U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, JULY 10, 2012

The Committee met in the Monet Rooms III and IV, L'Enfant Plaza Hotel, 480 L'Enfant Plaza, S.W., Washington, District of Columbia, at 9:00 a.m., Dr. Thomas Insel, Chair, presiding.

PARTICIPANTS:

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

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

IDIL ABDULL, Somali American Autism Foundation

ANSHU BATRA, M.D., Our Special Kids

JAMES BATTEY, M.D., Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD)

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

PARTICIPANTS (continued):

NOAH BRITTON, M.A., Bunker Hill Community College

SALLY BURTON-HOYLE, Ed.D., Eastern Michigan University

MATTHEW CAREY, Ph.D., Left Brain Right Brain

DENNIS CHOI, M.D., Ph.D., Simons Foundation

FRANCIS COLLINS, M.D., Ph.D., National Institutes of Health (NIH)

JOSE CORDERO, M.D., M.P.H., University of Puerto Rico Graduate School of Public Health

JAN CRANDY, Nevada Commission on Autism Spectrum Disorders

GERALDINE DAWSON, Ph.D., Autism Speaks

DENISE DOUGHERTY, Ph.D., Agency for Healthcare Research and Quality (AHRQ)

TIFFANY FARCHIONE, M.D., U.S. Food and Drug Administration (FDA)

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

LAURA KAVANAGH, M.P.P., Health Resources and Services Administration (HRSA)

DONNA KIMBARK, Ph.D., U.S. Department of Defense (DoD)

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

PARTICIPANTS (continued):

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

SHARON LEWIS, Commissioner , Administration on Intellectual and Developmental Disabilities, Administration for Community Living

DAVID MANDELL, Sc.D., University of Pennsylvania School of Medicine

JOHN O'BRIEN, M.A., Centers for Medicare and Medicaid Services (CMS)

ALEXA POSNY, Ph.D., U.S. Department of Education (ED)

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

SCOTT MICHAEL ROBERTSON, M.H.C.I., The Autistic Self Advocacy Network

JOHN ELDER ROBISON, Self Advocate

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

LARRY WEXLER, Ed.D., U.S. Department of Education (ED) (representing Alexa Posny, Ph.D.)

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PROCEEDINGS

9:01 a.m.

Dr. Insel: I am Tom Insel, Chair of your Committee.

I am delighted to be able to welcome you to what is, in a sense, IACC 3.0. We have actually had this Committee in one form or another since 2001. It was established by the Children's Health Act of 2000 and re-established by the Combating Autism Act of 2006, and here we are again with the reauthorization of the Combating Autism Act last September 30th.

So, we are having the first meeting to welcome new members. There will be a number of federal officials who will be joining us to do that.

But I wanted to take a couple of minutes to also thank some of the members who served on the past Committee, the 2.0 version, which terminated with the last year of September 30th. That was when, by statute, that Committee was supposed to wind down.

Many of them are with us today. I

want all of them to be thanked by the Committee for their service, which has been extraordinary. This was a very, very hard-working group. At one point, we counted 17 meetings in a single year. And each of the people who served in the past did much more than anyone could have possibly asked them to do.

On the federal side, Ellen Blackwell, who came from CMS, Larke Huang from SAMHSA, Gaile Houle from the Department of Education, and Henry Claypool from the Office of Disabilities, who were on the Committee in the past and are either being replaced by others or, in the case of SAMHSA, are not at this point represented on the Committee.

There are a number of non-federal members who were on the Committee before, either representing an organization or in some cases representing family interests or personal needs: Gerry Fishbach, Lee Grossman, Denise Resnik, Stephen Shore, Christine McKee, Marjorie Solomon, Ari Ne'eman, and Yvette Janvier, all of who were just vital members, making this Committee acknowledge everything that it did over the last four years.

I wanted to just take a moment for those of us who worked with them and for those of us who benefitted from their labors to say thank you. I notice that some of them are here. Maybe if you are here, if you could just stand up and be recognized? Great. Thank you very much.

(Applause.)

And that is a good segue to say welcome to the new people on the Committee. The Committee is larger than it has ever been. For those of you doing this for the first time, you probably had no idea what you were getting into. The number of forms, the number of regulatory requirements that you go through to be able to serve on this Committee, let me just say you probably have a whole new understanding of what it means to be a public servant. Those of us who work in government think about the word "servant" every day because that is a lot of what you are called to do.

In some ways, the hardest part is getting on, once you have been selected, and going through the entire set of regulatory requirements that are needed to be a special government employee. But you are it at this point. Everyone passed through that process and has crossed the finish line.

And so, this is probably a good time for us to just go around the table, have a chance for you to meet each other, hear a little bit about your own connection to autism, and introduce yourself in just a couple of minutes. We have so many people; we would take the entire morning, I am sure, if we were to do this with justice.

But let's begin perhaps on this side and let me ask you to start and tell us a little bit about how you came to be on the Committee.

You need to press the button on the lower righthand side. Otherwise, those listening by videocast will not be able to hear you.

Dr. Batra: Hello.

Dr. Insel: Good.

Dr. Batra: Great. First of all, thank you so much for the opportunity to serve on this Committee. It is such an honor to be in this group of such passionate and knowledgeable people.

My name is Anshu Batra, and I am a developmental pediatrician in Los Angeles. I got into autism really through having a child who is on the spectrum for autism. That is the journey that brought me here, actually.

I have a practice where I have many, many children who are on the spectrum for autism and serve many families, but I think, again, serving my child has been the impetus.

Again, my personal goal, my personal sort of wish, I guess, is to really help our children or individuals who are on the spectrum to help them meet their potential the best we can, the best they can, and help them integrate into our society to be functioning and productive individuals.

Thank you.

Dr. Insel: Thank you, and we are delighted to have you here.

Dr. Batra, is it okay if we call you by your first name, which has been a tradition of this Committee. It is part of our informality.

Dr. Batra: Oh, yes, please. Thank you.

Dr. Insel: Okay. Great.

Jim?

Dr. Battey: Yes, I am Jim Battey. I am the Director of the National Institute on Deafness and Other Communication Disorders. We have a modest portfolio in autism-related research. And I have been a member of the Committee since its inception.

Ms. Singer: I am Alison Singer. I am the co-founder and President of the Autism Science Foundation. I am also the mother of a beautiful 15-year-old daughter with autism, and I also have an older brother diagnosed with autism, who has really been through a lot with regard to his experience with autism, as has my daughter.

I am very honored to have been reappointed to this Committee to serve as a public member for this next iteration. I am really looking forward to us getting back to work. We have had a nine-month hiatus, and I think we have a lot of time we need to make up for.

I am also very excited to work with all of the new members of the Committee. I think the new appointees really reflect the diversity of needs that we have in the autism community. I think it is really time for us to get started. So, I look forward to working with everyone.

Dr. Farchione: Hi. I am Tiffany Farchione. I am a Medical Officer in the Division of Psychiatry Products at the Food and Drug Administration.

I am new to the Committee this year. So, I am actually rather excited that the Committee has reached a place where you are inviting FDA people now. My understanding is this is the first time you have had someone from FDA.

Dr. Insel: Actually, FDA was part of the original Committee --

Dr. Farchoine: Oh, okay.

Dr. Insel: -- up until 2006.

Dr. Farchoine: Okay.

Dr. Insel: And then, it was not, for some reason, included after the Combating Autism Act, and now it is great to have FDA back.

Dr. Farchione: Well, I am happy to be here. Thank you.

Dr. Choi: Tom, I am Dennis Choi. I am an academic neurologist, and I am here representing the Simons Foundation, where I have been for a couple of years.

Ms. Kavanaugh: Good morning.

I am Laura Kavanagh. I am with the Health Resources and Services Administration. I joined the IACC at the very last meeting, and so am relatively new to the Committee.

Within HRSA, we support intradisciplinary training programs related to autism spectrum disorders, including the leadership, education, and neurodevelopmental disabilities programs; developmental behavioral pediatrics. We support autism intervention research programs on physical health, behavioral health, and developmental behavioral peds, as well as an R-40 program as well.

And then, in addition, we support state demonstration grant programs where we have worked very closely with CDC and the "Learn the Signs. Act Early." campaign and with NIH on, in particular, our AIR-P Network.

It is such a pleasure to be here. I look forward to getting to know all of the new members. I agree, I think we have a tremendous amount of work to do together.

Thank you.

Mr. Robison: I am John Elder Robison. I grew up with this Asperger's thing in the 1960s, before people really recognized it for what it was.

After growing up myself, I married a female with Asperger's. She is now an ex-wife, but we are still close, and together we have a 22-year-old son with Asperger's. So, I have personal experience with autism from a number of different perspectives.

I, too, am honored to be a recent appointee to the IACC. The reason that I am here is that I am committed to helping further the development of tools and therapies to make life better for the autistic population living today, to developing tools to remediate autistic disability in all its forms, social disability like I have struggled with, and medical issues, and language issues that challenge others.

And finally, I am really looking forward to the opportunity to perhaps have some influence in our education and disability and accommodation policy because I would like to see not only recognition of the disability side of autism, but also the gifts and the unique things we bring the world, if only people accept us for what we are.

Dr. Hirtz: Good morning.

I am clearly not Walter, but I am sitting in for him until he can get here.

I am Deborah Hirtz. I am a pediatric neurologist with the Office of Clinical Research. I am with the National Institute of Neurological Disorders and Stroke. We are one of the participating Institutes at NIH that works together with the others on the Autism Coordinating Committee.

Dr. Mandell: Good morning.

My name is David Mandell. I am also new to this Committee and very excited to be here.

I am at the University of Pennsylvania School of Medicine, where I direct the Center for Mental Health Policy and Services Research. And I am also Associate Director of the Center for Autism Research at the Children's Hospital of Philadelphia.

All of my research is on improving quality of care for people with autism in the communities where they live.

Mr. O'Brien: Good morning.

I am John O'Brien. I am the Senior Policy Advisor at the Disabled and Elderly Health Program Group within the

Centers for Medicare and Medicaid Services. I am the CMS representative, but in no way could possibly replace my former colleague, Ellen Blackwell.

The primary focus of the work that I will be doing over the next several years is going to be focusing on what we call vulnerable populations, but, most importantly, individuals with autism, individuals with mental health conditions, individuals with substance use conditions, as well as HIV.

We are really wanting to spend some quality time with states over the next several years, providing them with guidance around what is good coverage, good coverage for prevention, good coverage for early intervention, and good coverage for services in general. And so, I think, clearly, this Committee and the charge of this Committee will be tremendously helpful in our efforts to shape that guidance.

Prior to being at CMS, I was at SAMHSA, where I was in charge of their healthcare reform efforts, as well as helping them think through the implementation of the Mental Health Parity and Addiction Equity Act; and prior to that, had spent probably a good portion of my adult life working with states, state Medicaid programs, specifically designing policies and reimbursement and service strategies around individuals with intellectual disorders as well as developmental disabilities, which included working with some states around their autism waivers.

And then, last, but not least, worked on the DD Council in a number of states, the protection and advocacy programs in a number of states, and Bipartisan Commission on Mental Retardation, Mental Health, and Substance Abuse in a state.

And I am very happy to be here, and thanks for the invitation.

Ms. Redwood: Hi. I am Lyn Redwood. I am one of the leftovers from the last Committee. And I am also a co-founder of the Coalition for SafeMinds.

In preparing for this meeting, I

went back over to look at the things that we have accomplished this past year and I read over the minutes to our previous meetings, and I watched videos. One of the things that stood out the most was the meeting that we had last April with representatives from both the Obama Administration and the Secretary's Office.

In response to the discussion that they had with the Committee, they agreed with us that we were, quote, "not doing enough" and we needed to redouble our efforts. They suggested that we look at what we have learned the last four years and ask how we can do better moving forward with the reauthorization of the Combating Autism Act.

One of the things that I have learned as a member is that, despite, Tom, all the meeting we had, that there has been very little that has actually been accomplished that directly translates into reducing the burden of autism for families or has really resulted in improvements in the health and quality of life for those individuals with the disorder.

The prevalence of autism has continued to skyrocket, and I think our numbers now are probably more in line with the numbers coming out of South Korea, which is 1 in 38. The data we recently got from CDC, the 1 in 88, is actually 12-year-old data.

Families are collapsing under the burden. Dr. Insel, at the meeting in April, you said that the word "crisis" is not an overstatement and that we don't have the answers.

I also noticed that in the packet that we received, we got the charge for what the Committee does. Basically, we serve in an advisory capacity. We create and update the Strategic Plan and Summary of Advances, and we monitor all federal activities regarding autism and report back to the Secretary. We are not tasked with establishing public policy or implementing service or research programs.

Last year, as you know, we sent two letters to the Secretary and we spent quite a bit of time. We had meetings looking at the important issues of seclusion and restraint and, also, wandering. And we were promised that those letters would be reviewed and we would receive recommendations back when people from the Secretary's Office were here in April. To my knowledge, that has not happened. I checked with Susan, and we have not received a letter back.

According to the National Autism Association, just since September, there have been a total of 194 reported incidences of wandering and there have been 17 deaths. The most recent was just last week when 5-year-old Jeremiah Conn drowned in a rainwater retention pond near his home.

So, one of the things I have learned over the last four years is that we desperately need an agency with HHS that is solely dedicated to the unmet needs of the autism community, that can establish public policy and implement necessary programs to address these urgent issues on a daily basis. We meet a few times a year.

In 2008, Barack Obama issued a

campaign pledge to appoint a federal ASD Coordinator to ensure that ASD receives the recognition of priority it deserves in the federal government. That person is yet to be appointed.

I think we also need an Office of ASD Research under the Director, modeled after the Office of AIDS Research, to fortify the activities of the IACC and to implement the necessary public policies to effectively respond to this urgent health crisis.

So, those would be the things I would like to see accomplished and moving forward. I would see that office working very closely with the IACC, where we would develop the Strategic Plan. They would be the ones responsible for reviewing it. They would ensure that what we have recommended is actually funded, which isn't happening right now, and to make sure that what is funded is aligned with the vision, mission, and values of the Strategic Plan, as developed by the Combating Autism Act.

So, Dr. Insel, you stated during

the April meeting that we needed a better way to think about autism and an effort to be efficient and more effective. I really believe that the appointment of the federal ASD Coordinator and the establishment of an Office of ASD under the Director are just a few of the opportunities that we might consider in moving forward in an effort to serve the families who desperately need answers.

Thanks.

(Applause.)

Ms. Crandy: Good morning.

My name is Jan Crandy. I am honored to be asked to sit on this Committee.

I am a parent first. I have a daughter with autism who just graduated from high school, was able to graduate from high school because she was lucky enough, fortunate enough that we could afford treatment and received 35 hours a week of ABA treatment until she was six years old.

I hope that this Committee recommends policy, public policy that provides access to treatment. My hope is that there would be a federal match to states for providing treatment, so that more children are receiving treatment. In Nevada, only 140 kids statewide are in our slot program.

Part C needs to require that children are diagnosed if all signs point to autism. This excuse that it is not federally-mandated that they have to diagnose keeps parents in denial and leads them to not treat.

I also would support and hope that this Committee looks for medical screening to be part of the diagnosis procedures. We need to look at underserved populations, rural areas, Native Americans, underprivileged families that don't have access to funds or insurance coverage, and to think that federal mandated Medicaid does not include ABA; those are the kids that states will be taking care of for the rest of their life. They should at least have the opportunity to be one of those kids that can reach their full potential.

Thank you.

Dr. Wexler: Good morning.

I am Larry Wexler. I work in the Office of Special Education Programs of the U.S. Department of Education. I manage the Individuals with Disabilities Education Act, Part D, Discretionary Grants Program, which is about a $300 million portfolio of discretionary grants.

We have significant investments in autism. We cut across technical assistance, professional development, technology. We run a parent training and information system across the country. We also do a significant amount of personnel preparation. In addition, my group runs the IDEA Data.

So, thank you for having us.

And I serve as Alexa Posny, the Assistant Secretary's alternate ego on this Commission.

Thank you.

Dr. Lawler: Good morning.

I am Cindy Lawler. I am a Program Director in the Extramural Division of the National Institute of Environmental Health Sciences, or NIEHS, where I manage an extramural portfolio of autism research.

I am here today representing Linda Birnbaum, who is our Institute Director, and regrets very much that she was unable to attend today's meeting.

The very broad mission of the NIEHS is to understand how the environment impacts people in order to improve and promote healthier lives. Children's environmental health is a priority within this very broad mission. Autism is one of a number of childhood conditions that are increasing in prevalence.

I think the research and search for environmental contributors to autism and some of these other complex conditions holds the promise of identifying public health strategies that could be put in place to help reduce harmful exposures and promote protective ones. Our current investment in autism research is around $6 million, mostly in epidemiology studies, looking for very early exposures that may alter risk.

What I think I would like the new

members of this Committee to know, that the efforts of NIEHS in autism have really been enriched and extended by the work that has gone on around this IACC table from sharing of information to joint planning, to reminding us of the urgency of our efforts. And I know that Dr. Birnbaum is looking forward to being part of a continuation of the very good work of this Committee.

Thank you.

Dr. Cordero: Good morning. Buenos dias.

I am Jose Cordero. I am a pediatrician, and I am the Dean of the School of Public Health at the University of Puerto Rico.

I am very glad to be, again, on this Committee. I had the luck of being in the version 1.0 of this Committee, when I served as Director of the National Center on Birth Defects and Developmental Disabilities at CDC. And I retired, and now I am working on autism in Puerto Rico, among other public health issues.

In the last six years, we have been able to open two Centers on Autism and actually work on developing a health insurance coverage that actually addresses the needs of children and adults, basically, over the lifetime with autism. I would like to talk more about that when we have a chance.

Thank you.

Mr. Robertson: Good morning.

I am Scott Michael Robertson. It is really an honor to be chosen to serve on this Committee. I am a new member. I am delighted for the opportunity.

I am autistic adult and a co-founder and current Vice Chair of the Autistic Self-Advocacy Network, a national nonprofit that works to improve life opportunities, self-determination, inclusion for all autistic adults and youth.

I also at the state level serve as a Council member on the Pennsylvania Developmental Disabilities Council. I, over the last several years, have participated in different roles for our State government agency on autism, the Bureau of Autism Services, including serving as a member of the Advisory Board for the Bureau.

Thank you.

Ms. Lewis: Good morning.

I am Sharon Lewis. I am the Commissioner of the Administration on Intellectual and Developmental Disabilities at the newly-established Administration for Community Living within the Department of Health and Human Services, and a returning member of the IACC.

We at AIDD are responsible for the implementation of the Developmental Disabilities Assistance and Bill of Rights Act, which includes the Developmental Disabilities Council that a few folks have referenced, the protection and advocacy agencies and the university Centers on Excellence in Developmental Disabilities across the country, as well as managing some smaller discretionary programs, including the Autism Now Project with the AHRQ of the United States.

Our commitment within the Administration for community living to people with autism is really based on the ideas of self-determination and inclusion, and ensuring that all people with disabilities, including people with autism, have the opportunity to live their lives as they choose in the community. And we are very excited to continue to participate on the IACC.

Thank you.

Mr. Britton: Hello. I am Noah Britton. I was diagnosed with Asperger's 10 years ago, when I was 19.

The last two years, I have been a psychology professor at Bunker Hill Community College, and I have done research and co-authored publications, but probably the reason I am on this panel is because I started the comedy troop Asperger's Are Us. That is A-R-E, in case you want to look it up.

(Laughter.)

I am here to represent the thousands of people with Asperger's who don't want to be cured, who have the right to say no. My shirt is about not abortion, but about Asperger's and autism and who say, "I am happy being a person with Asperger's and I love the other people who I have met with Asperger's."

So, thank you. I am excited to be here.

Dr. Dougherty: Good morning.

I am Denise Dougherty, the Senior Advisor for Child Health and Quality Improvement at the Agency for Healthcare Research and Quality, which is part of the U.S. Department of Health and Human Services, a small part of it, but we have a big mission, to improve the safety and quality, efficiency and effectiveness of healthcare for all Americans.

Probably our most visible efforts for this community have been the production of the comparative effectiveness, or now called Patient-Centered Outcomes Research Reports or Effective Healthcare Reports, one on effective treatments for children with autism ages 2 to 12, and then another one in process for adolescents and young adults.

In connection with those, we realize it is not just enough to publish a document on what effective treatments are, but we also have funded a group to help us identify the most effective strategies to disseminate the information about what effective treatments there are. And we have also done more on identifying future research needs for all of the comparative effectiveness research that we do.

We also have a few grant-funded projects on computer-assisted autism care being done by Steve Downs at Indiana University and a bunch of other grant projects on developmental issues more generally.

Thank you.

Dr. Burton-Hoyle: Good morning.

My name is Sally Burton-Hoyle, and I am at Eastern Michigan University. I am a teacher and I train teachers.

Seminal events in my life that led me to this wonderful, wonderful opportunity that I am so thankful to be here for was that I had the pleasure of growing up with a brother with autism, who passed three years ago from a heart attack at the really early age of 44. His diagnosis was a seminal day in my family. When my dad came home and told us and said our life would never be the same again, well, he wasn't wrong, but I take that all in a good way because, if it was not for Tim, I wouldn't be here with you wonderful folks and have this opportunity.

I became a special education teacher. That was a wonderful thing because of all the expertise I had from being in a family and seeing the good things and the bad things that education can do to a family.

I was Director of the Autism Society of Michigan for 12 years. Another day in my life that changed the course of the rest of my life was when Michael Renner-Lewis was killed. August 25th, 2003, he was secluded and restrained to his death. We worked with protection advocacy and sued the school district for training in that.

I realized then that I wanted to go back and teach teachers. So, that I have done.

We founded the Autism Collaborative Center across campus, OT, speech and language, social work, because we don't just want graduate students and PhD students to understand what autism is, and understanding autism and accepting autism is a far, far bigger job to me than them just knowing kind of what it is.

We believe that, no matter who you are with autism, no matter where you are in life, that you can have a good life through the full lifespan using education, Centers for Medicaid, and all the wonderful things that persons under planning and self-determination can do. It has changed the life.

And I am so happy, and I have cancelled committees that I am on elsewhere because I want to put 150 percent into this work. So, thank you again.

Dr. Boyle: Good morning.

I am Coleen Boyle. I am the Director for the National Center on Birth Defects and Developmental Disabilities at CDC, and glad to be back as part of the IACC again with my second round here.

CDC's activities focus on -- and many of you are familiar with them -- focus on public-health-related activities. So, several of you have mentioned the 1-in-88 figure, which is the update from our ADDM Network, our Autism and Developmental Disabilities Monitoring Network. That includes 12 states throughout the country to track and monitor the presence of autism.

In addition to our ongoing Data for Action piece, we also have an extensive network of epidemiologic research sites. That includes six sites that are involved in a collaborative epidemiologic study called the SEED study. That study is in its second round of funding. Hopefully, you will be hearing soon about the products and the research that are coming out from the SEED study.

The third area that we focus on is on early identification. We have, actually, under the guidance of Jose Cordero when he was Director for the Center, started the -- at the time, it was a health communication campaign called "Learn the Signs. Act Early," which is really focusing on trying to identify children as early as possible, and with the impact of getting them into early identification and early intervention.

That program has morphed now into an actual program versus just a communication campaign. We are collaborating with HRSA, as Laura mentioned, as well as others of you around the table, to really help drive early identification.

I am delighted to be here and look forward to some real action for the Committee.

Dr. Carey: Hi. I am Matt Carey. I am the parent of a young child with autism.

If I can, I would like to also start with just thanking OARC and the previous generations of IACC for all the work you have done. I have a huge amount of respect for all the people who have been working on this and the amount of work that has been ongoing.

Since starting, it has been interesting to see just how hard-working people are. I can't tell you the number of emails I have received. I am on the West Coast, and I will send something off when I get home from work and when my kids are asleep. And I will get an email back. And I will send an email back saying, you know, "Susan, isn't it like midnight your time?" Yes, these people are working very hard and are very dedicated. I think that is shown in every meeting, and it is no surprise to me to see that.

I think every aspect of the work that the IACC has been focused on I think has been very important. I have been watching IACC meetings -- I hope my manager isn't watching -- I watch IACC meetings as much as I can while I am at my desk because I feel this is so important to see this work being done.

And it is hard to single out any aspect that I think would be more important than others. But I think one aspect that struck me very early on, when I started looking at autism research, when my child was first diagnosed, was the concept of underdiagnosed and underserved populations. It bothers me a great deal to see that we may not be identifying and serving racial and ethnic minorities and people with lower socioeconomic backgrounds. I am very glad to see that that has been a big focus of both the IACC and I think, also, the research community in general. At IMFAR, you can see that as a major focus.

One, I think, underrepresented group that I would like to focus on a little bit would be, I think ironically it would be adults. I think that we don't have good numbers on adults. I think, in my opinion, adults are probably the largest population of autistics we have. Just because somebody isn't diagnosed doesn't mean that somebody isn't autistic.

But when I also look at issues with adults, it is also very much driven by my own interests, my own needs. I look at the simple math. My child will spend 75 percent of his life as an adult. My child will probably spend 50 percent of his life without my support as an adult.

I think learning as much as we can about adults now, rather than learning them from my son's generation, when he gets there, I would rather know now and learn as much as we can, everything. You know, support what health issues are there for adults as we go on.

Lastly, I would say my own work, I am a researcher and an engineer. I see a lot of excellent research going on here. I would say I would like to see more engineering, which probably would be translational work, see more subjects have an impact on bettering the lives of autistics and their families.

And one topic I would just point out that struck me in preparing for this meeting is the topic that Geri Dawson is going to speak about later today, I believe, you know, bringing together groups of people with epilepsy, the epilepsy community and the autism community. I think that is a great move forward.

I don't think it is directly

related to this, but if you have looked through public comments before, these are public comments I have made in the past. I mean, I think people read public comments. What people think, what people want is being listened to do. I don't think it was specifically me, but I think this is something the community wants and is happening, and the community can make a difference.

Thank you, and thank you very much for the opportunity.

Dr. Kimbark: Hello. I am Donna Kimbark. I represent the Department of Defense Congressionally Directed Medical Research Programs. We have a small autism research program that this year has a $5 million appropriation. Over the years, in 2007, we have invested $36 million in autism research. Our autism research portfolio goes from clinical trials with oxytocin to clinical trials about remote access, especially of our military members, to ABA, as well as the types of research like investing in research for the virtual reality training of teenagers with autism, so that they can learn how to drive and have independent lives.

So, this is one of the things that we do. Our main focus and vision is to improve the lives of individuals with autism spectrum disorders now, and that is the most important part of our vision, is that we put the word "now" in there, and through that, we do it with innovative research, promoting innovative research in many different ways. But, mostly, we look at applied research rather than the more basic research.

And I am very pleased to be here. Thank you.

Dr. Dawson: Good morning.

I am thrilled to be back on the IACC again and honored to be part of this group.

I am Geri Dawson. I am the Chief Science Officer at Autism Speaks. It is the world's largest science and advocacy organization focused on autism.

We have four pillars of our organization. One is increasing awareness.

The other is funding scientific research, and we have committed over $170 million toward scientific research to date. The third is advocacy and working with the government to pass legislation on behalf of people with autism. And then, finally, providing tools and family services.

I am a child clinical psychologist by background, and I have been in the field of autism since 1979, when I did my PhD on autism, and have worked as both a practicing clinician as well as a scientist, until I joined Autism Speaks in 2008.

I want to begin by expressing a sense of urgency. I did resonate with some of the things that Lyn said about our need to really be an action-oriented Committee.

Since we last met, we have heard the new numbers 1 in 88, and we see this increasing prevalence, which has so many implications, not only in terms of understanding causes, but just in terms of understanding the great need that is out there. So, I hope that we can keep that sense of urgency in everything that we do.

I think our goal is to reduce both the burden and the suffering of autism in all its different forms. I think, if you look around this table, it really reflects the diversity of what autism is and all the different ways that autism affects people's lives.

For some people, it is about being accepted and self-determination being the central focus, but for others it is prevention; it is treatment; it is dealing with very serious medical issues, whether it is epilepsy or GI or not being able to go out in public because of sensory issues. So, we really need to recognize all the different ways that autism does affect people's lives and to respect that, and to try to address that suffering in all of its different forms.

My hope is that this Committee will be action-oriented. We do have to set priorities and think about what is the most important thing to do now. We have got work to do in lots of different areas, certainly science in terms of understanding what are the causes, why are we seeing this increase in prevalence, but also developing better and more effective treatments all across the lifespan.

We do need to address major gaps in services. I really resonate with what you said, Matthew, about the adults and the fact that we have so many adults now that we are not prepared to help.

And then, also, dissemination. We have good, evidence-based practices that we aren't disseminating and we have great healthcare disparities that need to be met. So, I think the only way to do this is to join together across communities and across agencies in a coordinated fashion that does set priorities and is very action-oriented.

So, I look forward to a productive meeting, and I hope that what we achieve during this session of the IACC will have real benefit in improving the lives of people with autism.

Dr. Guttmacher: I am Alan

Guttmacher. I am Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, another of the Institutes at NIH.

And the reason why I am here, I think, is really in the name of our Institute, in two places really in the name of our Institute, child health and human development. We have historically always cared about human development. That has been a large part about why we exist.

In fact, the Eunice Kennedy Shriver part of our name, we are the only Institute at NIH that has someone's name appended to us. Why do we have that? It is because Eunice Kennedy Shriver, 50 years ago this year, because of her interest in the lives of individuals with intellectual and developmental differences, thought there should be an Institute at NIH that really was involved in research in these areas.

She had the advantage -- a tip to all of you who might want to lobby in Washington -- she had the advantage of having a brother who happened to be the President of the United States at the time, which makes for an effective lobbyist. When she called Members of Congress, they answered her phone calls.

So, the Institute, we were created 50 years ago this year. Both the issues of human development and the related issues of the lives of individuals with intellectual and developmental differences has always been core to our mission and, also, I would say, core to our values. It is part of what brings all of us to work every day.

As a logical outgrowth of that, we have supported for many years a wide variety of research across autism spectrum disorders in coordination with other Institutes at NIH. We continue to do that, continue to be very involved in the field, obviously. So, that is really why I am here.

By background, I am a pediatrician, a medical geneticist who, for both personal and professional reasons, has also had a long-time interest in autism.

Ms. Abdull: Thank you. I think we are sharing.

Hi, everyone. My name is Idil Abdull. I have a son. He is nine years old, and he has classic autism.

First, I really want to thank Dr. Insel, Dr. Daniels, and everyone here, for the opportunity that you have given me the last two years that I have been harassing you and saying we need to do something about autism in different ethnicities, in different communities, and particularly children that are on the classic or non-verbal or severe end.

As a result, CDC, NIH, and Autism Speaks have funded surveillance research in Minnesota for the Somali children. So, thank you for that.

I am also glad that there is a diverse group of people here this time around. There is always diverse, but America's melting pot, when you are in Africa, you say, "That's where I want to be. That's where Superman is."

(Laughter.)

And so, I came here with that dream, and autism knocked me down. It is no day at the park. It is challenging. There are meltdowns. There are behaviors. It is emotionally, financially, mentally draining.

And I am hoping, even though we are an advisory Committee, that we can have advice that trickles down to various agencies that have some impact.

So, I have got only three little goals, and that is -- I am glad that Alexa is sitting next to me -- how do we fund special education, not the 18 percent or so that is funded now, but up to the 40 percent that Congress promise? And Congressman Kline, the Chair of Health and Education in Congress, actually lives near me. So, I continue to harass him, and he tells me a promise made to our children should be a promise kept. So, I would like to hold Congress as well as the Administration to that.

Secondly, I would like to see CMS

pay for autism therapies and treatments that CDC and NIH recommend. We all recommend early intervention, such as ABA, RDI, DIR, based on the child's needs, but then you come to CMS and Medicaid, it does not pay for it. So, it sounds like your right hand is not talking to your left hand. If it is within the HHS, what you recommend should be paid by the other agency. Otherwise, it is just silly to recommend it.

And the third thing I am interested in is to look into research and recommend research, and, hopefully, even ask universities to participate in research that looks at genetic and different ethnicities, whether it is South Korea or whether it is Somalis in Minneapolis, that we are only there about 6 percent in the Minneapolis public schools, but 25 percent of autism. Clearly, there is a problem, and we didn't have this. We are an extremely oral society. It has silenced us.

And so, I would like to see research that looks at that not from public health only, but also from academia and research that also likes to decrease the disparity. Minority kids are diagnosed at least two or three years later, as Dr. Mandell very well knows. I would like to see that, not just talk about it and say, "Oh, you know, yes, we get you; we get you," but how do we really decrease it year by year, year by year, so that when you are a minority, your middle name is not "disparity," but rather "opportunity"?

Thank you so much.

Dr. Posny: Hi. I am Alexa Posny, and I am the Assistant Secretary for the Office of Special Education and Rehabilitative Services with the U.S. Department of Education.

And you will hear from me later. So, I am not going to share a whole lot, just probably more about myself.

But in terms of OSERS, the office of which I am in charge, we are the only part in the U.S. Department of Education that really serves people with disabilities from birth to the end of life. And that gives us a wide span and a lot of responsibility, should I say?

To kind of date me, I have been in the field of special education before PL 94-142 was passed. So, I have been in it, and I have seen the changes that have occurred over time. They have been great.

The other thing is that when I originally taught, I taught middle school and high school kids who were emotionally disturbed, but I do know that I had kids with autism at the same time. So, I understand it. And I will share the other information with you later.

