U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, OCTOBER 22, 2010

The Committee met in Conference Rooms E1/E2 of the William H. Natcher Conference Center, 45 Center Drive, Bethesda, Maryland, at 10:00 a.m., Thomas Insel, Chair, presiding.

PARTICIPANTS:

THOMAS INSEL, M.D., *Chair*, National Institute of Mental Health (NIMH)

DELLA HANN, Ph.D., *Executive Secretary*, Office of Autism Research Coordination (OARC), National Institute of Mental Health (NIMH)

SUSAN DANIELS, Ph.D., Office of Autism Research Coordination (OARC), National Institute of Mental Health (NIMH)

DAVID ARMSTRONG, Ph.D., National Institute of Environmental Health Sciences (NIEHS) (representing Linda Birnbaum, Ph.D.)

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

COLEEN BOYLE, Ph.D., Centers for Disease Control and Prevention (CDC)

PARTICIPANTS (continued):

JOSEPHINE BRIGGS, M.D., National Center for Complementary and Alternative Medicine (NCCAM)(representing Francis Collins, M.D.)

JUDITH COOPER, Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD)(representing James Battey, M.D., Ph.D.)

GERALDINE DAWSON, Ph.D., Autism Speaks

GERALD FISCHBACH, M.D., Simons Foundation

LEE GROSSMAN, Autism Society

ALAN GUTTMACHER, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

GAIL HOULE, Ph.D., U.S. Department of Education

LARKE HUANG, Ph.D., Substance Abuse and Mental Health Services Administration (SAMHSA)

JENNIFER JOHNSON, Ed.D., Administration for Children and Families (ACF)

WALTER KOROSHETZ, M.D., National Institute of Neurological Disorders and Stroke (NINDS)

CHRISTINE McKEE, J.D.

ARI NE'EMAN, Autistic Self-Advocacy Network (ASAN)

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

DENISE RESNIK, Southwest Autism Research and Resource Center (SARRC)

PARTICIPANTS (continued):

ALISON TEPPER SINGER, M.B.A., Autism Science Foundation (ASF)

MARJORIE SOLOMON, Ph.D., M.B.A., University of California, Davis and M.I.N.D. Institute

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

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PROCEEDINGS

10:03 a.m.

Dr. Insel: Good morning everyone. I want to welcome you to the meeting of the Interagency Autism Coordinating Committee. We have a very full agenda but because there are so many people joining us by webcam and by conference, I would like to just quickly go around the table and make sure we all know who is present.

So I will start. I am Tom Insel and I serve as Chair as well as the Director of NIMH.

Dr. Hann: Good morning. I am Della Hann and I am the Executive Secretary for this committee and I also have a day job at NIH.

Ms. McKee: Good morning. Christine McKee. I am a public member of the IACC and I am a parent of an 11-year-old girl with an autism spectrum disorder.

Dr. Briggs: I am Josie Briggs. I am the Director of the National Center for

Complementary and Alternative Medicine. I represent Dr. Collins on this committee.

Dr. Fischbach: Gerry Fischbach, with Simons Foundation in New York.

Dr. Boyle: I'm Coleen Boyle. I'm the Acting Director for the National Center on Birth Defects and Developmental Disabilities at CDC and I am representing CDC on this committee.

Mr. Grossman: I'm Lee Grossman, President and CEO of the Autism Society. I am a public member of the IACC and also the proud father of a 23-year-old son with autism.

Ms. Singer: I'm Alison Singer. I am the President of the Autism Science Foundation. I have a 13-year-old daughter diagnosed with autism and I also have an older brother with autism.

Dr. Koroshetz: I am Walter Koroshetz. I am the Deputy Director of the National Institute of Neurological Disorders and Stroke.

Dr. Solomon: I am Marjorie Solomon. I am an Associate Professor of Psychiatry at UC Davis and I represent the M.I.N.D. Institute and I am a public member.

Dr. Armstrong: I'm David Armstrong. I am the Chief of the Laboratory of Neurobiology at the National Institute of Environmental Health Sciences. I am sitting in for our director, Linda Birnbaum.

Dr. Van Dyck: Good morning. I am Peter van Dyck, Director of the Maternal and Child Health Bureau in HRSA.

Ms. Redwood: I'm Lyn Redwood. I am Executive Director of the Coalition for Safe Minds.

Dr. Guttmacher: I'm Alan Guttmacher. I am the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development here at NIH.

Mr. Ne'eman: Ari Ne'eman, President of the Autistic Self-Advocacy Network, and adult on the autism spectrum.

Dr. Houle: Hi, I'm Gail Houle and I am with the office of special education programs in the U.S. Department of Education.

Dr. Dawson: Good morning, I'm Geri Dawson. I am the Chief Science Officer at Autism Speaks and Research Professor of psychiatry at UNC, Chapel Hill.

Dr. Cooper: Good morning, I'm Judith Cooper. I am Deputy Director of the National Institute on Deafness and Other Communication Disorders and I am here substituting for Jim Battey.

Ms. Resnik: Good morning, I'm Denise Resnik. I have a 19-year-old son with autism and I am the co-founder of the Southwest Autism Research and Resource Center.

Ms. Blackwell: Hi, I'm Ellen Blackwell, Centers for Medicare and Medicaid Services. My 23-year-old son also has autism.

Dr. Posny: Hi, I'm Alexa Posny and I am the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

Dr. Daniels: Hi, I'm Susan Daniels, I am Deputy Director of the Office of Autism Research Coordination.

Dr. Insel: Well, terrific. Welcome to everybody and to those in attendance in the room here. We also have a number of members of the public who are going to make statements later that we are looking forward to as well as people joining us by webcam.

What I wanted to start with is to have you look at the minutes from the July 16 meeting and let the committee know if there are any changes or comments about those.

(No response.)

Hearing none, can I have a motion to accept?

Approved.

Any against or abstaining? I don't see any hands going up so I will assume the minutes are approved and that we are going to go on because of this busy agenda to get started with the work of the day, and that we are delighted to have our first presentation here from Dr. Alexa Posny, who just introduced herself as the Assistant Secretary for the Office of Special Education and Rehabilitative Services in the Department of Education.

She came here from Kansas, which gives her some link to the Department of Health and Human Services, where the former governor of Kansas is our secretary and your former colleague there.

We are just delighted to have you be able to join the IACC meeting. There's been lots of conversation about issues that have to do with education. Gail Houle has represented the department for both this committee and its precursor as well from 2000 on.

So rather than stealing any more of your time, with an introduction let me invite you to come up to the podium and you can begin to tell us about the view from the Department of Education.

Dr. Posny: Thank you very much and

I appreciate the opportunity to be with you and again, I am going to apologize up front because I know I am going to have to leave as soon as I am done and I have a policy of a meeting that I need to go to.

What I want to share with you is I just want to give you kind where we stand, and I know Gail has shared this with you and has represented us very well and it's kind of give you a history in the efforts in terms how we are supporting everything in terms of autism.

Just to kind of put a frame around it, the U.S. Department of Ed is very clear about its mission, that we do want to promote every child's achievement in terms of education and preparing that child for being competitive, and we do this through promoting and fostering educational excellence, but the piece that really speaks to me is when we ensure equal access.

And when we talk about that we are talking about equal access for absolutely every single child in this country.

When I think of OSERS, the department in which I work, and what we do, you can see how we take that mission and we strengthen it, because we are talking about the full integration and participation in society of every individual with disabilities, and what we do is we ensure equal opportunity, access to and excellence in, not only education, but in employment and community living as well.

We cross, we are the only department or the only caucus, as we are referred to, we are the only office in the U.S. Department of Education that literally works with individuals with disabilities from birth to death. There is no one else that crosses the entire spectrum.

The piece that influences me probably more than anything else is this very statement, the fact that there is a greater tragedy than being labeled as a slow learner, and that is begin treated as one. We must have the highest expectations for everyone with whom we work and that drives us every single day.

When I think back historically, this year we are going to celebrate the 35th anniversary of IDEA, the Individuals with Disabilities Education Act.

When I go back to 1974 and yes, I am very seasoned, I have been in this since before 94-142, we not only didn't have students with disabilities being educated, we excluded over 1.7 million kids with disabilities from ever even entering the school door.

Think back on that 35 years ago in terms of what we have done. Over the span of 35 years, we have had some tremendous successes. We have seen wonderful gains by many of the population that we serve.

But I also refer to the other things as we have had many learning experiences along the way as well, and we will continue to have those learning experiences. It was the mantra under which 94-142 was formed in 1975 that guaranteed for the first time a free, appropriate, public education for every child between the ages of 3 and 21, regardless of how seriously he or she may be handicapped.

That was a profound statement that was made at that point in time because I remember playing with a child with Down's Syndrome, and I remember he was more like me than unlike me but he never was in my school. He never attended school and I could never figure it out.

It's this, it's what we are talking about and what we are making sure that we provide for every single one.

This was a letter that was written by Jody and what she is saying -- and she wrote the letter to her teacher, and she said:

Dear Teacher

Today Mommy cried. Mommy asked me, "Jody, do you really know why you are going to school?" I said, "I don't know. Why?"

She said, "It's because we are going to be building me a future." I said, "What is the future? What does one look like?"

Mommy said, "I don't know Jody. No one can really see all your future. Just you. Don't worry because you will see. You will see." That's when she cried and said, "Oh Jody, I love you so."

Mommy says everyone needs to work really hard for us kids to make our future the nicest one the world can open. Teacher, can we start today to build me a future? Can you try especially hard to make it a nice pretty one, just for Mommy and for me?

I love you, teacher.

You know this is a profound statement for kids and this is an actual letter that was written to talk about what they think and what they need.

We know that prior to the 1990 IDEA amendment, children with autism were receiving services, however it was not under the category of autism. They were served under a number different categories.

Dr. Insel: Alexa, I'm sorry, we have got to get this fixed because I am afraid people won't be able to here so give us just a moment while figure out what the audio problem is here.

Dr. Posny: It kind of sounds like an ocean.

Dr. Insel: Sometimes it feels like an ocean.

(Off record exchange by phone participants.)

Dr. Insel: No, we can hear you so if you could mute both of your phones because we have had to stop the meeting because of background noise. Thank you. Okay, we are ready to go.

Dr. Posny: That helps. Okay the

reason this was so important it was because in 1991, autism was added as an optional reporting category. In 1992 it became a required category. It makes a big difference in terms of when we look at the numbers and what we see.

The focus of the law that related to our free appropriate public education in the 1997 amendments, because was very critical: up until that point, what IDEA said it was going to provide is that it provided access to an education. It did not guarantee a level of education and it did not guarantee outcomes and/or accountability.

It was in 1997 that for the first time, we were required to improve the results for children in our educational system, not just make sure that they had access to it.

And it also required states to be assured that for the first time, students with disabilities must have been included in state- and district-wide assessments. It was not No

Child Left Behind that made the different. It was in 1997, when that was put in.

So when we look at it today, go back to 1974 where over 1.7 million kids with disabilities were not in the public education system to today, where we are serving over 6.6 million kids with disabilities.

And the other fact that I want you to be aware of is that today, almost 60 percent of kids with disabilities are in the general education classroom for more than 80 percent of the day. That is a monumental change from when we started in 1975.

So, when I take a look at it and say have we accomplished our mission? The answer is no, we have not. We still have far to go and that's one of the reasons I want to share with you all the things that we are doing in terms of working with the population.

Now when you take a look at it, these are all disabilities under IDEA and this is the change in terms of kids who are being served under this, and what you are going to see is that we are serving fewer kids and we are identifying fewer kids.

And some people are saying now how can that possibly be? There are a number of things that have been put into effect and part of it is, and the category that I often talk about and it's one that I know you are familiar with, it's learning disabilities.

I believe for far too long we have identified too many kids as being learning disabled when really in true fact they are not. They are just so disadvantaged they look like, and they failed for so long that they look like that.

So we have put in a number of different aspects under IDEA, one that we refer to as response to intervention, or early intervening services, where we can provide services for kids who are not yet identified and use special education funding to do that.

What we are finding over the course

of time is when we can intervene as early as possible, we are finding that we do not need to identify as many kids as needing special education services. Makes people somewhat nervous but I believe by using the money and not having to provide a label, we can meet the needs of the kids in a number of different ways.

What we have is we have a -- you can see the number of kids that are ages 6-21. The 6.6 million includes our infants and toddlers and our Part B services, the 3- to 5-year-olds.

Under this category, a little over 333,000 are identified as having autism. Now, in terms of comparing this to the population of students with disabilities, this is just over 5 percent of students that are served under Part B.

In terms of the total population, this equates to about 0.5 of 1 percent of all students in the U.S. Now remember, these are the ones that are being served under Part B, under those particular services.

If you can look at, from the year 2005 to 2009, it's almost doubled in terms of the number of students who have been identified under the category of autism. We have gone from 193,000 to as I said before, 330,000.

In addition, in terms of personnel who are providing services not only to kids with autism, but across the country, we have over 3 million teachers total and 426,000 of them are special education teachers. This is 14 percent of all teachers.

In addition, we have almost the exact same number of paraeducators, about 413,000 paras assist the special educators and we have about 214,000 related services personnel. These are the occupational therapists, physical therapists, speech and language pathologists, social workers, transition specialists, all the others.

When you put all of this together, 21 percent of all the people in the public school system are specifically related to special education. That's almost one-fourth of everything we have within the schools is related to serving our population.

We also know that we put in a tremendous amount of money, and let me share with you up front. Do we have enough money? The answer is no and I know I'm speaking to the choir about that.

But we have IDEA Part B and Part C. For those of you who don't know, Part B are the school-age kids. We really start with three and we go all the way through 21. Part C is our infant and toddler program which is an optional program for states to participate in. So we serve, again, the whole spectrum under Part B and Part C.

IES, the Institute of Education Sciences now funds all the research. Up until about six years ago we had our own research arm. Now it is done through IES with John Easton. And what they do is they test the effectiveness of some preschool- and school-based interventions and with the purpose of improving the cognitive communication, academic, social and behavioral outcomes of children with autism.

There have been a number of studies that have focused specifically on that population in order to help us.

When we think about some of the funding that we have done, and this is Part D, the discretionary funds. In 2010 alone, OSEP, the Office of Special Education Programs, one of the offices of which I'm in charge, provided approximately $10 million in discretionary grant funds and it targeted specifically pervasive developmental disorder, of course the autism spectrum disorders and Asperger's.

OSEP also continues to assume a major leadership role in identifying and disseminating the effective practices, these evidence-based practices that we know work and specifically geared towards autism.

Now I know that you have done a number of strategic plans. I also like this one. I plan strategically, therefore I am. However, I know that you have put together a very strategic plan that talks about all the different stages at which we need to be engaged.

What I want to spend time talking about is I want to spend -- just sharing with you where you can turn for services and some of the things that we do.

The first one I want to talk to you about is OSEP, again the Office of Special Education Programs and what we have done. The mission of OSEP is very clearly to improve results. Go back to the reauthorization in 1997. It's no longer providing access. It's ensuring and improving results. And again, it cuts across and starts at birth all the way through 21.

One of the major things that is funded under OSEP is what is known as the PTIs. These are the Parent Training and Information centers. What I want you to understand is that there is at least one PTI in every single state in this country and this is specifically to help parents, especially new parents, in terms of being able to turn to a resource to say what do I do when they find out that they have a child with a disability.

We also have what's -- we also fund what is known as the CPRCs, the Community Parent Resource Centers. Again these are cutting across the whole United States so that everyone has access to them.

The idea is that we need to provide the information and advocacy for parents so that they are very comfortable with knowing what they need to do.

Whenever I would talk to a new parent who would be attending an IEP conference for the very first time, for the individual educational program conference, I always encourage them to call the PTI and have another parent come with them. It can be very intimidating, sitting at an IEP conference with eight to 10 professionals sitting around there telling you everything that your child cannot do, and it's very difficult.

I have sat through an IEP conference for my son many different times, and even with me, knowing the information that I needed to have, I never heard anything more than boy, I got a lot of work to do. So it's nice to take someone with you.

I also want you to notice that we also target some particular technical assistance for parent centers. There's one specifically for the national, there's one specific for the military, native American and then we have six regional centers.

What the alliance helps centers do is they offer innovative technical assistance.

Again, this is for the parents, to make sure that they are well aware of what their rights are, and what they should be expecting for their kids.

They also are a wealth of resources. I have visited several of these and it's amazing what they have available. They also prepare a lot of materials that are put into user- and parent-friendly language. IDEA can be very complex and they turn it around and make it understandable, hopefully, as much as they can.

They also collect data in terms of how much are we doing and what have we done and they have national conferences that they hold throughout the United States.

They also conduct regional conferences and I have presented at several of them and again, it's really outreach to the parents to make sure that they understand what needs to happen.

OSEP also funds some personnel prep

that are very specific to serving the needs of individuals with autism. There are grants to universities that train teachers specifically to work with kids with autism and other school personnel in terms of what they need to do.

What has been awarded for doctorate programs are five awards across the country, for Masters, 29 and for certificate programs there have been two.

Some of the examples that exist: Project Data out of the University of Washington is one. We have got one in New Mexico State that very specifically is preparing autism spectrum specialists. San Diego State is talking about empowering adolescents with autism for a smooth transition up into the work world and the University of North Carolina has TA and training centers in terms of providing professional development.

Other ones that they fund are programs that provide technical assistance in the implementation of IDEA including children with autism and technical assistance providers also work nationally.

We have a center that has been around for a number of years. It formally was called NICHCY but it is the dissemination center for children with disabilities. If you have never gone on the NICHCY's website, I encourage you to do so. They are a wealth of resources and I access their information and material all the time.

Another one that I am very familiar with, the Center for Positive Behavioral Interventions and Supports out of the University of Oregon.

Having just come from Kansas, KU partners with the University of Oregon in this particular program. We also put this in place across the state in Kansas and it has made all the difference in the world in terms of kids who are no longer suspended nor kicked out of school and it has made an incredible difference

The National Professional Development Center on Autism Spectrum Disorders - we very specifically have a center that is just targeted for this. The purpose of this particular center, again, is to promote the use of evidence-based strategies. Very significant in terms of what works for a group of kids in which we know they have a variety of needs.

It also works at the state and classroom level and it really works with the state departments to help build their capacity, to know what evidence-based practices might work. It's also to increase the number of personnel specifically related and serving kids with autism.

It's also to promote the development learning and achievement of children with autism and support the families and again, this information is to be -- you know, sent across the United States to help everyone.

This particular center is a five-year grant. I believe Gail just told me we are in the fourth year of this particular one. It receives about $1 million per year and you will notice that it is a multi-university center and we have found this to be probably one of the most helpful, is when we have different universities collaborate together to provide the service.

It's, you know, with the University of North Carolina, California and the University of Wisconsin at Madison, you know, are working on this together. What is really interesting, and I know we have someone here from Chapel Hill, but my program of study, my Masters and my Ph.D., are from the University of Wisconsin at Madison and I had the chance to work at the Waisman Center and it is -- I'm very biased. Of course it's a great program but so is KU and you know, there are a lot of them.

Where they are is, take a look at

it. currently they are working in 12 different states with the idea that three new states come on every year, but you can begin to see how we are beginning to cut across the whole country and that's the idea. We want to expand to make sure that every child in every state is supported.

The goals of the center, as I said before, to promote development, learning and achievement of all of the children and their families, increase the state capacity and of course the number of highly-qualified personnel.

Some of the products and resources that have come out of this: we have evidence-based practices briefs and again there is a website that you can access to follow these. There are also the online modules on evidence-based practices and some of them include the autism program environment rating scale, the goal attainment process, the online courses and the coaching manual that are all part of this.

NIDRR. Okay, NIDRR is the national information and dissemination resource aspect of OSERS and they have a number of different things that they work on in terms of autism. Their mission is to generate new knowledge and to promote its effective use to improve the abilities of individuals with disabilities.

They also want to expand the full opportunities and accommodations for all citizens with disabilities. NIDRR is the research arm that we still have and some of what their activities are that they have funded and they have done: the University of Kansas just doing a study on combining technology to maximize outcomes and it was the focus on telemedicine; another one from the University of Kansas Medical Center, which is located in Kansas City, Kansas rather than in Lawrence -- what they have done is they have done an evaluation of the intervention skills training program using videoconferencing for patients of children with autism, a very interesting study as a matter of fact.

Northeastern University is talking about animations and figuring out whether that facilitates the understanding of symbols. University of Michigan is taking a look at the physical aspect and is specifically taking a look at bicycle training.

One of the biggest populations that is excluded from physical education in the public school system happens to be students with disabilities and that has probably led to the fact that students with disabilities probably are more obese than the general population as a whole, and that is something that both OCR, the Office of Civil Rights, and I are going to be working together to make sure that we can turn that around.

And The Sandbox Learning Company has done the community skills video game for children with developmental disabilities. SEDL which is the southeastern one of the labs did a research study on vocational rehabilitation service models and the Virginia Commonwealth University also did it on vocational rehabilitation for autism. So again we have a number of different and separate studies that are done just addressing this population.

RSA is the third part of OSERS is this is the rehabilitative services and what they have put together and what their mission is, is to provide the leadership and resources to assist states and other agencies in providing the voc. rehab that is needed and ensuring independent living and other services to individuals to maximize their employment independence and integration.

One of the things that you are going to see coming out, hopefully within the next one or two years is a reauthorization of the Workforce Investment Act, and what we think is a major game changer that we want to see in that reauthorization is to have a focus on self-sufficiency, no longer that they just have access to employment, but we want people with disabilities to have gainful employment and to be able to be self-sufficient so that they are not just working or living at the poverty level.

When we think about the data and the placement of individuals with autism, in 2009 a little over 6,400 individuals with autism were served by voc. rehab and this is approximately a little over one percent of all individuals served that year and this is almost double the number that were served in 2006. Well it doesn't seem like a lot. At least we are going up in the right direction.

We also know that the VR program assisted a little over 2,300 individuals to achieve an actual employment outcome and this is 1.28 percent of all individuals who exited the program and this is an increase from the 1,400 that were served in 2006 so again, we are headed in the right direction.

In terms of some of the examples of

what RSA has done, in South Carolina they conduct training with an autism focus related to transition and functional living skills. Ohio has trainings that look at assistive technology and its use. Illinois produced a DVD that was entitled safety and Autism spectrum disorder, empowering children and adults with devices and technology. It's really about devices they can use to keep people with autism safe.

Missouri has done training materials again on assistive technology, a huge area, and Vermont works through the Autism Puzzle Foundation to provide facilitated communication and looks at other augmentative and alternative communication devices and toys. Again I believe this field is just going to explode as we look at technology over the next few years.

When we look at some of the TACE activities that are related to autism, in 2003 there were courses on introduction to autism for the VR counselors. In 2005, it became an entry in the Handbook of Disabilities. While that doesn't seem like much, to actually have it listed in there is critically important.

In 2007, the 32nd institute on rehab issues offered a report specific to autism. In 2007 there was a specific course offered on autism and transition, 2008, autism and job development, in 2009, an autism employment guide was put out. So again you can begin to see how there has been a major focus in terms of working with this population.

These are just some of the ongoing activities that are occurring across the country that are related to autism. There are some new voc. rehab service models that have been put in place across the country. There's a demonstration employment project that has been put in place.

Employment trainings have been provided to voc. rehab counselors and to a number of other people. Voc. rehab is reaching out to the advocacy groups to find out what more they can possibly do.

They are taking a look at the data on clients with autism, much more specific and much more focused. They are developing multimedia lessons and they have prepared scripts and support documents for the VR process, again, across the country.

As we take a look at this, what are our next steps and where do we go from here? Well as I said at the very beginning, we know that we need more money. We know we need that. We have 13 disability categories but what I want you to understand is that the focus of autism needs to become even stronger than what it was.

It's a population about which we still have a lot to learn and we need to do as much as we possibly can, and what I've seen in the gains and what has occurred has been nothing short of remarkable but we can still do more.

When I take a look at this and what is the future? We are very clearly working on the reauthorization of what we refer to as the elementary and secondary education act and when I look at the six different areas of focus that we have on there, the first one is talking about making sure we have college and/or career-ready students, that we make sure we have the best teachers and the best leaders in order to lead the students to these outcomes.

We need to make sure that we meet the needs of every single diverse learner, that we provide them a complete education. We cannot leave out the fine arts. We can no longer just focus in on math and reading and science. We must have a complete education.

And we must have successful, safe and healthy students. Bullying, especially of kids with disabilities, is of great concern to all of us and of course we have to foster innovation and excellence. That's how we get those evidence-based practices.

Why am I concerned about the reauthorization of ESEA? Because I think it's so critical to the population with whom we work. Our ultimate goal for what we want in this country is that every single student will acquire the same, essential knowledge and skills, that all students learning will be carefully monitored and that every child will be given multiple opportunities to show us what they know, and that any student at any point in time will receive the extra time and support they need whenever they experience any difficulty in learning and yes, teachers are going to let kids in on the secret. They are going to let -- teachers will clarify the standards that they use to assess the quality of a student's work.

And the last one is the one that I think that speaks volumes that all students will be the beneficiaries of educators who have promised to work together collaboratively to use the practices that have the positive impact on their achievements.

This is the one that I speak -- that speaks to every single one of us. We don't have a moment to lose with any child with whom we come in contact because their minds are in our hands.

President Barack Obama said it best when he said unless we take action, unless we step up, there are countless children who will never release their full talent and potential. I do not accept that future for them.

The former chief state school officer president, Ken James from Arkansas, also said, he said it's time to think big. Imagine what the future holds and identify the steps that will begin to move our education system aggressively to a place where all students will achieve at high levels, because again, I will come back to this, their minds are in our hands.

The last thought that I want to

leave you with, is you want to go fast, go alone, but if you want to go far, go together, and that's the value of a committee just like this. Thank you very much.

Dr. Insel: Thank you Dr. Posny. Let's take a few minutes for questions and comments if we can from the committee. Before, maybe, if you would just stay up there so we can see whether there are particular questions from the group here. Ari?

Mr. Ne'eman: Well first, Dr. Posny thank you so much for joining us and we appreciate all the very interesting information. I was particularly interested in the stuff you were talking about, about what RSA is doing as autism and employment is a topic that has historically been under-discussed.

I wanted to ask if you could share a little bit about OSERS' thoughts and activities on a topic that I know a lot of the members of the committee are very concerned on: aversives, restraint and seclusion and as you know, there is pending legislation in Congress on this.

So I guess I was hoping you could share both what OSERS' current and future activities on that topic are and also if you think that the legislation that recently passed the House and is now pending in the Senate would represent something that would be positive to include in the Elementary and Secondary Education Act along with a number of the other things that you had cause to mention earlier.

Dr. Posny: Okay, and let me just -- the premise -- I mean the major thing is, no harm should ever be brought to any child. I mean, that's the bottom line and you know, sometimes it amazes me that we have to have regulations and we have to put laws into place to do that.

But let me share with you. My teaching background is -- my very first teaching job was teaching emotionally disturbed middle school kids and then I moved up to high school and taught emotionally disturbed high school kids.

So in terms of having to restrain some of my kids -- now look at the size of me. Most of my kids were bigger than me. But the idea was, sometimes I had to do that so that they would not harm themselves or someone else.

The issue is, and let's go back to that focus on positive behavioral interventions and supports, that's where our time, effort and energy -- we need to be able to teach teachers how to put in these positive behavioral interventions so that they won't ever have to use restraint and/or seclusion.

Now in terms of the legislation that is pending, I know that Senator Dodd if I'm not mistaken -- the issue that is really holding it up right now is the ability to -- whether to put it into the IEP or not and that's the biggest issue.

And let me just share with you why that is a concern and why some of the school systems are concerned that if we can't put that into an IEP, what it may force them to do is to have to call in the police in order to stop a child from harming himself or someone else.

So this is kind of the tension. Do we support having appropriate seclusion -- appropriate, I don't even know what would be appropriate -- it's difficult to define. But every once in a while we have to stop a child and we need to be able to do that in the right way.

Mr. Ne'eman: Just if I could ask a quick follow-up question. Thank you for giving that information. You know, I have been familiar with the IEP issue, actually, that's an issue that is of great concern for many of the people here because of the fear that if restraint and seclusion is planned for, it won't be used in truly emergency situations where I think we all agree it should only be utilized.

I was curious, does the department have a position on the IEP provision of the Senate legislation or what are your thoughts on that?

Dr. Posny: No, we do not have a position. What we do is we just -- we understand the issue on both sides. We absolutely do, because I know once it's put into the IEP, then it looks like we have given carte blanche approval to have that done and then on the other side, if you don't have it in the IEP, and if they have to use it under some emergency circumstances, have we set up a lawsuit?

I think if they could figure out how to deal with that issue, then I don't think there would be really basically any disagreement.

Mr. Ne'eman: Thank you.

Dr. Posny: You are welcome.

Dr. Insel: Other comments or questions. Ellen?

Ms. Blackwell: Yes, I just had a quick comment. Dr. Posny and I talked about this when she came in. I just wanted to highlight that the Medicaid program and education programs are actually linked at the hip in a critical way thanks to the confluence of a 1985 law and the EPSDT program, which was put in place as part of the Medicaid program in 1965.

So in fact Medicaid and education are important partners in this effort to educate children who have IEPs and IFSPs who are Medicaid-eligible.

Dr. Insel: Lee?

Mr. Grossman: Thank you for that great talk. I truly appreciate it. This is a question I usually ask many of the presenters that come here, and since the Department of Education is the primary service agency --

Dr. Posny: That's correct.

Mr. Grossman: -- of people with autism from the time they are essentially born until they are 21, it seems as though there just hasn't been enough emphasis from this committee on this important aspect of service delivery for our population.

So I guess what I'm asking of you and what I have asked of other presenters, what would you like to see this committee do to support your endeavors? Where are we missing in terms of the collective thinking that we have here, in terms of being able to expand and develop further the service aspects that you are delivering to our kids?

Dr. Posny: Well, I mean, there are several things that come to my mind in terms of what you can do as a committee: one, just by having the committee in and of itself puts the focus on this particular population, because it's a population that has different needs from the other 12 disability categories.

So we need to keep that front -- we need to keep that out front.

The other one is -- remember I kept talking about evidence-based practices -- we need more and more information about those things that really and truly work, because when we talk about a spectrum disorder, we are talking about a whole range of needs and supports and interventions that are out there.

There is so much more research that could and should be done and this is why we want to work so closely with IES in terms of -- it's always we need to be five, 10 years from now, we already need to know what we should be doing five or 10 years from now so they can do the research that backs it up and tells us what to do.

As much as you can tell us or give us information about that, you know, you are from across the country. What are some other effective practices that we may not be aware of or what are some other things that are coming to the forefront that we should be promoting?

And again, just in terms of the TA, the technical assistance that we provide, are there other areas of emphasis that we should be providing? Is there an audience? And I know this is one thing that you guys have worked on and I know that you have been after it: we need to identify these cases as early as we possibly can, and I know we are now able to do that even as early as 18 months, but boy, it sure would be nice to catch them even sooner. I mean, you know because the benefits from being in the infant/toddler program and being in the 3- to 5-year-old program -- I mean, we have seen kids who didn't necessarily need services once they entered school because they were provided what they needed.

So it's all of these kinds of things where we can work hand-in-hand and work together to promote and enhance the kids. And I always refer to them as kids, but they do become adults at some point in time.

