cure. Certainly Risperdal is not a cure. I can recommend treatments that are educational or therapeutic, but I cannot give them the basic answers: What is causing autism, and what is the cure to this?

DR. INSEL: Mark.

DR. NOBLE: Sue, I agree with a lot of what's been said, and I think that you're right, that -- and I think, Bruce, you've alluded to this.

The perception shifts according to what your fears are. And the fears right now are of autism. But I think that there are

ways to do this. I think that we're less hindered by the problems that NCCAM faces, because we can present some well-defined questions with substances that have defined origins.

So, I think that we're not dealing with, you know, was it made in western China or eastern China or did it come from Korea, and was it harvested in the spring or was it harvested in the fall.

Those questions we're immune from, as it were. The question of the involvement of people like me in the discussions, I think the NIH is a great model of how you do this, that I've served on panels for all sorts of things, and there is a period when you give input, and then a review team is created that, if you're going to apply for grants, you're not on the review team.

The review team is other people. And I can tell you that being on the comment groups or not being on the comment groups

seems to have absolutely no effect on the probability of my later getting grants from the eventual grant process.

I think that the NIH is a great model of how to do that. I think the issue of trust for me is very simple. Definition of independent research is this: If I find out something that scares the heck out of you, and I'm free to publish it, that's independent research.

Anything that doesn't meet that criteria is not independent research. That's why my lab doesn't take money from companies, because one occasionally gets into those problems.

So, whoever funds it doesn't matter-- but, again, I think the NIH is the great model, that we always have scientists discovering things that people may not want to know, but the NIH leaves us as independent scientists.

So, I think you have the models,

and I think that trust is built on transparency. Great model here. People can come, hear what's going on.

Trust is based on respect for divergent points of view and willingness to listen, and not being condescending, and not being nasty to people with divergent points of view.

And trust is based upon a demonstration of desire to get something done, and that's the immediacy. So, I think you've got the mechanisms, and I know, listening to people, that you've got the will. Just let's get started.

DR. INSEL: Okay. I'm going to give you the last word, Bruce, if there's anything else you want to leave us with, because we're a bit over time.

DR. GELLIN: So, just to be -- so the concrete action is get some -- your club and my club together and talk about this? I'm not entirely clear what the next step is.

DR. INSEL: There's an old African proverb that says, "If you want to go fast, go alone. If you want to go far, go together."

We need to go both fast and far, so we would really like to figure out a way to work with NVAC to come up with a plan together, actually, the piece that is in the strategic plan saying that we'll join with you to get -- because you've got this expertise that we lack.

And you and I can figure out the mechanism by which that will happen, but I would like to do it quickly so that we can give some feedback to all the many people who care a lot about this issue.

And what I'm really looking for from your group is questions about what's feasible, what's useful. Are we talking epidemiology or are we talking cell biology, coming up with a sense from the people who do this really well where we're going to get the best information.

And we can -- in the process, we can explore all these trust issues as well. But I think from the conversations we've had here, people want to do something, and they want to do it with the best science, and that's where you can be very helpful to us.

DR. GELLIN: Okay.

DR. INSEL: Okay.

DR. GELLIN: Thanks a lot. Thanks for the discussion.

DR. INSEL: All right. Thank you, and thanks to both you and Mark for coming, and we will take a break at this point.

(Applause.)

(Whereupon, the above-entitled matter went off the record at 2:47 p.m., and resumed at 3:03 p.m.)

DR. INSEL: Okay. The next item on the agenda is one that we've bumped up against a few times, and we want to get your input about at this point. It's planning for the annual update for the plan.

We don't let the plan rest too long before we think about how to revise it, so we're already thinking about version 2.0.

Della Hann is going to take us through some of the issues around how best to monitor, how best to update, and what the options are for us as we think about what to do with this going forward.

Della.

MS. HANN: Okay. I realize it is very late in the day, and I will try to keep this as succinct as possible. I also want to say, just similar to what we discussed when Diane Buckley was up here talking about the summary of advances.

Really what I have is a series of issues for you all to consider, and then we can figure out how best to proceed with regard to those issues.

But just to remind everyone, I know there's a copy of the Combating Autism Act in your packets, but this is a

requirement, that the Committee is required on a yearly basis to update the strategic plan, including the budgetary requirements.

Hang on a second. Yes. Okay. So, the OR staff and I have been working on thinking about what some of these issues were. And in trying to envision what it would look like to go through an updating process.

We essentially thought of a cyclic process, and that's what you see on the screen and in the slide, where a phase of it has to be somehow monitoring progress. Another phase is one in terms of identifying strengths, weaknesses, opportunities and gaps, which for perfect Governments speak-- I'll refer to as a SWOG-- as we go forward.

Then that information needs to be analyzed somehow, and then finally ends up in some sort of revision to the draft.

So, if you look at each of those phases, then, the IACC needs to figure out and develop processes by which each of those

phases would be accomplished.