Thank you.

Dr. Daniels: Hi. My name is Susan Daniels. I know that most of you around the table have heard from me quite a bit by email. We are really excited that you are here. My whole staff has been really looking forward to this day to kick off the new Committee.

Our office is here to help in any

way to facilitate the work of the Committee. We do all the kinds of background work to support these meetings, any documents/research that you want to do. We also try to provide outreach to the community and to bridge the gap between federal policymakers, state agencies, advocacy groups, and individuals who are interested in autism. We try to help that communication.

And so, we hope that you will feel free to be in touch with us anytime that you need our help to get something done for the Committee or for the community. We are just really pleased to be here today and to be able to work with you. So, thanks.

Dr. Insel: Well, Susan, we have you to thank for getting us all together. I am mostly thankful that you didn't go into labor this morning.

(Laughter.)

So, we are able to have this meeting with you instead of without you.

I know that there has been an enormous amount of work getting us to this point.

I should just say a little bit about myself before we get into the work of the Committee. I think most of you know I am the Director of the National Institute of Mental Health. I have a second job as the Acting Director of a new Institute at NIH called the National Center for Advancing Translational Sciences.

That has been quite interesting because we just launched in December -- and it is a chance to do some of the things, actually, we heard around the table, which is how do you take science and actually turn it into new treatments, new diagnostics, and how do we make science work for public health in a translational sense.

And there is a science to that as well. And so, what the new project called NCATS does, which Dr. Collins has really championed in so many ways, is to put that on steroids and help, through 60 centers around the country, as well as through projects that we are doing in Bethesda here, to figure out what the tools and the techniques could be to be able to accelerate the way we can translate discoveries into changes in healthcare. So, that has been a large part of where I have been for the last several months.

By background, I trained as a psychiatrist in the late Pleistocene.

(Laughter.)

And over the last 20-some years or 20 years before coming to this job at NIH, I was a basic neuroscientist, spent most of my career doing very fundamental science on the molecular biology of social behavior and trying to understand the brain pathways and the molecules important for that. That is how I came to autism, was by understanding at a very fundamental level what happens in the brain to allow social interaction to take place, and then wondering whether people with autism might have a problem on the very same systems -- the one that we worked on was a peptide called oxytocin -- and whether that might be in some way involved with autism.

So, I came at this scientifically

and have become very engaged. For me, it has been one of the real high points of my service at NIH to be part of the IACC. As I have said on other occasions, perhaps one of the most inspiring parts of my jobs is to hear from people on the Committee and to hear about the kinds of struggles they have had and the kinds of successes they have had. So, this has been a great honor.

We are at a part of the meeting where we want to invite a number of federal officials to join us. Some will be drifting in over the next few minutes. I think what we might want to do -- by my watch, we are about five minutes ahead of that section -- is maybe I can take the first part of that just to give you a quick charge for the Committee. And then, when Secretary Sebelius arrives, which should be in about five minutes, Francis, maybe we can get you to usher her in, and we can have her talk to you about what the real work of the Committee will be, because, after all, we serve as an advisory group to her.

So, you have seen the agenda. Let

me quickly take you through this.

By the Combating Autism Act -- and we have one of the co-sponsors sitting here at the table with us -- we have essentially five responsibilities. We are to develop and update annually a Summary of Advances. We are monitor federal activities. We are to make recommendations to the Secretary.

You can see here the Summary of Advances at the top. The portfolio analysis is a way of monitoring activities. You heard already from Lyn Redwood that we have sent two letters to the Secretary.

We are to develop and annually update and submit a Strategic Plan for ASD research. I think all of you have received that. I want to stress that "annually update" means we have to do in 2012 as well. So, we will come back to that discussion later.

And by statute, we need to meet at least twice a year.

What we do, as you have heard already, is advise the Secretary. We coordinate activities. So, that the Autism

Coordinating Committee. We take coordination very seriously, very literally. And that is both for science and for services.

We focus and accelerate progress via the Strategic Plan, and we serve as a public forum, both hearing written comments, oral comments, and as you will see later, we have a set aside time at each meeting to hear from the public and a set aside time to discuss what we have heard from the public later in the day.

With that, welcome, Madam Secretary.

Secretary Sebelius: Thank you.

Dr. Insel: We are delighted to have you here.

We have just finished a round of introductions. We haven't introduced the people at this end of the table, and we are still waiting for Congressman Smith. But maybe we can have you begin, even without him.

Let me just say, by way of introduction and welcome, that, first of all, we are delighted that you could take time out of your schedule to spend a little time with us this morning. You were with us about two years ago, April 2010. That was an extremely important moment.

You came to us at that point to welcome a set of new members to the Committee who you had appointed. Many of them have served extremely successfully. Some are still here and some have just rotated off.

You also talked to us at that point about something that you called the Affordable Care Act -- (laughter) -- which we were hearing about to some extent for the first time, because this was at the very end of April 2010, and you may recall that was very timely in terms of your Administration and the history of healthcare reform in this country.

So, here we are, a little more than two years later. You are back, and it is a chance to welcome yet a new roster of members who you have appointed. And we appreciate your willingness to do that and your insight about the kinds of people who can serve on this Committee to make it effective and to make it representative of a very diverse community.

And we are looking forward to your thoughts and comments about how we can be most helpful to you.

Secretary Sebelius: Well, thank you, Tom.

I want to start by just recognizing Tom's leadership in this whole field. I think it is critically important. Not only does he bring expertise, but incredible passion and interest, and I know that day-in and day-out.

I am delighted to be back with you. I have to say, although I don't meet with you on a regular basis, I do hear regularly about the great work of this Committee, and your expertise and interest and personal experience really informs a lot of the priorities that we try to put in place. So, I want to say thank you.

I want to recognize Francis, who you will hear from after a bit, Francis

Collins, who directs the National Institutes of Health.

I know you are going to hear from a couple of Members of Congress. We have got Kareem Dale and Mike Strautmanis from the White House, a great partner from the Department of Education, Alexa Posny.

Alexa and I go back a long way. We both worked together in Kansas in our former lives. So, we are here together again on the national stage.

As Tom said, it is sort of fitting that I am here now a little over a week after the Supreme Court has said that the law that was passed in March 2010 is, indeed, constitutional and gives us, I think, the green light to continue to move forward. In spite of the fact that tomorrow the House of Representatives will take their 30th vote to repeal the law, we continue to plug ahead.

So, I am really, again, pleased to be back with the Coordinating Committee. I don't think there is any question that the Committee's work is critical, and the renewing of the Combating Autism Reauthorization Act was, again, a big step forward.

I know that we have some members here leaving the Committee who have been part of this effort for the last almost five years. I want to just say thank you to you. You have actually participated in some historic improvements in the nation's approach to autism. I think your advocacy and guidance have made it possible for researchers to open the door to autism causes and interventions. And your expertise has helped provide focus and attention on the needs of those living with autism and their families, creating new opportunities to reach a full potential.

So, I think on behalf of those families and individuals across this country, I really do want to say thank you. Thank you for your service. Thank you for your willingness to be part of this effort.

I know we have some Committee members who are continuing to serve, returning members, and, also, some brand-new members who will be making a major impact on the work that we have to do going ahead.

I want to specifically acknowledge three new self-advocates: Noah Britton, Scott Michael Robertson, and John Elder Robison, who I think by their willingness to, again, share their experience and their expertise, offer some critical perspective that we need going forward.

This new Committee is convening at a very important moment. No question, autism has been a challenge for years that families often dealt with on their own. We don't have to look too far back. It was as recent as the 1990s that autism was thought to be a rare disability, and we were saying it affected 1 in every 2,000 children. Families often had no place to go for answers or help. Those numbers continue to be updated, and now we are identifying 1 in 88 children living with autism in this country.

So, the need for answers has never been greater. Those of you who are struggling to find those answers know that all too well.

Now President Obama recognized

that need when he named autism as one of the top three national health priorities in 2009. We in the Administration have tried to sustain that urgency and tried not only to improve the research, but to improve the lives of those living with autism.

So, as Tom said, a perfect example of that has been some of what will take place with the passage of the Affordable Care Act. I don't think there is any question that it is one of the most significant pieces of legislation for Americans with disabilities that this country has ever seen.

We know access to affordable, quality health is critical for everyone, but certainly critical for anyone living with a health challenge. What the law will do is pretty straightforward. Currently, already in place is a provision that insurers can no longer deny coverage to children with preexisting health conditions, a huge step forward for families across this country.

New plans have to cover autism screening for children with no cost to the parents. It is one of the preventive health benefits that is now in place. So, as policies are renewed, that will be part of the puzzle.

And I think it will help to ease the financial burden for treatment and care of people living with autism by, again, a provision that is already in place, allowing young adults to stay on a parent's plan up to age 26. We have 7.5 million young Americans who now have taken advantage of that provision, again, putting some peace of mind in place.

And a benefit that also is already in place is the end to any lifetime limit on coverage. I talk to families all the time who are directly impacted about that.

When it comes to autism specifically, we are beginning to learn more about causes, getting a better understanding of how important interventions can be, and see a recognition of the full impact of autism and what it means for our country. And again, you have played a major part in that development of that information and expertise.

In 2009, you created an inspiring Strategy Plan to guide research, identify key questions and priorities that we really needed to focus on. And updating the plan every year helps to continue to reflect the latest science and keep a roadmap, and an accountable roadmap, in place, so that we can hold ourselves accountable.

But there is no question that, while progress has been made, and there has been significant progress, we absolutely know that there is a long way to go.

First, we need more answers from research. Now we continue to learn more about the needs of those with autism, but there are still populations, like non-verbal school-age children and adults on the autism spectrum, who we don't know nearly enough about.

We know we need to do a better job of putting resources where they can make the biggest difference. We have made some historic commitments to improve the knowledge of autism through research. In 2009 and 2010 as part of the NIH historic funding in the Recovery Act, we made the largest single, new investment in autism research our country has ever seen with more than $122 million going to federal funding at NIH and other agencies.

Today, autism research supported by NIH and by advocacy organizations is addressing nearly every major objective in your Strategic Plan. And thanks to the work, we have a foundation to make more progress.

For example, the Autism Centers of Excellence around the country are doing coordinated research on everything from causes of autism to the most effective interventions, to possible medical treatments. This year we announced funding for new Centers to build on and expand that work.

And the National Database for Autism Research has pulled together results from federal and private research with data from over 30,000 subjects.

Now a second area where we have to make a lot more progress is early detection of children showing signs of autism and better access to intervention for those who are diagnosed. So, whether it is screening, diagnosis, intervention, or services, the earlier we take action, the better.

But too many children still aren't diagnosed until they get to school, despite medical guidelines that recommend screenings start at 18 months. And even then, a diagnosis doesn't mean services start right away, and that needs to change.

So, we have tried to lead the way, supporting research on innovative interventions that can help children with autism thrive and taking strides to close the gaps in autism services, particularly in minority communities.

What we know is that many of the adults who spend the most time with our children, teachers, nurses, social workers, don't necessarily have the knowledge or training to recognize the signs of autism. So, our agency, the Health Resources and Services Administration, is working with universities and health training institutions to create an interdisciplinary curriculum with an emphasis on learning the signs and providing the best services to children who need help.

We are focusing on creating culturally-sensitive interventions for Hispanic and African-American children. This work recognizes that the way children display autism and the best ways to help them may differ with ethnicities. So, we are putting researchers in school districts, like one in Los Angeles, to work with minority children and actually test and learn what works.

We continue to support the CDC "Learn the Signs. Act Early." Campaign to get families, healthcare providers, and communities the information and resources they need on autism.

And finally, we need to create better services and supports for older Americans living with autism. The growing prevalence of autism in our country doesn't just mean more services for children and youth in school, but, increasingly, more services for adults and the community.

We know that living with autism has big challenges, and we know that people with autism often possess amazing skills and can make amazing contributions to communities. So, the mission is to create opportunities that ensure people with autism at all points in the spectrum can thrive and participate in all aspects of society.

Now, to that end, we have invested over $3 million to develop a National Autism Resource and Information Center called Autism NOW. The Center will use a national network, regional events, along with training assistance to offer people and families living with autism quality information about services and interventions in their own communities.

So, the vision is, ultimately, a nation where every person with a disability has a chance to live in his or her community and be treated with the dignity and respect they deserve. It is the right thing to do for all Americans, and it is absolutely will make us a stronger country.

That is the vision that really led to a recent reorganization in our Department. We have created the Administration for Community Living, which brings together the expertise of our service to people with disabilities as well as the aging network.

The Administration for Community Living is working to maximize the independence, well-being, and health of people with disabilities, including people with autism, to make sure that all Americans with disabilities have the opportunity to live fulfilling, self-determined lives.

For some, that might mean help with affordable and appropriate housing. For others, it might mean transition support as a young person moves from high school to adult life, including employment. For many families, it might mean finding support services and care. But, for all those needs, the Administration for Community Living will be there to help, building those networks at the community level.

So, if we are going to succeed in

understanding and meeting the needs of people with autism, we need to do a better job in all of these areas. We need to continue to make progress, not just for the sake of those living with autism and their families, but for the country. We can't afford to leave people on the sidelines. We have to make every effort to help them live up to their highest potential and make a meaningful contribution to their communities, their families, and their family.

So, thanks, in part, again to this Committee's ability to focus and coordinate autism research and services, we have made some significant progress, and we can't stop now. I know you all are here because you share that passion, and I look forward to working with you and with our health leaders to continue to improve the lives of people with autism, working together.

I would love to hear some comments and thoughts, if we have a few minutes, from some of our new members before they are going to put me back on my bungee cord and drag me back across town.

(Laughter.)

But, again, thank you for your service, and I would love to turn it back over.

(Applause.)

Dr. Insel: Very good. Let's open this up to some discussion. I know many people on the Committee, both new and former members, would love to have a chance to engage a little bit with you.

Secretary Sebelius: Sure.

Dr. Insel: And maybe we can start with Anshu.

Dr. Batra: Thank you.

I am Anshu Batra. I am a developmental pediatrician in Los Angeles, and I am also a parent of a child who is on the spectrum.

I have to say thank you. The words and what you said just resonated so much in terms of what my hope and wish is, again, to provide the best opportunity and whatever the individual is capable of to help them integrate and be as productive and meaningful in society. So, thank you. I appreciate it.

Dr. Insel: Alison?

Ms. Singer: Thank you.

I am Alison Singer, and I want to thank you for reappointing me to this Committee. I am honored to serve for a second term. And I want to thank you for your focus and attention on autism.

As you have said, I agree that we need to be more action-oriented and we need to focus on helping individuals with autism to lead fulfilling and rewarding lives, but we also need to make sure that they live safe lives.

In the last version of this Committee, Sharon, Lyn, and I chaired a Committee on Safety where we prepared two documents that we sent to your office advising on issues of wandering and restraint and seclusion, in which we proposed specific action steps that really need to happen in order to keep our children safe.

With regard to wandering, there is

a tragic story in the news almost every week now where a young child wanders off and often meets with his or her death by drowning or dies from his or her injuries. We need to have new preventative programs. We need to develop them, and we need to test programs to prevent our children from wandering off and meeting with awful fates.

We also need to make sure that we can have a missing person's alert specifically for our children with autism. So that, if the prevention programs are not successful, we can have a secondary step to make sure that we do everything possible to recover them alive.

We also sent you a letter specifically focused on issues of restraint and seclusion where we focused on the need to bring more attention to the fact that children are being injured, some children are dying, as a result of improper restraint and seclusion activities that are happening in schools. We need to have your commitment that you will, or members of your staff will, meet with members of this Committee who are committed to taking action and bring necessary change, so that our children can be safe and can, then, take the step toward leading fulfilling and rewarding lives.

Secretary Sebelius: Well, I will definitely follow up on a couple of these issues. I know Alexa is here representing the special ed and school-based issues. So, some of the steps about restraint and seclusion, you have the right person in the room.

And we will definitely follow up with some of the other issues, particularly I am not sure that CDC is currently involved, but it seems to me that CDC on the issues around wandering and safety and prevention and public alerts, that is the appropriate agency to get engaged and involved because of their community-based strategies and public health strategies. So, I will make sure that we have them in the loop.

Dr. Insel: Other comments? Jose?

Dr. Cordero: Thank you so much for appointing to the Committee. And I would like to thank you for the diversity at this table. I think this is very important.

And I just wanted to point out that, among Hispanics, we have just done a survey in Puerto Rico, and our rate of autism is 1 in 62. So, we are on the higher side.

And I think that we will need to pay more attention to what is the prevalence and what is the impact of autism in diverse communities. So, thank you for including such a diverse group here.

Ms. Abdull: Thank you, Madam Secretary.

My name is Idil. I have a 9-year-old son with autism, and I appreciate you nominating me here. I also appreciate what the gentleman before me said, the diversity of this group.

You had said a couple of things that I wanted to see if I can ask you a number of questions. No. 1, the healthcare law, how does it affect within CMS in terms of paying for services, early intervention, that CDC and NIMH recommend, such as ABA or RDI? Right now, CMS does not pay or Medicaid does not pay for it. I wonder if that is included.

And the second thing is there is always a talk about minority disparity. I wonder if there is a way for the grants that come from HHS to either universities or state health departments, if there is a way to put language that assures the staff and the public health officials are more diverse. Because, often, you will see a lot of, almost 100 percent the staff and the faculty or public health, but, then, the children and the people with autism 50 percent minority. As you said, it is about culture, culturally- and linguistically-appropriate services. Even though the standards of four to seven of the clause guidelines are mandatory, not many, including Minnesota, follow it. I would like to see HHS push for that, so that services and therapies are more culturally-appropriate.

Thank you.

Secretary Sebelius: Let me just say that the Affordable Care Act really does not change much in the internal composition of Medicaid. As you know, it is a state/federal partnership, and some of the services that you are describing are really at the state level added to programs or not added to programs. And it is not driven by the mandatory federal law that has been in place for a period of years.

The only impact on Medicaid that the Affordable Care Act will have is expanding the population of those eligible up to 133 percent of poverty, but it doesn't change the internal components of the Medicaid law. That really is kind of a state-based discussion.

In terms of the diversity of health officials, I absolutely agree that it is critical. I think it is one of the critical barriers for healthcare across the country, is having culturally-competent healthcare providers in all kinds of communities.

So, we are trying to use whatever levers we have. We can't, unfortunately, wave a wand and make sure that 50 percent of anybody in Minnesota necessarily comes from a diverse community. I think what we can do is provide training, provide culturally-competent information, and we have tripled the number of National Health Service Corps providers.

We are trying to place folks, particularly from underrepresented communities, back in the communities that they come from, have streams of money for training and securing additional healthcare providers, doctors, nurse practitioners, mental health techs, and others who come out of more diverse backgrounds. And we will continue to push that forward.

But I think you have identified it isn't just, unfortunately, for families and individuals with autism who need culturally-competent providers, but we find that a challenge to make sure that people get the health services they need. If they can't talk to somebody in a language that is understandable, if they don't have folks who are sensitive to whatever the cultural barriers are, the healthcare is just going to be provided.

Ms. Abdull: Right.

Dr. Insel: Just another point on the coverage, Idil, we will actually come back to this at 2:30.

Ms. Abdull: Okay.

Dr. Insel: So, there will be a chance for some of the experts to come in and talk to us about what is happening in the national picture, both private and, hopefully, public.

Jan?

Ms. Crandy: Thank you, Secretary, for inviting me to be on this Committee.

In the Affordable Care Act are essential health benefits, including behavioral health. But, yet, we continue -- in my State, I am having to go to committee after committee meeting to try to make sure they include, even though we have an autism mandate, they still are debating about including ABA in the essential health benefit package. So, I think that needs to be addressed.

Also, I think that we need public policy that ensures that Part C, diagnose if all the signs point to autism, and we need increased access to treatment, not just by insurance, but more funding needs to be spent on treatment. I think we need to push for a federal match to support states and promote states who provide assistance with the expensive cost of treatment. This could also define and set protocols for data collection to determine child outcomes and establish uniform impact data targets to track treatment effects.

I also think that we need the development of a medical screen to be included in diagnostic practices and comparison studies across all treatment models and the level of intensities.

I do believe that parents want to know and deserve to know if autism is a possible side effect of vaccinations.

(Applause.)

The Vaccine Injury Compensation Program has settled enough claims of vaccine injury to include autism to warrant more research, a more focused look into pesticides, specifically those which grow directly into our food.

I think that she brought up CMS covering Medicaid. I think that we need a long-term study of Medicaid recipients with autism to determine percentage of who will be self-determining adults versus those who will end up in our system needing lifelong supports because Medicaid does not cover ABA and specific treatment. These needs to be settled at a federal level. States are going to choose not to include it in their Medicaid, and they are going to continue to do so until federal says, "Do it."

Thank you.

(Applause.)

Dr. Insel: Yes?

Mr. Robertson: Thank you, Madam Secretary, for the opportunity to serve on the IACC. I am a new member and an autistic adult.

I greatly appreciate your comments and words about the need to innovate our research and services and practices for autistic people across the whole lifespan, particularly with research and best practices lacking for adults and older adults; and, also, your words about innovating supports for autistic people who use alternative forms of communication, the research there and the services innovation have also been lacking.

I wanted to add a little bit to the conversation. I think it is a good route to this, as a computer scientist myself. I think technology is something that should be a major part, I think, for the innovation in both studying it for research and then what we are looking at in practices. And I think that it will play a major role to be improving the lives of all people with disabilities, including autistic people, over the next 10 years in many different areas and creating more opportunities for autistic people and their families to live and work in our own communities and enjoy the life opportunities that everyone wants to have.

Thank you.

Dr. Insel: Lyn?

Ms. Redwood: I thank you, Madam Secretary.

I want to first share the concerns that Alison raised. I actually brought the two letters that we sent to your office, if you could pass those down. It would be wonderful if you could take those back and give us some guidance in terms of next steps with the recommendations that we have made.

When I first started on the Committee and our Strategic Plan, we recognized autism as an emerging national health crisis. In the last version of our Strategic Plan, we recognized that it is one. The new numbers out of CDC of 1 in 88 children with autism, and when you look at specifically boys, it is like 1 in 50.

The new study that was recently out of South Korea, which the numbers are much more recent than the data we have here in the U.S., which is 12 years old, is 1 in 38. That is essentially what I have heard from experts on the ground who are serving younger children, is more what we are seeing here today.

Dr. Insel, at the meeting back in October, you recognized this as a crisis, but we have not had an official recognition as a national health crisis from the Administration, and we desperately need that to be able to mobilize the services and the resources that we need to address this, the same way we would H1N1 or SARS or AIDS.

We function in an advisory capacity. As a member, it has been somewhat frustrating because we cannot set policy; we cannot fund research, and we need a specific agency that is able to do that for us.

Right now, in my opinion, it is a hodgepodge. We need an office under the Director, modeled after the Office for AIDS, that can be there day-in and day-out and address these urgent issues. Because, right now, we really don't have that and we are in crisis mode.

There was another recent study that just came out that looked at the estimated cost for autism. Those have also increased since we last met. The new estimates are up to $126 billion a year. This new figure expands on previous estimates by including indirect costs, such as lost family income and productivity, in addition to the direct cost of autism-associated services.

We have a tsunami facing us because a majority of these children are still under the age of 18. When they age out of the system, there is no place for them to go. So, we truly are in crisis mode and we desperately need your help.

(Applause.)

Dr. Insel: A last comment from Geri Dawson.

Dr. Dawson: I want to thank you for being here, and thank you for reappointing me to the IACC. It is certainly an honor.

I think what you are hearing here is a sense of impatience and frustration. I think the IACC in many ways has been a very effective group in setting a set of objectives that is literally a list of all the things that we need to do to address the priorities that autism brings. But there is a sense that, honestly, not much has changed.

In fact, if you look over the last several years, things have gotten worse. The prevalence has increased. In terms of treatments, we still don't have effective treatments. There are two FDA-approved medical treatments, and they are not for core autism symptoms.

The age of diagnosis, the median age in the last CDC report, was four years for autism and six years for Asperger's Syndrome. And yet, we know that the age that kids can be reliably diagnosed is 18 to 24 months.

Kids don't have access to early intervention. We have seen the cost of autism increase from $35 billion annually to $137 billion annually. And we know that the adults who are moving from adolescence to adulthood are unemployed and they are socially-isolated, and they are facing tremendous health problems, heart disease, obesity, other health problems.

So, I think that the frustration

here is that we have all earnestly worked together to identify all the priorities, but there is this real sense that things are not changing and that the government is not recognizing autism as a true public health crisis and emergency that needs some kind of national plan and top-down, coordinated strategy, people working every day to address what has become this true public health crisis.

So, we hope that we can change this culture from one of sort of an academic exercise to one where we can start seeing some of these real issues that I have just outlined change over the next course of our work together. So, I hope you can hear that, and I think many of us now have expressed that.

Secretary Sebelius: Well, let me just say I appreciate the sense of urgency and the sense of crisis. I don't have the personal experience that many of you have as either a diagnosed person with autism or a family member. So, I don't pretend to share that personal expertise.

I will tell you there is a sense of urgency. I am a believer that often an individual office is more isolating than having a range of services that are focused on -- an NIH, CDC, HRSA, out of our 11 agencies, the FDA, we have individuals in all of those who really are working on this day-in and day-out.

We do not have enough research going on at this point. We don't have the kind of screening at an early enough level, are trying to ramp-up those priorities. But I do think that having a focus, having a major healthcare framework that is in place and moving forward for the first time ever in the country, and the kind of impact that will make, not only for people who lack insurance, but anyone with a preexisting health condition will have a situation where they will not ever be able to be denied health coverage in the future. That is a step forward that has been talked about in this country for 70 years, but never realized.

So, I do think that there is

progress. It is not to deny that there needs to be a sense of urgency and more needs to be made. But you have identified a national plan. It is updated, and there is a great deal of focus throughout our Department, not in one office or one entity, but throughout agencies in our Department, to try to leverage, whether it is CMS or at NIH or with the health workforce or with the public health folks, to bring those assets together and figure out what we can do.

So, we look forward to it. I am eager to have your specific input about where those priorities should be. I know that Tom and Francis will, again, keep me posted.

And frankly, this is a good time to be meeting because we are having the preliminary discussions about the next budget cycle and where funds should be identified. So, your timing is very good. Those discussions are underway. Of course, we don't have a last year's budget yet. We are beginning to talk about next year's budget, and maybe Congress will catch up with the fiscal years one of these times and we will figure out exactly where we are.

But thank you, really, for what you are doing, for the work that you are doing, for the kind of passion that you bring to this effort, and for the information you give us. Thank you.

(Applause.)

Dr. Insel: Thank you.

We are going to try to stay on schedule. Our next part of our agenda is to welcome two Members of Congress, one of whom is here, Mike Doyle, who is a Democrat from the 14th District of Pennsylvania. That is the area that surrounds Pittsburgh.

Mike has been in Congress for 16 years and is a very active member of the Energy and Commerce Committee, which is extremely important for all of us in HHS. He is also one of only 10 Members of the House Ethics Committee, which tells you a lot about his stature and the respect he receives from his colleagues.

He has championed a whole series

of issues around alternative energy, and recently something more close to what we do, has introduced legislation requiring public access to taxpayer-funded research, a piece of legislation which has garnered great interest at NIH.

But he is here because he, along with his colleague Chris Smith, co-authored and cosponsored the Combating Autism Reauthorization Act.

And, Mike, we are delighted to have you here and hope you will be able to share some thoughts with the Committee.

Representative Doyle: Thank you, Tom.

Well, good morning. It is a pleasure, and I appreciate all of you for having me here today.

Tom, to you and to my Autism Caucus Co-Chair and good friend, Chris Smith, who I know will be here shortly, and to members of the IACC, I am pleased that I could be here as we kick off the first full Committee meeting with both new and old members of the Committee.

As many of you know, the Congressional Autism Caucus has been working for over 10 years to expand federal research on autism spectrum disorders and adopt federal policies that guarantee the necessary assistance to individuals with autism and their families. This bipartisan coalition has met several times this year alone to discuss many of the advances that have been made in autism research and treatment and to strategize on how to meet the increasing needs of the autism community.

Last year, Chris Smith and I introduced a bill to reauthorize the expiring Combating Autism Act, which was signed into law by the President last September. This bill reauthorized funding for federal research into autism spectrum disorders and ensured that the IACC can continue your important work.

Earlier this year, the CDC released a shocking and unexpected report that 1 in approximately every 88 children in the

United States has been diagnosed with an autism spectrum disorder. This revelation only confirms what a serious issue this is and re-emphasizes the urgent need for more federal action on research, diagnosis, early intervention, and treatment in dealing with autism.

The CDC doesn't know how much of the increase is due to better diagnosis and heightened awareness and how much is due to an actual increase in the prevalence of autism spectrum disorders. But what it does tell us is that much more needs to be done to understand the causes of autism spectrum disorders and to provide proper assistance to individuals with autism.

I am firm believer that when we all work together, great success can be achieved. We have seen that within our Caucus, and we have seen it in federal agencies addressing ASDs. I am confident that this room of outstanding individuals will continue that important work.

The work of the IACC is vital in

many ways. In coordinating federal research, we are working to make sure that no federal dollar is wasted, a goal I think we can all agree upon in these critical and challenging and uncertain fiscal times.

The IACC is a model of transparency, and I applaud you for opening your meetings to the public, so that all voices can be heard. We may not always agree, but I think it is important to remember that we all share the same goal: to increase the knowledge, services, and care available to individuals with autism and their families.

Now, as many of you know, the original Combating Autism Act required that the Department of Health and Human Services, along with the National Institutes of Health, put together a report highlighting federal action undertaken since the bill's enactment. This report was released in January of last year and showed significant advances and growth.

It singled out the critical work of the IACC, stating that the unprecedented coordination among the agencies has helped successfully identify key research and service priorities, and has fostered enhanced communications and collaboration.

Together with the IACC, federal agencies are actively identifying best practices and implementing programs to increase the quality of life for people with ASD across the lifespan. I agree that this coordination is vital and remains so. But, after much consultation with relevant stakeholders, Chris and I have come to the conclusion that some changes to the IACC are needed.

Consequently, we have introduced a bill, the Autism Spectrum Disorder Services Act of 2011. This bill would broaden the existing IACC by increasing public representation and by emphasizing an increase in the available services to individuals with autism as a major focus. This would include adding members to the IACC that currently serve individuals with autism, so we can have an even clearer picture of the true needs of those in the community.

To that end, this legislation also establishes planning and demonstration grant programs for services to children, transitioning youth, adults, and individuals of any age who may be at risk of injury, with a strong focus on making sure that states have the infrastructure to disseminate that critical information.

Chris and I have introduced several bills in this Congress that would increase the resources available to individuals with autism from birth to the classroom and beyond.

Unfortunately -- and I heard this from many of the comments to the Secretary -- the reality is in this fiscal climate it is highly unlikely that any new money will be approved. Now Chris and I remain committed to a fight for that, but this is the unspoken 800-pound elephant in the room.

We can't get a majority of Members in the House of Representatives to vote for new spending. Many of them have signed pledges saying that they would never vote to raise any tax of any kind to bring new resources into the government.

So, we are in a situation here, if we want to propose a program and we want to put new money into that program, the dilemma that Chris and I and others face is that we have to just cut something else that already exists. We can't even propose new revenue to pay for it. We have to cut something, and we can seem to never agree in the House of Representatives on what to cut. Even when we agree on what we want to spend, we can't agree on what to cut to enable us to have new money.

That is a debate, unfortunately, I don't think is going to be solved until after November. American people have to decide what is worth having, what programs are worth having in the country. And if we think they are worth having, are we willing to pay for them? Because if we are not willing to pay for them, and we are not willing to have any new revenue come into the government, we are simply not going to be able to do a number of things that not only Chris and I, but many Members of Congress feel are absolutely necessary to move forward to help families that need these services.

And this population is growing. It is not shrinking. And the problem isn't getting any cheaper; it is getting more expensive.

So, I heard frustration amongst many of the questions today. I want you to know many of us are sincerely frustrated, also, at the situation that we find ourselves in.

And I am not sure what the answer to that is. The answer is actually out there in the 50 states. And it is something we all, as Americans, are going to have to decide, how we fund programs we think are valuable to the country and to the people we serve.

So, let me just close saying -- and I wish I could spend the whole day with you; I, unfortunately, am going to be back in the Energy and Commerce Committee in hearings. So, I am being dragged out, too. But I want you to know that Chris and I have worked together for over a decade to try to raise awareness amongst our Members.

You know, when we started the caucus at the very beginning, a lot of people, their only recollection or knowledge of autism was they saw the movie "Rainman". Beyond that, they didn't know much about this at all.

I would say that at least one of the success stories, at least amongst Members of Congress, is this caucus has raised awareness about what is going on. And we would be nowhere without the parents of the children with autism. The parent groups, the grassroots movement in this is really what has brought us as far as we are today.

But we are being literally blocked right now. We are being blocked from being able to do the stuff that we want to do in order to get services out to families, out to school districts, because there is no money to be appropriated. That is just the reality we are living with today, as we address members of the caucus who want to do something. But, as soon as there is money attached to it, it is like, well, where do we get the money from? I think that is a decision that is not going to get settled anytime soon, but maybe, hopefully, next year Chris and I can not just introduce the act to reauthorize it, but start to put some real funding behind this critical problem that we both recognize and we know is growing.

And I just want you to know that many of us in Congress share the frustration of the families and the people who are dedicated to finding the causes of autism and getting services out to the community.

