U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, APRIL 8, 2014

The full Interagency Autism Coordinating Committee (IACC) convened in Bethesda, Maryland, at the National Institutes of Health (NIH), 31 Center Drive, Building 31, C Wing, Sixth Floor, Conference Room 10, from 9:02 a.m. until to 5:04 p.m., Thomas Insel, *Chair*, presiding.

PARTICIPANTS:

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

SUSAN DANIELS, Ph.D., *Executive Secretary*, IACC, Office of Autism Research Coordination (OARC), (NIMH)

IDIL ABDULL, Somali American Autism Foundation

JAMES BALL, Ed.D., JB Autism Consulting and Autism Society(attended by phone)

ANSHU BATRA, M.D., Our Special Kids

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

JOSIE BRIGGS, M.D., National Center for Complementary and Alternative Medicine (NCCAM)

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

MATTHEW CAREY, Ph.D., Left Brain Right Brain (attended by phone)

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

JOSE CORDERO, M.D., M.P.H., University of Puerto Rico

PARTICIPANTS (continued):

JAN CRANDY, Nevada Commission on Autism Spectrum Disorders

GERALDINE DAWSON, Ph.D., Duke University (attended by phone)

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) (attended by phone)

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

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

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

DAVID MANDELL, Sc.D., University of Pennsylvania

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

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

JOHN ROBISON, College of William & Mary

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

LINDA SMITH, Administration for Children and Families (ACF)

LARRY WEXLER, Ph.D., U.S. Department of Education (representing Michael Yudin)

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PROCEEDINGS:

Dr. Insel: Thank you. Good morning, everyone, and welcome to a meeting of the full committee for the Interagency Autism Coordinating Committee. This is our April 2014 meeting. We've got a pretty full agenda. I'd like to start just by making sure that those who are listening in know who's at the table here, and we'd also like to hear from people who are members of the Committee who are joining us by phone. Alan?

Dr. Alan Guttmacher: I'm Alan Guttmacher, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

Ms. Linda Smith: Yes, I'm Linda Smith, Deputy Assistant Secretary for Early Childhood at the Administration for Children and Families.

Dr. David Mandell: David Mandell from the University of Pennsylvania.

Ms. Idil Abdull: I'm Idil Abdull. I have a son with autism, and he's 11 now.

Mr. John Robison: I'm John Robison, autistic adult and Neurodiversity Scholar-in-Residence at William & Mary.

Dr. Cindy Lawler: I'm Cindy Lawler. I'm representing the National Institute of

Environmental Health Sciences today.

Dr. Sally Burton-Hoyle: I'm Sally Burton-Hoyle from Eastern Michigan University's Autism Collaborative Center.

Dr. Tiffany Farchione: Tiffany Farchione from the Division of Psychiatry Products, FDA.

Ms. Jan Crandy: Jan Crandy from the Nevada Commission on Autism Spectrum Disorders, and I also serve as the Care Manager for our State Autism Treatment Assistance Program, which provides assistance to families to help them pay for evidence-based treatment. And I'm also a parent of a 20-year-old with autism. Thank you.

Dr. Larry Wexler: Larry Wexler from the Department of Education. I represent Michael Yudin, the Assistant Secretary, and I direct an IDEA discretionary program.

Ms. Lyn Redwood: Hi. Lyn Redwood. I'm a Director for the Coalition for Safe Minds.

Dr. John O'Brien: I'm John O'Brien. I'm with the Centers for Medicare & Medicaid Services.

Dr. Jose Cordero: Good morning. Jose Cordero, University of Puerto Rico.

Dr. Judith Cooper: Good morning. Judith Cooper, Deputy Director, National Institute on

Deafness and Other Communication Disorders.

Dr. Anshu Batra: Anshu Batra. I'm a parent of a 16-year-old with autism and private practice developmental pediatrician in Los Angeles.

Dr. Coleen Boyle: Good morning. I'm Coleen Boyle. I'm the Director for the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention.

Dr. Donna Kimbark: Donna Kimbark. I'm a Program Manager for the Autism Research Program from the Department of Defense.

Ms. Alison Singer: Good morning. I'm Alison Singer. I'm the President of the Autism Science Foundation, and I'm the mother of a 16-year-old with autism. And I'm also legal guardian of my older brother, who has autism as well.

Dr. Susan Daniels: Hi. I'm Susan Daniels. I'm Director of the Office of Autism Research Coordination at NIMH.

Dr. Walter Koroshetz: Hi. I'm Dr. Koroshetz. I'm the Deputy Director of NINDS.

Dr. Insel: Good timing. Tom Insel. I'm your Chair. And who do we have with us on the phone from the Committee?

Ms. Laura Kavanagh: Good morning. This is

Laura Kavanagh. I direct the Division of MCH Workforce Development at the Maternal and Child Health Bureau.

Dr. Matthew Carey: And this is Matt Carey. I'm a parent of an autistic child.

Dr. James Ball: Hi. It's Jim Ball, President and CEO of JB Autism Consulting and Executive Chair of the National Board of Directors for the Autism Society of America.

Dr. Insel: Anyone else on the phone?

[No response]

Dr. Insel: Okay. Well, welcome to all of you. I also wanted to extend a special welcome today to John Robison's neurodiversity class from the College of William & Mary. Many of the students are around the room, which is why the room seems quite full today. We're delighted to have you join us and look forward to your thoughts about this process. And, John, thanks so much for bringing the crew here.

Mr. Robison: [Inaudible comment]

[Laughter]

Dr. Insel: John is going to introduce them later in the morning.

April, as I think all of you know, is National

Autism Awareness Month, and Susan will have some announcements about this month's activities later in the day. I think many of you know that for World Autism Awareness Day on April 2nd, there was a proclamation by President Obama that -- about supporting diversity and acceptance and calling attention to his BRAIN Initiative, which you're going to also hear more about later in the day from Story Landis, who's going to join us for that.

There's also a message from U.N. Secretary General Ban Ki-moon supporting education and employment inclusion in human rights for those with disabilities. That was released on April 2nd and both of those, both the U.N. announcement and the President's announcements, are on our website, so if you haven't seen them, please take a look.

Before we start on the agenda, I wanted just to walk back to the approval of the minutes from the last meeting that were sent out to you. Any comments, corrections, additions, deletions?

[No response]

Dr. Insel: Hearing none, can I get a motion for acceptance of the minutes?

Mr. Robison: I'll move.

Dr. Insel: John? Thank you. Anyone opposed?

[No response]

Dr. Insel: I'll assume we are all in favor. Unless I hear to the contrary, the minutes are passed. And we'll go on to hear about, as we've done at other meetings, a quick science update. I've been doing this for each of the meetings at your request because I just think there's so much going on in the research arena.

I just checked yesterday, and since our last meeting there have been over 1,500 papers published in the last 4 months on PubMed if you just scan for autism, so there's a lot going on scientifically. We can't cover all of that, but I wanted to just hit a few highlights so that we all stay abreast of some of the more important emerging trends on the science side.

And what we usually do, as you remember, is we organize these by the seven questions in terms of the first one. "When should I be concerned?" This paper from Lonnie Zwaigenbaum, Joe Piven, Bob Schultz, and all of their collaborators came out just about 6 weeks ago looking prospectively at parent report data in a bunch of toddlers -- 190 toddlers in 60 low-risk controls in the second year -- to ask is there something about high-risk kids

in terms of their repetitive behaviors. And indeed there was.

Although repetitive behaviors are really common in toddlers, what they saw in this study, which is kind of interesting, was that there was a particular style to the repetitive behaviors in high-risk kids that showed up at the 12-month time point. So it was apparently very early, and this goes along with so much of what we've been hearing about, what can be picked up at the 12-month time point. And those were highly correlated in this case with adaptive behavior and socialization scores and rather predictive of those kids who would go on to develop autism.

In the "Genes Beat Brain and Behavior" story that came out just about a month ago about using genetics to phenotype subgroups in ASD, this really gets to this issue we've talked about so much around the heterogeneity and whether there's something that can be done based on the presenting symptoms.

This group did something actually fairly simple. They simply divided up the large sample. They used the "agree" sample in this case to look at whether -- if you just looked at severity and if

you took the kids who are most severe compared to those who are least severe -- would you be able to make any mileage or make any sense of some of the genetic findings. And it turned out to be actually quite helpful.

They were able to replicate that in a second study, which they looked at, the Autism Genome Project. And they found that these two distinct subgroups that were largely based on just scores on the Vineland scores and the ADOS and ADIR were able to replicate an additional study. So it's one way forward to think about as we begin to try to make sense of these very large data sets.

I wanted to focus a little bit more on this study that's just out in the last few days from Sally Ozonoff and her colleagues, and this is a really thoughtful longitudinal look at high-risk kids. They point out that if you look -- this is, again, a younger sibs, baby sibs study -- that while a minority of them, as we've said before, go on to develop ASD, something like half of them have some part of this broader phenotype.

And the question they're asking is, what is that, and is there some way to detect that? And again, they come up with this interesting figure

that you can detect these differences in development on standardized assessment batteries by 12 months of age in many of these high-risk children now. That's a different group, of course, than the general population which doesn't have an older sib. But it is interesting that while 17 percent go on in this sample to develop autism, which is pretty high, another 28 percent show other kinds of delays or deficits, part of this broader phenotype.

And again, not surprisingly, where they pick up the differences, as you can see in that third bullet, are in reduced eye contact, extreme shyness, and delayed onset of gestures and speech.

And so, they make the recommendation that it is worth picking those up and maybe intervening as early as the second year when we're concerned about this broader phenotype.

What about question two, "How can I understand what's happening?" There's a lot going on there, as I think all of you know. The first paper here actually is not specifically about autism, but about the copy-number variance, the CNVs, that we've talked a lot about in this Committee. These are these usually spontaneous mutations in which a

large chunk of the genome, the whole structural area gets duplicated or triplicated or quadruplicated in ways that are not always entirely apparent why or when that's happened. But there's no question that there's a much higher rate of this happening in children with neurodevelopmental disorders.

What's been so striking is that we're -- originally in 2007 we thought that this was going to be diagnostic. It turns out it happens in lots of people who don't have neurodevelopmental disorders. And so, the question has been, does this mean anything in those other folks? And this study by Stefansson, which looks at the entire Icelandic population and polls every person who has one of these CNVs out of the general population, finds that actually it does mean something and that people with these CNVs, even though they have new diagnosis, show deficits in very specific cognitive domains.

So it's quite an interesting discovery that suggests that even when there's not a syndrome here that these structural mutations do have an impact, and they show both on brain structure, brain development as well as cognitive performance. And

while they're not in this case as impaired as those in the Icelandic population who get a diagnosis, they're sort of midway between that group and the controls. So it's an interesting story, which probably couldn't be done anywhere except in a population like Iceland in which every person in the population is genotyped with great detail.

The next story is one about neuroimaging, and I think it's worth noticing this because Nancy Kanwisher's group, which is one of the most accomplished groups in the world of social neuroscience, took a very close look at the literature around connectivity and white matter tracts in autism and frankly failed to replicate most of what's in the literature in a very careful study. And what they claim is that many of the reports in the literature may really be due to motion artifacts, something that all of us have worried about. So this is worth paying attention to.

At the same time, they do demonstrate that when you control for all of those motion artifacts, there is something that does still emerge, and that's this inferior longitudinal fasciculus, this one large track in the right hemisphere that does

show disruption, but it's, again, not something that is seen more generally in the brain. It's not found in -- she wasn't able to replicate much of what's there in previous studies. So again, I think this is a paper that bears some careful recognition and attention.

I want to spend a little more time on this paper that got so much press last week from Eric Courchesne and Ed Lein and their colleagues, both UCSD and the Allen Brain Institute. And this is *The New England Journal of Medicine* paper that came out, I think it was last week or the week before, suggesting that there are these patches within the cortex, within the neocortex, specifically within prefrontal and temporal areas that are disorganized. That is, when you look in post mortem brain, specifically in children, so these were probably one of the first studies that have been limited to post mortem brains of children who died with a diagnosis of autism and compared to those who died without any diagnosis.

They find these areas with, when they use molecular markers, not apparent with just constructional neuroanatomy or kind of classical cell stains, but when they use molecular markers

that are very precise for detecting the layers of the cortex. And as many of you know, the cortex is like a six-layer cake. It's got -- throughout most of the cortex in the human brain, there are six very distinct layers, and they're particular molecular markers reach of those layers.

And what they found here was that in those children who had a diagnosis of autism, there were sort of these focal areas in which the layers were simply disrupted and mixed up. It was as if the architecture had been broken in some way.
It's a little hard to see on the left -- actually it's very hard to see -- but on the right there is a color rendering of what this looks like. And these are patches that don’t actually make a lot of sense in terms of anatomical or functional boundaries that we know of. But it's still worth paying attention to this because these were found in 10 out of 11 of the children who had had a diagnosis of autism, found in only 1 of 11 of controlled brains that were carefully age matched.

And they were very careful about quality here. One of the things when you see this as an anatomist, you often think this is probably just an artifact of how the tissue has been handled or how

the brains were cut. In this case, they were quite careful to rule out most of those artifacts. And we're giving this a little more clout than we might have because they used these techniques from the Allen Brain Institute that have allowed them to look with much more detail, much more molecular precision at these areas than in previous studies that have been done. So this does bear looking at and certainly will be important to try to replicate in additional studies.

The source of this, of course, is completely unclear. They suggest that this is most likely reflecting an event that takes place at probably about the middle of the second trimester because that's when these layers are being laid down. But the cause of this they can only guess at. This is really just looking at something like a scar that would exist in these particular areas.

What about question three, "What caused this to happen?" Again, the group from California that Lisa Croen and others who are involved with, it looked at the importance of prematurity, and it's really quite striking. This is going through the Kaiser database of some 195,000 births that they were able to look at, so it's a very large sample

size.

And the prevalence of ASD in the kids who were born before 37 weeks was about 1.78 percent compared with 1.22 percent in those who were born full term, so that's a striking increase. But where it gets really surprising is in the kids who were born very, very early, so before 27 weeks, there was a greater than threefold increase in prevalence in that group.

Again, we've talked here about what are the environmental factors that we should be concerned about. I'm not sure that we've seen one before that has a threefold increase in risk, but that very early prematurity, it's not, of course, specific to autism, but that's a very high number to be concerned about.

The other thing we've talked about at times is the finding of rare mutations that will help to identify subgroups within the autism spectrum, like Rett syndrome and Fragile X.

And we have a new one that was reported here by Evan Eichler's group and others at the University of Washington in Seattle. It's this SWI/SNF-related syndrome. That SWI/SNF is a sort of master gene complex found in yeast, so it's not

actually even found in humans. But it's used here to describe a complex of genes that are affected by mutations in ADNP, which is a transcription factor. They've identified 10 children with a diagnosis of autism, and in this case there are some facial dysmorphias. There's a history of seizures as well.

Some have intellectual deficits. But it's clearly a new syndrome. They don't give it a name yet, but it falls within the autism spectrum. It's not going to explain many children who are within that spectrum.

But with all of the de novo mutations that have been discovered -- and there now are hundreds -- there have been very few that are recurrent. So there are very few that occur in more than 1 child or 1 family, but this is one that has been found now in 10 different families. So it's of interest that this, like Rett or Fragile X, is a new syndrome of note.

One other paper to note from this group I thought was pretty interesting -- again out last month -- the same group is looking -- they've been in the copy-number variants, and they've also been interested in the male/female differences. In every study that we look at, the ratio of males to

females is four to one or five to one. For many people, that's focused them on the X chromosome, and the question has always been whether autism is X linked.

What these show is that actually there's something else very surprising going on, that as you can see in the title of this, "Higher Mutational Burden in Females Supports a Female Protective Model for Neurodevelopmental Disorders," so not only for autism, but for a range of other disorders involving childhood epilepsy or intellectual deficits.

Where you find these high rates of copy-number variants these structural mutations in the genome, that girls are somehow protective. That is, they can tolerate a much higher burden of these, either longer, such deletions or replications, or more of them. Frankly, we don't understand that. We don't know what the mechanism is. We don't know what's protective. But it could be, again, one possible explanation of why there is the male preponderance for autism in other neurodevelopmental disorders, and it raises an interesting mystery that, I think, requires considerable more science behind it to figure out whether there's something there that if

you knew what it was would help males to be protected as well, but more to come on that.

Treatments, actually there's been -- there was quite a bit published over the last few months on treatments. I won't go through all of it, but I can capture just a little bit, the 12-month follow-up of the social communication treatment, as well as the one below it looking at the intervention for joint attention.

Both of these have been added to the literature to suggest that these kinds of behavioral interventions have an impact. The impact is lasting. But it's still, I must say, modest, and it's not nearly the kind of effect size that we would be hoping for. But still, it's still useful to have these rigorous studies that are randomized, that are using good outcome measures, and that are looking at long-term follow-ups.

There were a few papers on the use of oxytocin, one out of the Yale group that was published in December, and this one published in *JAMA Psychiatry* in February, which got quite bit of attention. This one probably does require a little bit more explanation. In this case, like other studies, they've used intranasal administration of

oxytocin in a single dose. And here they looked at a couple of things.

They had a project in which they first wanted to find out whether this affected the way the brain was processing nonverbal non-communication, so they showed people -- these are moderately mildly affected, so higher functioning people on the spectrum.

They showed them videos with nonverbal and verbal communication. They showed deficits, as you can see -- well, you can't see the deficits, but you can see at the top that oxytocin increased their ability -- the subject's ability to interpret the nonverbal signals relative to placebo -- and that that also was connected to particular areas that were activated in the brain, and the activation in the brain seemed to correlate pretty well with behavioral performance.

And as you can see here, what was really striking was the increase in the connectivity of two brain areas, the anterior singular cortex, which has got a circle around it and another farther down, the dorsal medial prefrontal cortex, where oxytocin caused a really remarkable increase in their sort of integration or correlation of

activity in these two areas in a way that was -- and it's very hard to read this, I apologize.

But I'll summarize it quickly to say that that increase in the functional connectivity was highly correlated with an increase in performance on this task of reading nonverbal signals, what they called a social perception task.

Does this make oxytocin an effective treatment? Well, the group at Yale felt that there was real improvement in social communication, social performance. But I think we need a lot more information about how that generalizes outside of a research setting.

"Where can I turn for services?" Actually not nearly as much published in the last couple of months around this, but there are a few projects. The Zablotsky et al. paper in psychiatric services added a little bit to what we've heard about the health care experiences and financial impact. This gave us data which was, again, based on the National Survey of Children with Special Health Care Needs, so it's a very large data set -- 53,000 children with ADHD and about 60,000 with ASD, and about 60,000 with ADHD, and another with intellectual deficits.

And the results there basically said that the big issue to be concerned about here is comorbidity, something that we'll be talking about later today. But it was the comorbidity that's sort of the -- that was much higher in the ASD group and that drove many of the costs as well as the frustration of families in terms of health care experiences.

The Lavelle piece in *Pediatrics* was another look adding to data from David Mandell and others around the economic burden. This differed from some of the earlier reports in that it looked not only at the health care expenses, but other expenses.

And their main claim here was that the health care expenses are actually in some ways a minor part of the story that the bigger piece actually costs in what they call total aggregate non-health care -- school, and ASD-related therapies and others. And you can see the numbers in this table. Their aggregate figure was that autism is costing the Nation something like $11 and a half billion per year. I think, David, your numbers are a bit higher than that, and their numbers would have to be increased now because of the increased prevalence numbers from the CDC that we'll hear

about in a few minutes. But again, this adds to the literature of trying to put numbers around what I think all of us understand is very expensive, not only in human cost, but in financial disorder.

"What does the future hold?" And again, this is a topic that we've been concerned about as a Committee that hasn't gotten enough attention. Actually, quite a bit is now being published on exactly this issue about adults with autism and how do we capture more of what's happening as children with autism become young adults and then not-so-young adults on the spectrum.

Michael Rutter and colleagues have this 40-year follow-up, which is worth taking a look at. This was looking at a group of 60 individuals who were identified back in the sixties and seventies, and following up on them to the extent possible in the U.K. The mean age was 6 when they were first identified, and they weren't able to get all of the people into the study.

The 40 that they looked at, what was really striking was how much the disability continued and how poor most measures of functioning were here at this point in middle age. So this is not a very hopeful picture, but of course, we're talking about

the results of treatments that were given 40 years ago, so not necessarily a predictor of what to expect 40 years from now.

But still, I think it's a useful and somewhat sobering picture, as is the next story about employment outcomes, which is a State of the States report. We don't have all of the data from this because it's not available through PubMed as a publicly accessible document. But from the summary, it sounds as if, again, the -- what we've heard before that employment outcomes are not nearly where they should be in terms of looking at young adults, as they call them, transition-age adults with -- on the spectrum and the same kind of picture from the quality of life across the lifespan. We're getting this picture that not only is this an area that needs increasing attention but is every bit as urgent and as serious a problem for public health and for functional outcomes as the many issues we've talked about in terms of children on the spectrum.

Finally, "What about infrastructure and surveillance needs?" This first piece on *DSM-5*, we may hear a little bit about this from CDC this morning because this uses the ADDM database. But

they decided to look at, to the extent they could, the data they had from ADDM and asked would the numbers have changed if they had been using *DSM-5* instead of *DSM-IV* in their analysis. So this is a big group. Over 600,000 children come out of this population.

These are not using the most recent numbers, but the 2006 and 2008 samples, and the results are actually quite interesting. What they end up saying is that instead of having a rate of something like 11.3 per 1,000, the rate would've fallen to about 10 per thousand. So they do suggest that there would be a reduction in the number of cases, a reduction in observed prevalence if they used *DSM-5* criteria. But they also suggest that there might be some fixes for that, so something that we may want to talk about as a group.

The next *MMWR* report is one I think all of you know about, the new prevalence numbers. We're going to take quite a bit of time with that, so I won't say anything more about that now.

And I'll finish up with this study, which you would not have seen. It doesn't mention the word "autism" anywhere in it, but I think it's extraordinarily important from last week.

Interesting, this came out on April 2nd, World Autism Awareness day, and it's the kind of resource that I do think will be critical in understanding the biology of autism.

This is the first transcriptional atlas. That is, it is the first way of studying brain development at the molecular level looking at RNA and how it gets expressed in various brain areas across fetal life and early postnatal into childhood and into adulthood. It's a very large effort. It was supported by the ARRA dollars that came to NIH in 2009, 2010. It's the project that was done by the Allen Brain Institute working in collaboration with several academic sites. We're not going to go into any of the details. This picture is one of several that were in this paper in *Nature* last week.

But the more important part is that this is a publicly accessible database. And it's like any atlas, like any Google map that's already been highly mined by people interested in autism and other neurodevelopmental disorders. It was based on this map that -- even before the authors here published this last year that -- a group took the major genetic findings in autism, which really

didn't make any sense if you put the 9 or 10 biggest hits and try to put them together to describe a pathway or a functional circuit. That just didn't work because they were looking in the adult brain.

But when they went to this developmental atlas, which was already available electronically, though it hadn't been published in *Nature* yet, what they were able to realize is that something like seven out of the nine genes fit together in the second trimester. They were not only found expressed in the brain, but they were expressed in the same region of the cortex, in the same layer of that region, and even in the same cells. So it in a sense solved the mystery, which would never have been solved except they had a Google map. They had this atlas available to them.

I think that's the first of what will be many, many studies that will be able to use this kind of a resource. So while the paper itself doesn't mention autism, it's extremely helpful to have these kinds of data available. And it's a big expensive effort but one I think will pay off handsomely as we try to understand exactly when and how this disorder develops.

So a very quick survey of recent findings, it's certainly not comprehensive. There's much, much more that's happened in the last 3 or 4 months. But I wanted to give you some of the highlights and make sure we have a chance to, to the extent possible, stay abreast of some of the science that's been coming out.

So unless there are any questions, we've gone a little bit over time, but good. Let's move forward, and let me ask Jon Baio from the CDC to join us and take us through the new prevalence numbers.

[Pause]

Mr. Jon Baio: Thank you, Dr. Insel. It's a pleasure to be here this morning. I've followed the work of the Committee for several years, and it's really important work that you do. And I'm happy to be here this morning to talk to you about -- give you an update on the latest prevalence numbers from the Autism and Developmental Disabilities Monitoring Network.

I know that some of you are likely familiar with the work that we do. I'm going to try to gloss over some of the methods. We have very detailed publications on this. I'm going to try to get

through that pretty quickly and save some time for questions at the end because I'm sure many of you have questions about this.

We've been tracking autism for several years at the Centers for Disease Control, and the main overarching question that we're trying to answer is how common is autism spectrum disorder. We've seen lots of different estimates come out through the years, not only from CDC, but from national surveys and other international studies. They use a variety of different methods to ascertain cases. They also through the years have applied a variety of different case definitions. Dr. Insel talked to you a little bit about our recent publication on the changes that are forthcoming that have actually been published in the *DSM-5* and will obviously affect our prevalence estimates.

And also, it's just very challenging to track autism prevalence. We don't have any biologic markers, although from the presentation earlier it sounds like we might be getting a little bit closer, but I think we're still a long way off for that.

We've come a long way since 2000 when the Children's Health Act required that CDC expand its

monitoring of autism and other developmental disabilities. And we created a network of funded entities that come under the umbrella of the ADDM Network. And the ADDM Network is working together to understand the magnitude and characteristics of the population of children with autism and related developmental disabilities to inform science and policy.

We've got 11 funded sites currently for ADDM. CDC also participates as the 12th ADDM site. We conduct autism prevalence among 8-year-olds in all 12 sites, and we're also piloting autism surveillance among 4-year-olds in 6 of the sites. And most of the sites also track another condition in addition to autism.

This is a map of our current funded States for the 2010 and 2012 surveillance years. I'll be talking to you today about the 2010 surveillance year. We're underway with data collection for the 2012 surveillance year, and we'll have a report out on that in a couple of years. We're also beginning a new phase of funding. There will be an announcement coming out in the next few months, and we are encouraging universities, health departments to apply for funding and become a part of that

Autism and Developmental Disabilities Monitoring Network.

You can see some of the sites are monitoring 4-year-olds in addition to 8-year-olds, and we will also be able to follow up those 4-year-olds at age 8 during the next cycle. So we'll really be able to see which children were more likely to be picked up at age 4 and those that were not picked up until they were 8.

Real quick, our methods involve multi-source, multi-site records-based surveillance. We screen and abstract records in the community at a variety of health and education sources. And once those records are compiled, a team of clinicians reviews them -- the information in those records -- and applies a standardized coding scheme currently based on the *DSM-IV* diagnostic criteria. As I mentioned, in the next phase, in the 2014 and 2016 surveillance years, we will be applying both the *DSM-IV* and the *DSM-5* to our data to determine what the differences between those definitions are.

We do a really rigorous process of quality control where we re-review 10 percent of the records to maintain quality. We also -- once the records go through clinician review -- we also try

to get a 10-percent sample and determine agreement on final case status in that sample. And we always shoot for 90-percent agreement between the two clinicians.

We did complete a validation study in Fulton County, Georgia. It was based on data that's almost 10 years old now. But at that time, we were fairly confident that when we called a child an "autism case" that it was corroborated by diagnostic instruments. Although at that time what we were finding was that we were only -- estimated that we were only -- picking up about 60 percent of children with autism in the community, that several children were not being picked up.

And to describe that a little bit, I think I'll tell you a little bit about our autism case findings net. So we start off with all of the children who are receiving services in the community at the programs where we go and collect data. Within that group, there's a group of children with select diagnostic and eligibility criteria whose records we review. Of those children, we review and abstract their records and send them to the clinicians. And the clinicians identified a subgroup of these as meeting the

autism case definition. But we also acknowledge that there are children with autism living in the community who are either not being served in these programs in the community or there is insufficient information in their records for us to ascertain them as having autism. We have a large population-based study. We use multiple sources, including health and education records. We also collect information on comorbidities and the presence of other developmental disabilities, which is a key strength to our methodology.

As I mentioned, we are aware that we are under-ascertaining children that are not -- especially children -- that are not being served in the facilities where we go to collect data. And also something that we continuously deal with is imprecision in population counts. We have lots of confidence in the decennial census counts that we get, so this 2010 data that I'll be reporting today, we have very accurate data on the population denominator. However, during the decennial census years, we base these on projected estimates, and those can vary widely.

Most of you are familiar with the work of the ADDM Network. The first report was published in

2007, and we identified 1 in 150 8-year-old children with autism in the communities that were covered there. In 2009 we released a second report for the 2004 and 2006 surveillance years. And when we compared 2006 to 2002, we noticed a 57-percent increase between those two time points. Our third report came out in 2012, and at that time we identified 1 in 88 children, so already by 2012 it has nearly doubled from the 2002 estimates. The prevalence increased 78 percent from 2002 and increased 23 percent since the previous estimate from 2 years before.

Our 2010 data, which I'm going to be talking about today, is based on children who were born in 2002. They were 8 years old in 2010. We had 11 ADDM sites reporting data for this surveillance year.

We covered an 8-year-old population of over 350,000 children, and we identified over 5,000 children with autism. These are not projected numbers. These are actually 5,338 whose records were reviewed and who were determined to meet the diagnostic profile of ASD based on *DSM-IV*.

This produced a prevalence of 14.7 per thousand, although we saw a large range of prevalence estimates across sites, from as low as

5.7 per thousand to as high as 21.9 per thousand.

In addition to the prevalence estimates overall, when we combine all the data from all the sites, in addition to those going up over time, this illustrates how within each individual site, the prevalence estimates have been increasing over time as well.

When we look at the prevalence by race and gender, we noticed that males outnumbered females by about four and a half to one. We also found that white children were about 30 percent more likely than black children and about 50 percent more likely than Hispanic children to be identified with ASD.

I mentioned the variation across sites. The highest prevalence estimates were for New Jersey, Utah, North Carolina, and Maryland. Three of the sites had very tight estimates, between 15 and 16 per thousand. And the four sites in the network with limited or no access to education records also reported the lowest prevalence estimates among all ADDM sites. And as you can see here, the triangles in red represent the sites without full access to education records. The triangles in green have access to education records on the majority of the

population. And you can see how those estimates differ with the combined estimate from all sites right there in the middle.

When we break the estimates down by the level of intellectual ability, we restrict this to the seven sites that had sufficient data on intellectual ability. These tend to be the sites that have access to education records as well as that is the primary source on IQ data. We found that 30 percent, 31 percent of the children with ASD had IQ scores in the range of intellectual disability or less than or equal to 70. And 46 percent, or almost half, had average to above-average intellectual ability, or IQ, greater than 85.

And as most of you have been following this for years will know, that really represents a shift. When we started doing this in ADDM, it was quite reverse. Almost half of the children with ASD had intellectual disability, and only about a third had average to above average in intelligence.

When we stratify by intelligence ability, some of the real striking things that we see are, for one thing, when we look at the male/female prevalence, you can see the prevalence among males

without intellectual disability is 16.8 per thousand. Males with intellectual disability, 7.3 per thousand, so the prevalence of ASD among males with intellectual disability is higher than the prevalence among females all together -- so that really illustrates the striking difference in the male/female ratio.

One thing I will mention: About 30 percent of females had intellectual disability -- about 36 percent -- I'm sorry. Thirty percent of males had intellectual disability. About 36 percent of females had intellectual disability. Again, this is much lower than our early estimates when most of the females we were identifying had intellectual disability.

Also when we look by race, some of the real interesting things we find is that the prevalence of ASD among whites was twice as high for children without intellectual disability compared to blacks and Hispanics. We also see the prevalence of ASD with intellectual disability. It's actually higher among blacks than among whites and Hispanics. And so, when we look at this, we see that most of the difference between the prevalence among whites and blacks can be explained by children without

intellectual disability. And most of the difference between blacks and Hispanics in the overall prevalence estimates can be explained by children with intellectual disability.

The age of earliest known ASD diagnosis is something that we monitor closely. And this report was fairly similar to our last report where the breakdown by diagnostic subtype was very similar, almost half with autistic disorder, almost half with PDD, and about 10, 11 percent with Asperger's disorder. We can also see that the age of diagnosis among children with Asperger's is much later than among children with autistic disorder or ASD PDD.

The overall age of earliest diagnosis for all subtypes combined was under 60 months, as it has been since we started this. But I think that this illustrates really closely that while the mean hasn't really moved over time, the sheer numbers of children who are receiving a diagnosis in these communities is increasing greatly. And I know the numbers at the bottom are a little bit difficult to understand, but the largest population base we covered in this slide was in 2002. And we actually covered less of a population in 2010, but you see exactly how many more children we were identifying

in those communities. I think the important thing here to remember, though, is that this mean age of diagnosis is not shifting very much. More children are getting identified at all ages.

