U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, JANUARY 18, 2011

The Committee met in Conference Rooms C and D of the The Neuroscience Center, 6001 Executive Boulevard, Rockville, Maryland, at 10:00 a.m., Thomas Insel, Chair, presiding.

PARTICIPANTS:

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

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

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

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

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

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

PARTICIPANTS (continued):

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

HENRY CLAYPOOL, U.S. Department of Health and Human Services (DHHS), Office on Disability

GERALDINE DAWSON, Ph.D., Autism Speaks

GERALD FISCHBACH, M.D., Simons Foundation (attended by phone)

LEE GROSSMAN, Autism Society

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

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

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

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

SHARON LEWIS, Administration for Children and Families (ACF)

CHRISTINE MCKEE, J.D.

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

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

PARTICIPANTS (continued):

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

STEPHEN SHORE, Ed.D., Adelphi University and Autism Spectrum Consulting (attended by phone)

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

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

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PROCEEDINGS

10:03 a.m.

Dr. Insel: Thanks very much, and welcome to everybody for another of the full IACC meetings. We are -- many of us are here at the building on Executive Boulevard, the Neuroscience Center in Rockville, but I know many others are on the phone.

So I think as a first order of business, just let's take a quick roll call, so those of you who are on the phone will know who is in the room and those who are in the room will know who is on the phone.

So I'll start off here. Tom Insel, and to my left --

Dr. Hann: Della Hann, the Acting Executive Secretary for this committee.

Dr. Janvier: Yvette Janvier.

Dr. Guttmacher: Alan Guttmacher.

Ms. Resnik: Denise Resnik.

Dr. Battey: Jim Battey.

Dr. Lawler: Cindy Lawler.

Ms. Redwood: Lyn Redwood.

Dr. Briggs: Josie Briggs.

Dr. Koroshetz: Walter Koroshetz.

Mr. Grossman: Lee Grossman.

Dr. Daniels: Susan Daniels, Deputy Director of OARC.

Dr. Insel: And on the phone?

Ms. Blackwell: Ellen Blackwell, Centers for Medicare & Medicaid Services.

Ms. McKee: Christine McKee --

Dr. Wagner: This is Ann Wagner from NIMH. I am just on to answer questions when you get to the Strategic Plan.

Dr. Insel: Anyone else on the phone? We thought we heard someone just a moment ago but it was very faint.

Ms. McKee: It could have been me, Tom. It's Christine McKee.

Dr. Insel: Okay, thank you Christine. Anybody else with us?

Dr. Wagner: Tom, this is Ann Wagner from NIMH and I was just going to be here to answer questions when you get to the budget estimates of the Strategic Plan.

Dr. Insel: Great. Okay, we got that in. Thank you. Well, appreciate those of us who made it in here. It was not a particularly good day for travel. There's an ice storm in D.C. and worse than ice storm in New York and Boston.

I believe that Geri Dawson is going to be with us but will be late and Gerry Fischbach and Marjorie Solomon will be joining us, but somewhat late by phone as I understand it, and there may be others that will still be coming in. Lee? Is Stephen Shore on the phone?

Okay. Great. All right. Stephen, we can't hear you but when you are able to -- hopefully you can hear us, and when you are able to send us a message, feel free to just beep in here.

I wanted to start by just quickly going through the expectations for the day. We are going to have a couple of presentations this morning around the Affordable Care Act, something that we are still wanting to make sure everybody is up to speed on.

Also we wanted to get, as we have done in other meetings, just updates from some of the members. We are trying to rotate this so that over the course of the year, all of the members of the committee will have a chance to talk about what is going on in their particular sector.

So today we will hear -- if Geri makes it in -- by 10:15 we will hear from her, if not we will delay that until later, Lee, Walter and Alison.

And then later on in the day we will take on the issue of the Strategic Plan and make sure that we complete the update, which is actually due to get to the Secretary this month, so we have to get that done today. And then we will have time for public comment and other discussions in the afternoon.

Before we start on the business of

the meeting, it's been a bit of a tradition that got interrupted, but I wanted to get back into the tradition as we did last time of just giving you a quick rundown on the science that has emerged since we last met.

That's a bit of challenge since we met only a month ago, so to try to summarize all of that science, you would think would only take a single slide.

But in fact, as a tribute to all the things going on, there is quite a bit that is relevant to the Plan. I will just give you a few examples. This isn't going to be comprehensive, but it's, again, my attempt to make sure that we are all up to speed on some of the breaking stories in autism research.

This one out at the end of last month on autoantibodies to the cerebellum in children with autism or more broadly with ASD. This is a follow-up of the studies that were done on maternal autoantibodies that made so much -- or at least created so much interest about four, five years ago, because they could be transferred and create what looked like an autistic-like feature in non-human primates.

In this case, this is actually looking at the children, and you can see that there is, for this one antibody, about a 45 kilodalton protein that is found in cerebellum. It looks like about a 9.7 percent rate in the kids with autism, 3.6 percent in the controls.

And that was correlated with greater impairment. I have to say that in looking at this closely, what really strikes you is the number of controls that have many of the same antibodies and this was one of about seven that they looked at. The other six, there was no significant relationship.

So I think there's still a work in progress and the surprising thing too is that there was no relationship between the findings here and the findings in the moms, even in the same families. When they went to look back at the kids who had this antibody and looked at whether the same antibody had been present in the mother, it almost never showed up. Jim?

Dr. Battey: Yes, I read this paper and I'm not sure it's going to stand the test of time.

Dr. Insel: Right. So again, there are multiple comparisons and they squeak out a significance with this particular antibody, but more to be written on this topic. I think it's an interesting area that is going to require some more rigorous research.

The other place -- yes, I'm sorry, Lyn.

Ms. Redwood: I just had a quick question. Did they differentiate with the controls, if they had any other diagnoses, like ADD, ADHD or some of the things that we see also as a spectrum with ASD disorders?

Dr. Insel: Yes, the controls in this study, as far as I can remember, had no diagnosable disorder. So -- but this is something that is coming up more often, is the -- you do see these antineuronal antibodies in children and adults where there's really no evidence of pathology.

Having said that, one of the most exciting areas right now are those rare cases where we find these anti-NMDA antibodies, which are really interesting and which do seem to be associated with a particular syndrome that is still being described.

So there is something here but it is going to take a lot more digging to get at it. The other finding in response to this particular chapter of the Strategic Plan is in the neuroimaging space and it was the study, still only available electronically in Biological Psychiatry, that looks at using a resting-state fMRI to look at functional connectivity.

And you won't be able to see the details, perhaps, with this slide, but suffice it to -- if you just look at those plots, you can get a sense that when they put the seed in the striatum and they look at five different parts of the striatum, there is really consistent hyperconnectivity.

And this is fascinating because it's not the hyperconnectivity that has been described so far in the cortex. This is hyperconnectivity to many subcortical areas as well, especially the pons.

So there's something very surprising here that is again going to require a lot more digging, but this is I think the first report over the last -- in this case it's actually not even yet fully published -- but it suggests that this concept that the brain in autism is overwired or overconnected is going to need again some more careful exploration and to try to figure out whether there are particular pathways which seem to be associated with particular aspects of the syndrome.

The other place where we have seen

a lot of action the last four weeks is on this question about what caused this to happen and can it be prevented. Two reports from the CHARGE study that are supported by NIEHS.

This one, which looks at these polybrominated diphenyl ethers, these are flame retardants which have been described so much as endocrine disruptors and as being so prevalent in the environment now.

And much to many people's surprise, looking at 100 cases here, there was -- and using GCMS spec, which is really the most sensitive way to analyze these, and looking at 11 different congeners, they didn't find any difference between the cases and controls, which was a bit of a surprise in this particular study.

Particularly, this is the California sample where the concentration of PBDEs has been suggested to be higher than almost any place else in the world.

The other piece of this was, with

some of the same investigators, reported in this journal, which is available online, that of all things, proximity to -- living near a freeway does seem to be associated with a higher rate.

In this case they just took a very large number and sort of segmented them by where the mom was living in the third trimester and postnatally and what pops out were the -- about a two, greater than two-fold increase in risk for those families that lived within 300 meters, about a kilometer -- I'm sorry, 300 meters of a freeway where the idea being that potentially something about air pollution, sulfur dioxide, carbon monoxide, it's not clear at all what would be the driver here.

They do rule out lots of other issues like SES level or race/ethnicity or other things that might have contributed. So again, bears more research, but it's an interesting lead that comes out as a bit of a surprise.

The other two papers: this one particularly got a lot of press coverage, from Peter Bearman's group at Columbia, looking at the California DDS data and looking at the second siblings, in this case even more broadly, in the whole California population, so 660,000 second births in California, and showed that those that occurred within 12 months of the first birth, that is, an interpregnancy interval of less than 12 months, was associated with more than a three-fold greater risk for autism relative to those that had a greater than three-year separation between pregnancies.

Mechanism really unclear in this case. This is an observation in search of a mechanism. And if the odds ratio weren't so high, it probably wouldn't have gotten so much attention, but the 3.39 is of interest and they did a lot of work to rule out lots of other things, like birthweight, problems with pregnancy and a number of other potential confounds here. So, interesting.

And then this report on the over 700,000 Danish births, which also showed the relationship to neonatal jaundice, but in this case really only in a very odd way, only in multiparous moms and in winter births, so it's a little hard to know exactly what to make of that, and again the odds ratio is not nearly as high.

And finally, one other observation from the last month, which I think is very, very hopeful. This is an RCT, published out of the group at Kennedy Krieger, Rebecca Landa is the first author on this project, looking at a behavioral intervention which this time is focused on fairly early, so it's 21 to 33 months. It's a small study, 50 ASD toddlers.

But it's all about this idea of interpersonal synchrony. So it's focused on getting at joint attention and social engagement. And what makes this interesting is two things.

One is that, for those particular outcome variables, this seems to work. It drives them from about 17 to 42 percent in terms of how the kids are doing at the end of the trial.

But much more interesting to me than that was this is one of the first studies that has shown that the findings generalize, so that the kids even outside of the experimental situation are beginning to take on much more of the social world than they had previously. So it's, I think, quite hopeful in that regard.

The effects, though, are small, so there was not actually a difference between the treated and the control group, which got kind of routine behavioral interventions. Both of them showed some improvement on these measures and they didn't separate on them, even though there was a more striking within group difference on measures of social engagement, when there was this focus on interpersonal synchrony.

So an interesting approach. It was something we have talked about a bit under the interventions chapter, you know, are there things we could be doing better that would be more targeted, that would go after particular subtypes, and this is an argument that maybe there are ways to focus behavioral interventions to get a greater impact, particularly on this part of the core symptoms.

The last thing I'll mention before we go to work here is that we were required by the Combating Autism Act, we being not the IACC but the Office of the Secretary, so the Secretary of HHS was supposed to send a report to Congress within four years of the act and the Secretary's office asked OARC to put that together and the group did that in a really excellent way.

This report is in your package and

it has been sent to Congress and it's an overview of many things that have happened since 2006. The Combating Autism Act, the law itself, is very specific about nine questions that they want answers to, and those are each answered in this document.

So I would refer you to the document in your package and if you have questions about it there are folks from OARC, especially Della and Susan here who can take you deeper into the document about the details.

And I think that's as much as I wanted to say in terms of getting everybody up to date on what is going on in the autism world from -- at least from the perspective of OARC.

Any questions or comments before we move on?

(No response.)

Okay, I will need you to take a look at the minutes from the December 14th meeting. Those are also in your packet and were sent to you prior to the meeting, and if you can let me know if you have any suggestions or comments on the minutes.

Hearing none -- Lyn?

Ms. Redwood: Tom, there's just one correction under the update from the IACC Services Subcommittee. I think in that third line it should be Mrs. Blackwell, not Redwood.

Dr. Insel: Okay, do you -- let's make note of that and with that change in place, any other recommendations or suggestions? If not, can I get a motion for approval?

Participant: So moved.