I want to thank you for inviting me today and beg your indulgence to run back to my Committee hearing.

Thank you very much.

(Applause.)

Dr. Insel: Thanks very much.

The other half of this dynamic duo has just joined us with an exquisite sense of timing. I think these gentlemen seem to have that in their DNA, since they got this reauthorization passed in the last hour, I believe, of the last session of Congress, which was the final moment in which it could happen.

Congressman Chris Smith is a Republican from New Jersey's 4th District, which is the area around Trenton. He has been in Congress since 1980. He is in his 16th term currently. He is a senior member of the Foreign Affairs Committee, Chair of the Africa Global Health and Human Rights Subcommittee. He has been really the leading figure in Congress around issues that have to do with anti-human trafficking laws and, also, the person who has really championed this cause of autism from the beginning, really a person who started the Caucus, along with Mike, and has led this every step of the way, including ensuring the reauthorization and the reestablishment of the IACC.

He has been recognized by many, many groups, most recently by the 2012 Easter Seals Advocacy Award for your leadership in autism. We are just delighted to have you here, sir.

Representative Smith: Dr. Insel, thank you so very much, and thank you to all the Board members of IACC for your extraordinary commitment, the new members, the old members who have done so much to make a difference.

You know, you are kind of lucky that we each get about 10 minutes and no more. I was keynoter recently at a big health conference here in Washington. It was on veterans' healthcare. I used to be the Chairman of Veterans Healthcare. I wrote a number of laws dealing with Persian Gulf illness and the like. They gave me an hour, and I spoke for an hour and 10 minutes, which I shouldn't have.

(Laughter.)

Got into the weeds like you couldn't believe. And at the end, because a lot of families were there, this little girl came running up and she said -- she was about four years old -- "Mister, your speech was long and boring."

(Laughter.)

She spun around and walked away. A few minutes later, her father came up and he said, "You know, I saw you talking to my little daughter Melissa, and she is at that awkward age -- she is four years old -- where she just repeats whatever she hears."

(Laughter.)

So, I have learned a lesson for life from that. So, I will be very brief.

And again, Dr. Insel, thank you for your extraordinary leadership. This model of IACC is really, I think, the prototype, the quarterbacking, the coordination to avoid duplication, to do the most effective research, applying scarce dollars to an overwhelming need.

Mike Doyle and I are close personal friends. We collaborate on all the issues. You heard him talk about the services bill and all the other pending bills. We do it all in a bipartisan way. Bipartisanship, I am happy to say, lives, despite the caricature created by some in the media, and there are some who polarize and live for polarization. There are a whole lot of us who believe, if you want to get something done, you reach across the aisle, you work aggressively, you build coalitions. And again, that is what Mike and I try to do with our Caucus and have been doing it for over 10 years.

I thought just briefly I would give you a brief overview of my commitment and some of the things that I have worked on for years. I actually got involved in autism in the first year of my first term, working with the Eden Institute. Dr. Holmes invited me to a group home in the Princeton, New Jersey, area. At the time, the prevalence common number as about 3 out of 10,000. And it was a very, very eye-opening experience.

At the time, David Stockman, who was then OMB Director, was looking to slash monies to disability as well as other health initiatives. We turned that back, believe it or not, and avoided a huge cut that he had sought to do. But it was Dr. Holmes and others within the disability community, including those involved in autism, that stopped and put a tourniquet on those early proposals.

Fifteen years ago, parents of two autistic children, Bobby and Billy Gallagher, walked into my District office and asked for help on what they believed to be a significant autism prevalence spike in their township of Brick.

They told me that, from 1970 to 1979, there was only one reported case of autism in Brick. From 1980 to 1989, they said that number, then, had jumped to four. And by 1990 to 1995, just five years later, the number of children afflicted had jumped to 27.

School administrators dismissed their research out of hand and suggested it was a case of people simply moving there. The mayor gave me a hard time when I started raising these questions and said, "You are going to hurt our property taxes." People on Town Council were very, very dismissive and antagonistic because they said -- because we had a cancer cluster in nearby Toms River, and they said, "Now what are you trying to do to Brick?"

And I said, "You go wherever the science is. If there is a problem here, we need to know it. If the pathway happens to be the Metedeconk River or some other pathway, we need to investigate it and we need to do it aggressively."

Concerned, I invited CDC, ATSDR, and the New Jersey Department of Health to investigate. Initially, CDC was very antagonistic to doing this. They didn't want to do it. I pleaded; I asked. The New Jersey Department of Health was very helpful in trying to bring them aboard to look into this.

Back then, not much was being done on the federal level. CDC's commitment at the time was a paltry $287,000. Let me repeat that again, $287,000 per year straight line for five years, five consecutive years. That doesn't buy a table. That doesn't buy -- I mean, what does that buy? It is almost better not to have anything than such an underfunded commitment to autism.

Within months, however, of the study, it became disturbingly clear that Brick had more cases that could be reasonably expected. I remember at the review-of-literature meeting, we had inspired parents talking about studies that they had found on the internet. And they said, "What's your view on that?" And thankfully, CDC was very open and said, "Give us that cite. Give us that information." And I think they began really believing that this was a pandemic, a disability pandemic, that had gone underfocused upon.

Equally disturbing, in addition to the Brick numbers, data calls from other towns and cities suggested an elevated number of cases in those municipalities as well. That began, in my view, the game-changing mentality.

So, in January of 1999, I introduced the Autism Statistic Surveillance, Research, and Epidemiology Act -- we called it ASSURE -- to establish a national program to combat autism that would include three to five

Centers of Excellence and a federal advisory committee, which was clearly the forerunner of this August group called IACC.

After months of intense lobbying -- and I mean literally walking the floors; parents did it; the groups did it; at the time I did it. I constantly was talking to my good friend and colleague, Mike Bilirakis, who was Chairman of the Health Committee. I was Chairman of Veterans. He sat right next to me as Vice Chair, and I lobbied the living daylights out of Mike, and Mike is a great guy, and I mean a very committed man.

He kept saying, well, we are getting this pushback that we don't do disease-specific. It was coming from the leadership, and he finally did his Children's Health Act. That very important piece of legislation put our entire bill as Title I of the Children's Health Act of 2000. I am forever -- and I think we all should be -- grateful for his leadership on that.

The Combating Autism Act reauthorization, as you know, was on life support right into the end of the fiscal year last year. And finally, at long last, we were able to get that passed as well, and it is $693 million over three years. It ought to be significantly more, but at least it is there.

Under Dr. Thomas Insel, IACC has diligently sought, as you know, evidence-based answers to an array of vexing questions concerning causation, risk factors, including genetic and non-genetic factors, parental age, and, as you know, premature birth and low birth weight, and the most efficacious interventions designed to mitigate this disability.

Great strides have been made in unraveling the mystery of autism, but, clearly, so much more remains to be done. For example, the California Stanford Autism Twin Study, as I think all of you know, looked at 192 pairs of twins and strongly suggested a link to environmental factors. If an identical twin develops autism, the study found some 70 percent chance that the other twin will do the same, develop autism.

Perhaps more significantly, if a fraternal twin developed autism, the study found a 35 percent chance that the other fraternal twin will do the same, raising questions that clearly beg additional investigation.

Finally, what IACC does not only impacts what you do, not only impacts Americans now affected by autism and their parents -- we all know the need for respite care and the like -- but you also have a huge impact on the rest of the world.

In May of last year, I chaired the first hearing ever examining the magnitude and severity of the global health crisis of autism. Dr. Andy Shih, for example, of Autism Speaks, testified that 1 percent of the world's population, or some 67 million people, are affected with a form of autism.

On one trip that I took to Lagos in 2000, Lagos, Nigeria, I met -- and I actually, believe it or not, have a hearing today at two o'clock on Nigeria and will be focusing on why the Administration has done nothing, and I have been admonishing them. I have a bill jointly introduced by my good friend Mike Doyle that would establish a program to combat autism globally. And I will be asking some very serious questions of why this has not been embraced administratively to do more to help these fledgling NGOs all over Africa and all over the world who have little or no services.

We had a woman from Cote d'Ivoire testify at our hearing. She said she was one of the lucky ones who was able to come to the United States to help her son get help. She said in Cote d'Ivoire, or the Ivory Coast as it is more popularly known, they had nothing -- nothing -- to help children who are now affected by autism.

While in, of all places, Lagos, Nigeria, giving a major speech on human trafficking -- I wrote the law to combat human trafficking in 2000, 2003, and 2005, sex and labor trafficking -- a man came up named Chidi Izuwah. He is the parent of an autistic child. His wife runs an NGO in Lagos. He said, "Hey, I like what you said about trafficking. What are you doing about autism?" I said, "Glad you mentioned that."

We had dinner that night, and we have been working now very cooperatively, and working with others throughout Africa and, of course, around the world to build a global coalition. We are working in the EU. We are working with a number of -- our Caucus has made a formal link with the Irish, with Wales, with many in the European Parliament on autism.

And I have introduced a bill, along with my good friend Mike Doyle, called the Global Autism Assistance Act. It didn't pass last year. It hasn't passed yet this year. But we will work, even if it doesn't provide new money, we need to prioritize. I mean, there are monies. It is a matter of discretion on the part of the Administration, at the White House, to say this is a priority and we need to develop money.

We also have recently, Monday, introduced a teach act designed to help train the teachers. We all know that there remains a huge gap in training of individual teachers. I have been trying to do this bill for almost a decade, as you know, and that is an idea whose time has come as well, to specialize the training, provide a refundable tax credit to those. So that we will take these wonderful teachers, especially those in the special ed area, and say, "You need additional training," incentivize that additional training, so you can deal with the unique challenges of autistic children.

So, again, I can't thank IACC enough. Dr. Insel, I can't thank you enough. And thank you on behalf of my good friend Mike Doyle and I for your extraordinary leadership.

(Applause.)

Dr. Insel: Well, thanks very much.

We want to move on to stay on schedule. If Congressman Smith can stay with us, maybe there will be some chance for further conversation.

I want to introduce Kareem Dale, who is with us, who is the Associate Director for the White House Office of Public Engagement and Special Assistant to the President for Disability Policy.

Welcome back. I think this is your third time joining the IACC. We are delighted to have you and always look forward to hearing about what is new and what is the perspective from the White House.

Mr. Dale: Thank you very much, Tom. I appreciate it, and it is good to be back and here with you all. And I certainly thank the Secretary for her comments, and Tom and Francis for their leadership and participation.

I will be very brief. You are going to hear from one of my bosses at the White House next, Mike Strautmanis.

(Laughter.)

Did he make a face or something at me? Taking advantage of the blind guy, clearly.

(Laughter.)

So, I will be very brief.

But, in my role as Special Assistant to the President for Disability Policy, I coordinate the work that we do across the Administration on disability policy. I work out of the Domestic Policy Council, which is run by Cecilia Munoz. And then, I also work out of the Office of Public Engagement, which is one of Valerie Jarrett's offices. Mike is in that office, as well as that office is run by Jon Carson.

So, it is my responsibility to make sure across the board that we are reaching out to the disability community and that we are putting in place the policies that are important, whether that be unemployment, education, transportation, housing, healthcare, you name it; we are working on it.

And so, it is the President's strong belief that these from day one have been issues that are important to him and that we want to see happen. It is why he has signed Executive Orders on the employment of people with disabilities. It is why we have worked hard in the education arena to make sure there are additional efforts around Part B and Part C of IDEA. It is why we have worked hard to increase funding for the Rehabilitation Services Administration, which is focused on, obviously, employment and school. It is why we have worked so hard on the Affordable Care Act, as you heard the Secretary talk about.

But it is also why we have worked so hard in this area related to the autism spectrum. You know, I heard some of the frustration that folks were talking about a little bit earlier with the Secretary. I can assure you that we share that frustration, and the President shares the frustration. It is never enough and we are not moving fast enough on many of these issues.

I go back to when the President was signing the Combating Autism Act, the reauthorization of that Act, just several months back. And we were in the Oval. Mike and I were standing there, and we were talking and he talked about how happy he was that we had gotten this done, like he had promised to get it done back in 2008. But he said, "You know, we have got to keep working on this and we have got to do more."

And so, we share your passion and your commitment to do more. I can tell you, with Mike at the White House, that is shared throughout the Administration and throughout the White House, and people understand the importance of this.

And so, we want to continue to work very hard with you all to get some real results and to build on what the Secretary talked about in terms of the historic funding that has gone into this. But we know we need more results as it relates to treatment, as it relates to early intervention. And so, my door is always open to each and every one of you all, as this Committee works to do its work.

And progress is being made. We started with no Strategic Plan, and the last Committee put together a Strategic Plan. And so, now we are going to do more than just do another Strategic Plan. We are going to build on that and, hopefully, come up with better results. That is the focus, to continue to build and have more progress where we need it. And we need it in all areas.

I will just close by saying that this often gets couched in the healthcare field, which is certainly understandable and appropriate. But, as I started with my remarks -- and I know Scott mentioned a little bit about this, and you hear about this a lot -- we need services across the board for children, but also for adults. We need those supports and services for employment. We need those supports and services for higher education opportunities for persons on the autism spectrum, so that they can go and get training or get a higher degree, so that they can be productive members of our society. We need those supports and services in transportation, in housing. It is why the Administration on Community Living, working with HUD, is so important.

So, we are going to hit it from

all fronts, and we are going to continue to stay focused on improving the lives of folks with disabilities. As long as this President is in office, our commitment is going to remain extremely strong.

So, thank you for all of your incredible hard work. It doesn't go unnoticed. The things that you do reach us at the White House. We appreciate it. But, more importantly than that, we need it; we want it, because it helps us make decisions and it helps us get it right and do it better.

So, thank you very much.

(Applause.)

Dr. Insel: Thank you. And, of course, as you said, your door is always open, and ours as well. We would love to have you think about this as an opportunity to join us at anytime you would like. And we have appreciated the chance last April of the year before; you had much of the Committee at the White House for a long discussion about what the issues were that you felt the White House needed to hear the most about. And we certainly appreciated that opportunity as well.

Mike Strautmanis is the Deputy Assistant to the President and Counselor for Strategic Engagement to the Senior Advisor Valerie Jarrett. He has been with the President since the President was a junior Senator from Illinois, when he served as then-Senator Obama's Chief Counsel and Deputy Chief of Staff.

He has been very active in a whole range of issues that have to do with employment and the President's Council on Jobs and Competitiveness.

It is great to have you here, Mike. I know this is an issue that you are particularly passionate about. So, we always look forward to your remarks.

Mr. Strautmanis: Thanks. I appreciate everybody giving me a little minute on the agenda.

Kareem Dale stole a lot of my thunder around the commitment in the White House. I was there with Kareem in the Oval

Office when he signed the reauthorization.

Thank you to my friends in Congress who have exerted such consistent leadership on this issue. We wouldn't be where we are here without you. So, Congressman, thank you, and to Congressman Doyle as well, thank you.

It is a daunting experience being in the Oval Office anytime. It is a daunting experience having the President say we need to do more on an issue that you care so much about. It is a daunting experience to have him say that and then look at you and then say, "Right, Mike?" Actually, he calls me "Straut". "Right, Straut?"

But the good news is that I could not have more of a sense of urgency about this work; it is not possible. And so, I met the President at that moment where he was, and I walked out of there with renewed determination to deliver not just for him, because it is my job, but to deliver for the community that doesn't have the opportunity to be there and talk to him and to speak on his behalf, and to make those calls from the White House that seem to get picked up quickly and to ask for reports that come and ask for updates, and to continue to create a sense of urgency.

So, I am here today not just on behalf of the President, on behalf of Valerie Jarrett, on behalf of all of us at the White house, but I am here today, as I always am, on behalf of Jason Jori Strautmanis, my now 15-year-old son. Many of you have walked this walk with me and have heard his name. You know, he's 15 now. The first time many of you heard about him he was four. But he is a big boy.

He doesn't live with us every day. His challenges became so great that it was, frankly, dangerous for our daughter and for us and for him, and we weren't able to provide what he needed, as his parents, in the home.

And so, when we talk about the community that is involved and the responsibility of our federal, state, and local officials to be there for families, I know firsthand what we are talking about. As difficult as that time was, and as much as I desperately want him to have everything that he needs to be able to grow and thrive, I know how lucky I am. I am lucky that I live in the State of Maryland that has made choices to provide a broad range of services through Medicaid for its citizens. I am lucky, as the Congressman pointed out, to live in the United States of America that has made a broad commitment to be able to take care of people with disabilities and, yes, to focus on autism.

But I also know that there is so much more that he needs. I know that there is so much that people who don't have the privileges and opportunities that I have need. And so, I think about them.

My job every day is to do outreach. And so, I get outside of those black gates at the White House and I talk to people about what they need, not just about autism. Autism, actually, is one very small part of my day-to-day work. But I do talk to people every day that need this government to be there for them and to do things for them that they, for one reason or another, need done collectively, that they can't do for themselves individually.

And so, I wake up every day with an incredible amount of energy to be able to push, so that we can, for the time that I am privileged enough to sit here, do everything I possibly can to deliver for the broad spectrum. And I know that word is used often when we talk about autism, but I am talking about the family, the broad spectrum of advocates and leaders and family members and people who are living with autism, people who are autistic, and those yet to come who, if you look at the numbers -- and I see the numbers every day -- I think the numbers overwhelm the system that we have that exists.

And so, so many today that are falling through the cracks, you think about that, and there are going to be so many more. So, that is the sense of urgency that I bring to this. Dr. Insel has heard this, and he shares it. And so, that is who I am; that is where I am coming from.

When you think about interagency meetings and you think about meetings with the White House, and you think about my name and Kareem Dale and Valerie Jarrett, and all of those, I want you to know what happens, what my focus is, and where I am coming from.

With that, I do want to say thank you to this Committee for the incredible work that you have done. We are further along than we were when you got here. That is progress. That is real. That makes a difference in the lives of people.

I know it is not enough, as I have just spoke to; there is more that needs to be done. But we need not dismiss the progress that has been made because accepting that, acknowledging it, and celebrating it is what gives us the energy and the pathway forward to do more. So, I celebrate your work and I deeply, deeply thank you for it on behalf of the President of the United States and everybody who works for him.

Secretary Sebelius I know was here

earlier. She has a lot on her plate. And so, I really commend her focus on this, her focus on this work, and the fact that she is always available to me, to Dr. Insel, and to the rest of us for her continued leadership.

The Members of Congress I have thanked.

Kareem is tireless. I don't quite know how he does it. But, you know, you saw he spoke from no notes. He spoke from his heart. But he also spoke from an incredible amount of knowledge. Him handling both the policy work for people with disabilities and the outreach work, it is just amazing to see what he does every day. We are privileged to have somebody that talented working with us.

And, Dr. Collins, we certainly do appreciate your work.

To the new members of the Committee, I say congratulations. Public service brings with it an incredible opportunity to make a difference. It is going to also bring with it an intense amount of criticism because you now are representing others, and they need you to get things done now. And so, I want you to stay positive, but you are here for a reason and we need your best, which I know you are going to give it to us. And we are going to come back, and we are going to celebrate the progress that you have helped us make to move things forward.

Finally, I guess I just want to say that another thing that has been important to me that I have tried to put in this work, I was asked to run the Office of Public Liaison -- that is what we called it then -- and intergovernmental affairs in the transition, when we first came onboard. It seems like a whirlwind. It probably lasted like a day, one long, sleepless day.

(Laughter.)

But one of the things that was important to me is that we had coordination within the federal government. You know, I had only briefly worked in the Executive Branch, but one of the things that always frustrated me when I was worked in Congress, when I worked in the community, is that it didn't seem like the federal government was talking to one another. You had to take your life, which was whole, and break it into pieces to be able to deal with these different agencies.

And so, I don't want us to lose the fact that you are talking to one another. This Committee is coordinating internally with the agencies, so that we work through our issues and are able to speak with one voice, and we can deal with the community as a whole and not have and force this community to figure out, well, what is a civil rights justice issue and what is a labor issue and what is an education issue and what is a healthcare issue, and, by the way, what is a research versus an issue around services. We are trying to deal with the community as it exists.

I am extraordinarily proud of the work you have done as far as that is concerned. And as someone who works with Valerie Jarrett leading our engagement work, I am also proud that you have been willing to engage with the community, that you haven't sealed yourself off and tried to protect yourself from hearing from people, the persistent, desperate, sometimes angry voices of people who have probably gotten very little sleep and are desperate to try to get answers for themselves and for their family members.

And so, I know that can be difficult, but, frankly, that is our job. I really appreciate your willingness to engage with the public in an honest and transparent way. I am very proud of that as well.

So, with that, I came a little late. Fortunately, I didn't miss my slot. I am going to have to run out because it is just, unfortunately, the life that I lead these days.

But I am taking everything with me. I read every single comment, public one, not just because I need to know, as Kareem said, to do my job, but because it is important.

Thank you, Doctor.

(Applause.)

Dr. Insel: Mike, keep up the fight. And again, anytime you can join us, we would love to have you at the meetings. You always bring a lot of great ideas, great passion, and we appreciate your input even between meetings as well as during.

Mr. Strautmanis: Thank you.

Dr. Insel: It is great to have you on the team.

Mr. Strautmanis: Thank you.

Dr. Insel: I would like to hear from Dr. Alexa Posny, who is a member, a new member, of the Committee. That, by itself, I think is a very significant statement from the Department of Education.

Dr. Posny is the Assistant Secretary for Special Education and Rehabilitative Services at the Department. She was appointed and approved by the U.S. Senate on October 5th, 2009. So, you have been in this job for a very long time already, almost three years.

She has a really critical role in setting policy and in management issues affecting special education and rehabilitative services. I will let her tell you what she does. So, I am going to turn this over to Alexa.

Dr. Posny: Thank you very much, Tom. And thanks to all of you, because I really view this as a great privilege to serve on IACC because it is so critically important.

In terms of the history of special ed -- and I am not going to spend a lot of time on it, but I think the numbers kind of tell the story in and of itself -- before IDEA, before 94-142, which was in 1975, only 1 in 5 students with disabilities were even educated within the public school system, and almost 2 million kids were totally excluded from having any opportunity whatsoever.

Today, we serve almost 7 million students with disabilities within the public school system. And the critical piece is this: more than 60 percent of students with disabilities are served in the general education classroom for more than 80 percent of the day.

So, think about just the change has occurred in a little over three decades. In 10 years, from 2000 to 2010, the number of students ages 6 to 21 receiving services under autism has increased from 80,000 to 330,000. And just in the last four years alone, the percentage of students with autism has doubled from 3.6 percent to 6.3 percent, and in our population that is an incredible increase. Between 2007 and 2011, the percentage of students with autism who attended a regular classroom for at least 80 percent of the day has increased from 32 percent to 38 percent.

What we know -- and we have heard it from a number of people -- the age of diagnosis in the U.S. is still about three to four years of age, and that is too late. We know that concerns are very readily apparent by the time the child is even 18 months. It has been diagnosed; it has become more accurate between 18 and 24 months, but we know that we need to do more because serving them as early as we can is critically important.

The U.S. Department of Education,

over the course of the last year, has collaborated across all of the offices, not just the Special Ed Office, and with other agencies. And what we have developed is the ED Disabilities Strategy Work Group.

What this Work Group developed are what we refer to as the five game-changers for the Department to put into place internally as well as externally. And I don't think any of these will come as a surprise to you.

First and foremost, we need high-quality early intervention and pre-school services in natural environments and inclusive settings to enhance each child's development. We want them to be ready for school long before they enter the school door.

We know that, as a result of Part C and Part B, 619 services, more and more preschoolers with autism spectrum disorder are entering kindergarten on-level.

Our second game-changer: children, youth, and adults must learn, work, and participate in inclusive, integrated settings in their schools and communities and be prepared and supported for college and/or career success, independent living, and full participation.

The third area, children, youth, and adults must have access to high-quality instruction and support services delivered by great teachers, leaders, and service providers who meet their individual learning and social and emotional needs and improve their outcomes. This was readily apparent in the State-of-the-Union address this year. President Obama said, "We know a good teacher can increase the lifetime income of a classroom by over $250,000. A great teacher can offer escape from poverty to the child who dreams beyond his circumstance."

Most teachers work tirelessly with modest pay, sometimes digging into their own pocket for school supplies. The Congressman made an eloquent statement in saying that teachers are the most important thing that we have to do in terms of education.

The fourth area, accountability systems. We must align them to career- and college-ready standards. We must promote closing the achievement gap, ensure the continuous improvement, and reflect high expectations for all children, and we really mean all, and youth and adults.

And the last one, research and innovation and the use of evidence-based practices are essential to improving outcomes for children, youth, and adults with disabilities.

When I think about the three divisions in which I am responsible, the first one is OSEP, the Office of Special Education Programs, where Larry works. OSEP is dedicated to improving the results for children with autism and their families.

And I want to applaud the families and parents who are here. What we know is this: that families are crucial to the success of the child. The National Commission on Excellence in Education stated, "As surely as you are a child's first and most influential teacher, a child's ideas about education and its significance begins with you." And that is us as parents.

We also know that OSERS has funded at least one and in many cases several different parent information centers in each state to help parents. These 107 centers across the United States are designed to provide resources for families of individuals with autism. They are there to provide information on how to access the systems, both Part C and Part B, 619. They also provide trainings, webinars, and one-on-one consult. I always encourage parents to go to the Parent Information Centers and use them to come with them to the IFSP and the IEP meetings.

We also know that IDEA Part B and Part C provide a number of formula-based grants to states to improve the results. Our current request for 2013 -- and I want you to understand this is a request; we don't know whether we are going to receive it or not -- but what we have asked for in Part B is to sustain the $11.6 billion that is part of the formula funds that go out to the states. This would maintain the same level of funding in

2012.

In Part C, we have asked for $462 million, which is a $20 million increase, because we know that early intervention is so critically important. And this is the first time that we have asked for an increase in Part C over the last decade.

We also know that OSERS funds are competitive -- and Larry mentioned this -- competitive and other special education grants. We fund personal development projects. We fund the National Professional Development Center on Autism Spectrum Disorders at the University of North Carolina. We fund technology and media grant projects, and we fund a lot of assistive technology state grant programs as well as state grant programs.

Now IES, when we think about the research arm of this, the Institute of Educational Sciences is the research arm. We do not in OSERS do our own research. But what IES is crafted to do is to develop or test effectiveness of interventions to improve cognitive communication; academic, social, and behavioral outcomes of children with autism.

The one thing we also do know, though, is that IES, in terms of the funding for the special ed research, was decreased, but we have asked for an increase.

In addition to what OSEP is doing to meet the needs, I have two other offices in which I am in charge. That is NIDRR, the National Institute on Disability and Rehabilitation Research, and RSA, the Rehabilitation Services Administration. This helps ensure the full continuum of services and supports for people with disabilities through the end of life.

NIDRR is dedicated to improving results by helping to generate new knowledge, to promote effective practices, and to expand society's capacity to deal well with people with autism. Some of their projects: they look at promoting daily living skills. They are looking at improving locational rehabilitation programs, and they do a wealth of research in terms of assistive technology as well as other health and social issues.

RSA, on the other hand, is dedicated to improving results by providing leadership and resources in the area of both vocational rehabilitation and independent living. The bottom line is they want to maximize the employment, independence and integration, which includes, of course, people with autism.

The RSA's major Title I formula grant program provides funds to state voc rehab agencies. In 2009, for instance, over 6,000 individuals with autism were served in all states. That is just over 1 percent of all individuals served that year, an increase from .57 in fiscal year 2006.

We also know that we need to continue to raise expectations. We know we need to support self-determination and self-sufficiency, which we have heard a number of times.

This afternoon you are going to hear more from Larry Wexler, the Research to Practice Director, on the document, the resource document, that we put together on restraint and seclusion.

A little more than a year ago, I had the opportunity to spend time with some of you as part of a meeting to talk about a document that we were putting together that was going to be released pretty soon. Well, it took a year, but we thought that was pretty good.

And Larry will talk to you about it. I am sorry I won't be here to do that, but it just so happens I am going to be doing a radio show this afternoon on the restraint and seclusion document. So, it will be covered very well. This document encourages a much more proactive approach towards helping students, including those with autism, achieve success in school.

And finally, to put it into perspective, I always like to hear it from a child's voice. This is a short letter which was written by a little girl named Jodie and the importance, she said, of planning for the future.

She wrote, "Dear Teacher, Today mommy cried. Mommy asked me, `Jodie, do you really know why you're going to school?' And I said, `I don't know. Why?' She said it is because we are going to building me a future. And I asked, `What is a future? What does one look like?' Mommy said, `I don't know, Jodie. No one can really see all your future just yet. Don't worry because you'll see. You'll see.' And that's when she cried and said, `Oh, Jodie, I love you so.'

"Mommy says everyone needs to work really hard for us kids to make our futures the nicest one the world can offer. 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." Signed, "Love, Jodie".

Let's continue working together to help build these great futures and improve the lives of individuals with autism and their families.

Thank you very much.

(Applause.)

Dr. Insel: Thank you, and welcome to the Committee. It is going to be great to have you at the table.

And finally, I am delighted to introduce Dr. Francis Collins, who is the Director of the National Institutes of Health, previously known to the Committee when he was Director of the National Human Genome Research Institute. He is technically also a member of the Committee, but usually Josie Briggs sits in for Dr. Collins.

Francis, delighted to have you here.

Dr. Collins: Well, thank you, Tom.

Good morning to all of you. It is a privilege to be able to be here with this remarkable group, with all of the expertise and passion you bring to this very important task of trying to identify what are the causes, the potential interventions that would turn around what is clearly a major health challenge, not just for those families who are experiencing it, although they have the most intense of those experiences, but for all of us as a nation and even as a world.

I want to assure you, as the NIH Director, that this is a health challenge that we take with the greatest seriousness. I want to also assure you that Tom Insel, as the person who oversees the activities of this IACC, is intensely committed to finding answers and puts huge amounts of his time and his thoughtful intelligence into trying to lead this enterprise in a way that would be most beneficial to getting those answers.

I want to thank other parts of NIH, well-represented here on this Committee, particularly three other individuals who are here at the table: Alan Guttmacher, who is the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development; James Battey, who is the Director of the National Institute of Deafness and Other Communication Disorders, and Walter Koroshetz, who is the Deputy Director of the National Institute of Neurological Diseases and Stroke.

I can assure you all three of these individuals are also deeply dedicated to identifying ways in which NIH can serve to identify, through research, answers to these pressing problems.

And I want to assure you that we are also making progress, although not as rapidly as we would like and as you would like. But I think there are things one can point to to show that progress is being made.

You may know the NIH invests approximately $170 million in research on autism spectrum disorders. That has gone up threefold in the last decade, even as otherwise our budget has been relatively flat. In fact, we have lost about 20 percent of our purchasing power since 2003.

And so, as you, as you should, press us to do more research on autism, I hope you are also pressing the case that medical research in general is a good investment for our country, recognizing that, in fact, we have been losing ground for several years in our ability to pursue the kinds of ideas that the scientists out there already have.

If you are a scientist coming to NIH with your best ideas about research on autism or cancer or diabetes, your chance now of getting funded is about 17 percent. Historically, that was more like 30 percent. You can imagine the impact that has on those individuals who have those ideas, who want to work in this field, and who find it very difficult to get their laboratories up and going, and then to sustain them.

And so, clearly, we are, as you heard from the Members of Congress, in a difficult time where financial support for anything the government is supporting is particularly stressful. But we are determined to make the most of those resources that the taxpayers do provide.

And again, I want to assure you of my personal commitment to looking closely at those opportunities for autism and seeing what more we could do on top of the things that are already underway.

But let's do celebrate that there

are some advances, even though they are far short of the ultimate achievements that we all hope for.

In the area of diagnosis, I think we have made real progress in coming up with methodologies, tools that allow diagnosis to be made at an earlier age than was previously possible. And you all understand better than I just how critical that is in terms of introducing interventions.

NIH-supported investigators at UC-San Diego are developing a test based on eye movements that appears to be quite a valuable and objective method of being able to assess in children one to three years old, with nearly 100 percent accuracy, with a method which is not as subjective as some of the other tools that have been used.

There is also a five-minute screening checklist developed and tested by our Autism Centers of Excellence to identify in a child's one-year checkup whether there are subtle signs of ASD that might provide an opportunity for earlier diagnosis and intervention.

In the area of behavioral interventions, clearly, that is a critical need for both developing and testing rigorously whether such interventions are providing benefit. And actually, the data I have seen is encouraging, that there are clearly ways in which early diagnosis followed by specific approaches improve functioning of kids who are diagnosed with autism spectrum disorder, especially in the area of, for instance, social skills interventions for high-functioning children, as well as behavioral interventions that in other ways target the social deficits and bring those around in a way that results in better outcomes, even among very young toddlers.

So, in the area, going beyond interventions, of causes, I think we all remain frustrated by the inability to identify amongst this broad spectrum of possible causes what in the given individual is going on. Clearly, there are environmental contributions. Clearly, there are also genetic contributions. Most of our insights will come, I think, by understanding how those two interact with each other.

In the area of trying to understand environmental causes, a recent publication in Pediatrics pointing to things that may happen metabolically during pregnancy that are potentially important, including gestational diabetes or obesity during pregnancy or hypertension, which seems to increase subtly, but in a statistical way that looks real, the potential of autism. What is that about? And how could we utilize that information to come up with better means of prevention?

And certainly, when it comes to the hereditary factors, the ability now to be able to be even more precise in scanning DNA to identify subtle changes has led just in the last few months to the identification of very subtle single letters out of 3 billion that have undergone a misspelling and being passed from parent to child that do seem to account for some cases, but certainly not all.