So, how is it that the Committee is going to identify and gather information from stakeholders. And by stakeholders, I'm including in that the funders, because sometimes the funders have launched initiatives which one won't see as we talked about earlier.

You're not going to see that in terms of public output for a while, so it will be important to have funders at the table as well as researchers, as well as people from the community with regard to what's going on with progress.

So, how will the Committee go about doing that? What will be the processes by which to do that? Then the Committee needs to determine how they're going to go about identifying the various strengths, weaknesses and opportunities based on some of that input that they're getting from the variety of stakeholders.

That will then lead to an analysis phase in terms of the strengths, weaknesses and opportunities, which would then lead to actually writing in terms of revising the plan, in terms of objectives, what do we know, what do we need, and have the budgetary requirements as well.

So, really, this is really the last slide. Okay. So, I'm going to try and purposely keep this pretty short, so I could turn it over to discussion for you all.

One of the basic questions to ask you is: Does that -- Do those four steps make sense? The monitoring phase, strengths, weaknesses, opportunities, analyzing information, and then revising the plan and the budgetary requirements.

If those phases -- and we can discuss that. That's open for discussion for you all. Then, after that, it's going to be who. Who is going to devise those plans and make sure that they actually happen?

Will that be a set of procedures that the full Committee is involved in? Will it be a subcommittee? Will it be just a series of work groups and meetings? And we can discuss that as well.

I think we want to be clear in terms of what the charge is for whatever group, even if it's all of you, that it's very clear in terms of what it is that is going to happen.

And then, how and when this planning process -- okay. I'm still just talking about planning. I'm not talking about actually doing. But the planning, how will that unfold? We have a short time today.

I did not envision that we would sit here and work out the mechanics at this meeting. So, I think what I would propose is that we convene a meeting to work out those mechanics of either the full group or the subcommittee, whichever you decide you wish to proceed with today, and that we can do that

either in person or vis-a-vis a webinar.

And that's it.

DR. INSEL: Good. Thank you.

This is open for discussion. Don't all speak at once. Thoughts about how to pursue this.

MS. BLACKWELL: I have one suggestion. Insofar as gathering the stakeholder views on the SWOG, I thought that the RFI process worked pretty well for us previously, so maybe that's something that want to take up in terms of gathering a public viewpoint on the strengths, weaknesses, opportunities and gaps.

MS. HANN: Well, I think the first question is do those four steps make sense to you. Does the model -- somehow, some mechanism put into place to be able to monitor progress, then go to the SWOG piece of it in terms of strengths.

Someone's got to -- some collective is going to need to determine the

strengths, weaknesses and opportunities based off of that, and then analyze and move forward. Are those the four -- do those four steps make sense to you? Or are there alternative or additional steps that you think would be more productive?

MS. REDWOOD: Does this also -- will it include somebody to actually do portfolio analysis as part of these steps?

MS. HANN: I would see that as being part of the planning process. So, if, for example, under monitoring progress, if one of the elements for monitoring progress is to do the portfolio analysis that you had mentioned earlier, that would be one of the phases.

But that would be something that whatever group essentially is going to make the planning, do actually the planning would need to decide.

MS. REDWOOD: You know, Della, also, if you look at the actual language of

the Combatting Autism Act, there is a suggestion in there for the development of an autism advisory board.

And I think it might be nice to have another group outside of this -- this Committee that could actually inform us and do a lot of this work for us.

They could evaluate the -- look at the completed projects, make recommendations for reallocation of resources and initiatives, also help advise us in the creation of new initiatives.

So, I almost think it would be nice to have another group that we could call on that would be an advisory board or something similar to the work group number two that we established where each Committee member actually appointed somebody to that work group that was an expert in one way, either as an advocate or a researcher or a clinician in the field of autism that we could also seek additional input.

I think we created all those work groups initially, what, four of them we had, golly, 50 or 100 different people advising us.

And I think it would be more helpful if we were able to establish a committed group, a smaller group that we could turn to to help advise us on some of the science issues in autism.

That would be one of my recommendations for the Committee to consider. And also possibly, in addition to that, a working group of the IACC or a subcommittee similar to services that would work on the strategic plan as well.

MS. HANN: I just want to draw your attention in the Combating Autism Act to the section -- it's under the section for the IACC, and it's a section towards the end, Section E where it talks about subcommittees establishment and membership.

And it says, "In carrying out its functions"-- that is "it" being the IACC--

"the Committee may establish subcommittees and convene work groups -- workshops and conferences. Such subcommittees shall be composed of Committee members and may hold such meetings as are necessary to enable the subcommittee to carry out their duties."

So, given the statute, the law, if we form a subcommittee, it can only be comprised of the people who sit at this table. And a subcommittee could therefore convene a workshop or a conference or whatever word like that that you wish, that could provide input, but that's some of the parameters that we have to work through.

Also, if we form -- if a subcommittee is formed, it would need to be a functional subcommittee. It would be composed of eight members or less, because otherwise you would have a quorum, which would mean that you essentially become the Committee.