Dr. Insel: Okay. Second? All in favor?

(Chorus of ayes.)

Dr. Insel: And the minutes are accepted as -- with that one change and we are ready to move on to our round robin. But let me see, I don't think Geri has made it in yet.

Do we know any more about Geri's plans?

Okay, so she may get here just as we finish. Lee, would you like to just lead us off here in terms of updates from ASA?

Mr. Grossman: Yes. Not really sure what I was supposed to report on so I figure I will just throw a few things out on what we're doing.

Dr. Insel: Yes, this is actually exactly that.

Mr. Grossman: Okay.

Dr. Insel: It's really meant to be an informal update of your colleagues so that once a year at least, and hopefully more often, we can all hear about what is going on in different sectors.

Mr. Grossman: Well, the first thing I would be most remiss if I did not report on, is the fact that our annual conference will be in July and I would encourage everybody to attend that. It's always a great event. It's in Orlando, on July

6th to the 10th this year.

It should be as other years. We are expecting 1,800 to 2,000 people there. It will cover every aspect imaginable about autism and I would expect -- and we have -- probably be talking to some people about if there's some involvement that the IACC will have there.

But I would encourage all of you to attend. It's a great meeting. It really represents a global perspective of autism and the participants, which now are about 70 percent professionals, 30 percent family members, really get involved in quite a great interchange of what is happening and sharing of their experiences, as well as making recommendations and suggestions how to move our collective efforts forward.

Much of our public policy efforts, which in many ways drive the organization, Jeff Sell is going to be covering here in the next session. But just wanted to highlight a few of those. Our work with some of the coalitions out there continued to expand and grow. Most importantly, the one that we have with CPSD, which is the Coalition to Promote Self-Determination, which is made up of groups such as -- and Autism Speaks is a part of that -- but other groups such as Down's syndrome and the Arc and Easter Seals and Fragile X societies and this is looking primarily at adult service provision.

Our first and foremost tenet is employment first and we are in the process of writing various position papers and forwarding legislation to actually enhance the lives of those with developmental disabilities.

The other group, other great coalition that we have is the Safer Chemicals, Healthy Families Coalition, which is made up of 200 plus various organizations that are concerned about chemicals and how that relates to health.

That organization has done a

couple of studies, one of which Jeff Sell has been involved in, and has been one of the lead agencies in terms of getting TSCA reformed, which is the chemical -- the toxic chemical act.

Our other coalitions, the National Association of Residential Providers for Adults with Autism, has recently had their -- will have their annual meeting at our conference, and they are the organization of residential providers that are looking at -- they primarily specialize in autism and -- Denise, are you familiar with them? Okay.

And they are out spreading the word and developing standards and working with some accreditation agencies of what adult residential providers should provide across the country.

One of our best coalitions --

Dr. Shore: All right then, what should I do? Should I hang up and --?

Mr. Grossman: Well, Stephen's

there, finally. Hi, Stephen. The other very important work that we are involved in is the network of autism training and technical assistance programs, which is made up of 80 different agencies and academic centers that are primarily interested in educational and technical assistance work.

And we have developed position papers that are now being used by the National Association of Special Education Directors and others in terms of what should be the standards for educating children with autism in secondary education.

We continue to expand and grow our contact center, which is right now a 9 to 5 call-in center. We every week exceed the number of people that are calling in that we can handle and we are right now looking for funding to not only expand that, but to turn that into a 24/7 contact center, and to expand it so that it is addressing multiple languages when people do call in.

And I would say that our primary focus this year in terms of our government relations and public policy is going to be driven by the outcry that we are hearing on a daily basis from families and from state agencies about the pending budget cuts.

It seems as though later this year everyone is anticipating an unprecedented -- and I can't emphasize it enough -- an unprecedented level of cuts, in services and supports across the board in each and every state.

We are looking at a probably 25 percent decrease in state fundings that will affect education, early intervention, adult services and from a community that is already in crisis and is lacking the proper services that are out there, we cannot emphasize how drastic the situation is getting out there.

And I think with that, I'll leave it and answer any questions.

Dr. Insel: Thanks very much, Lee.

Questions or comments? Walter.

Dr. Koroshetz: Thanks very much. So I'm Walter Koroshetz, the deputy at NINDS. I'm happy to just talk a little bit about what our institute does. Our mission as seen on the bottom of this slide, is to try to reduce the burden of neurological diseases and on this slide you can see that there are very many diseases that we have to deal with and so I think one take-home point is that what NINDS can bring to autism is not only the research it does particularly in autism, but potentially to the work it does in other diseases that may, without prior knowledge of how this happens, but cross-react with some of the problems that give rise to autism.

I wanted to mention just a couple of things that we do in autism research in terms of funding. I would say that most of our funding in autism goes to try to understand biological mechanisms that might explain the neurological disorder in persons with autism.

So we will do -- we will fund a lot of work in neurodevelopment and Tom mentioned the issue of brain wiring and a lot of our basic research is to try to understand how does the brain wire, what are the regulatory triggers that could potentially go awry but also give rise to development in normals.

We also fund a lot of work in synaptic function, which is understanding how the synapses, the connections between the brains, are working. But much of the autism we do is basically people who are in this sphere but then try to look at some of the abnormalities that have come up in the genetic studies of autism to see how those gene changes would affect synaptic function.

Neural circuits, many of them in the brain, we are hearing more and more about how they may be abnormal in patients with autism and now with new tools, such as being able to study the functional connections with resting state MRI for instance, the anatomy that people have done now can be actually investigated in living people. So things have kind of come together on both the basic sphere and the clinical research sphere.

We explore specific abnormalities with potential relevance to autism. I'll talk a little bit about that. And we do fund research in many disorders that are on the spectrum, such as tuberous sclerosis, Rett syndrome, mitochrondrial disorders and also conditions that are associated with autism such as epilepsy.

So that's kind of the big picture and I'm just going to illustrate in the short time we have with a couple of grants that we fund. The Norway Birth Cohort Study is, we think, a very important study.

In Norway, the state actually does a population study in pregnant women where they get detailed maternal and prenatal history, cord blood samples, history throughout the pregnancy, and this study is actually -- I think it's completed and 107,000 children were entered with data on their mothers so we would expect that there would be somewhere between 550 to 750 autism cases.

So this is a unique opportunity to try to get prospective data that would then predict who goes on to autism and potentially the issues such as parental age, nutrition, things that happen during pregnancy such as ultrasound, assisted reproductive technologies, infections that occur during the pregnancy, host immunity, immunizations, and other iatrogenic factors could be mined to see if there is an association with development of autism.

The problem with this study has been it's been very hard for our investigators to actually find the kids with autism. So they wanted to find them by age three and that pretty much failed.

So now it's pushed back and try to

get them somewhere around age 5 to age 7. So a great idea still requires execution.

In terms of molecular mechanisms, just some examples. So there's Matthew Anderson at BI in Boston, he's looking at a particular gene that is deleted in a syndrome which is related to autism. There's a study being funded to James Sutcliffe at Vanderbilt looking at network abnormalities in the serotonergic pathways in autism, regulation of SHANK3 and its association with how it affects synaptic regulation to Paul Worley at Hopkins.

And another thing we do is, and pretty seriously, is try to develop physician-scientists in particular disease areas. We think that the physician-scientist has a real role to play in trying to pursue the bench-to-bedside advances that are necessary to get at the mechanisms and treatments of diseases.

So this is just an example of someone who is a physician-scientist working in basic science in synaptic function and Aplysia, which has been a very productive animal model for synapse biology for a long period of time.

And the thought is that training somebody in this basic area, they will be able to really bridge the two worlds of the clinical and science areas.

Dr. Battey: Walter, could I just ask a question?

Dr. Koroshetz: Yes.

Dr. Battey: What is SHANK3? What kind of protein is it?

Dr. Koroshetz: SHANK3 is associated with, I think, development of dendritic spines.

Dr. Insel: Yes, I think it's a scaffolding protein in the postsynaptic density, so it's like one step away from contactin-associated protein 2.

Dr. Battey: So it's yet another example of a gene product that finds its way to the synapse in the -- where mutations are associated with autism. It seems to be a recurring theme.

Dr. Koroshetz: Yes, I think that's true.

Dr. Insel: It was actually, I think, this discovery that led a lot of people to say that autism is a synaptic disorder. Right?

Dr. Koroshetz: And similarly with neuregulin and neurexin, similar location of function.

In terms of specific abnormalities, we fund this interesting study to Karen Dobkins looking at the connection between early development of gastrointestinal problems and autism spectrum disorders, and a grant to Douglas Wallace, a long-term expert in mitochondrial disorders, to look into the mitochondrial etiology for autism.

And we also do meeting grants. This is an R13 grant to Rob Naviaux at UCSD on a mitochondria and autism symposium in 2010.

We do quite a bit of neural systems research looking at how frontal lobes function, occipital lobes function, the connections between basal ganglia, and there are grants that go particularly to look at how neural systems may be affected in autism, so for instance the grant on motor skilled learning in autism.

We may have 10 times as many grants on motor skilled learning than we do on motor skilled learning in autism but they think they are going to interconnect and help each other.

Auditory and sensory processing similarly, social cognition, and we have scientists who are outside the medical sphere, basic scientists such as the last grant to Dr. Ghazanfar at Princeton University looking at the integration of faces and voices in primate temporal lobe, so the idea here being that really strong science in primates, learning how they actually integrate face and voice, may have something to do with the issues that we have heard in the last year about how this is abnormal in persons with autism, or different with persons in autism.

Quite a bit of neuroimaging work in NINDS, some of it is tools, so Anders Dale works on developing new analytic tools to look at brain and to try and detect reliable differences and this grant actually has them looking at children with particular difficulties such as language impairment, high-functioning autism.

Martha Herbert, whose career -- autism research is a grant from us, look at the white matter in autism and another K grant -- K grants are another -- or a sign of a career development award to Dr. Kleinhaus, who is a pediatric neurologist at Wash U studying multimodal imaging in autism.

And a couple of studies looking at biomarkers I threw up here, a study from the

University of Missouri trying to see if they can use a simple test of looking at how the pupillary light reflex reacts in persons with or without autism might be used, and a study which is actually a clinical trial, a small clinical trial, trying to use biomarkers to look for evidence of the efficacy of buspirone in children with autism.

So these are just a couple of kind of vignettes that I wanted to just throw out in terms of the things that NINDS is doing and answer any questions.

Dr. Insel: Great. Thanks, Walter. Do you want to say anything about your prospects for funding this next year?

Dr. Koroshetz: Well, I think Lee can say more than I can say as a Federal employee, but yes, I think all the government agencies are expecting that there's going to be a tight buckling process that we are still operating now on a continuous resolution, but there is an expectation there may be cuts coming as well.

And even a flat budget, because of inflation in the medical sphere of sometimes six to seven percent, means a fairly significant cut in funding.

Dr. Insel: Okay. Probably we will hear more about that as the day goes on. Thank you. Geri is not yet here and Alison is not here yet either. We will just defer to hear them later in the day and let's go on with the next topic, which is based on a piece of the Affordable Care Act, which has been the subject of an IOM study.

This was something that the Secretary of HHS, who has charged us to help her on autism, has also charged the Institute of Medicine to take a look at the essential health benefits, to give some guidance around questions about what should and should not be covered.

And we are very fortunate to have Cheryl Ulmer, who is the study director at the

IOM, to join us this morning to take us through this briefly, and then we have asked for perspectives from both Stuart Spielman and Jeff Sell to hear something about its relationship to the challenges in autism more specifically.

Cheryl, thanks for being here, and welcome.

Dr. Ulmer: Thank you for inviting me. I just wanted to first go over what the IOM is. Maybe many of you are familiar but in the press in the past week, there has been some misperceptions about what the Institute of Medicine is.