Although if one begins to add up those numbers, it may appear that at this point we could identify with this very detailed research-based effort something in the neighborhood of a third of individuals with autism as having a specific DNA change that is associated, apparently, with risk.

So, all of those things don't really give us the answers we want, but they point to such answers.

Dr. Insel mentioned to you as I was coming in that one of the other hats he is being asked to wear now is as the Acting Director of the National Center for Advancing Translational Sciences, which is the most recent arrival on the scene at NIH, and it is something that many of us feel quite passionate about. It is one thing to discover the genetic or metabolic or molecular causes or things that contribute to disease. It is another to figure out what to do with that information.

That translational step in going from a basic science observation to an effective therapeutic tends to be long and very high in failure, and it is not something which the private sector alone can step forward and say they have got it covered, especially when it comes to puzzling conditions, conditions that are perhaps less common than what they are used to putting resources into.

And so, NIH has now stepped forward to create this new Center, and Tom has taken on the role of serving as its Acting Director, to try to identify those bottlenecks that get in the way of how you go from an observation that is interesting and potentially important, but may be many steps away from an actual effective intervention.

As part of that, we have actually made it possible for investigators who have new ideas about therapeutics to have access to dozens of drug compounds that have never actually been approved for any purpose because they turned out not to be effective for the disease where they were being tested. This was just announced about a month ago. There are 58 of these compounds, many of which cross the blood-brain barrier, which could now be utilized if autism investigators have ideas about how those might turn out to be valuable from what we are beginning to learn about what is going on in the brain with autism, particularly at the synapse.

And that is just one example of some of the creative ideas that we are trying to push forward to try not to have these very long timelines and big obstacles and high expense and high failure rates be so vexing in terms of the ability to develop new therapeutics. Because you all know we desperately need new ideas about treatment for autism, and we don't at the present time have that path very well mapped out. This Center hopes to help with that.

On top of that, I think there are a number of other things connected to this that NIH is trying to support in that broad portfolio, about $169 million. I would just mention one that I read about which sounds like it is probably a very practical one. But the jobs website that NIH is supporting, particularly to try to provide helpful information to individuals with autism on getting a job and how to keep it, for young people with ASD, this is a jobs site called Jobs Tips. It has already been visited by 30,000 new users each month. At least 25 U.S. schools have implemented the site into a curriculum. And it is even being used abroad.

It was funded by NIH through a Recovery Act research grant. Of course, Tom mentioned already how the Recovery Act dollars, that additional infusion of $122 million for autism research, has placed us in a much stronger position than we otherwise would be.

So, there is much more to be done. I hope you hear from all of us here who come from NIH the sincerity of our commitment to try to find answers, the determination to work with you to do so. I am here very much this morning listening to your concerns and appreciated the chance to hear the questions and comments posed to the Secretary.

If we don't all work on this together, we are not going to get where we need to go, and all of us are committed to doing that as a community through this IACC mechanism and to get the answers that we all need, and that you especially need. I am speaking particularly now to those who have family members who are affected with this condition.

Thank you.

(Applause.)

Dr. Insel: Thank you, Francis.

I was thinking while you were finishing up that, in all the years I have been on the IACC, I think this is the longest interval of time that the Committee has not talked and we have been listening the entire time. I want to make sure that there is some opportunity for us to discuss much of what we have heard. We will be able to do some of that this afternoon.

I think for us in sort of getting this new Committee off the ground it was important for everyone to hear from both the

Members of Congress who pushed for the reauthorization as well as HHS and the Department of Education and their overall vision and the priority they put on these issues.

We are edging up against our break. I appreciate your patience that we didn't take a bio-break anytime during the morning. I know that is asking a lot of you.

But I want to keep you here a little bit longer to finish up what I think is our charge. This will only take another five minutes or so. And then, if there are questions about that, with Francis and Alexa still here, we can discuss further about some of those issues.

This is, again, maybe three or four slides just to clarify what we are about, because there has been some confusion, and I noticed even in some of the public comments coming in there continues to be confusion about what this Committee is.

The first point, we did a little bit of that this morning already. You, I think, were really inspiring in your comments to the Secretary. Let's make sure that we follow up on that with a number of other opportunities as they come up. What we hear within our deliberations we need to communicate to her.

We are coordinating, and that covers the entire range from the most fundamental science to the most important applications and dissemination of services and social inclusion. We have a role within the Strategic Plan to be able to focus and accelerate progress, and, of course, we have a very important role to be a forum and a place where we can listen to issues as they emerge, not only from the non-federal members of the Committee, but from the public who comes to these meetings or who writes to us.

What we are not needs to be clear as well. We do not fund research. Lyn made this very clear before. We do not set policy, and we do not have the authority to force agencies to fund specific projects or to implement specific policies. We can't do that. We are an advisory group.

That sounds like we are very limited. What is remarkable is how much we have been able to accomplish as an advisory group and how -- and you will hear some of this this afternoon -- because of the work that we have taken on together, we have been able to make some important things happen. I am not going to go into details about that, but you will get more of those details later.

I think, importantly, this is a very diverse group, and it partly reflects the diversity of the autism community. There are people in this community who think of autism exclusively as an illness to be cured and prevented, some who think of it as a disability where the issues are all around social justice and civil rights, and some who think of it as an injury. And there, the issues are very different as well and have to do with everything from compensation to possibilities of future prevention.

All of those need to be at the table. We need to be able to talk about all of them, and we need to find some common ground because where we have been most effective in the past is not as a debate society, but as a Committee or as a community that comes together and identifies those things that we can all agree about, that we want to make either by accelerating progress or by pushing the envelope in terms of awareness. We want to make things happen.

One of the things that came up when we first were struggling with the Strategic Plan was an awareness that we needed to identify a set of shared values. And I want to put those up here. They are in the Strategic Plan, but they are worth remembering, worth highlighting, and we have occasionally come back to these when things get rugged in the Committee, and they will. That is part of our job.

These were all items that we agreed to in 2008, and they went into the 2009 Strategic Plan: the sense of urgency; a commitment to scientific excellence and rigor; a spirit of cooperation that, as we come into this room with our egos left behind and our commitment to getting a job done for those people on the autism spectrum and for the nation.

Keeping a consumer focus has been really important for us, asking not how is this going to help people to get funded, but how is this going to help people to recover. And that has been an issue we often come back to.

I think one of the members -- it may have been you, Alison -- who used the term "partnerships in action," which I thought was very helpful for us in the first Strategic Plan, in making sure that we understood that at the end of the day what really counts is what we are able to deliver.

And then, in putting together this Strategic Plan, we talked about making sure that there was accountability. We have come back to that word many times, but I am not sure that we have come back to it enough. And so, I am going to raise it again later today, and I will raise it again at every meeting that we have from here on.

What we defined as this accountability was up there as these kind of smart objectives. I think, again, I don't know if it was Lyn or Alison who brought this to the table, but this idea that they should be specific, measurable, achievable, realistic, and time-bound, but, most of all, we need to come back to those and we need to ask the question, have we done it? And if we haven't, why not? And if we have, can we show how we have done it and where we have done it? So, we will be talking a lot more about that over the course of the afternoon, hopefully.

You will see in the agenda that we have evolved a sort of kind of typical meeting. This wasn't it, by the way. We don't usually spend the morning hearing from people who are not on the Committee. But we do have a set of standard items on the agenda, and I just want to make sure you understand what they are for.

Public comments are a critical part of who we are. It is expected that you have read the comments that were submitted to the Committee and that you will be here to listen to the oral comments that are given by those people who attend the meeting.

We have had difficulty in the past because there is so much to do and there is often so many people who want to speak, and we just don't have enough time. And for that reason, we have encouraged more and more written comments, and we expect you to look at those carefully.

We do have time in this agenda for about 30 minutes of oral comments. That is not going to be enough, and it is going to mean that those people who have come often long distance to share their views with us are going to have to be curtailed in the amount of time they have. It is unfortunate. It is the reality of what the clock is going to give us this afternoon.

But we have built into the late afternoon a chance to go back to those comments, both the ones that you received written and what you will hear from, I think, 1:30 to 2:00, or sometime in that timeframe, or 1:00 to 1:30, so that we have a chance to talk about them further.

And that, we have learned in the previous iteration, in the 2.0 version, it was very important for us to have a chance to talk about these. Otherwise, people felt they hadn't been heard. And also, there are ways that we can decide how to follow up.

And actually, I think it was Idil who brought to us originally the Somali issue in Minneapolis as a public comment. And it was in the subsequent discussion within the Committee that we said, "Come on, guys. We need to do something about this. We have heard about it. What are we going to do?" And that was when we had a chance.

So, that you will see in every agenda, public comments usually sometime in the middle of the day, and then returning to the discussion with the Committee at the end of the day.

Generally, we take a little bit of time for scientific updates, just so you know what is coming out, so we are all on the same page in terms of where the discovery base is and where the science is moving. I will do that very quickly this afternoon. There is no way we can pay justice to this. It would take all day because of the explosion of science in this field right now, but we do think it is important for the Committee to at least stay up to the main issues as they are emerging.

The same with policy updates, not only things that have happened, but things that are being planned. And you will hear about those from different agencies.

We will try to use at each meeting a chance to go around the table. We can't do it with a Committee this big. So, in each meeting we will have a select group of you kind of report out about what is happening either in an agency that you represent or in an advocacy group or from your perspective what you think the Committee needs to hear about.

And then, finally, we will have, and you will see this this afternoon, time for

Committee business. That really is to address those things that are in the Combating Autism Act as our primary responsibilities. And Susan will take you through those, making sure that we are getting our work done.

Finally, just a comment about this group. It is different than the two previous versions of this Committee in some very key ways. One thing is that there are some obviously new members, new agencies at the table. FDA wasn't here last time. They had been previously, but they are back in. It is great to have FDA, AHRQ. We have this new entity that Sharon represents in the Department that is joining us, this Administration for Community Living.

So, we have seen some evolution, and I think that really speaks to where the field is going and the kinds of needs. We have wanted to have DoD in this Committee from almost the beginning because DoD has made a commitment to autism that has not been recognized. And so, it is great to have Donna at the table to keep us informed about that.

So, it is a different group in that sense.

There is a conspicuous absence of scientists with an exception of David Mandell, who is a practicing scientist, and Francis Collins, who is also a practicing scientist, and Dennis Choi, who was. But most of the people who are around the table are not people who are engaged in science currently, and that is a real change.

In our very first version of the IACC, it was about half of the group were people who would have served on your scientific advisory boards. They would be people who were the leading scientists in the country, helping us to think about what should be in the plan, what kinds of things do we need to think about.

This is a different makeup. It speaks to many issues, but I think it, most of all, calls out for us needing to find a way to engage that kind of expertise because it is not at the table. We don't have the people who can be most critical of the science because they are involved with it and they know what is coming out to be further supported, what should be really more critically avoided, all of those issues which the scientific community is very engaged on.

So, I want us to think about this as we consider how this Committee will work, particularly with updating the Strategic Plan, how we are going to get that expertise. We may need to develop work groups. We will invite people to the meetings, and we can always hear from people in any given area that you like.

But I think we need to be open and clear about this, that this is quite different than the committees we have in the past, and it is going to require a different way of operating if we want to get the scientific expertise, particularly because, singling out David, not to put you on the spot, but David can give us that, I think, very well in the services area, but particularly in areas related to biomedical research we are going to need to bring in people who are not here at the table.

We have got a very short timeline. We are terminated, we zero-out September 30th, 2014. And you should have no expectation that the Committee will exist beyond that.

So, you heard about the expectations, and you have heard about the great needs. We have lost eight to nine months here just in getting to our first meeting. So, we have lost almost a third of our lifespan here before we have even started to get to work.

So, we are going to have to operate in a much faster timeframe than what we are used to. I know people worked very hard, if you served on the Committee last time. This is going to be a different means of activity, if we are going to try to get this done.

Just as an example, if we have to update the Strategic Plan between now and December, you are going to tell me this afternoon how we will do that, because that generally is a much longer process than four or five months to get it done.

And finally, I think we all have to recognize what we have already heard this morning. I didn't realize that when I put these slides together last night, but this increasing frustration is only building. Even though there have been many signs of progress and scientifically this field is, indeed, exploding, and we are seeing just enormous excitement on the research side, we are also seeing increasing problems and frustration with the access to services, with problems of getting treatments that really work, with sort of catching up with other areas of biomedicine where we have biomarkers; we have very precise diagnostics, and we have therapeutics that are tied to those.

We are nowhere near that in this field. We have every reason to expect it and to be frustrated that it hasn't happened. So, the Committee is going to have to respond to that, to figure out how to go further faster than what we have done in the past.

Let's, basically, stop there. We

will have lots more to talk about. I am going to send you off to lunch with this admonition that we need to get to work, which seems like an oxymoron. But I do appreciate you are going to need a break.

What I am going to suggest, keep the vision statement in mind. Let's plan to reconvene here before one o'clock, so we can start precisely at one o'clock with public comment. And then, we have a very full afternoon of work to do to get on with it.

Thanks very much to all of you for sticking with us through the morning, and we will see you at one o'clock.

(Whereupon, the committee recessed for lunch at 11:55 a.m. and resumed at 1:00 p.m.)

AFTERNOON SESSION

1:00 p.m.

Dr. Insel: Okay. We would like to get started. It is one o'clock.

I want to welcome the Committee back to the table, ask the members of the public who are attending to take your seats, and those of you who are joining us on videocast, we will begin in just about one minute.

Now, given the large number of items on the agenda, we have only put 30 minutes on the block for public comment. And we have, I think, 10 people who have asked to be able to talk to the Committee.

You have their written comments in the package that was sent to you by Susan electronically. So, hopefully, you have had a chance to look at that.

But we would like the people who had asked to meet with the Committee to at least have a moment to do that. They won't be able to read the entire comments that they sent forward, but they can give you a quick synopsis. They will each have about three minutes. Unfortunately, we have to keep it that short.

So, let me ask Pam Rockwell, and we will just go down the list here, to start off.

Welcome.

Ms. Rockwell: Hi. Thank you.

I am Pam Rockwell. I am here because I want the IACC to dedicate more research resources to maternal antibodies that are linked to autism.

I know you are aware of this research, and that the federal government does support this research as part of larger studies of environmental factors in autism. But no one is considering that these antibodies could be causing autism when they are transmitted through blood products that are routinely administered to pregnant women. And no one is testing vaccines to see if the ones that are routinely administered to pregnant women, whether that could be increasing the titers of these antibodies.

And no one has considered that autism might be transmissible by contaminated transfusions, just like an infectious disease.

This research has been conducted since the early 2000s in research labs at the MIND Institute and the Kennedy Krieger Center. Both labs identified antibodies in the serum of mothers of children with regressive autism, and those antibodies bind to human fetal brain cells.

Both labs tested the human-derived sera on pregnant animals, and they demonstrated that autistic behaviors were in the offspring exposed prenatally to the sera of mothers of regressively-autistic children. The Kennedy Krieger team this with mice, and the MIND team used rhesus monkeys.

At IMFAR this year, the MIND team even presented imaging data that showed that the presence of these antibodies in the mothers was also predictive of brain enlargement that is associated with autism. And this showed up both in the human subjects and in the blood-exposed monkeys. In other words, this research showed that autism could be transmitted to animals by exposing the pregnant mothers to the tainted blood of the mothers of autistic children.

None of the research advances in this field last year were selected to be included in the IACC 2011 Summary of Advances, and the possibility that the immune system could be linked to autism was only briefly mentioned in the Strategic Plan as an immature research field.

I know that scientific progress is slow, and the complete nature of the connection may not be understood for many years. But I want you to act on this research proactively right now because we give immunoglobulins and vaccines to pregnant women as part of routine prenatal care, and we give transfusions to premature babies and to pregnant women during difficult deliveries.

The IACC should not be waiting on a few researchers to complete lengthy longitudinal studies or nail down every little detail of how maternal antibodies could cause autism. You should be proactively recruiting experts to develop tools and test blood products to make sure that we are not inadvertently contributing to the rise in rates of autism because of medical interventions that could have been screened for autism-producing antibodies.

Pregnant women who do not have the same blood type as the fathers of their unborn children are routinely given immunoglobulin collected from human plasma donors during their pregnancies to prevent an immune response to their unborn child.

Pregnant women who are potentially exposed to certain viral infections, like chicken pox, are also given immunoglobulin collected from immune plasma donors to prevent disease.

Collected immunoglobulin products include all the antibodies a donor makes, not just the target antibody. There is no reason that we should be injecting pregnant women with the antibodies that are even suspected of causing autism.

The IACC should direct the Secretary of Health and Human Services to ask the FDA blood products safety labs to test immunoglobulin products that are used during pregnancy for maternal antibodies that are linked to autism.

The companies that make these products have protected donor populations. If problems are found, then the company can test individual donors and stop using the ones who make the offending antibodies.

Sorry. I also want to point out transfusions are a common treatment during childbirth, and a newborn could be exposed.

And you cite an ASD rate of 8 percent of males born with less than 26 weeks of gestation compared to 1 percent in the general population. This is premature babies have a higher risk of autism. This could be from blood products as well. But you need better tests in order to test blood products like transfusions. Monoclonal antibodies would be a helpful thing to have, and the IACC should be asking Secretary Sebelius for help from NIH and CDC to develop faster antibody titer tests and to develop monoclonal antibodies of these things..

Dr. Insel: We are going to need to move on.

Ms. Rockwell: Can I get 20 more seconds?

The U.S. Government has experts with experience at making antibody titer tests and developing monoclonal antibodies and screening blood products, but these researchers usually deal with infectious diseases. They will not work on autism unless this Committee asks them for their help. So, it is really time to recruit these other groups from the federal government to help out with immunology in autism.

Dr. Insel: Thank you.

So, we will come back to each comment as you have wished later in the afternoon.

Eileen Nicole Simon?

And again, I am going to have to ask you to stay at three minutes because we have so many people we want to hear from.

Dr. Simon: Here?

Dr. Insel: Yes, whatever you prefer. You can either be up there or here. Here is probably easier.

Dr. Simon: Okay. Except that I decided to make a handout. I will just put it up.

Am I hearable?

Dr. Insel: Yes.

Dr. Simon: In my written comments, I cited a seminal paper by Seymour Kety, who 50 years ago used a radioactive tracer to investigate blood flow in the brain. His surprise finding was that blood flow is higher in nuclei of the brainstem auditory pathway than anywhere else in the brain. This has now been confirmed in functional MRI scans.

Children learn to speak by ear. This is why focus on the auditory system is important. And the highest priority for research should be to understand the brain impairments underlying the language disorder of autistic children.

High blood flow exposes nuclei in the auditory pathway to any toxic substance that gets into the circulation. Genetic disorders often result in transcription errors of enzyme proteins. Toxic metabolites may then be produced, and nuclei in the auditory pathway are likely to be affected.

Nuclei in the auditory pathway have, likewise, been found most susceptible to oxygen insufficiency at birth. The obstetric protocol adopted in the mid-1980s to clamp the umbilical cord immediately after birth is unsafe, especially if the newborn infant does not begin breathing right away. In 1964, Gerald Lucie found that bilirubin affected the brain only in newborn monkeys that had been subjected to asphyxia at birth.

Components of vaccines like hep B given soon after birth may, likewise, get into the brain if an infant has suffered even a brief lapse in respiration. The IACC should be in a position to suggest that immediate clamping of the umbilical cord be stopped and that hep B vaccination not be given soon after birth.

My oldest son will be 50 in September. I have now spent most of my life reading everything I can find on autism, language, and the brain. This horrible handicap should have been understood decades ago.

And I was told I should add I have a PhD along the way in biochemistry, which I was at Boston University Medical School at the same time you were.

And I have collected by comments for the previous meetings in a book, an ebook which is online called "Topics of Conversation". We need more conversation with members of the public. We have ideas that are valid and important to be taken into consideration.

Thank you.

Dr. Insel: Thank you.

Catherine Swanwick?

Dr. Swanwick: Can you hear me?

My name is Dr. Catherine Croft

Swanwick. I am the Director of Outreach for the nonprofit resource organization MindSpec.

On behalf of MindSpec, I am proud to present our new online science outreach resource, Autism Reading Room, designed to empower parents with scientific knowledge.

Founded in 2006, MindSpec's mission to achieve three main goals: develop autism databases, conduct autism research, and perform autism outreach.

Our team is led by Dr. Shamila Banerjee-Basu, a former NIH staff scientist from NHGRI who is also the mother of a 22-year-old son with autism.

I serve as the Director of Outreach and am also a former NIH scientist from the laboratory of the late Dr. Robert Wenthold, NIDCD.

Our team consists of three groups of experts, scientists, developers, and writers, all with extensive experience with biomedical laboratories or IT.

Our scientific expertise well-positioned us to create Autism Reading Room.

First, our autism database, AutDB, was the first genetic database to cure a common and a rare variance linked to autism. It is licensed to the Simons Foundation as SFARI Gene.

Second, we have published many original research articles, including a predictive gene map for autism in pLOS One. Moreover, AutDB is widely cited by the autism research community, cited more than 25 times since its publication in 2009.

To achieve our outreach goal, we recently developed Autism Reading Room, an online resource designed to enhance public understanding of autism research. Launched in April of 2012, Autism Reading Room features interactive tools to explain current scientific knowledge about autism spectrum disorders. Topics include risk factors, diagnosis, brain biology, brain imaging, biomarkers, stem cell research, misconceptions, and trends/statistics. All articles are written by scientists.

Tools include an autism

dictionary, an international public policy forum, and autism research news in context.

To help explain autism research news, we created five iconic guides related to major sections of Autism Reading Room. With the help of these guides, our team of scientific experts translate complex scientific concepts into language targeted for a general audience.

Additionally, Autism Reading Room contains Autism Quiz, a section which tests autism knowledge and features four types of challenging quizzes: basic, advanced, misconceptions, and in the news. Autism Quiz was recently released as a free social media app on iTunes and is currently under development for Android.

Finally, to introduce parents to Autism Reading Room, we are launching a webinar series called "Bridging Parents with Autism Science". Introductory webinars will be offered four days during the summer, July 24th, 26th, and August 21st and 23rd. And the fall will, then, feature monthly webinars highlighting different sections of Autism Reading Room. To register, please email me at Catherine@MindSpec.org.

Thank you to the IACC for the opportunity to present Autism Reading Room today.

Dr. Insel: Thank you.

Mark Blaxill?

Mr. Blaxill: Does this work up here? Yes.

Thank you.

My public comment will take more than three minutes to read. So, I won't. I hope you can read it in your packets. I will just say a few things and try to stay on schedule.

It was tough for a lot of us in the autism parent community to listen to the morning. And I have been in communication. Those of you who are in the meeting, there was a lot of thanking each other and congratulations for the work of IACC and NIH over the last years.

I understand the ways of

Washington, and it is always polite to congratulate each other, but a lot of us in the autism parent community aren't grateful for very much that has come out of NIH and HHS over the last decade or more. And we don't think you have accomplished very much. And so, we don't think there is a lot to be proud of.

In fact, our largest concern is that we think you are wasting our time, our children's time, and taxpayer dollars on research that isn't getting to the answer, and we are not stopping the epidemic the way we should. We are not treating this problem as the crisis that it truly is.

I have just this morning shared lots of messages of great frustration, concern, tears from parents who are looking at this Committee, IACC 3.0, and we are saying this is worse than the last ones. We are in this sort of Orwellian time warp where fantasy becomes science, and those of us who are actually pleading with you for rational policy to address this crisis are accused of being lunatics. It is difficult to be calm about it, but we all have to.

And I guess I would want to speak to all of you, both parents, parent representatives who are new and hope that you will represent the true interests of the autism parent community. Many of you have, and we thank Lyn, a lot of us thank Lyn for her service. Those of you who are new, we hope that you represent us well in addition.

And to the federal representatives, I would just say you need to understand you are working in a broken system, and it is hard for you to know how to fix it. It is hard for us to know how to fix it. But in a revolving door where your leaders routinely leave public service and go to work for pharmaceutical companies or consult with pharmaceutical companies about how to get drugs and vaccines through the approval process, it is hard to develop much sense of confidence in the integrity of our government and its functioning.

I guess the only thing I would say

is that you have important scientific work to do, but you also have moral responsibilities to these families and children who are suffering and the crisis that is the autism epidemic. I would just ask you, when you come to work here, don't be constrained by the broken system. Don't be constrained by the fantasy world that is being offered up as a denial of the epidemic. Find your moral center as moral agents and act on that, and please do something about all these children and stop the autism epidemic.

Thank you very much.

(Applause.)

Dr. Insel: Thank you.

Jake Crosby?

Mr. Crosby: Hi. My name is Jake Crosby. I was nominated for the IACC, but, obviously, not selected.

I am a graduate student at the George Washington University School of Public Health and Health Services, earning an MPh in epidemiology, and I am a contributing editor to Age of Autism, a daily web newspaper of the autism epidemic.

I am also a person with autism who favors curing and preventing autism. None of the three IACC members with autism share this point of view. HHS has violated its own policy that federal advisory committees must be fairly balanced in terms of points of view represented.

Also opposed to curing autism is Matt Carey, autism father who qualified for his IACC position by writing under a pseudonym for a UK blog and consistently defending the vaccine program. Carey defends IACC Chair Tom Insel, who blocked vaccine research while his own brother was a vaccine developer. Carey also defended HHS Secretary Kathleen Sebelius' efforts to cover up vaccine injury by telling the media to not report the other side.

Additional IACC appointees include a former Merck scientist along with a so-called scientific advisor to Alison Singer's vaccine industry front group which poses as an autism charity. IACC member Alison Singer tells parents to vaccinate recklessly, even though she, herself, admitted to splitting the measles, mumps, rubella vaccine for her second daughter who does not have autism.

During his tenure at CDC, Jose Cordero coerced the journal Pediatrics to fast-track a now infamous Danish report by indicted fraudster Poul Thorsen. The study fudged autism statistics to exonerate mercury in vaccines even though autism was going down after mercury was removed. Civil servants like Cordero should be fired, not appointed to federal committees.

NIH oversees the IACC, and a former Director of vaccine research planning at NIH who also previously worked for Merck announced a decade ago that four studies were being undertaken for the express purpose of ruling out a link between autism and thimerosal. He also said additional studies must be undertaken and publicized to allay fears that the MMR vaccine causes autism. Such fraudulent research would later form the basis of a CDC/NIH-sponsored report, produced by the IOM in 2004, rejecting a causal link between vaccines and autism.

Chairwoman Mary McCormick, before looking at any data, stated in a closed meeting that IOM would never conclude autism was a true side effect of vaccination. Yet, seven of IOM's nine studies denying vaccines cause autism actually support a vaccine/autism connection. When IOM reaffirmed this whitewash last year, it was fully endorsed by Geraldine Dawson, the Chief Scientific Advisor of Autism Speaks, who also sits on IACC.

The IACC was not formed to find the cause of the autism epidemic, even though it does include some good individual members like Lyn Redwood and Jan Crandy, but it was formed, overall, generally, it was formed to cover up the cause of the autism epidemic.

Thank you.

(Applause.)

Dr. Insel: Dawn Loughborough?

Ms. Loughborough: I call this "Autism: A Medical Definition Getting to Causation".

And thank you for allowing me to

comment. My name is Dawn Loughborough, and I am the mother of three children, two with chronic illness; one includes autism.

I am not here representing an organization, but speak in the interest of well-being of children. And my vocation is in professional management consulting, and I am here today to request a new task force.

First, I want to create a context with you. The work that has been done to date has coordinated many concerns of autism: psychological diagnosis, services, education, prevalence, safety, genetics, and adult transitions. And I acknowledge what has happened to date and continues.

And if you look at the prevalence numbers as they continue to rise, there is an area that comes to mind as missing from the portfolio management, that if we add it in, will make a difference in what matters to society. I feel the piece that is missing is environmental causation. It is the next action to take. So, here is the context:

First, to acknowledge that many

types of autisms exist. Second, to examine that the rise in prevalence numbers reflects complex, multi-system illnesses in children manifesting and presenting as autism. I suggest that viruses and bacteria and toxins are culprits in this complex disorder.

So, I am here today to request that a task force be created to address environmental causation. This task force will be responsible for identifying initiatives, structures, and operations for discovering environmentally-triggered medical conditions in autism causation. And the task force should be made up of credentialed, integrative leadership.

We have long looked at autism as a set of behavioral/psychological disorders. It is now time to also examine what is causing these disorders on a physical level.

The current medical model is looking to manage the condition. That work must continue. And we have to track and trend underlying medical concerns like gut dysbiosis, mitochondrial disorders, methylation breakdowns, depletion of vital nutrients, low glutathione production, viruses, bacterias, and vaccine reactions.

We need tracking mechanisms to look at the current population, to draw the research and conclusions using observational science. I am requesting to study children who are ill, reverse-engineer, and find out what chemicals, viruses, and bacterias are in their body and what systems are affected.

I want a world where we can get it all handled, every last puzzle piece gets put in place, where the standard of care includes psychological and physical/medical screening and treatments.

So, in conclusion again: please create a medical task force to find out environmental causation for autisms that will deter the rise in prevalence for future generations. We have to figure out how to slow or stop the dramatic rise in autisms.

The task force should be comprised of credentialed candidates reporting to Secretary Sebelius, charged with and creating structure, identifying risks, developing strategies for tracking, gathering, and analyzing information, then developing medical diagnostics, protocols, and standards of care with urgency.

Autism causation is the current space race for the U.S. I hope my comments today were clear and honor healthy outcomes for all children. And I would gladly welcome continued consideration and dialog to make that a reality.

Thank you.

(Applause.)

Dr. Insel: Thank you.

Katie Weisman?

Ms. Weisman: Good afternoon, Dr. Insel and members of the IACC.

My name is Katie Weisman, and I am here today on behalf of SafeMinds. I am the very proud mother of 14-year-old identical triplicate boys. Nick and Alex have PDD-NOS, and Donnie has autism.

I am here to tell you that the mercury/autism connection is stronger than it has ever been. For those who say a link has been disproved, I say go and actually read the literature. It currently supports a connection by a 2-to-1 margin.

Included in my comments are emails obtained through the Freedom of Information Act showing that autism rates in Denmark actually dropped in 2001 after they removed thimerosal. I have also included Mark Blaxill's graphic analysis of the early VSD data showing 7.6 times the relative risk of autism in children who received high thimerosal by one month of age compared to children who received zero thimerosal.

I have read most of the autism abstracts and PubMed for over four years now, and I have read hundreds of studies. I have followed the research for over a decade. I can tell you unequivocally the best-supported suspect for autism causation is mercury. It will not be the only cause, but it is logical to tackle mercury because so many of the exposures are easy to avoid.

And thimerosal is not the only

mercury exposure of concern in autism. Other mercurian sources: we have got fish, other food, dental amalgam, skin-lightening creams, fluorescent light bulbs, Santeria rituals, air pollution, and even tattoos.

Any candidate for autism causation must fit trends of exposure and cause symptoms that make sense. Mercury does. Both organic and inorganic mercury are involved. What we need are studies of total mercury exposure relative to autism for both mothers and children.

There is currently enough research to write a paper titled, "How the Known Genetics of Autism Support Mercury Causation". The most promising risk genes are on pathways that are also compromised by mercury. Mercury can cause both DNA mutations and trigger epigenetic effects on those pathways. Please read my full comments for some details of some recent studies, like last week.

Last year, Shandley and Austin found that the grandchildren of survivors of acrodynia have seven times the rate of ASD of the general population in Australia, 1 in 22. Acrodynia is a form of mercury poisoning in a genetically-susceptible population.

Aging parents, neonatal jaundice, low birth weight, prematurity, all autism risk factors that have connections to mercury. Please read the autism/mercury paper in your packet for a broader sense of these connections.

If we truly mean to improve the lives of those with autism and stop autism's most devastating effects, we need to stop ignoring the obvious. Therefore, I would ask the Committee to:

One, look at the autism and mercury literature and actually read the studies.

Two, hold a conference on autism with a sampling of the leading autism researchers from various fields and a group of mercury toxicologists to discuss the connections and plan the research that could be done.

Three, create a mechanism to

determine the effectiveness of the work you are doing. Can you show that any of the studies you have funded have actually made a difference in the lives of people with autism?

And lastly, rebalance the autism portfolio. Commit research dollars towards environmental causation studies, particularly mercury, and actual comparative studies of the best methods for teaching and providing services for people with autism.

Fund studies to treat the medical and mental health problems that so dramatically affect individuals with autism. Let's improve the quality of some lives today, and let's try to prevent the severe impacts of autism on individuals in the future.

Thank you.

(Applause.)

Dr. Insel: Thank you.

Caroline Rogers?

Ms. Rogers: Good afternoon.

My name is Caroline Rogers. I am a writer/researcher specializing in public health issues and the author of "Questions

About Prenatal Ultrasound and the Alarming Increase in Autism," which was published in Midwifery Today six years ago.

Ultrasound, although it is widely considered safe and non-invasive, has thermal properties that intrude upon the fetal environment that have harmed neurological development in animal experiments. It is well-established that fetal temperature regulation is critical to proper neurological development in humans, and elevations in maternal temperature during pregnancy caused by hot tubs, saunas, fevers, infections, viruses, organophosphates, as well as some drugs, can cause outcomes such as neural tube defects or autism.