Dr. Insel: Can I follow up on this question, because I think it -- I know we are running out of time but I would love to hear more from you about how we do this going forward. We are essentially convened to help HHS and yet, as Lee says, you have this enormously important role in autism, and Gail has served in a wonderful way on this committee, but she is one of 23 committee members at this point, I think, and one might ask why the federal government hasn't created something that is much more balanced in terms of having a lot more interaction.

You have mentioned so many activities that seem to be running in parallel to things that we do and that we are so interested in. Is there some other way, is there, for instance, a committee within the Department of Education specifically around autism that we could interact with, or is there some other bridge that we could build in the short term, that might help to educate us and we could help, as you were just saying, to give you some of the ideas that we are working on?

Dr. Posny: Is there a committee that currently exists? The answer is no, and one of the major emphases of this administration under President Obama and so forth is really to encourage -- not only encourage but really and truly work collaboratively across all the agencies.

I would have no problem working together with a small group that represents HHS -- I am even thinking of DOJ and DOL, Department of Justice, Department of Labor, anyone else who has that with a specific focus on autism.

Part of the issue is -- or I shouldn't say an issue. Part of the idea is it's how many people do I have in OSERS that are dedicated to autism? Well, you are looking at her. Now it doesn't mean that we have others that don't have an interest. It's just in terms of staffing. But it doesn't mean that it's not important.

When I'm thinking about the Workforce Investment Act, for instance, we are drafting legislation and very specifically we are doing that in conjunction with Department of Labor and HHS as part of it.

So we all sat at the table together. I think the same thing is true. Now we will be -- and I'm hoping -- that we will be reauthorizing IDEA right on the heels of the reauthorization of ESEA. To me that would be the perfect opportunity in terms of, is there something that we need within the law that we could be working towards?

Is there something that we need to put in there in terms of the research focus? I think there are some areas where if we had members from across the different agencies come together to work this out.

Also, I would love to see some joint

ventures. You know when I think about pulling all of this together, why shouldn't we be co-funding some of these things because it benefits all of us? I often think about Head Start and think about the early learning community.

When you look at at-risk programs, Head Start programs, our infant toddler as well as our 3- to 5-year-old program, these programs should be working together, because we can only be better when we do it.

And what gets in the way are the funding streams and the --

Dr. Insel: Well, that's -- our job is to overcome those obstacles. I think you have provided us with some really interesting opportunities that we need to think a lot more about. I should mention that all these slides will be available so -- because we didn't get them ahead of time, but you will have a chance as committee members to go back over some of the data.

Because of the time, I think we are going to have to stop at this point but I want to just --

Dr. Huang: Could I make a comment?

Dr. Insel: Is this Larke?

Dr. Huang: Yes, this is Larke from SAMHSA.

Dr. Insel: Yes, briefly Larke.

Dr. Huang: I will be very brief. Thank you very much for that comprehensive presentation, Dr. Posny. I just wanted to pick up on ways of collaboration and also the first topic brought up by Ari around seclusion and restraint and also your concept of using evidence-based interventions and at SAMHSA we have developed alternatives to seclusion and restraint with evidence-supported interventions because we also find that in schools, in treatment facilities, that it is oftentimes children with emotional behavioral disorders or children with autism that are the most frequently restrained or secluded and also more frequently injured.

And so we would love to work with you in some ways in terms of the strategies that we have been able to utilize to reduce the use, and sometimes eliminate it, in certain treatment, therapeutic schools as well as in treatment facilities.

And we do build some on the PBIS work, so I just wanted to point that out as a particular topic where we would love to do collaboration with you around that.

Dr. Posny: Thank you and I am well aware of the fact that you put together a document that was -- that had the suggestions on what people should or should not do. So I think that would be a great idea. I have no problem at all.

Dr. Insel: Well, Dr. Posny, thank you so much for joining us. I know you are really busy today but it has been great to have you here.

We are going to need to move on to

the second item on the agenda, which is a presentation by Wendy Fournier and Lori McIlwain on Wandering and Autism. This grew out of a discussion that we had at a previous IACC meeting from public comment that made all of us much more aware of the issues around safety that Dr. Posny just mentioned, and so we will have a chance to hear much more about that in depth.

Ms. McIlwain: Thank you to the committee for allowing us to present on this very important topic that we feel should be a priority. We have an important opportunity to save lives, we feel there are very reasonable measures that we could put in place to save lives.

My name is Lori McIlwain. I serve as Board Chair for the National Autism Association. I am also the mother of a 10-year-old child, Connor, who is a wanderer and we will be talking about his case in just a second.

But we have a lot to cover so I am just going to dive right in. Our April 30th statement before the committee outlined some of the more recent cases at that time and these were the fatalities that we covered.

Since that time, here are some more recent incidents, wandering incidents alone, too many to list them all, but I also included the fatalities in here, mostly attributed to drowning. Mason, he was five, his mother will be speaking a little later.

These are two cases that have stuck with us, mainly because of the circumstances, how long the children were alone, of course very frightened. Both winter cases and this is a concern during the colder months especially. These children are at risk for hypothermia, dehydration, these two particular children, James and Logan, died as a result of prolonged exposure.

And it is interesting to look at, in Nova Scotia, where James died, Project

Lifesaver was put in place in that area and just recently saved a little boy within nine minutes. James was gone for two days.

And I should note that James was found, he did have a pulse, but he ended up passing away in the hospital.

These are summer cases. These deal more with close proximity, so a different kind of wandering altogether as far as prevention. Ashley, aged six, Nathan, aged seven. Ashley's was close -- she went to a neighbor's pool, accidental drowning, Nathan, school -- a school pool.

Both incidents happened around sort of commotion. Ashley's happened during a family gathering outdoors. Nathan's happened during transition, during school, so two summer cases involving close proximity.

These are cases where children were struck by a vehicle. And I thought it was interesting, I pulled this quote, where police said Jack was wearing a medical bracelet that indicated his condition and there were no signs of neglect.

Now you will see under, to the right there, a blogger posted, "I'm very sorry to hear about this but parents need to be more attentive." It just goes to show that sort of the misconception out there is that this is all about neglect.

When it's looked at as a medical condition, it is looked at a little differently. These cases again are different because these children flee. They may run because of some sort of escalation trigger. They may run for unknown reasons. It's a different category altogether because of how you can prevent these types of deaths from happening.

Case studies. This is my child. This is Connor, aged 10. In 2007 he was picked up by a man. He wandered from a school playground, went through some woods, ended up on a side street. The man passed him, thought that he might be old enough to walk by himself. Luckily he turned around, questioned my son, did not receive any kind of functional language back so he put him in his car, drove around, could not find where my child belonged, ended up calling in the local authorities and then the police started driving around trying to figure out where he belonged.

Finally, they stumbled upon some teachers who appeared to be looking for something, so the police officer asked, "Looking for something?" And they did not call the police.

This was a goal-directed incident and my child is very attracted and fascinated by highway signs so he was on his way to the interstate. He obsesses over these and tries to get to them whenever he gets the opportunity.

So that is his goal. He is also attracted to water but it's the highway signs that make him want to actually leave and go seek those things out.

This is Connor again, because he falls under two different types of wandering. He also flees. Here he looks very happy. Here he is saying a word that no one else is allowed to say and I captured this because he is happy. He is trying to get over his fear of this particular word that we use in everyday language, but if he were here in this room right now and one of you were to say this word, and I don't like to say it publicly, he would run. He would run.

So very abnormal fight or flight response, a word can send him into traffic, so misplaced sense of danger there, how he can feel very scared, enough to run into the real danger and not be able to differentiate the two.

He has had eight incidents from three different schools so we know that the pattern, the supervision pattern there is the same. So we know that this is not -- we can't attribute this to just supervision alone. It doesn't really work to tell me to go find a teacher that is going to watch him better. That hasn't worked.

Two identical incidents since 2008. One actually happened three weeks ago. He was unescorted from speech therapy back to the classroom. He was told to go back to the classroom on his own. The classroom was empty. Identical incident in 2008.

So this is a therapist saying that he is encouraging his independence. She left him unattended. I am having to go and get doctors' notes to outline once again that this is a medical condition and he should never be left unattended.

But this is a real problem I feel is happening in our schools and we don't know if these children are being escorted back. Also, I wouldn't have been told about this incident had my child not repeated I was lost, I was lost.

Because of his functional language, they had to tell me about it, but they do not admit to any wrongdoing and I am told that I cannot decide to take him out of that particular therapist's care. So, more fighting with the schools.

Benjy Heil. In 2007, when my son went missing, it was around the same time when Benjy Heil went missing and I remember sitting on this case and reports came in that an AMBER Alert could not be issued because Benjy was not abducted and that was very surprising to me and most people don't realize there is very strict criteria there for an AMBER Alert to be issued.

A neighbor did see him walking. No one could say if an AMBER Alert would have helped, if the neighbor would have saw, but he was found dead in a nearby pond.

This is AMBER Alerts criteria, and they have to follow all of these criteria, mainly state guidelines adhered to all of these. But the reasoning behind it is because it gives that additional descriptive information of the car. It's difficult for police to just get the description alone of just what the child is wearing. They will get many calls.

But when they have the additional element such as the car, it's easier to track them down. That's sort of the objectives I have been hearing, or objections from law enforcement as to why this can't be more broad and include children with brain injuries.

But I feel like we are reaching a point where we need to do something where emergency alert systems are in place, for those with cognitive impairments, especially minors.

In our survey, in 2007, we found that 92 percent of parents reported that their child or children with ASD had wandered from a safe environment one or multiple times. We do realize that parents who affected by this issue are more likely to respond so that explains the higher percentage.

More indirect data, this is the California study from 2001 that we mentioned in our previous statement to the committee, and they found that elevated death rates were observed for several causes including seizures and accidents such as suffocation and drowning. Accidents could also be traffic. That's unknown, how many of those are accounted for there. Also, prolonged exposure, I don't know if that was looked at either.

Danish study from 2008. They found that the mortality risk among those in our community was nearly twice as high as the general population.

Here's what we know in terms of Alzheimer's. More than 60 percent of those with dementia will wander. If a person is not found within 24 hours, up to half of those individuals who wander will suffer serious injury or death and through the DOJ, Alzheimer's receives $5 million each year. I think that's up for a reauthorization for first responder training and grants for tracking technology.

Wandering-related dementia carries a medical diagnostic code and they also have the silver alert, so interestingly this is called the AMBER Alert for seniors and a lot of lawmakers will say well, our seniors deserve to have the AMBER Alert for them. They don't realize that it only applies to minors who have been abducted.

So in many states that have the silver alert, it's only for 18-plus. For those that have the AMBER Alert, it's only for minors but the criteria doesn't allow our kids in so our kids are completely left out of the equation here.

We have no formal estimates available for autism-specific wandering, no data to show how many wander, how often they may wander, from where they might wander under whose care, when, both time of day, time of year, how many die each year, the degree of diagnosis, what increases the risk of death, what safety precautions have or have not been taken, any kind of authority involvement or assistance. There's no study identifying ASD wandering categories.

I think this is important because this is really going to narrow in on patterns, putting identifiers on those patterns, being able to put prevention measures in place based on those categories, I think that these children do fall under different categories and sometimes they can fall under multiple categories but we do need to identify these types of wandering.

Is it goal-directed? Is it random? Is it fleeing? Because that is going to get us a different set of preventative measures and response, speaking honestly, so there's no data reflecting what types of wandering may be happening more frequently and why.

No federal grant dollars to combat these deaths. No federal first responder training specific for ASD wandering, no federal aid for tracking technology or oversight. I run the Found Program through NAA, we provide law enforcement agencies with funding for tracking technology. It's a drop in the bucket.

So obviously we would have wider capacity through federal programs and too, there's no medical sub-classification coding or general medical coding for ASD wandering. I feel this is very, very important for many reasons that Wendy is going to talk about a little later.

But in my son's case, that medical coding could really help in his IEP process to provide very sound reasoning as to why he should never be left alone. If I'm facing that problem, I know so many are facing that problem and I think that code would be extremely helpful just for that alone.

No mandates requiring parental notification. We don't know -- I know that he has wandered because he has told me and he has a photographic memory of dates. He could tell me every date he has ever gone missing.

But how many other children, especially the non-verbal ones, who are wandering within or outside of school premises or any other facility that in the significant incidents likely will happen if the smaller ones aren't addressed and we can't address those unless the parents know about it.

So no mandates requiring that. That, I think, is something that we could easily try to change or if nothing else, encourage. There's no emergency broadcast alert systems reminders. Just covered that. No programs dedicated to swimming lessons. That's another important thing, especially for the close proximity deaths.

Families living under a great deal

of stress, unable to leave their home, low quality of life, that word that my child is afraid of is on every kids' show imaginable. We can't go anywhere where there is a television set on.

Some parents hesitate calling 911. I have heard this from parents. They are scared they are going to get arrested. I have had parents talk about calling 911 and the dispatcher not being very friendly, blaming the parents.

Parents don't understand tracking technology. There's different kinds. It's confusing. It can be expensive. It can be inaccessible. Parents report pressure to allow the child more independence. I fall in this category too, but I hear this a lot from parents, you know, stop being so overprotective, stop being so overbearing. Let your child have some independence.

On the flip side of that, if their child goes missing, guess whose fault it is?

It's the parents. So there is a real no-win going on here and I think it's just kind of compounding the greater issue.

Children show no physical abnormalities, such as the man who passed my child, maybe he could have --- he would have kept going. I can't imagine what would have happened had that man not stopped and without the physical abnormalities there, people think old enough to walk alone, nothing wrong.

They also think, hey, this is neglect, this is choice wandering. This is the parents' fault. So they automatically put it in that category, that it's not medical and that just creates a way of thinking that does not help the situation at all and could possibly increase the risk.

Parents report little physician involvement, guidance and advice.

So Wendy is going to come and talk about what we need and how we can address these things.

Ms. Fournier: Good morning. I am Wendy Fournier. I am President of the National Autism Association and mom to my youngest daughter, Ali, she is now 10 years old and also a runner.

So as we were -- we have been surrounded by this problem for many years, Lori and I especially and our whole organization, actually, have really been the first ones to put some focus on the wandering issue. We are trying to develop a program that we are calling Found to try to address it, but our resources are minimal.

But because we have spent so much time on this, we are able to show you what the problem is and we have also put a lot of thought into what we need to do to address it so this part of our presentation will cover that.

There is no data collection and we have had some conversations with Cathy Rice, thank you very much, from CDC, to talk about the questions that we need to ask so that we can address this and hopefully lead to prevention and keeping our kids safer.

So the questions we need to ask are how many individuals are at risk, what settings are they wandering from, home school, residential facilities, outings, what are the circumstances that surround the wandering?

Is it an unlocked door or window, an unfenced play area, school incidents, family gatherings, we have lost so many kids, you know, personal friends to us, whose children have died during a family outing.

And parents who are listening on the web, there are a lot of things that you can do to protect your child, things that you can put into place but you know, one quick one I am just going to throw at you right now is a tag team system and if you are at a family outing and there are a bunch of people around, don't assume that somebody is watching the child.

Make eye contact with another adult

and say tag, you are it, it will help you to keep track. We do that at school and at home for my daughter.

So we also need to know what is prompting the incidents. Is it a goal-directed thing as Lori was discussing, is it fleeing, is it fear? How often are these incidents reported to the authorities?

Also, cost analysis, I think, is a really important question to ask because when it comes to the funding that we need for the technology to protect our children, it really is a no-brainer for the kids that are at risk.

We had an incident in the town that I live in, Portsmouth, Rhode Island, with a gentleman with Alzheimer's. He wandered away from home. There was a search that lasted just under 24 hours for this gentleman. He was found -- he was alive when he was found but had been exposed to the elements for too long and, sadly, ended up passing away.

This man, had he been protected with

a proper tracking device, which he would have been a perfect candidate for, would have been found, probably in less than 30 minutes, he would have survived at very minimal cost for the tracking technology and that particular search cost our community right around $50,000 to conduct and we lost him, so it was very sad.

We need to create awareness, resources and policies. We believe that toolkits are needed for parents to implement prevention strategies. We need to disseminate the information to caregivers through groups like the American Academy of Pediatrics. They currently do have an autism toolkit with family handouts.

CDC's Learn the Signs, we believe, could include some information about wandering, how it is prevalent in the autism community and what can be done to protect your child.

Creating wandering awareness

materials, we feel is needed for school personnel, who, the administrators are not aware that this is a very serious and life-threatening problem and they need to be prepared for incidents when they arise and they also need to protect these children.

First responders, there are specific challenges that are presented to first responders when searching for someone with autism, especially if they are non-verbal.

Physicians also, you know, we have asked parents in informal polls, did your doctor discuss with you wandering or elopement issues when you were in the office with your child? And not one person said that their doctor had mentioned that.

We need to develop training for first responders on those challenges of searching for someone with autism. If you have an individual who is non-verbal, cannot respond to their name when they are being called, you could literally do a physical search for them, be within two feet of that person, calling their name, and they are just going to sit there.

So that's where the tracking technology is really needed. Some people don't like the Big Brother aspect of tracking technology but if my child is lost in the woods and she can't answer when you are calling her name, I'll take the Big Brother, thank you very much.

We need to establish, we believe, a central source that is dedicated to focusing on just autism-related wandering that could serve as both a distribution center for information to, not only families, caregivers but first responders, school administrators, others that are dealing with our loved ones that are affected.

Quick access to information would be really nice for first responders to have, so the possibility of maybe developing a national registry in conjunction with this distribution center of information where families could go and enter information into this national database, making it available to first responders, so that if their loved one does go missing, they call 911 and immediately first responders are able to bring up this information: photo of the individual, what their likes or dislikes are, what their communication abilities are.

We could even get real personal to things like, my daughter is attracted to the theme from Barney, so play that while you are walking and looking for her. It would be nice to have that information readily available.

We also need to promote federal legislation that would mandate parental notification of wandering incidents, as Lori was saying. Parents have a right to know if their child is put in a dangerous situation. This should be a no-brainer. We should have immediate notification and protocols need to be put in place to prevent it from happening again.

Recently Lori and I have worked on a project called the AWAARE Collaboration. We reached out to other national organizations in the community, asked them if they would come on board to help us to develop materials and to help disseminate this information because there was nothing out there available to parents, no resources.

So what we have done is: we have created some promotional materials, a website, brochures that we have had printed and can send out on request or that are made available on our website for download.

Resources for caregivers are included, school administrators, law enforcement personnel, physicians and therapists can all find information at this website.

What we did with this is we made it a non-branded site, so this is not a National Autism Association site, it's not an Autism

Speaks site. This is the AWAARE Collaboration, the materials are not branded, which means that any organization across the country, any school, any non-profit is welcome to go and use this and distribute the information.

This is a screenshot of the homepage of the AWAARE website that we put together. We highlighted the things that we feel are most important for parents. There's a family wandering emergency plan that is up there that can be downloaded and filled out by families.

We feel like everybody needs to do this right now. Go get it off the website, print it out, fill it out so that you have a plan. When your child goes missing, you have people assigned to look in certain places, people assigned to make certain phone calls.

Share this with your neighbors, your family, any caregivers that are involved with your family. We also have a form there for first responders that can be delivered to your local police department so that they have information specific to your child online.

We would love to see something like this AWAARE site -- this is something that we put together ourselves, but we feel that we really need this to be done on a federal level. We need the credibility that comes along with that, we need the stamp of approval of the government that places this into the hands of the families and I hope that that will happen and that resources like this, and better than this, will be made available.

The emergency broadcast alert system that Lori was discussing, we really need to do something about this and I think that Mason's mom, who is going to be speaking this afternoon, is going to address some ideas that she has about that.

We either need a new alert system for individuals that are under the age of 18 that have a cognitive impairment, or we need to add provisions to the existing AMBER Alert criteria that would allow us to utilize the system.

This could save our kids' lives. If an AMBER Alert is issued if you have a child like Connor who is on his way to the interstate because he likes that exit 42 sign, there will be people in their cars driving down the road that are going to hear that AMBER Alert. They may be able to save his life.

We have to find a way to make this happen, to provide the protection that our children need and deserve.

The medical diagnosis code -- we found, actually, it was an ICD-9 code that we had found and it's already been established for adults, it's dementia with wandering so there is a medical code for that.

We would really love to see this happen for individuals for autism. We believe that if that happens we can start to classify the tracking technology as medically necessary devices that will be covered by health insurance, reimbursable by Medicaid perhaps.

It will also help us as parents and caregivers to combat that misconception that it's neglect or that this is simply bad behavior and our children are misbehaving.

The fact of the matter is they can't help it. My daughter is one of those children and it's not by choice. No children run off and run into the middle of traffic by choice. So we need to give credibility to that. We need to show that this is an important medical issue.

We have to increase the awareness of our physicians and clinicians and create some open dialogue there, strengthen the role of caregivers when dealing with schools. If we have this medical diagnosis code, we do have a much stronger position when we are dealing with the schools and we are asking them to put safety protocols into place for our kids.

Tracking technology is becoming a huge moneymaking commodity in this community and I am seeing more and more of this coming out, which is wonderful because I would love to see as many options as possible.

I would also like to see development of devices that are affordable to families, hopefully reimbursable by medical insurance, and I would also like to see some oversight on these companies that are now coming in and trying to take part in this industry. It's very important that oversight on reliability of these types of products and minimal requirements, I think, is going to be necessary.

Caregivers need to know that there are different types of technology that are available and they need to be educated on the differences between those, because there are benefits and there are some things that are lacking to each one.

Project Lifesaver is a program that has been around for a long time. Project Lifesaver is a nonprofit organization and they started out working primarily in the Alzheimer's community and now are doing quite a bit in autism.

They receive quite a bit of funding from the Department of Justice to serve the Alzheimer's community, but that funding is not available to their clients that they are serving that have autism, so we need to change that.

Let me back up just one second because I want to take a moment to explain to you the different technologies.

Project Lifesaver is a radio frequency technology. It is a wristband tracking device. The picture is here. This is the one that my daughter wears. It emits a unique radio signal once per second and the first responders in whatever your local area have to have receiving equipment, so we have a transponder on the child and my fire department has receiving equipment.

If she goes missing, I have to call

the fire department, they come and they start looking for her with this equipment based on her radio signal.

The drawback to this particular technology is that there is no way for it to notify me if she were to get out of the house without my knowledge, and this has happened before.

And so this is an issue if a child goes out in the middle of the night and everybody is sound asleep, and you are not going to know about it.

So what we would want, an ultimate device like this, because this radio frequency device can literally pinpoint somebody to inside a closet. It works that well.

But we want a notification system. That would be the ultimate thing. So my daughter escaped out of the house, everything was locked up, Fort Knox at my house all the time, you can't get in -- or, you can't get out. Anybody can come in any time but you just can't get out of the house.

So I was sitting having coffee on my couch and thinking everything is great because I had all the locks on the doors and it's all cool and I'm drinking my coffee and all of a sudden my doorbell rings and my neighbor is walking in the door with my daughter and said she was trying to get into my swimming pool.

My daughter was probably literally 30 seconds away from dying and I didn't even know that she was out of the house. So what she had done was pulled a screen aside in our sunroom. It had a little, tiny opening. She pulled it apart. She jumped seven feet down and she went for the pool.

So these are the types of things that you think you have as much control as you can possibly have but stuff happens. So if this particular device went beep, beep, beep or sent me a text message or an email, I would have known immediately that she was out of the house.

So while I love this program, that's what's missing there.

Also, sorry, let me back up one sec, the GPS systems that are available now also on wristbands, these are working on the satellite systems, these do have the ability to set a perimeter around your certain area so you can set a geofence around your home or your school, and as soon as your child or adult moves outside of that area that you have set for them, you will be immediately notified by a cell phone call, a text message, email, however you prefer to be notified.

Love that, but where that is lacking is you can't pinpoint the exact location of the child as well as you can with the radio frequency technology, and if you are dealing with somebody who is out in the middle of the woods, and doesn't answer when you call their name, that's a drawback.

The last one is cell technology which is also a wristband program, works on cell phone signals, basically triangulates a position within three cell towers. Not quite as effective, but you do need first responder intervention with that. It runs through the 911 system.

And Project Lifesaver is the same. You have got to get your local first responders, either sheriff's departments, fire departments, police departments, have to be willing to run these programs. It costs money and so if you want the cell phone technology, they need to be involved, if you want Project Lifesaver, they need to be involved and trained.

The only one that we can access as parents without any other involvement, if we can't get our police department to do it for whatever reason, is the GPS technology and you have to go search on your own.

So we need federal funding for families who cannot gain access to proven home safety methods, security measures. We are talking about home alarm systems, doors, window alarms, whatever the case may be for their children, fencing, tracking technology.

We need to provide access to special needs swimming instructions for families who cannot afford that, development and distribution of awareness materials, toolkits and training programs. We need that data collection to show the need and get us the big bucks, medical research for the IACC to consider, you know, we know that this is not behavioral. We know that this is not really by choice, so what is causing the wandering issue to happen with our kids?

With some kids it might be OCD. I have to go see that exit sign or I have to go and see my neighbor's pool or whatever it is. It may be the fight or flight mechanism. There may be biomedical types of research that we can do to look at OCD behaviors or fight or flight. There's research that relates to dopamine levels that might lead us there. But

I think we need to be looking at that as a medical issue.

So our recommendations to the committee that we hope you will consider today is to add a new objective to the strategic plan that is focused on ensuring the safety of individuals with ASD.

We would love to see a subcommittee focusing on safety issues that affect the community, with special attention to wandering and elopement. Our loved ones are dying. We need to jump on this but there are also other safety issues that could be addressed by the same type of committee including the restraint and seclusion issue, anti-bullying education programs, support for families at the breaking point.

We are hearing more and more stories about parents who are killing themselves, parents who are killing their children. What can we do to prevent these external causes of death from happening in our community? So we would love to see you address the safety issue and thank you so much for letting us talk to you about elopement today. We feel it's very important. Thanks.

Dr. Insel: Thank you. Wendy, can you go back one slide for -- I know that we are way over time but I do want to take three minutes for comments and discussion from the committee because you have given us a lot to think about.

Comments? Geri?

Dr. Dawson: Well, Wendy, I just want to thank you for coming and sharing this with us and I absolutely agree that this is an area I guess you would say of low-hanging fruit, where we can do things that are relatively straightforward and have just a huge impact and whether these are legal or technological or other kinds of support, it seems like that this is an area that we clearly need to focus on.

I did want to point out that Autism

Speaks has a toolkit on safety that people can access on our website and it has training for first responders and it's a drop in the bucket in terms of what needs to be done, but it's a step in the right direction. But thank you so much for this presentation. Very important.

Ms. Fournier: Thank you for that, Geri, and that is a wonderful toolkit. We like -- I think the distribution is the issue here because I think we need it to go out through the pediatricians and the diagnosticians and get it to everybody.

Dr. Insel: Ellen.

Ms. Blackwell: Hi. Thanks for your presentation. I just wanted to follow up on your comment about Medicaid. Under some circumstances, in home- and community-based waiver programs, which are optional, Medicaid can and does pay for things like parent, caregiver training, assistive technology, personal care and also environmental modifications, and our program has very strict requirements for health and safety for these optional home- and community-based waiver programs and also states, because Medicaid is a state-driven program, states determine medical necessity in Medicaid, not the federal government.

So we do fully support, of course for all our waiver participants, including children, that they are safe and healthy in our programs.

Dr. Insel: Coleen.

Dr. Boyle: Well, thank you very much for sharing your stories with us and I know we have had conversations about the issues around data and I have taken a look at the national surveys to see if they could provide us more information in that regard, and there is not information around this issue in any of the national surveys that are being conducted.

But there is an opportunity within the context of the follow-back survey that is being done with the National Survey of

Children with Special Healthcare Needs, supported by HRSA as well as the National Institute of Mental Health to add a couple of questions in regard to wandering.

So, at least we will be able to have a start to try to characterize this in a national survey, and actually that survey is scheduled to go into the field in early 2011.

Dr. Insel: Well, you know, I think you have given us a lot to work with and we don't have time to respond as fully as we should right now but I hope there will be time later in the day and if not later today we will make sure there's time at a subsequent meeting.

One of the things, beyond what you put on the list here, is since we are essentially an advisory committee to the Secretary, there is an opportunity to take a lot of what you have given us and to package it in a way that could be conveyed even prior to any of the other things that you have mentioned.

It feels like what you are telling us is that this is an urgent and a growing problem so at the very least, I think one thing that this committee can do after this presentation is to think about whether there is something we can do in the short term.

As you said, there is some value in having a federal statement or a federal process in place. And I think you have given us some great points to follow, so I want to thank you as well, from the entire committee. I think this is an item that has arisen really from you.

We heard this at a previous IACC meeting and you brought it to our attention, but the extent to which you have developed it and created a sort of road map for following this, and making sure that there are real solutions, is just so admirable. It's really terrific to see.

So we will get back to this, if not

today, soon. Hopefully, we will have some time this afternoon to circle back and I know we will hear more about this in public comment as well, as you mentioned, later today.

So we do have to move on, I'm sorry we can't take more time now. But again thanks to both of you for such an outstanding presentation.

This is really an information-packed morning and we wanted you -- we are not going to have time for a break. We started late, so we are just going to plow through here, because I wanted you to get as much as you can about some of the new opportunities and some of the new challenges like you have just been hearing about.

On the opportunities side, we have asked Dr. Richard Frank to join us, who I currently serving as the Deputy Assistant Secretary for Policy and Evaluation in HHS and Richard has been given a very full plate of responsibilities, some of which have to do with mental health parity, some have to do with the new healthcare reform law.

The piece of this that we thought would be helpful for you to hear about would be specifically around The Class Act, which is something that he is spending an awful lot of time on these days and is highly relevant to the needs of families with autism. So Richard, I will not take any more of your time. Thanks for being here.

Dr. Frank: Thank you. Do you mind if I do it from here? I am on PowerPoint cold turkey today, if that's okay. Are you okay with that? Okay, good.

What I hope to do is to provide you with a basic overview of The Class Act sort of Class Act 101, and I hope to do it really quickly, so that we have a lot of time for you to ask your specific questions because I am going to give you a broad overview and you can see that The Class Act is relevant to a lot of different populations. I want to make sure that I get your specific questions down.

The Affordable Care Act, which is otherwise known as health reform, establishes a national voluntary insurance program for purchasing community living or institutional services and supports known as the community living assistance services and supports program, or the CLASS program.

It is designed around options for people who become functionally disabled and require long-term services and supports, and it's Title -- no it's Title VIII of the Affordable Care Act and it was a passion of Senator Kennedy's.

He first introduced a Class Act in 2005 and he had hearings on it in 2007. Among other things a Class Act was estimated to contribute $72 billion to deficit reduction over the first 10 years of the Accountable Care Act so you can see why it received a lot of attention.

On the other hand, most of you

probably haven't really heard much about The Class Act and as one of my colleagues said to me, in any other universe, a program that set up a long-term services and support insurance policy that would account for $100 billion over 10 years would have attracted some public attention.

However we don't live in that universe. We live in a different universe.

So let me quickly get you the basics. Let me start with enrollment. Enrollment is strictly voluntary. It is focused on adults who are working, so age 18 and above, and people must be actively employed and have earnings in order to qualify for enrolment in The Class Act.

Employers can choose to enroll workers, deduct premiums automatically and enroll people through an employee opt-out. So rather than asking people to actively sign up, employers who participate in the Class program would automatically sign their employees up and they would have to opt out in order to not be in the program.