Real quick, I'll go through some of the implications of our findings. Obviously we still see autism as an urgent public health concern. We continue to see prevalence estimates increase in most of the ADDM Network communities. We do feel that this has a lot to do with better identification, especially among certain subgroups -- racial ethnic minorities, children with average to above-average intelligence -- but more needs to be done in that area. And we're really working to improve identification among all groups.

Also, the age of diagnosis has not moved very much. We know that we can move that age of diagnosis much lower, but we haven't seen very much. We're encouraged that more children are getting diagnosed and more children are being recognized with autism in these communities. However, still about 20 percent of the children we identify with autism have not been definitively diagnosed or classified with autism in the community. These are children that we are

classifying based purely on their behavioral profile.

We will do a lot of work to understand the variation that we see in the prevalence estimates across time and space. We've got a really detailed trend analysis underway right now. We're compiling all of our data from all of our sites from 2000 through 2010. We have six data points, and we are looking at the census tract level for a number of predictors. We don't have individual-level data on socioeconomic status and other characteristics.

However, we do know -- based on geography -- we do know some of the socioeconomic indicators in these communities, and we will be doing a longitudinal study to tease out some of those differences and understand which of these differences are more attributable to ascertainment and those that are things like access to health care, geography, things like that, as well as differences that are related more toward other factors, such as prematurity, low birth weight, birth factors, things like that.

Another big thing that we have coming up that I mentioned -- looking at the difference between *DSM-IV* and *DSM-5* we are coming up with -- as we

have a behavioral coding profile for the *DSM-IV*, we're coming up with one that matches the *DSM-5* criteria. The report that Dr. Insel mentioned earlier was really based on trying to map the behaviors we code under *DSM-IV* to a *DSM-5* counterpart and using the coded data to try to bridge that map. We're going to start from scratch beginning in 2014. We will come up with a case definition that is based purely on the *DSM-5* and not just estimating or cross-walking the *DSM-IV* behaviors that are coded.

And then finally, the limitations that we have in our data -- we have very little data on the severity of autism symptoms. This is something that is going to be required for a diagnosis of autism under *DSM-5*. And yet, clinicians do not have access to a readily available, easy-to-administer, reliable tool that they can use to document the severity of autism symptoms. And it would really help our work tremendously to be able to separate the data out that way, as well as for cost studies, economic studies, and other research.

In addition to the prevalence reports that you all hear about in the news all the time, we have -- like this *DSM-5* paper that came out which I need to

add to the list -- we have a number of articles that come out from the ADDM Network data during the time in between our big prevalence reports. And so, please keep an eye out for new information where we really dig deeper into the data and find out a lot more about this. I talked about some of our next steps. We have a lot of data that we obviously cannot get out in these prevalence reports, but we will be doing a lot of additional work.

My colleagues around the country have been involved in this for -- it's been 14 years now, and we have a great group of folks that are really dedicated to this work. For more information about this, please see our community report. I didn’t update this slide. We do have a new community report for the 2010 surveillance year where we go in depth in the data in the individual States, and this is available for download from our CDC web-site.

And just so that everybody is clear -- what we do at CDC besides the prevalence study -- we do a lot of work to promote early identification and to understand risk factors and phenotypes associated with autism. And our tracking work really feeds into this work at CDC as well internationally.

And I am going to stop there and take questions. I thought I had a red light that didn't start, so.

Dr. Insel: You're doing fine. Thanks very much, Jon. This is great.

Mr. Baio: So let's do some questions and --

Dr. Insel: Let's start with Jose.

Mr. Baio: Dr. Cordero?

Dr. Cordero: Jon, great job. Thank you.

Mr. Baio: Thanks.

Dr. Cordero: I have two questions related. One really is about the prevalence among minorities, African Americans and Hispanics. And given that this is a surveillance based on basically administrative prevalence, either there's a diagnosis or enough symptoms in the school record to make a call that the child meets the surveillance definition. And then looking at early identification, can you tell us a little bit more about how has it changed, especially among Hispanics and blacks? In the slide that you showed you distribution by age and earlier diagnosis.

Mr. Baio: Sure. Well, with respect to the change in prevalence over time, I did mention a couple of tricks with the denominator data that we

used for these. We are planning a trend study that we really are going to have a lot of confidence in the denominators we use. And we are going to be able to look back over time and understand the trends within different race and sex strata as well as within sites, similar to how we reported in the previous report.

And so, in the previous report we did see that the biggest increases over time were among black and Hispanic children. And we believe that that has mostly to do with better identification in those groups, outreach efforts to identify better recognition, and improvements in access to services. However, we see those disparities still exist, and we're doing a lot of work in these local communities to try to understand why those differences exist and what can be done to improve recognition and access to services among those groups.

In terms of the age of diagnosis, there really isn't very much difference in terms of the proportion of children with a community classification or the age at which they are initially diagnosed. There is not much difference between white, black, and Hispanic. However, as you

saw from the slide I showed on the prevalence by intelligence disability, you see that the black children that we're identifying with autism, they are more likely to have intellectual disability.

And so, those are children who are typically more likely to come to a provider's attention early, might be recognized as having autism earlier.

So we know that there's a -- there are factors that would indicate that we might expect to see a lower age of diagnosis among some of those groups when, in fact, we don't, so more work to do on that, but obviously a lot of it has to do with access to programs, as well as cultural differences and ways that people seek out help in the community and seek out services.

And also in the Hispanic populations -- very interesting that the Hispanic population in Georgia is very different from the Hispanic population in Arizona, in New Jersey. And those represent different cultural groups, and we're very interested in looking at those in much closer detail to understand what some of those factors are.

Dr. Insel: John.

Mr. Baio: Other questions?

Mr. Robison: Thank you for presenting all the data you just did. I have two questions for CDC. First, you said that minorities -- minority kids with autism diagnoses are more likely to have the intelligence disability diagnosis, and they are diagnosed in lesser numbers than white children.

And I wonder if that is really an indictment of our health care system suggesting that they had a lower standard of care and we only noticed the more severe problems. And if so, what would CDC do about that to study it and nail it down so that we can take some positive action?

The second question relates to your statements about diagnosis of girls. You said that boys outnumber girls in the group here by four to one still, but you've also said that the age of diagnosis for girls is later. And since we're basing our 1 in 68 number on studies of 8-year-olds as we have right along, isn't it possible that we're missing significant numbers of girls because our cutoff is age 8? And if so, could we look at a study of girls in particular that was maybe at age 12 and see how that might correct both current and previous data?

Mr. Baio: I love that question because I've been asking for us to be able to do prevalence studies of older children for a long time. I think it's really important to see not only in an older age, but even to follow up these children from age 8 to age 12, and see if we're really still picking up the peak prevalence at age 8 as we did when we first started this study and as we've based our methods on ever since based on the Atlanta data.

We noticed that the peak prevalence was at age 8 and that certainly some children are diagnosed, identified in the communities. We do feel that by age 8, most of these children would've come to the attention of a provider in the community and that we would have at least some information in our records to base a case definition on. Would love to follow up at an older age.

Again, to be clear, our methods do not rely on the diagnosis of these children. Some of these children were diagnosed when they were 8 years and 11 months old right before the cutoff from the data collection that we do. And so we do realize that some of these children are going to be identified after that age, so definitely I would love to do some additional work in looking at that.

I'm not so sure that it would give us more information about the sex differences, although it really has been remarkable how -- when we started this, the females that we were identifying were much more severely affected children with lower IQs and that children that were the more obvious presentations. And those were the girls that were being picked up when we first started. Now, we're finding --

Dr. Insel: Jon, we're going to have to move on pretty quickly. But what about the health disparity question?

Mr. Baio: In terms of health disparities, we do see that children from minority races and ethnicity are more likely to be seen only in the education system and not in the health care system that we're going to collect data. And so, I think if we're going to look at that, I mean, I think, true, you know, there is a health care disparity, but most of these children are identified in the schools. And I'm not sure how that would play into a health care disparity.

Dr. Insel: Larry, let's get one last question, and I know there's lots more to ask. We'll have time to discuss later. And, Jon, will you be around

the rest of the day?

Mr. Baio: I'll be here until after lunch.

Dr. Insel: Okay.

Dr. Wexler: So I won't actually ask a question so Lyn will be able to ask the last question. But I just wanted to say that, you know, from our perspective, from the Department of Education, you may be aware that at the end of March we released our annual civil rights data collection, which is a census collection from every school district in the country.

And these data are really an artifact of what we see nationally across all disabilities. And that is there is something counterintuitive to African Americans being identified with intellectual disabilities at two, three, four times the rate of white students as well, and Hispanics also being really disproportionately identified. That it speaks to something beyond whether they're being seen in health care and beyond, you know whatever.

But these data, you know, whether it's restraint and seclusion, and you look at what's going on or whether it's identification across disability categories, there's still a consistent racial disproportionality that's happening. And

this is completely consistent with what we're seeing within our civil rights data collection.

And I encourage people to look at the civil rights data collection briefs that just came out, which are very, very succinct and very stark representations of the data that are going on.

But I applaud CDC for a terrific study and a great presentation. And I will yield my final time to Lyn --

Mr. Baio: Thanks, Larry.

Dr. Wexler: -- if allowed.

Ms. Redwood: Thanks so much. It's a wonderful opportunity to have you here to ask questions. And I have four hopefully quick questions and then just one comment.

You mentioned that 20 percent were identified by the CDC surveillance program but had not been diagnosed by community professionals. I'm just curious whether or not that number has been steady over time. Is that an increase or a decrease?

Number two, in the National Survey of Children's Health data, approximately in the last few years, anywhere from 24 to 30 percent of children no longer carry the diagnosis of autism. So I'm just curious whether or not -- within

children that we're recognizing now that don't have intellectual disability -- if there's a way that we can follow these kids over time, because I'm just curious how many of these 8-year-olds will continue to have a diagnosis at 18. I'm also wondering what happened in Utah with the 6-percent drop in prevalence. That wasn't really addressed. And at what threshold would CDC consider autism to be considered an epidemic?

The comment is when you re-compete the data, can you make sure that the sites that you select have educational data and medical records both so we can have more consistency and try to keep those sites consistent over time so we can look at the prevalence over time? And that's actually in some comments in our Strategic Plan.

Mr. Baio: Okay. Great. Well, to answer, I'm going to go in reverse order. No, we can't hand select the sites that are in the Network. We have a set criteria that we ask people to respond to. And it's an open application, and so anybody from a health department, university who's interested in doing this work is welcome to apply. And the applications are rated by an external panel that, you know, that is -- that we don't have very much

influence on that.

Dr. Insel: Can I interrupt for a second --

Mr. Baio: Yes.

Dr. Insel: -- because this is such an important issue --

Mr. Baio: Okay.

Dr. Insel: -- that does get glossed over. As you go from year to year, even when you have the same State that's involved, are we looking at the same sites? Is it precisely the same sources within Utah or Colorado, or are they shifting from year to year?

Mr. Baio: Well, that's a great answer to the third part of your question, which is for the most part, these sites are -- cover the same geographic area that they've covered in the past. We do have some differences over time. Some sites are actually able to get access to education records in part of the surveillance area. And to the point that Lyn was making, we cannot even require for sites that applicants have access to education data because there is a Federal law that is interpreted differently across different sites.

And the reason that the current four sites don't have complete access to education records is

because of local interpretation of that Federal law. And so, you know, we can't really put out an announcement that requires people to interpret the Federal law the way that our other sites interpret it.

Dr. Insel: Again, I'm sorry to interrupt. Why can't an announcement require that as a minimum quality standard that both sets of records would be available? And if a State doesn't do that, you wouldn't be able to apply.

Mr. Baio: Yes. I mean, it really is considered almost a necessity for our methods. However --

Dr. Insel: So wouldn't that be a minimal requirement for being able to compete?

Mr. Baio: I think there's a legal issue, a universe of legal issues.

Dr. Boyle: So, you know, we have worked with our procurement and grants office, and that's their guidance to us. We have criteria in that help us in terms of selection, and we'll have, you know, stricter criteria this time around.

Mr. Baio: It definitely carries weight in the application process. However, we can't require it. So, to the third point -- the differences in the geographic areas. In our 2006 report, you might

remember there were 11 sites. In our 2008 report, there were 14 sites. That was part of the same funding cycle. In the very last year of that funding cycle, three of our former sites -- we received additional money, and we were able to fund three sites who had applied but were unsuccessful for the second round of funding. And those were New Jersey, Utah, and Arkansas.

And because they were coming in on the very last year of the cycle and they had to do the data collection in one year, they focused on a very small geographic area. And so, in Utah they focused on Salt Lake County, which was a population of about 2,500 children. In Arkansas, they focused on one county, Pulaski County. And in New Jersey, they also focused on one county as well.

When we come to the 2010 surveillance year, those sites all applied and were successfully funded to cover the minimum population required by our study, which is 20,000 children. And so, the Utah prevalence is based on, instead of being Salt Lake School District in the middle of Salt Lake County, in the middle of the diagnostic center there in Utah, they've expanded, and now they include one predominantly rural county as well as

two suburban counties. And so, I think that that has a lot do with the difference.

And when we look at the prevalence over time and we can confine it to the census tracts that were part of that Salt Lake district and we see that over time, we'll be able to see if the prevalence is, in fact, increasing in that area relative to the new area that's been added.

Ms. Redwood: What about the 20 percent of children that are --

Mr. Baio: The 20 percent who were not diagnosed, when we started this, it was down closer to about 70 percent in MADSPA. When we did '96 -- MADSPA '96 -- it was under 70 percent. With the ADDM Network over time, again different sites, different geographic areas, but it's increased from 72 percent to 77 percent. I think it was 79 percent in 2008, and now it's 80 percent.

So if we looked purely at the number of children diagnosed in the community, whether they were receiving autism special education services or had a *DSM-IV* or *ISD-9* diagnosis of autism, if we look at that over time, we would actually see much more rapid increases in the prevalence over time.

However, our method, we use the same method

over time, and we're actually able to compare those independent of the community diagnosis. I will mention that most of the children who do not have a community diagnostic have at least a suspicion of autism noted or somebody is considering an autism diagnosis.

The final question was about retention of an ASD diagnosis. And I don’t how visible this is to everybody, but the first article up there was from last year where we actually looked at children who had been diagnosed by the community, but then another professional came along later and said, no, this child does not have autism. And we looked specifically at those children. We compared the children from the 2002 to the -- I'm sorry -- from 2006 to 2008 surveillance years. And we looked at that subgroup, and we saw some distinct differences in the characteristics of them.

However, we still counted them as having autism for our surveillance system because they met the behavioral profile, and our clinicians were satisfied that this was an autism case comparable to the other children we identified. Another follow-up?

Dr. Insel: Well, there's, you know, a lot more

to talk about. Going back to the Strategic Plan, and I think Lyn is right to bring up several of these questions -- there was a call for a population-based study rather than just an administrative survey. And that, I gather, is underway with Autism Speaks using the South Carolina ADDM sites as a jumping off point, though South Carolina is not in the most recent data.

Mr. Baio: That's right. We were unable to get their complete data in time to be included in this report, but that study is underway in South Carolina. I think some people at CDC are involved in that. We'll mention that is not a CDC-funded study, and we haven't attempted to do that population screening like that in any of the ADDM Network official --

Dr. Boyle: So just to clarify terminology, this is a -- the ADDM Network is a population-based approach. So it defines a population. It has a specific methodology to tap into every source within that community to identify any case that meets the surveillance criteria. The difference with South Carolina is they're actually going to do screening, which is very different. So we refer to this as population-based.

Dr. Insel: So the reason I bring it up is that in the slide you showed, Jon, you had a 60-percent sensitivity when that was actually checked in earlier.

Mr. Baio: In 2005, yes.

Dr. Insel: So, Coleen?

Dr. Boyle: Yes. So again, that was years ago, and we do feel that communities are doing a better job essentially in identifying children in the autism spectrum. And you know, that reflects what Jon said in terms of the changes of children that are coming into the system that actually have a community diagnosis, or they're in the special education category for autism. We can see that in our data. That's changed over time.

Dr. Insel: And that's what's gone from 60 percent to 80 percent?

Dr. Boyle: From 70 to 80 percent over that time period.

Dr. Insel: Seventy to 80 -- okay. Well, I'm sorry we kept you longer than scheduled. We're way behind already in our schedule, but there's so much here that has gotten a lot of attention and that we, as members of the Committee, really care about.

We may want to circle back to some of these

things with you, Coleen later because I know there are still questions around the table.

Mr. Baio: And we do have other reports coming out this year. We've got a report on the 4-year-old prevalence. We'd be happy to present that here as well as some of the other work we'll be doing in the coming years. So any time you need us to come back, we're happy to come and answer your questions and provide an update.

Dr. Insel: Thank you, Jon. We are going to quickly move on to Linda Smith to talk to us briefly about Birth to 5, and we'll try to catch up with some of our schedule.

Ms. Smith: Right and I think I can do this fairly quickly. This is an initiative that we started at the Administration for Children and Families. And coincidentally, we ended up having it follow the -- which do I click here? Okay. It ended up being released on the same day as the CDC released the autism prevalence numbers. And so, it was quite a nice merger of two initiatives within the Department.

But what we were trying to do here is to really take a look at how we can get screenings out across this country at the earliest times for young

children. As many of you know, in my office we have Head Start, childcare, and a number of the early-childhood programs, and we touch the lives on a regular basis of close to 12 million children. And so, our goal with this was to get the screening instruments out there in a way that we can get to universal screening of our children at the earliest possible times.

So I'm not going to go into this other than to say that our goal was also to help identify instruments and give help to the early childhood community so that they would know how to screen children and how to get them referred to the appropriate services. So I think that was our goal, and I won't read these slides to you in the interest of time.

This actually is a son of our staff who worked on this initiative, and he was actually conceived and then born when we conceived this project. But one of the things that -- as I said, our goal here is a public awareness campaign to help people understand the importance of this and the important role that families play in this. So one of the pieces of what we were trying to do was to ensure that there was a component in the screeners that

engaged the families in the screening of young children.

So we ended up with the initiative Birth to 5: Watch Me Thrive! And this just goes through -- I'll skip through these, a number -- these are the partners that partnered in this. And I think one of the feedbacks that we've had on the whole project is it's about time government is doing this kind of work. If you look at the number of people involved in this over the last year and a half that is a wide spectrum of the Department of Health and Human Services as well as the Office of Special Education over at ED, so we all worked on this project in an effort to try and get this universally out there through every possible medium that we could.
In terms of the strategy, as I said, it was a public outreach campaign.

I think one of our messages has been trying to help families understand that, by ensuring that their children get appropriate developmental screening, that we help them celebrate milestones rather than put a negative spin on this -- that we're looking for problem. That by understanding the development of their child, they can celebrate those things that are very important in children's

lives, such as the first steps, the first words, and so on. And so, that's really the message that we've been trying to put out with this. And I think in large part we've been fairly successful with that already.

So the Birth to 5: Watch Me Thrive! has three components. The first is a compendium of instruments that the field can pick from. And we went through -- we had -- through our Office of Planning and Policy and Research at ACF -- had them look at all of the screening instruments and then give us feedback on who they were applicable to, you know, the target audience, et cetera, and, you know, their reliability, et cetera.

I want to call attention to one thing that I think is important right now, and everywhere I go I try to bring this up. As we have come to understand in screening instruments in this country, we have no screening instrument right now that is both valid and reliable in any other language than English. And I think for a Nation like ours, we really need to get after that and do something about it. Many are translated, but they have never been validated in another population. And so, I think that's something that came out of this that

we're trying to sort of -- through the use of the bully pulpit -- suggest to developers, et cetera, that they need to take this work on.

In addition to that, we have -- we developed user guides for multiple sectors of those people that were participating in the work to help them select the screening instruments best for use in their particular programs. And then we have a collection of resources that we put together for a whole host of audiences on how to use them and what supports then are available locally once children are identified.

So here's basically what is in the compendium. As I said, it's a series of at-a-glance tables and profiles for each of the tools. It includes information on cost, time, the evidence, et cetera.

This was very important to us because many childcare providers do not have the resources to purchase expensive instruments, and so we wanted to make sure that they had an understanding of what they would be buying and then what it would do for them. And also to, you know, the issues surrounding duplication, replication, and copying, et cetera.

And then we basically -- those groups in the last bullet down there, there's information. It can

be used by and it targets not only early-care and -education providers, but pediatricians, home visitors, welfare workers, et cetera. So we were trying to target the widest spectrum that we possibly could.

The criteria that we used to select what is in the compendium is up there, and I would just note in this one that one of the things that was very important to us, was family input. And there are some that are -- were -- not in our compendium that because they do not include that particular piece, and we feel it's very important, especially in the birth to 5 years, that the families participate in this and that their input is in there.

So I think -- the next one in terms of the user guides, we developed a series of user guides. And each of the agencies working on this project developed guides for their own population. And I think that is one of the unique and nice things about it, is that the targeted audiences were always pretty much kept in mind.

So it talks about -- we talk about -- developmental milestones, the screening and monitoring, how to engage families, how and where to refer if concerns are detected. One of my pet

peeves in early childhood is that most early-childhood providers know when something is wrong.

They don't know what is wrong, so they don't really know how and when to refer children and families for help. And so, this helps them know what their instincts are telling them about children. This helps them give them something to use when they refer, and then how obviously, you know, where to go and where the resources are.

Here are the targeted audiences for the guides, as you see a whole host of audiences that we're working with currently within ACF and throughout the Department. Especially, I think, interesting is the work that we're trying to do in homeless shelters. This is a particularly difficult population to get screened, and so we're trying through the work that we're doing in other areas to make that happen.

So the other thing that we developed with this is what we call the family screening passport, and it can be duplicated at the local level and given to families so that they can track their child's screening -- just like you do your child's shots and you keep your shot record with you. Our goal is to have families have this information with them at

all times so that they know the next time that they need to be having their child screened.

I think then this is just generally what is included in the toolkit. It's available at our website, and I'll give you the website on the slide, but these are all of the different things we did. The tips were pretty interesting for us because I don't know – I don't think anyone in this room was on that, but we had sent a number of researcher-provided tips for us on how to work on certain things, and those are in there.

And we are looking at how we can evaluate this. We're working with the Centers for Disease Control to look at how we can measure the impact of this, and trying to figure out if we're actually able to increase the number of children screened in this country. Obviously, our goal is all children get screened and to figure out how we can get there and then to look at a number of other ways that we can just see the impact of this. We want to know that if through a coordinated effort like this at -- throughout the Department and throughout the Government -- can we really make a dent in this issue of children getting screened early and often.

So I think that gives you the website. You can

go see it on our website. We're really pleased that Secretary Sebelius did a little introduction for us on the website. She's very committed to this work.

And I think -- I thank all of the partners that worked with us on this. I think it was a great effort, and we're now looking for next steps on how we can really take this to the next level in terms of following up with early childhood, especially the workforce in terms of training.

Dr. Insel: Thank you. Jose?

Dr. Cordero: This is wonderful, and it reminds me sort of this as a next step of what actually CDC has done with learning signs to act early. The question is that since you have Head Start and programs like that, how are you connecting this program with what happens in terms of Head Start programs throughout the country, particularly when they -- you have, like, early Head Start and have many of the children that are Hispanics and are African Americans, low income, that may actually not have other access to this kind of opportunity for screening?

Ms. Smith: Well, as part of the work that we're going to do in the next year, it will be to get this information in use. Head Start really

screens children now, so that's a part of their mission, but childcare not so much because childcare, you know, has such a mish-mash, if you will, of delivery systems, it's harder to make that happen. And so, I think our work is going to focus more on that.

We're also, as you may know, doing a partnership between Head Start and childcare -- early Head Start and childcare -- which we'll be launching in the next few months. And our goal in that will also be to make sure the children are getting appropriately screened and through these partnerships be able to reach into childcare programs through the Head Start vehicle to get the children screened. But Head Start does do this as a matter of course.

Dr. Insel: Idil?

Ms. Abdull: Thank you so much for presenting that. And, you know, as a minority woman, it's just heartbreaking -- I was just telling Dr. Mandell -- to hear year after year, decade after decade, there are racial disparities. I'm just really sick and tired. I would like some action.

And the fact that there isn't screening that is culturally appropriate and diagnosis that's

culturally appropriate in a Nation of immigrants is embarrassing and shameful for us, I think, in every department and every agency. And I say that not diplomatically. I'm just really tired of it.

And what I would like, I think, for this Watch Me Thrive! Because, CDC said the reason that black and Latino children were diagnosed with autism was more awareness. If the awareness was so good, it wouldn't be that late, and it wouldn't be children that already had intelligence disabilities or had more severe autism. Because children that are also black and Latino have Asperger's and higher functioning. It's just that the awareness is not there. The awareness is not there. The explanation is not there. Then the treatment is there. So a lot of these racially disparate children have Medicaid, so a lot of times Medicaid doesn't pay the same thing in terms of behavior intervention and early intervention.

And so, I suppose my question for you is, when you're doing this Watch Me Thrive!, and it's really just a critical age, birth to 5, how are you going to make sure that childcare providers and Head Start, that the staff are trained, they're trained properly and that -- because you have to get

licensed to be a Head Start. You have to get licensed to be a childcare. And I would really just recommend that even when you're doing this and you're funding through the States, unless that facility staff is trained well, they don't get the license.

And then if they have to, you know, get it again or recertify it, you have to make sure that they are trained. We have to make sure there's data. Did you train your staff? Were they able then to educate the parents because I've noticed at least in the Somali community, even if the staff of a childcare or Head Start area are trained, they're not really educating the parents. They can see there's something wrong with the child. The kid is maybe 2 or 3. That is the golden opportunity to catch them, but they are not getting the information from the staff to the parents.

And how do we make that connection so that we're not sitting here another 5 years saying there's racial disparity, because it's heartbreaking to hear that?

Ms. Smith: I think you've brought up a number of issues that we're very painfully aware of in the comments. I think the first thing that we are

trying to do, and the reason I bring up the fact that many of the screeners are not, you know, validated in other languages is a real problem for this country. And my role right now is to try and put that on the national radar screen because we cannot go out and validate these instruments.

They're privately -- you know -- they're developed, and it's up to the developers to do that.

And I think the more we call attention to it, the more that that puts pressure on the developers to actually do that work or someone else. I totally agree with you on that, and I was startled about that.

I think that you're correct on the training issues -- as we all know, not Head Start. Head Start has much higher staff qualifications than childcare does in this country. But the childcare staff is woefully undertrained to do the work, and that is one of the initiatives that we will be taking on over the next year. I know the Centers for Disease Control have done some staff training materials. SAMHSA has done work around this. And so, we will build on what we can that the Federal Government has already done.

We have rewritten the childcare reg. We're in the final processes of that from the Federal level. And as part of that, we'll be requiring more training of the childcare workforce once we get that reg out later this year. So we're aware, painfully aware, of everything that you say. And, you know, not to make excuses, but it is pretty hard to move, you know, a system in this country that is basically a State-based system with block-grant funding to, you know, in the ways that we want. So we're doing -- you know, we're trying as hard as we can.

Ms. Abdull: If I could just follow up. I think training is awesome, but then also a lot of these, whether it's childcare or Head Start, they're getting Federal funds. The States are paying them through Federal money. So if we can, as Dr. Insel was saying, for the collecting of data, that should be part of -- you want the money, you're going to have to be trained.

Ms. Smith: We agree.

Ms. Abdull: Do you know what I mean? Like, you can't just keep funding the same people to keep doing the same bad job and then complain about it.

We have got to connect the funding to the

education to the training, and then educating the families because even a good staff that's trained, it's worthless if the child and the family are not getting that information.

Ms. Smith: And the nature of the childcare is a block grant to the States with a lot of flexibility. We get that. But as I said, when we publish our regulation at the end of this year, we are taking every possible step within the limits of the law and the block grant to correct exactly what you said. So there will be mandatory training on topics included in that reg. And if you do take the money, the subsidy money, through the Federal system, you will be required to do that.

But I would correct one other thing you said. All childcare providers in this country are not required to be licensed. We have a substantial population of providers that work outside of the regulated system, which is a whole other conversation.

Dr. Insel: Last question to Anshu, and then we'll take a break.

Dr. Batra: Thank you. Thank you, Linda. This was terrific. Much needed. And I loved, loved, loved your presentation. I love this project.

So having been a practicing pediatrician now for over 20 years, I've seen this evolution, and I have to agree with what you said is that, woefully or unfortunately, most pediatricians do not use screeners. It's not something that's incorporated.

It's not something that we're taught, but we're not implementing it, whereas we probably are more likely to be looking for signs of autism. You know, are they pointing, are they responding to their name, et cetera, but not really using these screeners earlier to look for other issues in development?

And as I was listening to your presentation and looking at the document, a couple of things came to my mind. One is knowing how limited the attention span is of most physicians, pediatricians, just because of, you know, the time factor, I would like to see an abridged version of what you have as opposed to the 10 pages that sort of documents and talks about what validity means and screening.

Just a short one-page document that really just identifies the different tools, what they identify, what the cost is, what the time factor is. I think that's a very critical -- I think that

would be very useful, and I think I can definitely see that being then implemented in practices. Number two, I absolutely agree this has to be disseminated in a much more efficient manner.

And one way, again, that I can see this happening is really just it has to be handed to the pediatricians and the family practitioners who are seeing these kids six times a year, and at visits, whether they are federally funded or not. And so, I think we have to somehow partner with the American Academy of Pediatrics and have that as, again, one of the requirements, recommendations because that's what we listen to is our board, our governing body.

And so, have it disseminated in that manner, and then lastly again, the training. Oh, absolutely. I mean, you know, we're usually pretty good learners, but someone has to teach us honestly. And so, you know, and even if we're not taught, at least our staff is taught.

Ms. Smith: Good point.

Dr. Batra: And, you know, I think that that has to be -- somehow, you know -- make that a priority. And I just see it just as the signs and symptoms of autism over the last 10 years has become so much more, you know -- our community has

become more aware, I think we have to make -- do the same for this and, again, tie it into, again, our governing body. Thank you.

Ms. Smith: I would say that we have worked with the American Academy of Pediatrics on this, and they have seen this and been a part -- well, they weren't part of the working group. We've met with them. They're aware of it. They support it as do a number of other agencies, you know, that are nongovernmental. But I couldn't agree with you more, and I think what, as I said, our next goal is to get people trained.

Dr. Batra: Well, I have to tell you --

Ms. Smith: Again, I didn't think pediatricians were actually so --

Dr. Batra: Oh, my goodness. I mean, you know, we're the ones who see the kiddos in the first week of life. We see them in the hospital on day of life one. We see them, you know, a week later. We see them 2 months later, 4 months, 6 months, however long, you know, throughout. And, you know, I just renewed my medical license for California, which required that I had a certain number of CMEs, okay, documented. And, you know, as a board-certified pediatrician and a board-certified developmental

pediatrician, I have to take these exams every 7 to now 10 years.

So again, there are mechanisms that we could tie this into which then would mandate -- you know, hold people accountable for their certification, which then can be, you know, implemented.

Ms. Smith: That's a great idea.

Dr. Insel: Well, that's great. I think -- I hope you've gotten some good feedback, Linda, in terms of both the training issues, the health disparity issues, which I think many people on the Committee are concerned about. It's clear that you're concerned about those as well.

You mentioned in the slide about having an evaluation to look at impact that CDC will be helping with. So if we go forward as a Committee, I'm sure at some point we'll want to look at what the impact has been, and in a year or two from now hear back about the outcomes.

We are already 30 minutes behind, which is not very good if the meeting just started. So I want to cut our break from 15 minutes to 7, and return here at 8 till so we can hear about the BRAIN Initiative.

[Break]

Dr. Insel: It's a pleasure to bring back a Committee alumnus. Dr. Story Landis is Director of the National Institute of Neurological Diseases and Stroke. And I just want to make sure we get a quorum into the room here. People are drifting back.

She's here to talk to us very briefly about the --

[Laughter]

Dr. Story Landis: Yes, I'm going to skip half my slides.

Dr. Insel: -- the BRAIN Initiative.

Dr. Landis: Tom just told me.

Dr. Insel: Welcome, Story.

Dr. Landis: So I'm really delighted to be here, and I'd like to introduce Lyric Jorgenson, who's sitting in the back. Lyric, do you want to raise your hand? Lyric has been the mastermind of much of the BRAIN Initiative, as has Greg Farber, if you would also like to raise your hand.