Autism prevalence increased 78 percent during some of the same years covered in an ultrasound time-trend study in which the number of scans women received per pregnancy increased 80 percent. If there is a correlation between the two, there will be a steep increase in autism among children who turned eight in 2009 that won't slow down for at least six years.

In another development, a CHARGE study of maternal metabolic conditions found that obese mothers were 67 percent more likely to have a child with autism. While the authors did not suggest a direct correlation between obesity and autism, they raised the possibility that biological responses to obesity, which affects one-third of American women, could adversely influence neurodevelopment.

However, that seems less likely when one considers that South Korea, with the world's highest autism rate of 1 in 38, has an obesity rate of only 3.2 percent. This doesn't mean that we should dismiss this CHARGE study. But, unless the reason children in South Korea develop autism is completely different from why children in the CHARGE study develop autism, there must be a different common denominator.

Another CHARGE study found that maternal fever during pregnancy doubles the risk of autism. The results of this study can be interpreted to form the basis of the odd uncle some families report and other rare cases of autism that occurred before it became epidemic.

Although most scientists believe that autism is caused by a complex interaction of genetics and environmental factors, if that were the case, there would be peaks and valleys in charts showing trends, not the steady upward climb that autism increases show in all of the studies.

Prenatal ultrasound has increased by several measures, whether the percentage of women scanned, the number of scans per pregnancy, or the gestational window of exposure.

Since thermal intrusions on the fetal environment of any kind increase the risk of having a child with autism, prenatal ultrasound is the likeliest cause of the autism epidemic. It is time that this possibility, which has been ignored by the scientific community with the exception of two studies, one of which no longer applies to ultrasound applications common today, and the other of which has metric questions that remain unanswered, is given the attention it deserves.

Thank you.

(Applause.)

Dr. Insel: Thank you.

Tara McMillan?

(No response.)

Tara McMillan? Maybe I am not saying it right.

(No response.)

Okay. Mary Holland?

Ms. Holland: Thank you very much for the opportunity to speak.

This was my first IACC meeting, and I was impressed this morning by the self-congratulations, the words about the incredible work, the honor, the progress, the pride, the passion, the great ideas, the diversity of this Committee and its accountability.

I don't deny that most of you are here, people of good faith and who care deeply about this issue, but this is not the way that this Committee's work looks to the outside world. What it reminds me of from recent memory was when President George W. Bush commended his head of the Federal Emergency Management Agency during the Hurricane Katrina that devastated New Orleans, and he said, "Heck of a job, Brownie." And the country saw this and the country was outraged. In fact, Mr. Brown resigned.

I don't think the national public understands how devastating autism is. That is part of our job in the autism community. It is part of your job as the IACC Committee. But I do think that you must be living in a bubble if you don't see that when the last 2.0 started, the rate was 1 in 166, and it is today 1 in 88. It is a doubled autism rate. It is very troubling, as a stakeholder in this community -- I am an autism parent -- to hear you congratulating yourselves.

Rather, it sounded to me like this was the "Autism Acceptance Committee" or the "Autism Appeasement Committee," that autism is a static condition, that it is lifelong. And for the most part, I heard that it is really not very treatable, that we need to be looking for lifelong places for people.

And I heard the "V word" once. And you all know as well as I do that that the elephant in the room. The question on parents' minds throughout the country and throughout the world is, what is the relationship between autism and vaccine injury? Is there a relationship or not? If you are not looking at that, then this Committee has a very questionable role.

I am a part of 10 groups that submitted a letter to Secretary Sebelius in April. We didn't get a response. We got a letter from Dr. Collins that was non-responsive. So, we sent it again today. We hope that we will get a response.

We also prepared a critique of the IACC which we think would be of interest to those of you who are here. It is certainly available, and I would be happy to give it to you and talk about this issue.

It seems obvious to me that, if we stay the course as a country, and if this Committee stays the course, we should expect in 2018 that the autism rate will be 1 in 44, based on 12-year-old data. I think our children and our country deserve better.

Thank you.

(Applause.)

Dr. Insel: Let me just check and see if Tara McMillan is here.

(No response.)

Okay. If not, we will come back to a Committee discussion of the public comments at 4:30, and we will move on with the rest of the agenda. As I mentioned earlier, the process that we follow is a set of updates. We will be hearing a little bit from a former member of the Committee, Henry Claypool, about this new Administration for Community Living, and we take you quickly through a science update. We are going to make this very brief, so that we can try to get back on schedule.

What we generally do is to go

through each of the components of the plan. As you know, there are seven questions, the first being, "When should I be concerned?" I am not going to be able to do this in the detail that it deserves, but simply to give you a sense of where the work is going now.

There has been progress mostly on the search of biomarkers, trying to identify often in the studies of sibs at risk, so this is the baby sib studies, using magnetoencephalography or diffusion tensor imaging or EEG, other methods, to try to look at where does brain development or brain function begin to go in a different direction in kids at risk and trying to use that to predict who will and will not have a diagnosis of autism at 18 months or 24 months.

We have had a couple of meetings that have tried to summarize that information, and we will say a bit more about that in a moment. But I think, generally, we can say that particularly the MEG studies are the ones that seem to be most promising, and some of the work going on with cognitive tasks. Dr.

Collins mentioned video tasks that look at eye gaze have been surprisingly effective at separating out those kids who do go on to autism or have already a diagnosis from those who have other developmental disorders.

Lots of interest in developing better and better screening instruments that can be used at the one-year checkup. And that is still developing as a story.

The second question, "How can I understand what is happening?" And again, this is a broad range of studies that are covering everything from what is happening at the synapse to what is happening outside of the brain, looking at both GI and immune changes.

I think it is fair to say that the evolving picture of the biology of autism on both fronts, it is very much thinking about this as a synaptic disorder, trying to understand what is happening throughout the brain at synapses that seem to be not able to process information at the rate that one might expect, to looking at what is happening in other tissues of the body. And great interest now, particularly in the GI and immune systems, and a bigger understanding of how immune system and synaptic function might fit together. So, lots of interest there.

Interest in, again, applying some of the newer imaging techniques to understand what the brain looks like in both children at risk and those who have a diagnosis.

"What caused this to happen and can it be prevented?" This is probably the place where we have the most discussion on the Committee. Generally, it kind of falls into two camps, both genomic factors and environmental factors.

On the genomic front, obviously, as you already heard from Dr. Collins, lots of action on these so-called de novo mutations. They are interesting because these aren't mutations you got from your parents. That is, these are truly de novo. They are spontaneous. And it may help to understand something about the genetic factors that contribute to some fraction of people with autism spectrum disorder.

I would just point out one recent paper which has gotten a little bit of attention on this idea that carnitine biosynthesis is involved because of a mutation or a common variation that reduces the ability to actually make carnitine, which is amino acid that comes often from meat. And the concept is that, if it really is a contributing factor, it could be something you would identify by genetics and yet treat with diet.

And so, Art Beaudet and his colleagues in that PNAS paper have suggested a completely new hypothesis and a new approach to both the diagnosis, the mechanism, and potentially a dietary treatment for autism.

On the environmental front, lots of action from the CHARGE program. You have heard a little bit about that already. I am not going to go through each of these, except to say that Irva Hertz-Picciotto has been very busy with a whole series of reports, mostly focusing on the exposures during pregnancy, particularly second trimester, in identifying whether there are metabolic changes or infectious or dietary and nutritional changes, what may be contributing to an increase in risk.

"Which treatments help?" This, I think you heard earlier in the day the frustration that Geri Dawson talked about, how we still don't have medical interventions that are approved and appear to be powerful in the sense that we have from many other areas of medicine.

Lots going on here, though, and I must say that it is a little striking for me from the perspective of watching almost the entire pharmaceutical industry leaving the CNS disease and deciding that it is too risky and just too fraught with failure. So, they have stopped many of their programs on neuropsychiatric disorders.

The one exception seems to be autism, where we have now five companies announcing their new efforts, actually, the one place where they continue to invest. They are looking for biomarkers that could help to drive the trials that they want to do. They do have some interesting candidates, and they are mostly leveraging what has been done already with Fragile X and trying to use either Fragile X or Rett syndrome as places to find new targets that they can begin to develop new therapeutics around.

So, it is a wait-and-see process. I think this is not something that will happen overnight, but it is at least hopeful that in this one area there continues to be significant private investment in trying to find new therapeutics.

The NIH has created some new mechanisms as well. I thought I would just mention the FAS trials as a new effort, to be contract-based, to look at what we call proof of clinical mechanism or proof of concept, to try to identify which targets are worth going after at the molecular level.

And then, the Autism Treatment Network has a couple of interesting RCTs going as well. As was mentioned earlier today, that is a great collaboration between Autism Speaks, HRSA, and NIH.

It would be important to mention that there are also a number of breakthroughs on the behavioral front. Most of those are looking at what are the long-term consequences of some of the behavioral interventions that have been developed already, not as much in the way of innovation.

But I would point out that this one, the third paper on there, which was out a couple of months ago from Amanda Steiner and her colleagues, which is, I think, the first example of using a behavioral intervention preemptively. So, looking at children who are at risk who do not have a diagnosis and using in this case pivotal response training. It is a very small paper, very much a pilot, but it is an indication of the direction that the IACC had talked about in the Strategic Plan, that, ultimately, the vision would be to identify who is at risk and to preempt the development of the full spectrum by coming up with an intervention very early in the process. So, that paper, I think, may be the first example of the effectiveness of that kind of an approach, but it is completely a pilot at this point.

Services, something we have talked about already a bit at this meeting, but you can see that the literature that is emerging here looks a little bit different. It is more looking at the effects on caregivers, more information about the cost of healthcare for people on the autism spectrum, and the cost for families. And now, we have got some additional information from the UK, where there is a broader national healthcare system, as well as what is coming up from certain states in the U.S.

"What does the future hold, particularly for adults?" That was the penultimate question in the plan. When we came up with this, it was with a sense that there is just no one focusing on the needs of adults. And as you can see, just over the last year, we have gotten a series of new reports, as people begin, both in the UK with

Terry Brugha's look at the epidemiology, as well as Joe Piven's attention to this, and Paul Shattuck's looking at some of the service issues, increasing interest in this issue, which I think, hopefully, has something to do with the IACC trying to make this a priority for people in the research community.

And finally, "What about other infrastructure and surveillance needs?" You have heard a lot already about the CDC report. So, we have the new numbers that are out with about a 78-percent increase since 2002. As pointed out, that is looking at 8-year-old boys from 2008. So, that is already a cohort that was born 12 years ago.

I also want to point out that NDAR, the National Database for Autism Research, which just surpassed, I think, 30,000 subjects, and this is bringing together all of the research information from both public and private sources, and is one of the things that we pointed to in the Strategic Plan as a really urgent need, which was to coordinate not only at this level in the planning, but to coordinate that we bring all of the results to one place with standardized measures where we can begin to integrate the data and allow public access, so that people can begin to get, essentially, crowd source, what is happening in the autism research arena to accelerate the discoveries.

We will be hearing about other news. And so, I am not going to take any time with this except to point out, as already mentioned by Francis Collins, that we are about to announce the new Centers of Excellence at NIH. That will be out in the next few weeks.

We are going to hear more from people from Autism Speaks, Stuart Spielman and Peter Bell, in a few minutes about health insurance coverage and what has happened in that arena.

We will hear about seclusion and restraint from Larry Wexler.

The wandering issue, which is something that the Committee has really put a focus on, I will just mention where things have gone in that arena. We do have an ICD-9 code that was created by the CDC in consultation with the Committee.

These questions about wandering were now in the HRSA survey that is done every year. So, that is, hopefully, going to provide us some additional information.

And then, as you can see up here on this slide, there has been a joint effort of Autism Speaks, Autism Research Institute, the Autism Science Foundation, and the Global Autism Collaboration with IAN to launch a national family survey on wandering and publish a report on the findings. So, that will be really key to get a better sense of just the scope of that problem.

Finally, we haven't talked much about this today, but it is in the news so much, is the implications of DSM-V. And so, we have asked Sue Swedo, who is chairing that section of the DSM-V revision, to join us and to talk a little bit about this. We will hear more about that in a few minutes.

So, that is a very quick rundown

of where the science is going and new findings of interest.

We are just about back on schedule. I don't know if, Henry, you are -- terrific.

Why don't we move along? Unless anybody has a burning question, we can move forward and hear from a former IACC member.

Welcome back to Henry Claypool, who is going to talk to us about this Administration for Community Living.

It is good to have you here.

Mr. Claypool: It feels like old times to be here. Thank you for having us. We do have some exciting news.

Can I bother you for the remote? Yes.

The Secretary recently has taken an action to create a new operating division or agency at the Department. I am here today to talk to you a little bit about the agency.

This is kind of the Secretary's vision behind the establishment of the Administration for Community Living. As you can see, we are really focused on developing the long-term services and supports in community-based settings to make sure that people have the opportunity to live in their homes and communities with disabilities across the age span.

A brief overview of a new and small agency: we basically brought together the existing Administration on Aging, which was an agency at the Department prior to this reorganization, brought in the Office on Disability, which I am the former Director of, and the Administration on Developmental Disabilities, and the President's Committee on Intellectual Disabilities, and formed a new agency.

Why we have done this: there is really a lot that people with disabilities and older Americans share. There are certainly some distinct differences, but the broad swath of the work that the agency plans to carry out really is focused around that common agenda, around how we advance community living opportunities for older Americans and people with a wide range of disabilities.

As you can see here, we will be working closely together with a number of other agencies. I wanted to call out one specifically. When we mention aging and disability, most notably absent from our lineup is the resources around mental health. Those continue to exist at SAMHSA. And SAMHSA, while our new agency has a modest portfolio around mental health, one of our first priorities is to develop a strong and rich collaboration with SAMHSA, so that we can continue to advance work on behalf of people with mental health that are living in the community. So, a close partnership with SAMHSA is essential to the success of this new agency.

By way of background, I just think this is probably more instructive than the fact that there was a reorganization, to really share with you how we got to this point.

As you know, our society has a long history of change around how we treat people with disabilities and care for older Americans. In the sixties and seventies, we saw the beginnings of a real move to help people with developmental disabilities leave large, congregate, institutional settings for community-based settings. That really was an enterprise that grew in strength with the changes in the Medicaid program that created home- and community-based services waivers. So, that is an important point on the timeline that leads us up to this.

It wasn't just for people with developmental disabilities. Of course, older Americans are served by waiver programs as well as people with other disabilities.

Again, there is a notable exception around mental health issues. There are certain statutory prohibitions that make it difficult for CMS to pay for certain types of services for people that would require institutionalization for a mental health condition.

Leading up to this, we had a long bit of work in building capacity to serve people in community-based settings and lots of legal challenges. And those legal challenges culminated in a Supreme Court decision called Olmstead, and I am sure many are familiar with this.

The case was decided in 1999, and really affirmed the rights of individuals with disabilities to live in the most integrated setting appropriate to their need. That really was the impetus for great change.

What followed in the wake of the Olmstead decision was a series of grants to states to help them build capacity. They were called Real Choice Systems Change Grants, helping states to build greater capacities to serve more individuals in community-based settings, to really create an infrastructure that would allow people to begin to make a transition from institutional settings to the community.

In 2005, in the Deficit Reduction Act, there was a program called Money Follows the Person, which really empowered states with resources to make that specific move, to identify individuals in institutional settings that were ready for community and to put the resources around them to make that transition happen.

States have been successful in using the resources. I think CMS's numbers are above 20,000 individuals that have been helped through this program now.

One of the points of feedback that came from states after the Money Follows the Person Act was that housing was a real barrier. And so, when President Obama came into office, one of the first disability initiatives that he kicked off was the Year of Community Living, which called for a partnership between HUD and HHS to address these issues around the lack of accessible, affordable housing, particularly for individuals that required long-term services and supports to live in the community, and especially those individuals that were institutionalized.

Another part of the Year of Community Living was invigorated Olmstead enforcement on the part of the Department of Justice. So, the Department of Justice has been out working with states and issuing letters of findings, entering into settlement agreements with states, to help make sure that the rights of individuals with disabilities are respected, and that people are able to live in the most integrated setting appropriate to their need.

This is very long-term work. Many of the states have very significant challenges confronting them. The desire to live in the community really does require the infrastructure to exist to serve them. And this new agency really helps us focus on that very issue: how can we organize in a new way in the Department around this concept of helping people live in their homes and community?

Notably, after the Year of Community Living was the Affordable Care Act, which gave states new incentives to provide, through the Medicaid program primarily, home- and community-based services. So that states could, again, offer up new options and provided new incentives for them to rebalance their Medicaid program, a term that is often used in reference to how much spending there is on institutional settings versus community-based settings.

This rebalancing effort is something that CMS actively works with states on promoting new ways to help them balance their long-term care systems and make sure that states can offer up the community-based services that people need.

Again, after the ACA, it became clear to the Secretary that there was a need to create this departmental focus on living in the community with the right mix of services and supports. She basically has charged the agency to be led by an interesting group.

There is myself and Kathy Greenlee. Kathy Greenlee serves as the Administrator and the Assistant Secretary for Aging. So, she continues to fill her Senate-confirmed position as the Assistant Secretary for Aging. I serve as the Principal Deputy for the organization, and I carry another responsibility of advising the Secretary on disability policy. So, this new organization really is trying to balance the interests of aging and disability, and it is reflected in the leadership.

Notable in the leadership is Edwin Walker, who is with me today, who is the Deputy Administrator for the Administration on Aging. So, the Administration on Aging continues to exist. It is part of the new agency.

We also have another one of our leaders with us today, a member of your group, Sharon Lewis, of course, the Commissioner on what we now call the Administration on Intellectual Disabilities and Developmental Disabilities.

And we have a third Deputy Secretary that works on policy and integrated programs. We balance our work related to the disability and aging program through that office as well. So, we are trying to remain true to the interests of older Americans and those people with disabilities, as we go through creating a policy agenda that is going to reflect the interests and needs of those individuals.

Here is an organizational chart, so you can just lay eyes on this. We obviously have a Regional Office function. It has a modest amount of staff, and we are primarily located in five of the ten Regions with Regional Directors. We do have capacity to be in all of the Regional Offices, and you can look for us there.

I know that they are very eager to engage on disability issues. One of the challenges that the new organization faces is really trying to stay true to our funding. The bulk of our funding and our focus of energy really is on administering the Older Americans Act. The Regional Offices will need to ensure that their work is true to the appropriations we receive, and the Regional Offices will continue to have that oversight function of the Older Americans Act out in the states.

We are pleased to have some additional capacity there and hope that the other program that we administer, those associated with the DD Act, we can eventually build some capacity over time to assist Commissioner Lewis with the responsibilities that she has to oversee the resources associated with that program.

With that, it is a pretty quick overview. I would be happy to take questions, if there are any. And again, Edwin Walker is with me, if there are questions about how this relates to older Americans.

Dr. Insel: Questions? Sharon, anything you wanted to add?

Ms. Lewis: No, I think Henry provided a great overview. We are very happy to have ACL participating in the IACC and supporting the efforts here. As I talked a little bit about this morning, we will really be engaged around these issues as it relates to long-term services and supports with our colleagues from CMS and others at HHS. So, we appreciate the opportunity.

Ms. Abdull: Hi, Henry. Thank you. It is nice to see you again.

I was just wondering, there was something that you said that I found it really good. Obviously, being from a country where people with disabilities had no rights, I am grateful that America gives them that.

But you said that you want to make sure that they get the services and the support that they need to live in the community that they choose. But, for example, in my own little State of Minnesota, there are thousands of people on the waiting list for waivers.

So, on the one hand, we are saying we are going to support you so that you can live productive lives. On the other hand, we are saying, get in line, buddy; there are thousands ahead of you.

So, I wonder, with your new organization, how do you intend or what do you propose or how do you propose to tackle that? Because that seems to me a promise that we can't keep.

Mr. Claypool: Well, thank you for the question. I think it really is a very poignant one.

We have a legacy of waiting lists around the country for developmental disability services, largely due to states' inability to put the resources forward to match the federal dollars, so that they can provide the services through the home- and community-based waiver program.

We have a robust policy shop. We have lots of ideas. I think as we go through a process of formulating our new policy agenda, I think you will see some things reflected in it in the next six months or so that will really begin to highlight the new ways that we can approach serving families that might not have us relying on the more traditional approach of, say, states offering a fully-comprehensive waiver program to an individual. And then, the result of that is you can't fund additional slots because they are extraordinarily expensive, and we place families on waiting lists.

There have been, I think, a number of states that have been creative about supporting families. That is something that I think we should explore more, about are there new ways that we can support families, so that they can get some services and don't have to rely just on the promise of services coming one day in the future.

Dr. Insel: Scott?

Mr. Robertson: Just a quick question. I am judging that the idea behind ACL is, in part, more cross-realization, also, between aging and disabilities. I wondered how you all foresee particularly aging being able to provide some spark or some innovation and ideas that are being done in the aging community that could benefit the DD community in how services are provided and how we move forward for ensuring high quality of life for people with developmental disabilities.

Mr. Claypool: Well, thanks, Scott.

I think there is an awful lot we can learn from the aging community. There is a more robust infrastructure in the Area Agencies on Aging that are funded by the Older Americans Act. I think, through collaboration with them, we will find new ways of working together.

Probably one of the most notable examples is the Aging and Disability Resource Centers, which have largely been operated by AAAs in partnership with disability organizations. And again, I think the focus there is to try to get to the issues that are shared by those two communities and remain focused on that.

I would suggest that there are a number of innovations in the aging world that we will learn from. They may need to go through some translation. As you know, in the disability community the civil rights framework is something that the community is very identified with. In the older Americans' world, that rights framework isn't as -- people don't identify with it as much as they do in the disability community.

So, I think we can learn from the

types of services that the Older Americans Act and efforts to serve people that are older in their communities have really culminated in an opportunity for us to learn. So, how are we going to provide additional supports for people that aren't getting the support they need in the community? Is it something that we need to rely on the Medicaid program for? Or are there new opportunities to look towards community-based organizations that are providing certain services that people with disabilities can benefit from?

So, it might look more like moving some of the focus around disability policy to the state and local arena and exploring new relationships there, and finding opportunities to better serve the community.

Dr. Insel: Thank you very much.

I think, in view of the time, we had better move on. But, Henry, we really appreciate your joining us, and you are welcome to stay for the rest of the meeting, just maybe out of a sense of old times, and being an alum, we have a regular place for you here at the table.

We talked about seclusion and restraint. It came up this morning in the discussion with the Secretary, and it is an issue that the IACC struggled with last year, one of the areas in which we submitted a letter asking for some recognition of the issues.

We have asked Larry Wexler from the Department of Education, who you heard from this morning, to talk to us about where things are moving in that arena.

So, Larry, you have slides.

Welcome.

Dr. Wexler: Thank you.

Good afternoon, everyone.

Just to set some context, I started teaching kids with significant disabilities in 1970 and had any number of children that were labeled as autistic, certainly along the most severe of the spectrum.

In about 1972, I was privileged to get the first children who were outplaced just for the day, I might add, from the State Institution for Intellectually-Disabled Children and Adults. So, during that time period, I achieved a dubious distinction of becoming the State toilet-training specialist.

(Laughter.)

Along with that distinction came kids with increasingly-significant disabilities being dropped off in my classroom, as you can imagine. There were some reinforcers going at the time that it took me a little a while to figure out.

But, you know, in that time, children were being routinely restrained. Prone restraint was a given. It wasn't an exception. Children were placed in seclusion for extended periods of time. Children were placed in seclusion for punishment. I worked in programs at state institutions that were using cattle prods as treatment for inappropriate behavior.

In all that time, we learned that -- you know, they used Tabasco spray, everything you could possibly imagine and, frankly, is still used at a number of facilities across this country.

But I think that what people never quite comprehended was those treatments were ineffective. I have a long history with restraint and seclusion, and it was a privilege for me to be the steward of bringing this resource document to the public. Alexa said it took a year, but the truth is it took almost two years to get it out.

And it took that long because we had to clear 13 offices in the Department of Education, including the Office for Civil Rights as well as our General Counsel. But we also cleared the Department of Justice, and we cleared HHS also, and then it cleared the Office of Management and Budget.

So, to get this out and to come to some agreement was an arduous task. We received terrific support from our colleagues in HHS and DOJ. And I do want to thank them. And Sharon played a very pivotal role in getting this out.

And frankly, we frequently didn't

agree. You know, this was an iterative process, as they say in IES. It was a lot of iterations before it finally got to the point where we were comfortable with it. So, I just wanted to start with that.

What I want to reinforce is this is not guidance. This is not regulation. This is a resource document. There is no force of law behind this. We didn't have the authority to do that.

The real purpose of this is to say this is our best thinking. If you, as a state, a district, or a school are developing policies and procedures around restraint and seclusion, if you touch on these 15 principles, we think it will be a solid policy, a solid procedure.

It is not to say there aren't additions. It is not to say that everyone agrees or doesn't agree with these. But the point was to provide a context for states, districts, and schools who were trying to develop that.

And let me add that in the

document -- and it really needs to be viewed online. First of all, it is in color. It is much slicker, I might add. But, above and beyond that, all of the links are live in there. So, we lay out every state's policy or procedure related to restraint and seclusion.

And what we found when we reviewed them all is a lot of states and a lot of districts, what their policy is is that the district should have a policy, and what the district's policy is that the schools should have a policy. So, while a lot of states say they have policies and procedures, our feeling was, in fact, that is not getting down to actual practice. So, that is the purpose of why we developed this document.

So, what are the sort of key concepts with this? The first is safety. We just believe that every child in every school in this country and every other country should be safe, period. It is just as simple as that.

The second was it applies to all children, not just children with disabilities.

The civil rights data collection showed -- and that is their first collection, and I am in charge of data for IDEA. So, I can tell you, the first collection of any data is weak. It is just not exceptionally-valid. A lot has to be worked out.

But, even with that, 70 percent of children who were restrained or secluded were kids with disabilities, but 30 percent were not. We know that these practices take place with all children, especially -- and this was a revelation within my Department, frankly -- in preschools. You know, it simply happens because it can. People can force their will on small children. So, this applies to all children, not just kids with disability.

Prevention was a key concept here. Okay? We believe that the first focus ought to be on preventing the need for restraint and seclusion, not training everybody up on how to use it. If you build it, they will come. It is as simple as that. That is not to say that people don't need training, because we do say that, but first and foremost is focus on prevention.

No evidence of effectiveness. We know that there is no evidence that using restraint or seclusion is effective in reducing the occurrence of the problem behaviors that precipitate the use. Very simply, restraint and seclusion may be needed in an emergency situation, but those practices do not address the stimulus for the behavior. It is as simple as that.

If you don't address the stimulus for the behavior, you are not going to address it. When I watched people use cattle prods to stop self-injurious behavior, it was highly effective. Okay? A kid smashing his head with his fist a thousand times a day; you apply a good, high-amperage battery cattle prod. It reduced it to zero immediately. Okay?

Turn the page on the graph, though, and now they are tearing their skin because you didn't address the stimulus. Turn the page on the next graph, and then they are pulling out their hair, and so on and so forth. So, we know that there is no real evidence of effectiveness with this.

Again, policies and procedures are key. That is what this is about, is supporting states, districts, and schools in developing policies and procedures.

So, it can't be used as a punishment. We do not support that. And what do we mean when we say that? A child is overly active. He gets out of his chair. He runs around the classroom. We don't believe in terms of these principles that a child should be restrained in a Rifton chair because he is hyperactive. That is not the approach, because, again, the overarching thing is it is about supporting the child when he is in imminent danger, imminent danger of physical harm to himself or others. That is the overarching concept here.

So, if the child is running around the classroom, he isn't necessarily in imminent danger. If he is jumping out the window, that is a different situation. Of course, you need to intervene. If he is running across the highway in traffic, of course, you need to do what you have to do to prevent that child from getting hurt.

So, we have some other general principles. Most of these are common sense. Restraint and seclusion should never be used in a manner that restricts a child's breathing or harms the child in any way. We pay particular attention to breathing because you all have read the reports. Every day you read the reports. GAO documented, you know, prone restraint, a 300-pound teaching assistant sitting on a child's chest and the child dying. Okay? Anything that restricts a child's breathing we certainly would never support.

This was a challenging one around mechanical restraints and drugs or medication. So, let me just tell you what happened when we had these discussions.

We were looking at mechanical restraint and under what circumstances would it be reasonable to use mechanical restraints. We tried and tried and tried and couldn't come up with one. We simply couldn't come up with one, except as authorized by a licensed physician or other qualified health personnel.

And frankly, you know, I have worked in institutions, so the question becomes, is a Posey mitt that prevents a child from ripping his face apart, is that mitt inherently wrong? And the question becomes, the point of the principle that we developed isn't that it is right or wrong, but if you are going to use that as a mechanical restraint, it needs to be prescribed by a competent health authority. It is not something that the school says, "Oh, good idea. Let's put that on the child. That will help the child."

So, again, physical restraint or seclusion should not be used except in situations where the child's behavior poses imminent danger or serious physical harm to himself or others. This is something that is just the absolute foundation of what we developed.

We say that any kind of behavioral

strategy should address the underlying cause or purpose of the dangerous behavior. So, we are making a behavioral statement there. If you develop a program, some type of behavior program for the child, it should not just address the behavior. It needs to address the stimulus for that behavior, the underlying cause. At least that is what we believe.

Okay. Teachers and others -- this was key also. And I have to tell you, there was a lot of discussion around training. Okay? How much training would we recommend you provide?

No. 1, what we said is that teachers and other personnel should be trained regularly on the appropriate use of effective alternatives to restraint and seclusion. It is as simple as that, effective alternatives. First, do no harm. First, look at preventing the need for it. It should only be a last resort and needs to be discontinued as soon as possible. As soon as the child is no longer in imminent danger of physical harm, it needs to be discontinued.

Now, you know, there is a human rights sort of principle in human rights. It is called "the Grandma test". "The Grandma test" is, if you want to do something to somebody and your grandma thinks it is a bad idea, it is probably a bad idea.

We tried to apply a common-sense standard to the development of this document. So, again, the point is, if what you want to do, if a child gets completely out of control, and for some reason he needs to be put into some type of timeout situation, the point is, the moment he is under control, the moment he is no longer a threat, a danger to himself or others, it needs to be discontinued, and, obviously, monitored very closely.

I am not going to go over all 15 principles. But the point being, you don't say, "You're acting out. That act-out results in your needing to be secluded, but we are secluding you for a half-hour. No matter how you behave, you are in there for a half-hour." So, that is the kind of thing we are trying to focus on.

So, we are committed to doing what we can to ensure that every child has a successful educational experience. We know that an individual student's success is not based solely on school curriculum, but it is linked to the classroom and school-wide climate. And we need to make sure we do our best to make that learning environment engaging, positive, and safe, and structured to prevent the need for behavioral interventions.

To accomplish this, schools have the responsibility to make every effort to provide a behavioral framework, such as the use of things like positive behavior interventions and supports that applies to all children, all staff, all places in the school, so that the use of restraint-and-seclusion techniques are unnecessary.

Now let me credit SAMHSA and the work that Sharon has overseen, because they have done some seminal work around the economic benefits of eliminating or reducing restraint and seclusion. That is referenced in the document.

But let me finish by saying that, from the Department of Education's perspective, we believe that one case of inappropriate use of restraint or seclusion is one case too many.

Thanks.

Dr. Insel: Thank you.

We are going to have to move on, I am afraid, because of the time. But maybe we can come back to any of these issues later. We are still about five minutes over.

Alison, can it wait or is it a clarification point?

Ms. Singer: No, it's not --

Dr. Insel: Why don't we circle back to this, because I think there will be a lot of discussion over the subsequent presentations as well?

Let me see if Sue Swedo can come forward and talk to us about DSM-V.

Dr. Swedo: Thank you for the opportunity to speak with you today. It was two years ago that I came and gave you our proposed changes, and this update is somewhat different in that there has been little change in the criteria, quite a bit of developments in the text, but a whole lot of attention in the media and on our public comment site.

Asperger disorder, autism, and the autism spectrum disorders continue to receive the most public comments and run about 10 times higher than any other diagnosis. So, it has certainly received a lot of attention.

And our Committee has been working hard on this, actually, for five years. And so, the flurry of activity at the end was a bit surprising to us because of the fact that we had worked very hard as we were going along to develop the scientific base to justify our changes. But we also recognize that some of the things we are discussing and planning to propose are somewhat controversial.

They have certainly generated headlines, varying from The New York Times accusation that we would exclude as many as 35 percent of high-functioning individuals or those with Asperger disorder. And then, it actually got picked up on the Reuters News Service as 65 percent. So, we were getting rid of two-thirds of autism.

And that, then, led us to be charged with having tried to nip the epidemic in the bud by changing the diagnosis. I assure you, as I have others, that that was never our intention. In fact, it is quite contrary to what our process has been, our policies, and certainly our intent.

The concerns fall into three categories currently, and I will address each of these briefly, due to time. The first is that sensitivity was sacrificed in order to improve specificity. For those of you who don't use sensitivity and specificity on a routine basis, sensitivity is the number of cases that you pick up that are actually there and that you miss, who actually aren't there; whereas, specificity is the ability to catch only the cases that you are actually describing.

And for autism spectrum disorders, because of its overlap with so many other neurodevelopmental conditions and with neuropsychiatric disorders, specificity has been, indeed, a large problem, particularly in DSM-IV, where attention deficit hyperactivity disorder is an exclusionary diagnosis. So, if you have a diagnosis of autism, you can't have ADHD, and vice versa.