It is not a Federal agency. It's an external agency that is part of the national -- I might have skipped over, I might have pushed two -- yes, here we go. It is an independent, non-profit organization that is external to the Federal government, although we do have many Federal contracts, and in this case, for the Essential Health Benefits Study, we do have a contract from the Assistant Secretary for Planning and Evaluation in HHS.

The Institute of Medicine was founded in the 1970s and is part of the National Academy of Sciences that was originally chartered under Abraham Lincoln in 1863.

As I said, we are an independent organization that people come to for evidence-based recommendations and we form committees that are composed to avoid conflicts of interest and it's a neutral venue for dialogue and discussion.

It's also an honorific organization in the sense that people are elected to IOM membership and they commit to serve on committees. Committees, however, are not restricted to IOM members. We go out to gather the expertise that is relevant to the particular study, and all committee members serve without any compensation.

IOM is divided into boards. I am

on the Board of Healthcare Services. The IOM is not that large an organization. There's probably 200 staff. On our healthcare services board, we have about 32 staff.

We tend to focus on quality issues and past projects were things like to err is human, quality chasm, resident duty hours. We have ongoing studies now on clinical practice guidelines and systematic reviews.

And we have three studies that have come out of the -- that are related to the Affordable Card Act. One is -- two of them are funded by CMS and they have to do with physician payment, geographic adjustment factors and looking at some of the Dartmouth Atlas work on geographic variation around the country.

And we -- the third study is the one on essential health benefits. This study just gives you an overview of the study process. We get a statement of tasks for the study. Then we select the committee.

We have a series of meetings depending on the length of the study, but generally there are four meetings per committee. Then a report is drafted with a series of recommendations.

And then it goes into both an internal review within the Institute of Medicine. Then it goes out for an external peer-reviewed -- confidential peer review process and then when all the comments are back in, we have to address those.

Then the report is released. First the report is released to the sponsor and in this case, it would be about mid-September of this year. But when the report -- it's more of a courtesy for them to be prepared when the report is released about two weeks later to the public.

There is no opportunity for the -- for example, in this case, the Secretary to change the committee's recommendations. The committee recommendations come from the committee. And this should be released by the end of September.

Just going directly to the Essential Health Benefits Study, it comes out of Section 1302 of the Affordable Care Act, and in that section, it asks the Secretary to define a package of health benefits that would be offered by qualified health plans in the health insurance exchanges that are being set up in each state.

If a state opts not to set up a health insurance exchange, then there will be a Federal exchange for those particular areas. Right now, states have planning grants to set up insurance exchanges. In some places they already exist; for example, in Utah and Massachusetts.

The Secretary has come to the IOM not to specify every detail in the package of benefits. So it is unlikely that they would say this particular treatment for autism should be covered or not.

It is unclear to what detail the Secretary will go in defining the package as well. So we are to guide on sort of policy principles, criteria and methods for defining the package and eventually, how it should be updated over time.

From what we understand from the department, they will probably be coming out with guidance on the essential health benefits in the fall, not too long after the IOM turns over the report.

Now, while I say that the IOM recommendations are the IOM recommendations, that does not mean the Secretary has to do what they say. They can decide to adopt them or not.

Today we have formed a committee. It's composed of people with a variety of expertise in economics. We have a state insurance commissioner, a medical director from a health insurance program. We have consumers. We have healthcare services researchers.

So we have a spectrum of people on the committee whose expertise we thought was important to bring to bear. People are not on representing an organization. They are there for their individual expertise.

Before the committee was even named, which was -- they were named right before Thanksgiving -- we had put up on our website ten questions for public response and we have received over 300 responses to those questions and at the end there is a list of questions. I'm not going to walk through all of the questions right now.

But all of those responses and anything that is contributed or given to us to help influence the decision of the committee that is not otherwise publicly available, is put in a public access file. So all of those responses that we have received are in a public access file.

We held the first of our four

committee meetings last week, Wednesday through Friday, and there was simultaneous audio streaming of the public sessions of that meeting.

And, by Wednesday I understand, or late Wednesday, all of those audio files will be up on our website, along with any speaker materials that we received and we have gotten the copyright sign-off for.

So this is the project's activity page, website. It lists all the names of the committee members and our current activities.

So in 1302, there are 10 categories of care that are specified that are to be included within a package, and I think probably the areas that might be of most interest to you might be the mental health and substance abuse disorder services, including behavioral health treatment, as well as perhaps the rehabilitative and habilitative services and devices.

We had panels discussing those two

particular categories of care in a little bit more detail during our public session, as well as on last Friday, we did have some of the respondents to our survey come and talk and Stuart, who is coming after me, came and spoke to the committee on behalf of Autism Speaks.

So these are the 10 categories of care. So one of the questions is how detailed to get in terms of guidance and, as I said, that is still somewhat up in the air.

There are other elements in Section 1302 that will guide the Secretary in defining what is in the benefits and there isn't -- because of concern about the potential cost of any kind of benefits, the Congressional Budget Office scores bills. They needed to have some sort of box around that series of benefits that they were comfortable with, and in the legislation it says it should be -- should look like a typical employer plan.

So there is a Department of Labor

study on looking at what might be in a typical employer plan. We have heard, last week, that there's many different types of employer plans: is it a large employer plan, is it a small employer plan? So that is something of interest, probably, to you.

And then there's an issue of inclusion or exclusion of current state mandates in the benefits. There is a provision that says if the state mandate is not in an essential health package, the subsidization of that mandate has to be picked up by the state, so that is an area.

And then there's a whole section of 1302 that is called Required Elements for Consideration and there's a number of them, but basically I think the most important kind of message of looking that there isn't discrimination on basis of age, disability or expected length of life.

So some of the issues that were raised in the public session was, how do we balance the generosity of coverage versus the affordability for the consumer, as well as thinking about the sustainability?

Because in the exchange, there is subsidization up to a certain percentage of poverty.

This whole issue that I have mentioned before is, to what level do you specify at the Federal level which benefits are going to be in, or should there be more flexibility within states and among insurers to tailor policies?

And there's also certainly some concerns about if you put a particular treatment in a regulation, and if the process is not timely enough, can you keep up with that over time?

There were some strong feelings expressed about whether or not to define medical necessity, with insurance companies saying no, don't define it and then there tended to be more, although not uniform, voices, asking for definitions of medical necessity by consumers and providers, although individual providers have their own definition -- provider groups tended to have their own definitions of medical necessity.

Our first speaker at the meeting was Sherry Glied, the current Assistant Secretary for Planning and Evaluation, and something that she threw out which had not been thrown out before was perhaps the committee should take up defining what's medical and what's non-medical services.

And I think this has come up in the context that in hearing about legislative intent, there -- what has been raised to us is that for example if you looked at something like EPSDT, early periodic screening, diagnosis and treatment, that perhaps some of that went beyond what one would find in a current, typical employer plan. So that has come up as an issue.

And then in general was if, to

make a plan affordable, you have to set priorities in terms of what is essential and how to do that.

And then, finally, I think the big issue is what kind of safeguards do you build in at the national or state levels to monitor these coverage decisions, reimbursement rates or benefits designs.

So, as I said, I don't expect you to be able to read this, but I just thought, I know things are posted on your website after this and soon we will be taking down these 10 questions from our website, so I just thought you might want to have them.

But all of our studies are to be evidence-based. We really ask your community to provide us with information that not only you would like this type of service included, but provide the committee with evidence of denials, types of services that are difficult to access, how you would go about differentiating between medical versus non-medical services, or is that even the question?

Is something that's essential -- does that even work to define something along those lines? So that is basically the overview. We are just at the start of the committee's process and we will have a draft report in mid-June which goes into that confidential review process. It is not something that is out in the public for review and comment.

Dr. Insel: Great. Thank you very much. Let's see if there are any clarifying questions and if not, I want to move on quickly so we can hear about the autism-specific issues that the IOM grapple with.

Dr. Fischbach: This is Gerry, I joined.

Dr. Insel: Thanks, Gerry.

Dr. Fischbach: I heard the other folks but then --

Dr. Insel: Okay. Good to have you

with us. Any question or clarifying issue here?

Dr. Fischbach: No.

Dr. Insel: Okay. Yes, Ari?

Mr. Ne'eman: Yes. I have a question with regards to one of the other areas of consideration you mentioned that the Secretary was including in the determination of the essential benefits package, particularly the definition of a typical employer plan that the Department of Labor is currently investigating.

Could you possibly talk a little bit about the process and methodology they are utilizing to determine that question and where in the Department of Labor that process is unfolding?

Dr. Ulmer: Right. They are using a variety of things and one of the -- the Department of Labor came and spoke at our meeting last week so the specific testimony will be up on our website.

But basically there's the National Compensation Survey where the Department of Labor looks at what employers are paying and it has some limited things at a very kind of general level about -- do they cover medical services, do they cover this, do they cover that.

It is not very detailed in terms of the specific services that are picked up through the Department of Labor survey. But it does sort it a bit by employer size and that has some usefulness.

Then they have a collection of plan documents, brochures that they are going through, looking at exclusions and inclusions and they have found that the exclusions are pretty clear, but inclusions are not as clear in all of the Plan documents that they have been reviewing.

So in certain areas they are going back and trying to collect more detailed information.

Dr. Insel: Okay. Thank you. I want to make sure we have time to hear from two other speakers, so let me ask Stuart to take us through the private health insurance coverage picture for ASD.

Mr. Spielman: Hi, everyone. I am Stuart Spielman. I am Senior Policy Advisor and Counsel for Autism Speaks. Autism Speaks has historically been very interested in the area of healthcare coverage for individuals with autism spectrum disorders.

We look at this as a health issue, obviously, but it is also an economic issue. This is an issue that has huge implications for how families can access services of any cost, because healthcare, when the burden is not offset, can be a crushing burden for families with individuals affected by autism spectrum disorders.

And there are studies that indicate that autism treatments are entirely excluded from behavioral healthcare plans.

This is an early study that shows that autism is a categorical exclusion.

When you go on to the National Survey of Children with Special Healthcare Needs and this survey had an autism profile and it compared children with autism spectrum disorders to children with other special healthcare needs.

And as you can see from some of the slides I have up, the picture for kids who have ASD and the families of those children is not a particularly nice picture.

The families report that their insurance is inadequate much more often than other children with special healthcare needs. The families often have to stop work or cut back their working hours.

The condition causes significant financial problems for families. They go out of pocket to a fairly significant degree, and they have trouble accessing certain services.

We find that families with

affected individuals with autism spectrum disorders are less likely to be solely reliant on private insurance coverage. They are more likely to be on Medicaid or other public insurance and many of them have a mix of private and public insurance coverage.

So, what does this all mean? What this means is that families around the country have felt that there is a need for something to be done and that action has been taken initially at the state level.

There is a map of autism state initiatives circa 2001/2002 and you can see that there is only one state marked on the map, and that is the state of Indiana. Back in 2001, the state of Indiana passed a law requiring insurers to provide coverage for autism spectrum disorders.

Now in 2007 Autism Speaks started a nationwide campaign to encourage enactment of comprehensive coverage laws for people with ASDs and there are not 23 states that have enacted strong benefit laws.

You can see from the map that these laws are laws that have been enacted in northern states, in southern states, eastern states, western states, states that are regarded as liberal states, states that are regarded as conservative states.

They really have -- these laws have proven to have broad appeal and you can see that there is definitely a trend. Most of the enactments have occurred recently: 2010, eight states enacted new laws requiring coverage of autism spectrum disorders; 2009, one fewer state I believe.

So what we are seeing is an emerging trend and I want to get back to that and I want to connect this with something Cheryl said about state laws and the way the Affordable Care Act looks at state laws.

Now each of the state enactments is different, but what they have in common are coverage for diagnosis and coverage for habilitative care, including speech therapy and occupational therapy, coverage for applied behavioral analysis, a common behavioral therapy for individuals with ASD, and they also protect services rendered under the -- under IDEA.

The idea behind these laws is not to shift the burden from the educational system to the healthcare system, but rather to enhance the involvement of the healthcare system.