So on April 2nd last year, President Obama announced the next great American project, and the predecessor of this was the Genome Project, so I think this is a pretty high bar that we have to meet, and that is the BRAIN Initiative, Brain

Research Through Advancing Innovative Neuro-technologies. And the goal is to learn the language of the brain, and the vision that President Obama laid out is here in this quote: "Enormous mystery waiting to be unlocked," 86 billion neurons, each of which is connected in circuits to thousands of other neurons. And the BRAIN Initiative will change that by giving scientists the tools they need to get a dynamic picture of the brain, an action to better understand how we think, how we learn, how we remember. And that knowledge could be, will be transformative.

If you have not watched this clip, it's about 20 minutes long. It is unbelievably inspirational, and I recommend that you look at it.

Now, part of the rationale for this -- as we all know, brain disorders affect us all. I can think of no better group with awareness of this than this particular group, neurodevelopmental disorders, neurodegenerative disorders, cognitive affective disorders, injury- and insult-induced disorders. And we simply do not know enough about how the brain is organized and works to really be able to address these problems the way that we should.

The second really significant incentive for this is that the science is ready. It's extraordinarily ready -- Progress in neuroscience, new insights into brain structure and function. And you see they're a part of an MRI reconstruction. And there has been progress in optics, genetics, nanotechnology, informatics, which is being incorporated into studies of the brain and really advancing the development and design of new tools.

So if you think about a brain initiative, everybody here can probably think of 20 different things that should be a piece of that brain initiative. But there's been a very clear focus for this initiative, which is outlined in this approach. The goals are in the first 5 years to really accelerate development and application of innovative technologies to get a picture of the brain in action, integrate neuronal and circuit activity over time and space, and to do this by building on the growing scientific foundation from neuroscience, physics, engineering -- this whole list of disciplines to really catalyze an effort of unprecedented scope and actually to pursue studies across the spectrum from simpler model systems -- zebra fish, maybe fly, mice -- and into humans.

So there are a number of different Federal organizations which are involved in this. I'm going to focus for the next couple of slides on the NIH BRAIN and how it's going to work.

When President Obama announced this, to be perfectly honest we didn't have a real action plan for the BRAIN Initiative. And so, the first task has been to come up with a research plan, and this has been accomplished through a working group of the Advisory Committee to the Director. Francis Collins is incredibly interested and excited about this initiative, so he has -- Lyric and Kathy Hudson have been working on creating the plan.

And they've done that by putting together a working group, and that working group is to articulate the scientific goals for NIH research, and they were on a very fast track. They were put together really in May, and by September they came forward with high-priority areas for funding in Fiscal Year '14. This needs to get jump-started.

And as a consequence of those high priorities, NIH issued six requests for applications in December. The applications have all been turned in, and there are some spectacular projects that have been outlined in these applications. They'll be

reviewed in the summer, and they will be funded in September. But the task of the working group isn't done. They are to come up with a final report which will be produced in June. It should have timetables, milestones, and approximate costs. This is a list of the working group.

It was initially called the dream team because it has some of the most outstanding neuroscientists working in circuit in the country, chaired by Cori Bargmann who works on a simple system and Bill Newsome who work on primates and more recently on humans. Physicians, basic scientists, imagers, engineers, and they have met, I think, seven or eight times over the course of the establishment of this committee coming up with a plan. And ex officio members, Kathy Hudson, who's one of the Deputy Directors of NIH, Jeff Lane from DARPA, Carlos Peña from FDA, John Wingfield from NSF, and Lyric, as I said, has been the Executive Secretary.

The interim report is on the web under the -- if you Google "BRAIN Initiative" you'll come up with this. It's a wonderful document. And they came out with nine recommendations -- preliminary recommendations. If you're thinking about a complex system, you really need to know what the working

parts are, so that's recommendation one, create a census of all the cell types in the brain. And there are probably hundreds, if not thousands, of different cells in the brain. Create a map -- structural map, new techniques to record from populations of neurons in circuits manipulate those circuits, connect that activity with behavior because, after all, the output of the brain is behavior. Integrate modeling, theory, statistics, and come up with new ways to image the human brain.

So I'm giving you here a sample of three out of the six RFAs that were released. The first one is to come up with approaches, to come up with a way to classify all the different kinds of cells in the brain. The third recommendation is to come up with technologies and approaches for large-scale recording and modulation of the nervous system.

Wouldn't it be great if we could record from not tens of hundreds of nerve cells in a circuit, but thousands or tens of thousands? And then the sixth one -- I see I cut off the "six" with my figure -- is come up with new ways to really image the human brain. Magnetic resonance imaging, and diffusion tensor imaging, and PAT have transformed our ability to see how the normal living human

brain is organized and works, but it's not at the level of resolution. One voxel in an MRI includes tens of thousands of neurons. We need something that's much higher resolution and to be able to alter physiology in a way that's non-invasive. And as I said, hundreds of applications respond to these RFIs.

Now, we're not the only Federal agency that's involved in the BRAIN. As I said, DARPA is investing also significant money, and these are three of the projects that they have: SUBNETs - create closed-loop medical devices to measure and modulate networks of neurons in cases of intractable psychiatric illness and alleviate severe symptoms of disease. This kind of technology at a crude level has been applied through deep-brain stimulation in Parkinson's disease and essential tremor. They are much more ambitious. They want not only to stimulate, but also record and manage the stimulation.

The second is restoring active memory. Deliver a wireless device that repairs brain damage and restores memory loss. This sounds like science fiction, but they are optimistic that with using the systems that they'll be able to make progress.

And also better prosthetics that incorporate not just the ability to move a prosthetic arm but also to record the sensation that if it were a real arm, that arm would be receiving.

NSF is a little slower than DARPA and NIH in coming up with their initiatives, but they have had meetings, and they've also created one science technology center, very large, expensive, on Brains, Minds, and Machines.

So the goal here is that the BRAIN Initiative will have high-impact, high-quality science. And so, any piece of this has to be able to accelerate neuroscience research, brain science across the whole spectrum, from normal adult function development, and applications to disease. So it is focused completely now on tools, and those tools should be applicable across many areas. And so it's great to create a tool, but the tool has to be useful for understanding brain function, acquiring fundamental insights.

And our RFAs that we put out are actually posing the problems, raising the questions, but not dictating the solutions. We want the best ideas to flourish, and toward that end, these RFAs, with one exception, did not require any preliminary data.

You just had to say here's the state of the art, where do we want to be, and how will my plan get us from where we are to where need to be?

And for me, one of the most exciting pieces of this -- the whole thing is incredibly exciting -- is that public interest in brain research, in brain science, has certainly grown. We've had a sequence of first *National Geographic*, "New Science of the Brain." Wonderful articles in there about a lot of NIH-funded research -- *Scientific American*, and then finally *Science News* magazine.

So I would be pleased to take questions.

Dr. Insel: Great. Thank you, Story.

Dr. Landis: Whew.

Dr. Insel: Questions, comments? Idil?

Ms. Abdull: Thank you very much for that. It shows your enthusiasm. I love researchers that are enthusiastic, and you certainly are.

I just had a question about the -- you said you have a new brain working group. Right, and I don't want to seem like I'm beating a dead horse, but how many of those folks are people of color, and then the people that have submitted the other phase for applications, is it -- your guidelines -- is it possible to say that make sure that your

subjects reflect America?

So I've spoken with a lot of researchers after they've spoken here, and I've always said if they said they had a thousand, you know, people with autism, they researched 100 people, I've always asked how many of them were black and Latino. And many, many -- majority of them said, no, that wasn't a requirement, and so we didn't seek it. Is that something that your working group can maybe put that into it just so the end result can reflect this country?

Dr. Landis: So there were two African Americans on this committee, Dr. Emery Brown, who is an anesthesiologist, computational neuroscientist, from MIT, who worked on a lot of the suggestions for computational approaches, and Dr. Peter McLeish, who is a cellular and molecular neuroscientist studying the retina from Morehouse University. They had significant input, and I will tell you that Peter on many occasions espoused the notion that this effort should not just be for majority institutions on the coast but should engage the best and brightest wherever they are and whatever their backgrounds.

This effort is going to develop tools and

technologies. It won't be funding the studies that would use those per se, but I can give you an example of a major effort, the Human Brain Connectome Project, which the blueprint -- this is an aggregation of 16 neuroscience centers and institutes that NIH has been funding and that is creating maps with the current resolution -- maps of the connections of the brains of 1,200 people ages 26 to 35 normals and it has good gender balance and good ethnic balance.

So there is attention being paid where tools and technologies are being applied to an inclusive look at a population that reflects what we see in this country.

Dr. Insel: Anshu?

Dr. Batra: So again, I'm asking this question as a practicing --

Dr. Landis: Right.

Dr. Batra: -- community physician. And so, you know, when I listen to what's out there, you know, I automatically think about how is it going to help me, you know, to help the patients.

Dr. Landis: Right.

Dr. Batra: So on your working group, do you have people that actually are practicing in the

community that then are able to have sort of an understanding of what's sort of necessary, as well, you know, clear the science, --

Dr. Landis: Right, right.

Dr. Batra: -- which is so cool. I mean, you know, to be able to, you know, think up these possibilities of, you know --

Dr. Landis: So there is no one on this committee, which was designed to come up with a plan for the first maybe 5 to 10 years of developing tools, who serves in the community. I can tell you if I can back up, again, to the Human Brain Connectome Project, which in a sense is the way such tools might be used, there is significant interest now in moving beyond the 26- to 35-year-old range to create a developing brain connectome where one would be looking from ages 1 to 18. And a lot of enthusiasm for doing that because these data are now publicly available. I think it's 125 of these connectomes that have been produced.

And the goal is that they will serve as a basis for comparisons with people who have brain disorders in that age group. And if you had a developing brain connectome, I think it would again be normally developing kids but would serve as a

comparator for studies that might be done on kids on the autism spectrum. So to what extent are the behavioral issues of function of connectivity, and as we learn more about connectivity and possibilities for changing connectivity.

So it's not something -- now, you know, you could in your evening hours go and look on the Human Connectome website, but I think the use applications of this will come from comparisons with populations which have issues. So it's developing the tools to help us learn about the brain, and the more we know about the brain, the more we're going to be able to help practicing physicians come up with strategies for changing behavior. Tom, do you want to add anything?

Dr. Insel: No. I think this is a great summary. The only thing I'll say maybe by one way of closing is that we often bump up to our level of ignorance in this field. I mentioned this morning some of the recent science. And it's so clear that relative to the heart and the liver and the lungs, we absolutely have a poverty of information about this organ that we are so concerned about here. We don't even know what cell types are in it, and we don't know very much about how many of the cell

types that we do know about actually exist there.

So without a real picture of what normal looks like, it's very hard to know what the ranges are for the wiring diagram, for measurements of cell types, all of these things that are really critical. And the point of this effort is to give us the tools to begin to get that landscape for the first time, get that sense of what the parts list is, and we literally do not have that.

Dr. Landis: I mean if you just think about how transformative MRI has been in learning about pediatric disorders, heterotopias, brain tumors, imagine if we had something -- a tool that allowed us not to see big blobs, but actually intricate connectivity and even better, if you could -- had tools that would allow you to enhance re-training.

And one piece which I haven't discussed is that there is an interest in the President's Commission on Bioethics in looking at the implications of findings of this BRAIN Initiative.

So don't worry about our learning to do things that are inappropriate.

Dr. Insel: Well, thanks, Story. We wanted to let you know about this because it is something that's going to be launching its first set of

studies. We hope it'll be growing over the next couple of years. It is for this President his number-one scientific priority, so it's close enough to what the Committee does that we thought you should hear some of the details about it, and we'll keep you informed as this goes forward.

Thanks very much for giving us that very quick overview. I know there's a lot more that you could've talked about and didn't.

Dr. Landis: I could've spent 10 minutes on each of those slides. I had another hundred I could've shown, but Tom said no.

[Laughter]

Dr. Insel: Thank you.

Dr. Landis: You're welcome. Thanks very much.

Dr. Insel: We're going to move on to Dr. Donna Kimbark, a member of the Committee who is going tell us about the Congressionally Directed Medical Research Programs for the Department of Defense.

Dr. Kimbark: Thank you. I want to thank everyone for inviting me to speak about our Program.

First of all, I want to talk about what the Congressionally Directed Medical Research Programs is and why we're part of the Department of Defense.

First of all, we are a part of the Department of Defense. We are a part of the Department of the Army. We do fall under the Medical Research and Materiel Command. And where did we come about, and why do we have -- why are we in the DoD?

First of all, I want to give you a little bit of a history lesson. If you go back to the early 1990s, you'll recall that we had the fall of communism as well as the fall of the Berlin Wall. At this time there was money in the Department of Defense's budget that was extra, the peace dividend, if you recall. And advocates at that time marched on Congress and asked for some of that money to be moved to breast cancer research. Those advocates were successful, and the Breast Cancer Research Program was born.

Slowly over the years, other programs got wind of this, and other advocates got wind of it and decided that they would do the same. And they marched on Congress as well asking for a line of appropriation to be added to the Department of Defense's appropriation to have targeted guidance toward those monies. And this was an opportunity to leverage how that money was going to be used. So this is how the Autism Program was born in Fiscal

Year 2007. And I'll talk a little bit about what that means overall in a couple of slides.

So it really is about a partnership, the advocates that marched on Congress that talked to Congress about this. Every single year we are a yearly appropriated Program. We do not exist in the President's budget. We exist only as an appropriation onto the DoD appropriation. And so, every year it's about a partnership between the advocates, between Congress, the DoD program itself, and the researchers.

So some of the hallmarks of all of our programs are that the research funds are added to the DoD budget by Congress. As I said, we are not in the President's budget. I want to make a point that these monies are added to the DoD budget, but they do not take any money away from the soldier, the sailor, the marine. None of that money specifically specified to the DoD budget for the war fighter is taken away from them to put to this money at all. This is added on to support and benefit the defense health program itself.

The vision for each one of our programs all the way from autism down to TSC is adapted yearly, and how we solicit applications are changed as

needed dependent on the vision and mission of each program. Advocates participate throughout the process, and I'll talk a little bit about that in a minute. We try to fund highly innovative research and high-impact research. We fund both internationally and nationally, and we have a two-tier formal review of applications that was first developed through an Institute of Medicine model.

So I'm going to talk a little bit about that program execution. This is what we call our crab cycle. So we start out with an appropriation from Congress, and if it's at initiation of the program, we have a stakeholders meeting. And what that stakeholders meeting really is is that we ask everybody who has a stake in the program itself to come together, and we've had advocates come together with clinicians, and research scientists, and physicians, and psychologists all come together, sit in a room -- this all happened in March of 2007.

Everyone sat in a room and discussed what were the needs and the gaps. Where could we fit our small Program into the overall landscape of autism research funders? And those notes and accumulated knowledge were put together to hold our first

vision-setting meeting. The vision setting and several steps throughout our process is done through an integration panel. That integration panel is our select board of experts, okay?

And these experts get together each year to look at the vision, to look at what's needed in the whole research landscape -- not only by the research community, but by the community itself of people that have autism or their caregivers and so on. So the integration panel gets together, and it includes, like I said, clinicians, scientists, and advocates.

Once they give us an idea of what's needed, what we call program announcements are put out there to solicit applications and pre-applications.

Once again, the integration panel comes together to select the ones that will be invited for full applications. Full applications come in. They are peer-reviewed by a different panel than the integration panel. That different panel is a board of experts that are external to our program, and then once those are scored on their science and impact, they go forward to the programmatic review.

At programmatic review, then the ones that are selected then go to the commanding general for

final approval, and then we do negotiations, and we monitor those awards throughout their life cycle for progress and research outcomes.

So a little bit of the history of the Autism Research Program itself. It was started in '07 with an appropriation of $7.5 million. Some of the people here actually sat on that integration panel. So far, we have $47.4 million through Fiscal Year '13, and 115 awards have been made. For Fiscal Year '14, we have $6 million with which to spend.

These are our integration panels this year. Our integration panels do rotate. We do have people that are on it for several years. Our current chair is Dr. Craig Powell from The University of Texas in Southwest Medical Center. I want to make sure you know that we do have Colonel Cherri Shireman from the U.S. Air Force Medical Support Agency, as well as John Davidson from the Defense Health Agency.

These are our partners and our colleagues for the TRICARE and Military Health Systems in order to find out what are the needs of the military beneficiaries because I want to make one point, that people have a tendency to forget when they think about the military and its health systems is that most people that are taken care of by the

military health systems have never worn the uniform.

I myself am a wife of a 20-year Navy veteran, but I'm taken care of by the medical system through the Military Health System. To make that point, it's very important to take care of our families as well as the war fighter.

So the vision and mission this year of the Autism Research Program is to improve the lives of individuals with autism spectrum disorder now. And how do we do that? We do that by promoting innovative research that advances the understanding of ASD and leads to improved outcomes. We understand with only $6 million we have to do this kind of inventively because we don't really have a lot of money. So how does a research-funding agency -- we just fund awards, we don't do research.

How we do improve the lives of individuals with autism now? We have a discussion every year about that now that we're at the end. What does that mean? Can we fund early research? Can we fund developing, or are we only supposed to fund clinical and translational research?

We fund all of this over the entire spectrum. We fund very early concept awards, you know, the

back of your napkin. You're sitting at a conference, and maybe the researcher gets an idea and scribbles it down. That's our seed money. Those are the early, early ones -- concept awards, pilot awards, for instance.

Now, perhaps you have done that seed money and you've gotten some preliminary data and you want to now develop it, and you really want to expand your horizons. And this is what we call an Idea Development Award where you have some preliminary data, and you can really nourish it and go forward.

We do like to fund some translational and clinical studies, and we have done it even with our small budget within in a clinical trial. This year for Fiscal Year '14 we've already put up a preannouncement that we will be funding Idea Development Awards as well as clinical trials.

Each year what we really want to do is we want to tailor our solicitations for our applications in order to answer some of those needs that we hear at the very beginning during our vision-setting meeting from our stakeholders of what's needed out there. Where can it fit in the gaps that the broader, larger agencies are funding, and we can be supportive and complementary?

So what we've been trying to do is look at -- for the Clinical Trial Award mechanism, our areas of interest or focus areas are behavioral and other non-pharmacological therapies. We want to study pharmacological treatments in autism as well -- or in well-defined subgroups looking at genetic and phenotypic and co-occurring conditions. Our panel is very, very interested in co-occurring conditions.

They're also very interested in the fact that sometimes you get a really good idea and you get a really good behavior modification methodology, but it's not disseminated well, or it's not implemented well, or you don't have a standardization of it. So why don't we look at clinical trials in order to establish efficacious behavioral interventions? This is very important for the military for continuity of care.

And finally, for the Clinical Trial Award, we looked at therapies to alleviate conditions co-occurring with ASD from sleep disturbances, GI disturbances, aggression, and depression, and anxiety. This is a theme that comes up again and again at our panel, and we're really not getting the type of applications that we're seeking. So

we're hoping that this year with our clinical trial we can actually ping them and get the research community to be more responsive to those.

For our Idea Development Award, this year we're looking at environmental risk factors as well as mechanisms for heterogeneity within the clinical expression and response to treatment. We all know that there's a huge response difference in response to treatment for ASD. We have excluded new gene discovery because other agencies do that very well.

We don't need to supply our money for that. Once again, we're also looking here in the Idea Development Award where you're really just developing those ideas to look at co-occurring conditions.

Novel therapeutics, we're looking to assess novel therapeutics in valid preclinical models, as well as psychosocial factors promoting key success -- promoting success in key transitions in life.

This is really important when you think about, you know, life overall -- from learning a language to being potty trained to learning how to drive, for instance.

So where is our portfolio so far? Our portfolio is shown here against our areas of

interest. You can see that over the years from Fiscal Year '07 to Fiscal Year '12 our areas of interest have changed somewhat. We've had -- we've grouped them into larger pie areas so it's a little bit easier to understand. We've put a lot of money into biomarkers. We've put some money into infectious risk factors, as well as pharmaceutical interventions. You can see that our co-occurring conditions is only at 6 percent, and we're still looking to bulk that part of the pie up.

How do we all fit in with the IACC? One of the things that I want to point out is that every year we do send our portfolio to Susan, and we do go through and code all of our portfolio according to the seven questions. And you can see that most of our money is put into Question 2 as well as Question 4 where we're looking at how can I understand what's happening in treatments and interventions, although we have put some money into Question 5 -- Question 1 as well, which is when should I be concerned?

So I wanted to just highlight a little bit in the last half of my discussion about some things that we've actually funded over the years. I am not the scientist for these, but I did want to just

highlight them so that you can get an idea of some of the things that we've done with some of the money over the years.

One of the things that we've really tried to do -- what the program has really tried to do -- is we live in a very technologically advanced age. Why can't we use some of that technology in order to advance some of our initiatives? So one of the things that we've been looking at is advancing access through technology.

Dr. Ingersoll at the lower panel here from Michigan State University is really looking at developing Internet-based parent training interventions. And one of the things that's interesting is that for her feasibility study, what she did was what if you -- how good are these Internet-based intervention studies? If you just have parents look at the Internet, read it, do they understand it as well as if there's someone there to assist them in understanding it? There's a big difference.

So one of the things that she's doing is looking at the differences in that and how it can be really -- which is the better of the two approaches in order to get the types of

interventions that need to be out there for parents and so on.

And a nice complementary study to that that we funded is with Dr. Wayne Fisher out of the University of Nebraska Medical Center. What he's doing is he's doing a technologically enhanced early intervention behavioral -- early intensive behavioral -- intervention services for children with ASD in the military families. As you can imagine, military families are moving around all the time. Some of them do when they have a diagnosis of ASD get into what we call the Exceptional Persons Program, where they can, they don’t move as much, and they can stay put and get consistency of care.

But also overall you can imagine that this can be somewhat different if they do move, or demographically, they might not be in the right -- the best -- place to get the best care. So demographically, how do we make sure that everyone is getting similar care? So this is one of the things that the integration panel was quite interested in, and they also thought that this could be applied overall to underserved populations throughout. If we could fund this type of program,

how could we really relate it not only to military families, but to overall?

So what their idea here -- what Dr. Fisher's idea here is about not only about training the parents and getting information from the parents through recorded video of children's behavior in the home, but also to train by long-distance paraprofessionals. Those paraprofessionals are trained in the behavioral intervention. They're tested in the behavioral intervention. They're put on staff to do this, and then from afar they can then assist the parents in applying the behavioral intervention with the children. And the researchers can watch from their home videos about whether or not it is efficacious.

So these are one of the things that they're really looking at. They're looking at severe behavioral problems, feeding problems, sleep problems. So overall it is a continuous feedback system with technology in these paraprofessionals to see if there is any way that we can enhance those that are demographically underserved to actually help them out, get the consistency, and actually get the care that they need.

So other things that we've done as far as some

of our focus areas as far as transitioning on key life steps along the way is to advance independence. You can imagine that some places it might be very, very -- it might have a great metro system like the D.C. area has. It has a great metro system. No problem. You can get anywhere you want.

But I had to drive an hour in order to get to that metro system because I live out in the boonies. So it's quite an experience.

So if you want to be able to serve people that might not be able to have access to a metro system like some of us do in the city, people that live rurally like me don't have access to that. If I want to get anywhere, I can't even buy groceries without getting in my car and driving. My kids can't get to school without me dropping them off.

So you really have to be able to achieve independence where I live is to be able to drive, okay?

And Dr. Cox and Dr. Reeve from the University of Virginia first realized this and said, you know, this is probably really impacting some of the high-functioning individuals that are living with autism. How can we change this?

So what they did was in a very small award, a

concept award, they started to develop a virtual-reality driving simulator with eye tracking to see if this could help out in any way. After they got a little bit of that data, then they came back to us and they reapplied. And Dr. Cox with Dr. Brown from the University of Iowa came together and said they would like to look at evaluating and enhancing the driving skills of individuals with ASD.

So what they're doing is they're recruiting individuals. They doing the virtual-reality driver simulator and eye tracking in order to see if they -- in order to find out, number one, if the system actually works and, number two, to see if they can get people with autism to drive in a controlled environment so that it's easier to learn how to drive. Personally for me, I didn't learn to drive until I was 30, okay, because I was afraid of the traffic, okay? So you can imagine that a learning -- all of the different things with traffic might be pretty difficult. So virtual-reality driving simulator and eye tracking can be something that would be useful if it works. So that study is underway now.

And I just wanted to look at one other one, which is Dr. Alaedini from Columbia University.

He's actually done a study that we will be highlighting this month for Autism Awareness Month. And what he's been looking at is whether or not the gastrointestinal issues with kids that have autism, is it a response to gluten, and is it similar to people with celiac disease? And what he found was that there was an immune response, an IGG antibody, but it's not the similar type of thing that you see with celiac disease.

So he came back and he wanted to find out if it was -- what kind of foreign antigens might have something to do with that. So he looked at a variety of different, different antibodies -- I mean, antigens, and he found that they didn't have -- like Lyme disease, for instance -- they didn't have any connection either.

So he came back to us again with his data that he got from his concept award. He came back to us and he said -- he applied again this past year. And he said, "I want to find out why we're having this immune response to gluten in children -- a subset of children with ASD, but it's not like celiac disease. So let me find out how to do that by proteomic mapping." And that's what he's doing. We're just awarding that now for him to do.

So these are our current Idea Development Awards that are being negotiated. As you can see, I've just kind of outlined some of them just to tell you how much we've actually tried to focus in on our areas of interest from transition planning and health-related independence, anxiety disorders. I just talked about the proteomic mapping of the immune response to gluten, affective language comprehension, as well as trophic inhibitory signaling, biomarker development, and maternal brain-reactive antibodies, which we've been quite interested in as well.

This is our Pilot Awards. These are the small awards that are just kind of seed money trying to get some ideas. One of the things that we're looking at is obesity in co-occurring conditions.

Is it a co-occurring condition, or is it a drug side effect? Anxiety again. Circadian rhythms in children to see if that will help a little bit with sleep disorders, depression, learning abilities, and placental identification and immune quantification in children with ASD.

And so, I just want to emphasize once again that our vision and mission is to improve the lives of individuals with autism disorder now. I want to

point out Shelly Reynolds in the middle panel there with her son Liam. She is one of the advocates that sits on our integration panel, and she's helped us a lot along the way. And we've had many people that have helped us. We have advocates on our peer-review level that either have a diagnosis of autism or have family members that have autism, and as well on our integration panel.

And I thank you for the time, and that's our website.

Dr. Insel: Great.

Dr. Kimbark: And we will be releasing our newest solicitations by the end of this month.

Dr. Insel: Thank you, Donna. Let's open this up for comments, questions. John?

Mr. Robison: You know I hope I don't seem out of line for suggesting this, but we've just heard about a number of interesting studies that are really kind of all across the board. They cover all different areas relating to autism. We have just sat through this GAO review suggesting the risk of duplication of research. And actually until now, I didn't have any idea about the congressional mandate for the Army to be funding autism research.

But it seems to me that, you know that this is

perhaps a question we should be asking as group like the Army doing this kind of research. Would that be more productively targeted in a specific direction, or is there any kind of way to ensure that we don't have duplication? I wouldn't have thought of this except that we've gotten this detailed response for how we're at risk for that, and that's what I sort of heard even as interesting as the research was.

Dr. Kimbark: Okay. Yes, I can answer that. I mean, one of the things that I want to point out is that during our vision setting we do bring all of the work of this panel to our integration panel members. They sit down and they talk about it. I bring everything that's available. We actually have website connectivity during our vision-setting meetings to discuss what has been funded and what hasn't been funded, and actually that happens both at programmatic review and in vision setting.

That's one of the reasons why I'm not the person picking what's going to be funded because I am not an expert in this field. I rely on the integration panel that includes those experts to say, you know, this is an interesting thing. We've funded this part. There's been funding for this

part over at NIH, but there's no funding for this little thing over here. I would never see this funded over at NIH because they're focused on something different.

So, yes, there may be seemingly some overlap in that area or duplication, but we tried to make it -- do it at a different angle. And we try our best at that, and we do have constant communication with Susan.

Mr. Robison: Thank you.

Dr. Insel: Do you have any idea how many of those 115 awards had been NIH applications previously?

Dr. Kimbark: We don't know that particularly. We do know that many of the people that we fund do get NIH funding, and one of the things we do along the way when we do the negotiations is we look at their current and pending support. And if they have any current or pending support that may have overlap or duplication, we do either have them withdraw the award, or we might take out an aim that is being funded somewhere else. Most often, though, now we withdraw the award, and we don't give them the money.

Dr. Insel: Okay. Other questions or comments?

Ms. Redwood: I have to put in a plug for this Program. I served on the first integration panel for 3 years. And what was so incredibly unique was the ability for stakeholders and parents and individuals with autism to actually sit at the table and make funding decisions, so that's completely different. And I do know that they do a great job in looking at what funding has already been received. There were several grants that had been approved for funding, but we found out in the interim that they had already received funding, so they were withdrawn. And I don't know if that's something that NIH currently does when -- so that's good.

Dr. Insel: Anshu?

Dr. Batra: But again, as I listen to these presentations I think about, you know, how could I apply this to my day-to-day practice in life. And I love this process you described, this two-tiered model, you know. I don't have the language for it.

And it, you know, it brings in so many different levels of people that are involved in so many different ways. So I love that integrated sort of approach.

So how did it come up? Who was the visionary

for that? And, and as I see it, again, as a little old person sitting and, you know, doing what I do, how can we sort of use this model to change sort of what we have already existing to then bring in, again, the research community and the clinical, you know, applications community because that's what I'm hearing and that's what I'm seeing is you have the topnotch researchers with people that are looking at what the needs are. And then, you know, bringing them together and having a nice sort of, you know, almost a marriage. And, you know, it would be nice to see what comes out of it.
I know you're still relatively new in the process, but --

Dr. Kimbark: Right. I mean, how did it all start?

Dr. Batra: Yes, how did it all start, and then how we can sort of take that and then maybe make some adjustments in our current sort of system to then tie it to the needs of the community?

Dr. Kimbark: I mean, overall, I mean, how did it all start with the Congressionally Directed Medical Research Programs. That all started through the Breast Cancer Program. And all of our programs have been modeled after that, and that was

dependent on Fran Visco from the NBCC, okay? So she was a breast cancer survivor, and she brought her needs to Congress, and she was one of the people that marched on Congress.

For our Program, there are people on this panel right now that I know marched on Congress for the Autism Research Program and do so every year to continue to bring money to our program because, as I said, it's a yearly program. I don't know if this program will exist in Fiscal Year '15. I don't. We can't offer that. That's why we don't offer, you know, a continue-on funding. We just offer funding for a specific project, and that's it.

How to expand it? I see right here on this panel we have people that have been affected by autism right here on this panel, so I think that it's becoming more and more pervasive that we've suddenly realized as a scientific community that in order to do anything for any condition or disease or injury, we have to talk to the people that are affected, just like you do, and I'm talking from the DoD perspective. When you have a soldier out there that's having trouble in the field, he comes to his commander and says, listen, this is what I need in order to be successful in my mission.

So keep up doing that. Keep saying what you need and making sure you're part of the panel throughout, making sure that the physicians who are frontline are doing that as well.

Dr. Insel: Jan?

Ms. Crandy: So your pilot within TRICARE that did pay for -- that does pay for ABA -- did it start out as a research project in this piece first before it was moved into TRICARE to pay for?

Dr. Kimbark: I don't know. We are not part of TRICARE at all.

Ms. Crandy: Through the military?

Dr. Insel: Right. No, that was an entirely separate process.

Ms. Crandy: Okay. Thank you.

Dr. Insel: Last comment. Idil?

Ms. Abdull: Thank you, Donna, for presenting this. I love the idea of advocates marching into Congress. I hope we all do that -- march into Congress. And I also love the idea of having advocates, and parents, and clinicians, and scientists be part of the team because there is a saying in Africa, if you want to know what's wrong with someone, you ask the patient as opposed to the doctor telling you what's wrong with you. And so, I

love that inclusiveness.

And I just have -- I don't have questions, but I also love the idea of the Skype. There is a young woman from Minnesota who started A Global Voice for Autism. And she trains autism parents in West Bank, Palestine, and she's Jewish American, and they say there's no peace in the Middle East. In autism apparently there is.

So she does Skype, and she trains the parents, and she trains them in ABA interventions and even the diagnostic. And she has parent support groups through the Internet. So I love the idea of using technology to empower families and children even when the interventions are not available. And I'm really glad that people in the military are getting that because they move so much, and they are the ones that we depend on and our safety depends on.

So I'm just -- I love your presentation. Thank you very much.

Dr. Kimbark: Thank you.

Dr. Insel: Thank you. That's great. We're going to move on. While Greg Farber gets set up, just a comment, Anshu, just to make a correction here. The two-tiered kind of review is exactly what NIH does as well, so the first tier is peer review,

scientific merit, but the critical piece is the second tier, which is done by every Institute's council. And those councils include a whole range of stakeholders -- providers, patients, family members, down the list. So that's actually typical rather than being atypical.