And so, if you have a child in need of a great number of services because of their severe ADHD and relatively minor social skills deficits, they still might get a diagnosis of an autism spectrum disorder. In DSM-IV, it would be PDD-NOS, in order to provide appropriate therapy to that child.

There were also concerns raised about the fact that the social communication domain had been changed from two separate sub criterion to one, and that we were requiring all of those elements to be met. We will talk about that more in a moment.

And similarly, in the restricted interests and repetitive behavior domain, it is just a single domain. And therefore, we are requiring that individuals have two out of the four possibilities.

There has been a lot of attention paid to our proposal to merge Asperger disorder into the autism spectrum disorders, as a loss of identity for those who currently are diagnosed or self-diagnosed with Asperger disorder and, in fact, have social networks in which they identify as "Aspies", and, more importantly, the loss of uniqueness attributed to the Asperger disorder.

I think that that uniqueness is actually a reflection of the common use in the clinic of an Asperger diagnosis. Because when you look at the DSM-IV criteria and compare autism and Asperger’s side-by-side, Asperger’s is actually the more severe condition. It requires a quantitative impairment; whereas, autism is only qualitative, the difference there being that in Asperger's disorder they don't have to have early language delays. So, it has been used with some frequency for individuals that didn't have an early history.

That item we specifically fixed in DSM-V by allowing current by history, and when history is not possible or present, then you can imply from the other symptomatology.

And then, the final criticism has been the pre-/post-DSM-V research studies won't be comparable. My work has been in both autism and in obsessive compulsive disorder, and I know in Tourette's syndrome this was a huge issue when we went from DSM-III-R to IV. So, we have been very sensitive that we not do anything to make previous research useless.

However, I would challenge those who have raised this criticism to try to compare across studies using the current diagnostic criteria because one group applies PDD-NOS criteria in very different ways than another group. And I will show you some of those data.

So, as I have already said, three diagnostic domains will become two, a domain of social communication and one of restrictive, repetitive behaviors. Rett disorders and other etiologic subgroups will be described by use of a specifier, and that specifier is associated with known medical or genetic conditions or environmental factor.

As we originally tried to think of the subcategories of autism that would be required in order to describe the current panoply of known associations and potential etiologic factors, it just was overwhelming. And by doing this, you actually allow the clinicians to specify all of the factors they believe to be associated. So, it might not only be tuberous sclerosis complex, but also fetal alcohol exposure and others.

PDD will be replaced by the autism spectrum disorder, and individual diagnoses will be merged into a single behaviorally-defined disorder.

So, the concern that DSM-V was so much more restrictive and difficult than DSM-IV, frankly, took us a little bit by surprise because we were working the other way, and I show you two examples of that.

First, in DSM-IV, the checklist item is currently failure to develop -- I don't know what's happening -- failure to develop peer relationships and abnormal social play. Whereas, we recommend including higher order of impairments of difficulties adjusting behavior to suit different social contexts. So, these are the individuals who might be missed until they get to the junior high lunchroom, and in that instance they just can't navigate the complex social interactions that are required.

Similarly, we tried to address that in the age, recognizing that neurodevelopmental disorders begin prior to birth, shortly after birth, or sometime during the developmental period. DSM-IV had required that symptoms be present prior to the age of three years. However, we had experienced and know of individuals in whom the deficits are present early in childhood, but because of a sheltered early preschool environment or even grade school environment, they might not be fully manifest until the social demands exceed capacity. And we literally specify that that could be during later adolescence or young adulthood.

Asperger's syndrome and PDD-NOS

within one ASD diagnosis, this was a matter of going where the science was. And that was the fact that currently there is a great deal of variability in how the criteria are applied, and particularly even among states, institutionalized differences in diagnosis criteria.

And I didn't separate out the data I am going to show you from our field trials, but it was just so striking, that if you are looking at data from California, 90-percent-plus of the individuals will have a diagnosis of autism because that is what is coded and receives funding. PDD-NOS and Asperger disorder do not. Whereas, in other states, they don't make that distinction between them, and so you have a broader use of the criteria.

Lack of accurate historical information about the very early language development, since that was really the only thing separating Asperger from autism, we felt it reasonable to merge those two together.

And then, finally, if you control for verbal IQ, there is a complete overlap in the samples between autism and Asperger disorder.

This slide shows that overlap with various sites within the Simons collection. And what you can see is that there is some variability. There is almost a bimodal curve in some of the sites; whereas, others have very high scores right in the mean. But whichever site you are at, what you see is that there is quite a bit of spread around the areas of impairment and symptomology.

The Simons collection data were used as part of a number of samples, including those from the CPEA and STAART Centers and others that have been archived. And within the Simons collection, this data is now out in publication.

What we saw was that at various sites, the use of the PDD-NOS, shown in red, and Asperger's disorder, shown in white, just varied by site much more than it did by other determinable factors.

So, in summary, there is going to be a single spectrum, but recognizing that there is significant individual variability, we are asking clinicians to use a number of specifiers, including the severity of the ASD symptoms. There will be severity anchors for social communication domain as well as for the restricted, repetitive symptoms domain; to talk about the pattern of onset, whether or not regression has been present, and whether that regression was acute as well as the clinical course. Was this an individual who had minor deficits up until school age or beyond? Etiological factors, when known, and associated conditions, when not known. And associated conditions would also include the frequently-comorbid conditions of epilepsy and GI disturbances.

And then, finally, individual weaknesses and strengths because one of the things that became very clear was that the individual's overall IQ was a better determinant in many cases of ultimate outcome than was the severity of the autism symptoms.

We have, as one of several diagnoses subjected to field trials, the autism spectrum disorder criteria proposed for DSM-V underwent field trials at Stanford and at Bay State Medical Center. And so, there were a total of 293 individuals at those two sites in whom an ASD diagnosis was to be considered.

I merged the data, just because I didn't want to try to explain how all it went. But, in general, the process was that people were put into a bin, based on their DSM-IV diagnosis, and then those bins had minimum numbers that could be included. So, there was quite a few of the children who had an ASD diagnosis, but they had a self-injurious, non-suicidal behavior. And so, they were put in that bin because that was a more rare condition.

For purposes of today's discussion, I merged them together. And, remember, we were talking about 293 children and adolescents up to the age of 18, of whom 214 did not have a DSM-IV diagnosis of autism, Asperger disorder, or PDD-NOS; 79 did. And you can see the distribution there in the blue.

Then, using DSM-V criteria to interview those same subjects, 19 of those who had not had an DSM-IV criteria were then given a DSM-V diagnosis of ASD and 10 were given a diagnosis of social communication disorder, which is very, very similar to ASD except it does not have the second domain and restrictive, repetitive behaviors.

Notice that, among the 35 individuals with autistic disorder, all of them received a DSM-V diagnosis. We lost three children with Asperger disorder out of 21, and five with PDD-NOS out of 23.

My Work Group met in June. We were reviewing those tapes. Of the two that I saw who were in this PDD-NOS group, it was very clear that they were put there for the example I talked with you about earlier. Their ADHD symptoms were extremely severe.

However, we are concerned that our criteria may not be applicable and valid, as has been published in a number of papers now. Our charge would be to please require that such studies be done prospectively or at least using a wider dataset than data gathered with DSM-III criteria because those just didn't ask the same kinds of questions.

So, for more information, the APA has a website open. The public comment has closed, but is actually still open in that they continue to receive emails and to pass those on to us.

Thank you.

Dr. Insel: Thank you, Sue.

We have got about three minutes for questions. So, let's start with Noah.

Mr. Britton: Hi. I am just wondering if it was intentional that the language of the new criteria allowed for the existence of autistic people who did not qualify as having autistic disorder.

Dr. Swedo: Yes, to include the individuals who previously would have had a diagnosis of PDD-NOS.

Mr. Britton: No, I was just thinking in a general sense, like I can look at these criteria and say, though I may be autistic, I may not qualify for autistic disorder based on these criteria. Was that an intentional choice on your part? Because when I read it, I thought that it was.

Dr. Swedo: I'm sorry, I don't understand your question.

Mr. Britton: The idea that you can be autistic but not qualify for autistic disorder, was this part of the process? Was this something you had thought about?

Dr. Swedo: Absolutely not.

Mr. Britton: Okay.

Dr. Swedo: And we don't believe that we have done that, actually.

Mr. Britton: Okay.

Dr. Swedo: I would challenge anybody to look at the specific criteria, which are here, and not be able to meet all three of the deficits in social/emotional reciprocity, non-verbal communicative behaviors used for social interaction, and developing and maintaining relationships. Because when you look at the way those are defined, the non-verbal communicative behaviors is not just absence of eye gaze, which people can be trained to have. And therefore, it would no longer meet the old criteria, but could have difficulties with integrating the verbal and non-verbal communication.

Mr. Britton: Okay. Thank you.

Dr. Insel: Jan?

Ms. Crandy: My question would be children that have behavior intervention, they could actually lose the repetitive.

Dr. Swedo: Yes.

Ms. Crandy: So, then, are you going to move them to the social/communicative disorder then?

Dr. Swedo: That was just at the very top, and if we have to, we will put it in every single line in here, "currently or by history".

We had some superb advice from individuals in lots of different groups, but one of the most important to us was making sure that, if a person not even had received behavioral interventions that removed that symptom, but if they were in a supportive environment in which those symptoms weren't manifest, that they shouldn't lose their diagnosis and, therefore, lose their symptoms.

I think the example was given to us, if you need a crutch to be able to walk, but you walk perfectly fine with that crutch, you don't want to, then, say you don't need the crutch anymore.

Dr. Insel: John?

Mr. Robison: One question that I haven't seen addressed is in the new release of DSM-V, will we see the use of the Asperger and PDD-NOS words supported in the continuing language, even though they are now part of the ASD? So that someone who was describing himself as being a person with Asperger's today would correctly say that about himself next year?

Dr. Swedo: Yes, absolutely. That has actually been, also, a matter of contention, and you have not seen it published yet. But it is part of the text.

Mr. Robison: So, that is going to

hold true? Somebody can still say Asperger's --

Dr. Swedo: Yes.

Mr. Robison: -- and it will be a recognized part of the spectrum?

Dr. Swedo: Yes. Our limitation there is that we have to use the definition that is in DSM-IV in order to bring that forward into DSM-V.

Mr. Robison: So, one --

Dr. Swedo: I'm sorry, I was just going to conclude by saying that, for many of the individuals who are concerned about now losing their diagnosis, they didn't fully meet the Asperger's in DSM-IV. So, we are trying to work through social communication disorder to make sure that those individuals who didn't have restrictive, repetitive behaviors, but had the impairments of social communication will be covered.

Mr. Robison: So, to speak, then, to one of the big concerns people have with diagnostic codes as they relate to insurance billing, it sounds to me like autism spectrum disorder will carry forward the diagnostic code that used to be autism. And therefore, in states that recognize autism as a medical disorder, not a mental health disorder, what used to be Asperger's now becomes the medical disorder? Is that your interpretation, too?

Dr. Swedo: That will depend on ICD-11. The United States has chosen to skip ICD-10. ICD-9 codes will continue until ICD-11 is published.

Our Work Group for DSM-V has been working very hard with the ICD-11 Neurodevelopmental Disorders Committee. In fact, we just had a call with Mike Rutter, who is heading up that Subcommittee. They may retain separation of autism versus autism spectrum disorders, but the coding will be the same.

Mr. Robison: Well, certainly, if we could combine them into one, I think that would be a good thing for our community.

Dr. Swedo: It will be great, but, unfortunately, DSM-V doesn't determine codes. We have diagnostic codes within there, but they are not the ICD codes that determine billing.

Mr. Robison: Thank you.

Dr. Insel: Idil, last comment, and then we have to move on.

Ms. Abdull: Hi. I just wanted to ask, for children that have non-verbal or classic autism, in this, obviously, they will still be considered autism. But, then, there are sometimes children that are verbal that get a lot of behavior therapy or other methods of therapy that parents are willing and they want to lose the diagnosis, at least in my community. And some have lost the diagnosis of autism. But, then, when the intervention stops, unfortunately, it comes back.

And so, what happens sometimes is that -- do they have to be re-diagnosed again or how would that work?

Dr. Swedo: We hope that the ability to have “currently or by history” count means that autism would be a lifelong diagnosis. As with many lifelong diagnoses, it doesn't necessarily have to be causing impairments at the present time and would not necessarily be an object of attention for services delivery. But the diagnosis would remain, and it could be that one of the specifiers is “in remission,” if that is the situation.

Ms. Abdull: So, then, when sometimes insurance companies or even Medicaid, when a lot of advocates say, "We want this therapy to be approved, to be tested," the best outcome is to lose the diagnosis. Then, it is important to say it can come back, and it is important to keep that, at least on paper, the diagnosis, so that you can get the therapy later on at 15 or, you know, 12, when you need it.

Dr. Swedo: Right. This is a bigger discussion among the entire DSM-V Task Force because there are a number of disorders that are in exactly that situation. And so, it is not clear whether, specifically for autism and the learning disabilities, and some of the other conditions within our chapter, the neurodevelopmental disorders chapter, we will have specifier “in remission” or whether that would be something that would be a larger issue for the whole diagnostic manual.

Dr. Insel: Well, thank you.

Sue, there has been a lot of misunderstanding about this. So, it is going to be important. Maybe the IACC can help to get the word out. This is much clearer than descriptions I have seen previously. So, it is very, very helpful.

John had asked about insurance, and that, in fact, is the next topic up. So, I want to move hearing from Stuart Spielman and Peter Bell, both of Autism Speaks, who are going to talk about recent developments in insurance coverage for individuals with ASD.

I think what we will do is leave some additional time for discussion here, and then we will take a break afterwards, Geri, if it is okay with you and Deborah to do a brief comment after the break. That might be a better way for us to manage the time.

Peter, welcome.

Mr. Bell: Great. Well, thank you

very much.

Just in the interest of time, I am going to be the spokesperson for Stuart and myself today.

And I want to acknowledge the work that both Stuart Spielman as well as our colleague, Lorri Unumb, have put forth in terms of autism insurance reform. Stuart works primarily at a federal level, and Lorri is our State Government Affairs Vice President.

In fact, she is currently today in Hawaii working on State legislation there. Many of you may be familiar with the fact that earlier this year we passed a bill in Alaska. So, we do work in all 50 states trying to successfully enact laws that require insurance companies to provide coverage for medically-necessary and evidence-based treatments.

For a significant segment of the autism population, the experience of hearing the words "Your child has autism" is a life-changing event. Although the median age of autism in the United States is still over four years old, actually, more and more parents are hearing those words when their children are still quite young, in fact, toddlers. That is the good news.

Years ago, many parents were told that there was little that they could do to change the course of autism. Today, however, we know that autism is treatable, and that early intervention is one of the things that has the best possibility for good outcomes. That is one of the things that we, as a Committee, I think can all agree on.

And yet, still, the challenge remains, how do families access treatments that are available without going broke or causing severe hardships to the entire family unit?

Two weeks ago, the Supreme Court ruled on a very important decision that basically said that the Affordable Care Act was mostly constitutional. In fact, President Obama, in his address after this decision, remarked that a fundamental principle here in America, the wealthiest nation on earth, is that no illness or accident should lead to any family's financial ruin.

Sadly, there are few medical conditions, outside of autism, where financial ruin is more probable. As we learn more about the cost of autism, we hear some very disturbing statistics. We are all familiar with the seminal study in 2007 by Michael Ganz that said that the incremental cost of having a person with autism over their life was $3.2 million, and that the annual cost in the United States of autism was $35 billion. And more recently, we are familiar with a study that was presented by Knapp and Mandell, who is one of our IACC Committee members, that showed that the annual cost of autism was $137 billion and that the annual cost of an individual with autism ranged between $1.4 and $2.3 million per year -- or excuse me -- over their lifetime. That varies by whether or not the individual has an intellectual disability.

Anecdotally, we hear many, many stories about families who are spending upwards of $50,000, $60,000, $70,000 a year in order to get their child the treatments that their children need. In fact, many people talk about sending their child to Harvard year after year after year after year.

When we look at autism and the healthcare costs that are involved, we hear, also, some very troubling statistics. There was a study that was recently published out of the Child and Adolescent Health Management Initiative that shows the differences between children with special healthcare needs and autism and those who do not have autism. Again, these are children that also have special healthcare needs.

And what we find, that well over 50 percent of the children that have special healthcare needs and autism cause the family to cut back or have to stop working. We also have found that families spend more than 11 hours per week in providing care, and that is about 30 percent. Families have to pay more than $1,000 annually out of pocket for medical expenditures. It is about a third, only 20 percent, for those that do not have autism.

Children with special healthcare needs and autism whose conditions cause financial problems for the family is over 40 percent, about twice that for children that do not have autism and, also, special healthcare needs.

We also know that family members avoid changing jobs in order to maintain health benefits, and that number is about 30 percent. Again, about twice what the other population is.

In addition, David Mandell has also been very prolific in this area as well and has published a study that shows mothers of children with autism earn about 35 percent less than mothers of children with other health limitations, about 56 percent less than mothers of children with no other health limitations. Children with autism are 9 percent less likely to have both parents working, and that family earnings of children with autism is about 21 percent less than children with other health needs and about 28 percent less than children with no other health limitations.

When we look at how insurance is provided to children throughout the United States -- and I should note the fact that most of this discussion is focused on children. We know that, obviously, there are very significant health needs in the adult community as well. Most of the data is available for children, and that is one thing, certainly, I think the IACC should be aware of, is that there is a lack of information across the lifespan, and that more information about the healthcare needs across all ages is critically important.

But about half of the children have parents who work for employers who provide their employees with health insurance. About 60 percent of those are self-funded companies, meaning those companies actually take on the risk of providing the coverage for their employees.

What is important about that is those companies are exempt from having to follow the state laws. The other 40 percent do have to follow the state laws and have what are known as fully-funded insurance policies.

About 4 percent of the child population in America is covered or their parents have individual insurance, meaning they go out into the market and they actually buy off of what is commercially available.

About 34 percent, or a little more than a third of children, are covered by Medicaid. And about 10 percent are not insured in the United States. And that leaves about 2 percent that are eligible through other public types of plans.

So, what I am going to do is just very briefly cover some of the different initiatives that we have at Autism Speaks been involved in, in terms of autism insurance reform, both at a state level as well as a federal level.

As I talk about these things, I want to acknowledge the fact that this is not something that we have just done on our own. It is something that has required really significant community involvement across many different communities around the United

States. These are other organizations, both local and national. It is other types of professional organizations, whether they be behavioral or psychological types of associations, pediatric associations, and so forth. This really has been a community-wide effort.

So, if you imagine this map without all the green on there from just five years ago, this map would have only had one state, which means that only one state had a law that required insurance coverage of autism treatments. And that State was Indiana.

But, since 2007, 31 additional states have passed laws that now require insurance companies to provide this kind of coverage. I am being a little presumptuous here because there is one State, Delaware, that just it recently passed their legislature and the bill is awaiting to be signed by the Governor, which we are expecting here in the next few weeks. But these 32 states represent 75 percent of the population.

Some people have talked about the

fact that, since the passage of the Affordable Care Act in 2010, that this might slow the growth or the number of states that have passed these kinds of laws. But, actually, more than half, 17 of the 32 states have passed these laws since the Affordable Care Act was implemented in 2010.

What we are also seeing is that some states who have passed previous bills are now starting to expand those bills. They are realizing that this is good practice, that this does have a significant benefit. So, there have been a number of states, even in the last six months, who have decided to either lift their limits in terms of age or, also, to eliminate the need for lifetime caps in regard to some of the treatments that are available.

We have also worked with a number of different organizations and companies throughout the country who have voluntarily decided to adopt insurance policies. I referred to these self-funded plans earlier as those that are exempt from having to follow the state laws. These fall under what is known as ERISA regulation. That requires that they don't have to, as I said, follow the state laws. But many of these companies have decided to on their own adopt these benefits.

What we are also finding is that in states that have decided to enact these laws many companies are deciding that it is good business because, otherwise, they might lose employees to other organizations, valuable employees. This is the reality that many families are facing.

There is one very brief story I will share with you. We had a family from South Carolina who contacted us two years ago, and they were talking about the fact that they were going to give custody of their children over to the grandparents because the grandparents had an employee situation where they had a benefit through their employer.

Because the company that the father worked for was an ERISA-regulated company, we went to that company and we worked with them to adopt a benefit for autism, and that family was allowed or decided to, obviously, not grant custody over for their children. But that is the extremes that people are going to in America to make sure that their children get access to the treatments that they know will work.

Dr. Insel: Peter, before you go on, can you just define what you mean by autism benefit?

Mr. Bell: Sure. Primarily, what it means in this case is that the benefit will provide coverage for the behavioral aspects of the condition. So, that is the issue that most companies will have, is that it is not that they refuse to provide coverage for treatment of autism, whether it be the seizures that might be related to it or other conditions, but that they will not provide coverage for the behavioral component of the treatment when it is prescribed by a physician.

Does that make sense?

Dr. Insel: I mean, there must be limits, though, in terms of --

Mr. Bell: Insurance companies have exclusions, and this is the reason why we have had to pass these laws, is that they have very obviously said that "We do not provide coverage."

And the big issue is that they will say either it is experimental, it has never been shown to actually be effective, or they believe that it is educational; therefore, it is the responsibility of the school system. These are obstacles that we have been able to overcome, and I will address that a little bit later in some of the other health plans that have decided to change their policies.

I just want to briefly note that we heard a little bit about Medicaid earlier. Obviously, Medicaid provides services to individuals with autism across a number of different programs. There is one called EPSDT which is Early Periodic Screening, Diagnosis, and Treatment. This is a program that is available primarily focused on prevention and helping to address medical conditions early in children's lives. And some families have tried to use this benefit in order to gain access to the behavioral treatments. Unfortunately, that has been something that has been denied historically.

However, there is a legal precedent. There are two major cases that have been tried in the last several years, the one most recently in Florida that showed that ABA was a required treatment under EPSDT. Now I understand that this may be appealed, but there is a precedent to suggest that coverage can be secured through this mechanism. And certainly, that would be a significant benefit to the community.

So, there are a couple of different other programs that are available to public employees and employees of the federal government. For those of you who do work for the Administration or the federal government, you are probably familiar with the Federal Employee Health Benefit Program, which is how federal employees gain their health insurance.

The Office of Personnel

Management, which is basically the HR department for the federal government, had a benefit review panel recently that concluded that there is sufficient evidence that exists to categorize the ABA as a medical therapy, and not just as an educational intervention. This is important because this was one of the reasons why they refused to provide coverage historically.

And in April of this year, they issued guidance to the insurance companies that would be proposing health plans for FEHB later this year, and that they encouraged them to provide that coverage. It is not a requirement, unfortunately, but, certainly, it will allow them to include ABA as a covered service within the plans that they are proposing for the fiscal 2013 year.

The other program that is available to people that are very important to us is the military. People within the military gain their health insurance through a program called Tricare. There is currently a benefit for autism in Tricare. However, in order to be eligible, you have to go outside of the basic coverage that is available and access it through a program called ECHO, which is the Extended Care Health Options Program. Sorry, I thought it was something else.

But this is only available to military personnel who are in active-duty status. There is a cap on the amount of coverage at $36,000 a year. But, as you can imagine, this is a very significant hardship for those who might be considering retirement or even in the case of a wounded warrior who comes home and is not allowed to continue to have active-duty status.

There was legislation that was introduced last summer, called the Caring for Military Kids with Autism Act, that would allow this benefit to come back into the basic Tricare program. Fortunately, this was amended into the National Defense Authorization Act earlier this year. So, it has been passed by the House. The Senate Armed Services Subcommittee recently, their personnel division held a hearing that some members of the IACC testified at. And we are hoping for later this year a Floor vote on that amendment, so that it can be included and something that becomes a reality in the future.

And finally, the Affordable Care Act, which many of us are familiar with -- and we heard a little bit about this earlier today -- does have some significant provisions in for the autism community. Things that actually went into effect very quickly after this was passed in 2010 included coverage for certain preventative services are now required, such as screening for autism and developmental delays and other disabilities.

We are also familiar with the fact that it prohibits denials based on preexisting conditions. We also know that dependents can remain on their parents' health plan until the age of 26. All three of these are significant benefits and became immediately available to the autism community after this was enacted in 2010.

However, one of the other

provisions that we worked very hard on was to include in the essential health benefits a provision for behavioral health treatment, which, in essence, means ABA for autism.

This photograph shows -- can I finish, and then I will let you ask a question, John?

This photograph shows Senator Menendez, Bob Menendez, making an amendment to the bill back in 2009 which included or added in the behavioral health treatment, which was later passed by both the Senate and the House, and, ultimately, part of the law.

What this will do is that, by the year 2014, each state is responsible for setting up a State Health Exchange in which the plans that they have are required to have 10 essential health benefits. One of those essential health benefits is a behavioral health treatment one that I described earlier.

It is very important that that provision be part of those plans because this is how many people will be able to access the most expensive and, quite honestly, thoroughly-researched treatment for autism.

Unfortunately, the guidance that has been given thus far has been somewhat challenging and troubling and not terribly clear. It is unclear as to whether or not habilitative services, which are also part of the essential health benefits, how those will be defined and whether or not children that have autism can access services through that benefit.

There also is a provision that requires states to have to defray the cost of any mandates that have been passed since 2011, and that would include the three states that have passed laws this year so far.

And it is obviously very clear that the congressional intent was that all 10 of these essential health benefits be part of the State Exchanges. However, it is not so clear in the guidance that has been given thus far that these benefits will, in fact, be in there. In fact, we are starting to hear from many states who are starting to make decisions and are not planning to include autism within those benchmark plans because they have not been given the direct guidance thus far.

So, there are some challenges as we go forward. As I wrap up, I just want to real quickly summarize that there is no question that there is a greater burden illness related to autism in the form of special healthcare needs, comorbid conditions, as well as the functional difficulties.

We also are very familiar with the fact that the impact on families for caring for an individual with autism is greater due to lost wages, higher medical expenses, financial problems, and unique employment decisions.

Autism insurance reform has produced many meaningful changes. Thirty-two states now have a requirement to provide coverage of evidence-based treatments. There has been an adoption of autism benefits by many companies with self-funded plans. The Office of Personnel Management has given permission for ABA coverage to be in their federal employee health benefit plans, as well as the fact that there is a provision in the essential health benefits that behavioral health treatments should be in all Exchanges.

We will continue to work on more state laws. We will also push for an ERISA mandate that would be a requirement for all companies that follow the ERISA regulations to provide an autism benefit, and we also will be pushing for greater clarity in terms of how the Affordable Care Act is implemented, and that behavioral health treatments is included in the essential health benefits.

So, John, I know he had a question, and I am happy to answer any other questions.

Thanks.

Mr. Robison: I'm sorry, yes.

A couple of times, Peter, you used the words "behavioral treatment for autism". I wonder, first of all, does that mean just ABA specifically or does it mean other things?

Mr. Bell: Well, it can mean anything that has evidence, and behavioral health treatment is a broad term. ABA is one type of behavioral treatment. There are other types of behavioral treatments. ABA probably has the strongest evidence to date.

Mr. Robison: It is the oldest one.

Mr. Bell: But also included in that would be things like pivotal response and discrete trial training and the Early Start Denver Model, and so forth. There are a number of different behavioral treatments. The one, again, that seems to have the most evidence behind it is ABA, but it was intentional to be broad, so that anything that qualified and had the evidence would be included under that category of behavioral health treatment.

Mr. Robison: So, that leads to my second worry, then. In a couple of your slides there, you showed examples where states challenged ABA as being a so-called experimental treatment.

Mr. Bell: Uh-hum.

Mr. Robison: And it was, I guess, overturned or on appeal, or whatever. ABA has been around for decades. It is the oldest of these interventions.

So, now we have developed a number of new behavioral therapies that work on all different kinds of kids. We have evidence that those therapies work, but we do not have decades of evidence because they haven't been around for decades.

Is what you are showing up there suggesting that we are going to have to fight every state behavioral-therapy-by-behavioral-therapy to get them out there? Does it mean that every time we develop a behavioral therapy, someone is going to have to vouch for it before a state will accept it?

Mr. Bell: We have tried as hard a possible to make it as broad as possible, so that any type of behavioral treatment that meets the standard of having enough evidence to show that it is medically necessary and has evidence behind it, that it would qualify.

So, in most cases, the way that the laws are written is that it will include something as broad as behavioral treatments or health treatments, but also it will say, "for example," but it doesn't mean it is only ABA and that every other behavioral treatment that provides evidence will be able to -- so, for example, many states are providing coverage for Early Start Denver Model or discrete trial training anytime they describe it as being a behavioral intervention.

Dr. Cordero: Hi, Peter.

Mr. Bell: How are you?

Dr. Cordero: Good to see you.

Mr. Bell: Nice to see you.

Dr. Cordero: Well, first of all, congratulations. I think that it is remarkable, the progress in terms of ensuring that every state has something on the books in terms of coverage for individuals with autism.

But, in looking especially at its being focused on behavioral coverage, it sort of feels like, you know, I have a chronic condition called hypertension. It would be if like I would have to go to every state and have to fight for, well, calcium channel blockers have to be included when all they may have is beta blockers.

And it seems that, in terms of strategy, that is not the kind of thing that we would like. I don't think that that should be a decision made by law, but more in terms of that it has coverage, that it is covered, because hypertension is a disease that needs to be treated; the same way with autism.

I just want to sort of make the comment that in Puerto Rico what we have done is, instead of going to change the law, it is to work with people in Medicaid and in the health insurance to say individuals with autism need coverage. And the way to ensure that both behavioral or basically mental health and medical part are covered is that we have set up a carve-out for Medicaid. And those that are also in the health insurance that would be on Medicaid, which is about 50 percent of the population, basically, the child gets screened. And then, it looks like it could be autism. That actually is what triggers the coverage. Once the diagnosis is made, that is one that would continue throughout their lifetime.

It seems that we make good progress in going to states and saying, "Hey, there needs to be coverage for autism." But we need to look at going beyond and ensuring that there is coverage over a lifetime over the different kinds of issues that individuals with autism will have, whether it is in the childhood time or it is in the transition or adulthood time.

Mr. Bell: So, what our experience has been is that children with autism don't really have problems with getting coverage of their treatments. It is the kind of coverage that they are getting, particularly for the behavioral types of interventions that, quite honestly, are prescribed by doctors readily throughout the United States.

So, what often happens is that a parent will go get a diagnosis, and the physician, whether it is an M.D. or a psychologist, or whatever, will say, "I think you should get 20, 30, 40 hours a week of behavioral intervention." And then, when you go to try to get access to provide coverage of that, oftentimes and historically, what has happened is that the insurance company says, "We don't cover that."

So, it is not that the child with autism is not getting some kind of coverage or that their treatments are not being provided. We have seen some improvement, particularly on some of the related services. So, like speech and OT and physical therapy, and so forth, it has been getting better without the advent of these laws.

What hasn't happened, though, in the absence of a law passing, is any type of meaningful coverage or any coverage at all of the behavioral component. And again, we have tried to structure these laws in a way that it provides for as much of, I guess, a way to have a number of different behavioral modalities covered within the span of that.

Dr. Insel: John, last comment before we move to a break.

Mr. Robison: Is this a place that the IACC could maybe suggest the federal government could step in? We have the FDA in the Committee now. It seems to me that it is the federal government that determines, through testing, that a given drug is a useful drug to treat a condition, and every state follows the federal lead.

Wouldn't it perhaps be the federal government's place to say that emerging therapies for social issues in autism, for example, should be treated the same way, so that we would not have to win in our fight in every state in the country one at a time?

Dr. Insel: So, let me ask you, Peter, about this. In the discussions you had state-by-state, how often did you hear the concern that, in contrast to a calcium channel blocker where everything is standardized -- we know the two people who are saying they are writing a prescription for the same drug are probably, you are pretty sure the people are going to get the same treatment. With behavioral interventions, there is not the same quality control, not the same standardization, not the same oversight.

There is not even accreditation in many cases.

Is that an issue that came up? Did people ask you about that?

Mr. Bell: It is an issue that is raised by the insurance companies, and that is pretty much it.

Dr. Insel: How do you respond?

Mr. Bell: In some cases, we are working within the local jurisdictions to set up appropriate credentialing. Obviously, in behavioral treatment, there is the BCBA, which certainly has grown significantly in the last decade, and there is a very robust and well-defined credentialing process by which professionals receive that.

In some cases, states are deciding to go ahead and do a licensing process as well, and that does vary. But those are some ways in which states are trying to address that issue.

Dr. Insel: Tiffany, do you want to respond? This comes up with psychosocial treatments in general, not just behavioral therapy.

Dr. Farchione: Yes. I mean, I think part of the issue is, like you were saying, if somebody prescribes a calcium channel blocker in one place, you know, FDA has regulated all the way down to the production of that item. So, you know that if you write for a medication in Nebraska and somebody writes for that medication in California, the person receiving that medication is going to get the exact same thing in the exact same dose with the exact same inert ingredients and everything like that.

But even though behavioral therapies are treatments and they can be very effective treatments, it is not part of the FDA's purview. So, it is not something that we regulate. We regulate the drug side of things only.

Mr. Robison: So, is there no federal agency who could regulate a behavioral treatment for its efficacy?

Dr. Insel: David?

Dr. Mandell: So, Peter, first,

thank you very much for that really thorough presentation of what is happening in terms of coverage for autism services.

We should be worried about improving quality of behavioral care for people with autism because it is the right thing to do, and it is often at a much lower standard than we would want it to be.