Individuals with autism need educational services like everyone else. They also need good quality healthcare and the quality of their healthcare has been a particular issue.

I want to see if I can do this. I don't know if I can. I am going to try to do a hyperlink. Let me see if I come up. Okay. We have, as one of our sister web pages on our Autism Speaks site, an Autism Votes website.

And this webpage, this website

goes through state and Federal initiatives and is a one-stop shop for the development -- on the development of coverage initiatives at the state and Federal level and other legislation of interest to individuals with ASD in their families.

Okay. Now I need help going back. Okay thank you.

Okay. Now one of the questions that seems particularly apropos at this time of budget shortfalls is what is the dollar impact of these laws?

It is a little disturbing to actually ask this question because it is almost like how much is justice worth, but it is a question that is nevertheless being asked.

Autism Speaks retained the actuarial consulting firm -- national actuarial consulting firm Oliver Wyman and their mid-range estimate is that these laws will have an effect on premium of less than one half percent, 0.42 percent. So not only are these laws achieving justice but they are doing so in a pocket-wise way.

Now there are short-term costs to providing good quality healthcare but the information that we have and that the IACC has considered before is that long-term benefits come from the shorter-term investment in providing good quality services to individuals with autism at an early age.

And Oliver Wyman has shown this through their modeling, that we can actually expect savings by making a good investment in quality healthcare for individuals with autism at an early age.

Now, state autism insurance laws are significant. They are significant in their own right and they are significant in their effect on other laws. The enactment of a state law can affect other providers.

But the reality is that 59 percent of covered workers are in a self-funded plan and ERISA exempts self-funded plans from state insurance laws.

Many other individuals are in Medicaid or in insurance plans like FEHB that are not affected by state insurance laws, and about one in six Americans currently is uninsured.

So autism is not just a state concern. It is also a Federal concern. In 2009, the Autism Treatment Acceleration Act was introduced in Congress. Senator Durbin was the champion of this legislation.

His colleague Senator now President Obama was very interested in autism insurance issues and remains interested in autism, and Senator Durbin took the mantle and carried the legislation forward in the Senate.

Representative Mike Doyle, the co-chair of the Congressional Autism Caucus, which numbered 157 members in the last session, sponsored a companion measure in the House.

And the bill reflected President Obama's commitment, and this is from the Obama-Biden campaign. You see that among the commitments of President Obama, then candidate Obama made, was to mandate insurance coverage of autism treatment to enhance the services, the health services that individuals with autism receive.

Both versions of the Autism Treatment Acceleration Act contained a comprehensive autism coverage provision. It defined ASD, required coverage for diagnosis and certain treatment, including medications, OT, PT, speech, services provided by psychologists or psychiatrists, applied behavior analysis and augmentative communications devices.

Both the House and Senate bills would have required coverage by self-funded, employee-funded plans as well as individual plans.

The ATAA garnered significant

support, however Congress's attention shifted to broader healthcare reform and ultimately the ATAA was not enacted into law.

Now, the Patient Protection and Affordable Care Act, for all of its volume, does not specifically mention autism. It will nevertheless have a profound effect on people with autism spectrum disorders.

Regulations that have already been issued under the act require group and individual coverage for certain preventive services with no cost-sharing.

Covered services includes screening for developmental delays, it adds scheduled appointments and autism-specific screening.

The Affordable Care Act picks up on the Bright Stars, Bright Futures American Academy of Pediatrics guidelines on preventive screening.

Now, Section 1302 of the Affordable Care Act describes 10 general categories of essential health benefits. Now, as -- again as Cheryl mentioned, there are several of interest to the autism community: rehabilitative and habilitative care, habilitation, the line between habilitation and rehabilitation has often been the demarcation point for when services are delivered and when services are denied.

Individuals with autism spectrum disorders frequently need habilitative care and the inclusion of habilitative care in the legislation is a significant development for individuals with autism spectrum disorders.

Dr. Insel: Stuart could you define that? What does that mean in the law? What is habilitative care?

Mr. Spielman: There is no specific definition of habilitative care in the law that I can recall and Cheryl can help me on this, but there was significant discussion at the IOM on exactly what is rehabilitative care and what is habilitative care.

Dr. Ulmer: Marty Ford gives a detailed explanation of habilitative care and I am afraid that I would not do her justice. But it tended to include things that might be more the educational aspects as well as -- there was some fine line between some things like occupational therapy and other things of that nature.

Mr. Spielman: Right. Right. One of the panelists, Marty Ford, from Arc/UCP addressed this in her remarks but I do not believe that the act itself specifically defines habilitative care. It just holds it forth and it puts it in the context, again, of non-discrimination, that we have to -- that the idea behind the Affordable Care Act is to not discriminate among populations on such measures as disability.

Dr. Janvier: Just as a developmental, behavioral pediatrician and an employee of a children's rehabilitation hospital and having worked with Dr. Albert Scherzer at Cornell, who kind of coined the term pediatric habilitation, in children who are developing, and may not have yet developmentally achieved certain skills, we still may need to intervene.

I mean, it's very simple to understand if, for example myself, 3-1/2 months ago, I had shoulder surgery and I lost function in my shoulder and I required three times a week physical therapy to regain that function. That's rehabilitation.

But in a child who has not yet developmentally attained a skill, such as a six-month-old we would not expect to be walking, but if they have very low muscle tone and abnormal postures, we would need to intervene to assure normal postures and developmental progression to allow them to walk within an expected time frame.

In pediatrics that is really what we are dealing with, with children with disabilities most often, is not that they have had a skill that they have lost, but their attainment of those skills will be impaired or significantly delayed without certain interventions.

Mr. Spielman: It's worth noting that Marty referred to the state autism insurance enactments, which in a number of instances, most instances, define habilitative care along the lines of acquiring services that are typically acquired at a point on the developmental time frame that have not been acquired.

So that language may be a significant driver going forward of health services for individuals with autism spectrum disorders.

I want to refer to another of the categories in the Affordable Care Act, and that is mental health and substance abuse disorder services, including behavioral health treatment.

It was interesting for me, Cheryl, at the IOM meeting, that the panel on mental health and substance abuse disorder services actually didn't make much mention of the last four words in this category.

This is something that I felt was important to note. The last phrase was introduced as an amendment in the House by Representative Mike Doyle and in the Senate, by Representative Robert Menendez on the Senate Finance Committee, and there was quite a lively discussion.

I am going to play or try to play, if I can figure out how to do this, the first two minutes of Senator Menendez's statement in the Senate Finance Committee back in September of 2009.

(Video plays.)

Committee Chairman: Okay, Senator.

Senator Menendez: Thank you Mr. Chairman. Mr. Chairman, I am offering a modified amendment that would clarify in the mark that behavioral health treatment is part of mental health and substance abuse services.

Behavioral health treatments help to reinforce wanted behaviors and reduce unwanted behaviors, and the treatments are critical for individuals affected by autism, Down syndrome and a variety of other disorders.

They can help a child to communicate and care for themselves, they can help that child from -- stop him from hitting himself and those around him, they can enable a child to attend regular education classes rather than special education classes. They can enable a child to live at home rather than an institution.

All of these alternatives save money in the long run and this is an effort to decrease long-term healthcare costs. As modified, the amendment requires no offset, according to CBO. Very similar language has already passed in the House Energy and

Commerce Committee on a bipartisan basis by voice vote and let me be clear -- this does not expand the minimum benefits package. It merely clarifies what is already in the chairman's mark, clarifying that insurance plans must provide behavioral health treatment as part of mental health and substance abuse services, will ensure better quality healthcare and like all Americans, people with autism and other behavioral health conditions should be able to live healthy lives, and I urge the committee's adoption.

(Video ends.)

Mr. Spielman: All right, if I can enlist you again to -- okay. What followed afterwards was a lively discussion about how specific the language of what became the Affordable Care Act would be.

There was some disagreement about this amendment but ultimately, the amendment was adopted by the committee and became part of the Affordable Healthcare Act.

So, in discussions about what does the Affordable Care Act mean for ASD, I think it's important to look back at the legislative history and while there is this sort of flow, ebb and flow about specificity in the Affordable Care Act, how specific, how prescriptive is the Affordable Care Act, how general is it, there is certainly strong legislative history that in the case of ASDs, Congress intended that the status quo not continue, that there be improvements in the healthcare of individuals with ASDs.

The IOM has been charged with making recommendations to the Secretary regarding the criteria methods for determining the essential health benefits packages we all know, now.

And in separate letters to the president of the IOM, Senator Menendez joined by Senators Durbin and Casey, and Representative Doyle, confirmed that Congress intended to include ABA in the essential health benefits package.

Again, I would emphasize here that Congress, through the language in the Affordable Care Act, has clearly signaled that it is concerned with the healthcare of individuals with autism spectrum disorders, and that the end of the process should provide better healthcare than what individuals with autism spectrum disorders currently enjoy.

Now there was mention, Cheryl mentioned the provision in the Affordable Care Act that basically makes states responsible for healthcare that goes beyond what is in the essential benefits package.

Now given the state environment, the state budgetary environment, that leaves real questions about what states are going to do for healthcare that is not part of the essential health benefits package, and one of the IOM questions looked at, or asked for comment on, state insurance laws.

And in my comments to the IOM, I

pointed out that in the case of the autism laws, these laws are not mere debris of the healthcare system. They reflect a trend and they meet standards of providing justice to large populations that have historically not received good quality healthcare.

They are cost effective according to the best information that we have, and moreover people have already made decisions based on these laws. They have decided where to work. They have decided for whom to work. They have changed residences. They have gone from place to place.

And so in moving forward, I hope that the IOM consider the significance of these laws to the autism community.

Finally, Autism Speaks has previously argued for comprehensive health coverage for people with ASDs. We believe that the lives of people with ASDs can be significantly benefitted if this critical moment is seized and a decades-long pattern of discrimination in healthcare for people with ASDs finally comes to an end. That's it.

Dr. Insel: Thank you very much Stuart. That was great, and I'm sure there is going to be lots of discussion, but let's postpone the discussion until after Jeff's presentation and then the two of you together along with Cheryl, can respond to questions. I think that's the most efficient --

So thanks to Jeff Sell who is coming to us I guess representing Autism Society of America. So delighted to have you here.

Mr. Sell: Thank you. And actually I am probably going to get off my slides because I think I kind of want to paint a little bit more of an overview.

I think the detail that we get into with respect to the Affordable Care Act and how it affects the autism community has been covered very adequately, quite frankly.

But I do want to touch upon a few

things. I come from east Texas, where details are really frowned upon a lot of ways. We like to get the job done down there, and just kind of giving this an overview, the Affordable Care Act was very clear with respect to what services or what coverages the autism community was looking for.

And the four magic words, which Stuart touched upon already, including behavioral health treatments, I'm one of those guys that always argues don't make it so specific that it's going to come back and hurt you either in a courtroom or in a state house.

That is a very broad classification, behavioral health treatments, and I wanted Tom, if I could, to go back and give you a very concrete example on habilitative care and why so many states, the 23 states that have passed autism reform pieces of legislation, why that has been so important.

I have twin boys with autism, Ben

and Joe. Ben is nonverbal. We would always try to access speech therapy for Ben. We had a speech and language pathologist and it was routinely denied because the services were not seen as rehabilitative.

The argument that I got with a very straight face, and keep in mind I'm a trial lawyer and used to be an insurance company lobbyist, was Ben never had speech and so therefore it cannot be paid for under your insurance plan, which I had paid premiums out the wazoo for a number of hears; because he never had speech, the only thing that is in your plan is rehabilitative coverage, there is no habilitative coverage.

And if you just step back from that, it's really stupid. My other son, Joseph, talks and talks and talks. Ben does not. The one boy who really needed meaningful speech services was Ben, the nonverbal one.

Back in `98 we had a little bit of progress in the Texas legislature and seeing as I said, my background, I was able to access speech therapy just because when I was told no, that's not included, it's denied, I just simply answered with, I'd hate to see you in a Harris County courthouse.