So, I just throw those realities out there for everyone to consider, too, in

terms of our discussions.

MS. BLACKWELL: I think the only thing I have to add to what Della said is that, as you know, Lee and I are the co-chairs of the services subcommittee and, you know, we pretty much operate under what Della just described.

We do, and additionally, we're required to report to the full Committee. You know, we meet regularly and we have to follow the same rules that apply to the Federal Advisory Committee Act.

So, we're pretty much all under the same umbrella here.

DR. INSEL: I guess the question for us, going through your second point up here, Della, is if we're going to do this, is there a group of eight or less of us who want to do it, or does everybody want to be involved? Because that determines whether we would be a subcommittee or the full committee.

How many people would not want to

do this, and would be happy to see the other -- their colleagues, seven of their other colleagues, do it instead?

So, that's three.

On the other side of the question is what Della and our staff would find easier to work with in preparing this, the Committee as a whole or a subcommittee?

MS. HANN: Oh, that makes no difference to us. To be honest with you, it makes no difference. Because, as Ellen said, if we work with the subcommittee, it all has to come back to the full Committee for their concurrence and so forth, so really it's six of one, half a dozen of another.

DR. INSEL: I would think that for the Committee, it would be easier to have a small group to try to wrestle with the idea that whoever does it would be responsible, as Ellen was just saying, reporting it out to everyone.

You know, Lyn's idea is actually

-- it would be great if we could find people to assign to do this for us, but the Act doesn't allow that. So, it's not an option

MS. REDWOOD: There is somewhere in there, Tom, language referring to an Autism Advisory Board. Is it in the colloquy or in the --

DR. INSEL: It's in the colloquy. The problem is that for the Act itself, it really doesn't give us any flexibility here. It says this is our job and we have to do it, but we can use a subcommittee if we want.

MS. REDWOOD: Okay.

DR. INSEL: So, as much as it would be nice to have somebody come in and do it for us, maybe Mark Noble's work group could help the -- I think we're stuck. I think that we have -- really, the question is: Do we all want to be at the table, or do you want to come up with a group of eight, seven, six of us or less that want to do this instead.

DR. LANDIS: I mean, one scenario

might be to have primary and secondary responsibility for specific pieces, so that not everybody on the Committee is looking at all the different, the six parts, but that there would be smaller groups which would have primary responsibility for looking at one piece and then reporting back to the Committee as a whole with the thought that everybody would end up looking at all of it, but not everybody would have to look at it with primary responsibility.

DR. INSEL: Della, how does that work for you?

MS. HANN: Well, that's a possibility, but I think we're moving the cart a little bit before the horse or vice versa in doing that.

I think that the first is to get some idea, does the full Committee, or does the subcommittee want to get into the nitty-gritty about planning the details by which this will happen.

Okay. So, what will be the configuration for monitoring progress? Will it be convening workshops? Will it be simply doing a literature search?

I'm just, you know -- those are all your decisions, in terms of how this is going to roll out. And some -- we need guidance from you all because it's your report, how it is you wish this to be unfolded.

And then, similarly, who will be responsible for determining the strengths, weaknesses and opportunities. How will that process unfold?

So, while I know that sounds very tedious, I don't know -- I can't provide you with a fait accompli because it's your plan.

DR. INSEL: Here's an idea. Can I see a show of hands who would serve on such a subcommittee if we did it that way with the idea that you report back, rather than asking who would not serve.

Who wants to be involved with this?

(Show of hands.)

DR. INSEL: So, we've got two, four, five, six.

MS. HANN: And there's some people missing right now, too. Allen. Where did June go?

DR. INSEL: Stephen. Is anyone on the phone, Stephen?

MS. HANN: Jim left.

DR. INSEL: So, that's seven of us. Is that -- Ann, would that be okay with the full committee if this group of seven were to take this on? It's going to be probably lots of phone conferences, working closely with Della and her staff in coming up with ways of taking this forward.

MS. HANN: Right. What we would -- what I would propose is that the group would meet. It also has to meet under the FACA Guideline, and so the meetings of that

work group would -- or subcommittee, excuse me, would also be public, just like we do with the services.

So, we could do webinars, et cetera, in order for that work to go forward. I think it would be clear. I think it would be helpful if we're going to do that, so first of all, did you guys get the people --

Could you raise your hands again so that the OR staff could get the names of the folks.

So, it looks like Alison, Lyn, Lee, Tom, Story and Ed and Ellen.

DR. INSEL: And I may try to get Stephen to agree, too, but we'll do that later.

MS. HANN: Okay. Then, I think it's important for the Committee, for the full Committee to really understand what the charges of the seven of you, that what you're going to do and how you're going to report back essentially to the full group.

What I propose-- and it's your decision-- is that you become a planning committee, so that you map out a process by which this will unfold, and then that process, once you've hammered out what that process looks like, that the process be brought back to the Committee for a complete buy-in from the Committee, and then we will engage such process.