There is also an alternative process for people whose employees either do not participate or who are self-employed or work for small businesses or something.

The benefits are really designed to support independence and flexibility. So it's a cash benefit. The Secretary of HHS has to develop the benefit program. It's scaled to the level of functional impairment an individual displays and there can be anywhere from two to six tiers of benefits that will be determined by the Secretary based on the distribution of people with impairments.

The average benefit in the statute cannot fall below $50 per day and there is no upper limit. So you might expect, for example, people with relatively minor impairments might get $30 or $40 a day and people with fairly serious impairments to get upwards $100, $150 a day.

The aim is to help beneficiaries continue living in the community but money can be used to pay either for residential or institutional care, and it's anticipated that this would be done through an electronic management and cash benefit process, so essentially an ATM swipe card would allow people to either purchase services directly much as a debit card does, or actually to go to cash machines and withdraw cash.

Along with the basic cash benefit comes advocacy services, advice and counseling services, and essentially The Class Act contemplates that cash funds would be used to offset Medicaid long-term care spending for Medicaid beneficiaries.

If you are in an institution, 95 percent of the daily Class benefit is the first payment to that institution in lieu of Medicaid and for people in community-based settings, home- and community-based services for example, 50 percent of the daily cash benefit would go to community-based services as the first payer and then the rest gets paid by Medicaid.

So it's anticipated there would be some offsets. There are complexities on that side of the bill that we are working on in the regulation.

Let me talk about eligibility. Premiums have to be paid for at least five years and the person who pays the premium has to have earned one-quarter's worth of social security earnings for three out of those five years and just for those who don't remember what one quarter of social security earnings is, it's $1,120, so it's a fairly low bar to get over.

The functioning requirements to qualify for benefits are that somebody must be unable to perform two or three activities of daily living and that needs to be determined by the Secretary, or have equivalent cognitive disabilities that require supervision or hands-on assistance to perform basic activities.

And so there are any number of conditions that would qualify under that. In the determination process, eligibility will be determined by a uniform national system, where individual assessments, have to be made by a health professional.

The program is designed to be self-supporting, self-financing and it's required to be solvent over a 75-year period, much the way social security solvency is determined.

Premiums will depend on age at enrollment and the year that you sign up, but cannot be linked to the other types of factors that long-term care insurance typically uses to underwrite people.

So for example prior medical conditions are not a permissible reason for excluding people from these policies.

Premiums continue after enrollment and there are special provisions for people who fall under the poverty line, where they are only required to pay $5 a month premium. Those premiums are indexed to inflation and then the administrative costs of the program are capped at three percent.

For those of you who are financial in your orientation or economists, you probably have recognized that there are some challenges inherent in this. Voluntary programs with little underwriting sort of create some opportunities for risk selection and potential actuarial problems.

However the act calls for a balancing on the part of the Secretary between her duty to maintain actuarial solvency and to promote the self-financing of the program while also making sure that the flexibility and the priority populations that are implied by this program have their due and so there's this balancing in the act that the Secretary has to perform, and she is given quite a bit of authority to do that balancing.

There are a variety of important challenges, including the one around actuarial or balance selection. There are also things around the employer for example. Employers typically do not collect the kinds of information that you need in order to come up with a premium here. It's very important for us to try to figure out how to make this easy for employers to participate in, so that it then in turn makes it easy for people to participate in it. We are working very hard on the design of information systems that will link social security, individual demographic records with employers so that we can get them what they need to do in a way that isn't costly and burdensome to them.

The other thing that should be particularly relevant and of interest for this group is how we go about determining eligibility. We have gotten very good in this society at measuring people's ADLs. We are not quite as good at measuring cognitive impairment and what we do know is focused mostly on older adults and things like the Mini Mental State Examination.

When you start to move away from that into the world of intellectual disabilities or severe and persistent mental illnesses, our measures and our ability to assess cognitive impairment for the kinds of requirements that the statute lays out, is far weaker and so we are in the process of commissioning research and understanding what is out there so that we can try to bring the best science to that part of the problem.

The Class Act is grounded in the principles of consumer direction and specifies a cash benefit and that's a very good thing. It accords well with the values of this administration. However it also -- the statute also calls for a great deal of effort being put into program integrity.

And so automatically you have a tension that is created between a cash benefit and program integrity and so that, figuring out how exactly to come up with that balance in a way that is fair and transparent is something we are working on.

And then as I mentioned to you, the language in the bill around the interaction between class and Medicaid is a little bit messy and we are working hard on that with our colleagues over at Medicaid.

In fact it's not -- I would say it's not an exaggeration to say that in one sentence in that area it sort of says go right, go left. And so the good news is that that allows the Secretary and the regulators considerable discretion in choosing whether you go right or you go left.

So I will stop there and take your questions.

Dr. Insel: Great, thanks Richard. Let me just, before we get into questions, let's make sure we understand what we are talking about so if you could just put this into very simple terms.

If I am a parent with a 16-year-old who has got autism, who is severely disabled, what does this mean to me?

Dr. Frank: It turns out that the 16-year-old is not covered by this. It's the parent potentially who is covered. I think the -- I think what you are getting at is for example let's take someone with Autism spectrum disorder who is working in some capacity, maybe part-time.

Remember, the requirement is $1,120. They then would be eligible to enroll in the Class program and would potentially meet the earnings requirement and then they would, at the end of five years, be eligible for essentially a $50 a day, I'll just say $50 a day right now, benefit essentially for life.

Dr. Insel: And so then if the parent were working for the five years when their child becomes 21, it doesn't in any way cover the child's home care?

Dr. Frank: No. The -- unlike the way we typically buy health insurance in this country, which is as a household, what The Class Act does it signs up individuals and the individuals must meet the terms enrollment and eligibility.

Dr. Insel: Alison.

Dr. Frank: I think Ellen has a --

Ms. Blackwell: I'm sorry. Okay, Richard you were headed toward an example perhaps of let's say a 21-year-old who is high-functioning with autism and I was thinking that maybe you could keep --

Dr. Insel: Just one sec. Could we get you to mute if you are listening to us by phone? We are hearing a lot of rustling. Thank you.

Ms. Blackwell: Could you give an example perhaps of some services that might come through The Class Act for that individual who does have a job and earnings, who is enrolled in the program?

Dr. Frank: Yes sure. One of the things that we have learned from the experience with Medicaid is about is about 75 percent of the money that would be in a cash benefit like this would typically be spent on personal attendants and getting help with a variety of different activities, whether it be transportation or in the case of older Americans, bathing, or supervision of various types. Those would be the things.

But there's also flexibility in the act to, for example, make home modifications, to buy assistive technologies. I was just, during the last presentation, thinking about the tracking technologies and things like that, those types of things that will be eligible under The Class Act.

Dr. Insel: Ari?

Mr. Ne'eman: Yes, I'm wondering if you could expand on a point you alluded to briefly earlier, that being the eligibility determinations and also some of the additional benefits that come on top the cash benefits like options counseling and so on.

My question is, what is going to be done to ensure that that is accomplished in both a timely manner and when I think about the long, drawn-out process it takes to apply for SSI or SSDI, we would want to avoid something that would repeat that.

And then in addition to that, in a way that is accessible for people with developmental disabilities, because if it's all being done through say the Ageing and Disability Resource Centers, there's not a lot of necessarily expertise there.

So I wonder if you could talk a little bit around those two points in terms of what is going to happen when this program is stood up and those benefits are coming into play?

Dr. Frank: Let me start with one very important point, which is in fact this is not being done through the Ageing and

Disability Resource Centers. The Class office within HHS will be an independent office most likely and the Secretary will be making some announcements about this as she kind of finalizes her deliberations on this.

The national system of assessment in its construction within the statute cannot be something that is locally and flexibly run. It has to be a uniform system so the processes, the professional preparation and the standards that are used have to be the same in Juno, Alaska as they are in Tucson, Arizona, and so you need a national system, it has to be centrally run, the quality control has to be consistent across the country.

The model is definitely not the social security act assessment process. There is language in the statue about the speed at which the assessments have to be made, and rather the model here is more what you would see in private long-term care insurance where very quickly, for example, a trained nurse would go to somebody's home and conduct an assessment and it would be of cognitive impairment, of activities of daily living and the point that I was making was that we are sort of treading on some new territory as we move into standards for cognitive impairment once we step away from things like the Mini Mental, and that's actually a -- that's the scientific challenge here, but the goal is to have something that can be administered very rapidly in the same way that our current ADL assessments and our cognitive assessments are done for people in long-term care insurance or people in the Medicaid program who are sort of presenting themselves to a home- and community-based waiver program or to a nursing home.

Dr. Insel: Alison.

Ms. Singer: Is there any concern that requiring employers to participate in this program will actually serve as a disincentive for them to hire people with disabilities in the first place?

Dr. Frank: So this is actually very good because all the national misunderstandings are coming out onto the table here. So the first one, number one on our sort of frequently asked questions list is will it be through ADRCs? The answer is no. The question is are we requiring employers to join? No.

The answer is that it's a voluntary program both for the employers and for the individual, so the employer who chooses to participate is signing up to do payroll deduction and the opt-out. But there's nothing in the statute that requires the employer to participate.

In fact the statute says that if the employer chooses not to participate, there has to be an alternative enrollment process for people and in fact what we are working on is a couple of different alternative employment processes, one of which would allow employers to kind of only have half a loaf if that's what they wanted.

They could do the, for example they could potentially do the payroll withholding without the opt-out or something like that, so we are exploring that as one possibility and the other one is a direct consumer household sign-up process.

Dr. Insel: Any other questions or comments? If people here want to know more about this or there are people who are watching via webcast want to know more as this rolls out, what is the best way to find out about it?

Dr. Frank: The best way to find out -- well health reform, the health reform website in HHS has a section so if you typed in disability or cognitive impairment or long-term care, any of those things, you would get put into an area that describes The Class Act and has a bunch of previously asked questions and hopefully the frequently answered as well.

And then people are always free to, and I say this with a little bit of concern, contact me and we will do our best to direct your questions to the right people.

Dr. Insel: Okay, thanks very much for joining us Richard. Work in progress obviously and important.

We are going to move along to hear the final presentation before our lunch break and that we are really fortunate to have from Dr. Kevin Pelphrey, who is the Harris Associate Professor of Child Psychiatry at the Yale Child Study Center and has been doing some work that we thought all of you would benefit from hearing about.

Kevin, thanks so much, I know it was not easy for you to get here so we really appreciate you joining us.

Dr. Pelphrey: Thank you very much. I am delighted to be here today. This is a great honor to address this group, and I should tell you I wear two hats with regards to autism.

One is as a neuroscientist studying autism and the other is as a father -- oh, can't hear me? Okay. How about now? Is the speaker not working? Okay.

Dr. Insel: I'm not sure the mic is on. Let's hold on just a second and make sure we get you miked up so that people can hear who are listening in.

Dr. Pelphrey: Okay, better? Great. So I was saying that I am both a neuroscientist who studies autism and I'm also the father a two-year-old on the spectrum and a seven-year-old on the spectrum and so today I want to talk to you with my neuroscientist hat on.

And so my laboratory, we use neuroimaging tools and tools of cognitive neuroscience and these include imaging genomics, functional magnetic resonance imaging, eye tracking and virtual reality and our goal is to understand the brain basis of autism.

And the hope is that we will provide basic information that would then improve diagnosis and treatment both of autism and of related neurodevelopmental disorders.

And so for a while now, in my laboratory, we have been interested in this process of social perception, both from a basic perspective but also for what it can tell us with regard to autism, where there are quite pronounced deficits in social perception.

And so to give you a definition, I want you to think about the initial stages of processing biological motion and biological motion cues, and these are things like the way a person is walking, the way they are gesticulating with their hands, particularly their eye movements, where they might be pointing to, all examples of biological motion cues.

And biological motion cues are important because they are one of the most basic ways in which we begin to understand other people's psychological dispositions, their motives and their intentions, okay? So not only do you see the surface features of people acting, but you derive from those, during social perception, the underlying psychological dispositions and intentions.

So the work begins with what I think is one of the major advances recently in neuroscience, which is to demonstrate that there are specific brain regions in the brain that respond to different types of socially relevant information.

So for example, this is a model from Leslie Brothers who pointed out the role of the superior temporal sulcus region and sometimes you will hear me say superior temporal sulcus and sometimes the STS and what I am talking about is this region of the temporal lobe that is just above and in front of your ear, it sort of runs back.

And I will talk about that region

quite a bit today because it has shown up to be very important in our studies, but also the amygdala, orbital frontal cortex and a region that we call the fusiform face area.

And so we are interested both in these specific regions because of the ways in which they are specialized for processing social information, but also their interactions, which give rise to higher levels of social cognition and social perception.

So why am I interested in the social brain and social cognition? I am interested in it because I am interested in autism and in particular I am interested in the qualitative impairments in social interaction, so one of the defining features of autism is impairment in eye contact and social reciprocity and of course there are other components of autism, the qualitative deficits in communication, the restricted, the repetitive behaviors.

But I actually see those other characteristics as emergent from the developmental process of a primary insult to the qualitative impairments that give rise to the qualitative impairments in social interaction.

So I like showing this as an example this was my entry into the field of autism research where we demonstrated that individuals with autism failed to look at the eyes of faces, and this is something that everyone could have told you who has met a child with autism, but we wanted to quantify it and give us a quantitative phenotype that we could then use for subsequent research and so here you see, when we present faces to, in this case high-functioning adults with autism, a general lack of paying attention to the core facial features that display social information and rather an idiosyncratic pattern of looking.

So each little red dot connected by a line is a series of fixations to these regions, and this is in contrast to the typically developing pattern, which is to look predominantly at the eyes and every once in a while venture down to the mouth, and spend, though, the vast majority of the time on the eyes, do this triangular scan path, which emerges in typical development -- remember these are adults -- at about seven weeks of age.

So a very nice, quantitative phenotype that can provide us some information about the development of autism and I think serves as a good example of the very basic deficits in social perception that you see even in very high-functioning individuals with autism.

So I want to tell you about three things that I think are exciting going on in the lab right now. One is to tell you about social perception in the human brain and its disruption in autism and then I am going to focus in on studies of adults with autism.

And then, this is a

neurodevelopmental disorder, and we are learning very hard lessons about drawing conclusions from only studying adults, so I am going to tell you about studies of children, very young children using neuroimaging and then finally I want to leave you with some recent directions that I am particularly excited about.

So, as I mentioned before, one of the most basic aspects of understanding other people is to be able to differentiate between what is biological motion and what is non-biological motion, and it turns out that even newborn infants who are typically developing are capable of making this discrimination.

So it's something that we are born with, something that occurs very early in development and helps set up the rest of social development by virtue of being able to make this distinction.

But we wanted to know what are the brain mechanisms for processing biological motion and so this was one of the first imaging studies that we did, and we often use these virtual reality character animations because we can have very careful experimental control over our stimuli while nonetheless making them very engaging, particularly for child subjects.

And so in this particular study, this was simply a study of typically developing college students. We put them in the magnet and we showed them these four different conditions.

So a person walking, then the gestalt of walking, the impression of walking, but being delivered by what we called a robot, then the disjointed parts of that robot which we called mechanical motion, and then a complex nameable motion as a control, a grandfather clock moving.

Notice that you have a lot of the same parts, a lot of the same colors across the stimuli so we were able to control for very low-level features.

So this one we would classify as biological motion, and this one, but not these two, and our prediction was if a brain region is dedicated to processing biological motion, it would process to the robot walking and the person walking but not the other two conditions.

And we were particularly interested in two regions that show a great deal of specificity for motion. One is the superior temporal sulcus region that I mentioned before and then in this work we are very excited when we can find a nearby brain region that does something very different because then we have a sense of the specificity of different brain regions for processing social information.

So we knew of the STS region and we knew of this more general motion processing region shown here in yellow versus blue, and what we saw was that in the superior temporal sulcus, you had a very very strong activation to the two biological motions but essentially no activation to the mechanical motion, and this is in sharp contrast to the more general motion processing region that responded to all of these stimuli.

So the bottom line here was that we had found a region of the brain that responds specifically to biological motion and ruled out other interpretations of what it might be responding to, and differentiated it from other brain regions that process motion more generally.

So the next step though was to know is this brain region simply there for processing biological motion or does it do more? Because when we do social perception, we are using biological motion to figure out what other people are thinking about.

And so we wanted to know if this brain region is sensitive to mentalistic inferences that you can make from watching other people's actions. So we set up a condition where Caitlin, my lab manager here, looks towards a red cup, either a red or a green cup and she expresses positive regard and in that case, she did what you would expect: she likes the red cup so she reaches to it.

All right? So I'm going to call that congruent. And then she likes the red cup but she does something odd, she reaches to the other cup, all right?

And in our prior work we had seen that the STS, the superior temporal sulcus, was sensitive to this difference so it was sensitive to the incongruity or context of an action, and we made it a little more complicated.

So now she doesn't like the green cup so what she should do is actually reach to the red one and she does. And then here is Caitlin. She dislikes the green one and so she reaches to the green one.

And what I am explaining is

something -- I am sort of explaining it as the person is in the magnet and they are thinking about how incongruent this is. I want to point out that we only do that once during the introduction to the stimuli.

What I am talking about when I am talking about these brain systems is something that is beyond conscious control, that happens implicitly, it's always on.

So no matter how many times you show an incongruent stimulus versus a congruent, it's defined by this, the typically developing brain, particularly the superior temporal sulcus, responds more strongly to the incongruent than to the congruent.

And so we have a brain region, again, this right hemisphere, superior temporal sulcus region, that is responding more strongly to this incongruent action. So this is a brain region that is involved in processing the underlying context and psychological disposition in putting together the emotional expression with the subsequent action.

Okay, so what about autism? So the reason why this is interesting for the study of autism is that individuals with autism demonstrate a very interesting social perception deficit when it comes to eye gaze processing.

So here I am talking about children with autism. When you present them with something like this task, Charlie here, and you say, where does -- which candy does Charlie want? They can tell you Charlie is looking at the Polos here but they can't put together Charlie's looking at the Polos with what Charlie wants.

And so they tend to give you an incorrect answer about what Charlie wants, oftentimes saying what they like because that's a logical inference when you are not connecting together the biological motion, the direction of gaze, with the type of candy that

Charlie wants. So it's underlying, mentalistic reference.

So we went into studying high-functioning adults with autism, looking at the superior temporal sulcus region and we thought perhaps we would show a particular type of dysfunction in this brain region using this Caitlin task that I have already shown you.

And that is exactly what we saw. So red and yellow here are two separate MRI studies of typically developing people conducted at two different institutions on two different magnets by our group, and we were able to directly replicate our prior finding in typically developing adults and that is what we ought to be able to do given that we are using this technology and so we are demonstrating that it is reliable.

But in addition, in individuals with autism, in this particular brain region they are responding equivalently, so they are seeing the eyes move, because we are asking them to attend to it, but they are responding equivalently to the incongruent versus congruent.

And so what we are arguing is that we have found a brain mechanism that accounts for these deficits -- this particular deficit in social perception but more broadly, dysfunction in social perception.

But I should tell you that there was a great deal of variability in our data, and one thing that is true of autism is there is variability and variability in pretty much everything you can imagine, but in particular in levels of social dysfunction, right?

They all will meet criteria, that is by definition, otherwise we wouldn't have given them the diagnosis, but there's large variability.

So this is simply showing you the typically developing data, averaging over the time points versus the autism sample, showing you that the autism sample isn't showing this incongruent versus congruent effect but you see these standard error bars. They are quite large. That represents a great deal of variability.

So we had a little bit more information about these individuals. We had genotyped each one of these individuals and in particular we had genotyped them for the serotonin transporter gene which is involved in the amount of serotonin that you have circulating in your brain and it has been linked to social brain function.

So we wondered if this might actually be linked to the severity of social brain dysfunction in individuals with autism. So what I am going to show you here is one configuration of the serotonin transporter gene, the long, long configuration, and what you see is these individuals with autism, one way to put it is that they have an intact superior temporal sulcus response to congruent versus incongruent, but another way to put it is that they have a protective effect of having this long, long, or you can turn it around and you notice that if you have a short allele, the serotonin transporter gene, you have a more severe social brain dysfunction in the STS region.

And so these kids are really the ones driving our effect when we look at this grand average. These you can think of as either escaping it by virtue of this genotype, or this genotype moderating a more severe phenotype.

And what's interesting about this is that Cathy Lord and Ed Cook have done some beautiful work linking this particular gene to severity of social outcome as measured by some of our gold standard diagnostic assessments.

So if you have the short allele, you have a more severe social outcome. And what I think is very nice about this is that it offers the opportunity to begin to make specific predictions based on brain data of social dysfunction by virtue of a gene that is not necessarily a candidate gene for autism, although there is a long history serotonin transporter gene as a candidate for autism, but rather thinking of it as ma moderating effect of the social brain in individuals with autism.

Okay, so I have been telling you about adults but now I want to tell you about children and incidentally this is the cutest little girl in the world and she looks just like her mother.

So before we could scan children with autism, we had to develop a technique, a whole set of technologies that would allow us to be able to put them into the magnet, because many of you have probably had an MRI, imagine having one as a child. It can be a quite frightening experience, although I will tell you it's a little less frightening for children on average than it is for adults.

But one of the things that we do is

have a mock scanner that has no magnetic field so we can walk around it, we can climb all over it and that's exactly what the children do.

And while we are doing this, we can talk to the parents and provide a very extended consent process and you will notice the Thomas the Tank Engine and the rocket ship are painted on magnet safe materials and put in front of this so that we can get the children used to being in a fun environment within the MRI scanner and then we can move these panels over to the real scanner which is a little less fun.

And by then, though, we have trained them up to be quite still and so the way we do this is that we monitor their head movement while they are lying in the scanner, and we allow them to watch their favorite movie and we have a large selection and if it's something unusual, we have the parents bring it, and we go out and buy it because there are trends in movie tastes, particularly amongst children with autism.

And so we will play their favorite movie and if they move, this movement monitor that we have will turn off the movie and if they are very, very still, the movie will keep playing. So we are essentially operantly conditioning them to be still but put a different way, we are teaching them the coping strategies and the ability to monitor their movement.

And oftentimes this requires many training sessions but we are able to successfully get these children into the magnet. We have scanned children that are high-functioning with autism as young as four years of age in the magnet while they are awake and performing a task and we have actually begun a new study specifically focusing on very low-functioning children with autism and so far, in particular children with childhood disintegrative disorder and so far our child -- sort of our prize child was 12 years old and had an IQ of 20 and was completely non-verbal and we were able to get them through a full, functional MRI procedure and it's important to point that out because most of what I will tell you today and most of what the field can tell you about brain development in children with autism is the fairly minority group, that is high functioning enough to get into the magnet, and so particularly with functional neuroimaging.

So one of the first things we did when we were able to look at children in the magnet was to go after biological motion processing. So there was already good evidence to suggest that even toddlers with ASD show abnormal preferential attention.

And in addition, adults with ASD exhibit dysfunction within the right posterior STS, this region that I am calling a biological motion processor.

So we showed children ages 4 to 17

biological versus scrambled stimuli so the biological stimuli are of a person playing different children's games, in this case patty cake and these are point light displays so we create these by putting little infrared lights that are invisible to the naked eye but visible to a camera that is sensitive to infrared light on the major joints of a person and filming them.

And so here is the scrambled version, which is simply these biological motion stimuli, all scrambled up. And we had three participant groups and I am going to go through this slowly because it's important for me to tell you all about these different participant groups.

So one group we had between the ages of 4 and 17 was a typically developing group and by typically developing I mean we selected them from the community, we matched them in terms of average IQ and cognitive level but we ruled out autism or any additional neurodevelopmental or neuropsychiatric disorder.

And so those would be a typical control group in this type of imaging study. But then we also looked at a group of unaffected siblings and these were a very unique of unaffected siblings. These were the unaffected siblings from the Simons Foundation Simplex Collection.

So these were unaffected siblings where we went to extraordinary lengths to rule out autism or any pervasive developmental disorder as well as rule out any form of autism of various other developmental disorder in any immediate family member and we ruled out the broad autism phenotype in both the children and the parents of these children.

So they are truly unaffected siblings and to be honest we scanned them thinking that they would be the world's best control group because they grew up in a house where there is the stress of having a child with neurodevelopmental disorders but the whole logic of the simplex collection is to enrich for rare genetic mutations and so these kids shouldn't be carrying the genetic risk per se of idiopathic autism.

And then of course we looked at the same children who were the simplex children, so this is a simplex collection of autistic children so they are the only children in their family with an Autism spectrum disorder and you see the age ranges and the matching on cognitive variables.

And this type of design allowed us to look for three types of neural activity: one that we are calling state markers, so I am defining this as regions of dysfunction in children with autism relative to unaffected siblings and typically developing children.

You can think of this as those regions that tell you what in the brain is affected in autism and I like to think of it as just as likely to be the effect of autism, especially experience of expectant effects, as any type of primary causal mechanism.

And then you can talk about trait markers, which I am defining as regions of activity reflecting shared dysfunction in unaffected siblings and children with autism.

But what is interesting about this sample is that they don't have the behavioral profile of autism or the broad autism phenotype. So their behavior can't be causing these differences in the brain. These represent truly the underlying trait risk or an endophenotype for the risk to develop autism.

And then finally what I think are the most interesting brain areas, compensatory mechanism. So these are areas of enhanced differential activity. They are only present in the unaffected siblings. So what I want to show you is what we found with regards to this.

So this is state activity in the

brain and what we found is all of the usual suspects for social brain dysfunction in children with autism. One thing to note is that we were extending this now to four-year-old children with autism so we have superior temporal sulcus dysfunction, fusiform gyrus dysfunction, ventral lateral prefrontal cortex and the amygdala, all regions that are quite well-known in the autism literature, in adults, but now extended down to children as young as four years of age as being dysfunctional in this group.

We found a very nice behavioral correlation between the social responsiveness scale, which is a measure that we now use to try to understand something about the severity of the social phenotype in autism, but also social differences more broadly amongst the entire spectrum of development.

So the right posterior STS very nicely correlated with the severity of social impairment. But I think more interestingly is that we found areas of trait activity. So these included a different portion of the bilateral fusiform gyrus, the left dorsolateral prefrontal cortex and right inferior temporal gyrus.

And what is interesting about these brain regions is that these are present both in children with autism and their truly unaffected siblings, so they might represent our best hope for neuroendophenotype for looking at larger scale genetic studies where we use this brain marker as our measure of interest as opposed to the full behavioral phenotype or even components of the behavioral phenotype.

And then finally the two most interesting regions were a portion of the right posterior STS that unaffected siblings uniquely had and then a portion of the ventral medial prefrontal cortex.

And we are very curious to find out whether or not this represents the outcome of a developmental process that took these children from the genetic risk for developing autism but through an altered course of brain development, for whatever reason, they ended up on the side of the tracks if you will of not having autism or any pervasive developmental disorder.

And so putting them all on the same slide and then summarizing why I think this is important, one of the very first things that we can begin to do with this is use these brain regions particularly the trait regions as quantitative traits, quantitative endophenotypes or biological markers for the risk of developing autism and this will allow us to both look younger, see if we can do early diagnosis by virtue of these types of imaging procedures, but also use these for whole genome analyses, where we actually use the functional brain phenotype as the quantitative trait and recent evidence both out of the National Institute of Health but other organizations, particularly NIMH, and then other universities, has shown that you can get quite a bit of traction with the neuropsychiatric disorders by using the variability in the brain function as your measure when you are looking for genes relating to or candidate genes for particular disorders.

But also, because of the unique sample, not all unaffected siblings were showing these trait markers and so what we are very interested in is finding, using the brain imaging data to actually find the most maximally divergent sibling pairs, those that don't look anything alike in these trait regions.

And those are the ones that we will select with my colleague Matthew State for whole-exome analysis where we will go in and we will very carefully, very rigorously, in high resolution, look at the genes involved in coding proteins and therefore up our ability to look for candidate genes within autism from rare genetic events.

Okay, so I want to now, having talked about imaging as a neuroendophenotype I want to talk about imaging quickly as telling you something that wasn't obvious, and so I showed you an example of an obvious finding, children with autism don't look at the eyes. Now I want to talk a little bit about something that is non-obvious from the point of view of behavior.

And this is brain mechanisms for processing social exclusion. So we have been putting children with and without autism into the magnet, and having them experience a ball toss game, okay, so they are playing ball, basically, and they are throwing for example to Jennifer and Lisa here, and during this particular brand of the game, they every so often will be socially excluded so we can study the brain correlates of the process of being socially excluded and we have talked a lot about this morning social exclusion and so here we are looking at the neurocorrelates of it.

And so, in this case, every so often Jennifer and Lisa exclude you from the game, they don't throw it to you. And then in another version of the game that we thought would be particularly potent for children with autism, it's not about social exclusion but rather about rule violation, so here the -- you are the subject, you are represented by a red square and you are throwing to Dan and Max who are represented by a blue circle and a green diamond, and if the ball turns into a green diamond the rule is you throw it to Max. If the ball turns into a blue circle, the rule is you throw it to Dan, and of course Max and Dan should follow the rules so when it turns into a red square they should throw to you.

So it's not about social exclusion. It's about rule violation. And so now we have incidences of fair play and then sessions of rule violation and we were able to show that in adults, these are mediated by two very different neural systems.

And so this is the neural system involved in processing social exclusion. In particular look at the ventral anterior cingulate cortex. It will come up over and over again.

And then this is the system involved in processing rule violation. This is a region of frontal cortex and a region of parietal cortex that are very well known for their role in processing rules, following rules and simple tasks within the magnet but following attention, direction attention.

And then we were also able to find two different patterns of connectivity, all right? When we went in and we looked at these measures in children with and without autism, we had them play this game and then we asked them behavior questions like endorse whether or not you felt rejected. These were high-functioning kids with autism. So they were able to do this and they had the exact same behavioral results as our typically developing children.

Also for cyber shape I was annoyed when they didn't follow the rules. In this case their behavior was slightly different. They were much more annoyed when people didn't follow the rules. This didn't affect typically developing children very much, but the children with autism were actually much more annoyed.

So this is the structural ventral anterior cingulate cortex, so we just drew this brain region and then we looked at the correlation between the level of activity during social exclusion and the age the subjects and this is typically developing kids.

And what we found is something that again, might not surprise you very much. There is a trend with age that around the age of 13 to 15 going on into 17, your brain is much more sensitive to being socially excluded than when you are younger, although during the whole period you are sensitive to social exclusion.

But we found very different patterns of activity in children with autism. So this brain region on the top is the right insula. It's a brain region involved in perceiving disgust, feeling -- when you have a gut feeling about something negative.

So what we are seeing here is that during social exclusion, we are getting a much stronger response in typically developing children in the right insula as compared to children with autism.

But in contrast, during rule violation we are getting a very, very strong response in this brain region in children with autism but not in typically developing children.

And what I want you to take away

from this data is that the children with autism are responding at the level of their brain to the social exclusion in a way that is very comparable on average to typically developing children, and then in addition they have another brain system that when rules are violated -- either in social situations or when there is a clear rule game -- they are exhibiting a lot of activity in the very same places of the brain that individuals without autism are responding strongly during social exclusion.

So for them, one way to think about this data is that a rule violation is like a social slight to us in terms of our emotional reaction to it, not cognitively but in terms of our emotional reaction to it.