Dr. Insel: Welcome to Dr. Greg Farber from the NIMH. He's the Director of the Office of Technology Development and Coordination. He's going to just do a quick update for us on NDAR. Because we're so late in our schedule, he's promised to make it really brief.

Dr. Greg Farber: Yes, I will make it brief. But I'm glad to have the opportunity to update the IACC on what's been going on in NDAR.

So just to remind you, this is a joint initiative that's funded by many of the Institutes that are sitting around the table. It contains data from human subjects and the data available to the research community. But almost -- not almost -- everything I'm going to show you today is available on your browsers. If you get bored, you can tune in now. You can go and look at it tonight, so I think that is an important thing to remember.

The NDAR contains an awful lot of demographic

data -- clinical assessments, imaging data, as well as OMEC data. At the moment we have nearly 70,000 subjects who are in the database, so this is one of the largest data repositories period containing human subjects data. And we're holding over 400 terabytes of imaging and genomics data in the cloud -- in the Amazon cloud.

In addition to the data that we hold ourselves, when NDAR got started there were already a number of databases funded by Autism Speaks, by the Simons Foundation, by Johns Hopkins. And NDAR has established sort of a deep federation with all of those repositories so that when you go ask a question in NDAR -- and I'm going to show you a little bit about the queries -- the question actually gets distributed amongst all of those databases, and the results that come back are from data all throughout the system.

What makes that possible are two key features of the architecture. One are the data dictionaries, and I'll show you a little bit about that. And the other is the GUID, the global unique identifier, which has turned out to be really useful in autism, and it's been so useful that other research communities have asked to borrow it.

And we're working with them now to push the GUID out into those communities. And I guess the only thing is to say that virtually all NIH-funded investigators are expected to share their autism data with NDAR, and at the moment we have over 150 studies that have satisfied that requirement. Okay, the data dictionary, one of the two building blocks, so this is sort of a standard definition that allows researchers to bring their data into NDAR, and then that allows the community to query across that data.

We have over 500 instruments, and that's not a good thing. But we have curated much of that data so that you can do effective queries.

Something else that the data dictionaries allow you to do is it allows investigators to very quickly perform quality-control checks. Tom talked earlier today about a study, an imaging study, where replication was shown to be an issue. At least for the clinical assessments and for the demographics, the data dictionaries allow a researcher to very quickly find errors, and I'll show you exactly how that works.

So here is an example of what our data dictionaries look like. And you see we have a lot

of different categories, and here's the start of a complete list. You have to scroll down a long way to see all of the data dictionaries. If I clicked on any one of those, I would get to a screen that looks like this. And what this is that for this particular question, the values -- the allowable values -- should be between zero and 24. So a PII can quickly run through all of the data that's being collected in their lab. If it turns out that a researcher has incorrectly put in a number there, has switched a column, has any sort of the common data collection problems that occur, it becomes immediately apparent.

And although this looks trivial, this is not the sort of thing that's standardly done in the research community. And so, this really, I believe, has helped a great deal make the autism community's data far stronger than many other research communities are.

One other thing that NDAR allows you to do is you can go into any of those questions, like that one that had an allowable range of zero to 24, and you can immediately see what the distribution of data looks like throughout the whole database. Now, there can be some dangers with this, but if you

have an interesting new observation and you want to have some confirmation that what you see might be seen by other researchers, you just need to come to the database. You don’t need to have an account.

Just look at that question and you can see the distribution of data compared to what you're seeing and get some sense as to whether what you're seeing is in line with what's in NDAR or perhaps you're looking at a different group, and it's distinctly different, and that's a good thing. But this does give you a way to put your data, your observations in context.

The GUID, the global unique identifier, is the other key building block. And this is a Federal data repository, but we want to make the data very broadly available. And so, to do that we cannot hold any personally identifiable information about the subjects that are participating in research. So the GUID allows us to generate a unique identifier -- allows an investigator to identify -- to generate a unique identifier. And if that research subject in one lab is seen in another lab, we've arranged things such that the same identifier will be sent to both labs without NDAR knowing any of the PII. That's really kind of nifty, and you can

see why other research communities who have similar issues have been very interested in adopting the GUID. And I'll who you that that works in just a minute.

So this is the home page, and you see that we've spent a fair amount of time trying to make it easy to search through the database, and so we have queries in all sorts of different ways. I had already cut -- I had examples once upon a time of all of these different types of queries. I knew that we were going to be running a little behind.

I'm going to speed this up even more and not really focus on all of the queries, but I would encourage you to go and play with it because it's all available and easy, I think, relatively straightforward to use.

So this is an example of data associated with a particular research laboratory. This is Nancy Minshew's lab at the University of Pittsburgh. As you would expect for a data repository, all of these link out to other things. This gives you information about the funded award. Here are all the papers that associated with the award, and you can go to the paper in PubMed by clicking here.

And here are all of the data dictionaries that

Nancy used to collect data and the number of subjects that she's turned into the database. And you can look and see what all of those data dictionaries look like. So if you were a researcher who wanted to repeat experiments that Nancy had done, you would know exactly what she had done and how she had done it.

This slide shows all of the data that is available in IAN. I suspect a number of you around the table may have gone to IAN and deposited data. Many parents and subjects do that.

So IAN contains an awful lot of clinical data, but IAN doesn't contain any neuroimaging or genomics data. These are all examples of the GUID working. These are examples where someone who deposited data in IAN was also seen in a research lab and had images measured or had their genome done.

And this is our newest query, which is still in beta. This is in collaboration with Dr. Alexa McCrae at Harvard. The problem with having 500 data dictionaries is that you need to know something about 500 data dictionaries, right? Most researchers don't want to know about 500 data dictionaries. They might want to know about

excessive, repetitive actions, for example, alright.

So what Alexa has done is she's gone through the 50 or 60 most commonly used data dictionaries, and she said, okay, excessive, repetitive action, that happens in this instrument when this question has a value of one or two. It happens in this instrument in this question when the values are between one and three, okay?

So this is a way to allow you to search on a concept, and you can see that there are a lot of concepts over here and without having to know the details of all of the data dictionaries. And when you do this search, you push a single button and you get 500 subjects. And if you were interested in that, you would download the 500 subjects and do whatever with that data you wanted to do, okay.

So that's sort of a summary of clinical and demographic data. Imaging and genomic data are much tougher. So we've been working with a number of groups to try make the queries in those data types as easy as the demographic and clinical data are. We're getting close to being finished on that, and I think that in 6 or so months, we'll have a major update that will do that for the community.

But this will make volumetric volumes for brain images available. It will make specific mutations, specifically CNVs, specifically indels, readily apparent to the community. And that, I think, is going to be a good thing because you'll be able to then correlate that type of data with the clinical data that I was showing you earlier.

Alright, so getting close to the end here -- the question is always if you build it, will they really come, and that's not always true with biological databases. There are plenty of examples of databases where significant investment is made and no one really seems to use it.

So with NDAR, we've had a lot of data now for about 18 to 24 months. And the good news is that there are a number of people who have recognized that this is a valuable resource. We now have 270 users who are -- have access to the database. We are starting to see papers that use the data in the database to report results, occasionally just computational papers, sometimes papers where data from NDAR is combined with newly measured data to reinforce the point.

And something I can tell you since I look at NIH grant applications related to autism is that we

are seeing more and more people using NDAR as a source of preliminary data to justify doing a study. So I think we have some evidence that the database really is being used.

So that gets me to the final slide. My claim is that NDAR is really a very useful data archive that makes autism data easily discoverable, useful to a wide range of constituencies, citable, and, I didn't show you today, but directly linked to the literature through PubMed and other ways. And with that, I'd be happy to answer any questions.

Dr. Insel: Thank you, Greg. The Committee has kind of watched NDAR grow from embryonic to now being fully fledged. And since we're behind schedule, I don't want to take more than one comment or question, but if there's anybody that has a burning question?

[No response]

Okay, thanks so much for this update, and we'll have you back as we watch this get to its next phase.

We'll finish up the morning with John, and we're going to hear about the neurodiversity course and ask all of you for your patience before we break for lunch.

Mr. Robison: Well, first of all, I'll just show you -- I show here -- this is the William & Mary neurodiversity war pug. Now, for those of you who study the history of animals in China, you may recognize this pug. It's actually modeled after the imperial Chinese war pug. Those of you who aren't familiar with that, you can look it up on Google.

So we just heard about the latest estimates of the prevalence of autism. One of the things that we heard in that is that with the recognition of who's autistic in the population now, we are beginning to see that the percentage of autistic people who may be looking to go to college in coming years may not be tremendously different from the percentage of the general population looking to go to college.

That is a strikingly different observation than one might have made 20 years ago when the conversation centered around the vast majority of autistic people having intellectual disability. Now we know the spectrum includes a much broader range of people, and I think we have to decide then how are we going to address that in higher education.

At William & Mary we have started really what I think is the first neurodiversity programming initiative in the country, and what that is doing

is looking at two fronts. First, as a college that sends its graduates out into all walks of life, which is what most colleges hope to do, how are we going to make our student body as a whole a ray of neurodiversity in differences like autism, so that those graduates of ours who go out into government, psychology, education, law, medicine, social services -- even the sciences and general business -- how are those people going to understand, recognize, value, and support neurodiverse people, particularly people with autism? And I think the best way to do that is through a college-wide initiative and courses to actually teach neurodiversity.

We had our first course for neurodiversity open this semester, and to my great amazement the course filled up in 45 minutes of opening registration. And we actually have most of our students here, plus we have some grad students from psychology here in the audience today, which I think is really kind of a remarkable thing.

The other thing that we need to do in higher education is we need to have courses that are designed to help neurodiverse people fit better into the college environment. That means that even

a college like William & Mary, which is viewed as a very elite school, probably could benefit from courses on social relations, courses on organization, courses on doing the kinds of executive-function things that those of with autism are challenged by.

And as I thought about that, you know, we started talking about should we have spaces in our college where, for example, there was incandescent and natural light instead of florescent light.

Should we be talking about, you know sensitivity to clothing, to noises, to textures?

But, you know, I've realized that we autistic people -- of course, me being one -- you know, we are not weirdos and freaks in that we don't like those things. We are only the canaries in the mine shaft. We're the ones that roll over dead first.

I cannot imagine if I do not like tags on my underwear, how are those tags beneficial to any of you?

[Laughter]

If I don't like florescent lights, how do you benefit from florescent lights? So I think, like I said, we're kind of the canaries in the coal mine.

And I think that what's showing is that the

development of courses that will help somebody like me or some of our neurodiverse students succeed in college -- those are courses that are going to help everyone. And I think that the more we recognize that autism affects the whole human population, not just a narrow group, the more we are going to have to move in that direction in higher education. And I'm proud to be part of the effort here at William & Mary.

I know we're kind of out of time, and I've tried to do this quickly. Should I take a question or two?

Dr. Insel: I think you should get a round of applause.

[Applause]

Mr. Robison: I want to thank Dr. Insel back there because, you know, really this neurodiversity initiative, I wouldn't say it's because of him, but I think a lot of the advocacy that I have pushed for, and I've, you know, pushed for this and, of course, the college has fully supported it and all.

But, you know, I think that you're to thank for a lot of this, too, and for bringing us here.

Dr. Insel: Well until you told me this, I don't think I realized that tags on my underwear

were really a problem. And so --

[Laughter]

Mr. Robison: Well, I can't imagine how they can help you. I mean, really.

Dr. Insel: Let's see if there are other comments besides that completely irrelevant one from the Committee. Actually any statements from the students? We'd be delighted to hear from any of you as well.

Mr. Robison: Who's a brave, fast-moving student?

[Laughter]

Dr. Insel: Anshu, go ahead.

Dr. Batra: So, while they're thinking about their questions, so, John, I'm curious, you know, what your curriculum is and how you sort of developed, you know, the key sort of points that you want to teach the young and upcoming, you know, people that are going to be out there interacting and interfacing with our --

Mr. Robison: For our first course, we did not know if a neurodiversity course would attract a bunch of neurodiverse students, or it would attract people who were interested in neurodiverse students, or it would attract just psychology or

education students, for example, so we tried to cover a mix. We have people talking in our course about autism or neurodiversity in law, neurodiversity in education, and its role in those places.

At the same time, we are talking about dating and relationships, and things like job skills, and organization to get to class. So we are touching upon the issues that a neurodiverse student would think, “These are things that I have a problem with if I'm a student here.” We're also touching on the things an education or psychology student would think, “I need to know these things to work with neurodiverse people when I graduate.”

Dr. Batra: So, I mean, what I'm hearing is really just practical life, you know, skills, you know, that affect our population. So through -- so the college student gets what credit through what -- is it part of the psychology sort of credits, or is it just sort of through their general education?

I mean, how does this course then reflect in whatever requirements they have, number one? And then number two, how can my college student avail himself of this class?

Mr. Robison: Well, the course right now is not

a required course for any degree, so it's an optional course, and that actually interested me that so many signed up for it knowing it was required for anything. Right now the course is taught by faculty in the psychology department who are sitting over there and some over there and me.

Ultimately, what I would like to see is this course expand into a group of courses so that one could come to William & Mary and perhaps be a student in say education, law, government, psychology. And you could take a concentration in neurodiversity where you learned a lot about that.

And then to answer your final question, how could my college students get into that, that's actually -- that raises a very significant point. Your college students can't get into it unless your students can maintain, what is it, 3.62 now?

They've got to have a very high GPA to get admitted to William & Mary or any elite college. And it certainly ought to be true if they wanted to go to Williams or Harvard or Amherst, too.

And I think that highlights another problem in education of neurodiverse people, and that is we need pathways for folks like us who may not succeed in traditional high school to picked out, sort of

taught how to fit into a college, and then given pathways to a good college because I think there are many very bright people in high school who can't make the transition directly from a local high school where they may be failing to a William & Mary, or a Williams, or an MIT, or a Harvard where they might be stars.

And I hope that we can facilitate that through a transition year at our college and through the State community college system, and I hope that can be replicated around the country. But that's a big concern, how can your neurodiversity or autistic person get into the school?

Dr. Insel: Sally?

Dr. Burton-Hoyle: I run a college support program at Eastern Michigan University. And the first goal is having an autism-friendly campus and one in which the CDC numbers, where might be alarming to some, are helpful. And exactly the point you made, John, about the number of people who are going to be coming to college are probably the same kind of numbers of people with autism.

And our university has been absolutely great in admissions and registrations, but best of all, our students that are autistic who are taking and

majoring in everything across the board. And the neurodiversity course that you're talking about, we have one at my university that's an elective, but it's a humanities elective. So more and more people are taking it for that reason, probably not to the quality of what it is that you're teaching, I'm sure. But this is wonderful what you're doing.

You're laying the cornerstones for acceptance, go way beyond awareness. Sorry, folks, had it with the awareness stuff, we need to have acceptance.

Mr. Robison: The final thought I'd like to just say in closing about that, that when you want to have an autism-friendly campus, I've got to believe that for a college that neurodiversity as part of its programming has got to seem autism friendly to people. Recognize that all schools have their problems with florescent lighting and stuff, but putting it into our culture has got to be a help.

And we are also taking this idea out into the older working world, and we are now offering William & Mary neurodiversity courses through our Washington, D.C. satellite campus, so we're doing those in the summer school time for working people.

And I think that that's something I very much

hope other colleges around the country will emulate and build upon because there's going to be -- just look at all those 8-year-olds in that CDC study that are all going to be looking for a college if we do it right.

Dr. Insel: We're going to need to stop in just a minute. Linda has had her light on for a while, so I'll give you the last word.

Ms. Smith: Yes. I'm curious as to whether or not you've given any thought to such a course for other professors. It seems to me that one of the problems that we really need to look at is how we help the academic community itself understand --

Mr. Robison: We actually have thought about that, and we've talked about it. And the answers that we have for that right at this moment are we hope to develop sort of a foundation textbook and course materials, which we would be proud to make available to other colleges elsewhere in the country and in the world.

And the other thing that we would offer is that any faculty of colleges that want to learn what we're doing can sign up for our continuing ed type courses this summer. And that's the kind of thing we hope -- to attract professors from other

colleges to who want to come and talk to us who are teaching it to regular students at William & Mary, and then go back and do it in their own schools.

So, yes, thank you.

Dr. Insel: Well, that's terrific. I think you can see there's a lot of enthusiasm for this idea. We'd love to see it disseminated, and maybe a mook is in order here in thinking about next steps. So thanks so much for sharing this with us, and thanks to your students.

Mr. Robison: Well, thank all these students here. That's really a cool thing.

Dr. Insel: Yes, that's great. Thank you.

[Applause]

Dr. Insel: We're going to break for lunch. The cafeteria, as you remember, is on the first floor in the B wing or, I'm sorry, A wing, or between A and B. So you'll have to head back toward the main entrance of the building on that side.

Why don't we reconvene at, I'm going to say 10 after 1:00. We really want to get started as quickly as possible at 10 after 1:00 so we have full time for public comments, and lots of public comments today. We'll shift some things around in the afternoon so we'll be able to catch up.

[Lunch break]

Dr. Insel: Welcome to the afternoon session for the IACC. You have in your packets and received earlier by email both written comments and oral comments. So I'm assuming that all of you have taken some time to look at the written comments. We're going to take the next 45 minutes to listen to the oral comments.

There were so many people who had written in, we extended the time, but we still only, because of the numbers, and because of the time, and because we're behind schedule, we're going to have to restrict this to about 3 minutes per person, which is not very much for people who have traveled a long way. And I do want to make sure we have time at the end for some discussion of what we hear.

So let's jump right in. And we'll start with Carolyn Gammicchia.

Ms. Carolyn Gammicchia: Hi. I'm returning for my third time here, and I want to thank you all for this opportunity to be able to speak with you once again. Today is an actually an anniversary for me as a mom of a 22-year-old son with autism. Fourteen years ago today I was joined by thousands of other families in marching and rallying to D.C. for a

national -- the first National Autism Awareness Rally. That was 14 years ago.

I'm here today because I thought it would be a good and symbolic gesture in a sense to be here and actually say to you it's been 14 years, and we're still waiting, and we're still hoping that our children are going to be served by the Federal Government.

One of the things and the reasons I'm here, I did supply a written comment. My family supplied a written comment at the last meeting. We were unable to attend. Our concerns were with the GAO report and what it indicated in how research funding was being spent, and in the last 4 years, that over $1.3 million is being -- $1.3 billion is being -- spent combined on both research and non-research projects with Federal funds.

For a parent of a 22-year-old son with autism, I can now say for the last 14 years since I first came here for this reason to advocate for our son and our family and the autism community that we're very disappointed in the sense that a lot of that has not trickled down to applicable and transferable resources that our children and adults can use on a daily basis.

Additionally, within that funding we have the non-discretionary funds related to non-autism research -- I'm sorry. Those are funds that go and are discretionary toward things like the Department of Defense and those programs there, and awareness programs, identification programs, things like that.

One of the things, too, that I was concerned with when I attended the actual strategic planning meeting that you held in November is I sat here for the entire day purposely because I wanted to see the comments because I'm one of those strategizers and data people, and I wanted to see what was happening. I kept hearing comments, though, and I looked into the research. I looked in the materials that you provided. I wanted to see some comments from you as a Committee about that research.

The comments that I heard were saying we need more research or some research in this area, and that has research has already been done. So we're spending time with replicable dollars and research on things that have been done.

And, believe me, I know what research transpires. I know how it transpires. I have a behavioral science certification, and I have a B.A.

and a B.S., and I know how this stuff comes about.

I know how research funding comes across. I'm concerned, and that's why I'm here. I'm not seeing, again, the things trickle down to applicable and usable things for families and individuals with autism in the community.

Dr. Insel: So we're just at 3 minutes.

Ms. Gammicchia: Okay. And I also wanted to discuss the actual charter of IACC and the objectives and scope of those activities. You have my comments, and I'm not going to waste time because I know you've probably seen them. You're sitting on this Committee, you've been appointed to it, so you should've read those and what the fiduciary responsibility is.

This is our son. Last year he actually crewed on a sailing boat race from Mackinaw to Port Huron, or actually Port Huron to Mackinaw and back. He had severe autism at one time. He has been -- I testified today at the Disability Policy Summit in downtown Chinatown -- I testified today how he's benefited from Medicaid funds and SSI funds.

He had a children's Medicaid waiver. He's benefited terrifically from that. He would never be where he is right now. He's had SSI. He would never

be where he is without those. These are programs, and I urge everyone in this room to participate within legislation. We have things coming up for budget. We really need these programs.

There are individuals like my son that are on waiting lists waiting to be assisted like our son. He's successful right now, and he is -- I'm sorry. He is attending community college. He will get his bachelors of art -- I'm sorry, associate of arts in May -- and he'll be applying to a 4-year university. He had severe autism.

Currently under Medicaid, his vitamins and supplements are being provided up to $500 per month because he seeks complementary medicine. And I want you to know that because it's vital that somebody -- an adult with autism is choosing other than medication to lead a healthy overall life. He's the healthiest one in my family. He exercises daily and uses vitamins and supplements. And he knows how to self-regulate his anxiety because he's been taught that way through the behavioral intervention that he obtained through Medicaid and the waiver.

Dr. Insel: I wish we had more time, but we're at 5 minutes.

Ms. Gammicchia: But I want to thank you for

the opportunity. And I also want you to know that as a community we have an expectation of the IACC and that you are going to be re-funded hopefully as the CAA is being reauthorized. And I urge everyone here in the room to actually meet with your legislators and let them know what your expectations are of this Committee if it is funded again in September. So thank you, everyone. Thanks.

Dr. Insel: Thank you. And just as a correction, we may be reauthorized, but we will never re-funded since we have no budget.

The next speaker is Dawn Loughborough.

Ms. Dawn Loughborough: Good afternoon. My name is Dawn Loughborough. One in 68 children born in 2002 have been diagnosed with autism. That is a 30 percent increase from last year. Part of the increase in prevalence estimates stems from greater recognition. However, it is absurd to suggest that there were just as many or even anywhere nearly so severely affected individuals with autism in years prior.

One would have to believe that large numbers of nonverbal, sometimes combative, and often self-injurious children -- unable to pass basic developmental milestones toward independence, many

enduring intense pain from GI disorders or seizures -- were somehow just never noticed before. One would have to believe that individuals with autism wandered and died in comparable numbers just a decade or so ago, but again, they simply went unnoticed?

In fact, the numbers of such severely afflicted of our children skyrocketed, and if there is consensus on anything, it is that there are still far more questions than answers as to why this is happening, and there are still no advances in prevention for regressive autism treatment and/or cure for those affected by co-occurring conditions, nor adequate services for those living with autism.

We have a public health crisis that begs for urgent Federal response: 1.2 million individuals with autism. We need a special patient population defined so that when they show up, nonverbal or combative, in a hospital emergency room that the staff will know how to investigate their pain and diagnose their health problems using evidence-based medicine. We need coordinated services across the lifespan.

As medicine advances for autism, we will find

the underlying medical associations and sourcing triggers. I have included some examples from the CDC website. They basically state that developmental disabilities can be mental and/or physical, that sometimes we discover new ways of thinking disease as in the Hopkins research focused on GI issues triggering asthma. And last, that the cause of developmental disabilities can have genetic, environmental, and social factors.
This IACC has not fulfilled on the intent on Congress to investigate all potential causes of autism, in particular environmental causes, and a recent GAO report states a concern for potential duplicative research. Last night, I read the letter dated April 3 from Dr. Marcia Crosse, Director of Health Care at the U.S. Government Accountability Office, in response to Ms. Singer's letter of March 6th. Dr. Crosse's letter quashed Singer's rebuttal of the GAO report and continues to stand by the GAO evaluation, which raised concerns about the potential for duplicative research, as well as the use of data that is outdated, not tracked over time, and inconsistent or incomplete.

The letter also requested that both letters be posted on the IACC website, which is unfortunate,

demonstrating another potentially duplicative effort, taking up Dr. Crosse's resources to reiterate what was already stated in the GAO report. The public was pleased that not everyone on the IACC agreed to this unproductive posturing.

I'm starting to sound potentially duplicative here, so with that I will end this public comment, emphasizing that 30-percent increase is a no pass. Society wants answers and real help for this national public health crisis akin to an epidemic. It's a matter of national security and human rights. Thank you.

Dr. Insel: Thank you and for abbreviating your written comments, which we have as well. And just as a clarification, there were, I think, 10 members of the Committee, not just Ms. Singer, who submitted that letter.

We're going to move onto Holly Bortfeld.

Ms. Holly Bortfeld: Thank you for giving me the opportunity read my testimony here today. My name Holly Bortfeld. I am the parent of two children with autism. My son, who is here today, is 18, and my daughter is 20. Neither were born with autism. My son regressed at 2, and my daughter regressed at 5, hitting every developmental

milestone before them.

It has taken a lot of time effort, money, services, pain, and supposedly alternative treatments from some of the most prestigious hospitals in the country and also some nondescript medical offices to get my kids healthy. The medical establishment has fought us the entire way, never a partner in our health care needs. I would not have healthy children today if I didn't fight the medical system and their status quo.

It took more than 2 years to find medical practitioners who tested and treated my son's many co-occurring issues, and now he can do all the things that the best specialists promised me he'd never do. And I have no doubt at all that had I listened to them and drugged him into submission rather than treat the underlying causes of his autism. But they wouldn't have been right.

He would've rotted like many of his peers, died from wandering, or seizures, or spent the last 16 years in unnecessary pain. Parents should not have to fight their doctors for medical care and travel all over the country to get the help like we did.

I have calculated this cost me, insurance, and

the State $1.6 million to get my son to the condition that he's in now. He has not recovered from autism, and he'll soon need lifelong care, but he's not in pain anymore, and that’s priceless.

Now, let's have a reality check about what autism does to our country. With the recent CDC announcement of 1 in 68, what did we get from our Government? Oh, just better diagnosing, nothing to see here. Guess what? This is a national emergency.

This is huge. If it doesn't affect one of your family members yet, it will, and it will affect your pocketbook. Who do you think is going to pay for my kid's care and everybody else's kids' care? It's going to be taxpayers.

And between educational, medical, and therapy costs, my son cost the State of Pennsylvania $100,000 per year, and he still lives at home. The cost of average -- national average for -- residential housing ranges anywhere from $100,000 to $180,000 per person. Now if you just add up the 1.2 million kids that you've identified, much less the countless adults that you've never even bothered to count or even try, you're talking about $16.8 trillion. You all need to get in front of this.

Plus you have to add in the loss of their income and tax base since they won't be able to have jobs. More than 90 percent of people with autism are either unemployed or underemployed. And when they turn 22 and the school bus stops coming, guess what? All the parents now have to quit their jobs to stay home with their kids.

There aren't daycare centers where you can drop off your 22-year-old all day long while you go to work. And if autism was here forever, those services would exist because those adults would've needed those prior to now. They don't exist. All of us are going to have to quit our jobs. That's two people on Medicaid now and SSI and everything else.

Dr. Insel: We're just at 3 minutes.

Ms. Bortfeld: I wanted to say something about the CDC's Learn the Signs, Act Early. Approximately $3 million is spent on this program every year, and in the past 15 years the average rate of diagnosis is still at 4.5 years of age, which means that they've completely bypassed early intervention, making this program completely useless. Stop wasting our time and money with garbage programs like this.

We want the Government to declare autism a

crisis, the national emergency that it is. We want the CDC to actually count, not these prevalence estimates. It's not that stinking hard to get, you know, data from SSI or from Medicaid or from schools. The way the systems do it, if any of you had kids in the system you would know how they count and the way that you have to give up a diagnosis into SSI and Medicaid. Every single file has it.

Stop the duplicative research. We already talked about this. The Federal Government has spent $1.6 billion on autism since 2006. You haven't prevented one case of autism, not created one useful treatment for our kids. Unacceptable. Ridiculous. Nothing should be off the table, not one thing, not vaccines, not anything. Until the day that you can show exactly what causes or autism or autisms, nothing should be off the table. Prove it or keep doing research on everything. Every time you cut that discussion about vaccines in particular off, you cut off of your usefulness to our community, make yourself irrelevant, and we will make sure that you're replaced on this Committee.

The Government has a lot of work to do.

Fourteen thousand seven hundred-percent increase since the CDC started tracking this. You know, in the private sector this gets you fired this kind of behavior. Get on the right side of this issue and do it now. The clock is ticking, and we don't have any more time to lose. Thank you.

Dr. Insel: Thank you. Cassandra Oldham?

Ms. Cassandra Oldham: Hi. Just briefly before I read my testimony, I want to say I have three kids, and two of them have autism, and they're still not being counted. They're too young to have been in your stats.

I want to thank you for the opportunity to be able to tell you a little bit about my family and their struggles with autism. My family is more representative of a lot more families that are out there. I have three boys. They were all born healthy. At my middle son's second birthday, I have medical records showing him normal, healthy, developing on target. Right after that, he got sick. He regressed over a period of months and developed autism.

During that time he had a lot of physiological issues going on that experts and doctors told me that had nothing had nothing to do with his autism.

I was told I missed the signs. I started a home ABA program. Experts were in my home.

Nine months later my youngest son got sick, regressed over 3 weeks. He lost all his words -- clapping, pointing, eye contact, waving, and the ability to chew. I took him to the experts at Kennedy Krieger at Johns Hopkins. They tested him for stuff they never tested his brother for. He came up positive for mitochondrial disease. We brought in his brother. He came up positive as well. We did genetic testing.

I don't have mitochondrial disease. I don’t carry mitochondrial disease. My children acquired mitochondrial through an attack on their immune system via environmental toxins. Now, it's important to note that nobody else in my household got sick from environmental toxins.

This is how it was explained to me. If you get hit in the head hard enough you can develop epilepsy. Two people can get with the same force; one can have a seizure and the other can't. This isn't something we can test for or screen. We just have to wear helmets when we're doing activities where our head might get hit. We can't test, I was told, for what are our main threshold is. We just

have to lower what the stress that we're giving on our children's immune systems. We're giving them too much too soon.

So what I said to the doctor, okay, so they got it from environmental toxins. Let's test for what those toxins are. He said we can't. So I shipped my children's urine to France. My boys were sick, and their behavior was insane. No doctor that accepted insurance knew how to help them. I went to some doctors, but I had to pay out of pocket. With two home ABA programs costing more than twice a monthly mortgage, it took a long time to be able to afford access to those doctors. I couldn't bear the thought of choosing one child over the other. No parent who's paying for insurance should have to make decisions about which child to treat or test.

We finally get them tested. They had ulcers all up and down their GI tract, in their stomachs. My youngest had ulcers in his throat. They were in so much pain, and they were unable to tell us. When we treated their GI symptoms, they slept for the first time in 3 years. When we tested for other conditions, the self-injurious behavior went away. They stopped beating me up.

I put my son on antivirals, and he started to

talk. Seizures went away with other treatments. I had medical evidence that my children were harmed by vaccines. I did not have that in the 3-year window that I need to file in court because I could not afford the medical tests and could not find an attorney willing to help me with the process.

It would be ridiculous to expect someone who had a burglar in their home or another crime to do their own forensics. Why do we expect that of parents?

In my opinion, we don't need more studies. We need people to take action on what we already know. My brother got sick, and his brain was inflamed. They didn't wait for a study to come out. They didn't look for double-blind placebos on what the effect of drilling holes in his brain would be to relieve the pressure. They didn't say some of you guys are getting fake holes and we'll give some of you guys real ones and see what happens. They drilled holes in skull to relieve the pressure on his brain to reduce the brain damage of a little boy. Why won't they give my children and others like them the same care with the same urgency?

My children are gone. I'm left with the shell of a body of who they were. But who they could be

is gone. They have lost one of their basic human rights: They lost the speech. My children can't talk. They could, but they can't. Imagine that happening, and imagine the people that could actually do something and help doing nothing. I'm almost done.

A senator was shot, Gabrielle Giffords, and I was watching her husband on the *Today* show, and he said the worst thing about getting shot was when she couldn't talk. A little girl in my community just died of a brain tumor, and her mom was blogging about the days before she died. She said the worst thing was when she couldn't talk.

I'm here today because of my children, not for them. Help for my children is gone. Your inaction helped that. I'm here to speak for the children diagnosed today that maybe they don't get the same inaction you gave my children. This inaction speaks volumes. You can change that. We don't need awareness. We don't need acceptance. We need action.

Dr. Insel: Thank you. Deanna Mulvihill?