But I don't think we should be holding that treatment to a higher standard than we hold traditional outpatient therapies or even cognitive behavioral therapy when it comes to payment for insurance.

So, I think that these are two separate issues that need to be addressed separately. One is improving quality of care in the community, and the second is the issue of payment and coverage. I think insurance companies often intentionally conflate those two issues as a way of denying coverage, but it is the standard of care for autism. The extent to which it is delivered the way we would want in a systematic way, an important, but separate issue.

If I were going to ask the IACC to push for two things related to this, the first would be around habilitative care. One of the arguments that insurance companies have used is that many of these therapies are habilitative, not rehabilitative, and that they belong squarely in the education camp. That is a very important place for us to push, that these should be considered part of that package.

The second thing is, as the Affordable Care Act comes into place, we have states that vary tremendously in their mandates. In one state, the mandate includes any physician-prescribed service. In other states, the services are much more highly prescribed with specific dollar caps.

There is also a tremendous variation in the Medicaid generosity of both eligibility and service coverage for people with autism. These things within the same state are often very different, with one often being much more generous than the other.

As states begin to have to

synthesize these sets of benefits and decide what their essential benefit package is going to look like, we don't want them to go to the least-common denominator. We want them to go to the set of services that looks most appropriate, regardless of whether it is currently covered in Medicaid or through private insurance. And I think that those are the two areas where we really ought to be pushing.

Mr. Bell: One of the challenges has been, one of the products of our success is that we have created an environment of have's and have not's. It used to be an environment where most people did not have. And so, it was much more equitable.

(Laughter.)

But now you can have literally two families who live on the same street, and depending on what kind of insurance they have, you can have a child receiving 40 hours a week of treatment and it is being provided and covered by that parent's health plan, and another child who is getting absolutely nothing. And there is really no difference between that other than what kind of health plan the family has.

Dr. Insel: So, I am failing in my role as timekeeper. Last time, I didn't let Geri have the last word, and I will do it now.

Before you give the last word before our break, I just want to clarify for John; there is no federal agency that oversees or sets accreditation standards for psychosocial treatments in the sense that the FDA does for medical treatments. It doesn't happen.

Geri?

Dr. Dawson: So, with regard to this issue, one of the organizations that an insurance company looks to for guidance is a professional organization that would oversee that kind of treatment. So, if you were going to be talking about seizures, for example, they would go to the American Academy of Neurology and look at what the practice guidelines are in terms of what is standard of care.

And so, there are no practice guidelines in this area. We thought that the American Psychological Association seemed like a reasonable group to take that on. So, I have approached them about this, and they do have an arm of the APA that does develop practice guidelines. They are going to take this on.

It will probably be a couple-of-year process with its own systematic review, and so forth. But the hope is that, then, there would at least be one professional body that insurance companies could turn to where there would be defined clinical practice guidelines around early intervention, in particular, but behavioral health, in general, is the broader issue.

Mr. Bell: Could I just reemphasize one point?

Dr. Insel: Yes.

Mr. Bell: And that is the importance of this body helping to push for more research on the benefit of behavioral treatments across the lifespan. I think most of us realize that, even when you have adults who are in the community working, in housing communities, and so forth, behavioral treatments can have a significant benefit. But there is almost no data and information to support that at this point in time.

So, oftentimes, the way that these laws are structured is that it stops, and oftentimes at the most important time when they need the behavioral supports that many of them have grown up with. And so, I think it is important for us to look at the fact that we have really good data for children, but not so good data for adolescents and adults. And that is going to be an area that in the next five to ten years it is going to be really important to have a much better command on.

Dr. Insel: Great. Thank you so much for taking us through this.

We are going to take a 10-minute break. We will be reconvening at 3:30.

(Whereupon, the committee took a brief break starting at 3:22 p.m. and reconvening at 3:31 p.m.)

Dr. Insel: We want to get started hearing about the next topic, which is on autism and epilepsy. We have built a little buffer into the later part of the meeting, so we will be able to cover some of the areas that we are behind on.

I will welcome Geri Dawson and Deborah Hirtz, who are going to take us through autism and epilepsy, both from the clinical profile, and Deb will give us an update on a recent meeting held by Autism Speaks and NIH and CURE.

Geri? Thank you.

Dr. Dawson: Here? Hello? Okay.

Thank you for this opportunity. As Tom said, in a minute you are going to hear from Deborah Hirtz about a really interesting meeting that we had last summer. It was cosponsored by Autism Speaks, the National Institute of Neurological Disorders and Stroke, and CURE, which is an organization headed up by Susan Axelrod.

And the idea was to bring together two communities of investigators that don't talk to each other very much. In fact, one of the interesting things was that the folks in the epilepsy community thought of autism as a comorbidity, and the folks in the autism community thought of epilepsy as a comorbidity. So, that was fascinating.

What Deborah asked me to do before she tells you about the meeting is just to give a very quick overview of autism and epilepsy. So, I am going to do that as quickly as possible because I know we are running late.

Is this where I am supposed to be advancing to?

Dr. Insel: I think you will have to go back several slides since we skipped around. There we go.

Dr. Dawson: Ah, there I am. Okay. Good.

So, just very briefly, epilepsy, of course, is a very significant problem for people with autism. The estimates are that it affects about 15 to 30 percent of children with autism. In terms of long-term impact, it is associated with poorer outcomes, and this can be seen across a wide range of domains. So, adaptive behavior, social outcomes, increased behavioral challenges, motor difficulties, and even associated with increased mortality rate.

It is believed that the age of onset is bimodal. So, either children develop it before age five, or, then, another age at which you see more frequent seizure onset is adolescence, although seizures can have their onset in any of the years outgoing in adulthood as well.

One sees a higher prevalence of epilepsy in individuals who have syndromic forms of autism; also, individuals with motor impairments, and those with intellectual disability. It is also more frequent in females with autism as compared to males.

There has been a longstanding interest in the relationship between epilepsy and autistic regression. We still really don't understand that, and there is still controversy about whether those two are always connected. There is actually continuing, ongoing research in that area.

And then, another interesting report that came out in the last couple of years is that children with a history of infantile spasms are more likely to develop autism. So, it is actually a risk factor for the development of autism.

Now this is just a couple of reports that have come out in the last few years that pretty much show this same kind of clinical profile. So, one study was by Bolton, where he followed 175 individuals through age 21 and found that about 22 percent developed epilepsy, again, more common in females than males and more common in individuals with lower intellectual ability and social skills.

Now another nice report that was published in 2008 was a meta-analysis, and that actually brought together a large sample, over 2,000 individuals with autism and 1500 with epilepsy, again, showing the same pattern of epilepsy being more common in girls and, also, in those with intellectual disability.

And I thought I would show you some statistics from the Autism Speaks Autism Treatment Network. This is a patient registry that the Autism Treatment Network maintains. This is 4,321 individuals.

You can see that the rate in this particular sample of epilepsy is about 14.5 percent, so a little lower. But keep in mind that this sample is young children through late adolescence. So, as you go up in adulthood, you accumulate more people that have epilepsy.

You also see that, if we compare autism versus Asperger syndrome, that the rate is about tenfold higher in autism as compared to Asperger syndrome, and you can see, also, that same pattern, although not as robust as you might think compared to some of the previous studies. But you see a somewhat higher rate of epilepsy in individuals who have intellectual disability as compared to those who do not.

Now the other thing that is

important is that epilepsy is associated with sleep disturbance. So, this is true not only for people with autism, but also for individuals with epilepsy who do not have autism. The sleep disturbances are associated with things like aggressive behavior, irritability, inattentiveness.

And a recent analysis suggests that it is the sleep disturbance, rather than the seizure activity itself, that it is contributing to the irritability and the inattentiveness. So, if you have epilepsy, this is disrupting your sleep, and then the disrupted sleep is what results in some behavioral challenges, such as inattentiveness.

In terms of clinical evaluation and treatment, all seizure types are reported, but complex partial seizures are the most frequent. Now the symptoms of a complex partial seizure is actually similar in many ways to the autism symptoms themselves. So, lack of responsiveness to name, repetitive behaviors, and this can make differential diagnosis difficult.

And so, in this case, EEGs are helpful, but they are difficult to perform, particularly in young children. It has been shown that prolonged or overnight studies are more sensitive in picking up on seizure activity than routine ones.

We also see a high rate of abnormal EEGs in individuals with autism who do not have a clinical presentation of epilepsy. The clinical significance of this is unknown, although there is some current research on that, even looking at treatment in individuals who have an abnormal EEG that don't have epilepsy, to see whether the anticonvulsant treatments would be beneficial for those folks as well.

The other important thing in terms of an evaluation is an evaluation of genetic etiology, since we do know that seizures are more common in syndromic forms of autism spectrum disorder.

And then, finally, treatment involves anticonvulsant medication.

In terms of standards for treatment and management, there are existing standards that have been identified by the American Academy of Pediatrics, the American Academy of Neurology. And Deborah was just mentioning that the American Academy of Child Neurology, I think -- or is it Neurology? -- is about ready to undertake a review again of standards in terms of treatment and management.

But it is felt that the existing guidelines that are available are really inadequate. They don't give enough information about when you should be, for example, doing an overnight EEG, when should you be doing magnetic resonance imaging, when does a child need a full evaluation, and so forth.

So, the Autism Treatment Network, funded by HRSA as the Autism Intervention Research Network on Physical Health, is involved in developing physician guidelines for treatment of a wide range of medical conditions that are associated with autism, one of which is epilepsy.

So, they have developed now a clinical practice guideline for EEG testing as well as neuroimaging testing. And those will be published in 2013.

In terms of this meeting, the interest, again, is to look at the overlap between autism and epilepsy with the idea of exploring whether there is potential shared underlying biology -- there certainly is -- with the idea that this might, then, help us to understand common genetic or other kinds of risk factors, as well as point to common biological targets for treatment.

So, with that, I am going to turn it over to Deborah, who can tell you a little bit more about the meeting itself.

Dr. Hirtz: Thank you very much, Geri. I appreciate that quick run-through and explaining some of the introduction to this common, but really under-recognized and under-discussed problem, which we are now beginning to address.

And actually, the first major

meeting on this topic was about a year and a half ago. That was in New York, and it was sponsored by Autism Speaks as well as Cure, the Citizens United for Research in Epilepsy, and the International League Against Epilepsy.

That kind of set the stage for bringing forth the importance of this problem and the relationship which hadn't really been talked about by researchers and recognized well. As a result of that, we put together a workshop this past May, sponsored by NINDS, as well as the NICHD and Autism Speaks and CURE, again, to take a better look at this and to really set up a research agenda, and to bring these two research communities together.

The questions that we addressed were the following listed on this slide: who are these children specifically? What is it that causes this to happen? What do we know about it? What are the risk factors that we know about? What could we be looking at? What can we learn about the mechanisms from syndromes with both of these features that could help us understand much better both epilepsy and autism, and what causes those two? What do we need to know? What do we already know about neuroimaging, about the neuropathology, and as Geri talked about, about the EEG, which is neurophysiology?

And we talked about what kind of issues do we have to consider when designing studies in this population. What kind of resources do we already have and what do we need to develop? And finally, what are the short- and long-term goals for research in this area? And what are the very specific next steps that people need to be taking?

So, with regard to who these children are, Geri talked about that and mentioned that the risk is higher in those, if you are looking at epilepsy in the population of children with autism, then you can see that there is a much higher risk of epilepsy with both severe mental retardation and cerebral palsy or even just lower functioning, intellectual dysfunction, and that the risk is lower in those who have autism, but don't have those, are not low-functioning.

And then, if you turn around and look at the autism symptoms that you see in children who have epilepsy, again, that association holds, that it is really related to, there is a much higher rate of epilepsy in children who have cognitive problems as opposed to those who don't, although the numbers are less in terms of autism and those with epilepsy than the other way around.

So, on the topic of what causes this to happen, there were very interesting presentations and we have learned a lot in recent times about possible mechanisms, and these focused on two areas. One is what we call synaptic plasticity or the ability of the brain to adapt developmentally to new learning and, also, what could be particularly important in epilepsy, which is abnormalities or imbalances in the excitation and the inhibition. When you get that, you have a much higher risk for seizures, particularly when there is too much excitation and not enough inhibition.

So, early in life, it is possible

that with these two disorders there could be either a delayed maturation of inhibitory receptors or there could be too much maturation too early of excitatory receptors. These are really very likely to be important mechanisms. And abnormalities in neurotransmission that you see with seizures could also lead to learning and social and behavioral deficits.

So, an example was given of infantile spasms where this is an epilepsy syndrome in very young children that doesn't have a very good prognosis, and a very common outcome is autism. This could be an example of a syndrome to study in which you could look at how you could intervene early, so that you do actually prevent the symptoms of autism. And it could be a good model as well as some of the other single gene disorders that we talked about.

So, another area that Geri mentioned briefly was the issue about the EEG, or the electroencephalogram. Because, mostly commonly, when you have seizure disorders, you have to have a clinical seizure with the EEG abnormality to call it significant. But there is a really big question in the population on the autistic spectrum as to what does the EGG mean, and maybe this means something different. And it gives us a lot more information about development of autistic symptoms and avenues for treatment. Just having the abnormal EEG, even without having clinical seizures, what does it mean? And do we need to know more? When we talk about EEG endophenotypes, that is saying, are there certain types of EEGs that go along with certain clinical symptoms and clinical pictures which are important in autism?

We know that is true in epilepsy. We have syndromes of EEGs and clinical symptoms. But we haven't really defined those yet in autism. This is something we really need to look into.

We also know that this may be tied into genetic factors. Several models were discussed for looking at these overlaps of genes and gene pathways which may really help us understand both disorders.

And Geri also mentioned sleep issues and how important these are, and how intertwined they could be because sleep abnormalities as well as these discharges on the EEG, which we call IEDs or interepilepsy discharges, interictal -- whatever.

(Laughter.)

They are discharges without seizures. Anyway, they could have both regional and long-distance effects on neural circuits which we need to understand more about, and it could really inform us about functional connectivity.

We also talked about what we need to do to go forward with intervention and prevention trials. So, it would be very interesting and important to look at patients with both autism spectrum disorders and epileptiform EEGs, either with or without seizures, as subjects in randomized, controlled prospective trials, and the interventions that we need to look at are the anti-epileptic drugs, but perhaps some others, in addition, and what kind of designs we should have. And what is important to consider in those designs was discussed.

It was agreed that a primary endpoint would be not focused on the EEG, but it would be focused on, behaviorally, what was really the behavioral outcome, improvement in children with ASD in their language areas, in their behavior. And this could be compared to the baseline.

There are a number of other issues in designing these clinical studies. I will skip over these. But the point was that the kinds of treatment studies we need to be doing need to involve all children with all these different comorbidities, not just selecting a particular population with one problem, but the reality is that children have multiple problems, and these need to be addressed in the clinical trials.

And then, we also had speakers from a number of different areas in the clinical, to tell us about the tools that were now available. For instance, the brainbanking, the databases from both managed care, from the National Autism Database, from an epilepsy database called CHRISTINE, and the registry for Autism Speaks.

And lastly, we proposed and came to agreement on both short-term and long-term goals and opportunities for sharing resources and need for sharing resources, and the importance of looking for overlaps in databases in both conditions to integrate what we know in these databases, to look at the populations with autism to understand epilepsy, and vice versa, and to look at single-gene variants that can modify diseases. These would all be relevant for helping to identify novel drug targets.

The long-term goal is to -- and people were very excited about this; there was a lot of expertise in the room, and they were going to come together and develop ways to integrate the expertise in these two fields, look for shared mechanisms, look for environmental factors and genomic factors common to both areas, and develop the best kinds of clinical trials.

So, in summary, I think there was clear benefit to studying both disorders and how that would lead to understanding underlying mechanisms for both conditions, and would also help in designing and coming up with better treatments, better intervention plans that could address the two related conditions. And I think there was a lot of interest in collaborative research, plans for future meeting of this group again, and for development of very specific projects and proposals that would come to NIH and others for clinical research and other research projects.

Thank you.

Dr. Insel: Thanks, Deb.

We are going to have to move on to Committee business, unless there is any burning question for Geri or Deb. Anything? Lyn?

Mr. Robison: I have a burning question.

Dr. Insel: A burning question.

John?

(Laughter.)

Mr. Robison: I'm sorry to have burning questions. I hope you are not sorry you invited me in here to ask them all.

Dr. Insel: Not yet.

(Laughter.)

Mr. Robison: Yes, "yet," that's it, huh?

So, this is probably a question for Geri. We have all this evidence that there is abnormal EEG activity in people with autism and it is associated potentially with epilepsy. And we have now evidence from brain imaging studies and neurofeedback practitioners that we can alter those sorts of patterns through meditative behaviors or computer exercises, through interactions.

Have we funded and done any studies to see if we could alter those abnormal patterns and, in doing so, produce a different outcome in those ASD and potentially-epileptic children?

Dr. Dawson: I don't know the

answer to that question. I do think, in terms of neurofeedback, that typically they are looking at changing sort of the spectral EEG power. So, how much EEG power do you have in alpha, and so forth, which is really a different kind of underlying mechanism than what you see in seizure activity, which is a much more dramatic, synchronized kind of very focal activity as well in a particular region.

So, I don't know. Dennis, you may know, as a neurologist, or others. Has there been any attempt to use neurofeedback in epilepsy?

Dr. Choi: If we are talking generally in epilepsy, it is, generally speaking, not terribly responsive to anything other than the big guns, but there are some small numbers of epilepsies that are triggered by activities. Even things like reading epilepsy have been described, so the act of reading. So, those sort of unusual epilepsies may be sensitive to behavior modifications, but the rank-and-file, no.

Mr. Robison: I guess I just have

to wonder about that. Because I was at Pitt there and CMU, and I was talking to Marcel Just. He described to me developing therapies to exercise and activate very small areas of the brain.

You described neurofeedback as rather a gross thing where it elevates or lowers the whole thing. But Dr. Just described what you might call very precise, targeted mental activity interventions.

And I wonder if there is a place for a study like that, especially with what you just said, where we might take people who are not necessarily epileptic, but they have abnormal wave forms and they have autism, and we could produce a better outcome for those people through a non-pharmaceutical intervention.

Dr. Dawson: It is a very creative idea, I think.

Mr. Robison: I'll be quiet now.

(Laughter.)

Dr. Insel: Lyn?

Ms. Redwood: I just had a real

quick question. Is anybody looking at the etiology? I know there was one slide about possible etiologies, but I am just curious whether or not the inflammatory process in the brain that we see in children with autism, the microglial activation, the immune activation, the abnormal antibodies to brain proteins, is there any way that those predict later-onset epilepsy, and if that is something we could be looking for and targeting in terms of treatment because I see the seizure disorder is downstream?

Dr. Hirtz: It is certainly --

Dr. Insel: Please use a microphone.

Dr. Hirtz: Certainly at the workshop that was one of the things that was discussed and there are plans for. Everyone thought, or many people thought that that would be a very good avenue to pursue. There are research plans to do that.

Dr. Insel: We are sufficiently behind time that I am getting anxious, which doesn't happen that often. So, let's move us into the business session here. We do have a lot to do. We have some decisions to make. We need to make some plans about how we are going to take care of the job that we are brought here to do.

Susan, let me turn this over to you, and you can take us through the first part of this in terms of the new documents. And then, I will help on the plans from this point forward.

Dr. Daniels: All right. So, I wanted to share with you some of the work that the office and the IACC have been doing over the last few months, in case people are wondering how we have been using our time. In addition to trying to get the new Committee appointed, our office has been working with the old IACC to get these new documents and web releases together.

Many of you who are on our mailing list probably noticed we sent out emails late last night. It just didn't work out for us to send them during the day. But we wanted to make sure that everybody, including our audience that is out there over the webcast, and so forth, would have access to these documents for your review. We are really interested in making sure that everybody has a way to see what we are doing.

So, first, I am going to quickly run over the 2011 Summary of Advances. This document was released in April 2011. It is an annual document that the Committee does. The Committee identifies 20 research findings that they felt were the most significant ones in the given year in biomedical and services research. Each research article is given a lay-friendly summary that anyone can read to understand what is going on in research.

This document covered many different areas, including prevalence, biology, risk factors, interventions, and services. I am not going to read all of these to you, but this is a listing of all the different articles that were included in this year's Summary of Advances.

Of course, we have to select after the year closes. And so, that is why it comes out a few months after the year closes.

And so, this will be in the slide set that we will post on the web, for those who want to see that list. We also have the documents, all of our documents, outfront for anyone to pick up. They can be gotten off the web or you can write to the office and ask for a hard copy, if you would like one.

The next document -- this is newly-released -- is the 2010 IACC Portfolio Analysis. This document assists the IACC in fulfilling its requirement to monitor federal activities related to ASD. However, this document also covers private funders who have volunteered to provide their data, so that we can get a more complete picture of what is going across the nation in ASD research.

This document informs the IACC as well as stakeholders around the country, and perhaps in other countries, about the funding landscape in the U.S. and current directions in ASD research, and helps us monitor progress on fulfilling the different objectives in the IACC Strategic Plan, and gives the Committee an opportunity to highlight gaps and opportunities to guide future activities and the update of the Strategic Plan.

So, I am going to have to go very quickly through all of this. I will probably skip some of it, but it is all in the report.

In 2010, we looked at the federal and private autism funding and found that 82 percent of what we collected out of the $408 million was federal funding, and about 18 percent was private funders. We did add a number of new funders this year. The NSF, EPA, ACF, AHRQ are some of our new funders. And so, we always are striving to get a more complete picture of what is going on.

This is the full list. In red, just notice that there are a lot of private funders involved in this research, which makes this community very unique because it is so active and there is such collaboration and different groups working on different aspects of autism. And so, we also really appreciate the willingness of private funders to open up their data to be shared in this way, so that groups like this and the rest of the public can understand what is going on and what is being funded.

This is the distribution of autism funding across all of the IACC's Strategic Plan, all funders that we found this year. One difference that appears in this report is that you will see the services side is a little bit bigger than it has been in the past. This is largely attributed to the inclusion of HRSA's Combating Autism Act Initiative grants in more comprehensive detail, as well as more grants from the Department of Ed and, then, a few of those other new agencies that we found that also kind of rounded out other various areas of the plan. So, it was rather interesting to see how that came out.

This I can probably skip over pretty much, but it shows the alignment of objectives of the Strategic Plan. You will just notice, for example, in biology that about 60 percent of the grants are not directly related to objectives in the plan, but in some of the other areas they are more directly related.

In the 2010 Analysis, we tried to respond to one of the concerns that the Committee had about just this, where you see in gold the things that are not related to objectives. The Committee wanted to know what is in there.

And so, our staff really thought about this and how can we represent that and make it more clear what is being funded. So, our office developed a subcategory analysis to try to really categorize everything that is in the plan, even if it is not related to one of these very specific objectives.

And so, we developed this set of subcategories. They are not exactly listed here, but in this figure you see the seven questions of the Strategic Plan across the top in the colored bubbles. And then, below, kind of a description of what is in the subcategories, although in the report you will see what the actual subcategories are.

So, with Question 1, we divided it

into four subcategories, and that is the breakdown. I am sorry, it is really small and it is a little bit hard to read.

So, Question 1, 2, 3, these are the subcategories that we identified. If you read the report, then you will be able to see kind of what the breakdown is of the science in those areas.

And then, we also did breakdowns for Questions 4, 5, and 7. You will notice that Question 6 is not included because there were only 34 grants in that little portfolio, and most of them really overlapped heavily, and so, between vocational services, transition services, et cetera, to the point that we couldn't really separate them very easily and in a meaningful way. So, we know that that area is really emerging in research. We hope in the future that there will be more definition that will allow us to make subcategories for this.

We also did an analysis of ARRA because now we have both 2009 and 2010 funding available. And so, we tried to show the impact of ARRA on total ASD research funding as well as federal ASD research funding. And you can see that it was a fairly significant piece of the pie during 2009 and 2010.

And then, this is the distribution of those ARRA funds. Please note that in 2010 we got additional data from NSF and AHRQ about their ARRA funding. And so, that is added in with NIH.

Dr. Insel: Say what ARRA is.

Dr. Daniels: Oh, sorry. The American Recovery and Reinvestment Act, which was the stimulus package that came out in 2009 and 2010. And so, there was a significant infusion of funds into many areas, including ASD research. And so, that is all described in detail in the report.

And then, in this figure, this shows the impact of ARRA funding on alignment with the Strategic Plan. And so, in the gold, you can see the ARRA funding on top of what was the regular appropriated funding for all of the different areas and, also, private funders.

So, I also wanted to provide some information on what progress is being made on achieving the IACC Strategic Plan objectives. In 2010, progress was underway on 83 percent of these 78 objectives in the 2011 IACC Strategic Plan. And we do know in our office that, since then, two more objectives have been completed.

And so, I wanted to list here which objectives are not currently underway. So, there are 11 objectives total out of the 78 that have no activity, and they span six out of the seven questions. I am not going to read them all, but they are all here in this slide set, so that you can review them at your leisure later on.

And we hope that that will be really useful to the Committee in understanding what remains, not saying that everything else that is covered is fully covered. Some of them, you will see in the designation in our report we did a red light, yellow light, green light type of analysis.

And the yellow light objectives

represent objectives where either some of the projects recommended or some of the funding recommended was accomplished, but it would require more of a subjective analysis to decide, is that enough? Because in some cases possibly you could spend less money and get it done or you could have fewer projects and still get the actual science done. And so, we didn't really make a determination on that. We just tried to at least objectively come up with some criteria and then evaluate whether we were fully to the level or partially.

You look confused, Lyn.

Ms. Redwood: Yes, I am just curious, when I look back over 2009, whether or not you combined those objectives. Let's say there was funding in 2009 for a project, but, then, none in 2010. Have we looked at cumulative funding over the last three years?

Dr. Daniels: This was not cumulative funding. This was looking at what has happened in 2010.

Ms. Redwood: That might be one of the next steps.

Dr. Daniels: And so, I just wanted to say that all of our IACC publications and more information are available on our website.

And I would like to acknowledge our staff in all their work on these projects. Something that is really great about our staff is that we work very collaboratively, and every person in the office touches every one of the productions that we do, everything from doing the analysis and the research, reaching out to people, getting information back, getting things ready for web and for print publication. Everyone works really hard and they are very pleased to be able to be a part of this important work. And so, we thank you for that opportunity.

For the next couple of presentations, I am going to have a couple of my staff come and join us. First, I would like to introduce Dr. Elizabeth Baden, Policy Analyst in my office. She is going to take you through our brand-new IACC OARC portfolio analysis web tool, which is a database that is online.

Mr. Robertson: Excuse me. I just had a quick question with the documents. Would it be okay to ask it quickly?

So, you had mentioned the change in passing from 2009 to 2010 for the services funding to include training.

Dr. Daniels: Yes.

Mr. Robertson: And this seemed a little somewhat confusing to me. So, I hope maybe you can elaborate. Because when I looked at the document where it described the specifics on that, some of the training that was mentioned was more broadly developmental disability and not necessarily just autism-specific, and didn't necessarily seem like in all cases the training related to research studies. So, can you explain why the decision was made? I am just confused.

Dr. Daniels: This was an attempt to try to be more inclusive of different, in this case, federal programs that are related to autism. With our services agencies, many of them don't have really autism-specific programs. And yet, we do want to include them because they have a different way of looking at it. Some of the agencies, like NIH and CDC, have very specific autism programs which makes it really easy for counting. And so, we allowed the agencies to let us know what they thought was relevant.

In HRSA's case, most of those grants are in the Combating Autism Act Initiative. So, we felt pretty comfortable that they were related to autism. But the goal really is to try to be comprehensive in what we are collecting and making that available to the public, so they can see what information is out there.

Mr. Robertson: Thank you.

Dr. Daniels: Sure.

Dr. Carey: Is this going to cause any issues with kind of tracking funding over time? I mean, you have added something, kind of a different bucket of money, and it may look like an increase. I mean, was this funding there before or is it new funding?

Dr. Daniels: The funding was

already there; it just wasn't being counted. And so, this is something where we feel that over the three years we have been developing kind of a methodology and getting to a baseline. We think that we are much closer to the real baseline at this point, and that will help us with trend analysis in the future. But we wanted to make sure that we are not skipping things that are really important for people to know about that are going on.

Dr. Carey: Part of the analysis is also watching these trendlines. I like to tell people, "Look how much money is being" --

Dr. Daniels: Right. In the first two years of doing any kind of analysis, I think that it is kind of "iffy" about what kinds of trends you can really draw. So, now we are in the third year, and I think we are about ready to be able to start doing trend analysis.

Dr. Insel: But it is an important point because it is a moving target. As we get new agencies and new groups giving us information, we don't want to exclude it, but you can't precisely compare it to the previous year because it is a different pool.

Dr. Dawson: Well, and I think the important thing is how you message it. Then, you can't say, well, it has increased over this period of time. You have to say, well, we have added new people into the tracking.

Dr. Daniels: Right, which is exactly what is listed very clearly in our report, to try to make that obvious that it wasn't an overall funding increase; it was really just better, more comprehensive data collection.

Ms. Lewis: And I guess I would just add that I think it is important, an important potential parking lot agenda item for the IACC to discuss at some point is how are we going to make these distinctions. Because, as one of the partners that works on the LEND program and knowing the basis of that particular program, and while I understand that the funding came in through the CAA in terms of the authority, for a whole host of reasons, it is not an autism-specific program.

I question, then, our consistency in this approach around various efforts and some of the things that certainly we do that affect and impact individuals with autism and other developmental disabilities. And I don't know that this is a conversation for today, but I think it is an important question that has been raised and something that is important for us to discuss in the future.

Because, certainly, the balance and the lack of services research, and funding is a critical issue that the IACC has identified. I feel uncomfortable overstating our investments in those areas.

Dr. Insel: These are good points. I do think this is something that the Committee has to embrace. Of course, the Committee wasn't meeting when this was being put together. So, the office I thought was really obligated to report what they were sent, and that is what they did. I think they have to assume that the agencies and the organizations that are sending in the information have a certain fidelity to the principles and to the definitions that everybody else would use. In this case, it may be a little more complex because it came through the CAA, and maybe it wasn't so clear.

But we can come back to this as a Committee and make a Committee decision rather than leaving it to OARC.

Laura?

Ms. Kavanaugh: I just want to clarify from the HRSA perspective. So, the first two years that we reported, we deliberately only reported research activities and were asked to add the LEND and Developmental Behavioral Pediatrics programs, which are clearly training programs. I mean, I just want to clarify, and it is clear in our mind that one is training and one is research.

Dr. Daniels: Right, and some of the objectives in the plan are related to training. And so, it seemed that we were neglecting some things that were going on before, and we wanted to be more comprehensive. But this is an important discussion to be having.

Dr. Wexler: Yes, just as Education, had the identical experience. It was research initially, and then it was expanded, I think, this past year, which we were happy to do. But they were two pots of money.

Dr. Baden: Yes, I believe it is objective 5LC that addresses practitioner training. But, yes, just the practitioner training aspect.

But what I want to talk to you about is the web tool that we have. So, all of this data that we have been compiling for the past few years is now available to all of you online. We are hoping that this is going to be really useful for members of the Committee and the public and all of the stakeholders in the autism community, to go in and look at the same things that we are able to look at, to come up with these analyses.

Let me see. Let me just go right to a screenshot of the web tool, which is live online. I am just going to walk you through a little bit. So that, when you go and look at this yourself, you will have some orientation to what is going on.

So, one of the first things that you will need to do is choose whether you want to look at the 2009 or the 2010 data. I think Lyn made the point earlier that these analyses are not cumulative, but this would allow you to download data from both years.

So, up at the top righthand of the page -- I even wore my tall shoes; that didn't work -- you can select the year of the funding that you want to look at. Just below that are a couple of lines of introductory text. And then, over on the far left-hand side of the screen -- oh, a pointer; thank you; thanks, Tom -- there is a link where you can read more about the portfolio analysis report, and then, also, a "how to" page on some things that you can do with the web tool, which should be really helpful.

In the yellow box, we have all the different funders that have provided data to us. If you click on one of those funders, you will get a screen that looks something like this, which lists all the funders in the table. And then, the graph has the funders by year, each of the years that they have participated.

Below the yellow box, you have a search field. So, you can do a keyword search for any term that you might be interested in to find the projects that have that data. If you use a search term, it will come up if it is anywhere in the title, the abstract, anywhere in the entry for that project.

Just below the search box are some areas where you can browse by certain categories. So, you can browse by project, funder, Strategic Plan question, Strategic Plan objective, or by subcategory, which Susan mentioned is a new feature of our 2010 analysis.

And if you click on those, for example, the Strategic Plan question, it will come here. You have the graph on the right, and then on the left all of the questions of the plans are hyperlinked and it will go to a list of all of the projects that correspond to that question.

And you can also browse by funder, which does a similar thing. If you click on NIH, you will come up with a list of about 500 NIH projects from whichever year you are looking at.

And when you do your search, you will get a list that looks like the bottom of the screen that has the project title, all of the other data that we have for the projects. If you click on the title, a box will pop up with even more information, including the project description.

And if you want to export this information, it is all available right there. You can download it to a static PDF or an Excel spreadsheet, so that you can rearrange the data to help answer whatever questions that you might have.

So, I think that is it.

Quickly, this is the website where it is within the IACC website. And obviously, all of our staff works very hard, but I especially want to acknowledge Nicole Jones, who is our web developer, who took a very simple idea and came up with what we think is a really amazing and, hopefully, very useful tool.