Then the last thing I want to show you is taking this type of approach, this imaging approach, and studying much, much younger children, in this case infant siblings and in particular infant siblings that are at risk for developing autism.

And so we have an ongoing, large longitudinal study at Yale where we are looking at infant siblings of children with autism and we are following them to examine who develops autism and who does not, and try to then look back in the data and try to understand what would have been early predictors.

And one of the things that we have now begun to do is actually scan each of the children that come through for this study and we scan them quite frequently, so we will have longitudinal data to show how the social brain develops over the first year to two years of life.

So one of the things that is essential for this, when we are asking people to hand over their infants to us, is to do a long interview to really figure out exactly what their infants like and do not like and what will in particular get them to fall asleep, because we are actually doing this while the infants are asleep.

And so we do that. We have been quite successful in this. This was actually the very first child that we scanned, she was a 13-month-old little girl, typically developing and this is her waking up and then getting out of the magnet after a nice sleep scan in the middle of the afternoon. So we felt very triumphant after that. She actually started crying about two seconds later, but that was because we woke her up, not because of the scan.

And so what we are doing -- it turns out that these brain regions that we are interested in, particularly the ones that I was showing you involved in the state of having autism, are sensitive both to visual cues of social perception but also auditory cues.

So for example, the same part of the brain that responds to biological motion when it is viewed is also responsive to that category of motion when you hear it. So for example if you hear fingers snapping or the sound of walking, the same brain region will activate.

And so in infants, but first actually in sleeping college students -- which is the most popular study on campus -- we put them in the magnet and we played two different types of sounds: those that were communicative and those that were non-communicative.

And I am giving examples of each so that you can understand the difference, but infant-directed speech, adult-directed speech, in both cases, this is actually Japanese. So these are not Japanese speakers and so they are not actually understanding the content and they are asleep.

But also human communicative vocalizations like laughter, for example, and then we have human non-communicative vocalizations such as coughs, walking, clapping, sounds of water running, so sort of an object sound, and also rhesus calls, so another species that makes vocal sounds.

And what we found is that this region of the brain, the posterior -- posterior superior temporal sulcus responds quite strongly to all of these vocal sounds but in particular responds most strongly to those that are communicative, here shown in red versus the blue, which are non-communicative.

And so what we think that we have been able to identify is a way to go in and assay the perception of communicative intent in very young infants, even while they are asleep.

And so a perfect example of this would be: the best way to wake you up would be to call your name and the region of the brain that responds very, very strongly when someone calls your name is actually the right posterior superior temporal sulcus, and it does so whether you are asleep or awake.

And in this case what we are showing is a finer discrimination where it is responding to communicative versus non-communicative sounds which then gives you a handle into how the brain processes communicative intent.

And so now we are using this, and this is an example of an infant brain where we are showing exactly the same region that we are able to show in adults -- in this case it's a six-month-old brain -- responding to communicative versus non-communicative sounds in this characteristic way.

So this seems to be the same across all points of ontogeny that we have studied at this point, so it's something that could be a very early marker for the development of autism and it's something that fits in quite beautifully. I noticed Geri Dawson is here, in terms of early markers of at risk for developing autism, one of the very first sort of markers found was responding to your name and it's still the one that often gets our attention as parents very, very rapidly. And so that is the type of work that we have been trying to fo and I appreciate -- I want to give you acknowledgments and funding sources. Thank you for your attention but also thank all of my colleagues who have been involved in this, there are numerous colleagues. I work with a wonderful, large lab that helps me do this work and I just get to be the front person for it.

So, thank you very much and I hope I have time for questions.

Dr. Insel: Thanks, Kevin. As the lights come up let's see if we can take a couple of minutes before we break for questions or comments. Marjorie?

Dr. Solomon: Hi Kevin, thank you so much for that wonderful talk and for your wonderful work. I was wondering if, for the committee you could comment a little bit more, sort of a bigger picture question, on the role that you see developmental cognitive neuroscience playing in advancing our field and then also in helping with the development of treatments both psychosocial and pharmacological.

Dr. Pelphrey: Okay, great, thank you. So, developmental cognitive neuroscience, we are talking about the field that is studying brain development and trying to understand aspects of typical and atypical brain development.

And so where I see it fitting in, the -- I'll sort of go at one angle of that -- so if you think about the role of genetics in our field, so if you find a number of candidate genes for autism, the most recent reports are demonstrating that there will be numerous, numerous genetic pathways by which you can get to autism and so -- and that was a prediction out of a developmental psychopathology perspective, numerous starting points that could get you to the same endpoint, which is autism.

Where I see the value of developmental cognitive neuroscience is that it looks like you could have multiple, multiple genetic causes and then a smaller number but still a very large number of molecular pathways, but all leading to a phenotype of brain development, and they are emphasizing the developmental factor because we know from experience that looking at patterns of development over time you get a much better picture of what is going on than looking at a static snapshot. It's common sense but it hasn't been common sense in our field of science.

By looking at that, then you begin to have a mechanistic understanding of how you get to the behaviors that are characteristic of autism but at a neurosystems level. And so for the genetics to be relevant and important, you have to be able to make that bridge between the behavior and the brain and the genetics, and in many ways, I could say controversially, it may not matter the genetic mechanism by which you got there. If you are thinking about treatments, what you might want to target is the brain phenotype that is characteristic of the developing disorder and there you will -- we talked about the heterogeneity, but what is homogeneous across autism is this brain phenotype that is emerging and that becomes the target of treatment and targets of intervention, and I think that's where the field is leading right now in terms of being beneficial for practical aspects of treatment.

And so, for example, one natural outcome of the study we are doing or the study we did where we showed state, trait and compensatory activities, the compensatory activities become very interesting in terms of targets of treatment. So what we are doing now is proposing to go and actually do what's called pivotal response training with very young infants where we are starting to get both a behavioral indication of concern, but they are also a brain indication that their brain might be developing differently, go in, provide the treatment in a research setting and then monitor how the brain alters its development, if it does, and use that as an outcome measure as well as the behavior eventually. And the beauty of that is it's both a treatment study and so we will find something that might work, but also we will understand why it works and why it works for some children versus others and we will have the data to be able to predict after the fact which children it should have worked for, and then going into the next sample we will know what works better.

And so I think that's the most direct area and then in general, in ways that I think we can't even predict, knowledge of how the brain develops is the key to understanding the importance of the many, many genetic findings coming out. Otherwise it's a list of findings without any real function.

Dr. Solomon: Thank you.

Dr. Insel: Last question or comment from Geri Dawson.

Dr. Dawson: So I was of course intrigued by your work following the infants who are at risk for autism by virtue of having an older sibling, and I was thinking about an article that I read on the plane coming here this morning and it's the latest Newsweek article on Alzheimer's.

And they talked about the fact that they have been developing, really, I think biologically informed intervention strategies but using them with people who have developed Alzheimer's and had very unsuccessful results, but that the current trend is to identify using neuroimaging techniques that are at risk for Alzheimer's and then providing the treatment actually before the ravages of the plaque and so forth have affected the brain so much.

And so I wonder if you could comment on whether this is the direction that you see some of the work that you are doing going.

Dr. Pelphrey: Absolutely. Yes, so what I am arguing with the data from the unaffected siblings and the children with autism is that there are brain regions that are analogous to the effects of the plaques in Alzheimer's disease that represent the state of having autism and likely the outcome of having lived even four years with autism and showing that altered developmental trajectory.

Those are very interesting and they are important but what might be more important is being able to provide a picture, literally, of what the brain looks like on its way to showing the behavioral signs of autism. And I think that the trait activity is much more promising with regards to that, and then that would predict putting the children into particular types of treatment as essentially preventative measures, I mean of course the principle of do no harm applies, but in this case the things that we have that may be relevant would do no harm.

And we are seeing both clinically, intuitively and some research evidence now that being in these early intervention programs makes a great deal of difference, sort of taking -- you can never know exactly where a child would have ended up, but from clinical experience knowing, well, a child like this usually ends up here, we had the birth to three intervention, now the child is over here.

And so being able to actually quantify that and understand the mechanisms and predict which children would be assigned to which treatments would I think be the ultimate promise of imaging research and developmental imaging research.

And it's nice, because I think that

up until recent times, mostly the world of cognitive neuroscience has benefitted from the presence of autism, as sort of a very interesting case of social modularity, whereas now, cognitive neuroscience is beginning to inform autism, but I think it's sort of a new trend, starting to ask the right types of questions.

Dr. Insel: Terrific. We are going to take one last second for Gerry Fishbach to make a comment.

Dr. Fischbach: Just because in response to that very interesting observation, the reason, I believe -- I haven't seen that article -- this is possible in Alzheimer's disease, is because the government, industry and private foundations got together to establish standards for imaging large numbers of people, very expensive but incredibly useful and given the variability Kevin is talking about, that is going to be essential if we are going to have some early diagnosis convincing enough to begin therapies based on -- so that could be a great opportunity to talk about going forward, how one might collaborate across government agencies, industry and private foundations to standardize these methods.

Dr. Insel: Right, sounds like a topic for the strategic plan update discussion later this afternoon. We are going to break at this point. I'm sorry we went over, but what we will do is extend the lunch break to 1:15 instead of returning at 1, so let's make sure everybody can get back promptly at 1:15 for public comment. Thank you.

(Whereupon, the committee recessed for lunch at 12:38 p.m. and reconvened at 1:17 p.m.)

AFTERNOON SESSION

1:17 p.m.

Dr. Insel: Okay. We have got 30 minutes for public comment and there are five people who have signed up so we would like to get started so we can stay right on schedule. We are already a little bit behind.

Let me invite Sheila Medlam to join us and do you have slides that you are going to show as well? Okay.

If you would be more comfortable sitting at the table you are welcome to do that or you could stand at the podium, whatever you prefer. Great. Thank you for joining us and we will just make sure you are miked so that people who are watching by webcast will be able to hear as well. Perfect. Thank you.

Ms. Medlam: My name is Sheila Medlam and I just want to thank all of you for giving me the opportunity to speak. I am not the greatest public speaker so if you will just bear with me, I'd appreciate it.

On July 7, 2005, God blessed us with a beautiful autistic son, Mason Allen Medlam. He was full of boundless energy, tenacity and joy. He filled our lives with love and laughter and was constantly surprising us with the creative ways he could find to outsmart us and get into trouble.

Two years ago we moved to the country and Mason got his first taste of real freedom. We had a huge yard, chickens and horses, and just lots and lots of room to run and play and he loved it.

At first the only precautions we took were locking the door with regular locks, but he quickly figured those out, so we added hotel latches to the top of every door.

Within a month he had figured out how to unlatch those with a long stick, a chair, or the broom. We added double key locks to every door.

Most people think of autism as this

debilitating disease that robs the child who is diagnosed with it of everything that a normal child can do. I look at Autism as a disease that trapped my brilliant little boy inside his head.

Although he could not express himself with words, that wonderful mind never, ever stopped working and he had the problem-solving skills of a rocket scientist.

If he wanted something, he figured out how to get it. He would literally watch, without you realizing it, and if one person forgot to close the door all the way, or latch the latch, he was out the door in the blink of an eye.

Every fifteen minutes, I would ask, "Where's Mason?" I was hyper-vigilant with him. I knew he had absolutely no concept of danger. I knew he was a runner, and I knew he would be attracted to the most awful dangers if we didn't always know where he was.

During the five years that I had my

son, I never slept more than a foot from him. Never. I was terrified that he would wake up in the night and somehow find a way out of the house and be lost to me forever.

I couldn't take him to a babysitter's house because there weren't any that had taken the precautions we had. How can you explain to a daycare that the standard locks they have are not Mason-proof?

How many childcare providers are willing to add multiple locks to their doors and take such a risk as a child who wanders at the first opportunity?

From personal experience, I can tell you none that I know of.

On July 26th when the temperature reached 105 degrees outside our air conditioner stopped working. Our landlord came to our home and said he would be able to fix it in a couple days.

I went to the store and bought some fans. I put one in my oldest daughter's window. I sat the fan on the sill and closed the window halfway over it and then I went to sleep in another room with my youngest daughter and Mason. I fell asleep that night holding Mason's little hand.

The next morning I got up and thought about staying home. I was worried it would be too hot for the kids, but I decided to go for the morning and come home around noon.

I woke Megan up so she could watch the kids and left for work.

At ten thirty I got a phone call that would eventually destroy my life. My youngest daughter called and said that they couldn't find Mason. I rushed from work, dialing 911 as I raced to my car. I knew then that it was going to be bad.

A year before, when we didn't think Mason knew how to unlock the doors, we had been in one room uploading pictures from a party we'd had. The next thing I knew, my husband was racing out of the house after Mason.

There is a retention pond across our street with a large windmill. Mason had never been there before in his life, but I think the windmill attracted him, and then he saw the pond.

Kenny had pulled him out when he was chest deep in the water. From that moment on, we'd lived in fear of that pond. Mason never, ever, ever forgot something that he wanted.

The first words out of my mouth to 911 after I had told them Mason was missing were to send someone to the pond. I knew instantly that Mason had pushed the fan and screen out of my daughter's window and gone there. I just knew. I begged 911.

I told them my son was non-verbal and would head straight there. I worked 25 minutes from home. I drove over a hundred miles an hour, frantically calling every neighbor, every family member, begging everyone to go to the pond.

When I turned down the street that we live on, there were police and firefighters everywhere, looking in buildings, walking through fields, yelling Mason's name, but not one person was at the pond.

I went directly there, got out of my car and looked at the water. The first thing that I saw was something pink floating in the water. For an instant, I thought it was a piece of paper, but then I knew.

I just started screaming Mason's name over and over and I dove in and pulled him out. I threw him on the bank. His lips and nose were blue and his eyes were closed. I started CPR but all that came out of his mouth was water.

A policeman was about a hundred yards from me. He had drove past the pond and was headed up to a neighbor's house. He ran over and took over CPR.

I ran back to my car screaming, "No,

no, no, no." I knew then that Mason was gone forever.

They took Mason to the hospital and got his heart beating. For a moment we had hope. The doctors told us there wasn't any, but we refused to give up.

We prayed, we asked our community to pray. We just didn't want to let him go. I told God that if he wanted my son, he would have to come and take him from me. I would not take him off life support. I didn't care how I got him back, I just wanted him back, any way that I could get him.

If that meant caring for him in any state for the rest of his life, that is what I would do.

On July 29th, God came for my son. They tried everything to keep his heart beating, but slowly it just stopped. At 7:29 in the morning all the light went out of my life. My son was gone.

Unless you have a special needs

child that wanders, I think it is hard for anyone to grasp the relationship that develops between parent and child.

Mason was the center of my world. I revolved around his needs and wants. Our household was one big dance all designed to keep him safe. He literally was my joy. He was in my arms or by my side every second that I was home.

Unlike a normal, independent child, I was the center of his universe, too. He knew I loved him, and I knew he loved me. It was such a pleasure to watch him dance, or laugh at the wind blowing in his face.

I could sit and watch him go round in his car, stopping in front of the glass doors each time to wave at himself. He just gave me so much sheer pleasure. I couldn't have and wouldn't have wanted a better son. He was fabulous.

But under all the joy was a constant fear for his safety. I guess since he had no fear, I had a double dose of it.

The day we lost Mason, a lot of people failed him. I failed him by not seeing the window as an avenue of escape. I should have known that he would be able to figure out how to get into the big, wide world through that small space.

The next group of people that failed Mason were the first responders. They did not know how to search for a child for a child with autism and they did not take my requests seriously.

They assumed that this little guy would be near by. They didn't think that he would have made it a quarter of a mile to a pond in such a short time.

They looked in all the wrong places in all the wrong ways. They were shouting my son's name. They did not understand that a non-verbal autistic child is not going to respond to his name.

They didn't understand that an

autistic child is going to be drawn to what fascinates him no matter what is in his path or what danger that fascination poses.

Dr. Insel: Mrs. Medlam, we have your printed comments which are very, very powerful as is what you are telling us, but you are only about a third of the way through and we won't have time for the other four people who have come for public comment.

Ms. Medlam: Okay.

Dr. Insel: So maybe could I ask you just to take another minute and tell us what you think will be most important. This is such a powerful story.

Ms. Medlam: Well, I think that the most important thing is to realize that there are a number of deaths. I mean, there are so many that have happened before Mason died, and so many that have happened after Mason died.

These are just some of the children that have been lost in the months during the time that we lost Mason.

I also think that it's very, very important to realize that one out of every 110 children is placed on some level of the autism spectrum, 92 percent of those children wander and the number one cause of death among autistic children is wandering, and we would like to initiate an alert called the Mason Alert.

It would include a current picture of the missing child, the person's name and address and contact information, their fascinations, locations of all nearby hazards, whether the person is verbal or non-verbal, and this is very important when searching for a child because we tend to stand in one place and if you were standing beside Mason at any point, he would not have responded. And how the person reacts under stress and how to approach the child or missing adult.

The Mason Alert we think should be issued for anyone prone to wandering and that does not have the capacity to recognize dangerous situations and we think that the age criteria should not exist for such an alert, because unfortunately diseases like Down's syndrome and autism do not just disappear at 18.

And we also think that the AMBER Alert and Silver Alert are vital notification tools but the truth of the matter is they simply do not -- they are simply not effective when one of our children or adults with a cognitive disorder or Down's syndrome wander.

The Mason Alert would differ by providing first responders with the information they need immediately to react in a proactive way, and I also think that each time an autistic or developmentally delayed child or adult wanders, it should be treated though as though a kidnapping has just taken place.

That's the level of heightened awareness and diligence that is required to get them home to their families alive.

Anything else is unacceptable, in my opinion.

I just think that despite the time limits, the truth of the matter is I am here to stand witness for all of those children that have been lost and I am their advocate and I am the advocate for the ones that are still alive.

And this is not a situation that you as a council have been unaware of and my question to you is why did my son have to die? Why wasn't something done about this?

Waiting one day is too long. You have to do something now and I just think politics shouldn't be involved when it comes to these children because they are gone forever.

This boy is gone forever and he has left a huge hole in my life and I think that something should have been done a long, long, long time ago and I appreciate your time but you don't have time to wait. You need to do something now, before we lose anyone else. Thank you.

Dr. Insel: Thank you. This is an issue that we will come back to later in the day, as we have promised. It also fits in with what we heard earlier today from the first two speakers so this is clearly something that I moving to the top of the agenda for this committee.

I would like to ask -- the next public comment is from Caroline Rogers.

And again because of the time constraints we are going to have to ask that you keep your comments to something under five minutes. Thank you.

Ms. Rodgers: I need the first slide. Thank you.

Dr. Insel: And you should have these -- I think we have them in folders as well so they should be available. Okay.

Ms. Rodgers: What is causing the autism epidemic? Are we looking in all the wrong places?

The Environmental Protection Agency has identified the year that the worldwide autism boom started. It was with children born on 22 years ago in 1988 and 1989.

This was based on long-term data sets showing autism spikes in the U.S. and countries around the globe.

What could cause this epidemic? Vaccines? Genetics? Air pollution? Pesticides? Toxic chemicals? Numerous studies throughout the world do not support that vaccines, whether alone, in combination or with thimerosal, cause autism.

Gene abnormalities associated with autism only apply to a small percentage of people with the disorder.

Besides that, the gene pool does not change quickly, certainly not in as little time as 22 years. Air pollution has actually decreased significantly since the 1970s, but while air quality has been improving, the autism rate has only increased, especially in developed countries that now enjoy the cleanest air.

Pesticide usage does not explain the autism rate. Farm pesticide usage in the U.S. actually hit a low in 1988, the change point year for the autism boom. Besides that, pesticide use goes up and down like a roller coaster but that is not the way the autism rate has gone. The autism rate has only been climbing higher.

Chemical exposure is a whole can of worms and nearly 85,000 chemicals that are registered with the EPA for commercial use and most of them have no developmental toxicity information. And yet we only have a handful that are associated with autism and together they don't begin to explain the autism boom.

So we are back to square one because no single identified possible risk factor, whether vaccines, genetics, air pollution, pesticides or chemicals can explain the increase in autism.

Most researchers believe that autism is caused by a complex interaction of genetics and environmental factors. The elegant and emerging science of epigenetics -- in which DNA modifications change how RNA is read -- seems to be leading the way to discovering autism's cause, but wait. The EPA autism boom study found that autism increased rapidly at the same time in different countries around the world.

This presents impossible odds because every country has different gene pools, air and water quality, building materials, fabrics, diets, environments, chemical exposures and pesticide levels. It would take an impossible series of genetic and environmental coincidences to combine to cause such similar increases in autism at the same time in different cultures and locations around the globe.

But what if one autism risk factor

was in common use in all countries, had greatly increased in its exposure to pregnant women over the last couple of decades, had been the subject of a World Health Organization symposium that determined that fetal exposure to it suggested it could cause neurological or behavioral issues, in mice had been proven to cause changes in brain formation consistent with those found in people with autism?

What if this possible risk factor was approved for use by the FDA but that approval was not based on safety considerations? What if it had safety features mandated by the FDA that were ignored or misunderstood by most of the practitioners?

And what if it had almost no safety studies published in nearly 20 years, despite rapid changes? What is this possible autism risk factor? It is the elephant in the room. It is prenatal ultrasound.

Ultrasound is in common use

throughout the world even in remote, rural regions of developing countries such as China. Ultrasound has doubled in use over 10 years according to trend reports in two countries.

Prenatal ultrasound was identified by the World Health Organization in 1982 as having the potential to cause "neurological, behavioral and developmental changes in humans, based on animal studies."

Prenatal ultrasound caused changes in brain formation by disrupting neuronal migration in the offspring of pregnant mice, according to pioneering research at the Yale School of Medicine.

Although all ultrasound intensity limits are approved by the FDA, the Journal of Ultrasound in Medicine notes unfortunately these limits were not based on safety considerations.

Prenatal ultrasound machines have safety indicators required by the FDA but according to industry surveys, 70 percent or more of ultrasound practitioners could not locate the required safety indicators on their own machines, much less explain their purpose.

Why we don't have answers regarding today's ultrasound use? The short answer, the grants have been repeatedly denied funding.

There is emerging evidence that I won't even repeat now, I brought it up at previous full committee meetings and it's in the public record. What I want to say is that more research is needed.

Pardon?

PARTICIPANT: Can we see the slides?

Ms. Rodgers: Well, I had to cut it down to less than five minutes so I'm skipping through some of them. They will be in the public record. Thank you though for your interest.

Considering existing scientific evidence regarding prenatal ultrasound, the lack of safety measures in practice for prenatal ultrasound and the absence of other leading autism causes, prenatal ultrasound deserves the kind of attention, funding and research devoted to other possible autism risk factors.

The good news -- if prenatal ultrasound is causing autism, it will be easy to reverse the trend. The autism community is counting on you to lead the way. You are the experts. You have access to relevant data and connections with the autism research communities to seek answers.

As members of this task force it is your mission to accelerate high quality research and scientific discovery to find out what is causing autism. Only you can make sure that prenatal ultrasound does not remain the elephant in the room. It's time to start the conversation. If prenatal ultrasound is causing autism, there is no time to lose. Thank you.

Dr. Insel: Thank you and again all of the material is -- including the references

-- are in your packages so it's for those slides that we had to go through very quickly you will have a chance to look back at them.

The next person who has signed up for public comment is Eileen Nicole Simon.

Ms. Simon: I have changed a little bit what I submitted but it's essentially the same thing and I also think this is an issue of priority that needs to be investigated.

Developmental language disorder is the most serious handicap for children with autism. I am glad to see this discussed in the most recent revision of the strategic plan.

Autism has many causes, all of which may lead to injury of auditory processing centers in the brain stem.

The highest blood flow and metabolism in the brain have been measured in auditory nuclei of the mid-brain, the inferior colliculus, to be technical.

These highly active centers serve alerting and vigilance -- am I speaking too soft or too loud -- these highly active auditory centers serve alerting and vigilance functions and may be essential for normal attention to environmental events as well as learning to speak.

High blood flow and metabolism make these mid-brain auditory nuclei especially vulnerable to injury from prenatal exposure to alcohol, medications and other toxic substances and maybe ultrasound. I am talking about the auditory system.

These mid-brain auditory nuclei are also especially susceptible to injury during a difficult birth from oxygen insufficiency. Even after a normal, non-traumatic birth an infant can suffer a sudden lapse in respiration if the umbilical cord is clamped before the first breath.

Obstetric interventions are not always helpful. Clamping the umbilical cord can be most dangerous and I think we should investigate ultrasound and combinations of factors including vaccines, I think, two years ago I suggested a vaccine research strategy.

I hope that some of these ideas will eventually be discussed in public. Thank you.

Dr. Insel: Thank you very much. The next person to sign up for public comment is Lindsey Nebeker.

Ms. Nebeker: Good afternoon members of the committee. Once again I would like to thank you for providing us the opportunity to comment. My name is Lindsey Nebeker and I am personally representing myself as an individual diagnosed with autism.

I have a brother also diagnosed with brother and because of our drastic differences, I have a great understanding of the vastness of the spectrum and I strive to advocate for services which benefit the families and individuals across the entire spectrum.

I encourage that we continue to emphasize attention towards researching alternative forms of communication. My brother, who is 26, remains unable to speak and after trying speech therapy, sign language, PECS and AAC devices, he still struggles to communicate beyond a few basic sign language symbols.

His story is not entirely unique as there are a number of individuals with autism who struggle greatly with communication even with the advances research has made in exploring alternative communication methods.

As a female with autism, I also encourage that we continue the dialogue on research focusing on females on the autism spectrum and approaches to diagnostic assessments, treatments and other services specifically catered to females.

With further research we will be able to better identify the unique qualities and needs of females on the spectrum.

Now, I would like to introduce two relatively new yet important topics into the conversations in regards to autism research.

First topic: there has been a significant amount of concern and discussion on individuals with autism and the susceptibility to eating issues such as picky eating or dietary issues.

But what is not often brought up is the susceptibility to clinical eating disorders like anorexia, bulimia, EDNOS. Seven years ago, while undergoing intense treatment for anorexia, I made a revealing discovery. I discovered how my autism traits -- the rigidity, the rituals, the obsessive-compulsive behavior -- could have easily contributed to developing the eating disorder.

The similarity in the characteristics was striking and because of that striking correlation, I was convinced I was not the only one with autism who had gone through an eating disorder.

But what was amazing to me, after conducting thorough research, were the limited number of studies I was able to locate on autism and its relation to clinical eating disorders.

In the written copy you are provided with the links to the press articles containing a summary of the statistics and additional information on the only two studies I have been able to locate on the correlation between ASDs and clinical eating disorders -- one in the U.K. and one in the United States -- along with a suggested list of research goals.

Now not everyone in the autism spectrum is susceptible to developing an eating disorder, but out of the studies that have been done, the findings strongly suggest a possible correlation and performing more studies would solidify more answers.

And having a knowledge of this first hand, eating disorders can lead to a serious and have deadly consequences if left undetected and untreated, which is why it is crucial to include it in the conversation on autism research.

Second topic: I would also like to bring into the conversation a population which has received very little attention but definitely in existence -- the individuals who have an ASD and identifies with the lesbian, gay, bisexual, transgender and questioning population.

There have been very little information and research studies done which specifically focuses on the ASD and LGBTQ population, but after hearing the stories from several individuals, I have reason to believe that there are more youth and adults who fall into these categories yet are very afraid to speak up because of the possible negative consequences of treatment from school, family and the overall community.

To be bullied for your sexual orientation or gender identity can be tough. To be bullied for having a disability can be tough. To be bullied for both can be severely degrading, leaving these youth and adults still struggling to identify their role as an individual and be embraced by society.

By opening a dialogue and awareness on individuals who have an ASD and identifies with the LGBTQ community, we can figure out ways to research and develop effective strategies to promote unique approaches to therapy, interactive programs that embrace cultural understanding and pave a path to self-advocacy for these represented individuals.

In closing, as a reminder to all, the need for intervention and services continues to be crucial and focuses on services must continue not only in early childhood but throughout the entire lifespan.

Every child, adult and adolescent with an Autism spectrum disorder, no matter where they are on the spectrum, deserves to receive care, live to his or her full potential and are entitled to have a voice just like any other American citizen. Thank you.

Dr. Insel: Thank you very much and as I have said we will get back to each of these comments later in the day. The final person who has signed up for public comment is Idil Abdull and I think we do have slides, is that right or --? Okay.

Ms. Abdull: Good afternoon, everyone. Once again my name is Idil Abdull, I am from Somalia originally, and I live in Minneapolis where my son was born -- and I'm doing okay.

First I want to thank and recognize Dr. Thomas Insel and everyone on his staff, thank you so much for being so kind to our community.

I also want to thank you especially, Dr. Susan Daniels. You don't have it here, but I have a map of Somalia which is by the Indian Ocean, right near the equator and I have a map of Minnesota.

So then the question is: what do they have in common? Certainly not the weather. Somalia, it's on the Indian Ocean, it had, not now but 20 years ago, before the civil war, it had clean air, it probably had less than 10 factories in the whole country, the food was very fresh, literally from the farm or from the animal. Sometimes you will say, I am waiting for this cow to be milked and then I am just going to get that or I am waiting for the tomato from this farm.

And women were in a less stressful situation and environment with the extended family, not having a civil war, not having your husband, your brothers, people die, that you have to support.

In Minnesota everything is different, the culture is different. The pollution is different, the food has been in grocery stores for weeks, months, maybe even years -- I'm sorry if somebody is here from the food area -- and as you have heard by now, the Minnesota Department of Health, who I also want to recognize and thank, Commissioner Magnan and particularly Judy Punyko, the epidemiologist, had a report last year where they stated that children born in Minnesota to Somali parents were up to seven times higher to be diagnosed with autism in the preschool areas.

And autism in Somali children is mostly on the classic and severe end. Families having multiple, not one or two but three, four, five children with autism. So just imagine I have one with autism, if I had three, four, I would be pulling my hair daily. It's very, very difficult.

And from such an oral society, for good or bad, Somalis talk a lot, and Somali language was not even written until 1970s, so for our kids to be so severely autistic to the point that they are not talking, we are calling this the silent disease. It is as common as Somali tea in our community, from the young Somali American that wears their pants down, listening to hip-hop, to the older Somali American that is listening to BBC News, autism is common in our community.

And I want to just talk about -- I know I have five minutes -- and just three points. In autism services, that is, it's not enough and not equal in Minnesota and nationally. Health disparities exist always and autism is even higher for Somalis due to lack of language, different culture, and stigma from mental health associated with autism mostly in third world countries.

Therefore it is important for us to advocate for services for all children whether they are -- regardless of where they are on the spectrum and regardless of their parents' socioeconomic status.

Second point: autism resources. I think to a parent, it is extremely confusing, it's scattered and it's scarce. And parents are left to navigate such a very complex and confusing system, not knowing what your child needs, is it ABA, is it RDI? I mean, there are so many acronyms you get a headache just thinking about it and if you don't speak the language, it's not your -- you are not from here, that's even harder for us.

And so I ask you, this committee, and I don't envy your job, if there was a way a national hub that parents of no matter where their ethnicity was could perhaps call or contact and that could help you navigate the system in terms of services, what is evidence-based, because sometimes evidence-based is in the eyes of the person who is presenting the information, that would be -- and it must be services that are culturally and linguistically appropriate.