DR. INSEL: Okay. Is there anything else you need from us at this point? Anything the Committee wants to hear from Della? Are we ready to move on to public comment?

(No response.)

DR. INSEL: Terrific. Thank you.

MS. HANN: Thank you.

DR. INSEL: I think the group is running out of steam here, but we've got one very important activity still in front of us, and it's the part of the meeting that's devoted to public comment, and we have several

people who have written in to ask to speak to us.

There's a list I have here of seven, and I would ask each of them to identify themselves and also, if they're part of an organization, to identify the organization.

We have time for each person to have really no more than five minutes. So, I will signal you when we get to the five-minute or close to the five-minute mark.

The first name I have on the list is Katherine Walker.

And, Della, are you giving up your seat for this? Okay.

MS. WALKER: Hi. Good afternoon. I'm Katherine Walker. I am a member of SafeMinds, but I'm before you today as a mother of a son-- five-year-old son with PDD-NOS-- and I want to preface my statement with the impression that I'm very hopeful for the discussion that has taken place today, and I

am hopeful that it does produce some action on research into vaccines and their connection, their possible connection with autism.

And I wanted to use a metaphor that I thought of when I was in the room in January when the research items were actually struck from the strategic plan.

So, please don't take any disrespect with my metaphor. I'm a mom of three young children, so it may seem very childish.

Good afternoon. My name is Katherine Walker. I'm a mother of a five-year-old son with PDD-NOS. Today I need to let the IACC know that my son's health and safety and the safety of thousands of children who have yet to be vaccinated are not a hot potato.

The game of hot potato is a favorite among young children. You remember, you throw a small object among a circle of friends and try not to drop it.

Well, as a childhood game this behavior is appropriate, but in the business of ensuring that federally-mandated vaccines are truly effective and safe, this behavior is not acceptable.

As a mother of a vaccine-injured child, I am angry, of course. I am hurt and tired of all the work it takes to just get through the daily routines of life with my son.

Yes, I am not here to lay blame at anyone's feet for what happened to my son. This issue of blame is one Ms. Story had brought up, I believe, in November. Blame is not my intention. My intention is to encourage the fiduciary duty of the federal government and each of you sitting here as representatives of that Government.

If the Government mandates it, the Government should study its safety. I do challenge the IACC with the task of ensuring that from this point forward the safety of

vaccines and their relationship to autism is not treated as a hot potato.

I need not repeat the fact that there is scientific basis for the vaccine research items that were struck from the strategic plan on January 14th. Even if I were to concede there was not a scientific support, is it still not your fiduciary responsibility to ensure the safety of susceptible individuals, especially as the so-called anecdotal evidence is rising?

We are quickly approaching a point of no return. The IACC may want to ignore this issue. They may desperately want to play hot potato, saying, "We don't have the expertise" or "We don't want to duplicate work being done by another agency."

However, the wave of public awareness and opinion is just beginning to rise. Now the IACC has the opportunity to be ahead of this wave, to be on the proactive side of this epidemic.

I acknowledge that there is, indeed a conflict of interest with different entities of HHS having responsibility for the vaccine program, while at the same time tasked with vaccine safety research. How could there not be conflict.

In order to restore the trust needed to truly have an effective vaccine program, the HHS must ensure all research done on vaccine safety and the vaccine/autism relationship is conducted by independent and nonbiased organizations.

If there truly is a desire to determine the etiology of autism, there must be a sincere approach to thorough investigation of even the claim of harm done by vaccines.

This is not debatable. You mission and core values must include an authentic commitment to uncover and curb the causes of ASD. It must be done without bias to any industry or governmental interest or

initiative. It must be fair and balanced.

I thank the IACC for allowing me the opportunity to speak and, once again, I leave you with Thomas Jefferson. "The force of public opinion cannot be resisted when permitted freely to be expressed. The agitation it produces must be submitted to."

Thank you so much, and I really am hopeful that your collaboration will work.

DR. INSEL: Thank you.

Theresa Wrangham.

MS. WRANGHAM: Thank you. Good afternoon. I'm Theresa Wrangham, president of SafeMinds and mother to an 18-year-old daughter with autism. I truly thank the Committee for the opportunity to speak today.

I state the obvious today: many autism organizations are extremely dissatisfied with the IACC's actions to remove previously-approved vaccine research objectives due to concerns regarding the IACC's band-aid.

Government agency conflicts of interest and ongoing vaccine injury litigation, NIH lack of experience to conduct vaccine research, and that these objectives did not originate from the IACC science workshops.

Respectfully, our concerns were founded in science conducted by respected members of the scientific community who share our concern. The countless citing and recitation of the Combating Autism Act's colloquy statements to the IACC should leave no doubt as to the undeniable congressional mandate and the wishes of we, the people.

This Committee is charged with including vaccine research specific to autism and the strategic plan.

The NIH website states, and I quote, "NIH has a long and fruitful history of vaccine research." A quick search of the clinical trial search engine produces 433 studies using keywords "vaccine, safety, NIH."