But I will do that because my reading is it's not excluded in my policy, therefore it is covered. But that is a good, I think, concrete example of Ben never had speech so how could we provide him with that type of coverage and we moved on.

Stuart, I think you did a really great, as you always do, job covering what the Affordable Care Act means to those in the autism community, and I think just that clip from Senator Menendez at the very end, really just summarized it all.

There is no doubt that intensive or behavioral health treatments are covered in the ACA. It was passed in both houses, in the House and the Senate, both chambers I should say, and this is one of those areas where I think, you know, the work that the IOM does and the recommendation that they will make to Secretary Sebelius is crucial and it's very important, and some of the press that we have been reading over the past few weeks be very -- we need to step back because everybody is going to be asking for their share of the pie, coverage provided for you name whatever disease or disorder or what we are looking at.

The autism community came together and we got this included in the Affordable Care Act, and I think when the recommendations are made, we need to be very cognizant of the fact that the legislative intent and the legislative history is crystal clear.

These medical interventions are meant to improve the lives of those affected by the autism -- in the autism community.

If we also step back a little bit further, the autism community is crying for help. It's more a question of accessibility than anything else. We know what treatments work. We know what interventions work, and we know that these treatments and interventions make a meaningful difference in people's lives and they make a meaningful difference in people's lives today.

We have families in all the states across the United States that are just crying out for help and going on this constant, never-ending battle. Even in some of the 23 states where legislation has already been passed we run into the problems with ERISA - well, it's a self-funded plan, so -- I live in this state but I am still not able to access this coverage.

But I think we have the attention of folks who can make a difference. So those 23 states and the interactions between that and the Federal law -- Stuart covered that adequately as well.

And I want to just end on the thought -- the Congressional Budget Office, which scored this, said it's not going to have any substantial increase in cost whatsoever. The actuarial reports that we have seen in all 23 states and across the Federal level, are very clear as well.

I'll try to break this down into a cup of coffee if I can. There is not going to be a significant increase in cost. If you look at the actuarial reports that look at the cost versus the benefit, the benefits far outweigh the cost.

The de minimis cost per consumer per month that is going to be passed on, is about the cost of a cup of Starbucks coffee a month and that is something our nation I think can fully understand.

I have seen figures thrown out, and please, I should say don't quote me on this, but I firmly believe for every dollar you spend, you are going to save seven later with respect to the services that are needed in the autism community.

We have run into the problem of

focusing of two to four -- two-year cycles: what can I do over the next two years to get me reelected?

Some of the interventions that make a meaningful difference in people's lives are accessible now, and with the Affordable Care Act, and with intensive behavioral interventions that are mandated by the Affordable Care Act, I think that's something that all of us here in this room must be very cognizant about and when we are going forward in determining what's in the essential benefits package, that we become a little bit more proactive and just demand what was passed in the legislation in both houses.

I am going to end on that and I realize I kind of -- oh, 11:30, perfect timing, and would be happy to answer any questions that the panel may have.

Dr. Insel: Great Jeff. Thank you. Why don't you -- Stuart, if you go up as well, let's open this up to the full committee to get questions or comments.

Mr. Spielman: Thanks, Jeff. Coleen?

Dr. Boyle: Thank you very much for -- all of you -- for the update. I think it is an extremely important issue. I am a little unclear about the 59 percent of covered workers who are cared for by the self-care plans. How does this impact them? Maybe you can just reiterate.

Mr. Spielman: That slide was in reference to state autism insurance laws and state autism insurance laws cannot reach people who are covered by self-funded plans.

Most insurance in the United States is through employer-provided coverage. Fifty-nine percent of employer-provided coverage is self-funded coverage.

What self-funded coverage is, is in essence, the company bears the cost or bears the potential burden of providing for healthcare, whereas in a fully-funded plan, the insurance company acts as we typically understand an insurance company: they not only process the paperwork, which is a constant in healthcare, but they also assume the risk of having to make a payout for sickness.

Self-funded insurance is not covered, not subject by state, not subject to state regulation.

Dr. Insel: Let me ask, I thought Cheryl did a great job in sort of laying out the dynamics of this discussion that will take place in the IOM, the generosity versus affordability, the specificity versus flexibility.

These are really the issues that the committee will have to deal with, and what I heard from all three of you, in talking about this, was that there are sort of some obvious things that you would like to see in this.

But where does the specificity come from? So it's one thing to say behavioral treatments or to say even ABA, but where does the decision get made about how many hours, what intensity, over what period of time, what kind of coverage?

Because if -- I can understand that the IOM committee may not want to go there, but you also -- sounds as if the Secretary wouldn't go there.

So if it ends up devolving to the states and then private insurers to make those decisions, you could be pretty much back where you started, right?

Mr. Spielman: Well, Jeff do you want to handle this or --

Mr. Sell: You go ahead --

Mr. Spielman: Yes. I think that we all have ideas of what a product involves. If you were to drive your car in for a new tire, an old, bald tire would not really be a new tire purchase.

So when categories or specific treatments are indicated or suggested, I think we have to assume that the category is subject to reasonable understanding of what that's entailed.

Behavioral health treatment should be understood to mean behavioral health treatment as we understand it to be effective, not behavioral treatment that merely meets the most superficial notions of behavioral health treatment.

That's what I would argue, that including behavioral health treatment in the 10 essential benefits meant that the behavioral health treatment has to be reasonably expected to provide some help to the covered individual.

Mr. Sell: And behavioral health treatments have been around since the `40s. This is not -- nothing new. There are plenty of studies out there that really get into the specificity of what a good behavioral treatment plan looks like.

There's the National Academy of

Sciences report back in 2001, Educating Children With Autism, and they really lay out some very specific guidelines as to what we are looking for in terms of, not necessarily best practices, but what are the most effective interventions, how many hours are these interventions provided both in the private setting, in the healthcare setting and in the educational setting, and they come back kind of full circle.

Autism is such a broad spectrum disorder, as we all know in this room. Some plans may -- or some treatment protocols with respect -- use my son's for example, I have twins and they are on different ends of the spectrum -- what would work very well for Ben would also not work as well for Joe, but I would like to see them -- and I think all of us here would like to see these individualized, tailored, medical plans associated with addressing their individual needs.

But we are not talking about anything new here in terms of behavioral health interventions and what is required. It's just a matter of setting the specificity and making sure we have enough flexibility to adequately address the people's -- or the individual's affecting their needs in some way when we are doing that balancing act of cost versus benefits.

Dr. Insel: So, just to clarify, that is what I was really asking, so where does the specificity get set? Who will do that?

Mr. Sell: I would prefer the healthcare provider, quite frankly.

Dr. Insel: Gerry.

Dr. Fischbach: I just wanted -- and this is Gerry Fischbach. You say nothing is new, but a lot is since 2001 and the NAS' first report. I mean, issues of early and earlier and earlier intervention, perhaps being more effective, and the specificity is tremendously important.

So is it time for another scientific review to back up some of the policy matters as to effectiveness and new modes of behavioral therapy?

Dr. Insel: I think Geri Dawson may weigh in on this as well.

Dr. Dawson: So, well let me first just mention for Gerry Fischbach's question, which is that as part of the Combating Autism Act, there was a requirement to conduct a review of what is effective in terms of children and adolescents.

And the report on the children has already been drafted and has been conducted and now there is a second report that will be coming out in the next year or so that will be on later adolescents and adults.

And this is the Agency for Health Research Quality, is that right?

Dr. Insel: AHRQ.

Dr. Dawson: Right, so, and I know

a number of us have participated on some of the technical expert panels of that. So, I think that is just one example but there have been other reviews, as well.

I just want to briefly say --

Dr. Insel: Geri, if I can.

Dr. Dawson: Yes.

Dr. Insel: Those, actually, are summarized in this report that you all have today to Congress, so we talk about what AHRQ did and what they reported out.

Dr. Dawson: Yes. So they are really well worth reading because it was an incredibly arduous process where they really have gone through the literature on virtually every kind of treatment that you can conceive of, I mean, it's a pretty remarkable task.

I was just going to say, when I was the director of the University of Washington Autism Treatment Center, and we actually advocated and were successful in getting Microsoft to be the first company that provided insurance benefit for early intervention, and so then we worked with several insurance companies including Aetna and BlueCross and others.

And the way it works is that essentially, the prescribing clinician, which could be a psychologist or physician, sets up a program based on their judgment of what is needed.

And then in our case, we had to provide very specific, therapeutic goals and very specific prescriptions about how to meet those goals, and then provide the insurance company with regular updates about the progress towards those goals.

So it did vary, child to child, depending on the needs -- but I think that's a pretty typical way in which that kind of benefit is implemented.

Dr. Insel: Great, thank you. Lee?

Ms. Blackwell: Yes, this is -

Dr. Insel: Was that Ellen?

Ms. Blackwell: Yes. We are having a little difficulty. I just had a comment and a question for Jeff and Stuart.

So there is in fact guidance to be found there. And, although I have heard Jeff and Stuart talk a lot about one particular benefit of applying behavioral analysis-based treatment today, I wondered if they might take a few seconds to address the larger benefit to people with autism that is in the Affordable Care Act.

Dr. Insel: Did you get that?

Mr. Spielman: I got enough of it to make up anything I want to.

(Laughter.)

Dr. Insel: Go for it.

Mr. Spielman: But, I heard what Ellen said about the regulations and she is right. There isn't a blank slate on habilitative care. We do have some guidance, not just at the state level but at the Federal level, as to habilitative treatment, and that undoubtedly will be affecting the IOM and the Secretary going forward, even though the Affordable Care Act itself just ends at the word.

I would be remiss if I didn't acknowledge my colleagues at Autism Speaks, Lori Unumb, Shelly Hendrix and Judith Ursitti who are riding the circuit, going to coffee houses and state legislatures, and meeting with people and trying to shift a dynamic.

I think the discussion of healthcare for individuals with autism is an interesting discussion, because some years ago, we may have been more inclined to look at this as an educational issue that looking at healthcare for individuals with autism has been one of the developments over the last decade where we look at the autism-specific healthcare needs and the comorbidities of autism.

This has been a real mark of progress and I think marks a shift from the way we approached things back in the days when the only law, the only real Federal involvement or perhaps state involvement, was through IDEA and its state counterparts.

I think it's important that we acknowledge that healthcare for individuals with autism is just that: it is healthcare. It is not a part of the general background of raising children that all of us expect from the schools; that individuals with autism have defined and clear healthcare needs as separate and apart from their educational needs.

Dr. Insel: Lee.

Mr. Grossman: Well, the point I was going to make, and I think that this addresses somewhat of what Ellen was saying also, is that in the Affordable Care Act, one of the most important provisions of it go well beyond behavioral treatments, and that is the fact that we no longer have the preexisting condition mandate.

And that is a critical aspect that

needs to be preserved. My family is a great example and I would think that most families with autism suffered the same way I did, where I couldn't get insurance for my son because of his preexisting condition, the fact that he had the flu, he had rashes, he had GI issues, allergies.

I was left -- we were left at our own behest to pay out of pocket for those just because he had -- he had this preexisting condition of autism and I would say that those other issues that he was dealing with contributed to his behavioral problems, but really had very little to do with his autism.

So that is one important aspect of the Affordable Care Act that needs to be preserved and I think was, at least for the autism community and many people that I have talked to, one of the prevailing provisions that we needed to have in there and were very grateful to the last Congress for passing this legislation.

Mr. Spielman: Yes, if I can take up on that. You are right. I think that what we hope to see and I hope we are seeing this, is something of a normalization of healthcare for individuals with autism, that individuals with autism receive comparable healthcare to the healthcare that individuals with other serious and chronic conditions receive.

That's not been the pattern. What the pattern has been are historic exclusions, and Ellen brought up that the Affordable Care Act in that healthcare for individuals with autism is more than ABA and it absolutely is.