Autism research is my third one. I think it's underfunded. I don't think there's enough interest. There's not enough awareness. And I was watching that Stand Up to Cancer that everybody probably watched and people were so united. With autism it is not like that. There is so much controversy, there's so many things that we don't know what causes -- I think we need to be united and try to figure out what is causing this and so I ask you, I ask you as you sit here and you are mostly scientists and researchers, if you want to know the answer to autism, come and study us. This is your gold mine. What is it about us that seems to attract this devastating disorder?

Somali autism families, it's altering our dreams, it's draining us emotionally, physically and mentally. You know we came to this country, like those of you immigrants before us with the hope of life, liberty and the pursuit of happiness, but we encountered a devastating disorder that has changed everything.

Nevertheless, I believe that everything happens for a reason and, who knows? The answer to autism, to solving this puzzle may be found in a Somali kid. That's the mom of me. I am pissed off all the time.

The advocate of me sees the hope, sees the help and I am hopeful that there is a light, not at the end of this tunnel, but in the middle of this tunnel, maybe in the forefront, with people like you, there has got to be a light in this tunnel and, united, we will get there. Autism will not remain a mystery. It will be solved for all of our children's sake.

I thank you so much. May God bless you and may God bless all children with autism. Thank you.

Dr. Insel: Thank you, Mrs. Abdull. We will come back to talk more about this later. I think you have come a long way and we appreciate your joining us to share this. It's an issue that has surfaced before as we have looked for clusters and wondering whether there is an opportunity there so I think we will make sure there is time towards the end of the day to have a further conversation about this.

We are moving into the part of the agenda that has to do with various meeting updates and because we are so far behind time, I think we may need to switch a little bit the agenda.

One of the meetings that we wanted to hear about was a meeting that was on genetic risk factors for Autism spectrum disorders that was held in September, and Stephen Scherer was going to do this with Geri Dawson but they were -- Stephen wasn't able to join us here but he was going to call in at 1:50, so, Stephen, are you on the phone now?

Maybe not. Maybe he hasn't joined us yet but if not, Geri, is it okay then if we move ahead, and we will loop back, maybe by two he will be with us. Do we know any more about whether he has called in?

Okay, so we will go back to the

original schedule and we will hear about the NICHD workshop on disparities, something we have just been hearing a little about already, from Regina James.

Dr. James: Good afternoon. Well, partly Regina James and partly Alice Kau. Good afternoon. My name is Regina James and I am the Director of the Division of Special Populations here at NICHD, and part of our mission in the division of special populations involves information dissemination and information sharing with the academic community and the lay community regarding research efforts as it relates to maternal and child health disparities.

So in this capacity of working with and listening to various communities, a recurrent question came to our attention and that was: what research efforts are underway to address children who are not being either picked up or appropriately diagnosed with autism?

There was a sense that many children were being misdiagnosed or not diagnosed at all and that this delay was putting the child at risk for poorer health outcomes and I think I have just moved all the way. I am not using slides.

Because these questions dealt with potential differences in health outcomes for certain communities -- racial, ethnic, rural communities -- our division wanted to try and address these concerns with input from the research community.

We initially reviewed currently funded research projects to see what were the ongoing efforts, particularly looking at assessment and diagnosis in underserved communities. There were a few research projects that were under way but there were not many.

So in moving forward we decided to call upon our colleagues here at NIH and experts in the field to help us address this concern. I initially spoke with Alice Kau who manages our autism portfolio at NICHD. I then shared this idea with the NIH Autism Coordinating Committee.

Given that autism research is a trans-NIH, effort we wanted to have all hands on deck to receive input. They were very supportive and not only did they volunteer suggested speakers but they also helped set the agenda.

And so with this team approach, we were successfully able to identify and bring together a cadre of investigators that not only provided research updates but suggestions and recommendations on how we could address this important question.

So I am going to ask Alice to come up and share the specifics on what those recommendations were.

Dr. Kau: I would like to have those slides back if someone could help me. Thank you.

Dr. Insel: No, go the other direction. It's the previous slide set. Okay that's the end. There we go. Good.

Dr. Kau: All right. Thank you, Regina. So here is the list of the speakers who came to our symposium and here is the list of the planning committee. So first of all, when we speak about disparities, we need to know that diagnosing autism in all children of very young age remains challenging.

But the children from culturally and linguistically and other diverse backgrounds pose additional challenges.

Now here is additional backgrounds that I listed here. Autism has repercussions throughout all aspects of family members' lives and all the speakers emphasized that we should see autism as a family problem, not as an individual problem.

Secondly, early diagnosis is vital for receiving very likely the long-term benefits of early intervention and autism is often diagnosed several years after the onset of symptoms and we all know this, and these patterns of delayed and sometimes misdiagnosis, like Regina mentioned, may be exacerbated among medically underserved racial and ethnic minorities.

And just to review you some of the backgrounds of the disparity phenomenon, children of ethnic minorities and low SES are screened and diagnosed later than children from higher SES and non-minority families.

There are also disparities based on geography, school system, parental social class, education and patient age.

Gender-based disparity. Research has shown that when equally qualified for reaching a diagnosis more boys are diagnosed than girls, so the record review shows the girls are meeting the criteria but they are not being picked up.

And also among low resources, minority families, especially when they speak another language, those children tend to be diagnosed later and receive less services.

Finally, disparities are related to unequal application and dissemination of knowledge, rather than with lack of information.

So the important thing is that we apply what we know to all the children regardless of where they are from.

The goals of this symposium are twofold. One, to examine the barriers of this disparity phenomenon, and second, to formulate a diagnosis to reduce the disparities.

So the first areas of disparity or barriers that I have kind of synthesized is among the healthcare systems. Disparity in reimbursements between different insurance plans, Medicaid and hospitals all contribute to disparities.

Cultural and language barriers when -- there are numerous examples of the barriers between the providers and the patients and not knowing, not understanding each other in communicating contribute to the barrier.

The next is the lack of buy-in among providers for autism screening. Physicians are very busy and when the whole healthcare system is not set up to accommodate or to reimburse such services, it's just very hard for them to do it.

And finally, physicians' unwillingness to give bad news and lack of knowledge about treatment services and just even how to convey the findings posed an obstacle.

The next categories of barriers that I synthesized is from the side of families. A lot of the times families or parents are not aware of developmental milestones. They just don't know that the kids are delayed and there are also different cultural expectations of development at different ages, so there are cultural factors involved and some parents, sometimes, I think, they don't want to admit that there could be problems in their young children. They are waiting, maybe some day the problem will go away.

And then in some families they are just not convinced how important it is to figure out -- there's a checklist. So that's another barrier.

Finally, I also identified some barriers in the research community. It's just things that -- research are ongoing. We don't have a definitive answer in many of the areas.

First, there's a lack of consensus on the best ages to screen, lack of consensus on autism-specific screening tools. There are several out there but everyone disagrees with which one is the best.

Dr. Insel: Alice, we are running pretty short on time. So --

Dr. Kau: Okay, I am almost done.

Dr. Insel: Okay.

Dr. Kau: Lack of validated diagnostic tools for children less than two years of age and this is getting better with the ADOS, the version just coming up, just came up.

Lack of a cross-cultural validated broadband screening tools and lack of reliable biomarkers for screening and diagnosis. If we had a biomarker, things would be much easier.

So those are some of the needs that we identified. More clinicians, researchers of diverse background and language, autism researchers and service providers with a greater presence and role in the community. And some of the research indicates that if the researchers go into the community then it is easier to pick up children from different backgrounds.

Wider varieties of autism screening tools. Some recommend that we should have tools that the parents can use at home so they can check out, see if the development is on target.

Autism screening mandated and

reimbursed. Recognition that autism is a family problem, not an individual problem and that each family is unique.

Recommendations -- establish a clear and more systematic route for receiving diagnostic and treatment services after screening because we need to lay out the path, so if I am screening where do we go? And it's very important.

Obtain more information on different cultural views on autism and child development. Gain more information on how clinicians should present the results of screening and diagnosis to patients of different cultures.

Educate medical communities about autism symptoms and the value of formal screening.

Encourage research to address questions on racial barriers to screening diagnosis and services. Obtain a better sense of the number of false negatives in autism screening. I think it's important to have effort in this area to find out how many are missed in early screening.

And publish all tools for families in multiple languages. Increase parent training in implementing meaningful interventions at home and that will reduce the disparity in having to go to a clinic to get treatment. That's all.

Dr. Insel: Okay. Thanks to both Alice and Regina for both putting this meeting together and also for reporting out on it. Stephen Scherer is on the phone, I believe, is that right

Dr. Scherer: Yes, I am.

Dr. Insel: Great, welcome. So we will move to your presentation next and then we will loop back to hear from David Armstrong in a few minutes. Geri, do you want to introduce Dr. Scherer?

Dr. Dawson: Hi, Steve. So this is a conference that Stephen Scherer, Andy Scherer and I organized on the translation of genetics into diagnostics, and Stephen is a well-known scientist in the area of genetics, has really spearheaded some of the major findings in the research on CNVs and the discovery of rare variants and has been involved in some of the major papers coming out in Nature over the last year.

He is located up in Toronto and, Steve, I am going to let you take it away.

Dr. Scherer: Okay. Thank you. I was actually on the line earlier. I think I was trapped in my BlackBerry. I could hear you but you couldn't hear me. So thank you for the opportunity to give you an update on the meeting.

Dr. Dawson: Steve, we've got -- we are sort of behind schedule so we would love to hold you to something under 10 minutes if we can.

Dr. Scherer: Yes, should be fine.

Dr. Insel: Thanks.

Dr. Scherer: So, we had a gathering of experts from science, medicine, regulatory agencies and business, stakeholders, philanthropists, parents and individuals with Autism spectrum disorder. The meeting took place in September in Toronto and the objective was to consider how recent advances in genetic and genomic information might be applied for the benefit to those affected individuals with Autism spectrum disorder or ASD.

This multi-disciplinary group numbered about 100. There were seven countries represented. The program was organized around four perspectives. First, the science; second, the industry, healthcare and regulatory issues; third, clinical genetics, risk communication and ethics; and fourth, community impact.

Each section comprised presentations from the invited speakers as well as breakout sessions and open discussion and summaries of key issues.

Dr. Alan Guttmacher provided the keynote address, studying autism in history and vision of the genome era and Geri Dawson and I served as the host of the meeting and we asked participants from the respective perspectives to consider these two questions: is the science of autism ready for translation to clinical diagnostics and secondly, how can the various stakeholders work together to accelerate progress?

We also challenged the participants to communicate and also to be -- (telephonic interference).

The approach to genetic investigations both for research and diagnostics has really changed dramatically in the last five years with the advent of microarrays to screen genomes for variations and single bases for larger segments of the genome copy number variations.

In addition, rapid advances in whole

genome sequencing are bringing this technology towards routine application in the near, foreseeable future.

With these tools, conditions such as ASD are revealing their multiple and complex genetic underpinnings, allowing a handle with which to understand the underlying biology that leads to these collection of phenotypes.

The shift from primarily genetic analyses to whole genome analyses has been the key to these fruitful developments and this was what we discussed in the meeting. The technology is or will soon also sufficiently be robust to provide reliable data, and really the dilemma that we discussed at the meeting is interpreting what this data means, delivering the information to create knowledge and to generate value for the families who are seeking the information.

The complicating parameters that we talked about involved issues of heterogeneity, volume of demand for analysis, distinguishing data relevant to the question at hand, recognizing variations of unknown significance, dealing with incidental findings and just too much information and in some cases negative outcomes.

Clearly the greatest concern of the conference participants was that we are not at all prepared for the communication needs to ensue from this paradigm shift, moving to whole genome analysis.

At the same time the speakers throughout the conference acknowledged the potential for useful and helpful information to derive from these analyses. Some of this was anecdotal, some was more empirical but what was really discussed was the need to have this genomic profile information presented in a comprehensive way and coupling that to longitudinal studies studying the extensive phenotypes and their contributions.

One very interesting presentation followed about 250 consecutive ASD diagnoses from Newfoundland, Canada, using detailed phenotyping including imaging, and they showed that 25 percent of individuals had dysmorphology or additional clinical complexity, and in these individuals about 30 percent had so-called positive microarray results also, so these numbers are actually quite high.

So I think one of the other things that came out which was interesting was the recent papers that came out from the American College of Medical Genetics, the Canadian College of Medical Genetics and the International Standard Cytogenomic Array Consortium or ISCA, that essentially have indicated that running these microarrays as genome scans has become the standard of care for autism diagnosis, and this was discussed, the relevance at the meeting.

So I will just now summarize in a few -- my own comments. This came out of the wrap-up meeting reports from the breakout sessions.

The first question, is the science ready? It was unanimously agreed on that autism is complex. There are monogenic forms, some complex forms. But it was agreed on that for the highly penetrant genes that have been identified, for example SHANK2, SHANK3, neurexin-1, neuroligin-3 and 4, more recently the PTCHD1 gene, de novo rare copy number variants and some of the rare inherited CNVs like maternal chromosome 15 CNVs, that in fact the science was ready.

And this would constitute about 10 percent of consecutive cases from most studies. For common variants of combinations of common variants, it was thought that the data was still somewhat rudimentary, since the relative risks associated were still quite small.

Interestingly, the technologies were never really considered an issue. It was deemed that the technologies were high quality and could be reproducible across laboratories.

In saying this, it was thought that the question of "is the science ready" was really a moot one because everything is already happening in the diagnostic laboratories. Companies and diagnostic labs presently and continuously stress how much they depend on academic publications to identify new tests and how they use the statistics.

In some cases, some of the attendees thought perhaps they were overusing the statistics. So, important to publishing high quality data, data depositions in the right databases and proper media releases around the relevance of the findings was discussed extensively.

There is also much discussion how the field was moving very, very rapidly and moving towards the discovery of rare variants as opposed to common variants, at least for autism. And including the sequencing of exomes or the genes of the genomes and ultimately to whole genomes.

There was one big NIH-led project, sequencing approximately 1,000 genomes and controls, and also an Ontario project which I am leading, sequencing an equivalent number of 1,000 ASD cases and controls.

But it was discussed that this is not going to be enough. We probably need something on the order of 14,000 cases and controls sequenced to fully dissect the genetic etiology of autism and this was something that should be done.

Challenges in translating the science, really around volume of the demand of tests and the lack of professionals to interpret the data fully. Also, the dynamic nature of the data being an issue, so once you have a genome sequence or microarray that becomes relatively static, genetic data but the databases that you compare against are constantly changing.

Phenotype assessment is a bottleneck. Variants of unknown clinical significance came up over and over and over again and also the overlap of some of the genes identified in other neuropsychiatric disorders, so, for example, SHANK3 and neurexin-1 are also coming up in schizophrenia and other conditions.

So of course it was discussed that ultimately, as higher resolution tests come out, there will be even more complexity in the data, the nature of rare variants lead to insufficient or improper use of controls. I think this was an issue that needed resolution. There needs to be more investment in generating data from population controls.

Okay, so just a last, a few more comments. So how can the various stakeholders work together to accelerate progress? It was thought that the scientists involved in generating the primary discovery data needed to be more involved in advisory roles of how these tests are developed and how the data is interpreted.

Educational efforts needed to initially be focused on the clinicians ordering the tests, and particularly for autism, this could come from many different disciplines: for example, neurology, psychiatry, clinical genetics or primary healthcare physicians, each having their own biases and abilities to understand what they should do.

Of course, one of the challenges is to deliver the most accurate information and this was something discussed by genetic counselors, but with genome-wide data eventually becoming static in comparison to the database, how does one do this in the most dynamic and accurate way?

It was also discussed to develop a specific database for autism variants with population frequencies and attributable risk which really does not exist yet.

Ultimately, we need more data, approximately perhaps, maybe 15 percent of the variants in autism are identified, so there was a recommendation that a very large international sequencing project would be timely. Stakeholders could be more proactive to work with companies and hospitals in delivering these tests to make sure they deliver real benefits for the families and individuals involved.

And there was a sense that some of the companies were actually overstating the yields in their tests and perhaps over-interpreting the results.

In the immediate term the greatest impact will be for early diagnosis, allowing early interventions, but there needs to be more investment across the jurisdictions to make sure a seamless process is in place to allow this to happen.

For example, what happens after the family gets their so-called genetic diagnosis?

Is there a system in place to follow the steps forward? This will also eventually apply to things like therapeutics, companion drugs to the genetic tests.

All stakeholders need to develop appropriate communication strategies to educate and inform the community, the example of community focus groups, risk messaging, concerns with individuals with autism.

And I would just close by sharing something with you that I learned at the meeting that I had not thought of before. One of our presenters was an adult with Asperger's, and as Geri and I did at the beginning of the meeting we emphasized the importance of communication and he also emphasized this, that communication is key, but he reminded us that we need to think about not only communicating to the general lay public these important results, but also to the Autism spectrum disorder lay public, that is adults with Asperger's or ASD or parents who quite often may be on the broader autism phenotype, because they, along with much of the rest of the world, will contextualize this genetic and genomic information much differently than scientists, clinicians and funders do.

Thank you very much.

Dr. Insel: Thank you Steve. Geri, go ahead.

Dr. Dawson: I'll be quick. I just want to underscore the potential clinical importance of this kind of investigation for individuals with autism and their families and one Steve already mentioned which is probably the kind of earliest application, is that it would be wonderful to be able to start interventions very early in life and this potentially could allow us to do that and then in that way provide the best outcomes and reach the greatest potential for people with autism.

The second that was, I think, very

illuminating at the conference, in the case series that Steve mentioned following cases that have rare mutations, it turns out that different rare mutations are associated with risk for different medical comorbidities, so some individuals are more at risks for GI problems. There are actually risks for certain cancers in cases, and some with seizures and so having information about potential risks that could be associated with your specific genetic etiology could be important.

And then finally, as we know, the heterogeneity in autism is great and if we are going to be able to target our interventions in a reasonable way, in a personalized way, then having some background about genetic etiology could very much allow us to develop treatments that are more targeted for specific subpopulations.

Dr. Insel: Great. Going to need to move on. So we are going to hear about -- thanks, Steve, very much for joining us. It's very interesting. We are going to hear from David Armstrong, who is representing the Environmental Health Sciences Institute and report out on a meeting on autism and the environment that happened also in early September.

Dr. Armstrong: Hi there, so as Tom said, I am Dave Armstrong from the NIEHS and a few weeks ago we had a meeting down in Raleigh-Durham that was organized by Autism Speaks and the extramural division of our institute. It included people from the autism community, government scientists and people from -- university scientists all of whom were -- not all of whom were working on autism but all of whom were interested in what they could bring to bear, if there were any -- and the principle question we were trying to ask is, are there any novel opportunities to accelerate research on environmental factors in autism?

And so the three questions we asked

are listed here. I just want to emphasize that we interpret environment broadly, so industrial, agricultural chemicals. The CDC measures over 200 chemicals reliably in people's blood that they are exposed to, and as someone mentioned earlier, there's actually thousands that are produced every year and haven't been tested.

Just to give you one example that has been in the news, several of these industrial chemicals have weak estrogenic activity. They are endocrine disruptors. And as we have learned recently, it's estrogen, paradoxically, that drives masculinization of the developing brain.

And so it's possible -- some people have compared autism to over-masculinization of the brain and so one concern would be that exposure to some of these estrogen disruptors could be contributing.

Another important point I needed to make is that it's not either/or. It's not genes or environment. It's always genes that are in an environment and so, even though an exposure might not directly cause a specific defect in the nervous system, it might -- some genes might make you more or less susceptible to those exposures.

And again, from the point of view of comorbidities and interactions, it's important to consider what you eat and what microorganisms you have in your gut, what pharmaceuticals you are exposed to, et cetera.

So the challenges that, from our point of view, at this meeting, were that there is a lack of chemical exposure data from humans and many new prospective epidemiological studies that are beginning now are starting -- have the potential of identifying some of these exposures. One out of UC Davis where Marjorie is from, has already started to identify people who -- correlations between exposures and people's susceptibility to showing Autism spectrum disorders.

And the other thing of course is that even brief exposures can have lasting impacts on brain structure.

For most of the scientists like me who work at the cellular and molecular level, the real problem for us in trying to help understand the origins of autism is the lack of cellular and molecular phenotypes from humans, and, of course, we are hoping that recent imaging studies like the one you heard this morning will start to identify the populations of neurons in the brain that are dysfunctional in children and also the genetic association studies you just heard about from Steve will start to identify some of the molecules that have been disrupted and the genes and their proteins that have been disrupted in the disease and that would give us a handle, because in the absence of animal models or cellular assays it is hard to screen toxicants.

Just to give you an example of how difficult the problem is, to prove something is a carcinogen actually takes two years and costs $2 million and that, you are assaying whether a tumor develops in the side of a mouse.

And so you can imagine how much more time-consuming and expensive it will be if we just have to screen all chemicals against behavior, because it's not even clear yet exactly, although many behavioral correlates in mice, defects in social behavior have been identified, it's not exactly clear how they map onto the human condition.

And that is why we are hoping that some of these genetic changes, once they are identified in mice, will be able to allow us to say this is the behavior that maps most closely and then it will be easier to screen some of these chemicals.

And the NIH is funding a collaborative cross to develop mice, inbred strains of mice, who, if they show these behaviors, it will be easier to find out what genes are associated with these changes.

Another thing I want to draw your attention to is a government partnership called Tox21. You can Google Tox21 and find it right away, but it is between the National Toxicology Program, the Environmental Protection Agency, the Food and Drug Administration and the National Chemical Genetics Center here at NIH.

And they have developed robotics to screen 1,500 of the most common or most highly suspected environmental chemicals in a cell model. So if you can -- and these are in 1,500 well plates.

So if you have an assay that you can run on a few hundred cells and the output is fluorescence, then we could start to look for things. So for example one thing I have been involved in is setting up is screening for oxytocin. As you know, recently the oxytocin receptor in the brain has been implicated in the development of social behaviors and we have cloned that receptor and put it into a stable cell line and put in a fluorescent indicator of calcium signal which it signals through, and so we are up to -- in the flipper we are up to 92 well plates and we're hoping to scale up.

So in a few weeks this will go up to the NCGC and they will start to ask whether there are any chemicals in the environment that disrupt signaling through the oxytocin receptor and that would get us a foot in the door to move forward.

Dr. Insel: We are going to have to wind this up pretty quickly, David.

Dr. Armstrong: And finally, there is a hope that pluripotent stem cells, obviously you can't take neurons and put them in these small plates but if you could differentiate pluripotent stem cells especially taken from some of the patients then that would be another way of moving forward.

So I will skip this slide because in fact the autism community has been very fast at identifying the complexities of these kinds of disorders, but I just want to emphasize the middle one, using a full range of model organisms, and just remind you how important it has been using Drosophila and C. elegans, the little worm, in Parkinson's cases to identify environmental toxicants that influence disease progression, because we know the target, it's dopaminergic neurons and we can screen much faster and much more cheaply to identify things that disrupt the survival of dopaminergic neurons.

So the strategies for moving forward are again common to -- everyone is aware of these. We need better exposure data. We need better bioinformatics to integrate the kind of data that Steve is talking about with exposure data and from other examples, disorders, we need better model systems as I just alluded to, where we can study mechanistically the effects on   synapses and immune responses for example and better infrastructure for sharing this data. Thanks.

Dr. Insel: Great. Thank you.

We are going to move on to hear about a Simons Foundation meeting that was held in September from Gerry Fischbach.

Dr. Fischbach: So I will try and be brief and will try and skip through slides quickly. Our goal of the foundation is to improve the quality of life of people on the autism spectrum.

Ari, I have been very much influenced by our discussion in New York about language being used and I agree with you.

That is our goal, and right now we are focused on genetics, molecular mechanisms and how that is translated into clinical phenotype neural circuits and behavior.

So what I am going to tell you about is the result of our second annual meeting held in September in Washington. We now support about 100 investigators. This is different from the Simons Simplex Collection and other major resources that we have gathered for the research community.

These are investigators, many of them new to the field of autism, and at each meeting we have about a third of them present. Now please don't try and read this but this is available if anybody wants it. These are the list of speakers at the meeting, a two-day meeting and I will tell you about selective results that I found particularly interesting.

First, you have heard about copy number variants and rare variants. These are differences in the genome that were completely unexpected five years ago and in the last three years, these variants have become associated with autism in unusual ways.

You think of inheriting one gene from your mother and one from your father. But during the process of forming sperm and eggs, there are rearrangements of those gametes so in some cases a particular segment of the DNA is deleted and in some cases it's duplicated so that you don't inherit exactly the same genes your mother and father have.

And in the past few years it has become realized this is the major source of variation in the human genome, not spelling errors, what makes you different from your neighbor are how many deletions and duplications you have.

This is just a picture of one. I don't know if I can point to it, but traveling along the genome where these are all about the same, it means that the proband, the child with autism has the same genes as the mother and the father but here, at this particular segment of the genome, there is a deletion and this seems to be, in this case, unique to the proband, not seen in siblings or in the parents.

And here is a case where traveling

along the genome, the probes show that the proband has more of this segment of the genome. It's a duplication. And the challenge now is to find out which one of these deletions or duplications is related to autism.

They are individually rare in autistic cases, as you have heard, occurring maybe in one in 200 or one in 100, but there may be many of them, and altogether they may be quite common.

So this was a slide presented by Evan Eichler at the meeting and I just want to point -- call attention to the fact that he now estimates, and others do as well, that large copy number variants may account for 10 percent of all idiopathic, that is autism of unknown cause, and that smaller ones may account for another 10 percent.

And then once we get down to the level of DNA sequencing, looking for new small segments that are not present in mother and father, it may be as high as 50 percent.

Now imagine that. Three years ago we had no idea of the source of variation in the genome and now this is going to be food for thought and the hope is that although there may be 100 or 200 of these risk factors, that they will converge on one or a few processes that we can understand better to understand the environmental influences, the effect of therapies, biomarkers for predicting what are the really vulnerable populations, and most importantly who might develop side effects from particular therapies.

Here's one pathway which was discussed extensively at the meeting and you should take this home as a lesson. This was presented by Tom Sudhof and he has studied a group of proteins called neurexins and another group called neuroligins.

They were initially thought to be cell adhesion molecules. But now one realizes that they are much more than that. They instruct synapses, the junctions between nerve cells, on whether to become excitatory or inhibitory and they instruct them on various forms of plasticity and they connect with networks of molecules in the cell.

So you can imagine many of these risk factors converging on the neuroligin neurexin system at synapses in the brain. That may be one of a few I hope, only a few systems that we will focus on.

I am ending with this notion of imaging. We have to find out where these genetic risk factors act in the nervous system and when they act during development: prenatally, post-natally, one of many critical periods.

And we heard a wonderful talk from Randy Buckner at Harvard. This is just an illustrative example of an image showing the language area in the brain in the left hemisphere, very active when individuals are speaking and understanding words.

I am not showing it for localization but I am showing it because Randy's main point, as emphasized by Kevin Pelphrey, is that there is enormous variation in the human brain. This in some people could be half the size or twice the size. It could be a few millimeters to the right or left. These things are not as precise as you might gather.

And one thing that has held up autism research is that all of the imaging studies use very small numbers of individuals. It's hard to gather vulnerable people of the right sort and image them, especially young children who are difficult to study in the magnet.

So Randy has developed a really extraordinary idea. It's not a system, it's an idea. He has gotten about eight different places in the Boston area to cooperate and anyone who has an MRI, he tacks on a 15-minute quick survey relevant to autism.

And he is studying what is called

diffusion-weighted imaging and rapid functional MRI and he has now screened 2,200 individuals and it is quite remarkable that this population is being built up and we will have a much better notion of normal variation in the general population and we hope this will be used in a similar way to study individuals on the autism spectrum. So it's going to be a great resource for individuals around the country.

I am not going to go through this last bit but I can't help but mention a fellow at the University of North Carolina, Philpot, has studied a particular gene, you don't really have to remember the name of it, but I will say something about it now, because it bears out what I have just said before.

In this particular case the gene is called Ube3a and in the brain, the gene that one inherits from one's father is turned off by an epigenetic mechanism so only the maternal gene is expressed in the brain.

And this has been identified, this gene has been identified as a risk factor in Angelman Syndrome and more recently in autism and it is deleted in Angelman Syndrome and it is duplicated, just as I showed you earlier, it is duplicated in cases of autism.

And the thing that is quite remarkable, that is so hopeful here, is that Philpot has developed -- is trying to develop drugs that will turn on this Ube3a gene in Angelman Syndrome to make up for its lack, and different drugs which will turn off the extra Ube3a gene in the brains of people with autism.

And this of course will take great care in identifying who is at risk here, but it is one of the first examples I know of screening for small molecules based on this type of genetic information, and the results he showed at the meeting were extremely hopeful. Thanks.

Dr. Insel: Very good. Thanks Gerry.

We are going to move on to hear what is both a research update from a meeting as well as a new program or grant that's been funded that was the reason for the meeting. So Ann Wagner from NIMH is quickly going to tell us about this project.

Dr. Wagner: Hello. So I will be brief but I will tell you how you can get more information. So earlier this year NIMH issued a request for proposals for a grant to conduct the study of health outcomes of children with autism and their families and after an open and fair competition as we say in federal contract speak, the award was made to the Lewin Group. The award is $4.2 million over two years, so it's a two-year study.

The overall goal here is to use existing administrative data to further our understanding of ASD including variables related to diagnosis, health, and health care utilization of children with ASD and their families.

So we wanted to address a gap in our knowledge base which is that what little research there is, is usually done on clinical samples and small populations so this would be a population-based study making use of a large dataset, or several large datasets as it turns out.

This is the study team, the team leads, it's a large team but these are the leads. Principal investigator is Taylor Dennen who is a health economist and has I think 30 years of experience in health services research.

Anjali Jain is a pediatrician and also health services researcher. Craig Newschaffer, many of you already know from his work in autism surveillance and autism risk factors and Donna Spencer is also a health services researcher with a lot of experience managing large datasets.

There were advantages to this contract proposal. They are making use of three large datasets with health information of over 70 million Americans under the age of 65.

These are commercial and employer-based health care insurance companies that are under a large umbrella company. So this is claims data, electronic medical records, pharmacy data, sociodemographics. So they are not going to be contacting families or individuals but this is all existing data.

And a big advantage to this particular group is that they have the ability to link family members within their dataset. And I also should have put on here that they have the ability to track longitudinally so they are going to look at a sample that has claims from 2001 to 2009.

So the study objectives are: identify a large and diverse number of children with ASD and a control cohort, along with their families. So this is primarily a descriptive study at this point looking at the characteristics of the population, geographic and socioeconomic distributions and figure out the extent of the longitudinal data within this dataset.

They also will utilize a chart extraction methodology to validate the accuracy of the ASD diagnosis as well as other diagnoses of interest.

So this in and of itself I think is going to be a methods development project which will inform the field in terms of future ability to use these kinds of datasets.

So they will compare the health trajectories of children with ASD and their families, and similar families without a child with ASD, describe and compare the use of health services by the two groups of families and assess the utility of claims data for future studies of risk factors for ASD.

So part of this is to find out what data that might be relevant to risk factors actually exists in this kind of a dataset and how confident one can be sure of its completeness and accuracy.

So there is a need for stakeholder input and obviously this is the -- we have heard a lot today about health concerns. I have been taking notes a lot today, and then there are also scientific reasons why this is important.

So the Lewin Group has convened an External Advisory Committee that consists of individuals with ASD, parents of children with ASD, care providers and researchers to meet and provide their expertise and guidance several time points over the course of the two years. I think they have six meetings planned and then there will be subgroups probably meeting as they go.