One titled "Research to Advance Vaccine Safety" contains the objective identification of risk factors and biological markers that may be used to assess whether there is a relationship between certain diseases or disorders and licensed vaccines. Collaborating organizations include NIMH, CDC, NICHD and NIHES.

Despite statements to the contrary, the previous approved vaccine objectives were supported in the IACC science workshops, and according to February's IACC transcript of the strategic planning work group, Dr. Craig Newschaffer confirmed that initiative 34, risk factors -- risk factor studies in other special populations as a perfect fit.

The scientific community involved in the strategic planning work group on numerous occasions and in agreement with autism organizations and many public IACC members stated the need for vaccine-focused

research, acknowledgement of autism as a multi-system disorder and cited a bias regarding the state of vaccine research and recommended the inclusion of limitations for studies currently cited in the "What we know" section of Question 3, with the addition of research supporting vaccine concerns.

Many SafeMinds board members were also present via telephone when these issues were discussed at great length during the July 8th meeting of the work group.

The outcomes from these discussions were not wholly-presented in the screen presentation made to the IACC on July 15th, and no attempt was made to integrate them via the SafeMinds document furnished to the Committee on July 10th that summarized these outcomes.

Coincidentally, SafeMinds has since been informed that there is no audio file for the July 8th meeting and no transcription taken, which calls into veracity

the screen presentation made to the Committee on the 15th.

Thus, the justification for the revote was without merit and requires IACC to reinstate the objectives.

However, in light of Dr. Insel's acknowledgement of the existing inherent conflicts of interest within HHS to conduct this research, which includes NVPO, reinstatement will require the addition of provisions for independent entities to conduct the research, as well as mechanisms to provide objective oversight and transparency in the grant review and monitoring process.

Furthermore, inaccuracies in what we know in Section 3 must be corrected. In closing, we remind the Committee that over a million affected individuals and families and communities depend on your expedient action to correct what are obvious errors.

People with ASD deserve optimal health and affordable access to treatments,

supports and services to lead happy and productive lives. Their best interests must supersede the political imaginations at work within this body. Thank you.

DR. INSEL: Thank you.

Just as a point of correction, for those of you who haven't looked at the strategic plan recently, many of these issues are actually very much still in there. There's an issue of one that looks specifically a gene-by-environment interactions, which means trying to understand about who's specifically susceptible to environmental triggers.

Those could include vaccines. It could include infections. I could include all kinds of toxicants. There's another process in there around environmental factors. Those two together account for over $50 million in the budgetary requirements of the plan.

Additional initiatives around metabolic and inflammatory processes. So, I

think it is important to remember that there isn't really any aspect of this research that cannot be done, if that's what people decide they want to do within the strategic plan.

What we did decide, we being the whole group, the majority of the group, anyway, at the last meeting, was we didn't think we knew enough in terms of what the NVAC was doing and what the opportunities were out there, and that was really the reason for deferring a discussion about this until we could bring people together today, which is what happened.

So, I think it is important to recognize the facts of where this Committee has gone, and I wouldn't want to be suggesting that there in some way was a change in the process. We have done this in a way that has always been in cooperation with what the majority of the Committee asked for.

And, of course, if the majority of the Committee decides the want to do something

very different, any of us are free to bring that up.

The next person on the list is Peter Bell from Autism Speaks

MR. BELL: Thank you, Tom. My name is Peter Bell, and my most important affiliation is being the husband of a great woman, and the two of us are the parents of three children, the oldest of which has autism, and his name is Tyler and he's 16.

I'm also the executive vice president at Autism Speaks, and as most of you know, Autism Speaks is the largest autism advocacy organization in the country. We are dedicated to funding research, raising public awareness, advocating for the rights and needs of those affected by autism, and working to ensure that these individuals and their families have access to services like insurance, therapies and resources to improve their lives.

In collaboration with a number of

other autism advocacy organizations, Autism Speaks played an integral role in the Combating Autism Act and getting it drafted, legislated and passed over two years ago.

Thus, we also see ourselves as the stewards in the process of making sure that the intent of Congress is fulfilled and reflected in the strategic plan.

I would like to further point out that my colleague, Dr. Gerry Dawson-- who's the chief science officer at Autism Speaks-- and I were both members of the Strategic Plan Work Group that helped develop the list of initiatives that eventually became the research objectives that are now part of the plan.

I am here to express our concerns about the events that transpired during the previous IACC meeting on January 14th involving two issues.

The first being the process by which the changes were made to the strategic

plan and, the second, the substantive merits of those charges.

Until last month there was a sense of genuine partnership that was being forged among the public, scientific and medical communities that had the support of a broad consensus of the autism advocacy community.

A significant component of the approved plan was the inclusion of two research objectives relating to vaccine research. These objectives have been approved at the December 12th IACC meeting with broad support among the public members as well as several Federal members.

Disappointly, this all changed at the January meeting. The process by which these two objectives were reconsidered and then moved out of the objective section of the plan has undermined the trust that has been developed over the past two years.