There is the whole package of benefits that we normally assume when we are buying autism -- when we are buying insurance coverage, and I'm sure Jeff can address this.

I mean, we have expectations when we buy insurance coverage, reasonable expectations, that conditions that we anticipate and don't anticipate will receive a reasonable degree of coverage.

Unfortunately in the case of autism, those expectations are often very quickly dashed, for specific and somewhat special therapies like ABA, but also for much more commonplace therapies like speech therapy.

In the case of autism it is fairly common, not at all unusual, for children and adults who require speech therapy to have those services denied on any number of bases, be they habilitative, be they -- somehow speech therapy becomes experimental for an individual with autism.

And if we are looking towards significant improvements in our healthcare system, we are looking towards diminished costs, fewer emergency room admissions, fewer emergency situations, a good way of approaching that and making sure it happens, is if we treat people with autism spectrum disorders better than we have in the past.

Mr. Sell: It's essentially about

treating people with autism spectrum disorders equally and ending the discrimination that we have faced for so many years.

I have two daughters in addition to my two sons and one of the problems we have run into with the boys so often is the 299 diagnostic code. If Ben would need a gastroscopy or an endoscopy, it would be seen as something that is probably related to his autism and therefore his behavior and we really don't know why we are going to look at his gut and then lo and behold when they do look in his gut and find it inflamed and find massive ulcers in his stomach, his behavior improves in school and he has a better outcome, he pays attention while he is in class.

It's really not that overly complicated. For years the autism community has faced a very unfair discrimination in the context of the insurance world, and what we have tried to do is methodically set about eliminating the preexisting condition exclusion which has been a bugger for a number of years, and also ending annual and lifetime caps.

Some of the caps that we have had, for example speech and language, you get 20 visits. Well, my son still doesn't talk. He could still use a little bit of speech. We'll mix and match. We'll do some through the school, we'll do some privately, but I would like my insurance company to also pay for a little bit of that.

That's why getting habilitative care coverage was so important because now I can get a little bit back in terms of what I pay for in the premium dollars.

Dr. Fischbach: This is Gerry. You know, the preexisting condition -- this is something that occurred to me during the discussion -- is tremendously important for autism and all related or unrelated developmental disorders.

And I have just been looking through this wonderful report to Congress in December of 2010. How is this report -- and especially an emphasis of keeping the elimination of preexisting conditions -- going forward? What is the use of this report? Where is it going?

Dr. Insel: Gerry, this is Tom. The report was required by the Combating Autism Act, that it go to Congress, and in fact Mike Doyle has already put on his website a response to the report. It came up a couple of weeks ago.

So there is -- it's out there and it's being used.

Dr. Fischbach: It is being used.

Dr. Insel: Yes. Yvette had a comment.

Dr. Janvier: No, I just wanted to point out something that you have finally touched on, that the same speech and language pathologist may be working in a school setting and providing a similar service to a child, whereas in a medical setting, a rehabilitation setting or habilitative setting, would be providing let's say a similar service.

And you know this is where the grey area exists: what is educational, what is medical? Occupational therapy, it's the same issue. ABA someone mentioned it's an educational method. I mean, I clearly understand and appreciate and recommend in home ABA focusing on specific challenges or problems.

But this has historically been the issue, is that well, if the schools can do it, it's not medical, but again, these are healthcare professionals. They happen to be working in an educational setting or in an educational program, but they still are healthcare professionals and you know, I certainly I agree with the coverage that should be there for these services under healthcare insurance.

Mr. Spielman: I think, if I can just make a brief comment. The notion of children with disabilities being in a school setting is hardly new. There are many children with disabilities other than autism in the school setting, and we have established ways of pulling apart what are health services for those individuals from what are education-related services.

I really doubt that we would look at services that are for example rendered outside of the school property as educational services because a somewhat comparable services provided on the school property -- a teacher let's say works with the child on articulation, I don't think that that would somehow prevent a speech therapist in a clinical setting from having her services, his services reimbursed through insurance plans.

Dr. Insel: We are going to need to move on, but I really thought it was important for the committee to hear about this. We often try to bring to you scientific opportunities as they come up, so you have heard about epigenetics and next-generation sequencing and all kinds of things that will really change the landscape for research.

This is an equivalent kind of an opportunity that's happening in a very different sphere, and it will, as you heard from Cheryl, this will evolve over the next several months, but between now and the fall, there is a lot going on that will help to determine how the Affordable Care Act will be implemented.

And I must say the same thing is true for the Mental Health Parity Act which is going in parallel at this point in time.

So this is a really critical moment between now and probably the end of this fiscal year, which will be the end of September, for many of these decisions, and it's going to be very important for people in the community as well as all of us in the

Federal sector to keep our eyes on this and to make sure that the best evidence is brought to the fore and that there is a deep discussion about both the expected and the unexpected consequences of some of these things.

But -- so there will be more about this I think, as I say this is an evolving conversation and Cheryl, we really appreciate your being here and the two gentlemen who have taken us through the details, it's really very, very helpful so let's give them a round of applause and we will have to move on.

(Applause.)

Thanks Jeff and Stuart. So we have some business to do. We will, as time permits, get back to the updates from Geri Dawson and Alison Singer. I think Alison is still on her way. She is in a taxi someplace between here and Dulles, so sorry that all that you have had to go through to get here, but we are delighted that some of you have made it even though you have been late.

We have got some work to do on the Strategic Plan still, and I'm going to turn this over to Della to take us through how we are going to do that.

Dr. Hann: Okay, hello, everyone. For those of you who are here in the room, in your packets there is a draft of the 2011 Strategic Plan. There is also -- in front of it there should also be a suggested crosscutting theme for the IACC Strategic Plan introduction.

So I believe those will be the two documents that you will be wanting to reference throughout this.

Dr. Daniels: There also is an additional document that is coming around. It's another Strategic Plan theme, a crosscutting theme for the introduction.

Dr. Hann: Okay. And we have sent the second one out? Okay, great. So for those of you who are on the phone and are able to get into your computers, you did receive these materials as well, so hopefully you can access those through the conversation this morning.

At our last meeting, we made great progress in terms of the updates and we were able to move through chapters 1 through 7 in terms of the text.

We have yet, for the committee, to discuss proposed changes to the introduction, which I believe, correct me if I am wrong, we will do first, be walking through that.

Then the last piece of business will be to walk through, in looking at the budget recommendations for those objectives that either were added or were significantly modified, that they may need additional budget recommendations, and so we will do that.

And then we will be done with this year's update. Hallelujah. And congratulations. So with that, I will turn it back to Tom.

Dr. Insel: Great. So what we want to do is focus initially on the introduction.

Much of this is the same. There have been some recommendations for some wording changes. Obviously this is -- doesn't involve objectives, doesn't involve budgets, but there are some new crosscutting themes.

Lyn, you probably have done more work on this than anyone. Do you want to quickly just walk us through the major points that the subcommittee recommended? And we will see if people have questions about them.

Ms. Redwood: Sure, as Tom stated, there weren't a lot of major changes to the introduction. There was an addition or proposed addition of three crosscutting themes.

In looking at updates to the introduction, we went through the public comments that we have received over the past several years, and one of the areas where we received quite a bit of criticism was related to the introduction with regard to the sense of urgency that autism creates, and that we were not really acknowledging ASD as a national health emergency.

So when you look at this very first introduction there, you can see where that has been beefed up quite a bit and some of this language actually comes from the Autism Speaks website.

So what has been added is that today autism is more common than childhood cancer, juvenile diabetes and pediatric AIDS combined, and that the increasing numbers of children being diagnosed with autism has created a national health emergency.

The other thing that was suggested is that we also put in something regarding President Obama specifically citing autism along with cancer and heart disease as one of the three health conditions targeted for major scientific research investment through the American Recovery and Reinvestment Act, and that the president expressed his hope that research into genetic and environmental factors would result in strides in early intervention, treatment and therapies to help people affected by autism achieve their fullest potential.

So those are the first changes. I'm trying to read the comments out to the side. You can see some of the things that were deleted and added. So I guess that would be the first thing for the committee to discuss, whether or not they are have any suggested edits or if they are comfortable with what has been proposed.

Dr. Insel: Alan.

Dr. Guttmacher: One minor edit. I wonder if we might add in what is line 2, I guess, "is more common in the U.S. than childhood cancer, juvenile diabetes" et cetera, because we don't have good data for some other countries and in certain areas, for instance, of Africa, unfortunately pediatric AIDS is so common, et cetera.

Ms. Redwood: I think that's a

very good point.

Dr. Insel: Ari.

Mr. Ne'eman: I have concerns with regards to the comparison of autism to cancer and AIDS and other terminal conditions. I think a number of people in the self-advocate community would view such a comparison as inappropriate.

And while I think we want to communicate a sense of urgency, the challenge here is by implying that autism is a terminal condition, I think this very often sort of distracts attention from and implies that nothing can be done about the many areas of health and safety concerns that we have been talking about elsewhere in this subcommittee.

I think what we want to communicate instead is that autism is a condition to which there is tremendous urgency because of unmet service provision need and unmet human need and that that should be the dynamic that we communicate in our introduction.

Dr. Insel: So if I can say, this is a point of discussion in the subcommittee, and Lyn, it might be helpful just to summarize the conversation we had there, because what you're bringing forward was actually the group decision. But this was very much part of the conversation.

Mr. Ne'eman: My understanding was the subcommittee had talked about bringing this to the full committee.

Dr. Insel: Right, but I wanted to reflect that the subcommittee looked at this, they have considered alternate language, this is what they are bringing forward, but this is for the whole committee to consider.

So we can revisit anything that is in here, but I wanted to make sure the full committee knows that we have been down this road in some detail already.

Ms. Redwood: Right. And what the full committee decided, and again, this was not a unanimous decision, which is why we are having the discussion here today, is that we were not implying that we were making a direct comparison between individuals with ASD and AIDS as a terminal illness, but just that those were very high-profile health disorders that the public is aware of.

So we wanted to increase the awareness of ASD as having similar numbers to these other very high-profile diseases, because we don't hear about it as much in the media.

So that was the intent behind this comparison, not to compare those disorders specifically to ASD.

Dr. Insel: Geri.

Dr. Dawson: So I just wanted to point out that I think that the language is very much in the same spirit that President Obama was referring to the heart disease, cancer and autism as being our three greatest public health challenges that we need to address.

So again, I can't say exactly what he meant, but I would -- I think the intent there is to draw attention to the scale and the scope and the urgency, rather than to say you know, autism is cancer, autism is heart disease.

So you know, I think President Obama's use of the same terms is in the same spirit.

Dr. Fischbach: I must say I absolutely understand Ari's point of view and I just would love to see something, a statement that said autism is one of the most prevalent issues facing the medical community today, rather than get into details, especially with -- we know budgets are decreasing, going to be cut back, and why get into battles with particular disorders at this time when it's just irrelevant to me frankly. I don't see what the point is.

Dr. Insel: Ari.

Mr. Ne'eman: And I think Gerry makes a very good point about the issues with regards to avoiding the impression that we are trying to play one disability or condition or diagnosis off against each other.

I respect the issues of intent that were certainly brought up, and I certainly understand them, but you know, I just would also add here, that this Strategic Plan, and particularly the introduction to the Strategic Plan, is intended to capture the thoughts and sentiments and the needs of the broad level of -- broad and different types of stakeholders that exist in the autism community, and regardless of the intent, I think this language as it stands will be very inflammatory for a great number of the people that we are aiming to serve.

Dr. Insel: Other comments or thoughts about this? Can we get -- Lee, go ahead.

Mr. Grossman: Yes. I understand

where Ari is coming from with this, and not to get too wordsmithy on this, but if we just added terminology like in terms of a comparison of research dollars spent, some type of wording around that, then I think that that kind of puts it in a greater perspective.

I am also a little bit troubled by this introduction. I've looked at it, I don't know, so many times, dozens of times and we have discussed it so many times.