Ms. Deanna Mulvihill: Thank you for this opportunity. I'm a grandmother of two children who have the diagnosis of mitochondrial disease and

regressive autism. I am also a nurse with a Ph.D. and extensive experience in general pediatrics and child psychiatry. When I first went into nursing 50 years ago, autism was a rare disease, but I did have experience with these children.

And although my grandchildren share some of the symptoms with them, they are also very different. Those children did not have the physiological symptoms that my grandchildren have. They did not have the low blood counts or the ulcers throughout their GI tract. The fact is they did not have an autoimmune disease that my grandchildren and many others have today.

Evidence is accumulating that symptoms such as oxidized stress, mitochondrial dysfunction, and inflammation in the GI tract, exposure to environmental toxins, immunological abnormalities, and infectious agents are related to developmental regression and seizures. These abnormalities may not only cause many of the symptoms of autism, but can also cause severe pain.

Children should not be left in pain simply because they cannot tell us about it in words. Many times treating these symptoms, there is an improvement in functionality.

Many physicians and other health care professionals are not recognizing the physical symptoms. And even if they do, they are not treating them. They just say he has autism; this is to be accepted. Fortunately, other physicians have not accepted this, and they have opted out of the system and have begun caring and treating these children. For example, one of my grandchildren was pulling his hair out, banging his head constantly, and bouncing so much on his buttocks that he had permanent bruising.

All of these symptoms, these self-injurious behaviors, these symptoms of severe pain, stopped after an IV/IG treatment. This treatment is not recognized -- not a recognized treatment by insurance agents for children with autism -- but it would be for an AIDS patient with the same blood work. This is just not right. Neither is there any recognized treatment for heavy metal levels in their bodies, yet there is research on the symptoms of neurotoxicity that these metals cause.

My grandsons were both born normal and became ill and regressed. I thank God for my daughter and my son-in-law's determination to search everywhere for physicians and treatments that have made them

more comfortable in their bodies.

Dr. Insel: We're right at 3 minutes.

Ms. Mulvihill: These dedicated physicians are studying and working with each other to develop protocols, and they can be found at the Medical Academy of Pediatric Special Needs, MAPS, led by Dr. Rosenthal.

Autism needs champions. It needs persons who can wake up to stop spending money on genetic research, to stop this epidemic. I had a son with Reye’s syndrome who survived with his brain intact. When he had it, they already knew that aspirin and viral infection were two of the causes. They also knew that there was a third factor. We never found that third factor because we stopped giving aspirin for viral infections, and we stopped giving aspirin to children any time.

We may never know all of the specific factors involved with individuals in the development of autism, but let's fund comparative and translational research on the numerous protocols that we have. Let's get the information of the symptoms and the treatment possible out to all physicians, and let's stop this suffering.

Also, there are so many disagreements between

the different professionals and organizations that say that they are there to service the families. Unfortunately, they disagree with each other, and they discuss these disagreements with their clients, and leave parents confused and caught in the middle. Many therapists are not licensed. They should all be educated and licensed, have background checks, and routine drug testing should be mandatory.

However, the icing on the cake is the public. For those of us who bring our children to parks, theaters, or even family restaurants, when our children have made strange noises because they're delighted, we have been told not to bring our children out until they learn to behave, or, worse yet, not to bring them out until we medicate them.

Dr. Insel: We're at 5 minutes. I'm going to have to ask you to sum up.

Ms. Mulvihill: Yes. Many professionals are still labeling this disease "autism" so they don't have to do anything about it. So now I ask this Committee, are you going to be the champion we so desperately need?

Dr. Insel: Thank you. James Williams? And again, you've got extensive text here, so I want to

try to keep people to three minutes. We haven't done a very good job of that so far, but --

Mr. James Williams: Okay. First, I would like to thank the IACC for giving me the opportunity to present at this meeting. This is my first time presenting at an IACC Committee meeting.

I'm a young male with autism. I'm 25 years old, and I was diagnosed with autism at the age of 3 in 1991. I currently live in Northbrook, Illinois, a suburb of Chicago. For the past 14 years, I have written about, and I've been presenting about autism all across America. My career began in 1999 when I was only 11 years old when I answered questions at the Medical College of Wisconsin in Wauwatosa, and I've presented on autism ever since.

There's a lot of good talk today, but today I've decided to talk about biomedical issues with autism from an insider's perspective, not from a parent's perspective or a doctor's perspective, but from a perspective of a person with autism who's endured many of these issues in their life so I can give a voice to so many children who cannot talk about these issues.

One year after my career started in 2000, I

endured a major life-changing experience. I got very sick. I almost starved to death. My immune system shut down. At the height of my illness, I weighed only 95 pounds and I was 5 feet tall. And as I became emaciated, I started developing symptoms of schizophrenia and voices in my brain.

Doctors would send me home tell my parents there was nothing wrong with me even when I was starving to death. Finally, a holistic doctor saw some blood work, a regular doctor who saw it for what it was. My white blood count was low. I was very malnourished, and my digestive system had collapsed.

I finally recovered after 10 months. My recovery was made possible by a combination of many remedies -- acupuncture, teas, and mineral supplements such as zinc. The zinc remedy was recommended by Dr. Jeff Bradstreet, a doctor who treats many individuals with autism with biomedical problems. To this day I take these supplements, many of these supplements just to function, and I am strictly gluten free. If I eat a bite of gluten, I get very sick.

More research needs to be done regarding the nature of biomedical issues people with autism

endure. I have met adults in their thirties, forties, sometimes in their fifties who have endured some of the same biomedical issues that kids today are facing. I actually have a co-presentation I give with a woman with autism named Ruth Schneider, who told me that when she was a kid growing up, she was told that her biomedical issues were just figments of her imagination.

But what I also don't like is how often this research is suppressed because we assume it's all anti-vaccination, when it's not. In my community, there was an orthodontist that engaged in dishonest practices and was considered a quack by most other orthodontists. Will we argue because this doctor was a quack that all orthodontics is dishonest and the field of orthodontia is wrong? No. Yet we often discredit people who research biomedical issues with autism because a few people happen to be discredited, regardless of whether or not they were truly dishonest people.

I come to the IACC not to complain, but to ask how can we support research on these issues. How can we stop this vaccine controversy from getting in the way of conducting research on the symptoms that so many people with autism suffer from on a

daily basis, and how we can give help and assistance to the countless people with autism and their families who are enduring such issues?

I'm going to close by saying this. I hope that the IACC and other agencies start to take the biomedical issues of autism more seriously. Anecdotal evidence and data regarding an issue or topic should not be used to discredit the issue entirely but to trigger further research. Thank you very much.

[Applause]

Dr. Insel: Thank you. Desiree Kameka?

Ms. Desiree Kameka: Thank you for having us. Last week I visited a friend in Seattle who used to live in a group home. He met me at the park with a Ziploc® bag containing his meds because he had been living in a homeless shelter and was too embarrassed to tell me. He has desperately tried to find employment, but his vocal communication is somewhat incomprehensible. It's not easy to find a job if people don't think you communicate effectively.

I'm not a parent. I'm not autistic, but I have a lot of friends who are. The current and future demands for affordable housing and support-service

options are overwhelming the supply. Almost all States have waiting lists for accessing funding, and opportunities that provide autism-specific supports for adults are far and few between.

The growth in out-of-home placements in nearly 20 years for an entire population with developmental disabilities is both meager and unsustainable. Michael John Carley, a self-advocate and witness at the last congressional hearing on autism, testified that our greatest need is in the present and that autism is a national service crisis. Communities across the country are rolling up their sleeves to create local solutions.

They know they cannot rely on government supports alone, and there's no time to waste. We need more research into issues of adulthood. We need immediate housing and support-service options.

And we must eliminate barriers and policy and regulations for people trying to create public/private partnerships.

Fortunately -- unfortunately, two barriers are standing in the way. The first is lack of research in adult-specific supports for adults. How do autism-specific settings, program structure, and/or sensory from environments influence quality of

life? Those who have the most challenges are often the ones that are denied opportunities.

What are better supports for those who need help from self-injurious behavior or for those who become so frustrated their only way to communicate is through physical expression? These individuals are most often isolated in their family, being continuously excluded from their community. Where will they live when their primary caregiver can no longer be there? What trainings, assessments, and attention strategies are most effective for direct-support staffing?

The second barrier is restrictive public policy. Policy must not limit the opportunities for autistic adults to live self-determined lives. New HCDS regulations stigmatize farmsteads as an example of an isolated settings, despite the fact that no research has been done on the quality of life for those who live in agricultural communities or intentional communities. Yet for neurotypicals, *The New York Times* has reported that agrihoods are the newest housing trends -- residential developments in which a working farm is the essential feature in the same way that other communities may cluster around a golf course or a

pool, a fitness center.

Why shouldn't autistic adults be able to choose an HCDS waiver for a home and community of their choice?

Research is needed to answer the following questions: What incentives can influence the immediate increase of direct-support staff and affordable housing opportunities to meet the needs of 1 million adults with a developmental disability who are living with caregivers over the age of 60?

The housing and support options available for autistic adults in every State must be qualitatively and quantitatively assessed.

How do they plan to meet the demand? Who's being left out or falling through the cracks? Are they meeting the needs and preferences of their constituents? What factors influence quality of life in private opportunities in comparison to publicly funded options? Are they more financially sustainable?

The Coalition for Community Choice is not a special-interest group. We are a coalition of families, advocates, and organizations willing to work together on real meaningful and self-directed solutions to give adults in the spectrum the

options they want for the future. Please, please advance both research and policy that decreases barriers and increases person-centered options for autistic adults. Thank you.

Dr. Insel: Thank you. JaLynn Prince? And you've got, again, very long text, so I'm going to ask you to try to --

Ms. JaLynn Prince: Oh, I've consolidated it a lot.

Dr. Insel: Okay. Thank you.

Ms. Prince: JaLynn Prince, Madison House Foundation. IACC is making some promising strides, but yet there is still a crisis that exists and is growing. I refer to the growing number of undiagnosed and underserved adults with autism. They are largely invisible, and they and their families are in crisis. We have both a moral and economic imperative to respond.

We know for a certainty that the 8-year-olds that we've been talking about will live a vast majority of their lives as adults, and they are likely to have few or no services. That 13 years will go by in a blink of an eye. These beautiful children will disappear from view and will join an existing population of uncounted numbers who are

already adults.

We know that among these thousands, if not millions, of individuals, there are those who have not been able to qualify for adult services -- those who have limited services, those who are living with aging parents, those who are on the street, and those that have taken up residency in our penal institutions. This invisible group is called adults on the autism spectrum.

Let me share three quick examples. This past week a mother sat across from me in our foundation offices. She's in her mid-seventies. Her son, now 30, was not diagnosed with autism until the age of 26. Because of a late diagnosis, he has been unable to secure any services. Unless he becomes violent, or is a threat to his parents, or has an altercation with the police, they will not be able to get much-needed help in the foreseeable future.

His elderly mother has just one resource, a few respite hours, and they are quickly running out.

A second mother came to talk about her son who was is 28. The parents served our Nation in the diplomatic corps, transferring from country to country throughout their careers. Because they were

abroad and didn't live in a State, their son has no funded services. He is living at home, and his mother is his 24/7 caregiver, teacher, health care provider, and advocate. She is without help and is exhausted. The father has retired from working with our embassies but is now taking jobs to enable to them to fund their son's future and care.

My own son Madison represents a typical story of a young adult aging without services. He graduated 20 months ago. The student body even gave him a standing ovation. He has transition in place.

But the intramural program did not have in its place anyone who knew anything about autism, though we were assured they did. Although he was promised a position for the following year, the ball was dropped. And since last May because of retirements, quitting, transferring, he has had over six case workers. And as a result, the program that he was to be in he has been rejected from because of lack of follow-up.

If this can happen to me and I'm an autism professional, what is happening to parents across the country that are single, have few resources, that have other children, or perhaps other children on the autism spectrum? And what is happening in

our neighborhoods with the silent group that is among us with families suffering and having a very difficult time coping from day to day with particular types of autisms?

Many decisions that have been made on behalf of those with disabilities are placing large portions of our population at risk. All of us need to roll up our sleeves and take a look at the big picture. What is being done that needs correcting, and what needs to be done that is not being done?

We need a more comprehensive approach looking at things between each of your agencies with none of ourselves in a position of defending policies that don't work. We need to be in harmony with creating better person-centered positive futures.

We need to innovate to have public/private partnerships to address the issues before us. Madison House Autism Foundation and thousands of parents and individuals stand ready to help find comprehensive solutions. We need your unwavering leadership. We need to work on behalf of those on the spectrum and beyond our own careers. We can retire from our jobs, but these individuals will be living with autism for the rest of their lives.

Thank you.

Dr. Insel: Thank you. Eileen Nicole Smith? I'm sorry. It's Eileen Nicole Simon.

Dr. Eileen Nicole Simon: Thank you. Two kinds of autism are in the news: one, a non-disabling difference, and two, a neurological disorder that prevents normal language development. Repetitive motor movements are also part of this neurological disability. The Combating Autism Act was clearly intended to address the neurological disability and its increasing prevalence.

The increase in autism prevalence began in the mid-1980s. This is when an obstetric protocol was put in place to clamp the umbilical cord immediately after birth. There is no health benefit from clamping the cord. Clamping the cord before the first breath is dangerous. It can cause asphyxia and the need for resuscitation. Could the IACC recommend that this procedure be stopped?

My son Conrad had to be resuscitated at birth. His older brother had suffered head trauma at birth and at 20 months of age was diagnosed with cerebral palsy. We felt greatly relieved that Conrad did not have delayed motor development like his brother, but before we had heard of autism, we were worried about his language development and his hearing.

An article on asphyxia at birth in the *Scientific American* appeared shortly after Conrad's diagnosis of autism, with pictures of damage in the brain stem auditory pathway. The auditory pathway? This seemed to explain Conrad's problems with language and his hearing.

Develop of the language areas in the cerebral cortex is just beginning in infancy. Maturation of the language areas over the child's next 5 to 10 years is guided by trophic neurotransmitters produced in brain stem auditory nuclei. Damage of these small nuclei cannot be considered minimal I would appreciate discussion of my comments by members of the IACC.

Dr. Insel: Thank you. Linda Varsou?

Ms. Linda Varsou: Hi, everyone. It's really heavy and hard to listen to public comments because they are true. This is reality. And I would like to ask the Committee for reasons also for democracy and transparency to put on the Internet all the oral and written public comments because they show the real situation in autism. Okay.

Today for the first time I'm going to present to the -- this Committee -- the issue of chronic parental denial of their child's autism, which is a

situation with terrible effects in the family, and the children with autism is the final victim. I have explained the details. There are three presentations before. You have the records of that. Now, we have a serious study from Israel. All on the Committee, you have this document, 53 to 57 the prevalence of denial just in autism. United States' professional report, around 45.

The problem is not only the family, it is when we do research, and if we don't take into account this particular factor of denial, then your research can be not valid, not totally reliable. Anyway, I'm not going to continue.

I would like to thank IACC for everything they do, but to tell them to listen more to the parents as well. And I would like particularly today to thank John Robison for his fantastic neurodiversity teaching, which goes along with my concept of an autism-friendly society is the best society for all of us.

I did an experiment with my son in teaching. His initial label was that he would be never able to learn English, computers, much more to go to college. Today he's an honor college student in computers, English. And we continue for university

maybe because I made it an autism-friendly environment for his studies.

I did an experiment with many medical graduate students I've had for many years. And I found out that when I scheduled a course which was often, frankly, like scheduled, predictable, safe, stable, the result was amazing. My students excelled. But when it was like a common course, there were medium, or some failed.

So finally, autism-friendly society and teaching an autistic child this method, we benefit. All students, the good students will excel. The medium student will be good and so on. Please take this experiment. I did not make publication. Believe, if you want publication, believe me, I will do that. It's very easy for me. Thank you.

Dr. Insel: Thank you. The next two presentations may be done together I suspect. Bobby Enayati and Albert Enayati?

Mr. Bobby Enayati: [Inaudible comments]

Dr. Insel: Separate, one? Okay.

Mr. Bobby Enayati: Hello. My name is Bobby Enayati, and I am here today to draw attention to the autism epidemic that is affecting millions of people in the country.

The Centers for Disease Control has just reported that 1 in 68 children in the United States suffers from autism, a 1,000-percent increase over the past four decades combined. So what does this mean? It means we have a big crisis on our hands, but more so, it means that this problem is worsening. It's getting worse, not better, and whatever direction we're currently heading is not working. Whatever research has been implemented has failed, and it has done nothing to find the cause or obtain a cure.

My brother now 24 years old, healthily progressed after birth and was functioning just like any other normal American toddler. He received seven vaccinations in one day, and then suddenly he lost his speech and cognitive abilities and was then diagnosed with autism. Many are quick to point to genetics, but if it was genetics, how do you explain the spike in autism?

If genetics was the culprit, then why has autism only been caught and noticeable in the 20th century? Did the generation past decide to take a break all these past centuries and suddenly decide to spring into action in the 1990s? Or is modern medicine's common introduction to vaccines the

culprit?

Human beings are at the most sensitive and vulnerable point in their lives when they're born. Vaccines are preparations of weakened or dead viruses which are introduced to a person's body in the hopes that the body can fend them off. But what happens if the body can't fend them off?

What happens if the subject body is only a few minutes old or if toxic chemicals, which are mercury or aluminum hydroxide, are including that vaccine, or border fetal cell lines? What happens if the mother of the border fetus had a psychiatric disorder? Is this practice really safe?

What you have is a recipe for disaster, a disaster where children are abruptly vaccinated immediately after they're born without positively knowing if or how the child's immune can successfully respond to the injected vaccines. Worse, this hasteful decision to vaccinate can be a larger mistake when one does not take into consideration past family history and be able to respond successfully to vaccinations.

Vaccines may prevent one to succumb to a disease in the future, but they also carry incredible risk and can actually cause a new

disorder in the present. Currently, this risk is being ignored, and vaccines are being given out with hardly any oversight. This unsupervised ability to administer a vaccination, especially to newborns, infants, and children, must better be regulated in addition to conducting research by impartial groups and entities to obtain a better understanding of vaccines and the links of causation to autism and other neurological disorders.

Is it really a coincidence that there's a spike in autism at the exact same time as the introduction of HIV and hepatitis B vaccines in the last 80s, this same HIV vaccine which tricks the immune systems of infants that produce antibodies? Or couldn't DNA of border fetuses be found in MMR and chickenpox vaccines? There's clearly a correlation between autism and these vaccines, and we need to get to the bottom of this.

Isn't it questionable that the former head of the CDC, Dr. Julie Gerberding, became the head of Merck, one of the largest vaccine manufacturers on the planet? It's painfully obvious what's going on here. There are major conflicts of interest with the vaccine manufacturers, and that's why nothing

is getting done.

We also have you, Dr. Insel, to blame. In the past 8 years, the IACC portfolio was $1.65 billion, and you didn't allow one cent to be spent on vaccine research. Zero percent of the $1.65 billion which was allocated was spent on vaccine research because every time the topic of vaccines came up, you brought it up for a vote and made sure it would get defeated. You advised to investigate every topic except vaccinations. You made sure to steer away from the vaccines topic, and it's because of these decisions that we're not getting anywhere.

Thank you.

[Applause]

Dr. Insel: Thank you. We'll move on to the last public comment from Albert Enayati.

Dr. Albert Enayati: Good afternoon. I have a commentary before I do my presentation. Dr. Insel, distinguished members of IACC, in a space of 8 years you have spent more than $1.65 billion. At the end of the day, you did not help my son even a bit, nothing, zero. Zero.

My presentation is related to vaccine and autism. I could guarantee everything in this room as soon as I leave this podium, my presentation

will be discarded because Dr. Insel would not allow any research protocol to go through IACC portfolio that has the word of "vaccine" in it.

My question to you is, Dr. Insel, in 2010 you -- it's on the record -- you and members of this Committee revealed that you are -- you do not have the expertise of vaccine safety; therefore, you asked the National Vaccine Advisory Committee, Dr. Ruskin and his team, to come up with some protocol of the research to satisfy the parents' concern regarding vaccine and autism. They gave you a protocol. You added it to the portfolio of IACC, right? And then you came back and you took it out.

Why did you take it out?

My son regressed to autism. You saw the video of my son. We can't live with him because of him hitting himself. My son was perfectly normal. He regressed to autism. Do you understand English? I'm really frustrated. $1.65 million dollars. My son sees zero percent. Does that make sense to you? I want your next meeting in July that regressive autism should be on the agenda of OARC. I need you to bring the Food and Drug Administration, Dr. Metu and his health team. I want you to bring National Vaccine Advisory Council to this meeting. We need

to look into the vaccination. I'm asking you to do so. I've talked to you before. I'm going to ask you again. We need to do that.

Now, I'm go ahead and do my presentation, but I'll try to do it very quickly.

Dr. Insel: Okay. But just be forewarned, you've used up about two and a half minutes, so we don't have a lot of time left.

Dr. Albert Enayati: I will do that. Human DNA in childhood vaccine. Many of the routine recommended childhood vaccines for use are derived from human cell lines including MMR, chickenpox, hepatitis A, and DPT polio/HIV combination. The two particular fetal cell lines that are used in the production of current vaccines are WITI and MRC-5.

The cell line MRC-5 was aborted psychiatric reasons.

The final vaccine is never completely pure, and DNA and cellular debris from the production cells are in the final product. For example, the package insert for the chicken pox vaccine: That vaccine contains residual components of MRC-5 cell line, including DNA and protein. Merck, the manufacturer, documented that Varivax® is contaminated with over 2 micrograms of human fetal

DNA fragments.

The human DNA in this vaccine has the potential to become incorporated in the host gene by the process illegitimate or homologous combination. It is possible that human DNA-contaminated vaccine contributed to these cases of autism. One hypothesis presented to us is that the homologous combination of DNA from another human incorporated in the host DNA may cause an autoimmune reaction and subsequently somatic mutation. The autoimmune reaction could result in neurological injury.

Emerging research is showing continuous brain malformation in those with autism. The knowledge of autism is comparable with the human cell link. Since 1983 or earlier, the MMR vaccine in the U.S. has only been produced using aborted fetal cell line. Consequently, severe autism began to rise in the U.S. in the 1980s, increasing from less than 1 child per 10,000 to about 1 in 500 by 1990. The current rate is 1 out of 68.

On May 8, 2013, at the Vaccines Biological Products Advisory Committee meeting, Dr. Keith Peden, chief laboratory of DNA virus at CBR, quoted, "Still no one knows whether or not

extraneous vaccine is safe." The FDA -- Dr. Insel, are you listening to me? The FDA, Food and Drug Administration, Dr. Peden is the head of the DNA research. I'm going to show it to you. He doesn't even know what it does. He doesn't know what human DNA does in the child vaccination. They don't know. How could it be safe?

Why don't you bring this -- why don't you listen to us? Why don't you listen to the parents? Why? Why? Answer me. Why? Eight years, $1.6 billion. Zero percentage to vaccine and so many frustrated parents. They come here and begging you, asking you you're going to look into vaccine, and you don't do it. So what do you want me to do? What should I tell to my autistic son? Why should I tell him that he has no language? He is constantly hitting himself. What should I tell him? Dr. Insel doesn't want to do it, doesn't want to find out what's going on?

Dr. Insel: Thank you, Dr. Enayati. We're going to now take some time for discussion. And because we're well behind time, I think what we'll do is to move the presentation that had been planned for 2:00 to later in the afternoon when we have a little more open time. But let's take our 15

minutes or so now to cover what we've just heard and use this as a basis for Committee discussion. John?

Mr. Robison: I'd like to offer a couple of thoughts. First, I've heard both from the commenters who spoke and also from the commenters who wrote into us a lot of commentary this session on regression. And when I hear "regression" in the same sentence with "vaccine," what I see is happening is I think that we are jumping to a conclusion, and I don’t want to start about, you know, vaccine.

But I'd like to point out that regression was noted very clearly by Dr. Connor and Dr. Asperger in the literature almost 80 years ago.

It is likely that regressive autism is a significant serious issue that is separate from the kind of constant autism, if you will, that affects somebody like me. And I think the people raise a very good point that we should study and get to the bottom of it. And I'd just like to say that, you know, I hope we don't push aside the need to study that question because of the vaccine controversy that the autism -- that the words are often tied to. Clearly Dr. Connor and Dr. Asperger noted

regression long before there were vaccine questions.

The other thing I'd like to mention and I want to say it, you know, here because it was not in the spoken commentary, but it's in the written commentary. One of our commenters reminded me of the real tragedy of wandering and listed some of the young people with autism who have died principally from drowning since our last IACC meeting. And I wonder if we could ask for an update on the folks on our Wandering Committee for the next meeting.

And finally, also in the written commentary here, we have a couple of people who are talking about the terrible problems that their autistic family members are having in the criminal legal system in this country, and I think that's something that we have paid all too little attention to here. We have brought in lobbyists like Stuart here. I mean, these guys have done a wonderful job in lobbying for civil legislation, but we've done precious little to help people on the legal front. And I wonder if we could bring in someone from Justice and have a discussion on that, which is rather different from, say, training first

responders that we've talked about.

So those are, I guess, my points.

Dr. Insel: John, if I can just respond to your final comment, which did come up in the written comments.

Mr. Robison: Right. Yes. Yes.

Dr. Insel: We didn't hear it so much on the oral side. Just earlier this morning, the Treatment Advocacy Center, which is based in Arlington, Virginia, released on its website a very detailed, perhaps the most detailed study yet of how people with either developmental disorders or mental illness end up in the criminal justice instead of the medical system. And we can provide the link to that report. I suspect it will get some coverage in the media as well.

Mr. Robison: If you could send that to me, I'd be very interested in it.

Dr. Insel: Okay. We'll make sure that goes out to the Committee. Tiffany?

Dr. Farchione: So I just wanted to comment on the last two folks. So I'm in the Center for Drug Evaluation, so I'm not in the side of FDA that works with vaccines directly. But because I saw the comments in advance, I did get a hold of someone in

our Center for Biologics who, you know, does work.

And so, I have some comments from him that I can just read if that's okay.

So what he said was that "The proposed mechanism for development of autism based on injection of DNA fragments is not supported by scientific studies. Humans are routinely exposed to much larger quantities of DNA in their bloodstream both from food and in the normal process of cell breakdown and have been since long before vaccination became routine.

At the time the varicella vaccine was licensed, a study showed no evidence of anti-DNA autoimmune responses among vaccinees. There is no plausible epidemiological evidence associating vaccination with autism; thus, a vaccine-related mechanism for autism would be very unlikely."

And the final comment was that "Previous FDA meetings describing theoretical concerns with the use of cell lines focused on the question of whether DNA from tumor cells could somehow transmit a tumor-related phenotype to vaccine recipients.

The cited meeting describes some of the discussions related to that issue. The statement according to the Sieber Office, 'the agency still

does not know whether or not extraneous DNA in vaccines is safe' is both taken out of context and is false. Considerable data now exists to support the safe use of human -- the safe use of tumor-related cell lines in vaccine production as was discussed even at the cited meeting." So that was the official response from the biologics folks.

Dr. Insel: Idil?

Ms. Abdull: I was wondering if there's a way we can -- the IACC can -- address the housing issue. We've heard time and time again that the waivers in every State, there's a long wait list, and people when they get -- when their bus comes after 18 what do you do for these children? Where do you go if you don't have the income to buy a duplex and make your child live next to you? How do you -- and how do you help them?

And I see that John is not here, but is there something we can recommend or send maybe to the Secretary, somebody? What do we do for these children that become adults for the housing issue, whether they have -- regardless of where they are on the spectrum, regardless of what the cause and the cure is, we have to -- they cannot be homeless.

And I just wonder what people here or, Dr.

Insel, what you think about what can we suggest for housing. Every time we hear there's a housing crisis.

Dr. Insel: Response? Yes, David?

Dr. Mandell: So I agree with you. I think trying to both simultaneously address the huge housing issue that we're going to have -- especially for more severely affected individuals as they reach adulthood, or even those who have not yet reached adulthood, but whose familiar for various reasons are not able to care for them in the home, -- is that is a real crisis that we have to address.

I also think we have very little evidence about the best strategies to do that. And doing that kind of -- and gathering that kind of evidence is going to be much more expensive than almost any other kind of research we can do because it involves residential costs.

At the same time, there are places around the country that are doing it well, at least anecdotally. And I wonder if it would be good for the IACC to hear from some places around the country that have been very creative in combining Medicaid waivers with Section 8 housing or have

developed residential settings that should a lot of promise to be able to make some sort of considered educated statement about what the housing and residential needs of this population are going to be?

Dr. Insel: Those of you who have been on the Committee for a long time will remember when Denise Resnik was a member of this Committee, she really championed this issue. And within Phoenix through her organization SAARC has worked out some best practices for residential policy, housing opportunities, a whole series of things that she's done that talked to us about that.

In terms of what we've done since then, it's actually conspicuously little. It's not been on the agenda very often here. Maybe this is something where we want to bring in someone from HUD or other agencies that can help us think about what would be possible. I'm open to ideas that any of you have.

We could also bring back people like Denise who have really thought about this and have tried this out and have come up with what looked like pretty good experiments, although we wouldn't call it research. They've got lots of experience, if not experiments, to show what works. So that's

something else we might think about in the future. Jan?

Ms. Crandy: And before -- I believe in the last meeting -- I had asked if Medicaid could come back and talk to us about those home- and community-based service waivers and the new regulations that came down and how it impacts. So maybe if John is going to get to speak on the State of the States -- if he's going to -- that he could comment on those and how it impacts us.

You know, on Question Number 6, it probably was the least funded of our questions for research, so we probably should add housing for our next agenda. The other thing, you know, listening to all these families talk about vaccinations and the increasing number of families that are choosing not have their children get vaccinated. So it's not an unethical situation now to do a unvaccinated versus vaccinated study --

[Applause]

Ms. Crandy: -- or at least to add some transparency and help parents to feel more safe about getting vaccinations, maybe we should put it on our agenda and have experts come here and talk about vaccines, and why they are safe, and what's

the potential, and what are possibilities that we could change the schedule, or look at kids that -- prior to giving them the vaccinations, if they have low immune systems -- that maybe we could put it on our agenda. I think the public would appreciate us at least talking about it maybe at our last meeting. Thank you.

Dr. Insel: So I might add, we have just done that study looking at, in this case, tens of thousands of children in a large health care system -- younger siblings, many of whom did not vaccinated. So we could, whether you like it or not, compare what the risks are, both the risk for autism and the risks for medical consequences for not being vaccinated versus being vaccinated in children who have presumably some genetic risk because they're young sibs.

And those data are submitted for peer review. We should -- maybe by July we'd be able to have that presented here. So I'll be happy to, since we've funded that through, be happy to ask the authors to come and talk to us about the results.

Ms. Crandy: Thank you, Tom.

Dr. Insel: Lyn?

Ms. Redwood: Gosh, I don't know where to

start. It's just incredibly difficult to sit meeting after meeting and listen to these public comments that bring me to tears. And, you know, I have to agree with everything that was said today.

We do have a national crisis on our hands. And, Tom, this Committee meets four times a year and is just not able to address the needs that autism presents to our country. So I really think we need to go looking somewhere else to get the answers from our Federal Government to really address this the way it needs to be addressed.

In terms of the comorbidities, I heard the families share with us today and that I've heard on this Committee for, what, 8 years, and that I witness personally with my son that were overlooked.

Back at our last meeting in July, we agreed unanimously to form a subcommittee to look at these co-occurring conditions, and that was 9 months ago. That's how fast this Committee acts on things. It's very frustrating, and it is something where we could help these children today.

And I really hope that our discussion this afternoon, at the end of the day when we get to the point of looking at establishing this work group to

focus on comorbidities, that we're able to do something that was done similar to the BRAIN Initiative with the work group that put together.

There's a lot of opportunity there to help families now, and I really hope we don't overlook that.

In terms of the question about public comments being on the website, we've been asking for that for quite some time now, Susan. What's the status of that happening?

Dr. Daniels: So, I have had meetings with the legal team at NIH, and they need to review our entire database that we're designing. And so, we are going to have technical experts as well as legal experts looking at this, but it's going to take some time. We are preparing all the public comments in terms of getting them ready to put into the database, and many of them have actually been added into this draft form of the database that we have. But it will require review, and we will have to get approved before we can put it up.

Ms. Redwood: To the people here today and to anybody that's been here presenting public comment, if you want to email those directly to me, lynn@autism.com, with your permission to put them

up, we can put them up on our website until NIH is able to get those up.