The topic of vaccine research, so controversial and complex by nature, was not

on the published agenda, nor was advance notice given to the public members.

The decision to revisit it and propose significant changes to the plan without advance notice and adequate time to respond was unfortunate.

It did not reflect the collaborative and transparent spirit with which the IACC had been functioning.

The justifications given by several federal members of the IACC for removing the vaccine-related objectives from the plan were, frankly, either flawed or insufficient.

Autism Speaks regrets that because of these breaches in process and trust, we were compelled to withdraw our support of the strategic plan, despite the many important and good objectives it embodies, and the tremendous amount of hard work that has gone into its development.

This brings me to our second

concern, the merit of the changes that were made to the strategic plan. Autism Speaks supports programs that ensure the public health, including an effective and safe immunization program.

Our position regarding vaccine safety and research which is clearly stated on our website is that the best way to ensure that parents are confident in the safety of our vaccine program and at the same time protect the minority of children who may be at increased risk for serious adverse effects of vaccinations is to foster collaborative, trusting relationships among the public, the medical and scientific communities as well as the federal government whose mandate it is to conduct research on vaccine safety.

To that end, we advocate for directly and immediately addressing ongoing legitimate questions regarding the safety of vaccines through rigorous science.

Authoritative safety studies

require time and resources, but quick government action will instill necessary confidence and trust.

Recent discoveries in science have raised new questions about the role of environmental factors in autism, including whether immunizations are associated with increased risk for ASD.

As acknowledged in the CDC's draft scientific agenda, fundamental questions have not been addressed, such as whether the use of combination vaccines confers increased risk for adverse events and whether there are subgroups in the general populations such as children with certain genetic and metabolic conditions that are more vulnerable to serious adverse effects of vaccines, including ASD.

Such research could help to identify subgroups of children at risk and develop different vaccine schedules for them, along with the recommendations for careful monitoring of adverse effects.

In conclusion, Autism Speaks still believes the IACC can reclaim the promise of the strategic plan had following the December 12th meeting.

It is our hope that the IACC will seize this opportunity to renew confidence, trust, and a true spirit of collaboration by incorporating their original approved vaccine research objectives, including the same budgetary requirements as priority items in the soon-to-be drafted second version of the strategic plan.

Individuals with autism and their families and the general public will be best served through this action. Thank you.

DR. INSEL: Thank you.

Yvonne Hershey.

MS. HERSHEY: Good afternoon. My name is Yvonne Hershey, and this is my 17-year-old son Derrick. We are here today because of the profound impact mercury has had on our lives, and we are here today because we

believe it is critical that research into the effects of mercury continue, so that all families with children suffering from autism spectrum disorder can realize the same happy ending that we are experiencing.

Thank you for giving us this opportunity.

Ours is a story of transformation. This healthy, sensitive, intelligent, witty and musical young man sitting beside me today bears little resemblance to the adolescent of four years ago.

We'll start at the beginning. Derrick was happy as a baby, as a toddler and through his elementary school years. Very early on, however, we became aware of focus and attention problems.

MR. HERSHEY: When I started middle school, things got much worse. By 7th grade I would go to my room immediately after school and come out only to eat dinner.

MS. HERSHEY: I discovered bottles

of pills stashed in his dresser drawer. Derrick's dad and I were at a complete loss. What had happened to our son?

Things continued to spiral downward until they hit bottom when Derrick was in 8th grade. He was severely depressed, and his explosive rage controlled our lives.

Life every day was hell for him and for us, his parents and siblings. It seemed inevitable that his life would either end by his own hand or be spent in a correctional institution.

After a suicide attempt, Derrick spent one week in a behavioral hospital. Medications prescribed by a psychiatrist for ADD, rage and depression were not only ineffective, but made things worse.

In desperation we began exploring alternative solutions. In this process we found a research clinic in Quakertown, Pennsylvania established by a medical doctor.

MR. HERSHEY: After a lot of

testing, I was diagnosed with mercury poisoning caused by high levels of thimerosal in the childhood immunizations I had received in the early 1990s.

MS. HERSHEY: While it is true that many children suffer no ill effects from their immunizations, the presence of mercury reached neurological havoc in Derrick.

MR. HERSHEY: When I was 14 I started treatment that lasted about 15 months. I took two different things, Vitamin B-12 to break up the mercury that had lodged in my brain and Glutathione to move it out.

My parents say they began to see changes in less than a month.

MS. HERSHEY: It would be to overstate the transformation that unfolded. I remember vividly the moment when, for the first time in years, Derrick looked directly at me and responded to a comment I had made.

And in his eyes I saw a glimmer, a spark of light that had been nonexistent for

a very long time. For me, that marked the beginning of hope for a complete recovery.

And what a recovery it has been. Derrick loves life. He loves people. He even loves school, at least at times.

MR. HERSHEY: I don't have trouble concentrating in class anymore. Several years ago I was on the verge of dropping out of school, but now my grades are better than a B average. My goal is to do even better, and I've started thinking about where I want to go to college.