And if we were really to address the sense of urgency, it still to me is lacking in that, particularly since, if we are to address the sense of urgency, it can be best done immediately through improved services and supports, and that is not really addressed here.

It's more of looking at it strictly as a research component, and I understand this is a research Strategic Plan, but I still think that somewhere in there, in the intro, to address the urgency of the matter, we can add one more sentence along the lines that the urgency can best be addressed through improved services and supports across the lifespan.

Dr. Insel: Denise.

Ms. Resnik: I'd like to offer maybe some slightly revised language. I understand the intent. I am also very sensitive to not wanting to alienate or to Ari's point, turn off a significant number of members within our autism community.

And since the president does cite autism as one of the three major health concerns for our state -- or our country, what if we just change that, wordsmithing a bit, just to acknowledge today the dramatic increase in the number of children being diagnosed with autism has created a national health emergency.

I don't think you actually need those three different diseases there if the president has already acknowledged something here, and we wouldn't want to also set ourselves up in terms of competing with those other diseases.

I guess the spirit of what we are trying to do here is critically important for people to want to read on and I just don't think we would want to intentionally or unintentionally -- I'm sure it's unintentionally -- offend anybody in the process.

So I do think it's important that we acknowledge that.

Dr. Insel: Ellen.

Ms. Blackwell: In looking at the 2010 plan, it looks like to me the easiest thing to do might be to use the language in here and then just put a period after national health emergency and insert, as Denise has suggested, the language about President Obama's visit to NIH.

Dr. Insel: Geri.

Dr. Dawson: You know, I do -- I

as well am concerned about the sensitivity and you know, it would be great to come up with language that everyone felt comfortable with.

I would point out that one of the things about this sentence is that it captures the prevalence issue, right? Because I do think that the average American does not appreciate the scale in terms of the number and most people have a sense of things like juvenile diabetes being a condition, you know, that is prevalent and people care about and a lot of people don't realize just the size of the issue.

And I think size is important. So I wonder if there could be language added rather than taken away that would convey, you know, make sure that this is not interpreted in the way that I think Ari has concerns about, which I think are legitimate, but not take away from the impact around prevalence.

Dr. Insel: Stephen.

Dr. Shore: Oh okay, you can hear

me. Yes, I understand what Ari is saying and I think we are all pretty much on the same page, and that is the emergency being that -- the emergency relates to the lost and wasted potential of people on the autism spectrum to contribute to society.

And by focusing the idea of the emergency being put towards providing support, I think that could be more helpful.

Dr. Insel: Ari.

Mr. Ne'eman: I think -- and I agree with Stephen and Lee's comments here about the need for some mention of service provision. I think to Geri's point, it would seem to me that the easiest and most direct and non-controversial way of making the point about the prevalence is to simply state the prevalence.

So it would seem to me that the best way to educate the public is to state today autism estimated to exist in approximately one percent of the general population or something to that effect, rather than --

Dr. Insel: It's in the second paragraph.

Mr. Ne'eman: Well, then, I mean to suggest that that would be the most appropriate way to make the point about prevalence, rather than comparisons that could potentially alienate part of our community or increase tensions with other communities.

I would also add that I think some additional language we may wish to consider is to edit where we say "national health emergency," to state instead a national health and civil rights emergency, to acknowledge the tremendous unmet service provision need.

Dr. Insel: We're going on half an hour for the first paragraph, and we have got a lot to do today, and we can't leave until we get this done. So I know people have lots of opinions about how this should be worded.

I want to start because so much

discussion has already gone into the language you have here, so if a majority of the committee wants this to stand the way the subcommittee referred it, that would be helpful to know and we will just move on.

If not, we can go back and try to figure out how the wording could be changed so that it would be acceptable to the majority. Ellen?

Okay, so can I get a show of hands and then we will ask those on the phone as well, with the addition of "in the U.S." after "is more common," whether you would want to take what the subcommittee has referred forward or not.

Those in favor of accepting the language as is?

Dr. Hann: One, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13 in the room vote in favor.

Dr. Insel: And on the phone?

Dr. Fischbach: No. I'm Gerry.

Ms. McKee: In favor. Christine.

Dr. Fischbach: What?

Ms. McKee: Sorry, in favor, Christine.

Dr. Insel: And anyone else on the phone voting?

Dr. Shore: Not in favor.

Dr. Insel: Okay.

Dr. Hann: Okay. That's 14 voted in favor of that. And Susan, that's over half the committee, correct? That's over half.

Dr. Insel: So, we are going to move on. Lyn.

Ms. Redwood: Sorry about that. The next area that is highlighted in purple, I just want to point out that this is not a change from the Strategic Plan.

There is only one word highlighted in the very last sentence that was "continuing," and that was changed to "increased." But this section of the Plan was also something that some of the committee members, especially the new committee members, were uncomfortable with and wanted to bring forward to the full committee for discussion.

So that's the reason that this area has been highlighted. So I guess the discussion from the committee, whether or not they are comfortable with this staying in the Plan as it was written several years ago.

Dr. Insel: Ari?

Mr. Ne'eman: Just to provide some additional context, I think the area of concern, at least to my mind is primarily with the line: "The cost to society of ASD is currently estimated to be $35-$90 billion annually, the higher estimate being comparable to Alzheimer's disease."

Once again I understand the intent here, with regards to indicating potential cost savings for the provision of additional service provision or research, but I think it's a very dangerous path to tread down whenever we try and estimate the cost to society of a particular population of people.

Once again I think it could run the risk of alienating a potential -- a significant portion of the stakeholders we are aiming to serve and I would request that that sentence be stricken from the Strategic Plan.

Dr. Hann: That sentence or that phrase?

Mr. Ne'eman: I think it's the sentence.

Dr. Hann: So even the cost estimate itself, without any comparison?

Mr. Ne'eman: Yes.

Dr. Insel: Again, we had some discussion about this. Lyn, do you want to summarize kind of where the subcommittee ended up on this?

Ms. Redwood: My understanding is that the subcommittee felt comfortable with this cost comparison, the cost of ASD, staying in the Plan and felt as though it was important in being able to justify the spending on research that is in the Plan.

Dr. Insel: Other comments about this? So in favor of holding the original language or those who would vote for a change, so in terms of retaining the language as is, can I see a show of hands?

Dr. Hann: One, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 15, 16 in the room.

Dr. Insel: And opposed? And on the phone?

Dr. Fischbach: I'd be opposed.

Ms. McKee: In favor, Christine.

Dr. Insel: Anyone else on the phone?

(No response.)

Dr. Hann: Okay, that's a vote of 17 to keep. The motion carries.

Dr. Insel: Let's move along.

Ms. Redwood: Okay. The next item is on page 3 and this was a very minor edit, just acknowledging the fact that this year we did include progress toward accomplishing our research objectives, so that was added.

If there's not any concern about that I will keep moving forward.

Okay. Under crosscutting themes, one of the comments that were received from the public RFI was that the statement "nonverbal," "are nonverbal," was used to describe individuals on the spectrum, that they felt as though wasn't appropriate as an identification for those individuals that weren't as high-functioning.

So in place of that was substituted "cannot live independently and require 24-hour care and supervision." So that was one substitution that was offered by the committee.

The second version you can see highlighted in blue, which reads, "The spectrum includes people with ASD with significant disability who need a great deal of assistance through physical health care and community-based supports and services to live in preferred home and community-based settings, and others who, with minimal or no services are able to support themselves and live independently in their community."

So those would be the two things that the committee would need to decide upon language.

Dr. Insel: Sorry to do this, but I have a question about this crosscutting theme. I read it again preparing for this meeting, and there is -- the previous sentence, I want to make sure that I understand, not the ones that are version 1 or version 2, but the sentence before says, "In the context of ASD, the term "heterogeneity" refers to the constellation of behavioral and medical conditions and symptoms that may accompany the disorder."

Is that what we mean by heterogeneity? Or are we talking about the disorder itself, that is even the core symptoms exist along a broad range?

Okay, I have just -- for those of you who are deep into this, what do you want the heterogeneity to mean here, what is the right definition?

Dr. Dawson: Well, we could change it to "that may comprise and/or accompany the disorder."

Dr. Insel: If you do that, then couldn't you just add the word severity and you wouldn't need either of these two versions?

Dr. Dawson: So how would that --

Dr. Insel: You would say, "The term heterogeneity refers to the severity of behavioral and medical conditions and symptoms that comprise the disorder."

And you don't need to get into whether it's 24 hours a day or 12 hours a day or whether they are getting appropriate services or not. Okay.

Ms. Redwood: So that's one of the

alternatives that we will discuss.

Dr. Insel: Sorry about that but -

Ms. Redwood: No, I think that's a wonderful idea.

Dr. Insel: I just in reading this, it sounded like neither of them were really addressing what you wanted. Jim?

Dr. Battey: I like your suggestion.

Dr. Insel: Hearing no other concerns, Della?

Dr. Hann: I was just going to -- I thought you were moving to vote on it --

Dr. Insel: Yes, okay.

Dr. Hann: Sorry. Okay, the option that Tom just read, we will vote on that first, that it would then read if you heard you correctly, "The term heterogeneity refers to the severity of behavioral medical conditions and symptoms that may comprise the disorder."

Those in favor of that change?

Okay, it appears to be unanimous here in the room.

Dr. Insel: On the phone?

Dr. Fischbach: In favor.

Ms. McKee: In favor.

Dr. Insel: Okay, let's move on.

Ms. Redwood: You could have saved us some time with coming up with that.

(Laughter.)

Dr. Insel: I'm just looking at lunch and so that's the goal here. Let's move along.

Ms. Redwood: Okay. We are moving into the crosscutting themes and there were three suggestions. One was to add a crosscutting theme that addressed some of the co-occurring conditions, and this was based on the presentation that Dr. Dawson did from the Autism Treatment Network and the number of children that also had other co-occurring conditions that could possibly interfere with the way that they might gain from other types of therapy, say behavioral therapies.

And if you address some of these underlying, co-occurring conditions, it might make the behavioral therapies and some of the other treatments become more effective. I am not doing a good job describing that because I was trying to get away from reading that entire paragraph because I know we are sort of under a time crunch.

So if people want to read through that on their own.

Dr. Insel: Yes, if I can just add, this was an interesting discussion we had in the subcommittee, because as we got into it, we felt that something like this needed to be added, but none of us felt confident that these co-occurring conditions were really separate from autism; some of them could be actually part of the disorder itself.

We don't know enough yet and we felt we needed to capture that as well as to find some language that we could then take all the way through the Plan, so that each time, people would understand what we were talking about.

We struggled with a lot of different words for this but this is what we came up with.

Ms. Redwood: And the importance of a multi-disciplinary health assessment and effective treatment guidelines was added too, and this was language that I think Tom, you offered and several people in the committee.

Dr. Insel: Comments or questions about this? Okay, shall we take this to a vote?

It needs a little syntax work but we can do the wordsmithing. There's some tense problems in there but --

Dr. Hann: We'll fix that. Okay, I will not -- I also will not read through the entire paragraph, but it is before you, and for those of you on the phone, it's as written in the document that you received.

Those in favor of adding this to the introduction?

Okay. All right. It appears to be unanimous here in the room.

Those on the phone?

Ms. McKee: In favor.

Dr. Fischbach: I'm in favor too.

Dr. Hann: Okay. It carries.

Dr. Insel: Okay. Moving along.

Dr. Hann: Walter?

Dr. Koroshetz: I hate to do this but does anybody have any objection if we bring the seizures into the percent with problems as opposed to -- I think it's a purpose served to bring attention to the prevalence of epilepsy in autism for a number of different reasons.

Dr. Insel: And the number's what, 20, 25 --

Dr. Koroshetz: I'd have to look it up.

Dr. Insel: So okay, unless I hear

resistance to that idea, we can -- OARC can go ahead and move that around as part of their syntax fix.

Okay, moving on.