And also, I feel horrible. This packet of written public comments, this came in the mail -- by email when I was traveling, and it was large that my server bounced it. So I've been trying to read through these today during the breaks. During the meeting is the first opportunity I've had. And there's no way to respond to all of these, and I apologize. I know you've been coming for a tremendous amount of time asking for our response, and we just don't have time to. So if you want me directly, I won't speak for the Committee, but I'll be glad to share what my responses are to these public comments.

And the last thing I want to say, Dr. Insel, is I'd like for you to answer the last person's question about adding vaccines to the agenda, the meeting that we had previously with Dr. Gellin.

What is the status of that, because it is still an urgent issue that needs to be addressed and needs to be researched?

Dr. Insel: Well, as I thought I said clearly, we're just completing or have just completed a fairly large study of very much the kind of thing

that the Committee at one point talked about, comparing vaccine --

Ms. Redwood: But that's an epidemiological study, correct? I think what the families are looking for are studies that go beyond epidemiology, that look at the children that regress with mitochondrial abnormalities after vaccinations, like Hannah Poling, and other studies that look at things beyond just an epidemiological study in a high-risk population.

Dr. Insel: Well, this would have been a high-risk population. I don't know that there would be mitochondrial data from any of the subjects because, you're right, it was essentially through a health care system, so it's a records kind of study. But it does give you a sense within a group that you would think would be high risk, whether choosing not to vaccinate as protective, choosing to vaccinate increases the risk. So I don't think it'll be a single definitive study, but it does provide insights that we wouldn't have had without it. So I think we should wait and see what that looks like.

The study you're asking for, the idea of looking at individual cases, was something that was

taken on -- if you remember, I think it was -- with our strong encouragement by Sue Swedo many years ago, something that the Committee almost requested for her to do. And she set up a national program to go around. I think you were even part of the group at one point that was designing this to interview individual families for whom they had a very clear story of regression.

And if you like, we could have her come to the meeting and report out on that. I don't think the data are published, but I'm sure she would be willing to say what came out of that.

Yes, go ahead.

Dr. Burton-Hoyle: I wanted to speak about that, the housing issue. The Centers for Medicaid and Medicare calls for -- with people that are dual eligibles, Medicaid and Medicare eligible -- for person-centered planning, which is an individually directly process where people talk about based on their strengths and weakness what might be best in their life as far as what they do with their day and where they live.

And I think that would be something that -- it's mandated. It's in our mental health code in Michigan that it's done for each individual. Is it

authentically and correctly done for each person? No. But when it is done, positive results can be yielded about what it is people on the spectrum might want and need, anybody that's in the mental health system because there is no one size fits all. There is no “this residential program or that.” It's really got to be individually directed.

So I would encourage that everybody become more familiar with what person-centered planning is, and that the -- is it in your -- you know, each State writes their own Medicaid plan. That's not done at the Federal level. Each State does it and then gets it approved by the Center for Medicaid Services. So to look at what person-centered planning is -- I've done that for lots and lots and lots of years because that was a good way to look at what people with autism wanted and needed.

My own brother left a highly touted residential program in another State where several people were marched off as felons because of the abuse that went on there to have for -- 10 years -- the 10 remaining years of his life he had a life.

And that was self-determination, and that was chosen who his staff was, and he flourished. But that was all based on the person-centered planning

option.

In any event, it's not an option in Michigan. And I don't know what each and every State has, but it's something that happens in schools and happens lots of places. So I would encourage that we look at that strongly for folks on the spectrum.

Dr. Insel: You know, there are a couple of comments here that make me feel we need to make sure that John O'Brien is in the room and can help us sort our facts out on some of these issues. So, Susan, maybe at the next meeting we can have him on the agenda to help us understand some of these -- Jan, you brought up about the policies and waivers.

And I just think we ought to hear from him directly. And he was also going to tell us about the State of the States report, so that would be good to capture some of that. Anshu?

Dr. Batra: A couple of comments -- a couple of questions, comments. So one is I wanted to discuss Eileen Simon’s comments and her request, which was that we discuss it – her issues around language and obstetrics. And so, again, I'm new on the Committee and I don't know what's been done in the past. But I'd like to see how we can perhaps -- is there someone from the obstetric -- American Obstetric

Society can maybe come and speak to us about what the procedure is around the birth process, whether it's vaginal or C-section, and just so we can get some more clarification about that process, and see how then we can maybe, you know, look into this issue that Simon brought up because, again, what we're talking about are the subtleties that oxygen deprivation, even for a millisecond, may then create these -- whether it's an impairment or a difference in functioning. So we're talking about functioning rather than defect, which, again, I think is -- all of us here who have or see kiddos, you know, that's a large portion of what we see.

And then, secondly, along with having John O'Brien on the agenda for the next meeting, I would like to hear more of what Sally Burton-Hoyle has to offer in terms of the issues around transitioning a team into adulthood around, you know, higher education. And the -- just the real-life issues that she, you know, she and her staff have to deal with that make the person's day-to-day living and the family's day-to-day living with that individual better. So, which again, I think that that's ultimately what I hear, you know, the public. And I count myself as the public, you know. I just want -

- I want things to make my son and my life better for him. So I'd like to see her also discuss some things that she's learned and can share with us as well as the community.

Dr. Insel: Other comments? Jan?

Ms. Crandy: Tom, to your knowledge, have there been studies that look at that clamping before the first breath, or is it common practice that they don't wait for the first breath to clamp?

Dr. Insel: It wouldn't be something I would know about.

Ms. Crandy: Okay.

Dr. Insel: Dr. Guttmacher probably knows more about this than anyone here.

Dr. Guttmacher: There have been a number of studies that looked at cord clamping, but they've looked at it more for short-term outcomes, including for both the mother and for the child.

They look at such issues as maternal hemorrhage, which is a concern for the mothers, this need for phototherapy and the infants.

Basically, the dynamic of cord clamping is that if it is delayed, you are essentially removing more of the blood volume to the child and taking it away from the mother. So the balance has always

been how do you balance those things.

In general, there's pretty clear evidence that for preterm infants, it makes sense to delay cord clamping. For term infants, there's more sort of variety and practice, but still most folks these days do delay cord clamping for 30 to 60 seconds.

But there have not, that I know of, been studies that look at longer term outcomes of the children such as development of autism or other neurodevelopmental issues, et cetera. But again, the only thing that would seem to really be changing in this is the blood volume immediately post-delivery.

Dr. Insel: Well, I -- go ahead, Lyn.

Ms. Redwood: Tom, I just wanted to make one more comment, and it goes to the woman who had two children -- Cassandra, I think it was -- who regressed and what you struggled with to help your children medically. And it seems as though there's a disconnect in the research literature because we have volumes of data that support oxidative stress in autism. Out of 115 studies, every single one of them have found an association. They've documented low levels of glutathione, high levels of oxidized glutathione.

In terms of immune dysregulation and inflammation, out of 437 studies, 416 of them found an association. The same with mitochondrial dysfunction. Ninety-five percent that looked at mitochondrial dysfunction in autism found associations.

But right now, the medical community isn't really -- those things are not on their radar screens. We don't have intake questionnaires that routinely ask questions to even look at those issues. We don't have set testing in terms of -- terms of how do you evaluate those types of issues in children with autism.

And as we've heard over and over again from several of the people today, the young man who's an adult who's done biomedical treatments, my son, they've all benefited greatly from these things.

And, you know, the parents are doing these things independently, and they're paying dearly to find clinicians who will help them do that. And it's helping, and we need to study those treatments to determine safety, efficacy, and if they are, then we need to somehow get those in guidelines so these individuals can be effectively treated.

We've focused a lot on the gastrointestinal

problems, but that's just one system that's impaired. And we've focused on the neurological system. But, you know, this is a whole body disorder, and we're just missing so much that we could focus on. And again, I don't know how we make this connection between the research community findings and clinical practice. So any guidance anybody on the Committee could offer on that would be much appreciated.

Dr. Insel: You know, I think one of the things we're struggling with here, and we keep coming back to this, is we're not talking about a disorder.

We're talking about many, many disorders, and unfortunately they have one name. But if we came together as a Committee to coordinate research and services around fever, we'd be having a very similar discussion because there'd be some people who would be intensely ill with an acute bacterial infection and others who would have thyroid disease. And they would all have the same label.

So one of the things, I think, before we talk about large randomized clinical trials, is we've got to find a way to figure out what are those subgroups that would have to go into any given trial so that you would have some hope of actually

being able to know who should get the kinds of interventions that you're talking about.

And we'll come back to this maybe when we talk about the Co-morbidity Work Group. But I just think it's going to be essential for us as a coordinating group to advise at least the research community to get the biomarkers, to get these classifiers, and put those into play before we talk about intervention trials. Otherwise, just like if you did an intervention for fever, you wouldn't find out that antibiotics have any value whatsoever because they wouldn't work in half the people. So it's going to be important for us to really think this through at that level.

Lots more to talk about. I guess what I came away with most of all from many of the people we heard from was just the frustration and anger that we haven't delivered as a Committee, as a Government, and even speaking to the private funders as well, that we have failed -- as people said -- failed to prevent a single case, failed to provide a single cure. And that is not unique to autism, but that shouldn't make us feel any better.

That is really an important statement to sit with and to realize that whatever it is that we've

been doing isn't yet delivering. And so people have every reason to feel frustrated, especially as they see the numbers go up and not down. So we're not bending the curve. The curve is actually going in the wrong direction.

One of the things that we did want to hear about are changes in policy. And so, given the late hour, I want to move forward. We're going to put off the discussion of the new services RFAs from NIMH for a little while. We'll come back to that later. But I think we'll jump forward and leapfrog to Stuart Spielman, who's the Senior Policy Advisor and Counsel for Autism Speaks and who's become really an expert on what's happening at the level of policy.

Mr. Stuart Spielman: Thank you, Tom. I know there's great interest in the room on the status of reauthorization. At this point there's nothing concrete that I can describe. There is no bill. There's a lot of discussion. There's a tremendous amount of interest by everyone up on the Hill, families. We're all interested in reauthorization of the Combating Autism Act.

But my purpose today is really to be rather selective in describing what's going on. And I want

to focus on one piece of legislation that is very much ripe for action, and that I think is very important for our community. And that is the ABLE Act of 2013. And I say this from two perspectives -- one is as someone who represents Autism Speaks, but also as a parent. And one of the great issues that families face is an inability to provide for services, provide for care.

The threat of poverty runs through disability, and right now the structures that we have in place actually discourage families from saving for individuals with autism and other disabilities, and the ABLE Act is an attempt to change that. So ABLE would change the Internal Revenue Code, and we have under the Internal Revenue Code 529 plans. These plans are very good for kids who are college bound, but for many kids with disabilities and adults with disabilities, higher education is not in the prospect. And other needs are going to be met or not be met. So the ABLE accounts would essentially create an analog to the current 529 college savings plans and allow people with disabilities and their family members to save for future needs.

[Pause]

The variety of benefits that ABLE accounts

could provide are many. ABLE accounts could be used for educational programs. They can be used for housing. We've had a discussion here about housing needs and the tremendous needs in our community for housing -- transportation, employment support, health and wellness, and miscellaneous expenses as well.

So I think it's important to think about what we have right now in terms of how we're looking after the future needs of individuals, and we have some devices out there, such as special needs trusts. But the one thing that is lacking is an easily accessible means to save for the future, and that is the niche that the ABLE account is designed to fill. It is really very much like a 529 account, and it responds to some of the same pressures that I recall were in place when there were discussions about college savings years ago and the inability of families to have a ready, easily accessible device to save.

So the critical issue has always been with savings for individuals with disabilities, the SSI and Medicaid limits. And the ABLE accounts would enable individuals who have assets of under $100,000 not to have an impact on monthly SSI

benefits. So this would actually enable people to put aside money without making that choice between ABLE accounts or losing benefits. And again, this has always been a critical problem that we've always faced a choice between having entitlement programs that provide a social safety net and allowing individuals to save for the future needs.

[Pause]

Now, I mention this, and I'm focusing on this to the virtual exclusion of other things, because this is so ripe as far as what we see on Capitol Hill. It is extraordinary that we have 70 Senators and 354 Representatives cosponsoring ABLE. Just a couple of weeks ago, both leaders in the Senate, Majority Leader Reid, Minority Leader McConnell signed on as co-sponsors of the ABLE Act. And that is a real rarity in Washington to see leaders signing on as co-sponsors to major legislation.

So, you know, if we're looking at deliverables, if we're looking at things that can change in the near term, this is one of those areas where a difference can be made. And so, you know, there are many, many things we can talk about that are going on in Washington as far as legislation, but this is very ripe. And I'm hoping that in the

next few months we're going to see this enacted into law.

Dr. Insel: Okay. Thank you, Stuart. Before we get into a discussion, could you just explain what's the argument against this? I mean, it doesn't sound like --

Mr. Spielman: Well, you know, there really isn't an argument against this except one, and which is that ABLE, you know, there would be a cost to these accounts because these accounts -- the money in these accounts -- would be tax advantaged.

They be not taxed if they were used for appropriate purposes, and so, there's a potential revenue issue here. That is the only issue.

Dr. Insel: Comments or questions? David?

Dr. Mandell: Can you say a couple of words about how these interact with, or not, those special needs trusts and differentiate their purpose a bit for us?

Mr. Spielman: Well, these are not designed to supplant special needs trusts. They're designed to be another tool. And for different individuals who reach different conclusions as to the best device for savings, the special needs trusts require some startup. They're more of a boutique product. They

require a filing of a 1041 return. They're more complex in a lot of ways.

The idea with the ABLE accounts was not to create one single savings device that would replace all others, but really to give another choice, just as 529 plans are for one choice to family savings for college.

Dr. Mandell: So it sounds like these accounts also would be a more accessible mechanism for families of fewer means.

Mr. Spielman: And I think that very may well be their primary use. This would amend the existing 529 -- Code Section 529 of the Internal Revenue Code -- and provide this variation on the 529 theme.

Dr. Mandell: Sorry, one more question related to that.

Mr. Spielman: Sure. Sure.

Dr. Mandell: It sounds like -- so if one of the potential purposes of this is housing for families that may not otherwise qualify -- who have children who may not qualify -- potentially qualify for housing under other means, then this seems like a wonderful start and a great mechanism. But $100,000 seems like kind of a low cap.

Mr. Spielman: Well, you know, Washington is a study of what's possible. And I would not object if you become king and raise the cap.

[Laughter]

Dr. Insel: Other comments either about this or other policy issues that you want to hear from Stuart about? Anshu?

Dr. Batra: Yes, a quick question. So what is it that we can do to help support this, I guess, you know, as the public?

Mr. Spielman: I think that just speaking with Members of Congress. You know, we have so many Members -- we have 354 Representatives and 70 Senators. I don't know who represents your district, Anshu, but the more Members of Congress that we have, you know, it becomes -- it just becomes -- a crescendo, and people notice that, you know, especially in times when it could be difficult to reach consensus. We have people on every part of the political spectrum supporting this, and just the more Members we can get, the more people hear from people like you -- Members of Congress hear about what's going on and their support for this -- that's what's important.

Dr. Insel: Great.

Mr. Spielman: You actually have a list. That's great.

Ms. Gammicchia: [Inaudible comment] I have a list – [Inaudible comment]

Dr. Insel: Tiffany?

Dr. Farchione: I'm just wondering if you have any idea if there's an intent to bring it to the floor, you know. I mean, it's one thing to have all the cosponsors, but if it never makes to the floor for a vote…

Mr. Spielman: Yes. Yes. Well, I think with this kind of core of support, it will be propelled along. Things take time in Congress. Things take a lot of time in Congress. But I think that those of who have been working on this bill for many, many years think that this is the year.

Dr. Insel: Idil, last comment.

Ms. Abdull: Thank you, Stuart, first for Autism Speaks in general. A lot of people talk about -- there's one parent in particular that talks about parent denial -- and what Autism Speaks has done is take away the denial bit by raising more awareness. So I really appreciate that.

I have a question and maybe a comment, not in particular to this bill, but in general because

Autism Speaks works a lot about policies and making sure that you change what services are covered, particularly early intervention State by State by State. And you send delegates or people, advocates or lobbyists to each State, and you advocate to change the State regulations and the State rules for that particular State for private insurance, which I'm very grateful.

And so, I was wondering what your take is when -- if you can go to each State and also make sure that not just the private insurance is changed -- the rules for private insurance coverage -- but also for public insurance because often the same State legislatures are regulating the private market, but they could also regulate the public market, the Medicaid rather, because we know that each State has their own Medicaid rules which gets approved by CMS. But the State legislatures can do the same thing that they have done for the 35 plus States that now have private insurance covering early intervention.

I just really think to gap this disparity, we want to make sure, you know, Michael Smith, low-income, Medicaid kid and also Michael Smith, higher income, Blue Cross/Blue Shield kid get access to

the same services.

Mr. Spielman: I can assure you that we care about Medicaid. This is an issue that I've talked about to some of the people on the table. And this is just on a personal basis. The very first thing that I did as an advocate was work on HCBS waiver in the State of Maryland. I did this back in the nineties.

And we are committed to quality health care regardless of source, whether the source is public insurance coverage, whether the source is the military health care system, whether the source is private insurance, whether the source is insurance through self-employed plans or State-regulated plans. So we are committed to improving health care for all kids, and I can't emphasize that enough.

Ms. Abdull: I'm sorry. Can I just follow up? So I'm glad that you -- that Autism Speaks in general cares -- but I just wonder when you're going into a State, and we've had a lot issues, you know, within Minnesota. What happens is Autism Speaks folks come into the State, and they pick up a bill, or they sponsor, they ask a State legislator to write a bill to make sure autism therapy, particularly early intervention, ABA is

covered for children with private insurance.

I just really would like that same person to do the same push for the children that have public insurance. In other words, let's push for all children at the same time for the same services rather than saying we'll come back for the public later. I don't want my kid to be come back for. I would like -- do you know what I mean, Stuart?

So if we could've had now 35 States that have had not just private coverage, but we could've had States that had public. And in Minnesota we fought. We fought. We said, you're going to help all kids or you're not going to help anyone, and we were able to pass that, but it was with great fight. And it would be nice to partner with Autism Speaks funding, and, you know, lobbyists, and advocates, and say let's make sure children with Medicaid and also Blue Cross/Blue Shield medical, whatever the private insurance, are getting access to the same services.

I just -- I really would like you to address that so your group are going into the States to help the low income and the upper higher income.

Mr. Spielman: Again, I think we're doing that, you know. And this is something that has been a

focus of ours for years, you know, us as individuals and us as an organization.

Dr. Insel: Thank you, Stuart. We're going to move on to Committee business, and I'm going to turn this over to Susan.

[Pause]

Dr. Daniels: Alright, I want to give you an update on some of the things that we've doing in the OARC first, and then we will move onto the regular Committee business.

So I've sent you all information about some of the recent publications that we've put out. Members of the public who are on our list serve also received this information.

Our Office prepared the Combating Autism Act report to Congress on behalf of HHS, collecting information from all the agencies in HHS, Department of Education, EPA, DoD, and NSF that are doing autism-related work, and put it together in this comprehensive report that was released in February. It's up on our website and can be accessed there, and it's been submitted to Congress. So I wanted to make you aware of that.

And you have copies at your place, and we do have hard copies available as well. And if anybody

in the public wants a hard copy, they can just write to our Office at iaccpublicinquiries@mail.nih.gov.

There are some other documents that have recently been published as well. The IACC published a statement on *DSM-5*, and that was released last week, and I have a slide up here just to tell you a little bit about that. The statement addresses implications for both research, practice -- well, all three -- research, practice, and policy. And this statement focused on trying to understand the potential impact of the new criteria on diagnosis, prevalence estimates, and access to services.

And one of the key messages in the whole report, I've put in red at the bottom that services should be based on need rather than the specific diagnosis, that it would not appropriate to deny someone services because they do not meet the full *DSM-5* criteria if a qualified clinician or educator determines that the child could benefit from services. And so, you'll want to read the entire statement that's up on our website, and we have a press release also. So the website is provided on the bottom.

And I want to give you a preview of a couple

of documents that are going to be coming out. We haven't done the full release of them yet, but you have a preview copy of a pre-pub draft at your places, and we have just a few out on the table.

But we will be announcing this publicly very soon, the summary of advances for 2013 by the IACC. So your top 20 picks for the most significant articles of 2013 are in this volume, and it's written in lay friendly language so that members of the public and read it and learn more about these important advances, and it covers all of the areas of our Strategic Plan. So you'll want to see that document. And similarly, it will be up on our website. We will put out an email blast, put it out on Twitter. And anyone who wants a hard copy can write to our Office and ask for one.

Also, we'll give you a preview of the 2013 IACC Strategic Plan Update, and you all approved this update in January, and we're just in the final stages of getting this printed and published. And so, we will be putting out the official announcement here in the next few days about this document. But you have a prepublication draft on the table, and we put some copies of those drafts out in the lobby as well. And we will be announcing

it. It'll be up on our website.

These are actually -- these previews, they are -- on our website, but right now they're only linked from the materials for the meeting. So if someone in the public who's listening in wants to see them, you can see them on our website. But we'll put them fully linked from our homepage when we make the full announcements.

Too loud? Oh, wow. I've been having trouble hearing all day, so I moved this closer to try to be heard better. I know that I don't have a very loud speaking voice.

I wanted to just show you a slide. This is not an OARC or IACC document, but the State of the States of Services and Supports for People with ASD was put out by the Centers for Medicare & Medicaid Services in January 2014. And I know that a number of you are interested in this publication. It is accessible from the IACC website if you go to the non-IACC reports link.

However, I have had problems accessing it through the link over the past 2 days, and I'm not sure why that is. They may be having some web-site problems at CMS. But I did send out a PDF to the members of the Committee, and this contains data on

Federal- and State-level services and programs and policies in all 50 States. And we have invited John O'Brien and people from CMS to come and give a presentation in July, so hopefully they can give you a full update on this report. They weren't available -- the key people that have been involved in this report weren't available -- for the April meeting, so I think this coincides with spring break for some.

Dr. Insel: The link was working yesterday.

Dr. Daniels: Okay. I had problems late last night accessing it, so I don't know. Maybe it's my computer. But anyway, this report does respond to Objective 7B of the Strategic Plan for conducting an annual State of the States assessment, and so this is the first of its kind. And we'd encourage you to have a look at it, but we will hopefully receive the full report in July.

I also wanted to give you some Autism Awareness Month announcements, and Tom may have some comments about this. But this is the NIMH Special Lecture for Autism Awareness Month that the OARC is helping put together. Autism's Powerful Affinities: Prison or Pathway by Ron Suskind, who is an author who's been in the news quite a bit

lately. Tom, do you have any comments?

Dr. Insel: I think many of you know the story about Ron and Cornelia and their son, Owen, who had severe autism that they were finally able to reach through Disney animation, Disney characters. Have you heard this story? It's been on NPR multiple times. And he tells the story in a very moving way, so I'd encourage anybody who's available on the 24th to join us.

Dr. Daniels: Yes. So we will be webcasting live, and people are also welcome to come to the talk if they'd like. It's here on NIH's campus.

And I wanted to highlight a few other Autism Awareness Month activities that are going around in the Federal agencies. So within NIH, there's an NICHD conference on military-connected children with special health care needs and their families that's happening next week, and that's on the main campus. We have an NIMH Twitter chat that will coming up with Sue Swedo, who was mentioned earlier, talking about when should I be concerned, along with Dr. Audrey Thurm. So those of you who are Twitter connected might be interested in doing that. NIEHS is going to be holding a virtual forum on autism and the environment on April 22nd from

2:00 to 3:00 p.m., and that will also be webcast live.

CDC has a couple of events, so there is an Autism Awareness event that's going to be featuring Alexis Wineman, who is the recent Ms. Montana, who's a young woman with autism, discussing the challenges facing teens and adults with ASD. And that'll be happening in Atlanta. Is that going to be webcast? Okay, so that one is not webcast. CDC Grand Rounds: Autism Spectrum Disorder: From Numbers to Know-How, that'll be about -- that one will be webcast.

Dr. Insel: Coleen, are you doing that?

Dr. Boyle: No, I will not.

Dr. Daniels: So the next two items that I just wanted to quickly mention were HRSA and AUCD are doing two virtual forums, one on ASD and transition and one on reducing disparities, so you may be interested in tuning into those. And all the information should be up on our website in the non-IACC events section if you're looking for it. I think -- the last couple I don't think all the information is published yet, but we'll add it to our website as it becomes available.

So the next item that I wanted to turn to now

getting to Committee business is a GAO letter update. And I wanted to turn this over to Alison Singer.

Ms. Singer: At our last meeting in January, there were several members of the IACC who expressed concern about the GAO report that came out in November, particularly that the report could be used to try to cut funding for research. You can read about the discussion that the Committee had in the minutes. But in general there was concern about the use of the terms "potential duplication in autism research," because "duplication" was defined as more than one project being funded under each IACC Strategic Plan objective or multiple agencies within the Government funding studies under the same objective. And the underlying report -- the underlying tone of the report was really to equate the term "duplication" with wastefulness.

So there was also some concern expressed that the GAO didn't really understand the role of replication in research and didn't really understand how the IACC Strategic Plan was put together in the first place, and that I was focused on filling gaps, and that the goal was actually for there to be multiple projects supported under each

objective.

In the report, the GAO identified that 84 percent of the projects listed in our Plan had the potential for duplication, although they only found four actual instances of duplication. For me the key there was that if they found four, it means they looked for actual duplication and only found four.

So we wrote a letter in response. The letter was signed by more than two-thirds of the public members of this Committee. It basically outlined the concerns I just identified. It's in everyone's packet. It was delivered to the GAO on March 6th.

We received a response from the GAO on April 3rd. The response was somewhat disappointing. It basically just restated the points that the GAO made in its original report. They wrote that they never came out and formally stated that there should only be one study funded per objective, just that a multiplicity of studies had the possibility to be duplicative. The letter uses the words "possibility," "potential," "can be" many times.

They also made a point of stating in the letter that the purpose of the GAO is to focus on improving Government performance.

So my feeling at this point with regard to this issue is that they wrote the report. We responded. They responded to our response.

Everyone's point of view is on the record, and I don't feel that there's any further action that we really need to take on this matter.

Ms. Redwood: You know, Tom, I'm having a difficult time not following the GAO recommendation. And I'm just curious how is the Committee, when they've pointed out a potential problem, that we would not want to investigate it.

And to just, you know, that it doesn't exist without actually looking, I just think that's a really bad position for the Committee to be in.

And if we're concerned about research funding being cut to this Committee, then I think one of the things we should do is respond to the GAO report in an appropriate manner and look at this as a Government agency that’s providing some type of opinion, and that we should determine whether or not that's valid or not valid. But to just have this knee-jerk reaction that, no, there's no duplication of funding, I don't think is appropriate. I don't think that's the appropriate position for this Committee to take.

Ms. Singer: Can I just --

Dr. Insel: Go ahead.

Ms. Singer: It seems to me, though, that if they were able to determine that there were four issues of actual duplication, that that implies that they looked for issues of actual duplication and found four. So what would be duplicative would be if we looked again.

Ms. Redwood: Well, no, Alison, that research portfolio is huge. I mean, that is a huge undertaking, and I don't believe they even had all that information collated at the time when this review was done. This is the first time we've had the last 5 years of research all together to really go back and look. So I really do think as a Committee we should --

Dr. Daniels: They did have all of the data.

Ms. Redwood: They had the last 2 years, too, Susan?

Dr. Daniels: Yes, they did. Yes.

Ms. Redwood: So all 5 years?

Dr. Daniels: Yes, they did.

Ms. Redwood: Okay.

Dr. Insel: So, Lyn, what would you recommend? You said that you don't think this is an

appropriate response and that the Committee should do something more. What would more be?

Ms. Redwood: I think we should go through the research projects, Tom, that have been funded by the different agencies and look to see if there are areas where the same project or a very similar project that has very similar goals that's being funded either by the same investigators or investigators at the same institute is occurring among these different agencies.

Just to me, that seems like it would make us good stewards of the money that we're using for research. And the fact that they've brought this up, I just think we should look at it as an issue. And to say, no, it's not without looking just seems as though it's -- we're not fulfilling our role as being good stewards of what we're spending our money on.

Dr. Insel: It's just so --

Ms. Redwood: I also think it would help to respond to some of the community concerns, too.

Dr. Insel: Donna?

Dr. Kimbark: I just wanted to answer that a little bit from the part of someone who does the management of the awards themselves, and I'm pretty

sure that NIH and some of the other agencies do this as well. During the time that we're actually looking at to fund the awards during the negotiation times, before the money is actually obligated to the Institute, one of the things that we do is we look at current and pending support, and we do a lot of searches.

We get in contact with our counterparts at the other agencies when we see that there's a possibility that there might be overlap or duplication, and we do an analysis with them. And we decide whether or not we should be funding this, and we withdraw. We also have during the whole monitoring of the life cycle of the award progress reports that come in. And the applicant -- I mean, the awardee -- it's incumbent upon them and the Institute to report back to us what they have -- what the research outcomes are.

One of the things that we do during our progress report reviews is to look at what they've reported, look at what's reported on NIH RePORTER and so on, to see what has been funded by other agencies during the time period where we might be blind, okay, during this time period because they're not submitting things anymore.

We have them now submit their current and updated pending support so now we can see what's happening during the time period of the life cycle of the open award to find out if there is duplication. This is an answer to that, and we've been doing this all along. But when we reported to the GAO, and I'm pretty sure that when everyone else reported to the GAO, we couldn't seem to make them completely understand the process of award management, which is too bad.

But the thing is that as a Committee, instead of going through something that the Government is actually already doing on a day-to-day basis with our grants management, instead of doing that, taking that huge task on, what we should do is as a Committee possibly it might be a good idea to state what our policy is as, you know, each one of the funders. This is what we do. We look at current and pending support. We manage. We're active. We're proactive to make sure that there aren't -- that there isn't potential overlap. That's what we do. That's the job of the grants management sections.

Ms. Redwood: What about other nonprofits like Autism Speaks and Simons?

Dr. Kimbark: It does those as well.

Dr. Insel: Walter?

Dr. Koroshetz: I think that it's critical to have precise language in what we're talking about here, so duplicative research is not necessarily a bad thing.

Ms. Redwood: And they say that in the report.

Dr. Koroshetz: Right. So I think that I personally agree with you that we shouldn't just sit down and roll over and ignore this. I think we have to basically justify the research that we fund. But I think we have to get into the precision of language, which is, you know, the bad thing about duplicative research is research is, you know, answering a question that's already been answered. That's duplication. This thing is settled. You shouldn't be doing it anymore.

If you have open questions, you still need to do research, and it may be that, you know, you can't say that genetic research is duplicative because you're learning something new every time you're doing it. So it is genetic research, but it's not, you know, duplicative. It may actually look duplicative to GAO because you're collecting samples from people with autism. But, you know, some people are African Americans. You know, you're

looking at a different sequencing way of looking at things. So everything is kind of -- to move the ball forward, you need to have a body of research where everything is lining up. And I think the GAO made the mistake of assuming that that was duplicative research.

The most dangerous research of all is the kind of research where there's only one person doing it because those results are completely -- you don't know whether to believe them or not. So I think what we need to do is be more explicit about what the research questions are, what the value of research of multiple different avenues of research on the same question are, and maybe make that apparent in the next report, because I think given the GAO report we have now, I think we have to make a response to them with data. We can't respond -- I think you responded with a letter. That didn't really resolve -- they didn't around to our position. So I think we have to go after data.

Dr. Insel: Well, I just can't resist saying that so many people at the NIH spent so many hours over months explaining just what Donna explained about all of the mechanisms that are put in place to ensure that we aren't giving multiple dollars to

the same individual or to two different individuals to answer questions that have already been funded.

So I'm not sure that writing it down and saying it yet again will have much value, frankly. It does feel like, I guess, the way Alison put it, that we've responded, they've responded, and it seems like we're going to agree to disagree here. Larry?

Dr. Wexler: Thank you, Tom. Yes, I would tend to agree with you. I mean, personally having been through a whole plethora of GAO investigations, the headline, which they produced, which is “Potential for duplication,” is about as complimentary as you can get from a GAO report.

Dr. Insel: That's exactly what they told Susan and me. They said this is about as good as it gets. What are you complaining about?

Dr. Wexler: And I think it's true. They did not say that it was duplication. I mean, there's potential for anything. I mean, there's no statistical treatment for "potential." There's potential that a meteorite is going to hit right now, you know. It doesn't mean that it's likely, or it doesn't mean that, you know, NORAD has let down their guard because they didn't blast it out of the

sky.

So I really think that going back and forth with them, they've decided that that's the headline that they want. And for whatever reason, that's the headline they want, you know. I was more concerned about some of the other things that they said in there and in a positive way. And I think it's something that the Committee needs to look at in terms of what does it mean to coordinate research, you know. And that's something very different, and I think that's a valid concern that they raised and that it's something we ought to eventually kind of take on and look at.