My depression and rage are gone.

MS. HERSHEY: Derrick is full of conversation and music. His rich bass singing reverberates throughout our house, and after years of deafening silence, it is indeed music to my ears.

I am not a scientist or a medical professional or an expert on autism spectrum disorder. I am only a mother who has witnessed firsthand the devastating effects of

mercury poisoning on my son, and the astounding change that occurred when the mercury was removed and his brain was allowed to heal.

The pain and cost of autism spectrum disorder are far-reaching and devastating to individuals, to families and to society.

I am here today because I believe it is absolutely essential for research to be ongoing, so that answers can be found and people educated about the causes and treatment of ASD.

MR. HERSHEY: And I am here today because I got off school, and I think it would be great if other families could get the help they need.

MS. HERSHEY: We ask that you please consider our story and the story of thousands of others as you make decisions on funding for research into the mercury/autism link. Thank you.

DR. INSEL: Thank you.

John Erb.

MR. ERB: Good afternoon, ladies and gentlemen. My name is John Erb, and I'm the independent researcher you've been warned about.

After 20 years working directly with individuals with autism, I had realized that in some ways they were smarter than the rest of us, and following up research led to my publishing a book in 2003 called "The Slow Poisoning of America."

In that I theorized that the food additive monosodium glutamate could be linked to the possible increase in alterations of the brain itself.

Further studies done since that time have shown that there are over a dozen vaccines that include glutamate.

In 2006, the Director of Food Safety for the World Health Organization, Dr. Jergen Schlundt, asked me to send him a direct

report on the dangers of MSG. And in that report I managed to find a 2006 study published that shows that glutamate alters the proliferation and differentiation of brain cells.

November at the inaugural meeting here I presented my research and discussed how dangerous monosodium glutamate in food and vaccines is to the human body. My second visit here, last year, I brought a food scientist to outline how glutamate can be shown to directly increase mercury in the body as well as show many of the gastrointestinal problems, many of the symptoms that autism has.

I further at that time reported on studies, 13 of them dating back to 1949 that purposely gave monosodium glutamate to mentally retarded children to make them smarter and to alter their brains.

These studies the Government was well aware of. As a matter of fact, Margaret

Gianninni, previously on the Committee, remembers back in 1950 giving MSG to these children to try to make them smarter.

The Genome Study, the largest of its type, determined that glutamate-related genes were the promising candidates for contributing to autism spectrum disorder.

A study done in 2008 showed that glutamate carriers and altered calcium homeostasis play a key interactive role in the cascade of signaling events leading to autism.

Another study done in 2006 had its conclusions as abnormalities in glutamate made partially underpinned the pathophysiology of autism spectrum disorders. This one from 2006.

The present studies suggest that an abnormality in glutameturgic neurotransmission may play a role in the pathophysiology of autism.

You've got these in your notes, and I'm not going to read through them for the

sake of time, but dating back to 2001 there are studies where conclusions-- subjects with autism may have specific abnormalities in glutamate receptors and glutamate transporters in the cerebellum.

These abnormalities may be directly involved in pathogenesis of this disorder.

There are several more studies dating back to 1996 that insinuate that abnormal plasmatic levels of neurotransmitter amino acids may be found in some autistic children.

When is MSG going to make the forefront? I'm not waiting. As I said, when I came to the inaugural meeting I would get MSG out of the food supply. Since that time, my petition is on the docket at the FDA to remove MSG from the food supply.

I'm going several steps further. Last week I received an email from the president of the World Autism Organization

inviting my research before her committee of scientists and inviting me to Europe to tour many of the facilities there.

I'm going another step further, and at this time announcing I'm going to be creating the Global Autism Institute and Academy, and it's going to bring together information on Autism studies throughout the world, and be sponsored by many member countries.

But furthermore, in 55 days, I am going to make an announcement worldwide that I believe the cause of autism has been found. I believe it is monosodium glutamate in food and vaccines, and I believe that the sooner these are removed from the food supply and vaccines the sooner we see an end to this insidious and terrible disorder.

Thank you very much, ladies and gentlemen.

DR. INSEL: Thank you.

The next name on the list is

Miribel McIntyre.

MS. McINTYRE: Good afternoon, everyone. I am a mother of a four-year-old with autism, and I'm just going to talk about how every rule has an exception. We all know that.

Throughout history, the role of science has been not only to explain those mysteries that we cannot understand, but also to find answers to complex challenges.

To understand the world around us before the scientific method was ever designed, we mostly relied on the information that we receive through out senses, even when this information did not seem very logical.

Let me explain. Folklore has it that Lake Superior does not give up its dead. Sounds strange, doesn't it? Normally, the bodies of those who drown will eventually float.

Actually, the scientific explanation is that a cadaver in the water

starts to sink as soon as the air in the lungs is replaced with water. Once submerged, the body stays underwater until the bacteria in the gut and chest cavity produces enough gas to float it to the surface, just like a balloon.