This advisory committee is chaired by Francisca Azocar, who is a clinical psychologist actually by training and also is quite experienced in health services research.

And then NIMH is holding a

stakeholders' meeting. The committee members should have received this announcement about this meeting. It's scheduled for next Friday, from 2:00 to 4:00 in Rockville at the neuroscience center. It's also open -- people can participate by webinar so we have been trying to distribute the information about this widely and this is the link to register.

So if people want more information about this you can go to that link or ask me but we really would like participation and to hear from people what they think the most important health issues are and also what the potential challenges to trying to figure this out with this kind of dataset might be.

Dr. Insel: Great. Thank you very much Anne.

Yes, Helen.

Ms. Blackwell: Ann, I have a quick question.

Dr. Wagner: Oh sure.

Ms. Blackwell: I just wondered, and

maybe you haven't decided yet, but when you used the term health services, are you looking at medical services or community-based services or --

Dr. Wagner: No this is health services, so these are medical insurance claims. So it's anything --

Ms. Blackwell: Okay. Excellent.

Dr. Wagner: that will show up in a medical --

Ms. Blackwell: So in Medicaid you would just be looking at claims for physical health for example?

Dr. Wagner: Yes and this won't be used in Medicaid.

Dr. Insel: It wouldn't be just physically health though, it would be also any mental health --

Dr. Wagner: This will be -- right, so these are commercial databases and there will be information about behavioral health in there.

Dr. Insel: The last update we wanted you to hear about was from NDAR and Mike Huerta will take us through this at lightning pace.

Dr. Huerta: Yes indeed. Thanks everybody. Something that Gerry mentioned this morning, the notion of public and private interests getting together to develop standards resonated with me. That is what we spent much of the last year on, working with Autism Speaks, the Simons Foundation and others.

You can categorize what we have done in the last year as two things really. One is increasing the quality and usability of the data in NDAR and available through NDAR and the other is increasing the quantity of data available.

With regard to the former, as I mentioned, much of this has been done through developing standards and promoting the use of standards such as GUIDs for research subjects.

We have worked very hard to enhance our data dictionaries so the data are precisely defined so anybody going to NDAR knows exactly what they are looking at.

And we have worked with Autism Speaks, Simons Foundation and IAN in our informatics consortium to develop a common computing framework, including core data elements, imaging standards and so forth.

We have also worked on increasing the amount of data available and one of the ways we have done that is through our federation, and in 2010 we federated with AGRE, IAN, ATP, the Autism Tissue Program, and the Pediatric MRI Data Repository and you can see for 2011 and 2012 we are moving forward beyond those.

In addition to federating, we have increased the amount of data streaming into NDAR greatly. We are now targeted to receive data from 45,000 research subjects, from 60 NIH projects including the ACEs, ARRA grants and others.

And we are now actually sharing these data, specifically data that reside in NDAR that are being shared right now, are shown here. The red line is what you should pay attention to most, I guess, and you can see in the far right hand column we are now sharing data from over 10,000 research subjects. These are data that researchers can go into and have access to. Of course they have got to go through our data access committee and so forth.

Next month we plan to increase this by a couple of thousand subjects and now you can see we are starting to share data from ARRA and the pediatric MRI data repository and we are on track to share data from some 14,000 subjects in April. These are all in the pipeline and this is the data that will be shared in April.

So we have come a long way. The final slide is really the most exciting and that is due to the commitment and support from NIMH as well as NINDS, NICHD and NIEHS, we are poised now to meet Objective 7H of this group and that is to receive and serve up data from some 90 percent of newly initiated projects starting in 2012. So with that, I thank you for your attention.

Dr. Insel: Wow. That was fast. Thanks Mike. It's an amazing sign of progress. Alison, you get to make a comment because the last time I think you were the most critical so it's --

Dr. Armstrong: I think you have done a great job in collecting more data. I want to commend you on that. I just -- it looked like most of the data that was coming in or the data that were coming were from the NIH and the private funders. But what about the other federal funders, like the CDC and HRSA and CMS and DOE and --

Dr. Huerta: Yes, so we have had initial conversations with all of these other agencies but we had to wait until we had the fiscal commitment to know whether we were going to be able to do that or not to actually start turning the key on these things. And we have been contacted recently by some of these -- I won't name them at the moment because I might mix them up -- some of these agencies, so that's going to happen and that's a plan for 2012 and 2011, federating with those sources.

All right. Yes?

Dr. Fischbach: Mike, are GUIDs now required by all NIMH, well actually all NIH-funded investigators?

Dr. Huerta: So we now have in place the expectation that anybody submitting a grant application that comes into any of the standing program announcements soliciting autism research, will submit their data to NDAR and part of that is needing to use a GUID. I should mention we have over 39,000 GUIDs registered in NDAR right now.

It is possible for somebody to come in with an unsolicited application but our program staff, we work very closely with, they are very good and very vigilant about this and I am guessing that very few of those would get through without getting GUIDs signed.

Good question.

Dr. Insel: Okay well this was a lightning round of going through a lot of recent meetings. It's remarkable how many different conferences have been held in the last eight weeks. We have a lot of committee business to do but I am going to recommend that before we start on that we take a break for about 10 minutes, reconvene here right at 3 o'clock and then we will start on the business that we have to take care of.

(Whereupon, the committee members took a brief break starting at 2:51 p.m. and reconvening at 3:01 p.m.)

Dr. Insel: Everybody is having far too much fun here. We need to get back to work.

Ms. Blackwell: Yes and we are going to continue the fun with our next presentation.

Dr. Insel: Oh, that's just what we wanted to hear. Ellen is going to take us through the workshop update from the Services Subcommittee. And I guess you have help in this from Lee Grossman is that right?

Ms. Blackwell: Well Lee and I are cheerleaders for this meeting because this is truly, I wasn't just joking, going to be a fun IACC meeting. I really believe that and we have an incredible lineup of speakers who will be with us on November 8.

We will be at the Rockville Hilton. People can attend via videocast or tune in by phone as they are today. So I hope we have great participation both in person and from folks who can't come over -- with electronic help.

So what are we doing on November 8?

We are hoping to write recommendations to Secretary Sibelius for reforms in the services system. We also, as you probably know if you have perused the materials for today, do not have updates to Chapters 5 and 6, the ones on -- well I don't have -- and 7, that's right Tom. Okay thank you for being technically correct.

So we may be informing Chapter 7 as well as Chapters 5 and 6. And we will be looking at a couple of things. What cost-effective high quality systems and practices are working in states or hold promise?

I think one of the very cool things about this workshop is, as you will see in a moment, we have heavy participation from our state partners and that's really important because these are -- as all of you know who are involved with autism, what you get in the services system really depends on what state live you in, what county you live in, what geographic municipality, so these are the people who are really out in the weeds doing the work and they are doing very good work in an environment where diminished resources are high priority so that's another thing that I think is really exciting, what can be done -- what is happening out there now even with these constraints?

I am pushing the wrong button here. I have got too much electronic stuff. So we are going to hear in the morning from Nancy Thaler, who many of you know. Nancy, for many years has been -- Lee knows Nancy really well -- an incredibly strong advocate for people with developmental disabilities and Nancy heads up all the developmental disabilities directors in the United States.

She will be followed by Bill East who has a dual role with the special education directors. And then we are going to be hearing from Charlie Lakin. We haven't heard from Charlie before but he is not just a charming and brilliant person but also very knowledgeable. Charlie runs the Core Indicators Project for NSDDDS, the first NASDDDS, they have identical acronyms.

And the Core Indicators Project looks at quality of life indicators for people with developmental disabilities and there is some very interesting data coming out on people with autism out of that project that I think you guys will find absolutely fascinating as I do.

Then our first state presentation is from Michigan, Mike Head, many people familiar with the services system know Mike. He has been around for a long time. Mike runs all the mental health programs in the state of Michigan. We at CMS work frequently with Mike. He is a strong advocate for people with mental disorders and substance use disorders.

And Mike and Jim will be talking about self-direction and self-determination. Jim and Mike did a project a few years ago that actually looked at cost-savings in self-direction so that will be very interesting.

Then we have a presentation coming from the state of Washington on universal standardized assessment. Washington State started using a standardized assessment tool called the CARE tool a few years ago and the DD division there developed a specialized version of this tool. A typical way of assigning services is for a client or family to go meet with a case manager and then the case manager decides what services are available that the individual needs but in Washington, they took a sort of a different tack and they started asking the same sets of questions that are strength-based questions, so instead of a what do you do need kind of approach it's more of a how can we help you get better approach.

And so it also provided the state with a very clear way of approaching its state legislature with monetary needs so I think that's going to be great.

Then we have a wonderful woman from the state of Delaware, Kevin Ann Huckshorn. I don't know if Larke is still on the phone but Larke and her colleague Sharon Lewis have both worked very closely with Kevin and she is amazing. Kevin is going to talk to us about the prevention and reduction of seclusion and restraint and for those of who you aren't aware, Sharon worked in this field for a long time and she probably knows more about it. I don't believe she will be with us that day. She is going to be in Orlando at another meeting, but this is of course a very important topic. We have heard a lot about it today already.

Kevin will be followed by Carrie Blakeway. Carrie is our consultant. She has done a lot of work with CMS on the importance of training the workforce, the people that go into schools and homes and work with people who have autism, and Erika Robbins is with the Ohio Department of Job and Family Services and she is going to talk a little bit about what Ohio has done in this realm. She also runs the state's money follows the person demonstration which is a CMS project.

Then we have Sheldon Wheeler from the state of Maine. There are only a few states that have put state-based programs in place to help people with disabilities get housing. Now this particular program is really aimed at people with mental disorders and substance use issues. Again, these programs are few and far between and the lack of affordable housing as Denise -- I see Denise nodding -- will attest, is one of the most serious problems in the United States.

And so this program actually helps people get into their own home prior to the time that they become eligible for a housing choice voucher and then Joe Wykowski is going to talk about the good things that happen when people do get into their own home. Joe is from Oregon and I know that some of the committee members know him.

Then we have a panel on peer supports. Someone from the Autism Network International, Jim Sinclair, Lisa Crabtree, who is from the Towson Center, and then a woman named Julie LaBerge who is from a school district in Wisconsin where peer supports have been implemented at the elementary, middle and high school levels and Julie is going to talk about what the impact of that was, not just on all kids with disabilities but in particular on kids with autism.

And then to top off our day, Lee and I spoke yesterday with this gentleman, John Martin, who is the Director of Ohio's Department of Developmental Disabilities. He is just such a dynamic person. John has done amazing things in Ohio with more to come.

But John will be talking to us a little bit about how the state has -- we hear so much about fractured systems, schools, developmental disabilities, voc. rehab, and what has Ohio done to streamline getting those systems together?

And then we had so many things that we wanted to talk about this day that we started a list of parking lot issues, that's -- Denise coined this term, so I thought it would be good for you to at least see okay, what we have in the parking lot.

And this was just what I came up with the other day when I was quickly writing these slides: diversity; cultural sensitivity; recreation and communities, family support -- Jennifer added that one -- home- and community-based characteristics, I think that's one of Ari's issues that he is -- of course we at CMS are also very interested in this; employment vocational issues including benefits counseling through social security; early childhood issues; infrastructure; person-centered policies and planning; medical homes and health homes -- the latter is an optional benefit that has been put into the

Medicaid statute through the Affordable Care Act so many states interested in that option; quality measures for children and adults -- again, the latter, quality measures for adults, our partners at AHRQ and CMS were working on that as part the Affordable Care Act; the very fast expanding role of managed care delivery systems and services and supports. More and more states as they look at how to deal with these fiscal contractions as using managed care and what's the impact of that especially on our population; mental health parity, a subject that we at CMS are working busily on; criminal justice diversion -- there's a program in Taunton, Massachusetts that I think is pretty amazing that I would really like the committee to hear more about where different systems -- police, social work, the judge, everybody got together and you have a lot of people with autism that they are doing a fantastic job keeping out of the system. So we couldn't get them in this time but I think that they are just amazing. They did this all with volunteer funding; post-secondary education; rebalancing the long-term services and supports system; community asset building; environmental and home modifications.

So that's just my short list parking lot list, okay, it's a pretty big parking lot and we really hope that everyone will come and I just think it will be a great day.

One more thing. Our invited lunch speaker, we haven't heard back yet but we are hoping and trusting that Tom Perez will be with us from the -- or Sam Bagenstos, but Lee is nodding his head no. Well, we are working on our lunch speaker. Someone else from the Department of Justice will be with us to talk about Olmstead and Americans with Disabilities Act issues. It's been a real focus over there. A decision was just issued in the state of Georgia that is very interesting, Georgia being the state where the Olmstead decision initiated.

So you know this is a really big deal in the world of people with autism and developmental disabilities. So please tune in. Lee, do you have anything to add?

Mr. Grossman: Yes I do want to emphasize what Ellen said about this being a fun day. Why is it going to be fun? It's because this is a -- we have brought together speakers that I didn't even think we would be able to do this, but it appears that everybody has committed themselves to this notion of systems change and its importance the fact that we have to break down the silos and many of the speakers that we have brought in, they are just -- they are not only breaking the silos down, they are chopping them up and throwing them to the trash heap.

We wanted to have people that would come in that would really look at what it takes to build comprehensive systems that are life-span in orientation and we have been able

-- that we have done that to just about the best we can. They have models, they are talking about autism specifically, they are talking about the disability community in general, and we should from there have a really good working -- be able to start to develop the types of recommendations that will be meaningful to the Secretary.

We are going to be wide open for what the next -- which is going to be in March, April or May, the next workshop will be, and I think that we will learn a lot from this first workshop that will make a difference on how we plan the second one.

But I almost believe that we are going to come up with a great set of recommendations out of this one that will pretty much just hopefully at the next workshop we will be not only discussing them but putting them forward in a comprehensive plan.

Dr. Insel: So just to clarify, the

idea for this workshop is to actually end up with a deliverable, a set of recommendations on some of the issues that you are teeing up here, is that realistic --

Mr. Grossman: Is that realistic?

Dr. Insel: -- and could this -- could you come back to us with a December meeting to share the suggestions and then maybe we can help get those to the Secretary which is actually what we are supposed to be doing?

Mr. Grossman: Yes, I think as much as we would love to have recommendations back to you at the December meeting, that is a pretty heavy lift.

Dr. Insel: Maybe a couple of recommendations? Something we can --

Ms. Blackwell: Yes, maybe.

Mr. Grossman: No I think that -- I mean the Services Subcommittee is really going to have to roll up their sleeves and put pen to paper to make that happen by December.

Couple of recommendations, I think that the committee would have to look at do we piecemeal this or do we put together a comprehensive plan? Once we have that decision made, I think we will have a better idea of how these recommendations will come together. Does that sound reasonable?

Dr. Insel: Well, you know I think we would love to see even the beginning of -- you know something that we can start to put forward. I think part of what a lot of the people on the committee feel, if I am channeling the whole committee here, which I may not be able to do, is that we have done a lot of things on the research end, and we have been able to put not just the strategic plan but the updates and lots of conferences and lots of -- there have been lots of deliverables there, and maybe not nearly as much on the services side, so I am pushing you a little bit because I think we do need something to begin to point to that says we are moving this agenda, and it's great as you say Lee, that the plan is to really break down barriers and get out of the silos and move this forward, but I think we need to be able to show that in some way beyond just having a meeting. I think we need to have some real definite asks and I think we are going to circle back to this issue about safety, which we already have heard about a lot today.

But I just -- I guess I am not wanting us to wait another year, another six months for another set of meetings. I'd love to be able to actually see us take some of these things on and push them forward. Lyn?

Ms. Blackwell: Actually -- I'm sorry.

Dr. Insel: Go ahead Lyn and then we will come back.

Ms. Redwood: I was just going to say Lee, also I think this information is going to be critical for reauthorization of the Combating Autism Act, so I think a lot of the recommendations that come out of this committee we should look at possibly trying to get that into the bill and that is going to be happening or is happening right now.

Dr. Insel: Yes, that is a great point.

Ms. Blackwell: We actually debated what you mentioned Tom, whether it would be better to send the recommendations with the revised strategic plan, the updated strategic plan or send them as a separate document, so our initial thought was to send them along with the strategic plan in January.

Dr. Insel: Well, we might, I mean I think that's something we can discuss as a committee but I heard very clearly from the public comment today the sense of urgency around for instance in this case issues that have to do with safety, which is part of the services agenda, and I just don't think people want to wait for us to have another set of meetings and another set of discussions before they see us actually send something to the Secretary on some of these issues and think about what the real solutions could be in implementing them there.

So I am just encouraging you on behalf of all your colleagues here to -- even if you can't get the whole thing together as a strategic plan, to give us some pieces that we can start to run with and be able to point to and as Lyn says, this next few months is going to be very important for the reauthorization of this committee and I think it needs to be very clear that we have been attending to not just the research side of it, but to the mandate we have to attend to services and to make recommendations to the Secretary accordingly.

Okay. Yes, Denise?

Ms. Resnik: And I want to commend the group and Lee and you Ellen for a great line-up here. This is tremendous. At the same time I am very interested and I think it's critically important that we look at some process in terms of how we develop those recommendations based on the outreach that you have done, based on how these people were selected and how others were not and I think that's going to be critically important that as we set forth these initial recommendations, that there is a real understanding of how and why these have been prioritized because we know that there are many priorities, and I just think it's going to be very important that we manage some expectations here and we do define a process for how we come up with such important recommendations.

Dr. Insel: Good point. Anything else before we move on. Walter?

Dr. Koroshetz: Yes well, I mean I would just -- I agree with you Tom about the services issue but I think there's still -- I would still like the committee to try and make that connection between the problems and research that can solve the problems so I guess I am wondering in this meeting, can we actually get into that?

I mean we just heard for instance about the safety issues and so I am trying to think, is there a technological solution to some of these safety issues? We fund a lot of SBIR grants that could potentially be valuable here, so just knowing more about that -- now we know the problem, we know what some of the things are, if we just knew a little bit more about how the research could solve the problem, it might actually fall right into our research portfolio.

So I am wondering is that something that you think can happen at this meeting or has that got to be a follow-up meeting?

Dr. Dawson: Yes, I just wanted to underscore what Walter was saying. One of the things that really struck me when we heard the morning presentation about educational services and she ended with what do we need? And the very first thing she said is we need more empirically based recommendations that without that strong research base of what is actually effective, not to say that we shouldn't go ahead and implement everything, best practices, that we can, as fast as possible, but simultaneously building an empirical base for what is most effective in the long run I think will allow us to advocate for things like insurance coverage and also ultimately use funds most effectively.

Mr. Grossman: Well I mean I don't disagree with any of this and we do need more empirical data. I think that what that means though and what I was interpreting Alexis to say was that that is getting the data together, finding ways to review and research the data that is coming out, that's being introduced at the schools system level that applied scientists are putting forth and moving forward with that and to validate or to provide evidence-based information that we can move forward on, on the service sector.

And I don't -- so I think that there is always a -- there will always be a place for research. I don't think that any of the good services and the models that are out there I wouldn't imply that they are not doing good research. They are collecting the data on the services that they are providing and they are making decisions based on what seems to be effective and what is working.

Dr. Insel: Yes I don't think we are trying to make this an either/or situation but I guess Walter's comment is, and if I hear you right Gerry, there's the need to make sure that we weave all this together so that as you hear about needs on the service side that the research agenda -- and we will see this a little bit in the update -- will also reflect that as well.

Okay, if there's nothing else, we will look forward to November 8 and I am sure you will be looking forward to November 9 as well because this will be a lot of work to get this thing together but it should be a really interesting meeting. That's right.

By the way I am assuming the room that this is being held in is large enough that if people from the IACC want to attend there won't be a problem. Is that right?

Okay, good. We wanted you -- so there are now a number of other issues related to information that the committee has asked for and we will start with the request for information. Della, can you take us through the update on the RFI?

Dr. Hann: Sure. Okay. You all will recall that we did issue a request for information over the summer months primarily to gather input from the public with regard to the strategic plan.

And it was issued in June. Those are the dates that it was issued, and the closing date was on July 30. People were able to respond via webform which greatly facilitated our efforts to be able to catalogue the information.

Respondents essentially were asked to provide their views on any or all of the chapters in the strategic plan as well as the introduction and to provide their views as to what issues and topics should be added, what issues and topics that are currently included could be modified or removed, as well as any other information they wished to provide to the committee.

We received 54 I guess really we should say respondents. So there were 54 unique individuals who provided comment but they provided multiple comment so it wasn't like there were just 54 little comments, and all of those comments now are available and can be seen on the IACC website.

Members of the planning committee received them in hard copy so that they could begin to take them into consideration with regard to the updates to the strategic plan.

Okay, that's basically it.

Dr. Insel: So questions or comments about this? Lyn.

Ms. Redwood: I just, in reviewing over all the comments, the way that the comments were solicited, the questions that we asked them in terms of what the gaps were, I don't know if that really segued nicely with how we are doing the updates because we are not actually updating the strategic plan line by line, like we had started off doing in the previous years. We are doing the bookends at the end.

So my concern is maybe we should have done that RFI a little bit differently so we should decide in advance how we are going to update the plan so that when we issue the RFI, the RFI matches how we are doing our update, because this year it didn't.

Dr. Insel: Did the -- so those who were on the planning committee, the committee to plan the update, did you find the RFI useful or was this organizational problem really an impediment to being able to take those comments into consideration?

I know people read it because I heard about it at the committee meeting so there was -- it engaged everyone. But what's the sense?

Ms. Redwood: Tom, I know I tried to take them into consideration in making the line edits, but when we did it the other way, I couldn't incorporate them. That was my concern about the way the RFI was issued.

Dr. Insel: Okay. Well, we will have a chance to think about this again for the next update because I think this is still a learning process. Each year we are modifying some of what we do. Any other thoughts or comments about the RFI beyond Lyn's suggestion that we look at the format of it for next time?

Okay, we wanted to hear about the portfolio analysis as well and Della can you take us through this?

Dr. Hann: Okay so members of the committee, you have in your packets actually the information on the portfolio analysis. Also it has been posted in the IACC website. I believe I sent around a note -- was it just yesterday, it feels -- I don't know when -- to the members of the committee to tell them this.

That's right. There's actually two documents. There's the sort of short document and then there is a more lengthy one.

And what I am going to do now with the slides is try to go through some selected high points. It's not everything but it's selected high points.

So just as a basic recap, what the purpose was for conducting the portfolio analysis, there was great interest on the behalf of the committee to try to get a better understanding of the landscape of all research funding that was going on both in the federal sector as well as private sectors with regard to research into Autism spectrum disorders and that is really what the portfolio analysis is about.

This is our second attempt at trying to produce -- well actually we did do it. We did a first one and now we are doing a second one. It's just that it evolves each time that we do it.

So we basically are doing this to try to first of all identify and catalogue what all is going on and hopefully to get a sense if there's been some progress in terms of the kinds of research and issues that are being studied, and then two, to highlight if there are gaps, particularly with regard to how it relates to the strategic plan.

I want to greatly thank all of the funders. They were very, very helpful this year. We had to work with several of them back and forth a few times and they were always very kind with regard to working with us.

As you can see, these are the

federal folks as well as the private funders who are providing us information. This is very similar to last year in terms of who is providing the information.

What we asked of each was to provide the number of research projects and to really provide us an itemization of the research projects, for them to tell us what their total was with regard to research funding for ASD, and most importantly for their portfolio analysis, was from the funders' point of view, how well the projects they are supporting lined up with the different areas in the strategic plan.

So another way to put this is the funders did the coding. They coded the projects according to the list of objectives and chapters et cetera that are in the plan.

This is an overview of all of the organizations that provided information, the total number of projects that were provided as well as the total funding that that added up to.

You will see at the top is the National Institutes of Health followed by the Simons Foundation and the grand total overall for this portfolio analysis is it includes approximately $316 million with regard to research funding both federal and private in the United States.

Dr. Insel: The asterisk on the DOD is what?

Dr. Hann: Actually I think that can go away.

Dr. Daniels: The asterisk indicates that with DOD's funding, there were some FY `08 projects that were included in that number because they weren't in last year's report.

Dr. Hann: Right, so one of the things that we find when we work with other organizations as well as agencies is how they operate their calendar or their fiscal year differs and so it can lead to a great deal of confusion and this was the compromise that we arrived at with regard to Department of Defense. It has to do with their fiscal calendar and when they consider it to be `08 versus `09 versus `10.

Dr. Insel: I know you will say more about this but just for the committee's clarification, the NIH numbers represent both Recovery Act and base funding. The Recovery Act money is only for 2009/2010 so it's a little bit misleading to see it as a single number since it has a completely different appropriation.

Dr. Hann: Okay. You are correct. It does include both. If we take that total of $316 million this is the basic breakout where it's roughly 24, 25 percent is from the private sector and 75, 76 percent is from the federal government.

Then we get to what Tom was just talking about with regard to funds that were provided through the American Recovery and Reinvestment Act, fondly known as ARRA and NIH was able to benefit particularly in the area of autism research with regard to the ARRA funds and $64 million was infused through that process to the funding of research projects but as Tom says, those are time-limited projects and they were funded for fiscal year `09 and fiscal year `10.

And those were some of the other statistics with regard to the ARRA funding that are provided there on the slide.

Okay. This is for NIH-ARRA versus non-ARRA funding and you can see that by looking at the ARRA funding, the ARRA funding essentially is accounting for about 27 percent.

If we again look back at the $316 million in terms of how it breaks out according to the different areas in the strategic plan, that's what this pie chart is trying to depict.

You will see that similar actually to last year, a fair amount of funding occurs for question 3, which is what caused this to happen and can this be prevented?

We also see a good chunk of funding, 21 percent, in how can I understand what is happening, 19 percent in which treatments and interventions would be helpful and then followed 13 percent in when should I be concerned.

If my memory serves me correctly, that may be a slight increase with regard to the treatment research compared to what we saw last year.

It is very difficult though to compare last year to this year because the number of objectives did change significantly between the previous plan and this plan so we have to take that with a -- keep that in mind in terms of any kind of comparisons over years.

In terms of the ARRA funding, you can see that that very closely mimics the breakout that we just talked about, again, with the largest portion going to question 3 then the second largest going to question 2, question 1 and question 4, which is treatments. Very similar.

Okay, now I would like to walk through, and I know it will, for most, it will seem like a run through, of how it breaks out per objective or excuse me, per chapter.

And to do so I asked that we -- I said to folks yesterday I said let's include a little legend because it can be a little confusing for folks.

We are going to list out the projects and list the objectives that go along with that and we did a coding scheme this year to try to -- again we are always striving to figure out how to present the information in ways that can be easily grasped.

And we developed sort of a green, yellow, red dot kind of functionality where our green dot indicates that the objectives -- they have greater than or equal to the number of recommended projects and greater than or equal to the number of recommended funding that is going on for that particular objective.

Yellow indicates that the area, the objective has some degree of funding that is close to but it's not necessarily at the exact targets that the IACC had recommended.

And then red indicates that there are no projects or very, very little funding that is going on on a particular objective.

You will also see in the next few slides we have a little button called "new" sitting out on the left hand side and that is to indicate those objectives that truly were added as of last year.

So this is the very first one. I realize and I apologize this is difficult to see. You may want to look actually at the portfolio analysis in your packet to get a closer examination of it.

But this is question 1, when should

I be concerned, and it's the objectives, each of the objectives that are listed for that. You can see that three of them are in the green and there are three in the yellow and one in the red.

Dr. Insel: But Della, just I don't want to sound defensive here but just to make sure I understand what you are taking us through, the one that is in red is a 2010 objective --

Dr. Hann: Correct.

Dr. Insel: and we are looking at 2009 spending.

Dr. Hann: That's right.

Dr. Insel: Okay, so it ended up going into the plan in 2010 because somebody felt it was missing from what was being done in 2009 so it shouldn't be a surprise --

Dr. Hann: Correct.

Dr. Insel: -- that's not in the green. If it had been in the green probably it wouldn't have been in the plan to begin with.

Dr. Hann: Right.

Dr. Insel: Okay.

Dr. Hann: Okay. For question 2, this is the breakout for that, where there are no red dots at all, and actually some of the new objectives that were added were already in the works apparently.

So don't shoot the messenger. Okay, question 3, again, many of the areas are in the green. There are a few in yellow, two of which were new additions last year.

Question 4 has one red area. That was something that was added as of last year. Three areas are in green and five areas are yellow.

Question 5 has one area in red, also was a new area as of the plan that was adopted in January, two greens and three yellows.

Question 6, as you can see, almost all of question 6 was redone last year so a number of these -- there are no greens affiliated with question 6 at this time.

And question 7, actually I have two slides for question 7. There were a number of objectives in that particular chapter. This is the infrastructure and surveillance chapter. Again, the two that are red were newly added. Oh excuse me, there were three, sorry, and there's another red that appears here on this slide as well.

There are also, as I said, the funders are the ones who are making the decisions on where their projects fall with regards to the plan and there were projects which they felt did not fit any one of the particular chapters and so those we just sort put into "other" and provided that information, but then you get, by taking all of those chapters together as well as the other category you arrive at the grand total.

And again the -- one of the purposes for doing the portfolio analysis was to help inform the update of the strategic plan to get a better understanding of the landscape and identify underfunded areas.

We also want to be able to continue to conduct this type of analysis on an annual basis in order to look at progress over time.

But I do -- I think it is important as I said before to remember that when the plan changes significantly, that makes the longitudinal analysis a little more difficult.

Dr. Insel: Okay thank you Della, this is a huge amount of work from a lot of people and I am not sure that we have comparable data for any other illness that NIH is involved with so it's a great model to think about elsewhere.

Questions or comments about this? Coleen.

Dr. Boyle: So on our subcommittee we mentioned or the issue came up about the funding that was not specified for any particular objective. Did you --- were you able to take a look at that at all? No.

Dr. Hann: Not yet, no.

Dr. Boyle: Okay.

Ms. Redwood: Yes, I went over this in fairly good detail on the plane and I had a couple of questions and things that sort of stood out that I wasn't certain about.

If you go to question 3.S.B., it has what are the highest priority categories of exposures for ASD, and the standardizing measures -- I'm going to make sure that's the right one, yes -- for markers of environmental exposure in biospecimens. And it looks like the three projects that are funded are genetic studies and I am wondering if those were supposed to be in 3.S.A. or 3.S.C. It looks like they would fit better there and if those were moved, because I don't know maybe I am wrong but they just don't look like they are markers of environmental exposure the way I would think of markers of environmental exposure.

Dr. Hann: We can go back and double check but again, this is what funders were telling us.

Ms. Redwood: Well NIH is the funder.

Dr. Hann: Right but I didn't do the coding for the NIH.

Ms. Redwood: Ah, okay. Because if those were moved to what I think would be the appropriate categories, then that would change from a green color to a red color.

The other thing that I wanted to point out, when you look at it, let's see, what is it, question 3.L.B, which is one of the genetic questions, I think we were projecting what, 33 million and we have 44 million, so we have gone way over in that category in my opinion, but then when you look down to the treatment, let's say question 4.S.C., which is on treatments, let me find that one, it's just in my opinion way under.

We had budgeted or sort of thought that 27 million for safety and efficacy of at least five widely-used interventions. So far we have spent approximately three million and when you look at those studies, there's really only five of them that were funded by the NIH.