Dr. Dodson: Good afternoon, everyone. My name -

Dr. Carey: Can I interrupt you? On this topic, two things. One is I think I see a lot of interest in tracking the work that is being done and making this easier. As somebody who has like gone through NIH Reporter a few times, it is not a fun experience. And so, making this a little bit more accessible is very good.

But I would say, sort of on this and kind of the previous talk, I was kind of expecting to see more environmental risk factor work. I mean, based on what I was seeing in trends of what the Strategic Plan was putting out, I think that is probably the kind of thing that people will look at this very quickly and say, a lot of the community, as you know, will look at that and say, "That's what I was hoping to see more of."

Maybe in my mind I am a Strategic Plan ahead because I know I have done the calculations myself of some of the Strategic Plan budgets, and I have said, "Ah, look, environmental risk factors are getting much bigger." In fact, one of them, I took environmental and gene environment, and it actually was now greater, at least from the government side, I think, than pure genetics. And then, I saw that it was kind of small.

So, anyway, I guess it is more of a comment than a question there.

Dr. Daniels: Sure. Matt, I will just address that.

OARC doesn't actually create the research that is out there. So, we just report on what is there. So, it is up to the agencies and organizations to be doing the research, and we just try to keep track and give the information out to everyone.

Dr. Dodson: Right. I actually think that is a good segue to the next publication, which is about ASD research publications.

And again, we don't create these publications ourselves, as IACC doesn't fund these publications. But it is a really great way of looking at the landscape of what is being funded.

Quickly, just to introduce myself, I am Sara Dodson. I am serving as a Policy Analyst in the Office of Autism Research Coordination.

And we just posted this publication online. You can find it on our website here.

I know I don't have much time to really go through this. It is a pretty extensive report. I hope you are very excited to read it when you go home tonight on the plane, on the Metro. But let me hit you with a few highlights and to quickly describe the purpose.

We undertook this report really at the request of the former IACC to aid in the monitoring efforts that the IACC does as well as OARC to assist you all in this charge to really look at autism research efforts across the U.S. In this publication, we have extended that to look at autism research across the globe.

We utilize autism policy expertise that we have in-house, in OARC, and also reached out to Thomson Reuters, who have extensive expertise in scientific publications and data analysis. This really helps us describe the state of science for autism research.

And additionally, we were able to map all of the research publications to the IACC Strategic Plan, to get a really good idea of the landscape of research, what is the level of activity that is happening across the Strategic Plan. This really provides the IACC with another additional tool, really in addition to the portfolio analysis that is tracking funding and inputs. Here, we can look at research outputs in the form of publications, identifying opportunities and research gaps as well.

So, quickly, just to sort of introduce where this report fills a unique role in the purpose of the IACC's activities and OARC's activities, this diagram sort of displays the autism research pipeline and all of your efforts and strategic planning.

And really, where the publications analysis comes in is right after the research outputs and publications stage and taking a snapshot of what is happening in that arena, to really help inform the strategic planning process and serve, again, as another tool.

We mapped all of these publications to the plan. By now, you are becoming quite familiar with the plan. Some of you are already very familiar with the plan.

So, we were able to develop really an automated approach, so that we could categorize a very large number of autism research publications across the seven areas.

And we were really interested, having strategic planning in the background, answering these six key questions. And again, I don't think I have much time to go through all of these. I do want to hit maybe a couple of highlights.

I will start with the first key question here of how much has autism research grown. As I mentioned, we did develop an automated approach, first, to identify autism-relevant publications spanning from 1980 to 2010. So, we used a keyword approach to pull out autism publications, and we identified a little over 25,000 autism-relevant publications between 1980 and 2010, in that 30 year span.

We did notice an interesting trend when we looked at this across time. This graph really just shows the volume of autism research publications. You can see this in the blue line. Really, starting in 1980, you had roughly 200 autism publications that were produced in that year. Looking at 2010, which was the last year of this analysis, there are nearly 2500 publications. So, there is a twelvefold growth starting from 1980.

And we compared this to a comparison group. You can read a lot more about the details of how we developed this comparison group in the report, but suffice it to say that this orange line really shows what we expect to be the growth of autism research compared to the growth of general scientific and services research and related fields.

In 2010, you would only expect to see around 500 autism publications. So, we really see a very interesting inflection point that happens around 2010. Autism research has really taken off in the last 10 years. I think this is one of the things that makes Dr. Insel's job so hard, when he tries to describe scientific updates. Twenty-five hundred a year is a little hard to cover in four IACC meetings.

I think, in the interest of time, I will sort of skip through some of these. There is so much more in the report. I will show you quickly in terms of the automated approach that we use to classify the publications across the plan.

In 2010, this is the distribution of autism publications. I think that you will see that it greatly mirrors what you see in the portfolio analysis. So, it is not too surprising.

It is probably worth noting that, biology being quite large as a basic research area of foundational and really research discovery, as well as risk factors, these are more basic areas of research. They really account for a much larger proportion of the pie than some of the more applied and translational research, which you would see in treatments and interventions, diagnosis and services.

So, I think we see that autism research is a little more basic right now than translational. There are more growth curves, according to the Strategic Plan. There is also in-depth analyses of risk factors and treatments and interventions.

And Matthew's comment recently about environmental research, you can also see how the 2010 publications are breaking down by environment or genetics.

And I think, with that, I am going to need to wrap up. We also performed analyses on funders being acknowledged in the plan. We looked at where research is being published across the globe.

This, quickly, just shows there is research from 50 different countries in 2010. The number of international collaborations you can see by the lines connecting different countries. And we tracked the volume of autism publications by country, and all of that is also in the report.

So, with that, I will probably wrap up and give you guys some time to do more Committee business. Again, you can find the full pre-publication draft at the IACC website here. This is a pre-publication. The final report will be posted on the web in the next few weeks.

And I just want to quickly acknowledge this was a very collaborative effort between the Office of Autism Research Coordination and Thomson Reuters.

I do want to send a special thank you to Duane Williams, who was my counterpoint over at Thomson Reuters. He really helped in planning the report. And, of course, under the guidance of Susan Daniels and really our analysts at OARC, this wouldn't have been possible.

So, thank you very much.

(Applause.)

Dr. Insel: Thank you both, Sara and Elizabeth. Those are great.

Geri, you had a question?

Dr. Dawson: I will try to be brief.

I think this is an incredibly important thing that we do, is track the funding and where is the funding going. It is not only important in terms of the Strategic Plan and the function of this Committee kind of internally, but it really is important when we advocate on the Hill and talk to the government about what kind of funding is coming in.

So, there are two things that I would request about this report. One is I do think we should distinguish between services and research because we are talking about it as research. I know somebody said, well, it was 5C. So, I looked up 5C, and, you know, 5C is really to evaluate and test the efficacy of training programs, right? So, that is not exactly what LEND is doing, I don't think. Maybe you are actually doing an evaluation in terms of services research on the LEND program. But I think we really do need to say this is what we are doing in services and this is what we are doing in research.

Then, the other thing I think that is really important is autism-specific versus autism-related. We have to be careful. I don't know, actually, if only autism-specific work is included in this, but I know if you go to NIH Reporter -- so, Autism Speaks went in and actually went to every single abstract in NIH Reporter or Report that was counted as autism research. And then, we looked to see whether, is it really about autism or is it maybe on the underlying biology of social behavior, which, of course, would be relevant to autism, but I don't know if you would count it as autism research.

And we found that about 70 percent of things that are counted as autism were actually autism-related. I think that is an important distinction, too. Now not to say that those basic things are not important for autism. But like, for example, when we see that, wow, a lot is going into biology, it would be interesting if maybe that reflects the fact that there is a lot of basic biological research that is going on that is relevant to autism right now. So, that would very much shade how we would interpret that data.

So, those are just two distinctions that would help me really kind of get into the details of this and then think about, okay, where does funding need to go from here.

Dr. Insel: And I gather from what we have just seen that you really can get into the details now. So, all of this for anybody to look at and actually get granular enough to say this is what is being done within biology.

Idil?

Ms. Abdull: Thank you.

I just want to echo what Sharon and Laura had said about, when you hear the Combating Autism Act, you think all the funding from that is going into autism, but not necessarily. So, for example, the LEND program, where there is supposed to be training, and you were talking about training and services, a lot of that training is not necessarily training autism therapists. Many of them don't go into the field of autism. It is other disabilities.

And not that we don't want to help them, but it can leave it confusing and inflate and make us think, oh, there is so much money going into autism because of the CAA or because of all these programs, when it is sort of combined funding that comes from HRSA or from others. It is more all disabilities.

And I just wonder if there is a way to break it, so that when the public is seeing it, they are not thinking, "Well, autism funding has increased. Why are there still no answers?"

If there is a way to just put autism research and which training, maybe even the LEND -- I don't know how you could break it because the LEND programs, for example, in Minnesota 70 percent of them are not autism-specific. They are going into other fields.

Ms. Kavanaugh: I haven't seen that specific data for the Minnesota LEND program, but our authorizing legislation specifically says autism spectrum disorders and other developmental disabilities. So, the training programs are addressing the spectrum, correct.

Dr. Insel: Jan?

Ms. Crandy: I actually am on some subcommittees in my State for the LEND. I have had to make sure that autism is included in a big portion, and looking for other State things to partner with them for the parent education piece to make sure that autism is included. But it is big on the milestones, which is going to help us find our kids earlier.

Dr. Insel: Larry?

Dr. Wexler: Yes. Thank you.

Could you comment a bit on what you mean by research here? You know, it sounded like you all are doing a word search along a body of literature. But, I mean, what standard are these studies meeting? Are they single subjects? Are they random control? Are they quasi-experimental? Or is it just they are doing research?

Dr. Daniels: Which publication are you talking about?

Dr. Wexler: Well, she was listing, you know, that there was a huge increase in the research from 1980 to --

Dr. Daniels: Oh, sure. So, you are talking about the publications analysis. So, that was an automated approach that we used, and we trained an algorithm to be seeking this in an automated fashion. It was looking at thousands and thousands of publications. So, it is not something that is easy to do manually.

Certainly, most automated

procedures have some error rate, but we did try to really minimize the error rate and use standard methodology that is used for doing bibliometric analysis for other fields of science.

Dr. Insel: But I guess the question is, Susan, was this looking at PubMed? Or what was the database?

Dr. Daniels: The database was ScienceWire, which is a Thomson Reuters database that does have Medline in it.

And what is the other, Sara?

Dr. Dobson: Web of Science.

Dr. Daniels: Web of Science. And so, that also includes social services research. So, that is why Web of Science is part of it. So, Medline and Web of Science are the main components of ScienceWire, which is a standardized database that Thomson Reuters offers.

Dr. Wexler: I would still be curious -- and I don't want to take up more time -- as to the threshold for what was considered research. When we did, when NICHD did the kind of seminal meta-analysis of reading research about 15 years, they studied 100,000 studies, and they found like 112 were RCTs.

And a lot of practice was being based on the fact that there was supposed research to support practices that were simply not effective based on the methodological approach. So, I am only saying that I think there needs to be some sort of truth in publication here as to what that number of studies represents.

Dr. Daniels: Sure. If you read the report, there was a separation between primary and secondary research. So, things like reviews, and so forth, were not included in the primary research. But if you want to delve into the methodology, we have extensive appendices, and certainly we are happy to engage with you further offline to talk about our methodology and how we did this.

Dr. Wexler: Thank you.

Dr. Insel: We can look at it at the next meeting.

Scott?

Mr. Robertson: Not related to these points, but related to the publications, it really struck my interest that you are looking at these globally. Because I have thought for some time that there may be some topics that some other countries may be studying better at times than the United States. And I would be interested to see some of it broken down to even a smaller level on topics, on how they fit into per country.

To give you an example, I am studying bullying and cyberbullying for my dissertation research. A lot of the peer-review literature comes from researchers from outside the United States. I think that that topic is not alone. There may be some other topics across the lifespan maybe by researchers not in the United States. And it would be interesting to see comparisons on that and to see how maybe they are doing things better in terms of how they are approaching research, et cetera, in other countries and how it could impact how we consider research in the U.S. So, the whole global thing is something I would like to see more discussion on how it could influence how we consider things in research in the states.

Dr. Insel: A great idea.

Last comment from Donna.

Dr. Kimbark: I just have a comment a little bit about the Summary of Advances, sort of going a little bit farther back in your presentation.

These are like, more or less, highlights, 20 highlights, of what has been funded. What I am interested in is whether or not the office or the IACC has any plans in the future to do a program evaluation where you will actually assess the portfolio of research accomplishments rather than just what has been funded.

Dr. Insel: That is precisely the next order of business.

(Laughter.)

Thank you. It couldn't have been queued better.

Dr. Kimbark: I'm a plant.

(Laughter.)

Dr. Insel: Susan, I don't know if you want to take us through these or if I should just jump to the Strategic Plan issue.

Dr. Daniels: Do you want to jump? I can always come back to this.

Dr. Insel: Yes. Okay. Let me quickly, because we do have work we actually have to do relevant to the question you just asked, Donna.

Remember our responsibilities. You saw all of those at the very beginning of the day.

What we have done operationally in the past is to divide up into two working subcommittees, one around services and one around science or research.

The Strategic Plan, which we have talked a lot about today, by statute, is a research Strategic Plan. There is some coverage of services research in that, but it is mostly research that is not specific to services. And that has been the domain of the subcommittee that has worked on science.

I think we are too big a group to be able to actually function, to develop any of the kinds of the things we have just been talking about. I would recommend, and am really just putting this out there for discussion, that we consider as the working part of this IACC having these two subcommittees. By law, we have to come together for any kinds of decisions, recommendations. Advice we give to the Secretary comes from the full Committee.

But the opportunity here is to divide up. We would need to have Co-Chairs. In the past, what we have done is to have a federal and a non-federal Co-Chair oversee these.

Again, it is a FACA Committee, Federal Advisory Committee Act kind of Committee, which means that the members of the subcommittees have to be limited to IACC members, but we can have work groups that include non-IACC members or we can bring in advisors or speakers who may have more experience on a particular scientific problem.

All subcommittee meetings have to be public. As I mentioned, anything that is a product will have to go through full Committee approval.

So, I would like to at least get your input about whether these are the right divisions, whether, if we do this, you are willing to volunteer for one of the two. I can't allow people to serve on both. We have tried that. It is probably not fair to either you or to your colleagues to do that. We have to have Co-Chairs.

And we have to begin meeting very soon because -- and this gets to your point -- we have to update this plan, and we have to do it by December of 2012. What I would like to suggest to you, and following your comment, is that we think about the update not as can we add 12 or 15 or 20 more objectives, but we look at what is there. And rather than just counting the number of grants that have been funded, we ask, what has been the result? What have we got? What do we actually know, based on this?

The way that those objectives were written, the accountability, unfortunately, was very sort of process-driven. We will fund three grants related to "X". You know, it is easy to say we have done it or we haven't, but what, of course, you really want is to answer a question, not to fund grants. Grants are a means to an end.

And I wonder if we are at a point now, since we are three years in, when we ought to be looking at the plan -- three years in from the time the IACC started, and even though we have updated the plan a couple of times, we can now look at it to say, in terms of the accountability that the Committee first wanted, can we look at each of these pieces, the seven questions, and say, what do we know; what do we need now in 2012? And bring in the experts to help us answer that question.

Now I am putting that out there as a suggestion. You can shoot it down or come up with another idea. But, folks, we have got to do something quickly. We are going to run out of time today, and we don't have a lot of time to debate what the update will look like because we have got to get working on this to get it done by law in 2012.

Alison?

Ms. Singer: I agree that I think it is important to go through and see what accomplishments, and really see not just what we have done with regard to the spend, which is what we really count, we track the money that we spend, but we are not really tracking the value.

In our efforts to be outcome-focused and stakeholder-focused, I think we really need to spend some time defining the right metrics of value. I am not sure that counting the number of publications is really any more outcome-focused than counting the number of grants. I think publication is an intermediary step to providing real value to real people. So, I think one thing we need to do is spend some time defining the appropriate metrics by which to measure value.

I also think that we need to prioritize the objectives in the plan. Right now, there are 78 objectives in the plan. The way the plan reads, each is equally important.

So, I think it would be very valuable, even in light of what Peter said in his presentation, to look at where we need to focus, where the gaps are, and really maybe determine 10 items that warrant specific attention and set those as priorities in the new plan.

Dr. Insel: Would it be a new plan or would that be an update?

Ms. Singer: Well, an update.

Dr. Insel: Okay.

Ms. Singer: But focus on where we need to really focus and where the gaps are and what the priorities are. But look at the fact that there cannot be 78 equally-important objectives, and that there has to be some prioritization.

Dr. Insel: Lyn?

Ms. Redwood: Yes, I agree with that approach. I think we need sort of a two-tiered approach in terms of evaluating our Strategic Plan today.

One is whether or not these specific projects that we identified as being important have been funded. And No. 2, did it actually relate to improved health outcomes in ASD?

And I agree, Alison, we do need to define what that Level 2 objective is going to be. But I also think it is very important to have a mechanism in place, when we identify these gaps, to be able to convince Institutes to put out RFAs and to have special-emphasis panels to review those. Because, right now, we are retrofitting the research into the plan. It is funded. And then, we look to see if it fits a specific objective.

When we have gaps that aren't funded and things that we identify as a priority, I think we need to have some type of mechanism to make sure those gap areas are completed, especially when it is really critical information that we need to be able to advance the science. So, I would like to put in a plug for that as well.

Dr. Insel: John?

Dr. Koroshetz: Well, I think everybody has really good ambitions, but I think we have to be a little realistic about what we can accomplish because the things we have just mentioned are really, really hard to do and there aren't real precedents.

So, I think if we are going to go that direction to actually impart value to research, that we are doing something really new, and we would have to just take a little piece and bite it off and try to work it. But we would never be able to do that across the whole spectrum of the research. So, that is one point.

And I have another potential compromise, which is, as you mentioned, the issue is, has the research gone to a health impact? So, the way I see research is that it is on a continuum, and there are some things that are very basic and there is this translational, and then there is this early-phase clinical, and then there is a clinical trial. That is a very simplistic view of things. But it allows the research to be seen on the spectrum.

So, I think that would be something doable, and we could see if there are certain areas of research where everything is kind of botched in in one area and we are missing this piece. So, I think we could do a descriptive process in that kind of a frame. But this idea of a value frame, I think that is a really tough thing to do.

I think it would be worthwhile doing for a certain area. Like you would say genetics; you know, what have we actually learned? We put all this money in. I think somebody could work for six months and maybe get something there, but I don't think we could get it across the whole plan like that. If we tried it, I think it would be very superficial, and no one would be happy at the end of it.

But if we took a piece maybe and did the value part on just a piece, at least we would develop a mechanism, a procedure, and we could kind of expand out. But this other way of describing the research along the continuum I think is potentially doable across the whole spectrum.

Dr. Insel: Anshu?

Dr. Batra: I think what we are doing is using different terms for, I think, the same thing we are trying to say. I don't know if value means the relevance of that research to the community and the community practice. How does it help the individual? And so, health impact or value, I am not sure; I think they might mean the same thing.

Ultimately, for me as a pediatrician who sees families daily and as a parent with a child who is on the spectrum, I want something that will help my child be better, do better, fit in better. And as a practitioner, I want something to offer to my families. So, whether it is value or impact, I think they are the same thing.

Dr. Insel: David?

Dr. Mandell: I don't know that it requires a radical revamping of the process as much as perhaps some more thought and shown effort related to the process. So, for example, if you look at the Summary of Advances now, we select articles. The process is a little opaque as to how those articles are selected. I know that nominations are requested, but I don't know the metric on which they are -- so it is a vote.

And then, the abstracts are cut and pasted into the Summary of Advances? Okay.

Dr. Daniels: Our office writes those lay-friend summaries. We have a science writer.

Dr. Mandell: All right. So, they are lay-friend summaries. I don't know why it is important, though, necessarily. When I read the article, if I think about it in the context that Lyn just said or that Anshu or Alison just presented, I am not -- I think we could add more text that puts the article and what we are saying in a context that maybe adds to the discussion ahead of time and then helps other people understand why we think of those as the critical advances.

Dr. Insel: Yes. So, we are

talking about two different things. I want to make sure we are clear.

What we are concerned about is the law requires us, as one of our responsibilities, to update that document by December. We are meeting in mid-July. The next time we could possibly meet, if we started tomorrow, would probably be October. How are we going to get this done between now and December? You are going to have to tell me because it is not -- I mean, we can sit around and talk about the different documents that have come through already, but every one of you is responsible for figuring out how to update this. And we don't have a lot of time. In fact, we have only got 10 minutes in which to decide.

(Laughter.)

And that is not counting the time we need to discuss public comment.

So, I need some help from you to come up with a plan.

Geri?

Dr. Dawson: So, perhaps what we

need is a plan for this year and then a plan for next year, right? Because you're right, we have a very brief time.

I would say, realistically, this year what we can probably accomplish -- and I think this would be ambitious -- is to have work groups that could try to sort of assess where we stand in terms of gaps of knowledge and what we have actually learned and what we have achieved, looking back, say, since maybe the three periods of IACC or since we have made the Strategic Plan.

And then, the other thing is the prioritization, right? So, if you have 78 objectives, what are the key -- and we can decide how many or how to prioritize, but there does need to be some sense of prioritization. And I think if we could do those two things this year, that would be a huge step forward.

I think next year one could consider, for example, actually trying to define some goals that we think are critically important. So, we think it is really important that we reduce the age of diagnosis and access to early intervention. We think it is really important that we improve healthcare for adults. We think it is really important that we develop medicines that address core symptoms.

And then, if you have those defined goals, then you say, "Okay, what are the gaps? What do we need to get there?" And it can be anywhere along that continuum. It could be that you have to start with basic research, so it is not going to have an immediate impact because you first have to discover; we want to understand the causes of autism. Well, that is not going to have an immediate impact. First, we have got to do the research.

So, I think just finding those goals in the long-run is really critical, but it is probably too much tackle in the short-run.

Dr. Insel: Alan?

Dr. Guttmacher: It must be environmental from sitting next to each other;

that is essentially exactly what I was going to say.

I will return my time to the Committee.

(Laughter.)

Mr. Robison: I would just second that, that I think that the only thing we could reasonably do, given the timeframe, is update the goals and prioritize the goals as an objective for this year. And then, for next year, look maybe at a system of evaluating the value of the research.

Dr. Insel: Alison?

Ms. Singer: So, I mean, are you talking about including updating the "What do we know? What do we need?" to cover what has been learned and what is presented in the portfolio, in the Summary of Advances since the last one?

I mean, I think we could do that. I think we could update each section's "What do we know? What do we need?" and, then, do the prioritization. I think that would be a worthwhile, additional step.

Dr. Insel: Jan?

Ms. Crandy: If we don't improve access to treatment, having a diagnosis and waiting there knowing your child needs treatment, and not being able to access treatment, we have to change that within our states. That has got to be a priority.

Dr. Insel: So, I will take that as you are volunteering to serve on the Services Subcommittee, because that could be very much the essence of what that group would look at.

John?

Mr. O'Brien: So, here is the piece that is still missing for me, and I understand you have got some time pressures between now and the end of the year to update this.

But I am kind of putting my Medicaid Director hat on and saying, what do I need to know about these services in order for me to be able to do some proactive planning?

And certainly, the website with all the research up there is helpful. These documents are helpful. But I can tell you, in the life of a Medicaid Director, you know, they have got to really hone-in on kind of what does the research tell us about what are effective practices, for whom, and for what periods of time.

And so, to the extent that we can somehow think about maybe next year or sooner -- I would vote for sooner, but I don't know want to kind of distract us -- to be able to say here's what we know about what works, both in terms of prevention and treatment. That would be, I think, immeasurably helpful to those Medicaid Directors that are trying to do the right thing.

And so, again, I just want to put a pitch out for kind of summarizing these in a very pithy way -- and frankly, David has done a very nice job with some of the interventions -- in order to be able to translate this for those Directors that, again, are really trying to think through what this means both in terms of the regular Medicaid program, but, frankly, even for the expansion population.

You know, it is going to be important. Yes, we talk about EPSDT; there is no doubt about it. We are a little skinny, to say the least. We have got some boutique programs out there. But, frankly, I am always concerned about it even after EPSDT. You know, we have got folks that then turn 22, and then what?

And so, I think, to the best that we can even begin to influence what some of those decisions are going to be for those adults post-22, it is going to be incredibly important with all the research we have here.

Dr. Insel: In the seven minutes or so we have left, we do need to make a decision about whether we will create subcommittees again. If we want to do those particular subcommittees, one of them will take on this business of updating; the other one will deal with some of the issues we have just been talking about, whether it is access, quality, issues that we have dealt with before, such as safety. I actually have the list up there of the many things that these committees have done in the past. Health disparities and costs and some of the kinds of things that we talked a little bit about today with insurance coverage would all be very much in that services arena.

A couple of hands up over here. So, I want to make sure that people who haven't spoken -- Coleen?

Dr. Boyle: Yes, having been through this update once before, I guess I am having a little bit of a challenge taking what you have proposed here with what the Strategic Plan has. So, last time we took it question-by-question, and we broke into groups, subgroups, based on updating the question, which I feel is the easiest way to update.

I feel like you are imposing a different structure on top of that. So, that is a little confusing to me.

I think it is easiest to start here and maybe taking some of those issues and including them within the context of these questions, and maybe even breaking down into more than just two groups, because it was a lot of work. To do it well -- you know, I think I was on the Subcommittee with Geri and others. I think we did maybe three of the questions, and that is a lot of work to go through the literature and really give a sense of what the accomplishments had been and really feeling like you were reflecting that.

Dr. Insel: Alison?

Ms. Singer: So, I think this is where we talked earlier about needing to bring in some external expertise with regard to some of these scientific issues. I think the process we used the last few times to review the "What do we know? What do we need?" involved bringing in external expertise for each of the seven questions. It was a lot of work, but I think we came out with a product that reflected that work. And I think we need to challenge ourselves to take that on again and go outside and get the expertise that we need, and come up with an update to those sections.

Dr. Insel: This isn't, actually, that different than what we have done in the past. What we had was a Research Subcommittee that did a lot of that, that did break into groups, and that took on two questions at a time.

So, here's my anxiety, which is that this group is too big to do any of the things we are talking about. It is just we can't do it with 30, 25 people around the table. We need to have a smaller entity of people who are much more plugged into the topics.

It is true that we will still need to bring external experts in, I think. But what I am asking is, what should be the working groups for this Committee? I think the whole IACC is going to be very cumbersome to try to -- as you saw today, it is very difficult for us to even stay on schedule because there's so much that everybody wants to get engaged with.

If we are not going to do these two, what would they be? What are the working groups? How will we manage this? What is the process that you think would work best?

Dr. Boyle: So, I was just suggesting that we have subgroups around the questions, and that there may be three subgroups, you know, handling questions that sort of coalesce together; that's all. I wasn't suggesting we all do it.

Dr. Daniels: From an administrative standpoint, you can have other subworking groups under subcommittees. But a subcommittee is an official entity that can vote, and it has all the FACA requirements. I don't think to do little pieces of the Strategic Plan you need a completely FACA-ridden entity. I think within a subcommittee you could decide to break into little groups and work on things.

Dr. Dougherty: I was going to suggest that we have seven subcommittees, being new to this, to write, focus on the questions. Are there seven questions or eight questions? I mean, it is a big group, so you can have a small number of people focus on a particular question.

Dr. Insel: Scott?

Mr. Robertson: I thought the old structure was fine, but I am flexible on that. But if we are going with the old structure, I would like to be involved and be part of the science, or whatever we would be calling it for the Research Committee, you know, working through the questions. I would like to volunteer for that, depending on what it is going to actually look like in place.

But I think it makes sense if we have groups to break it down within the subcommittee. Because, as has been stated, it could be heavy for the whole group as a whole to tackle. And then, it might make sense for the subcommittee to have -- whether we call it subunits or something on there, but yes. So, I think that the older structure worked fine, but I am flexible if the rest of you all want to have something different.

Dr. Insel: Anshu?

Dr. Batra: Yes, maybe my question is a bit naive. But I think science drives services. So, both of those issues are important. So, how do you combine the two, basically?

Dr. Insel: That is what we do. That is actually John's question. That is precisely what he was trying to get at: how do you get the science to inform questions around coverage, around service delivery? But that is what the full Committee can embrace.

I think what I am looking for is a way to operationally get some of our work done that comes back to the full Committee, but where people can do a deep dive on specific questions. If we have to write up new versions of "What do we know? What do we need?" for seven topics, we are just not going to do it by the Committee. We will have to do it in the smaller groups, and we may have to bring in some help.

So, I need your help now. We literally have to adjourn, by law, within a couple of minutes. So, what I need from you is how you want to proceed and whether this kind of a process is workable. We can, then, get your electronic -- you can volunteer electronically as to which one of these you want to be on, and we can figure out the leadership accordingly.

Alison?

Ms. Singer: I am going to make a motion that we vote on the idea of having two subcommittees, one to focus on services and one to focus on science, which would include the topics there, understanding that within the subcommittees we could convene working groups that would bring in external expertise.

Dr. Dougherty: I have a question. Is it time to ask a clarifying question?

Dr. Insel: Denise? Yes.

Dr. Dougherty: So, I guess it goes back to this whether we can divide services and research. If our main goal is to get this Strategic Plan update done, and you said that the Services Committee would focus on things like getting advice to Medicaid Directors, and so forth, I don't understand why we would even focus on that at this point, rather than just everybody focusing on getting the Strategic Plan update done, which should involve some services, right? It is not just a research report?

Dr. Insel: No, it is truly just a research report.

Dr. Dougherty: It is just -- okay.

Dr. Insel: Yes. In the law, it is very clear about that.

Dr. Dougherty: Okay.

Dr. Insel: Yes, Geri?

Dr. Dawson: So, I just wanted to second Alison's motion. I think the reason why it is important to have the two groups is, if you do want us to do the prioritization, I assume that you don't want to just have prioritization within each question, right? That, really, you would want to look at the science as a whole and say these are really the timely issues?

And so, that would be done by the whole group, but you have these working groups to flesh-out and get the "What do we know?" part done.

Dr. Insel: Okay. Last comment, and then we have to decide.

Ms. Abdull: Okay. Well, first, please add me to the services.

I agree with Alison, but I am thinking, based on the research, if there could be the working groups, the genetic, and then the environment, just so we can get both.

And then, for the services, if we can also make sure that Medicaid, the EPSDT is there, in addition to private insurance, which is what Peter was discussing, and that it is just not a law. Congress has to pass the law. We could recommend from here to Timbuktu, but if it is not a law, it doesn't get done. And so, I want to make sure that we send our recommendations to Congress because they are the ones who make and change laws.

Dr. Insel: Yes, we have to. That is also required --

Ms. Abdull: Right, right.

Dr. Insel: -- that we do an annual update and send it to Congress.

We have a motion on the floor. It has been seconded. We have about 30 seconds left in the meeting.

So, let me call the question, whether people are in favor of this division and going ahead with two subcommittees or not.

Dr. Burton-Hoyle: I'll second it.

Dr. Insel: Okay. So, can I see a show of hands for those who would like to proceed this way?

And maybe you can do a quick count.

(Show of hands.)

Okay. And those opposed?

(Show of hands.)

Two. Okay.

So, the motion carries.

What I would like to recommend is, because we won't have time to line up according to these two, if you could send Susan, within 24 hours, which of these you would like to serve on -- as I said, we can only allow you to serve on one -- we will convene meetings of each of these groups, and then in that meeting can work out the Co-Chair.

We do want to do this in the way

we did it before with a Co-Chair from both the federal and non-federal side. That worked pretty well for us in the past.

Dr. Daniels: What I can do is I can send out an email and you can respond to me about which subcommittees you want to be on. If there are any difficulties -- we can only have up to a quorum on any given subcommittee. And if everybody volunteers to be on the same subcommittee, we will have to do more work and we will have to do that on the phone and call another FACA phone meeting.

Dr. Insel: Okay. We are out of time, but, obviously, not out of ideas or out of needs. There is a lot more to talk about.

Final comments from anyone before we quit? Lyn?

Ms. Redwood: Yes, we did not get to address public comments.

Dr. Insel: And we will have to do that at the beginning of the next meeting.

Ms. Redwood: Can we have a called telephone meeting? Because I am worried, Tom, like you. I mean, we need to be meeting almost weekly at this point. And I know there are requirements in terms of publication of our meetings.

When can we meet again?

Dr. Daniels: Yes. So, there is a month lead time to get a FACA notice out. So, if we started tomorrow to get one out, I could get an emergency one. They don't like us to do emergency ones, but that could be done in about three weeks. The normal is four weeks. And then, we would have to see how we could get that accomplished.

Dr. Insel: It might be a good idea, given everything in front of us and the fact that we have run out of time here, maybe we should plan to have a phone meeting of the Committee in about a month. We can do that by FACA rules. Susan won't be around for that, I don't think.

(Laughter.)

But we will have someone else help to organize it. And we can use that time to both go over public comment and, also, to talk about progress on this process. Okay?

Dr. Dawson: Do you need a motion for that?

Dr. Insel: No. I will do it.

Thanks, everybody, for getting engaged with this. As Mike Strautmanis said, it is not easy; it is messy, and it is not always fun, but that is the job. And I really appreciate everybody's willingness to stay the day, to be engaged the whole time, and I look forward to working with all of you on a really important problem.

We're adjourned.

(Whereupon, at 5:06 p.m., the committee adjourned.)