So, with this information, how can we explain the bizarre occurrence in Lake Superior? Well, apparently the frigid waters of Lake Superior slow down bacterial action, and that's why the bodies tend to remain sunken.

To me, this sounds like an exception to an expected process due to unique characteristics-- and in this case, is the water temperature. As we all know, there's always an exception to every rule.

In theory, the human body should be able to detoxify itself from the neurotoxins contained in vaccinations, but what happens if the body cannot detoxify itself? What would be the effects, changes and

consequences of having substances such as mercury and aluminum trapped in your body?

What happened to those special populations that do not follow the expected process of detoxification from neurotoxin? So many questions that deserve to be answered.

This is not about placing blame. This is about understanding the mystery of autism and finding answers. Just like those people who noticed Lake Superior's peculiar behavior-- which has been explained by science-- as parents we notice changes in our children's development and health when exposed to neurotoxin-contained vaccinations.

So, please, let's design, explain what we see. Let's study vaccine safety and the effects of neurotoxin on children, and remember that the goal of public health is to improve lives through the prevention and treatment of disease.

Thank you very much.

DR. INSEL: Thank you.

The last public member to speak is Paula Durbin-Westby.

MS. DURBIN-WESTBY: Hi. I'm Paula Durbin-Westby. I'm here representing the Autistic Self-Advocacy Network.

First, the Autistic Self-Advocacy Network would like to take this opportunity to thank members of the InterAgency Autism Coordinating Committee for inviting us to present on ethical concerns in autism research this past November.

We also applaud the effort the IACC has made so far in developing a strategic plan for autism research. Much remains to be done. Funding allocation has been skewed in the direction of finding causes and cures.

For example, $75 million have been allocated toward just one research initiative that -- that of identifying animal and cell models and the attempt to find a cure for autism. Compare that with the mere $1.6 million for the entire services research area.

Public Law 109.416 has a broader mandate than research into causes and cures. For example, services research is mentioned as one of the topics to be reported on in the yearly update on scientific advances.

Although the short title-- the Combating Autism Act-- was geared toward obtaining congressional and public support for the act, it is time to take a step back and seriously think about what funding priorities mean to people who are on the autism spectrum, their families and communities.

The research agenda should respect the wishes of autistic individuals and their families, many of whom have written in response to requests for information. If you look at the sheer volume of comments and response to the December 19, 2007 RFI, you see that approximately 90 comments were received on services and related issues under the "Treatment" section.

If we add the comments about

education, assistive technology and concerns about the future, the comments number in the hundreds, a sizeable percentage of all comments received.

The Autistic Self-Advocacy Network recommends a shift in focus to research into areas that will actually help families and individuals on the autism spectrum.

Such research should address the demands measured by the World Health Organization Quality of Life Instrument, including in the area of independence, mobility, activities of daily living, communication, and employment.

Regarding communications technologies and systems, the strategic plan mentioned picture exchange communication systems, but did not address any other systems.

Picture exchange cannot adequately represent the entire realm of augmentative and alternative communication and assisted

technology.

The strategic plan should recommend funding specific research initiatives into emerging promising communications technologies, both for those with no or little expressive language, and for those who do have expressive language but cannot always access it reliably.

Examples of such emerging technologies abound, including aided language stimulation, story book aided language stimulation, natural aided language, functional communication training with AAC and language acquisition through motor planning.

Augmentative and alternative communication and assistive technology allow people on the autism spectrum to use and develop language in ways that are natural to us, even if it is sometimes not oral language.

Many of the most popular communications systems have been developed entirely without the input of individuals on

the autism spectrum. To develop effective communications tools, autistic individuals must be consulted at all stages of the research, from design through implementation techniques and evaluation.

Thank you.

DR. INSEL: Thank you.

And that's the full roster of public comments that we had scheduled from what was sent in before the meeting.

As you know, that as with previous meetings, all comments will be both shared with the full Committee and also available through the Committee.

We're drawing to the very end of the agenda. I want to just ask if there are any final comments from the group, anything else that you think needs to be on the table before we adjourn.

DR. JANVIER: I just had one comment. I appreciate the comments about communication, and I thought maybe we could

have a presentation on some of the alternative communication, augmentative communication options.

I think Battey's not here, but his group specializes in that.

DR. INSEL: Why don't we put that on the agenda for one of the upcoming meetings It's a great idea. And hopefully Paula will be there to also tell us whether we've covered the bases or not. So, that would be useful.

Anything else? And that's also -- Yvette, you remind me that if there are other items that people want to make sure we get to at a future meeting, this is a good time to let Della know.

Hearing none, I want to thank all of you for staying engaged in this very long and difficult process. We've got a lot more to do. I think you heard from public members in the last half-hour that we're not finished. There's still a lot that we need to be thinking about and working towards, trying to

make a difference.

Thanks, everyone, and the meeting is now adjourned.

(Whereupon, the above-entitled matter was concluded at 3:57 p.m.)