But, but I agree we have -- you know, we go through D-U-N-S number, and if you're within the government you know what that is. We go through financial D-U-N-S numbers. We do risk management.

We look at what else is being funded around before we give money. And we're not a big -- we don't give out a huge amount of research. The other side to this is you're talking, what, a billion dollars? If you duplicated a couple of grants at a million dollars a piece that's about a thousandth of the investment. That's about as efficient in the Government that you could ever get.

So I think they made a report, we made a response, we sent a letter, they responded. There is potential for duplication, no question. There's potential that the next speaker will say the exact words that I just said. It's unlikely, but there is potential. And I don't mean to be flippant about it, but I think we're kind of gnashing our teeth over something that is at this point with GAO a dead issue, and it's probably time to move on.

Dr. Insel: Donna?

Dr. Kimbark: And I agree it's time to move on. I was the one person in my office that had to answer to GAO, so I spent a lot of time doing it.

But I did want to make a point about what you're talking about as far as interacting with different government agencies and trying to really communicate so that everyone can know what everyone else is actually funding. And that's one of the things that my office and NIH are actually working on right now.

I'm not the technical coordinator to that because I don't have that kind of technical expertise. But they are trying to make computers talk to one another right now so that it's easier. So we are moving in that direction.

Dr. Insel: And that is -- and we'll come to that in a few minutes with the round robin. But one of the things we could do here is rather than just having the portfolio analysis which retrospectively says what did we fund last year, we could -- as we develop initiatives -- get them out on the table here and figure out to what extent they can be shared initiatives -- who would be accountable for which part, how we can ensure that there isn't something already going on that doesn't need to be redone. All of those issues would be one of the ways which the Committee could be more effective here. Idil?

Ms. Abdull: At the risk of potentially repeating what you said, I think that -- don't do it, I know -- for research, though, you have to duplicate. You have to repeat. If we did one study for, for example, ABA, then parents would complain and they say, well, that's not good enough. You need more. Policymakers would say, well, how can we fund this because we only have one research.

So we have to duplicate it. We have to replicate it. We have to have the DoD do it, NIH, HRSA. We have to have them doing it. So I just feel like, just put it to rest. You can't win for

trying.

And then the second thing of the coordination, I would say the Somali autism study is the perfect example, which they've mentioned, of coordination between public and private. And it just came from a mom. It didn't come from any of the government agencies. It just came from somebody in the public.

And that the public -- the private foundations and the Federal Government took initiative and coordinated that study. And not just fund it, but to the last end, literally until the last minute.

And so, I think we have to pick our battles, and I really just don't want to fight with GAO. I think we should move to something else.

Dr. Insel: So, Lyn has suggested that we dig into this a little further. Is there anybody else who has an interest in doing that? I'm just trying to get a sense of the Committee how you want to respond from here. We could let it lie. We could continue to -- Jan?

Ms. Crandy: I just want to comment that I think the potential for duplication, those words, that I think that we went after that. There was a lot of other things that could do positive changes for our Committee, and that's what I looked at in

there. And the things that they're addressing, it's on page 3. It's four bullets that some of -- it was outdated, not tracked over time, inconsistent, and incomplete. Those are things that our Committee could fix. It seems like it could be easily done.

And the thing that you brought up about the coordinated effort. I liked what you said, Tom, about bringing it to the table, that we're driving the research. I know our questions out there are supposed to drive the research, but we could have more input on the research. I believe this Committee could.

Ms. Redwood: And in responding back in terms of what we're planning to do, I think that would be helpful. And, Walter, you also had a comment.

Dr. Koroshetz: I'm just worried that somebody will say that's the GAO report and starts, you know, slashing budgets. So I'm not saying we have -- I don't think we have to -- I don't think there's that much work we have to do, but I think in the next report to Congress, I would like to have something in here that says we read the GAO report, we looked at, and the next year we looked at the research, and this is our statement on duplication.

I mean, that’s just to make sure that people,

you know, who don't see, you know, this kind of -- don't see closure to this issue on the chance that it really does --

Dr. Insel: Well, I think if the Committee is reauthorized, which is still a 'potential' for reauthorization --

[Laughter]

-- it's likely that there will language that will require something relevant to this, some sort of a statement, some sort of a way of following in the same way that we do the portfolio analysis -- analyzing whether there is sufficient replication, sufficient duplication.

The last thing I'd say about this is what we always worry about most of all is that the same subject is ending up in multiple studies because you have groups that are often competing for that perfect left-handed, 7-year-old African American with the following ADOS score, right? And so, this person ends up at Yale, and at Columbia, and three other places, and yet you would never know that.

And that's why the GUID –

Dr. Koroshetz: that's why.

Dr. Insel: -- yes. And so, you know, that is probably -- that's a problem for all rare disorders

and many common ones where you have often people who become research subjects over and over again.

And we've solved that for the entire Nation with the GUIDs. And so we'd like to get a little credit for making sure that a real insidious form of duplication can't occur within the autism research framework that could occur almost anywhere else that doesn't use a GUID. John, you get the last word.

Mr. Robison: My recollection when we talked about this maybe a year or two ago was that we couldn't publish a list of research that we had just funded because of the confidentiality of the applications. But I wonder if we could establish a subcommittee in IACC on duplication that would be out of the public view for the reason of looking at confidential research to address that question.

Would that be a constructive response to GAO or no --

Dr. Insel: So just to clarify, we can discuss here RFAs that have been put out -- initiatives. We're just about to do that.

Mr. Robison: -- discuss an application, is that --

Dr. Insel: We can't -- well, but we wouldn't

need to discuss the applications. I think what the Committee needs to do is talk about the concepts -- that are -- we're trying to fund and to make sure that those get coordinated in a good way. And once those concepts are approved in the case of NIH by our counsel, they can be -- if they become publicized RFAs, once they're published -- we can discuss them here. We simply can't discuss it with them and give anyone an unfair advantage by having advance notice that there will be a competition around a particular topic once they're published and they're on the website or published in the guide.

Dr. Koroshetz: [Inaudible comment]

Mr. Robison: But, of course, then they're done deeds, right, because they are funded, if there's duplication we did it. We can't undo it.

Dr. Insel: No. So the key time would be between the time when there is an RFA that's put out and the time when there's actual funding of the projects that have come in. You're about to hear an example of that when we talk about the services efforts that are underway. We don't do that enough here, but we do have a series of initiatives, but often people don't hear about them until after

everything has been funded and we come to you with the results, not so much with the concepts when they're fresh, so that we can do, and we should.

Dr. Carey: Tom?

Dr. Insel: Yes?

Dr. Carey: Matt Carey. I know you just gave the last word to John, but it is possible to interject something very quick?

Dr. Insel: Please do. You have to speak up a little bit. You're kind of faint.

Dr. Carey: Sure. Is that better?

Dr. Insel: That's better.

Dr. Carey: Okay. As I mentioned last time, you know, when the GAO report first came out, you know, I requested from Susan a bunch of the data. I looked over it. I mean, I think all of us have had that opportunity. I looked over it. I didn't do, you know, an extensive analysis, but I did not find, you know, a great deal of actual duplication.

So we have been able to do that, and I for one have done it. So, I mean, if anybody is interested, I mean, they could -- you know, individuals can go ahead and do that.

The other statement I would make on this is, you know, there's all these -- the other issues --

that the GAO brought up of, you know, things -- work that needs to be completed. And my -- frankly my statement back to them would've been, you know, how much further would we be along on those tasks if Susan's team hadn't had to spend so much answering to GAO?

[Laughter]

I think a huge effort went into that, and it took time away from what we were doing. Now, the Congress is our boss, and we're going to do that. But we would be further along. Just those two statements.

Dr. Insel: Okay. Well, thanks, Matt. And I don't think you could hear people here laughing, but they certainly concurred with you. I'm sure Susan would concur.

So the sense I'm getting from the group is that you want to make sure that we do address this in future reports so that there's some evidence that we care about the issue and that we've considered it. And I think Walter's call for greater precision around the language would probably be useful. But I'm not hearing a sense of the Committee that you want to spend a lot more time on this particular issue at this particular

time.

So I suggest -- we've got two, three things we need to do. We need to spend some time on this comorbidity work group. Lyn and I want to sort of pitch that to you and get your sense about how you want to develop it. I want you to hear about the services initiatives from NIMH, and Denise Juliano-Bult is here. She has been very patient since 2:15 when she was supposed to talk about this, and we want to do a round robin.

So can we take 5 minutes for a stretch break and then reconvene, and we'll get started on those three things.

[Break]

It’s in line with what we were just talking about around making sure you hear about initiatives early and not after they have been fully funded and the data are already in, I wanted you to hear about a series of initiatives from the NIMH. Denise Juliano-Bult from the Division of Services and Intervention Research there is going to take us through these rather quickly.

Ms. Denise Juliano-Bult: Yes.

Dr. Insel: Thank you.

Ms. Juliano-Bult: Okay. And this is the up and

down arrow here? Okay. So the initiatives that we're talking about today were issued as three separate, but related, what we call RFAs, or requests for applications. And the RFA mechanism involves setting aside an estimated amount of funds to be used for a competition. And in this case our estimated set-aside was $10 million to be spent in 2014, the first year of the award. And, of course, awarding it is contingent on the quality and significance of the proposed study and their proposed findings and also the fact that we're not funding duplicative things -- unnecessarily duplicative studies. And we make these decisions based on the scientific review committee and their evaluation -- internal evaluation -- of the program staff and leadership.

And RFAs typically -- have -- are reviewed by a special review group, and that was the case for this one also. It's a big challenge because it was very hard to find reviewers who weren't conflicted one way or way another with the applications that have been submitted.

So here is some of the language from the announcements about their purpose. I just wanted to highlight in this that we solicited studies of

interventions that were intended to engage people with ASD in services with the goal of improving their functional and health outcomes. And what differentiates the three different initiatives that we put forward were that they each targeted a different and important lifestyle for people with ASD, early childhood, the time of transition to adulthood, and adulthood.

So we took our cues for determining these critical life stages from what the existing science tells us about people with ASD and also from components that were highlighted in the 2012 IACC Strategic Plan, specifically from Questions 1, 5, and 6x here. I'm not going to go into detail about what those are. You guys wrote the document, so you know what they are.

And I want to just tell you a little bit about what each of these specific initiatives were. For our early-childhood announcement, we solicited studies of service strategies targeting children within the first 2 years of life. The goal was to develop and test a multicomponent intervention that implements a comprehensive or universal screening strategy in the community setting and then expedites and ensures follow-through on receipt of

evaluation and diagnosis and then expedites an ensures follow-through on linkage to treatment and services when indicated.

So we asked for studies to test the effectiveness of a longer range complex service strategy, and we also wanted that strategy to be usable and effective across a variety of service settings. And just to note, as in all three of announcements, we ask that interventions also be designed to reduce disparities and outcomes for underserved populations that are documented in the literature.

So that first announcement asked for a full-scale test of an intervention or what we call an R01, a hypothesis-testing study. For the next two announcements, we asked for pilot studies that will lay the groundwork for a future full-scale test of an intervention. And the reason for this is that the two other age groups that we've targeted are ones for which there's not much existing evidence based on interventions to build from.

So this particular announcement is looking to foster development of services, strategies that help youth transition to adulthood and adult functioning and services without lapses in services

and supports or setbacks in functioning. The intervention being developed is intended to target improved functioning in the community in a number of domains. It is not as prescriptive as the early childhood announcement, but it is also intended to look for strategies that reduce ASD symptoms.

And then the third announcement we issued was one to support pilot work in developing service strategies that optimize independence in functioning of adults with ASD. Again, we anticipate that the eventual full-scale test of the strategies will target improvement in behavior, functioning, and health as outcomes similar to the transition to the adulthood announcement.

So here is our timeline relevant to the conversation that we were just having or you were just having. The announcements were issued in May -- May 30th, 2013. The receipt date, which got moved back because of the furlough, was extended to November 1st in 2013. And the review of all the applications that were received just happened about 3 weeks on March 14th.

So what we received were 36 applications. We received many, many, many, many inquiries, and there was a lot of interest in the announcement. It

boiled down to 36 applications received. You can see how those were spread out over the different age groups that we targeted.

And here is where we are with our next steps for deciding about funding. We are in the process of having the investigators respond to the critiques of the review committee, and we're also starting to have our internal discussions about what to fund. In May we're going to discuss what our funding recommendations are with our advisory council, and I didn't come prepared to give you details about what was submitted, but I can tell you that also relevant to the conversation you just had, that first one that was about screening, referral, and engagement, and treatment was very, very specific about what we were asking for.

And that is one that we are, in particular, taking a good look at to see that there isn't duplication -- unnecessary duplication among the applications that came in.

The other two announcements were much broader. They had a lot more leeway on what kinds of outcomes or what kind of strategies people could target, investigators could target. And so, we don't anticipate a lot of overlap for that. The

earliest start date for any of these is July of 2014 pending us wading through all of the feedback and comments, and opinions, and making funding decisions.

So that's it.

Dr. Insel: Great. Thanks, Denise. Questions or comments? Idil?

Ms. Abdull: Thank you for that. I was wondering if you could clarify. You said that one of your initiatives or one of the things that you want to do is to reduce disparities in underserved communities in terms of referral, engagement, and treatment. I was wondering how you plan to do that.

Ms. Juliano-Bult: Okay. Actually we asked that all of the applicants pay attention to that. But it's up to the applicants to propose a strategy for that, but most often it focuses on where they do the outreach to populations, what kind of service-providing entities they're working through that would do the greatest outreach to underserved populations. And it also factors in where we asked folks to have inclusive recruitment so that the racial, ethnic, and other kinds of representation in the subject sample that they're recruiting would be representative of all those underserved

populations.

Ms. Abdull: Just a suggestion, if I may. I was wondering what you think of making sure -- let's say that you fund a mainstream researcher or organization or institution, what you think of making sure that they partner with a community organization of color that is on the ground. So if you live in Los Angeles, you want to make sure -- you want to reduce racial disparities that you're partnering with a community that's basically where the blacks and Latinos live rather than just maybe hiring somebody, because one person can't do a lot.

But if you partner and you make sure they're partnering and collaborating with minority-based organizations that are based in communities of color, then they can do that -- you know, the legwork and do the referral and engagement in a way that is more, you know, trustworthy.

I think Dr. James Perrin when he was here talked about parents want to talk to organizations and people from organizations that they trust, that they have something in common with, that looks like them. And so, I just wonder -- just a comment maybe that's something that you can look for and see.

Sometimes a lot of people can just submit a

really pretty proposal, but it doesn’t really collaborate or partner with communities of color that are based in that community, whether it's south central L.A., or south side Chicago, or north Minneapolis. You need people who are placed there that the parents trust and will talk to and will engage with.

Ms. Juliano-Bult: Well, it's a great idea, and when we ask for that kind of recruitment and that kind of representation in the studies, it is one thing that the review committee looks at because it's a question of the feasibility of actually being able to engage that population in the studies. And then again, when we ask for interventions that are going to be broadly usable and broadly implementable, we'll look for some evidence that what gets developed in the course of this study is something that many community settings could use, even the settings that you talked about.

Dr. Insel: And we track.

Ms. Juliano-Bult: Yes, and we track.

Dr. Insel: So on a quarterly basis we can tell you exactly what the makeup of the population is. David?

Dr. Mandell: Denise, I really wanted to applaud you for these RFAs. I think they're great. They're so nicely tied to the IACC Strategic Plan. I especially appreciate the focus on adults and transition-age youth, and I look forward to seeing what the outcomes are.

One of the things that has come up and that Idil is touching on with a hint of frustration that's come up again and again is the documentation of disparities in the literature without any specific interventions to reduce disparities. And I think it's wonderful that the RFAs explicitly mention that and require a plan for that. I wonder what the potential is for an RFA that is specific to reducing disparities in outcome for individuals with autism.

Ms. Juliano-Bult: Well, looking at Tom, we have a growing emphasis on disparity -- reduction in disparities -- and I think that we have a number of things -- potential -- that would allow us to do that.

Dr. Insel: I think the way you said this is really critical and important for a number of areas, not just autism, but there tends to be a lot more energy to document the disparity than to fix

it. And that's why we're about to do a series of supplements this year in 2014 that will try to get at some of this. And I don't know whether it will fit in time for these particular RFAs, but it clearly is an area of increasing need and interest. Jan?

Ms. Crandy: And maybe you said this and I'm just tired. Did you say what percentage would go to the adult studies? And was a listing of the all studies provided yet, or that information is not available to us yet?

Ms. Juliano-Bult: It's not available yet. We are looking -- we've separated the way we're thinking about funding at the moment into looking at those three categories separately, the three announcements, and looking to fund the best scoring ones in each. The announcement didn’t say the money had to be divided equally, and there was some -- you know, the early-childhood ones had some advantage since there's already been a lot of work done in that area -- but we're looking to try to fund comparably for each of the age groups.

Dr. Insel: That's very helpful, Denise, to go through this. I just hope the Committee realizes that this is really a product of the Plan in so

many ways. These were areas that had not gotten very much

Ms. Juliano-Bult: Right.

Dr. Insel: -- traction with many of the agencies. We heard this morning from ACF about the new screening opportunities.

But what we're worried about is you can do all the screening you want, but if there's no one to refer to or there's a 9-month waiting list to get into the clinic, it doesn't really help you to have had the screening. So this was meant to provide that follow-on process.

Ms. Juliano-Bult: Right.

Dr. Insel: And then we've also heard a lot from -- about the needs for adults -- so including today in the public comment from Madison House and others. So we're hoping that this will be the beginning of a foundation of some future work. But again, I think this is a place that probably wouldn't have gotten this sort of financial commitment without the Plan to make us feel like this is a place that just had not received adequate support. And it helped to have public comments that have supported that as well at these meetings.

Other comments about this?

[No response]

Dr. Insel: Okay. Thank you, Denise.

Ms. Juliano-Bult: Okay. Thank you.

Dr. Insel: Nice job. Lyn, why don't -- can we talk about the co-morbidity work group, and maybe I can turn this over to you? Do we have slides?

Ms. Redwood: We do have slides.

Dr. Insel: Okay.

[Pause]

Dr. Daniels: So there are a couple of slides here. We're just going to put them up. Sorry I need to be back. Okay, so we are going to be talking about the Co-Occurring Conditions Planning Group that the Committee wanted to form. The goal of the Group is to develop and complete a project to address conditions that co-occur with ASD. And here's a list of all the members so far who have volunteered, and it's still open if anybody else wants to volunteer to be on the Group.

And I would like to turn it over to Tom and Lyn to talk about this as they were the first two to volunteer back in the fall when we had all these other groups forming. I think that folks might not have had the ability to be able to commit to doing more at that time, but now we have a full

complement of members who want to be involved here.

Dr. Insel: Maybe I'll just set up for this. We've been talking about this for months at multiple meetings, and it's been hard to kind of get this going. So we wanted to put it back on the agenda today with a timeline that really ensures that whether the Committee gets reauthorized or not, over the next 3 or 4 months we will actually begin this project and have some progress to look back on.

So, Lyn, do you want to say a bit about how you see the charge and what you think are the key issues to address? We've heard a lot about this today in public comment already, and it's been something we've talked about at previous meetings as well.

Ms. Redwood: Actually, Tom, I had prepared a series of slides. Susan, is it okay to use those?

Dr. Daniels: I don't have your slides in the queue.

Ms. Redwood: Okay. Will you go back to the slide right before that that had the goal -- the goal -- to develop and complete a project to address conditions that co-occur with autism? In looking at this, I went back through the Strategic

Plan and specifically the area in the introduction that dealt with the comorbidities. And it specifically says in there that co-occurring conditions, if not treated, can limit a person's ability to benefit fully from educational and behavioral interventions and fully participate in community life.

So based on that, I sort of envision the goal of the work group as being a little bit different, that the goal of the work group -- and this is also actually in the language of the Strategic Plan -- is to "Advance our understanding of the scope and potential causes of co-occurring health conditions, along with the development of comprehensive health assessments and safe and effective treatment guidelines in an effort to immediate improve the quality of life for individuals with ASD and their families."

And that was just taken directly out of our Strategic Plan. So to me, that seemed to be what the goal of the work group would be.

I also had outlined objectives to be able to work on that and some of the products that this work group would need to have in hand to be able to address this. And one was being able to identify

exactly what are the co-occurring medical conditions that are associated with autism spectrum disorders, because until we flush that out, we're not going to be able to get into treatment guidelines.

And then also to identify if those co-occurring medical conditions -- Are there already existing standards of care that are appropriate for treatment? For example, with GI disease and for seizures, there already are, you know, appropriate treatments that could be utilized across the board, but for some of these other co-occurring conditions, they're not. So that's something that I think the work group would need to look at in terms of whether or not there are standards of care already present or if we need to determine new standards of care.

I think the work group would also need to look at treatments that are currently being utilized by clinicians that may not be supported by evidence or treatments that have been found to result in negative effects –

[Inaudible comment]

or that could be harmful. So I think that's another area where we can help give parents some

guidance.

I think it would also be important for the work group to look at some of the novel treatments that are being utilized to determine if they have reached a threshold of research yet where they should be utilized in clinical practice. We have these anecdotal reports of them being effective, but they've not ever been subjected to real clinical trials. Then that information would then be fed back into the Strategic Plan to be able to update our research to add in specific initiatives to look at potential treatments that might be beneficial.

For example, there was one study that came out that looked at the use of n-acetyl cysteine for disruptive behaviors. And that's not been verified, but it was a small sample size. It's something that could be utilized that I think deserves further research. So those are just sort of examples of what the objectives would be.

The model for pulling together this work group -- we had a presentation this morning on the Department of Defense model that was developed by the Institute of Medicine in 1993. As we heard, it uses the expertise of scientists, clinicians, and

stakeholders working together. And there's actually been a review by the Institute of Medicine that suggested that this model should be used for those who desire to work in partnership on critical health issues.

So I would see that as sort of the model for the composition of this work group. We're allowed to bring in outside members. I know that Dr. James Perrin had volunteered to serve on this work group.

I think it would be wonderful to have the American Academy of Pediatrics, because that also gives us a segue to be able to get any guidelines that would be developed disseminated to the pediatric community either through CME programs that we heard this morning that would beneficial.

The work group deliverables and I know this is very ambitious, especially if this Committee only has a few more months. But the first work group deliverable would be publication of the sort of extensive literature review we would do of the co-occurring conditions. The second would be the development of comprehensive multidisciplinary health assessments and effective treatment guidelines that could be utilized by all health care providers serving individuals with autism.

One of the things that we don't really have now is a questionnaire that sort of drills down into some of these specific comorbidities to be able to determine whether or not these children need additional screenings. I know the American Academy of Pediatrics has worked on that to some degree, but I think that the document that they published several years could be updated because the science is advancing so rapidly.

The third work group deliverable would be a recommendation from the work group in terms of how these products would be disseminated and any mechanism that would be needed to provide continual oversight, updates, and additional recommendations.

So I know that's very ambitious, but, you know, we had a talk this morning about the BRAIN Initiative, and they pulled together this dream team. So I envision getting a dream team together to really try to help these kids that have these severe health issues associated with autism.

Dr. Insel: Okay. Questions, comments? Jose?

Dr. Cordero: I think that it is a fairly large scope of work, but nevertheless I'd like to add more. From the discussions that we have had here during the day and in other meetings, one of the

questions that does come up is the heterogeneity of autism. Tom, you mentioned that we have a word out, "autism," and under that we have many conditions.

One of the areas or one of the approaches that we can use is to begin to sort out like that, what is autism and nothing else, those that have, say, an issue with epilepsy or co-occurring conditions.

And that could begin to be a process. I think that we need to begin to think of how the so-called autism spectrum -- What does it include, and how could it be split into different areas?

That's exactly the approach that we followed when we were trying to understand a lot of the birth defects -- take spina bifida -- and separating what is spina bifida, isolate it versus those that are multiple, help us sort out what actually was, in effect, a folic acid. But we need to begin to think with the concomitance which conditions were co-occurring. Do they represent the distinct clinical entities that should be looked at in a separate way from the purpose of etiologic studies?

Dr. Insel: Judith?

Dr. Cooper: Could we go to the slide with -- the one after this. Okay. So I guess my reaction

since I'm one of the people who's on the Committee is that every one of those issues that you raised sort of reminds me of what we do a workshop on that one issue or what the IOM takes a year to do. So I would think that we would need -- and now Jose has added another issue.

So, so especially if we're looking at September and maybe we won't even be here after September. It seems like maybe the first step is to, I don't know, short-term goals, long-term goals, most priority, what's reasonable for us to accomplish. Do we have the expertise on the Committee even to answer a lot of these questions?

I would say, you know, I don't. And so, we would need to pull people in, and our time is limited.

So I think trying to figure out what our scope is going to be might be our first task and try to figure out a reasonable timeline for what would we like to accomplish between now and September and then what would be the next step should we be reauthorized.

Dr. Insel: Walter?

Dr. Koroshetz: Also worried about losing focus and not being effective. And so, I guess I'd just

throw out one idea, and that is that the key thing we'd like to do is to improve the care of the kids who are suffering from these multiple conditions. Now, that care is going to be, you know, provided medical experts.

And so, I would say, you know, from the NIH half, that the best thing we could do is get the medical experts who have actually worked on guidelines, try and understand from them where they think the research gaps are, and then establish those, because I think that's where we can be most effective is providing research to fill in the gaps.

I think for us to make guidelines, I think that would be tough. But there have been groups that have been engaged in this process, and so they kind of know what the limitations are. So I think that would be my kind of strategy.

Ms. Redwood: Walter, there was a similar meeting with the American Academy of Pediatrics when they worked on the guidelines for gastrointestinal illnesses that were published, and it was a really across disciplines. So, you know, I envision this as having clinicians there, obviously. And as you're saying, there's not the

expertise on this Committee to do this.

But that it would be something that could even transcend this Committee; like, NIH could be there with helping to provide, you know, information or putting things into our Strategic Plan that would address the research gaps.

But could this be a standing committee underneath, say, NICHD or NIH, or not a standing committee, but a work group similar to the work group that Francis Collins established for the BRAIN Initiative, that then it wouldn't be tied to the reauthorization of this Committee. That would be another way to get around sort of the short timeframe, because I agree: This is not something that's feasible to even, you know, begin to tackle if we're ending in September, but I think it's something that deserves a long-term strategy.

Dr. Insel: Yes. I'm struck by Walter's idea. I think if the goal ultimately is to have treatment guidelines or best practices that's not something that any of the Federal agencies do. It's interesting how in general the Federal Government steers away from that, and they leave it -- with one or two exceptions they leave it to the professional societies, and especially the American

Academy of Pediatrics has been very active. And even on their website they have that whole series of guidelines that they publish.

I wonder, you know, especially because you mentioned Jim Perrin as being interested in doing this, whether this might work best as a collaborative effort with them in which whether we're here or not it could continue through the American Academy of Pediatrics. They did have that interest particularly, in the gastrointestinal issues.

I don't know. Walter would know this -- whether they've done as much on the epilepsy side or on seizures in ASD. But, I don't think so. I don't think that's been as much of a focus.

Dr. Koroshetz: But there was -- I think Deb is here, right? There was -- I mean, the Academy of Neurology did -- didn't they do a guideline on the workup of autism?

Dr. Deborah Hirtz: Yes, well, Anshu is on the committee. The current -- is working on through the American Academy of Neurology did participate with representatives from psychiatry and pediatrics. It does cover some, but not all of it, so it's completely possible to do. So it's basically

behavioral and pharmacological, but it does include, for example, some guidelines. It does not include anything else. So we do need to address some other way, some other evidence-based dialog for --

Dr. Insel: But one thing we could do then is we could become a bridge to bring a few of these groups together. There may be others as well. ACAP has some interest in these issues. We can think about that. Lyn?

Ms. Redwood: I think that particular GI consensus was also funded by Autism Speaks and the Autism Research Institute. So it was a really nice collaboration between the advocacy community and the American Academy of Pediatrics. So it would be nice to model that and bring NIH into that piece of the puzzle, too, to help provide some of the research initiatives that would be necessary.

Dr. Insel: But your sense is that that particular effort, which is about 2 or 3 years old at this point, needs to be redone, or it needs to be done for other areas?

Ms. Redwood: It needs to be done for, like, metabolic and immune and these other systems that we're now acknowledging as having abnormalities in

autism.

[Pause]

Dr. Insel: Other suggestions or thoughts about this? John?

Mr. Robison: I think that we're seeing a, you know, an increasing division of purpose here, where we are seeing the need to study what I would say are serious medical complications of autism in one population of people. And we are seeing the need to develop therapies in the psychology department for a distinctly different group of people, and those needs are really rather independent of each other.

And it concerns me a little bit that those two groups of people often feel that we are ignoring them at the expense of the other. And perhaps we might, you know, do something to have two groups that are working toward the delivery of equal value to both those people in the autism community. It seems to me that that would be a fair thing to do.

I think, you know, we talk about housing, for example, and education, but we have a group of people at one end that needs the help of psychologists, and we've got the group at the end that needs the help of doctors. And those are two quite different areas, both legitimate and both in

need of services, and frankly neither of them getting real help right now.

Dr. Insel: Other thoughts just, again, to focus just on this particular one. I'm not sure we want to start on the second one until we get this one. But what I'm hearing in the discussion is something that looks maybe like a workshop in which we reach out to some of the professional societies as partners. Lyn, if I'm catching your message correctly, that maybe the focus in this case would be more on immune and metabolic issues that are associated with autism or with some subtype of autism.

Again, Jose's comment about even building into this the possibility that what we're talking about is another syndrome, not just an associated disorder, but something that helps define a subtype of autism that may require a completely different treatment and has a completely different cause. Is that where we should -- I'm trying to understand what the next steps are and what this would actually look in terms of what we should do now. Is it reaching out to the professional societies? Is it finding a date for a meeting? Is it creating an actual charge? Help me out here.

Dr. Koroshetz: I would think about trying to get some people from the different pediatric specialties that are kind of the ground floor treating autism patients that have been involved in the guideline process before -- just get a couple on the phone and try and explore this where we could really make some improvements.

I think even a guideline that's 2 years old, and my guess is that the people who make those know where the gaps are, and it would be good to just hear from them. That would be a more mature stage where they look at the evidence, they know what the problems are, they know what research needs to be done. That would be helpful.

Some of the other areas are going to be tougher because there's not that much know. The road hasn't been paved yet. I think those are worth dealing with, but it might be nice to have a mix of things that are more mature and things that are less mature. I think to make those choices I think would like to hear from the patients and the docs who take care of them to know exactly how it's structured.

Dr. Geraldine Dawson: This is Geri Dawson on the line. I'm wondering if I can make a comment.

It's always hard when you're not there to raise your hand.

Dr. Insel: We've been waiting all day, Geri, so thank you. Finally.

Dr. Dawson: Sorry. I had another meeting today, and I'm sorry I missed, you know, the earlier part of the meeting. And this may have been said because my phone went out. But, you know, it does seem, like, that bringing in the AIRP, the Autism Intervention Research Network for Physical Health that was funded by HRSA, those folks, it would be really helpful. And as you know, they published guidelines in collaboration with the Autism Treatment Network for the assessment and treatment of GI conditions, sleep conditions, and also ADHD in pediatrics about a year ago.

But they're also rolling out a number of other guidelines. I know that when I left Autism Speaks, they were actively working on seizures, and the Neurology Subgroup was working on, you know, what kinds of assessments do you do for kids who might be at risk for epilepsy and so forth, and as well as a number of other guidelines. And I do believe they were working on some metabolic-related guidelines as well.

So it just seems like that would be a great group to take advantage of because they've been involved in both research as well as guideline development on these conditions.

Dr. Insel: Geri, could you help us with? Would you be able to reach back and get information about it? I don't know whether Autism Speaks is continuing to do this, but it would be good to know if they are.

Dr. Dawson: Yes, absolutely. I'd be happy to be the one to follow up on that and find out where they are and, you know, who would the best people to involve.

Dr. Insel: Great. Other thoughts about this? Coleen?

Dr. Boyle: So just a little bit more information. So that’s partly funded by HRSA; is that correct, Geri? And Jim Perrin has been the lead there. So kind of coming full circle with some of our conversations, connecting those dots in getting those folks involved.

Ms. Redwood: And bringing in ATN through Autism Speaks as well as Dan Curry. And Dan, I think, also was volunteering to be a part of this.

And then some of those guidelines or at least

could be funneled back into the ATN networks.