And I think when I added all those up they came up to $1 million so I am wondering if we can communicate back to the funders that we have these gaps in treatment and how we are going to address the disparities in our funding portfolio, and can we do things specifically to get the things we think are critical funded?

Dr. Insel: You know, Lyn, I think you bring up the critical question which is, what do you do with this? So if the point of this was to begin to look at how the funding, both public and private, arrays with what this committee felt should be funded, but this committee doesn't fund anything, so the question you are asking I think is something the committee really has to wrestle with, when if there is a mismatch, how do we bring attention to that mismatch and try and make sure that the funding shifts in the direction that all of us have worked so hard to prioritize.

So I will just leave that question hanging but I would be really interested in thoughts that people might have about this process. This is especially relevant since we have just come out of doing the Recovery Act money which gave us a huge amount to invest in new projects. We will not have that opportunity again.

Ms. Redwood: I would be curious to hear from the people who are representing the institutes here, how their specific institutes could help to direct funding into these areas that are underfunded.

Dr. Dawson: Well, in terms of -- and I will actually respond to both of your questions I guess at the same time -- but I think the usefulness of this is exactly what Lyn is attempting to do for us, which is that you look through and look to see what are the areas in which there are gaps and I would think that looking at gaps is one of the ways to direct funding priorities. I mean certainly we do that at Autism Speaks in terms of right now, as you have noticed from the workshop, we are trying to really build the environmental factors field because we feel like we have put a lot in genetics. We feel like we have put less in environment and we are trying to address that gap.

And with treatment, having an example of that would be having treatment review sessions, panels, that are separate from all of our other review panels so that they get evaluated in a different context because often if you put a treatment study and some of the basic science studies in the same review panel, the treatment studies don't do well. So that was one way of emphasizing treatment.

So I do think that this information is really useful. Ultimately, we have to make sure that the coding, I mean that is sort of what is the quality of the data and analyzing it, but assuming that we feel confident about the coding and I think you have already raised some questions about that, then I think it's very useful to identify gaps and to look at where shifting and funding needs to go.

Dr. Insel: Alan.

Dr. Guttmacher: Yes, I think first of all the question of the coding is certainly a good one and there are always issues I know from NIH in terms of coding things accurately. One would think it should be easier than it is but it presents so many challenges.

But let's assume for the moment we get the coding correctly, I think the informed advice of this committee is very useful to the institutes as they think about where they are going with their portfolios, particularly in identifying gaps and areas that seem to be underfunded, et cetera, but realize while it is informed and very useful, it's one of a number of streams of informed advice that come with the institutes and help them figure out what to do. And on top of that, of course, a lot of the spending that NIH does is not sort of programmed from above but it bubbles up from the individual investigators who submit to us proposals, whether they be related to autism or anything else across the broad spectrum NIH is interested in, and it's a question of how it gets reviewed in peer review. Peer review is the predominant way that decisions are reached at the NIH about funding and if folks come in with wonderful applications in some area that for whatever reason the committee has relatively downgraded and it gets wonderful scores, it is likely to get funded and vice versa even if there is an area that we try to spotlight -- and I will come back to that in a minute -- that does not have good applications in, or applications that score badly, they are much less likely to get scored.

Now, that said, there clearly are

ways -- and some of them are ones I think you all know about -- that institutes can highlight particular areas where they would like to receive applications and show their enthusiasm for the scientific opportunities in those areas, and I think that's particularly where the committee's informed advice to the institutes has been helpful and will continue to be helpful, is the help the institutes figure out in what areas should they really sort of spotlight the fact that they are perceived to be both -- it's a combination of scientific opportunity and public health need -- areas where we see one or both of those occurring.

Dr. Insel: Josie.

Dr. Briggs: Yes, just to echo this, this is a core problem in building scientific programs in areas where the scientific community may not be submitting the application stream that we would all like to see, and some of this lies in peer review and some of it lies in a document like this being credibly valuable in outreach to scientific communities to say, here, we have got some real gaps.

And so I think this analysis will be extremely helpful in pinpointing those gaps.

Dr. Insel: Walter.

Dr. Koroshetz: I mean, I am sure Lyn, you know as well as anybody, but when you go through the coding, I think it was helpful to see the aggregate, but what I found most helpful was it kind of focused me on, when I read the whole list of titles that you could actually see what really is -- much more concrete sense, so to have those titles I thinks is incredibly valuable.

So I would say you know, take a look at that and then you look at the titles and see if your thoughts are confirmed. The titles are very helpful I thought.

Dr. Insel: But just on that basis, it's clear that there are some titles that don't match with some of the coding numbers that are on here. Lyn has pointed out the one around the standardization of environmental exposure through --

Dr. Guttmacher: And sometimes it's a coding problem, sometimes it's a title problem.

Dr. Insel: Yes, understandably. I should say that on the environmental side, it's -- we are very focused on autism, there's a piece out yesterday in Science magazine pointing out that this is an issue for chronic diseases in general and calling scientific community to account for what the author from UC Berkeley sees as a real imbalance in the funding stream for environmental factors writ large. I don't know that autism is even on the list there, but looking at lots of others, and I think part of it is what Alan is speaking to, the sense that there hasn't been quite the scientific traction in this area that there has been in others and so scientists tend to go where they feel like they can make the most progress and this is a really tough one to do. David?

Dr. Armstrong: Yes, I just wanted to add exactly that, that even though I am from the Environmental Science Institute, I think no one could have anticipated even three years ago how powerful deep sequencing was going to be and because it's a new technology it also turned out to be more expensive than everyone thought it should be.

But I think we have -- that was one of the most exciting things, the new genetic data at that meeting we had and so I think it would be sad if we had to miss out on -- opportunities in science are often serendipitous and I think we should take advantage of them when they come even if we don't anticipate them.

Ms. Redwood: I guess I wasn't suggesting that we don't take advantage of them but that there is also this huge problem with every one in every 110 kids having autism when we don't have that many effective treatments. So I think that that sort of sense of urgency that we hear from the public we need to try to address and I am -- I guess the question I am asking is whether or not some of the institutes could issue RFAs or create special emphasis panels to get this critical work done.

The other thing I think would be important to do is to go back through the analysis again and look at some of the ones that are coded incorrectly. It appears as though all the DOD funding was put into the "other" category. So maybe we could just look back over the whole portfolio again.

Dr. Hann: Who? Because again, this is the way DOD did --

Ms. Redwood: I know.

Dr. Hann: -- their funding, so that's how they wanted their information to be presented. If the committee or the subcommittee wanted to override that, that's fine, but this is what they did reflect to us.

Ms. Redwood: Oh, I understand Della. I know it's not anybody's -- it's just it doesn't -- I think some of this could fit into some of our categories and --

Dr. Insel: Do we have a list of their individual grants? And I think the number is up here. It's not astronomical.

So it's a total of 15 projects. So is that something that OARC could do, to add the 15 projects to this list to see where they would fall?

Dr. Hann: Okay yes, there is several of them that are under Question 3 right now but not specific to any particular objective.

Dr. Insel: I see, so the question was how to array them within the sub-objectives.

Dr. Hann: Right.

Dr. Insel: Okay.

Ms. Redwood: Didn't staff last year

do something where they reshuffled some of the initiatives to put them in the right category? Am I remembering that wrong?

Dr. Hann: That was just a very few that the committee highlighted. It wasn't like a whole, almost an entire funder's portfolio.

Dr. Insel: I think what I am hearing from several people around the table is that it is worth going back and doing a sort of QC run on this because there, just looking at the titles, there are clearly some that are probably -- either the titles are wrong or the category is wrong but they don't really seem to match with the objective. So it's worth taking a look.

But overall I hope that people found the concept of the green, yellow and red as a helpful way to quickly collapse a huge amount of information into giving us a sense of where the gaps might be. And I think Gerry is right. This is going to be most effective as a gap analysis tool, especially as we go into the next topic, which is the updating of the plan,

Is there anything else?

Ms. Blackwell: Can I just say?

Dr. Insel: Yes?

Ms. Blackwell: I was just going to say thank you to the staff at OARC who worked so hard to wrangle this information out of everyone and put it together. We really appreciate your hard work.

Dr. Dawson: It's a huge amount of work, just an amazing amount of work that went into this. I want to just recognize both Susan and Della. I am sure the two of you must have -- did the heavy lifting on this so thank you for that.

Dr. Insel: I am curious whether -- is this useful to Autism Speaks when you look at this? I mean is this a way that you can also --

Dr. Dawson: Yes, it is. I do think that the QC -- and I was just laughing because I think we could look at ours in the same critical light as some of the NIH categories, and the question is how do you code these things?

As a behavioral scientist who has done a lot of coding, that's a science in and of itself, right? And then I think the other thing is that many things fit into multiple categories and that is unfortunate because depending on which one someone chooses, you are under-representing sometimes how it is contributing to another area.

So one of the things that we have started to do in Autism Speaks is to have multiple keywords that can be associated with a grant so you can really -- they are not mutually exclusive and I actually think that is kind of important.

Dr. Insel: Well, we have been there. It's -- there's no perfect solution to this and you know, as you get more and more granular it gets sometimes more and more confusing, but I think what the committee was hoping for from this really was just the big picture of where the gaps might be and I think we are already beginning to see some of them. So that's very, very helpful.

If there aren't any other recommendations or comments about this, we will move on to the next issue which has to do with the process for updating the plan. And maybe I will take you through this very quickly.

We -- let's see. Where we ended up at our last meeting was recommending that the planning subcommittee get together and this year not rewrite the plan but tweak it according to any very substantial breakthroughs that might have occurred, and they recommended that we use that based on what came in through the RFI, what came in through the yearly report of advances, including now a semiannual report of advances, and then also looking at the portfolio analysis which we only had in a draft form by

October 6, but was still pretty useful to the group.

The group met on October 6 and I guess this slide tells you what I just told you. It was a chance to look at each of these pieces of information and the question that we were struggling with was what do we want to do in terms of an update?

Well, on the one hand, I think we recognized that there were no transformative breakthroughs that would cause us to completely alter the plan and there weren't any parts of the plan that we were ready to say mission accomplished on, although there were some where we had made significant progress. On the other hand, there were a lot of new people around the table who felt that they were not around when the last update was done and they certainly had lots of great ideas about things that could go into an update.

And so a lot of the discussion was

really on that axis: do we tweak this with a little bit here a little bit there, or do we rewrite again and create an entirely new document?

What you will see was that we kind of came up with three options out of that. One is we could go back and do what we did last year and essentially rewrite it line by line, and the next possibility was to actually put in what we were calling bookends, although in some ways it's sort of a one-sided bookend.

It was to look at what had happened since last year, add some comments and potentially new objectives and make this essentially a separate document, not just -- not enmeshed into the current plan. And the third was to do both, to both add in comments at the end and to make the line by line edits.

We took a vote and voted to take number 2, that is to create a new document which will be called an update and that will still look at each of the chapters in the plan but rather than going back and trying to rewrite each chapter, it would take a look within each one at these basic concepts.

So it would say what is new in this area, what have we learned in the past year. What gap areas have emerged -- and some of this is what we were just talking about based on looking at the portfolio analysis. And then what new opportunities and objectives should we now think about that weren't there before.

So those were the sort of three pieces of this template of what would go into the bookend, and we talked quite a bit about how to do each one of these.

The issues for today are really two -- we wanted to bring this process to you, to make sure that you were comfortable as a full committee because remember the subcommittee simply makes recommendations to you, to do this kind of an update, that is to add in this comment at the end of each chapter which will be essentially a new publication, and the second was we have given you draft -- I want to underline the word draft here, this is not by any means a final recommendation but we wanted you to see what this might look like for first four chapters. We have not done five, six and seven as a subcommittee.

But we do have something for you to chew on from one through four and I think what you will see there is it is very substantial. There is an awful lot that has been put together by a very hardworking subcommittee and at last count I think there were something like 30 new objectives just from chapters one through four.

So we are putting this in front of you because we are going to need some feedback from the full committee at this point on both of these issues. The goal will be to complete this whole process given your feedback today and be able to come back with final recommendations for updates for the December meeting, so that we can still make an end-of-

January timeline, let us hope, for having the annual update as required by the Combating Autism Act.

Now I am speaking on behalf of a lot of very hardworking people who are involved with this subcommittee, so let me ask the people first on the subcommittee whether they have additional comments about our October 6 meeting or the process that we are engaged in. Ellen?

Ms. Blackwell: I have a question and a comment. The versions that we received to look at in preparation for today's meeting, there was a lot of material flying about the subcommittee, so are these just the ones that the lead drafters put together or do they incorporate comments from everyone who commented during that process? I wasn't sure.

Dr. Insel: So this was the -- for each of the chapters there is a lead person or persons and what you have in front of you, what's in that packet, is the current state of that draft. It's not final. But it's something that we wanted this full committee to take a look at so you could get some idea of the scope of what we is under way.

Ms. Blackwell: Okay. Thank you. And then --

Dr. Insel: Geri? Geri has been very involved so she might be the right person.

Dr. Dawson: So having been the lead drafter for three and four I can tell you what I did, which was that I essentially tried to incorporate every single person's comments and of course sometimes they were -- did not fit together for whatever reason and so then I just tried to meld it as well as I could, but I did try to reflect everyone's perspective in the version that is there.

Ms. Blackwell: And then I do have a comment that plays on something you mentioned, Tom. I was kind of surprised when I went through this also at the number of new objectives, especially based on the research that was quoted that preceded it, so I do see that as a concern.

Dr. Insel: Right, so this is an issue that came up at the meeting and I guess one of the -- one way to think about this is you want a strategic plan that has a clear sense of priority and as the number of objectives goes from 30 to 65 and now over 100, it begins to look much more like a menu than a strategic plan.

So I think that is something that the whole committee is going to have to take into consideration. On the other side of this, we have got a lot of smart people with good ideas who see real needs and so some of those things are going to be impossible to ignore, some of the objectives. Other comments from people on the subcommittee first, so let me just check with those of you, Geri, Lyn, Alison, Coleen, I think you are also involved. Any other? Okay. And Ari, yes.

Dr. Dawson: One other quick comment,

which is that in terms of the number of objectives, because I as a person who was taking the lead in trying to put this together I felt like wow, this is a lot of objectives.

But as the lead person I also didn't think it was my role to either prioritize which was more important than the other. I often felt that they could be combined but again I didn't want to step on people's priorities or sensitivities by doing that myself, so I thought, well, let's just put it all in there and then it's the whole committee that needs to prioritize or combine or in some case maybe even eliminate. I don't know.

Dr. Insel: So Geri, if I can just respond a little bit to what you have said or what you didn't say which was that in addition to the objectives, I think you and a few of your colleagues spent a lot of time on the piece of this that is the previous piece, the what is new in this research area in the past year, and I for one found that extremely helpful, I mean it's a very good summary, which doesn't come through quite as well in some of the other documents that we have.

So I think there is a real advantage in getting people who have an investment in the area to pull together whatever it is that has come up in this past year that we may not always be quite as aware of as a committee.

So we may want to separate out that piece which is really helpful, which we didn't do last year as part of the plan. So, Ari?

Mr. Ne'eman: Yes I just sort of have some thoughts and a question around the process. Are we looking at this -- and clearly these are not final drafts -- but are we looking at this as a draft that we are working from or are we looking at this as a draft that represents a broad scope of the input and then the committee as a whole, including those on the committee who aren't on the planning subcommittee -- because I want to be fair to them as well -- are going to be needing to make individuals votes on?

I guess my thinking around that is on the areas in which we all have consensus that clearly doesn't matter very much, but if there are areas in which there is a difference of opinion, there is probably a very different dynamic if the question is, well, are we going to be taking a vote to change something from our working draft, or are we going to take a vote as to whether or not a point under contention should remain in?

So it's a process question but it's I think an important one.

Dr. Insel: Well, I will throw this back to the subcommittee a bit. My understanding from the last conversation we had in the subcommittee -- but maybe I don't have this quite right -- was that no one felt that this was ready to come for a final vote to this committee, that what we wanted to do was to tee this up today so the full committee could get an idea what we were thinking about in terms of its scale and scope.

If the full committee came back and said, my goodness, we don't want any more objectives, sorry but we did this last year, we are fed up with doing updates on the strategic plan, case closed, just come back to us with no more than five lines for the next year, I think that would be important to hear at this point. Because when we last talked about it with this full committee, what we heard was something more akin to that than 35 new objectives and what we are giving them at least begins to -- if we are on pace to be more like 50 new objectives if we keep up the same pace of what we have done with the first four chapters.

And if the full committee doesn't want that, I think this is the day to hear it. I don't think we need to spend a lot of time on each of the objectives that we have in these chapters one through four and try to iron that out here, it's too many people to do it with and it's really the job of the subcommittee to resolve all the sticky issues like that.

Mr. Ne'eman: Thank you, that makes the entire process question at least for today a great deal more clear.

Dr. Insel: Until our next meeting when it will become a real problem.

Mr. Ne'eman: I look forward to it.

Dr. Insel: Lyn.

Ms. Redwood: Tom, I just wanted to comment about adding the new objectives and I can't remember if it was Question 2 or Question 3 when we had our meeting where there was something like 40 percent in the other category that didn't fit anywhere, 30 or 40 percent. We were scratching our heads, like how are we so off target?

And then one of the things that Walter did, he is not here now, but once we got the information with regard to the specific studies, some of the new objectives that we had Walter went back in and looked, like for this one about launch studies that target underlying biological mechanisms at co-occurring conditions, there were several in there that are being funded now, so I'm thinking that with some of these new objectives it will be a way to capture the things that are in the other categories that weren't reflected previously.

So in terms of diluting out and creating more objectives I think some of these actually are making what the researchers are doing now fit into our plan. If that makes sense.

Dr. Insel: So this is an interesting point. If it's something that is currently being funded to the full extent of what it was that somebody wanted to put in -- so it's not a gap, do you still want to put it in as an objective or do you want to find some other way to capture it, because it seems to me that it is a different category in a way and we don't really have a category for something that people is important to do, not yet in the plan, but it's already being done. Ms. Redwood: But it's not done to the level, one of the things you pointed out -- is it being done to the level that we need to have done and then I think we need to realize that those things are being done so I think I look at it almost as a better way of classifying some of these ones that are falling in the other categories that obviously the NIH and researchers think are important, we should have them in the plan so we get credit for actually getting things done.

Dr. Insel: For what we have done. Okay, fair enough.

Mr. Ne'eman: And let's take into account just another consideration here, too. There are objectives that arise because of research findings that have come to -- that we have become aware of recently. There are also objectives that arise because of new policy environments.

For example, a considerable amount of discussion around health disparities is now infinitely more relevant because of the Affordable Care Act.

So I do think it's important for us to consider new objectives not just in the context of, well, what can tie to the evolution of specific peer review journal articles, but also to a new service provision and new policy opportunities that are coming up in 2010.

Dr. Insel: And that is something that could be captured in that section of what is new and what have we learned this past year. It may be that that's a place to also include changes in the climate. That would be important to address. Alison? Did you have your hand up? Okay.

Well so those are -- so I wanted to just sort tap the people on the committee --

on the subcommittee. Let's open this up, then, to other people's ideas about this and Denise I'll let you start off.

Ms. Resnik: I think 100 objectives is startling and overwhelming for any organization and the amount of time and investments that we make in strategic planning and doing more strategic planning I think takes us away from some of the implementation components of this plan.

And when you reflect on the vision and the mission of our plan and all those core values that we spent time creating, we talked about creating a focused, coordinated and high quality research and scientific discovery plan.

So I think we need to be working the plan and I am not in favor of adding 35 or 36 new objectives unless some of those other objectives come off. And we spent a lot of time in the first effort to go through it, so I don't want to see us rewriting this or adding an unmanageable number of objectives to this plan. We really need to work it.

And I do agree with what was said earlier that where there certainly are new research discoveries it needs to be flexible enough to capitalize on those and where there is new research that is being funded, yes, I think there should be another area so we can continue to track that, because it may represent opportunities for the future.

But I have been a part of too many organizations that just spend their time planning and I don't want to see that happening here.

Dr. Insel: Yes, and I guess to be fair to the subcommittee, this was a conversation that people had in the subcommittee, that they wanted to see at least an equal amount of energy going into the accountability side of this and asking of the things we have put out there, how are we really doing?

Not only in terms of number of grants funded but also what is coming out of this. So that isn't reflected in what you have in front you but it was part of the discussion we had.

Ms. Resnik: And I will add one other thing and that is that evaluation is critically important because as part of a strategic plan and working a plan, course corrections need to take place and if the return on investment isn't there based on what we might have thought two years ago, in terms of what should be invested then we might not want to continue funding if it's not providing some type of return for us.

So I don't think strategic planning is an exact science but I know what it means to be overwhelmed by 100 objectives and I don't think that is what we want to be doing to ourselves.

Dr. Insel: Okay. Judith.

Dr. Cooper: I would like to speak

from a program person's perspective. We have several institutes represented and I know that when we all get together and we use the strategic plan as Lyn was saying we are looking for gap areas, we are looking for the areas that maybe are a priority based on the discussions that we hear here, and based on the portfolio analysis we already have several gap areas, several areas we know we need and we are all today listening very carefully to what you are identifying.

But the more objectives that get added, it does become I think from a program person's perspective a laundry list and it's like so where do we go if we have 100, if we have 30 -- you know, I don't think any of us want the committee to say you must do these three areas. I don't think we are looking for that, but we all know what the budget situation is and we know that money is going to be tight for a while and so I just don't feel like it's in the best interests to add too many more objectives because it doesn't become useful to program people who are trying to decide well now what exactly which direction should we be going? Thank you.

Dr. Insel: Geri and then Alison.

Dr. Dawson: I was just going to move to a couple of ideas for solutions, which is -- it seems like there's sort of two solutions besides just saying no more new objectives. That's one solution, I guess. But a second solution is to task the subcommittee with prioritizing x number, right, and say you can come back with your top x.

And then another one I think, just having come up with a laundry list because I didn't feel like it was my place to sort through, is that a lot of them could be lumped. A lot of them are two or three or four things that actually pertain, or are a fleshed out group of objectives around a molar objective and so I think some organization would go a long way in terms of collapsing those objectives.

Dr. Insel: We'll do Alison and then Ari.

Ms. Singer: I totally agree. I was just going to also add that I think Question 2 was an anomaly based on a decision that we made in the subcommittee last year on Question 2 -- and last year I was the co-chair of Question 2 -- and we talked about, you know, a lot of the studies that are classified as "other" in question 2, they are a large number and the reason is because many of them are imaging studies, and when we talked about the objectives last year in Question 2, we decide that imaging was not in itself an objective but was rather a methodology.

And so we did not create an objective specifically for imaging, but because of that the result is that there are now all of these studies in Question 2 that have no place to fall. So we may want to just make a course correction as Denise said to take care of that and to fix that decision so that if we have a clearer reflection, a clearer picture of what is happening in section 2, because I think in retrospect that might have been a mistake.

Dr. Insel: Ari?

Mr. Ne'eman: So I can certainly see the argument to be made for a more precise, more specific representation of objectives, but I guess one thing that I would bring up as another possibility in terms of adding to the solution is the question of at what point do we look at objectives that we have had in the past and come to the conclusion that they have served their purpose, that funding has been appropriated to these priorities, that there is not a gap there anymore and that it may make more sense for us to make different priorities going forward.

So I guess if we are going to be looking at narrowing the scope of objectives, which by all means I agree we should, let's not hold sacrosanct that which has been placed in the strategic plan in previous years if it has already been funded and the relevant findings from it have already come out and now is the point to evolve that into something that is going to be more relevant.

Dr. Insel: Yes, I think part of what we are up against here is just the marathon of science, that if you decide in 2009 that something is a good idea and you put out an RFA in 2010 that gets funded in 2011, the work will happen between 2011 and 2016 at which point it will be funded - or it will be published.

So there's not going to be a lot of things that were in the plan from 2009 that will have been completed. There may be some because we had some very short term objectives and if those are -- we really ought to identify those and see whether they can get sort of a green plus of saying done, and could move into a different category, but my sense was that there wasn't very much like that. I think we had one on a screening instrument that we wanted to have developed by 2011 or 2010 which I think may have been already been done but -

(Off microphone comments.)

Mr. Ne'eman: I guess my question is so there is the funding -- I am not necessarily saying that we are saying these are priorities that no longer need to be funded anymore. But if a commitment has been made, if a multi-year commitment has been made, and if we look at the strategic plan as something that should be guiding the future of the new commitments that are going to be made, the new applications that are going to be coming in, that has to guide our thinking to some degree, doesn't it?

Dr. Insel: So I think what we are up against is the reality of how funding is done and you are hearing some of that here. And I take Judith's comment to heart that if there is a very long list, none of these will become RFAs, frankly people -- and if they see them changing every year, program people are just going to say there's no way we can do this.

So and then you will be left with unsolicited research, some of which will fit in well, because we will make this public, people will know that this is what NIH is -- and the IACC considers high priority, but it is very difficult to direct in that way without actually doing an RFA. But if we want RFAs it's going to be very hard to get those unless we have clear priorities when you have 100 or 110 different objectives. Lyn?

Ms. Redwood: Tom, I was just going to say that when we did this exercise back a few weeks ago and it was really rushed for the people who participated in this, we did not have this whole portfolio analysis of projects. So I guess what I would like to suggest is that the people who drafted those specific chapters go back -- we have another meeting, what, in two weeks or three weeks -- and look back over this more closely.

I know that Marjorie said there were edits she was wanting to make to Question number 2. Look at this and see if there are projects that could come off and do what Geri suggested with regard to collapsing these to make it more manageable, and then bring it back to the committee.

As we said, this just a draft and is nowhere near being ready to present to the committee, so that -- I want to throw that out as a possibility, to let us have some more time to work on this and bring it back.

Dr. Insel: Right, well I think that's very much the spirit of this, is that we are in process and what we really want from the overall committee is just a kind of temperature of how you think this ought to be done. So, Josie.

Dr. Briggs: As I listen to this conversation and as I think about the process of really making a strategic plan that truly guides the programmatic assessment, I am hearing that the temperature in this room is a very finite number of new objectives. Is that right? And maybe we even want to try to see whether we have got a consensus about a number.

Dr. Insel: It's interesting because I have to say we started there as a subcommittee and then as we got going, as Geri can tell you, we just quickly got very expansive.

So this is tough. But I think if the full committee wants to give us a charge we will be able to respond accordingly. It would be very helpful, actually. So if somebody wants to make a recommendation along those lines, that would be great. Judith?

Dr. Cooper: Okay, I will make two recommendations. One is the middle recommendation of bookends but not with line item edits and that the objectives be limited to three. Because if you do that it's three times seven chapters, right? That's 21 new objectives. That already to me is a little bit overwhelming. But I think that's my recommendation.

Dr. Insel: No more than three, right? So -- that's helpful. Marjorie?

Dr. Solomon: So as for the members of group 2 who have 50 percent unclassifieds, I think we can probably make some small tinkerings to the existing objectives that would make studies fit more neatly under those. And then I think we could probably accommodate three new objectives. It's just that a lot of the imaging kinds of studies that we have don't neatly fit and I think that's what is resulting in the 50 percent over.

Dr. Hann: I have to ask -- because I am having a little disconnect from where we started from -- about the meaning of the portfolio analysis. And it may have changed.

But when we first started this, the first thing was to help identify the science that was going on relevant to a question. And then we thought, well, it would also be very helpful to know if there was also things going on in the objectives.

So the idea that most of the science that was going to be conducted for a given chapter was going to also be tied up in objectives I don't think was part of it at that moment in time. So I guess I am trying to understand from the committee where you are going with this. I mean do you really view the -- do you want the plan to be such that most of the science that is being done is captured by an objective?

Dr. Solomon: I would say yes, just because otherwise it makes it extremely hard for us to evaluate what we are doing. I mean if we have 50 percent of what we are doing that doesn't fit into our plan, then we just really can't figure out if we are --

Dr. Hann: But you know you have that much going on in that area of science, so I just -- and you have identified objectives that you thought were priorities. I am just trying to understand the logic of it. I am not saying one is right or wrong and I don't mean to be argumentative. I am just trying to understand what the meaning is of what we are trying to do.

Dr. Solomon: Well, I think the ultimate meaning is to identify gaps that are out there, but in order to figure out gaps and gaps that might end up representing funding priorities for agencies, I think we need to know what is being done and have that put out there really nicely so we can say, hey, we know that there's already many, many studies going on that address in our case I think there is a desire to try to connect biology with symptoms.

And so we know there are already 100 studies being done that do this and now that we have re-tinkered 2.L.A. we know that we can put a lot of those under there and then we know, okay, that is going to get a green dot. We feel better about that. We know where we are at.

So for me, it's mostly I think the key issue is to identify gaps and if we know what we have got, we are just in a better position to identify gaps.

Dr. Insel: Ari.

Mr. Ne'eman: Yes, I guess my thinking around this is I do feel it's somewhat premature to identify a limited number of new objectives, particularly split evenly across every chapter. As I think was mentioned earlier -- I think Lyn brought it up -- we have only just gotten the portfolio. Presumably the portfolio should help inform to some degree where there is a need for new objectives and where there isn't.

If we are seeing an area that isn't really receiving any significant amount of funding in terms of a question, it may very well be that we may need to retool or add or make some alteration to the objectives present there. If we are seeing an area that is already being quite well funded, it may very well that that area doesn't require any new objectives.

So I don't know that a split three, three, three, three, three is quite where we need to go, at least not quite yet.

Dr. Insel: Chris.

Ms. McKee: Yes I don't like the arbitrary -- I don't like the arbitrary limitations either, and the reason is that when we have areas where science and workshops and large public outcry has shown clear gaps, like the non-verbal area, I hate to say, gosh, sorry, but we have got a limitation of just three.

So I would rather be responsive and come back and not set up a limitation right at the beginning.

Dr. Insel: Sure. Okay. Other thoughts about this?

Dr. Dawson: How about three to five?

Mr. Ne'eman: But once again the question really does come up, does it make sense for us to be placing the same limitation on every chapter? I think we need more time to absorb this portfolio, to see what we can -- where there is opportunities to merge objectives, as you suggested, and then once we have that opportunity to gather that new information and to see what we can finagle in regards to what is currently under consideration, we might be in a position to place those limits.

I have to agree with Christine. Avoiding arbitrary limits is probably in our best interests and the public's right now.

Dr. Insel: Any other thoughts or comments about this?

Ms. Redwood: I agree with Christine and Ari and I think we can come back and even take some of these off, Tom. I really think we can tighten it up.

Dr. Insel: Okay. Denise?

Ms. Resnik: And I also agree with Ari and Christine. And thinking that in terms of process, as we go through the input that we have received, what we might want to identify is whether current objectives have been substantially completed, whether there have been new findings that would require that we consider new objectives and if there are voids in the current plan then I think we can acknowledge and put them in a parking lot so that we can consider whether they should be added at this time, but I would hate to put all those voids in there because we did the best we could, we are doing the best we can, and it's not only in terms of administering, as Judith was saying, you know, this overwhelming number and trying to create some priorities, it's also communicating out to the public and I think we just confuse the public too with too many priorities.

So I would agree that we don't have an arbitrary three for each chapter, that we come up with a process that we can evaluate. Maybe it's no more than three, if any should be added at all.