Dr. Dawson: Right. And just to clarify: So the AIR-P, they were the ATN site, so they really are the same people, the difference being that the AIRP funding went to develop the guidelines per se and also funded research projects, whereas Autism Speaks funded the patient registry and the clinical care component. So it really was a public/private partnership.

And I know there have been transitions recently and certainly with Jim, and not to say that Jim is not still involved. I really would have to check back. But I know that he has -- you know, some of his role has changed with the -- his increasing role at the American Academy of Pediatrics.

But I'd be -- again, I'd be happy to go back and just see what's going on and who are the right people to involve. But regardless, they've been doing this for a number of years, and they'd be good to bring in.

Dr. Insel: Geri, I think what would be helpful for us, because, as you say, they've already covered ADHD and GI. And I think --

Dr. Dawson: And sleep.

Dr. Insel: And sleep. And they've done something, I think, on seizures.

Dr. Dawson: Yes, very close.

Dr. Insel: What we don't know here is the extent to which they've looked at immune issues or metabolic issues.

Dr. Dawson: Right.

Dr. Insel: So if you could capture that for us, that would be great, and figure out who we need to follow up with.

Dr. Dawson: Yes, I'd be happy to do that.

Dr. Insel: Great. So let's think about other next steps. So Geri will look at that group. We can reach out at the same time to the American Academy of Pediatrics. And Jim will cover, I think, several of those bases, so that's one phone call. Lyn, what else would you foresee as next steps? Can you use your mic?

[Pause]

Ms. Redwood: Based on the outcome of those phone calls, Tom, I would think pulling together a workshop and bringing together those experts would be sort of the next step.

Dr. Insel: Could we envision that? This is now, what, mid-April -- that we could get a better

sense within 2 to 3 weeks, and then plan for something this summer? I know the Government regs around meetings and travel have become almost prohibitive. And, Susan, you deal with this more than I do, but what is realistic given that we've got a sunset at the end of September?

Dr. Daniels: So to set up a public phone call, I need 4 weeks, so -- to put out the *Federal Register* notice, et cetera, because we do everything in the public. It's all transparent, and people can listen in.

Dr. Insel: So even for just a phone call, not for --

Dr. Daniels: Yes. All our phone calls are public. We don't do any private phones for the IACC. So we can schedule a phone call. I need clear guidance on who needs to be on that phone call, so can I count on you all to tell me who has to be there? And are we focusing just on the immune and metabolic or on all different kinds of comorbidities?

Dr. Insel: Anshu, what's your --

Dr. Batra: So when you say "metabolic," are you -- are we inferring that that means mitochondrial disorders/deficiencies?

So I just wanted to make one quick comment before I forgot. You know, when we get experts together to talk about these conditions and their experience in it and their research in it, I guess I would like to, again, make sure that -- you know -- sometimes when you have people, you know, researchers, they're going to highlight what they're sort of focused on, and I guess I worry, again, as a layperson in the community, I guess I would want to make sure that we have unbiased sort of opinions so there's no conflict in terms of what's being said.

And again, I think everyone has got good intentions but, you know, if your focus is one aspect of a disorder, then that's what you're going to focus on, I think. And that's what, you know. So I guess I would want just to caution the -- you know, broaden, I guess -- the field of experts that we invite to give us insight into this in terms of not only their research-based experts, but maybe, you know, clinically based experts so that we can sort of, again, combine the two.

Ms. Redwood: To that effect, I was thinking the DoD model also has, you know, advocates, individuals with, say, mitochondrial disorders or

metabolic disorders, parents of children that have suffered with these disorders, and clinicians who are treating them, and then researchers who can help us research the gaps would be a good mix.

Dr. Insel: One of the nice things about a work group is it doesn't have to be just us. We can bring in a range of voices and perspectives, which is good. Walter, if this goes toward mitochondrial disease, is NINDS the home for that, or what's the best source at NIH?

Dr. Koroshetz: It's split.

Dr. Insel: But split with who?

Dr. Koroshetz: Split with NIDDK. But, yes, I think we can handle -- we know the autism mitochondrial people.

Dr. Insel: Okay.

Ms. Redwood: I would hope it would be beyond just mitochondrial because there's a lot of other metabolic abnormalities, too, that there's potential treatments. If you look at the work of Jill James with folinic acid and things to help supplement glutathione levels, n-acetyl cysteine. I think those researchers would be important to bring to the table, too.

Dr. Insel: Idil?

Ms. Abdull: As I listen and I try to digest this and look at it from a parent point of view, and as I listen to a lot of the parents in the public, and I've done as a mom a lot of those things. I've sent my son's urine to Paris, France, with nothing. I've done the folic acid. I've done all these things which cost thousands and thousands and thousands of dollars that are not covered by anyone, public or private. And not just me. There is maybe 30 Somali parents alone that have done probably $200,000 or $300,000 worth of stuff, and it hasn't helped.

So I just want to make sure that when we're doing this, we're recommending, as Walter was saying, research to look at this so that if guidelines are set and if we're going to tell parents if you have a child with autism, he might have a GI, or a metabolic, or immune system, try one, two, three. And then we're also making sure that the pediatricians are aware of this, because many of the things I've done, my child's regular pediatrician was not okay with it. He thought I was nuts, but as a mom you were so desperate.

And so, I just really -- again, you know, what you were saying, no conflict of interest. I want to

make sure that it's research based and that we're not recommending parents to chase, you know, your tail. It is exhausting without doing all of this. And so, from here because the IACC, we recommend research. We don't fund, as Dr. Insel reminds us a lot. And I don't know if we can set guidelines of something that doesn't have conclusive research, that's not duplicative, but it's still good replicated research.

And I think maybe we should start with the workshop and get people that are in the field, people who are going to be not biased and give us objectives. And also, here you often don't hear from parents who have tried all of these things that it has not worked. I am here to tell you it hasn't worked. I've done even the going to Mexico against Dr. Susan Daniels' suggestion. I said, well, you know, maybe that could be the one thing that works.

Dr. Daniels: Off the record.

So I just -- off the record, right? But, I mean, giving you just as advice, as a friend, that parents are desperate, and we've tried many things, and they haven't worked. And I really would like us to be cautious, especially the Federal Government,

recommending something that we don't have the research for. I think we need to get the research.

Ms. Redwood: Idil, that's the exact reason for this, is because parents are desperate and they're trying things that we don't know are proven safe and effective.

Dr. Insel: It would be great to have you on this group for just those reasons, to have someone who is not advocating for any particular intervention. I think, Anshu, you had --

Dr. Batra: Yes. Well, this is exactly the reason I went and chased Dr. Briggs down the hall because I actually didn't realize she was the head of this agency that -- Alternative and Complementary Medicine.

Anyway, so again, as we're thinking about gathering people together, it may be worthwhile to have, you know someone from her agency because we're really talking about that, I guess. Not that it's just -- you know, I don't know if I want to just put it only in that category because in some -- to some professionals, as soon as you say "alternative" and "complementary," they think of it as fluff, and they turn their mind off to those things.

And to speak to you, Idil, so things that you've tried haven't worked for your son, you know, things I've tried that have worked, and things that many of my -- I would say all of my patients and families have tried, and some of which have worked a bit, and some have not, and some have -- you know. And so, and everything across the board.

And so, I think we do need some guidance. We need some guidance, and then we need to provide some guidance to practitioners and families and government officials on how -- you know, what's the best -- what's the good next steps so we do no harm. And it's not, you know, a cost of a family double-mortgaging their home for something that they are so desperate to obtain.

And then my last comment before I miss my flight

[Laughter]

is that, again, I see this as such an important issue, as is what John mentioned in terms of the need for the transitioning population for housing and employment and psychosocial issues.

That's huge, as I'm experiencing with my 16-year-old. But the big picture here is that we need to, I think, start shifting from our paradigm of

autism into a new sort of thought process of looking at several autisms and starting to sort of maybe develop some language in describing these or recommending that people start doing that.

And again, it all starts from the top, so if we start recommending that this is a shift that needs to happen, then we need to start developing these phenotypes that then help us to better customize therapeutic interventions for these groups, then I think that that really what is needed in the community, and that's what I'm hearing from families every single time I sit here every day is, you know, we want help for our child, and the problem is their child is so different from my child, and Idil's child, and your brother, and your sister, and, you know. So that's what I'd like to see is -- from us, you know -- a recommendation that we need to start changing how we think about autism and how we describe autism into several autisms.

Dr. Insel: So I'm hearing interest in this. I still think there's a little ambiguity about what the deliverable is at the end. I'm not sure we'll be able to do treatment guidelines in the way that you recommended, Lyn, but clearly there's an

interest in getting input that allows the Committee to be better informed in terms of what we know and what we don't know where the gaps are. David?

Dr. Mandell: So possible deliverables that may be within the scope of the Committee. So one of the things I heard a lot from the public comments was the lack of screening for potential co-occurring conditions when children with autism are presenting, especially with behavioral problems. So one deliverable could be what should -- you know, what should the standard of care be for assessment for physical comorbidities when children present with autism?

A second deliverable is a call for research on where the holes are in relation to the association of these comorbid conditions with autism. A third is a call for guidelines, and a fourth is a call -- and the part that we often miss is it turns out that when we create guidelines, they don't change practice. And so, what is the -- so there's a call for either efforts or research on using those guidelines to change community practice.

And so, those would be four -- so in no case are we saying we're going to do the research or create the guidelines, but many of the times the

voice of this Committee, as you pointed out with the services phase, has been used to then make recommendations about funding that have turned into funding. And it could be that those are the four areas that -- where those recommendations come out for this.

Dr. Insel: So, Susan, if you will summarize this in writing, we can distribute it to the members, and hopefully we'll get Idil on this committee as well.

Dr. Daniels: I still need a little bit of clarity. Are we focusing on immune and metabolic, or are we focusing on all comorbidities, because that will determine how many people, what kinds of people we're getting on the phone.

Dr. Carey: This is Matt.

Ms. Redwood: I would think because we already have guidelines in place for, say, GI, and sleep, and ADD, ADHD, that to focus on the ones that we're hearing from the public that don't have guidelines that are often overlooked, we'd be able to narrow it down.

Dr. Daniels: So a potential process could be having a phone call followed by a workshop, in which case, if we're going to have a workshop, we

need to set the data now because it takes several months to set up a workshop. And so, we can't come to the end of May and say, oh, we'd like to have a workshop in June because that won't happen. So if you want a workshop, we might need to find a date right away, even though we don't quite yet know what the scope of that workshop would be.

Dr. Insel: Would it be possible for our collaborators -- let's say the American Academy of Pediatrics -- to actually organize the workshop, and we would join them for that so that doesn't fall on all of the restrictions that we face in the Government?

Dr. Daniels: Sure. So we could set up the phone call first and see if they're willing to potentially do that.

Ms. Redwood: Could we hold a date just so we don't lose it, because if it's 4 weeks for a phone call and then they say we'll have to get back with you --

Dr. Daniels: It's months for a workshop. We need a lot of lead time. So I would say the end of July maybe, but I know that runs into people's vacation time. We have a meeting on July 8th.

Ms. Crandy: Could we add days onto that so we

save airfare? That's cost effective.

Dr. Daniels: I think in terms of our staff putting together a workshop and an IACC meeting at the same time, it's not doable. We have -- it takes a lot of preparation to prepare even a meeting like this, which might look a little -- seem a little surprising, but it actually does take a lot. And so, for us to be preparing two different things that are happening at the same time would be pretty tough for us. We need a little bit of time in between to set them up because we do want it to be quality and for you to get what you want out of that workshop and not have it feel like it's been slapped together quickly and not very well.

Dr. Insel: We have a group, so we can do some of this offline, presumably in terms of making the next set of plans. It does sound like this is going to be a joint effort with the American Academy of Pediatrics. We need to reach out to them to see if they're even interested in doing this with us because if so, we may be able to hand off some of the burden of this to them.

Dr. Daniels: Sure, so in terms of offline, for example, if you wanted to talk to individuals and then bring information back. But any steps that the

group needs to take to make decisions need to be done in public meetings.

Dr. Batra: Tom, I was thinking with the AAP, you know, they have a national -- we have a national meeting usually in October, an annual meeting. And, you know, if it's possible, you know, it's several days long and maybe have the workshop sort of tied into that, you know. It's sort of late in the stage to plan it for this October, but it may be something that they could do. I don't know. But I see that being an efficient way to utilize services and people.

Dr. Insel: So we did have a previous meeting on mitochondrial disease and autism, and I think it was right after you arrived, Walter. We did that in just that way. We kind of at the last minute added it onto the International Mitochondrial, whatever it is, Organization -- Foundation. And it was in Minneapolis, I think, or someplace like that, or Indianapolis. And it was done fairly quickly.

Because everybody was already there, we asked them to stay an extra day. And it wasn't an IACC meeting. They decided to sponsor it.

So that may be -- I'm not sure we want to wait until October, but it may be that the American

Academy would already be set up to do something like this much more quickly than we can do it. John?

Mr. Robison: -- but I have to -- I'd just say I like that idea, and I'd like to see us do something to separately recognize the psychological and medical issues as two separate, like, primary challenges we have. And I wish I could stay, but I'm worn out, and I got to now, thanks to the Government, take my hour-and-a-half cab ride to the airport because I can't fly from the local airport.

Dr. Insel: Thanks for coming. And we'll be breaking fairly soon. I want to make sure before we leave this issue, and, Anshu, you have to leave as well? Okay. Is there anything else that we want to put onto the docket, onto the table, for this planning group?

Dr. Daniels: So the next steps then, I'll talk with you. I will try to get a date together for the phone call, which will be probably sometime in May. And we might do some legwork offline with these groups to see how they might participate and so forth and then be set for that phone call to make some decisions.

Dr. Insel: And Geri will give us some

information in the short term.

Dr. Daniels: Right.

Dr. Insel: Walter? All set?

Dr. Insel: Okay. Round robin, just a chance -- we've got a few minutes left -- to hear from all of you about either activities that are planned for this month or other things that you want your colleagues to know or you want the public to know from your organization, from your own interest. David?

Dr. Mandell: You brought this up, and please tell me if this is not appropriate for this venue, but we didn't have as much chance to discuss the CDC prevalence study as I would have liked. And there are some things about the prevalence study that are concerning other than the rise in number, the dramatic difference in prevalence by site, the dramatic difference in the change in prevalence by site, the dramatic change in the proportion of individuals identified with intellectual disability, and the identified racial disparities, even though all door-to-door evidence we have would suggest no difference in prevalence by racial or ethnic group. And so, you know, it's a heroic effort. It takes a tremendous amount of work. It

may be the best we've got.

I was wondering -- I would love to hear from you, Coleen, and I'm sorry I didn't get a chance to ask John, how you think about these differences in making decisions about whether these numbers constitute true prevalence versus -- and certainly the language of awareness and better diagnosis is woven throughout the studies, which would suggest that you're not thinking about this as true prevalence.

I worry about what presenting a number like 1 in 68 means up from 1 in 88, up from 1 in 110, and what that means about the potential utility of this kind of study. But you can tell me that that's not -- I mean, that's a lot of questions.

Dr. Insel: So, Coleen, are you comfortable --

Dr. Boyle: Dale is in the room, so I'd be happy to, I guess, address some of that and actually have a discussion. It's not like I have all the answers. So, I mean, I think of this as -- what our surveillance does is take a snapshot in time. We refer to it as identified prevalence, so that's, I think, telling in terms of your question about, is this what we consider the true prevalence? And the graphic representation that

John had about, you know, what it is that we're measuring at any point in time, I think, is a nice way of capturing that. So clearly, if a child has not been identified in some way, shape, or form within the context of the community services, they won't be represented within this.

We do know that over time communities are getting -- and I don't want to use the word "better," but that identification is changing, okay? So whether it's “better” or whatever the adjective we're to use there. And John mentioned the fact that, you know, 10 years ago when we started this, 70 percent of the children who came into the system actually had either a community diagnosis or they were in a special education class receiving autism services. That has changed over time. That's increased over time, and that's clearly a reflection of -- you know.

Again, surveillance measures, it tells us what's going on in the community. It gives us some clues as to why. But it doesn't answer all the questions about why, and that's what that is. I mean, all of the work that we do within the context of other research, both CDC, NIH, other organizations, try to answer some of that why

question.

So, and you mentioned this. In many ways it's a Herculean undertaking. It's a large effort. It's a large study, 360,000 children represented by that over -- 5,300 children captured, that the clinician reviewers feel fairly good. Our 7-year-old or 8-year-old validation studies suggest that there's, you know, good, positive predictive values. If we call a case a case, it's likely to be a case. But are we missing some children? Undoubtedly. Are we getting better at capturing some of these children? I think we have clues to suggest that from the data alone that that's happening.

Dr. Mandell: I was wondering if the reverse may also be true, that as it becomes more useful to have an autism diagnosis, that the language that triggers red flags for autism is more likely to make its way into charts than it was in years past. Certainly when the '96 data was used for that initial study in Atlanta, which found such positive predictive value of a community diagnosis.

And I wonder if the changing criteria with the *DSM-5* offer an opportunity to test that. So when Matt Maynard went through the -- you know -- and found, like, such a smaller percentage of

individuals using those -- the current charts would've qualified for a diagnosis under *DSM-5*. If there's something about the community clinicians' and educators' use of language that's triggering potentially a false positive, then we should see that language change in response to *DSM-5* in the health care records, not necessarily in the education records, because education systems don't need to adopt the *DSM* criteria. But if that were to happen, it would suggest that community clinicians are responding to the change in diagnostic criteria to obtain a useful diagnosis.

Dr. Boyle: I think Matt, if I'm understanding you correctly, I think Matt in his discussion actually pointed that out, that obviously we're measuring pre-implementation of *DSM-5* and even pre-knowledge of changes in *DSM-5* versus actual community implementation. So I think that's an issue that -- it's hard to address.

Dr. Mandell: Because if the diagnosis -- if the problem goes right back up, it suggests that community clinicians are responding -- are gaming the system in some ways.

Dr. Insel: Lyn?

Ms. Redwood: I just wanted to comment on the

intellectual disability piece, Coleen. What I'm seeing on the ground with families that the children being diagnosed now, we call them autism light, and that they have normal intellectual abilities, and they turn around very quickly with intervention. And I know my son, his IQ is 51, and he was very sick. And it was a completely different picture it seemed with the older children than the younger children now that are being diagnosed. I know there's a woman in my neighborhood who, you know, sought me out because her son had been diagnosed and asked me to come by, and he's running around playing and talking, and he has good eye contact, and I'm sort of going, really, he has autism? Okay.

So I'm just -- I almost wonder if we learn the signs, act early, if we are picking up kids. And that's why I asked the question this morning about the 30 percent of children in the National Children's Health Survey who, "Oh, my child was diagnosed with autism," but they never have it. We really haven't drilled into that to know were they misdiagnosed. Were they treated? If they were treated, then what did you do because we need to do more of it.

Dr. Boyle: So you know one of the things that hopefully we'll be able to do now since we have four-year-old data and we'll be following up the 4-year-old children to when they're 8 so we'll be able to understand how those changes occur. Again, just trying to get a better and more accurate picture of what's going on as children progress.

I mean, ideally I know my group back in Atlanta would love to be able to longitudinally follow versus trying to do these snapshots within the context of the community and even understand how autism evolves as a child progresses to age 12 or age 16. But right now, we've been focusing on the younger age children.

Dr. Insel: Is there some reason you can't do a longitudinal survey? Are you prevented from doing that?

Dr. Boyle: No, it's just resources.

Dr. Insel: Okay. Jose?

Dr. Cordero: Well, I'm glad that you asked that question because that -- I was going in the same direction. One of the things that impresses in looking at all the data over time is the change that we're having with, say, lack of intellectual disability versus what you see in African Americans

and what you see in Hispanics. And then, sort of compare that to, like, what we have done in Puerto Rico, and we see a different picture in terms of the proportions of intellectual disability.

And I really wonder if part of what the challenge is with our best tool is to do administrative prevalence if what we're seeing basically reflects differentials in terms of ascertainment of cases, especially when they are not seen with intellectual disability.

And frankly, I think the only way to answer that is to develop something in a longitudinal way. And when we look at the Korean study and look at the hyperability sample versus the general population, I think that there are some major differences in terms of the rate of concomitant conditions.

And so it seems to me that somehow I think the priority here ought to be some form of longitudinal study linked to a systematic or early screening that actually AAP recommends and being able to from that determine what the real prevalence is.

Dr. Insel: Alan?

Dr. Guttmacher: Yes. I'm hoping we'll have some answers before then, but maybe we won't have

sufficient answers. The National Children's Study would be -- for those of you who don't remember hearing about this -- it would basically pick up 100,000 kids longitudinally until age 21, and picking up many of those kids, exact proportion to be determined very soon before birth. And if you take the 168 prevalence numbers, you know, if you just use that, that's about 1,500 kids out of that 100,000. And we would have both very good phenotypic data about kids' development, about kids' health problems, about kids' growth, as well as having good, for many of those kids, even data about not just exposures in pregnancy, for instance, but both biological samples and even environmental samples going all the way back through the pregnancy.

So we will probably -- my best projection at this point would be that kids will start being enrolled in the main -- the pilot out there now is of only 5,000 kids, but the main study we'll probably be enrolling something like, you know, two, two and a half years from now that it would start. So since the diagnosis would be made within the few years of life, we would think, then we would have -- begin to be able to have some of what

you're asking for in, you know, five or six years.

Dr. Insel: Larry?

Dr. Wexler: Just to add another element to this: John this morning talked a little bit just sort of in passing that they're going to do some socioeconomic cross-tab. And I don't think that can be emphasized enough because, you know, it may be that it's not about race, you know, and that overrepresentation is really not correlated with race, but it's correlated with money. And that that's -- you know, and that can apply to an overrepresentation of ID within autism within autism within particular races because of the sampling and just how that works.

So from our perspective, we've certainly -- we're not CDC, God knows, I mean, but we have a data set of every kid, you know, who -- we have a data set of every kid by all of the 13 Federal disabilities, including autism. And we have run numbers by ZIP Code, by SCS, which is not nearly as highly developed as what CDC is capable of doing.

But there is a relationship, I don't think there's any doubt about that, between prevalence and socioeconomic status in general. So I hope, Coleen that what John said, that we should not

forget that, that that is a huge factor that is being looked at even now.

Ms. Crandy: Larry, then can I ask you a question since you have that data in those areas? Is, like, intellectual disability higher, that those kids are falling into that? If these kids were always there, they would be in another eligibility category.

Dr. Wexler: Let me say that it is -- the work we've done is not nearly as scientific. When you're playing with census data, SCS data, and ZIP Codes, it's not precise. We just -- we took a look at autism in particular and there seemed to be a relationship between socioeconomic status and prevalence. And the numbers are small, though, you know, also.

And the other side to that is what we can't do is in that our data and awful lot of preschool and early intervention kids are listed as -- they can be listed as developmentally delayed. A lot of them get picked up in speech language just depending on -- and that's -- there may be a socioeconomic piece to that, too, in terms of label preference at any given time.

So like I say, it's not incredibly precise,

but there's enough indicators of it that I'm really looking forward to the work that CDC will do.

Dr. Insel: You guys have got a lot on your plate. Coleen, we often come back to the same set of questions sort of the way David posed them, that, you know, the data are really interesting. But at the end of the day, we can't tell whether there are more kids detected, more kids affected, is this really a change, how much of this is ascertainment.

So what would we need to do? I mean, what would be the study that we could do that would give us a really definitive prevalence for, even if it isn't for the whole Nation, at least for some part of it? Is there something that we should be thinking about or something that the Committee should recommend?

We're always back to this same set of questions that nobody has answers to. We point to the data from South Korea, but we don't want to be using South Korea data. I mean, is there something else we can do that would be more rigorous and, for us, a little more definitive?

Dr. Boyle: We heard -- I guess we heard a while back about the South Carolina study that

Autism Speaks is funding that's piggybacked on top of the ADDM site there. I don't know the details of that, but, I mean, that's the idea is trying to do -- combine what we're doing, which is sort of what South Carolina -- not South Carolina -- South Korea did with actual screening within the community setting.

So it might be helpful at some point for the Committee to get a sense of how well that's working, where they are, and get an update from that study. Again, going back to John's Venn diagrams, you know, the idea there is trying to find those children who for whatever reason, and I don't know if we want to call it autism light, but those children who have not come to attention for some reason.

Now, remember all of these children are receiving services or have come to somebody's attention. So I mean, it's not like we are finding children who have needs. And that's an important thing for all of us to keep in mind.

Dr. Insel: But just to clarify, in the South Korea study, which I think was, what, 1 in 38 was the prevalence rate only a third of those kids had ever gotten a diagnosis. Yes. So I guess, there's

no other agency that's doing this, is there? I mean, there's no Federal group that's trying to kind of get to this ground truth from a very intensive door-to-door, you know, let's get the final number here so that we'll know in 2015, at least in this envelope, in this one area, what the real prevalence is.

Dr. Boyle: I mean, the closest that comes to it is really the National Children's Study if, in fact, you're doing some type of structure screening for these children at various points in time.

Dr. Guttmacher: Yes. That won't be able to give us -- it won't give us trends over time because it'll just be done once. But it would give us trends in terms of, you know, being comparable in some ways to South Korea. It won't have the same kind of going into schools, et cetera, et cetera. It's going to rely on parental reports, but it will also have, you know, exams of the kids done as part of the study. And that's going to include some of the instruments that we all believe in, so it ought to be pretty good at picking them up.

Dr. Boyle: You know every study has its challenges and its limitations. South Korean -- South Carolina and South Korean -- the South Korean

study has a lot of modeling that went on in that study. You know, it was very challenging to get the participation within that community setting. So, I mean, there are challenges to any approach that we take with this. And again, we reflect identified prevalence.

Dr. Insel: Cindy, you've been quiet, so you get a --

Dr. Lawler: I just want to follow up a bit on what Alan said, because I agree that it's really important to sort of identify, you know, the best prevalence estimate, but it's always tied to a place in time. And the real challenge, and I think, you know, the really important questions do have to do with, you know, how that changes over time, how can you dissect out the contributions of the different things that factor into those sort of, you know, secular changes over time.

And I, you know, have struggled for a long time to figure out how to do that or even think about doing that and wonder if you might have some thoughts.

Dr. Boyle: It is a challenge, and as John was alluding, we have a group of investigators that are working on just that, trying to sort of at least

tease apart the socioeconomic, the concepts that we can measure within that -- the demographic factors, the racial factors, the educational issues -- all of those things that might lead to forces within that community that might influence diagnosis -- you know, identification and diagnosis and services.

It doesn't -- they're not going as far as trying to understand sort of the changes in environmental risk factors, which might be the next level that we add onto that. There was a recent paper actually from the ADDM group that looked at changes in three perinatal risk factors, so being born too early, being born too small, and I can't remember what the third one was -- C-section. All of those are fairly well-established risk factors. It may not be the causal factor in and of themselves, but they reflect sort of a constellation of factors related to maybe poor pregnancy outcome.

And, you know, in combination those three factors predicted about 12 and 13 percent of autism risk, but it didn't change over time. Now, a short time. It was like -- I think they looked at 2002 and 2006, so don't quote me -- or 2008. But again,

those three factors, which are, again, in combination important risk factors for autism explaining, you know, 12 to 13 percent of that variation, didn't seem to have changed in terms of their contribution. But that would be perhaps the next level that you could add onto that.

Dr. Lawler: It seems like we're always trying to think about, well, okay, if this much of an increase was due to factor A, and then, you know, we can assign this proportionality to this other factor, and we keep doing that. And, of course, all of them have really wide confidence intervals. And, you know, the question is, oh, well, what's left. If there's still something left --

Dr. Boyle: So remember, these data are not just -- these data are important to communities for them in terms of understanding the needs of their community. So it's not just tied to understanding perhaps the ideologic issues. It's really trying to understand the service implications, the whole spectrum of policy-related aspects into autism.

Dr. Lawler: I agree.

Dr. Insel: That's just a critical point. I think that's the point that we don't make often enough that that's really the value here, not so

much around the ideology. Idil?

Ms. Abdull: First, I want to just say to CDC that I think no one is perfect, but you do a wonderful job, but nobody ever thanks you. So thank you very much for what you do. Everybody is always mad at them,

[Laughter]

and so I just want to say that it's very difficult to say something is wrong with children, right? Children are a gift from God. And then to say, well, we don't have a reason, we don't have a cause, it's very difficult to say that and parents not be mad at you or the community or the whole country not be frustrated by that.

But I just wonder, you, and John, and everybody always says this is a snapshot. I wonder if it would make it more of 11 States out of 50. It is a snapshot, right? So do we need maybe more -- do we need to march to Congress to push to have more funding to have more ADDM sites? And then even when you go to a State, you go to, like, either a county or a district, a very tiny area of that State, so it's not even the whole population of that State. I wonder what your thoughts about that.

And then I'm just going to get all my

questions out. And then I have the other question for John or for Larry -- I'm sorry -- from the Department of Education. Of course, it is poverty. It is socioeconomics. But in terms of education, it's supposed to be free public education. And so, the fact that children are not getting even identified irrespective of whether they live in a poor community or a rich community, not until 5 I think is a failure of the Department of Education in terms of doing targeted outreach, not just funding and saying, well, you do the best you can.

But you have got to change the system.

The status quo is not working. There has to be a way for birth to 5 -- the agencies that get funding irrespective of how limited they are, to do targeted outreach of not just even minorities, but low-income and rural areas -- because everywhere there is a school district -- why are they not catching these children at 18 months, at 15 months, at 2 years?

Dr. Wexler: Yes. Let me respond very quickly. I did not say that children weren't getting services. I didn't say that at all. What I said is that they may be labeled something other than autism. So if a child needs speech/language

services, they need speech/language services. They don't necessarily need it under a particular disability category. If they need physical or occupational therapy, they don't need it whether they -- it's the need. It's not the label that drives the services, and we're very, very clear on that.

So for us, if a parent decides I want my child -- it's an option to be labeled as developmentally delayed because frankly we know about self-fulfilling prophecies. And when kids are labeled at a very early age, they fulfill their prophecy, where if they can get a more generic label, a lot of times they're served differently.

And so, that's a parent choice that we respect as I'm sure you do, and there are certain options under the law as to how a child is, in fact, labeled. But we serve the kids, and we serve an ever-increasing number of kids who are, in fact, coded, you know, with autism.

Dr. Insel: Jose?

Dr. Cordero: I think in Larry's and also the Department of Education's defense, if it gets to them and they're the ones that are making the recognition of autism, then what's failing is the

system of what is the good care in the first 3 years of life that's supposed to happen in terms of medical home. And that is where we are having the problem.

We have developed the recommendations for screening at 6, and 18, and so on, at different times. And that is not happening, and it isn't happening because it's the way that the health care system and the time that actually pediatricians have to really look at and do that as part of their health care.

There are issues of reimbursement. There are issues of how you engineer or plan your practice and your visits for those what are supposed to be well-baby visits, and that's where we need to pay attention. If we agree that it should -- every child with autism ought to be recognized by age 3 at the latest.

And so, if we are to really pay attention to what needs to be done, it is -- What is happening with the systems of services from birth to 6 months to 12 months and so on? And what can we do to be sure that each child gets appropriate service in order to be recognized early?

Dr. Insel: We're going to need to end in a

moment. But Jan has, I know, a lot of feelings about just this issue, so I'm going to let her speak.

Ms. Crandy: Yes. I'm wondering, too, Larry, could the Department of Education bring your numbers to the table here and just tell us what your -- what States are reporting to you? And I know not all States report. They report differently. Nevada just made a law that passed as of '13 that all eligibility, any kids if they had multiple labels, had to be reported for autism. And our numbers just in our education system went up 2,000. The number increased by 2,000 once we started counting everybody.

But the birth to 3 -- States have the decision to make that -- do those screenings. It's not a Federal guidance that says -- you're telling them to screen autism? No. We let the States decide, so States are doing it different. Some States aren't doing that screening, and some are, so we're not going to get those. We need that Federal guidance to say do it.

Dr. Wexler: I'll bring --

Dr. Insel: You'll bring the numbers.

Dr. Wexler: I'll segregate it for you before

the next IACC meeting.

Dr. Insel: On that note, it's now 5:00. We do need to bring this to a close. Thanks to all of you for -- it's been a long day. We'll meet again in July. I'm sure it'll be much cooler in this room in July than it was today. I hope so.

Dr. Daniels: Yes. So July 8th is the decided date for the next IACC meeting. I did take information from all of you, and that's the date we came up with. So we'll see you on July 8th.

Dr. Insel: Thank you. And we're adjourned.

(Whereupon, the IACC meeting was adjourned at 5:04 p.m.)