Dr. Insel: Well I think we are not going to vote on this because we don't need to, but I think the subcommittee is getting some pretty clear signals about what the larger committee would like. The other thing that I am hearing is that this first part of it, the what is new in this research area and what have we learned in this past year, and I think you will see this as you look at the documents that we have in the folders, there's a lot of richness in that one page or sometimes less than a page description.

It could include the comments that Ari is bringing up around changes in policy. This has been an amazing year for changes in policy that need to be discussed when you are thinking about comparative effectiveness research or research on services where a lot is going to change and we want to have research that informs those changes.

And then the other piece would be there Denise, just like you are saying, if something has been completed or largely well addressed as we have seen from the portfolio analysis, it wouldn't -- it might be a good idea to include a paragraph that says over the past year, the following major objectives have been largely addressed and then that leads into where the gaps remain.

So Geri I think did most of the heavy lifting on these introductory comments and they are really terrific. I would recommend you read them if you haven't seen them, but the -- that's so far largely focused on what has been published that is really new and exciting and of course I have to say that these were done two weeks ago and even in the last two weeks, there is a lot of additional really interesting work that now one might want to add to some of these chapters.

So that's always going to be a moving target and at some point we are going to have to just close the door on new science that we want to cite, but bringing back, tying this back to what we have done so far might be a good idea as well, in that since this will be kind of a standalone supplement, in a way, it will be different than the plan we did last year, I think it's a good way of tying it in and making sure people know who read it that there has already been a lot that is going on and these are some remaining gaps and some new opportunities that we will then address if there are going to be new objectives and I hear your concern about that.

Ms. Resnik: And one of the -- and I am not sure if I am following you. I agree with you what you have said in terms of a separate document though, again I am thinking about the public and how user friendly it is and how we are communicating out that I would like to base it on this and if we can incorporate it with those sections, those annotated sections that say here are the additions to the plan, just so that people don't have to go through how many different documents to figure it out.

Dr. Insel: Right. Nobody is going to want to look for objective 2.1.A in another document.

Ms. Resnik: Right and I am also very much in favor in creating a plan to make sure that we celebrate those achievements and those should be highlighted. Thanks.

Dr. Insel: Marjorie.

Dr. Solomon: I had a question about the research updates because what we did in our group I we used the 2009 semiannual and the 2010 and we limited ourselves to that literature because obviously there's always a ton of literature.

And so the question would be, are we

limited to using those, the things that this committee has come up with, or can we expand it?

Dr. Insel: That's a great question for the committee. What's the sense?

Dr. Briggs: My sense would be that if it is in the published literature, the more up to date this can be, the better and one may not always capture the latest but if it's published --

Dr. Insel: Well especially if it's transformative, so if it is a finding that you really think would be essential to informing a new objective or to completing an objective that is there, it seems to me it would be silly not to include it but I would have a very high bar for what we talk about and I think that's true in the document we have now. There are not a huge number of publications that are cited but the ones that are cited are very substantial, and they really do speak specifically to the needs of the plan. David?

Dr. Armstrong: I was just going to say that it would be interesting to see what comes out of the Society for Neuroscience meeting but then I saw you got you subcommittee meeting scheduled for the Friday afterwards so you will be able to do that.

Dr. Insel: Right, and actually what we have done is to make sure that it has to be published before we would cite it so it wouldn't be an abstract. Geri?

Dr. Dawson: About literature, so one of the things when I started getting input from a lot of different people, people were bringing in and I even did this in the beginning myself, a lot of earlier literature so that became sort of rewriting the plan, right?

So at one point when I realized that I had done this and other people were doing it, I made it so that really the only things that could be cited were things that happened in -- that weren't available as of when you guys wrote the last plan, so it was 2010 essentially or there was maybe one in 2009 that was not available at the time and that changes the flavor because once you start going back and people start rewriting things, it got, that got --

Dr. Insel: Oh yes I think think that's an important point. Is there anything--

Ms. Blackwell: I actually, I feel guilty because I actually did that to Geri. I noticed she had gone before and then I went oh no, we have got to start with where we left off and then anything up until now that was peer reviewed, that was my perspective as well.

Dr. Insel: Yes, those are the criteria that we have been using. Ari.

Mr. Ne'eman: So I largely agree with you Geri, I just want to raise one potential caveat in terms of where older, not old, but maybe things from `06 or `07 or `08 may make some sense to include, and that is where a new policy window opens up an area of discussion and it is necessary for us to look through the peer-reviewed literature as to how best to take advantage of that.

So if there is something in the Affordable Care Act, that opens up the possibility for an objective that we have never had before and there was some good research on three or four years ago that we can build on. I so still want us to keep open the possibility to cite research that is a little bit older but as Tom said it's a very high bar.

Dr. Insel: Okay so in closing this out, let me see if I have on behalf of the subcommittee if I am reading this right, it sounds like the full committee is okay with the method of updating we are doing generally, which is the bookend approach so there will be something that will be added to this document and it will be worked into this document but it won't be a line by line rewrite. Each chapter will have a section about those items that are shown here in this template and am I right about this? So let me know if there's any heartburn on this topic. Okay.

So we will go ahead and continue with what we planned, and then in terms of what you have seen in the draft updates, you are telling us, if I am hearing you right, to try to consolidate as much as possible and to -- though you don't want us to have a number, a target, to be very careful about getting too expansive, which we would love to do. So we are -- we hear the message and we will be going back to work in the next few weeks and we will come back to you with something that is not such a draft and that is going to be spectacular in its scope, will be inspiring for all of the progress we have made and for all the opportunities and if there are objectives in there they will be very consolidated and they will also be only put in if there is absolute need to demonstrate that we can fill an objective or we can fill a gap in that way. Okay?

Anything else the subcommittee needs? All right. We have got our work cut out for us. November 19, we are going to be busy.

The last thing we need to do here for the meeting today is to circle back to the public comments which were really today particularly rich and diverse and while we have left some significant time to do that because there are so many things that could be discussed by the full committee, I think rather than tee this up in any specific way let me just ask you for your responses and overall thoughts about what we heard there, of course many different topics , but I know that those who volunteered to share their ideas and thoughts of us would love to have some feedback. So committee what do you think? Ari?

Mr. Ne'eman: I'll just start by throwing out here two opportunities I heard for the Services Subcommittee going forward and maybe these are things we can tackle after we write the recommendations coming out of the services workshop.

Clearly there is a need for more on culturally and linguistically competent service delivery and I thought the presentation from the Somali community was particularly compelling on that. And then I wonder if we can't reach out to the Department of Justice and get somebody from there to present to us the model they are doing for the Alzheimer's program, the tracking -- Alzheimer's safety program they are doing over there and see where the opportunities for adaptation are. I put a pin in that for our work next year.

Mr. Grossman: Regarding the Alzheimer's organization we have been working with them to see how they have approached this and it's been very interesting and it is an ongoing project of the Autism Society in terms of our safe and sound program.

It's -- we expect them to be very involved in our next conference when we do a safe and sound program. And yes I think that this is a very important aspect of the service subcommittee and going forward we need to move this forward. The safety across a lifespan for individuals with autism is tremendously underserved. We get calls into our office daily that are just horrible, that are about bullying, victimization, incarceration, prison, institutionalization as well as parents that are considering suicide or homicide of their children as well as the children that wander off and this is a very, very important topic that needs to be addressed across the lifespan.

Dr. Insel: So I would like to just get a sense from the committee about his because if you think back about what we heard today, from the very first presentation from Alexa Posny, through the presentations from Wendy Fournier and Lori McIlwain and then this really moving and heart-wrenching comment from Sheila Medlam, I was thinking all day long what can we do and how can we respond.

I think it's -- I would agree that this is going to be important for the services subcommittee but it just seems that there ought to be something that we can do in the short term that will raise this as an urgent issue.

Our job is to be advisory to the Secretary of HHS and so I wonder what the committee thinks about that and whether this is an issue where we should step out and do something quickly and forcefully with the Office of the Secretary. What's the sense? Lyn?

Ms. Redwood: I think we should draft a letter to the Secretary sharing these concerns and say that it's an urgent, very unmet need. I also thought the recommendations of establishing a subcommittee to look at these issues would be hugely important and I think some of the things that need to be done are really outside of the venue of the IACC in terms of say for example establishing a diagnostic code for wandering. Absolutely needs to be done but I think that is something that our medical societies or I am not certain who the government entity is that establishes medical codes, but we need to make sure that we communicate those recommendations to the appropriate people along with the sense of urgency.

Dr. Insel: Ellen?

Ms. Blackwell: I mentioned this earlier today but I think that it is important to stress it again that a lot of people with autism and other developmental disabilities participate in home- and community-based waiver programs and associated with those programs are key quality assurances that states must meet to run these programs in concert with the federal government.

And in my mind, the most important

of those is the quality assurance that surrounds health and safety. And it's been interesting in this budget environment to see what happens. I mean there are some maintenance of effort requirements that surround the programs but how do states save money when they don't have enough? They cut a service or they cut the provider's payment rate. I'm sure, Lee, you can rattle them all off instantly.

So we look very carefully at CMS because if a person is going to be participating in a waiver program the state has to tell us -- and they want to receive federal money that the person's health and safety is assured.

So there are certain reporting procedures that are in place and we work with our states to make sure that they are in compliance otherwise they can't participate in our program. So there is a lot going on, especially in home- and community-based settings that already supports health and safety.

Dr. Insel: Geri.

Dr. Dawson: Well for me one of the things that was most compelling about Wendy and Lori's presentation is the very, very specific recommendations that were made, which were very doable.

And so things like having a diagnostic code that is similar to Alzheimer's for wandering so that could be considered a medical condition, that the technology that could make a big difference then could be covered by insurance so that people could have access, or having a website where information -- we do this animals, right, where we have information of tracking animals and yet we can't do it for children or individuals with autism?

So to me it just seems like to hear a presentation like that, to be IACC and not just honestly just respond and get this taken care of, you know we are not doing our job. I really think we just need to address it and these are -- it's addressable.

Dr. Insel: Ari.

Mr. Ne'eman: Well actually I agree with Lyn in terms of the possibility of a new subcommittee. It seems that some of these issues are not strictly speaking services issues and they are not strictly speaking research issues, so they fall into a broader category and I think some of the things they mentioned weren't even just around elopement but also things like bullying, restraint and seclusion and so on, that perhaps could be termed rights protection or rights protection and safety or something of that nature.

The services subcommittee is looking at any number of policy recommendations around service provision but not everything is going to fall -- not everything that we need to look at around policy change is going to fall into that. So I would ask us to consider and perhaps we need to allocate some more time to discuss this at the next meeting, the possible creation of a third subcommittee. I think it would be a good way of showing responsiveness to the public comment and also affording a venue for us to discuss these topics in more detail and take some concrete actions.

Dr. Insel: Alison?

Ms. Singer: With all due respect to what Ellen said about systems that are already in place, every day children are wandering and dying so I think if there is a system in place the system is clearly broken and I think that this is an issue to which we need to respond immediately. We talk about a sense of urgency, there is no greater urgent problem than children with autism dying from something that as we learned this afternoon is really preventable through some of these tracking programs.

So I would like us to not wait and discuss it at the next committee meeting. I would like us to move today to form a subcommittee because I agree with Ari, it is really not part of services. I think if it had been part of services then these five issues that they identified would be reflected in the services seminar we were having. We are having a full day seminar and none of these issues were brought up by members of the services committee.

So I think we have to pull this out and have a separate committee and I am going to move now that we establish such a committee.

Ms. Redwood: Second.

Mr. Ne'eman: I would like to second. Oh, well. Excellent.

Dr. Insel: You have to rush to be the second here.

Mr. Ne'eman: Great.

Dr. Insel: Other comments, other thoughts? What about the idea of a letter to the Secretary?

Ms. Singer: Well I think if we establish this subcommittee now the first thing the subcommittee could do was draft the letter and present it to us at the December 14 meeting so that it could go immediately to the Secretary and we could charge the subcommittee, its first thing could be to work on such a letter, but not wait.

Dr. Insel: Ellen.

Ms. Blackwell: Alison I just wanted to say that I can only address the people who are participating in Medicaid programs and CMS's programs, so again this might be -- this is an area perhaps where CMS goes beyond our programs obviously because not everyone participates in Medicaid.

Ms. Redwood: And I know in our state we have got years and years and years of people on waiting lists trying to get Medicaid waivers. It's just horrific so I know in Georgia it's not getting answered and that doesn't take care really of the children that so desperately need this.

Dr. Insel: Other thoughts about this? So we have got a motion on the table here to form a subcommittee or we could call it a workgroup I suppose which would -- I has to be a subcommittee, you are right, because of the language, and the subcommittee would have a task initially of drafting a letter for the full committee that would go to the Secretary. I have to say, the letter is pretty well written from what you saw this morning. I am not sure that there is a lot more work to do. There's a very clear charge to us from the presentation that was given to us this morning so somebody has already done a lot of the heavy lifting with the data that they have collected and everything else. So this could happen rather quickly it seems to me.

We might also want this subcommittee to go beyond just writing a letter but to actually then explore some of the things that Geri is talking about that those things that are ready to do and to figure out who might be able to do them.

Some of the things I think we have linked to CDC and some to I was thinking to HRSA actually was probably the major player here Peter. There's an opportunity through HRSA because you do similar kinds of activities in a broad way.

Dr. Van Dyck: We'd had to review our portfolio but I think most of those activities could fall within our existing legislation and we do have an anti-bullying website that is really very good and used and I don't think there is a specific reference to children with autism there but there could be one added.

Mr. Ne'eman: See I would think Henry's office would play -- Henry Claypool's office -- would play a very critical role here given all the work they have been doing on Olmstead compliance.

Dr. Insel: I think we have just named the subcommittee. Let me see who else would like to serve on it, if we have --

Ms. Blackwell: Well I think no, I am not volunteering I am volunteering another agency, okay? I don't think we should ignore our partners at the Substance Abuse and Mental Health Services Administration who are also are very involved in these efforts, Peter, as you know.

Dr. Insel: So we will have HRSA, SAMHSA, I think CDC really should play in this arena and then who else from the committee would like to serve?

I realize we actually didn't vote to whether to do this so let me just first take a vote of whether the committee feels that we should have a subcommittee to look at this issue.

All in favor.

Opposed.

Abstaining.

Okay the motion carries so we have a subcommittee.

Mr. Ne'eman: Brief point of order. Howe are we defining the issue?

Dr. Insel: Which issue?

Mr. Ne'eman: The issue that the subcommittee -- the issue that the subcommittee is tasked with addressing. I had put forward the phrasing rights protection and safety previously but I don't know if that was what was specifically mentioned in the motion.

Dr. Insel: So let me read you what we heard this morning and we will see if this matches what the committee would like.

Establish a subcommittee focusing on safety issues affecting the ASD community and addressing external causes of death.

Mr. Ne'eman: It's broader.

Ms. Blackwell: I -- we actually came up with a topic name for this. Maybe you will like this Ari, which is we sort of -- the services subcommittee put this under the rubric of community safety.

Dr. Insel: Marjorie?

(Multiple speakers.)

Ms. Redwood: What if we let the people on the committee decide when they meet for the first meeting.

Dr. Solomon: Well actually you might also want to be informed by what they asked for which was establishment of a subcommittee focusing on safety issues affecting the ASD community and addressing external causes of death, wandering and elopement, restraint and seclusion in schools, anti-bullying education, support for families at the breaking point and education for law enforcement.

Dr. Insel: That's a pretty good list of tasks. I think we could add to it but that would be a good place to start, but I would, now that we have established a subcommittee and we have a description, I am assuming that people are okay with this, I really want to task this group to start with a letter, I do think we need to, as part of our role as an advisory group, to send along very quickly a very strongly worded letter about what we have been hearing and make sure that the leadership in HHS knows about this and then we can begin to drill down on some of the specifics. Geri?

Dr. Dawson: I am wondering whether with such a letter and IACC takes the lead and is the lead author of it, but I also wonder whether having this signed by other organizations would be useful because I know that Autism Speaks cares very deeply about this topic and I am sure there are other organizations, I mean obviously NAA has been taking a lead in this and so I don't know whether having people, other organizations sign on to the letter or at least mentioning endorsement or something would convey the breadth of community support for this issue.

Dr. Insel: Well I think it would be great to get additional letters but I think for the IACC, just in terms of who we are as an advisory group, the charge we have is to -- and I won't get the wording exactly right but it's something like to advise the Secretary about emerging needs in the services arena or something like that and if ever there was one, we heard it today, so I think to meet our charge we need to do that but others could send in supplementary letters and we could bundle them together.

Mrs. Medlam if you had a comment we would be happy to --

Ms. Medlam: (Off microphone comment.)

Dr. Insel: We will have to -- I think what we need to do is find a way to convey just how big of an issue this is.

The other thing is I would hope that the subcommittee could come up with some rapid low-hanging fruit kinds of opportunities as well. I mean we heard about some of the things again in the presentation that are not going to require an act of Congress or even a secretarial policy decision. There are things that we could probably push out quickly and if we don't have the groups around the table like DOJ certainly we could bring them in at a meeting and make sure we have a discussion.

And I think all of this raises a question about whether in the future, some of these other federal agencies need to be at the table so that we have the people here who can actually put some of these things in place. Lee.

Mr. Grossman: I mean, there are some decent demographics that we can help provide to this to support that's very important cause and we have many, many letters that we can add and are willing to add to what you have because it is such a terrible problem.

I am going to volunteer Sharon Lewis though to be a part of this committee and maybe even take a lead because he is recognized in D.C. as perhaps certainly as the leader in restraint and seclusion and she has done a great deal of work in that area so she already brings a great deal of credibility and respect to leading this effort.

Dr. Insel: So we have all the names down.

Dr. Hann: So yes. Here is what I have been hearing. I heard HRSA, CDC, SAMHSA, Ari, Alison Lee and now Sharon Lewis, ACF.

Mr. Ne'eman: And I would agree with Lee, I think Sharon would make a great chair.

Dr. Insel: Sorry, Ari?

Mr. Ne'eman: I said I would agree with Lee, I think Sharon would make a great chair of the subcommittee.

Dr. Insel: We could vote on that but I am a little reluctant to do this for someone who is not present. Of course there is always the penalty for not showing up that --

Now we heard a lot of other things through public comment so let me just make sure we have a chance to circle back to other comments you heard and things that you think we need to follow up on.

Lyn?

Ms. Redwood: Yes, Tom I think we have something in the plan already I am pretty certain that looks at special populations so I would think that doing something with the Somali population in terms of studying them extensively is already sort of reflected in the plan.

I don't know if there's currently research going on in that area. Are there studies going on now?

Ms. Abdull: (Off microphone comment.)

Ms. Redwood: Well a few years ago we went into or ATSDR CDC went into Brick Township because there appeared to be a cluster there so if we are seeing something like this in a population, why can't we mobilize our federal agencies to go in and study it rapidly?

Dr. Insel: Coleen.

Dr. Boyle: So I have had or we have had conversations with and have been supporting the Minnesota department of health and there's a number of actions steps when they have issued their report back in March of 2009 there were a number of action steps that they had and we did recently get an update on that and they are continuing to work within the context of the Minneapolis Public School System to update the prevalence, they are looking at some of the cultural issues that in terms of services as well as some of the issues around the cultural sensitivity of the actual diagnostic and screening instruments.

So they are doing a number of things and I did ask them if they would be willing to come perhaps at our next meeting and sort of give an update in terms of what they are doing. We are actually, have a -- perhaps another RFA that will be coming out on looking at surveillance issues and are encouraging them to consider replying in to that FOA.

Dr. Insel: So that sort of deals with the question about whether there is a cluster but from everything I have been able to figure out and I have talked to a few people who have begun to look at the data, there doesn't seem to be much doubt from what I can tell that there is something like a five to sevenfold increase in this population which I don't think we have anywhere else as far as I know and so I think what is likely to happen is people could do more work on describing the epidemiology.

I guess the question for us is, is this an opportunity to understand something around causation? And so I wonder whether NIEHS for instance would want to see this as what may be a unique opportunity for what we have now. I don't think we have anything else that corresponds to this and yet from what I can understand, nobody is really bothering to unpack this and try to figure out what could be special about this Somali population. It's not happening that other Somali populations so there's some very interesting cluster that we don't understand.

Dr. Armstrong: Linda saw the comment and they are thinking about it and I so I won't speak to her but I have definitely written it down and I will remind her again that it was an issue of concern for the committee and an opportunity.

Dr. Insel: Yes the question would be whether, I mean if it really is the goldmine that some people think it is, whether there is a way to supplement a charge study or one of the other big projects that are going on now to quickly take a look at this even if they are looking at mostly administrative data to try to understand whether there is something unique here.

I don't have a clear plan for this but it does seem to me that when we hear about something like this that comes up in an IACC meeting, we should recognize that it is an opportunity that could be pursued. Lyn?

Ms. Redwood: You know, I can't help

but think if this was an E. coli outbreak in spinach, we would be all over it and we just don't rise to that level of urgency and I really wish that we would do something more than just consider adding it as another special population. This is huge crisis for the section of our population and I think we could do more to address it.

Dr. Insel: Is there anything going on through -- is Autism Speaks involved or is any of the private groups?

Dr. Dawson: Well after actually -- in the beginning when this came up as an issue and I know that Idil and I have communicated many times about this, we talked to the CDC and my understanding was that you were really trying to do more of an in-depth study.

However when we had the meeting the NIEHS meeting, this came up and Linda Birnbaum and I and others talked about this as an opportunity to potentially understand environmental factors and so since that meeting we have at Autism Speaks, been doing sort of a deep dive on that area you know what is known, what do we know about the Somali populations in Europe et cetera so we are kind of in the fact-finding stage coming out of the NIEHS meeting and deciding how to respond.

But it is definitely on our radar and so I think we are kind of at the same place with NIEHS with this.

Dr. Insel: So could we get the two of you, maybe -- I don't know who the point person David at NIEHS, but if we could get somebody there and somebody at Autism Speaks to take this on, I just I guess I feel the way Lyn does, that this is not something that we should sweep back into the strategic plan. I think we have been given an opportunity here and it would be a shame not to pursue it.

Dr. Dawson: And we are doing that anyway. I have Michael Rosanoff actually doing a whole comprehensive -- I have asked him, I gave him that charge to go in and really look, what is the CDC doing, what do we know, what is in the literature, and so we can come back with sort of a report and a set of recommendations if you want. And we can do it together.

Dr. Insel: Good, yes I think that would be great.

Ms. Abdull: If I may just add one comment. I really just strongly urge that Center for Disease Control take up more of a leader role because Minnesota department of health doesn't have the budget, capacity and as Lyn was saying if this was E. coli or any other problem, CDC would have been on it and I just, as much as you have done I think it's important that we don't wait for MDH but that you take the leader role and you work with the National Institutes of Health and Autism Speaks and you make a charge and come up with something because there is a problem. So many of us are not even coming out. The ones that are coming out are the ones that are classic severe. The kids that are talking are not even telling the community they have a child with autism. So it's a big problem and I wrote to your director Dr. Frieden saying you need to tackle this as you did the smoking in New York when you were the commissioner there.

Dr. Insel: So go ahead, so CDC is -- Coleen?

Dr. Boyle: Just, I mean the way we do work is through health departments and we have been assisting them fairly actively in terms of trying to respond to this so I mean the one thing I do want to clarify at least on the report that came out and looking at the Minneapolis Public School System is that the case finding, and again this was based on administrative prevalence, and the case finding among the other populations, the other ethnic groups, was actually the prevalence rate was actually much lower than anticipated so one of the recommendations was to go back and to really do a much larger look within the

Minneapolis area, the county itself, not just the concentration at the school system.

So I think there's a lot of unanswered questions based on the first evaluation of this and going and doing a much more thorough investigation I think is really important.

Dr. Insel: David.

Dr. Armstrong: I guess I am going to stick my neck out here but I think it's an unfair comparison to use E. coli or tobacco and the whole point is that we know what the cause is there and so of course you can be rapid because you can test for E. coli or you can reduce tobacco exposure.

The problem in autism, which we have discussed this morning, is that we don't know what that thing is that we need to measure quickly or prevent exposure to quickly. And that comes back to I know it's frustrating, and it's slow but I still think science is the fastest way forward to identifying -- for example the gene sequencing techniques we heard about earlier, if we had a marker, then we could move quickly. If you tell us what to measure, then we can do it but otherwise, it is difficult problem. I don't think we should underestimate how difficult it is to respond when we don't know what the source of the problem is.

Dr. Insel: Ari.

Mr. Ne'eman: I have a question for -- I'm sorry I don't recall -- so I have a question for Idil. On the service provision side, what more can be done in respect to that? What more could be done to help families have easier access to services that are linguistically and culturally competent, to help families that are not disclosing and getting their children access to necessary special education and support services. What are the steps that need to be taken in that direction?

Ms. Abdull: I think that that's a

really good question and because we are mostly new immigrants we mostly have Medicaid and so in Minnesota I think Ellen was saying that there is a wait list and home community waivers -- there is years and Minnesota doesn't even participate and there are a lot of services such as intensive therapy, ABA, that Medicaid says we are not even going to pay and so that is one issue that federally we can have maybe a better mandate and make sure that children that have private insurance and also have Medicaid get the same services so that it's not just private pay, Medicaid not so much. That's number one.

The other one is that our children, because of the culture and the language it's so, it's different and we don't know the system, I honestly don't know any Somali person that had autism the way we have it now. There needs to be more awareness and more culturally appropriate services so that children are diagnosed earlier because our kids now are being diagnosed at 6, 7, 8 because parents just say oh he's going to talk, that's okay, he's just in a new country, he's going to talk. So we don't have that service piece of people telling us no, no, no you need to get this kid into speech therapy. That's one area.

The other thing is we really just need more services I mean obviously the supply -- the demand outweighs the supply. There are not enough providers. Therapies for children with autism and I am not sure how to tackle that but you could be on a wait list just to get into a therapy provider, even when you admit it and you know the language and you have somebody that can help you they will say two-year wait list.

Mr. Ne'eman: So --

Ms. Blackwell: Can I respond for just a second Ari?

Mr. Ne'eman: Okay, yes, please.

Ms. Blackwell: Because I feel like I

am the defender of Medicaid today I mean, first of all, Lyn and our guest, I have to emphasize that you know states participate optionally in the Medicaid program and they offer these home- and community-based services at their option. The Medicaid program is set up to offer certain mandatory services and optional services and unfortunately as states face these fiscal problems that you hear about every time you listen to the news, they are permitted to establish waiting lists, all the federal government can do is say okay, let's make sure your waiting lists are fair and we do that.

So that's one issue and the second is that Minnesota does offer five home- and community-based waivers. Minnesota is a state that uses managed care delivery systems extensively and there are specific requirements throughout the Medicaid program, our early EPSDT program for children and also specific requirements that apply to managed care that require cultural and linguistic adaptability for anyone who is applying or participating in Medicaid. So if a Medicaid participant can't access services, there are grievance and appeal procedures and other ways, ombudsman procedures, so there shouldn't be issues accessing services through our programs and if there are you should definitely get in contact with your state Medicaid agency and complain.

Mr. Ne'eman: I don't mean to -- I don't think any of us meant to put you on the defensive but I think a lot of people in this room would disagree with the idea that waiting lists in this country are moving at a reasonable pace.

Ms. Blackwell: I didn't say that.

Mr. Ne'eman: No I didn't meant to put words in your mouth. I guess one thing I would put out there in respect to this is we are writing a letter to the secretary already. DOJ is taking a very close look at these

Olmstead compliance issues of which waiting lists are clearly one of them. There is a mechanism, correct me if I am wrong on this Ellen, within HHS through the office, HHS office on civil rights to also place more close scrutiny on some of these issues. I wonder if that might be something we can work into the letter we are putting into the Secretary or that subcommittee's broader work.

Mr. Grossman: Not to get off our primary subject of what is happening in Minnesota, but there is a coalition that I will make you aware of Ari afterward that is a group of disability organizations that are determined to reduce if not eliminate waiting lists and that is something that we can discuss later.

But in terms of the situation that is happening in Minnesota, the question that you asked Idil was a great question and your response was wonderful as well. And I think it showed a tremendous contras with what is happening here, certainly what Walter said earlier, kind of impacted me a little bit where he said that he wishes that he wishes that services would follow research.

I have a different tack here. I wish research would follow services. It did not take us a lot of research to realize that children are dying from wandering and take action on that. We don't have to have an E. coli outbreak or treat positions of tobacco to get us moving on addressing what we obviously know is a situation that has reached a level that demands attention such as what is happening with this increase in the Somali population in Minnesota.

So I would encourage us the same way that we are taking action and don't need further research to know that children are dying of wandering, that we do the same thing in the Somali case. Let's not be held back by trying to find the obstacles that keep us from doing what obviously demands attention.

Dr. Insel: If I am hearing what we have put in place there is a group of three people who are going to take responsibility for getting a plan together and get back to us at the next meeting. And Coleen, some of that will require just finding out exactly where we are at in terms of data collection and it could involve also looking at service needs and what is going on there which will be very helpful.

Other comments or thoughts about, reflections from the public comment? Lyn?

Ms. Redwood: The other things that we heard today were ultrasound, cord clamping, we have heard soy before, I think several of these can fit under David what you described today as the environment being very broad. So as we are working on our updates to the plan, maybe we should consider specifying some of the things that we have heard from the public that we think would be important as we look at these environmental factors.

Dr. Insel: Right so while this conversation was going on, I was going through the actual language to see if it was in there. We talk about factors but we don't -- and we have some examples. We have limited numbers of examples and so one thing we could do with an update is to reflect what we are hearing in terms of opportunities for further studies. Ari?

Mr. Ne'eman: I just wanted to add very briefly, the two additional issues that were brought up was the cooccurring issue of eating disorders and we mentioned cooccurring conditions a number of times including mental health conditions and others in the strategic plan so it is certainly possible for us to incorporate that as an example.

But also we have been talking about in the planning subcommittee of including gender on the list of various things that we need to be culturally competent around and the other issue that was raised in the public comment was sexual orientation and gender identity and certainly I think we can incorporate that as well so at the same time that we are culturally competent in the context of race and ethnicity and income and socioeconomic status, we can also incorporate sexual orientation and gender identity into those considerations as well.

Dr. Insel: Excellent points. Anything else that the committee wants to discuss? Lyn.

Ms. Redwood: This goes back to the services, not the services, the strategic planning subcommittee. I am just concerned that with our next meeting the time is really limited. I know this last meeting that we had, we had like three hours, and it is just not enough time Tom. We have got so much work to do, and then we have to come back again and again and so I am wondering if there is a way to dedicate a day or more time to get it done.

Dr. Insel: Have you been reading

Della's mind? Because I have a feeling that she is thinking exactly the same thing, because it was so difficult to get through what we did last time and I think we took, didn't we take half a day or?

Ms. Redwood: No. Three hours.

Dr. Insel: Three hours, okay. So we will have to look at this. It's an important point. And it's going to require, especially because there is still some difference of opinion about some of the specifics.

What will help us I think in going into that is if we have more refined documents so if we can get those of you who have taken charge of different chapters to really go back through the portfolio analysis, see where you can consolidate, see what we can make a little bit more succinct for the full committee I think that will be helpful.

Any other business for the full committee?

If not I want to thank those who

joined us by webcast, those who came to the meeting especially those who provided public comment, which as always is extremely helpful for the committee, and all of you who participated throughout the day so the meeting is now adjourned. We will be meeting again December 14. We will see all of you then.

(Whereupon, at 5:21 p.m., the Committee adjourned)