Ms. Redwood: The next one -- well actually, I have a question. There were two other crosscutting themes that I have just received. One is a crosscutting theme regarding ethical, legal and social implications of autism research from Ari and the other was a crosscutting theme on self-determination. It was submitted by Jennifer Johnson.

So I'm not certain, since these are late additions, where we would want to add these and where their discussion should come up but I think everything else in here is somewhat minor so I would recommend that we move to these two crosscutting themes to discuss.

Dr. Insel: Actually, is it -- maybe we should go ahead and just finish up, and then we'll circle back to those to make sure we have got everything else is done, if that's okay. I think there are just a couple of other little things.

Ms. Redwood: Yes, they're on page 6, there's a minor edit under early detection, ASD is considered a developmental brain disorder, considered was added.

Under public-private partnerships, there was a sentence added, "and to prevent unnecessary duplication of research efforts," and that "the existence of such partnerships is a critical component in ensuring the success of the Plan."

And then also there was some additional language added to community engagement in ASD research, specifically the inclusion of stakeholders being essential, to ensure that the personal experiences of people with ASD and their families is reflected in scientific considerations, investment strategy, and research focus, and that strategies are needed to increase community engagement in an effort to incorporate the first-hand experience of people with ASD, their families, and caregivers into the Plan.

Those were the other recommended changes outside of these.

Dr. Insel: Any comments or concerns about those? Ari.

Mr. Ne'eman: Yes, I support all of that, the only thing I wanted to say is it makes note that I was going to provide a sentence on the participatory action model. I actually sent that to OARC in December so I don't know that it was reflected here. I have that sentence here now if nobody has any objection.

"Community engagement and study design, implementation and analysis will maximize both the effectiveness and relevance of new research. Community-based participatory research or participatory action research models represent an important avenue to solicit the needed perspectives of adults on the autism spectrum and family members in autism research and should be adopted wherever possible."

It's actually two sentences.

Dr. Insel: Geri.

Dr. Dawson: Yes, I think those sentences add a lot and I would personally support adding those.

Mr. Ne'eman: Thank you.

Dr. Insel: Ellen.

Ms. Blackwell: Is it just adults who would be involved in participatory action research, Ari?

Dr. Insel: Maybe you should read it again. It was not just adults.

Mr. Ne'eman: I had adults on the autism spectrum and family members. The reason I stated adults rather than people on the autism spectrum is simply because when we are talking about participatory action research models, we are generally not talking so much about who is being studied. We are talking about involving the people who are being studied.

So adults and youth might make sense, but the model probably wouldn't hold if you are talking about children three or four, something of that nature.

Dr. Insel: Other comments or questions. Lyn?

Ms. Redwood: I support the addition of that as well, but my only concern is since we don't have it in front of us, to make sure that there's not duplication. So if OARC staff, when you receive that, could just make sure there's not, you know, two words that are the same in the same sentence or are not saying the same thing twice with what was proposed here with the language we have in front of us.

Dr. Insel: Okay, with that provision, can we get a show of hands for people to -- basically doing this en bloc for the last few additions and changes. Those in favor?

Dr. Hann: It's unanimous here in the room.

Dr. Insel: Yes, and on the phone?

Dr. Fischbach: In favor on the phone as well.

Dr. Shore: In favor.

Ms. McKee: In favor.

Dr. Insel: Okay, great. Now let's go back to the crosscutting themes. We have two additional ones and Lyn, maybe take us through these.

Ms. Redwood: Well, since I didn't author these, I'd like to ask the people who submitted them to discuss them, but I guess I would suggest that for the crosscutting theme on ethical, legal and social implications, that that be where community engagement and ASD research, either right above or right after.

And then self-determination, I am

not quite certain.

Dr. Insel: I should clarify, even though you are seeing these at the last minute, we actually did talk about these. We just hadn't developed them fully, so the specific wording hasn't been vetted by the subcommittee, but the concepts were discussed and we essentially volunteered the people who did them to come back to the full committee with some recommendations. Coleen?

Dr. Boyle: I did read the ethical, legal, social one on my BlackBerry coming up this morning, because it came last night. But do we have a hard copy of it?

Dr. Insel: It's in the folder.

Dr. Boyle: It's not in mine.

Dr. Insel: No? Okay, we can make sure you get a copy. Alan? Since you were the one that was put on the spot about the ethical legal and social implications, and you are our resident expert on this, is there something missing, something more we need to hear, or does this cover the ground we need?

Dr. Guttmacher: My impression was that it covered it actually pretty well. Let me borrow back the hard copy again, but I thought it actually captured it. I mean, you can always go on more and more and more, but I think the major issues are there.

Dr. Insel: Ellen.

Ms. Blackwell: I would just ask that maybe OARC change the language or we agree to change the language that refers to the adult, capital A, Autistic Community. It might be better to say, it is critically important to include people with autism, family members of individuals on the autism spectrum et cetera.

Mr. Ne'eman: So, I used the language that I used intentionally. You know, if there is going to be a change I would suggest altering it to read, to include the autistic self-advocate community.

Dr. Insel: Geri?

Dr. Dawson: First, I want to say I think this is great and it's very badly needed and I think Ari, you have done a nice job of drafting this. One of the things I wonder is whether on the fourth line when we say in particular genetic research, whether that should be broadened, because I do think there really are a range of different ethnical issues that autism research brings up: screening, we talked about various intervention techniques that impose on self-determination, you know, the wandering issue.

So I think there really are really a broad range of issues that fall under this area of concern. I do want to raise, when we get into the last part and about how we refer to the autism community and people with autism, I would actually include children here, and would not exclude them, and certainly as a person who has done research with children all my life, when we think about IRB and ethical issues and even issues around self-determination, you know, you have to -- not have to, but it's a good thing to and you need to include assent language and things like this and it really is addressing a lot of these ethical issues.

So I just -- I think broadening those two pieces would help, but otherwise I think this is excellent.

Dr. Insel: Ari?

Mr. Ne'eman: I think that's a great idea. How do you feel about, "It is critically important to include adults and youth on the autism spectrum, comma, family members" and so on?

Ms. Blackwell: I really do think we need to revert to our language elsewhere in the Plan which is "people with autism."

Mr. Ne'eman: I think the language is, is that not all people in the autistic community utilize person-first language.

Dr. Insel: Ari, would it help to just say the broad autism community?

Mr. Ne'eman: Well, I think we want to call out -- if it would come down to that, I am -- you know, I think it's important we specifically call out the different stakeholders within the autism community to make sure the self-advocate stakeholder is included.

So, you know, I am not going to force the issue. My preference is for "adults and youth on the autism spectrum," but if it is going to come down to whether or not we are going to specifically mention individuals on the spectrum in general, I can accept Ellen's use of person-first language.

Dr. Insel: Denise.

Ms. Resnik: I suggest we keep it broad to individuals or people with autism. I would feel much more comfortable with that. I like this addition altogether though. And in terms of the in particular genetic research, if our staff could help us there just broaden it -- I don't want to limit it in terms of what Geri said, I thought your point was well taken. Autism research would be great. Just broaden it.

Mr. Ne'eman: Could we say, "autism research including genetic research," just because I do think, although there are a lot of other areas, it does make sense to particularly highlight the unique risks around genetics.

Dr. Insel: So my concern about that is that often the place where we have the most difficult ethical issues are actually on some of the interventions questions that come up, and I am a little too -- I am a little concerned about kind of focusing too quickly on one part of this space and missing something that could also benefit from this ELSI approach, but again, that is maybe because I tend to focus more on the intervention side, so there's -- I'd be interested in --

Dr. Guttmacher: As one of the

folks on the genetic side I agree with you, that we ought to generalize it more I think, that there are certainly distinctive issues there but there are in so many other issues regarding the autism community, that I think, if we are going to start calling them out, we would have to call out a whole number.

Dr. Insel: So, but maybe there is value in at least giving some examples, so people know -- rather than just saying autism research poses unique ethical risks, would it be helpful to actually say such as within genetics, screening was one that Geri mentioned, interventions? Would that -- because I think you want readers to know what it is you are really trying to focus their attention on, and if it is too broad, it's just hand-waving.

Mr. Ne'eman: I do like that, and I actually am glad you raised, or whoever raised the issue around interventions that may have implications on self-determination. It would seem to me that that would make sense as another example, in addition to genetics.

Dr. Insel: Geri.

Dr. Dawson: If we said "such as genetic screening and intervention research" -- again, I do think it is broader even than that, but you know, that would at least be examples.

Dr. Insel: Okay, so what do we have here, because this is always difficult to wordsmith by committee. We'll leave OARC to do that, but we want to make sure we get the concepts in here and again, because this is one that the subcommittee didn't really look at a proposal ahead of time, we are hoping to get it in, but if you are not comfortable with it, we can put it off until next year.

The first sentence it sounds like people are comfortable with and then you want to say something like "autism research including or such as" and we'll leave the three examples in there, "pose unique ethical risks" and then at the end, "such efforts are undertaken it's critically important" -- and the language again, Geri, or Denise, it was to include people with -- can you read that or say it?

Dr. Dawson: Well, one suggestion would be people with ASD.

Dr. Insel: And then family members -- okay -- and other stakeholders. Okay. Does that capture what you want in here? Okay. I see heads nodding. All in favor?

Dr. Hann: Okay, the vote is unanimous here in the room. Those on the phone?

Dr. Fischbach: Yes.

Ms. McKee: In favor.

Dr. Hann: Okay.

Dr. Insel: I'm going to leave it to OARC to figure out where to put it. Are you comfortable with that? Okay. The last piece is from Jennifer Johnson on self-determination, and Ellen?

Ms. Blackwell: I know this is the first time that that we have seen this but there was a lot of discussion about self-determination over the recent past in the subcommittees and I like what Jennifer wrote but I just have a couple of quick suggestions to maybe make this a little bit more positive.

I would actually strike the line that starts, "while people with ASD may have characteristics that can impact the development of self-determined behavior, research has shown that," I would strike that, so that it just says, "interests instead of being coerced or forced to act in certain ways by others or circumstances. People with ASD can, with educational supports," et cetera. And then I would put a period after "daily living" and strike this -- and it says, it talks about relying on others for choices. That just seems to make this a little more positive.

Dr. Insel: Ari?

Mr. Ne'eman: I agree with everything except the last edit with regards to striking "rather than rely on other people to make all their choices for them." I think sometimes we understand the concept best by its comparison and so in that sense, I do think it's important to emphasize that when we talk about self-determination, we are talking about empowering autistic people to make our own choices with or without support, and so that comparison is a useful one.

Dr. Insel: Alison.

Ms. Singer: So, when we were in the committee discussing this, I expressed a lot of concerns about this. I think self-determination is a great goal, but I think that realistically, there are a lot of individuals who are on the more challenged end of the spectrum who may not be able to reach the goal of self-determination and I don't want us to really have any material in the Plan that either negates or diminishes the progress that they have made or the value of their lives.

So Ellen sent me to school on this. She sent me many documents to read, and many people to talk to and in the course of that, I came across a term that is sort of batted around in this community called supported self-determination, which I think recognizes that in some cases, the goal of self-determination needs to be supported.

And I think if we were able to add that word, it would certainly address my concern about not excluding individuals who are on the more challenged end of the spectrum.

Dr. Insel: Ellen.

Ms. Blackwell: Well, I did send Alison a lot of materials and I know what she is referring to and Henry, feel free to chime in, is many years ago, when the discussion first started and these words "self-determination" started being used in the disability advocacy community, a lot of people didn't understand self-determination as a stand-alone concept.

So this idea of supported self-determination was sort of put out there to help people understand that you could be -- anyone can lead a self-determined life, with support.

But over the course of perhaps the past 10 years, the word "supported" has really disappeared from discussions of self-determination. Henry, do you have any other comments to add?

Dr. Claypool: Well, I think Ellen makes the point pretty straightforwardly. If there is a real resistance or a lack of understanding of where self-determination has been and where it's going, and we need to bring the ASD community along by adding additional language, I think that's also acceptable.

But maybe there is a minority view

or are we just trying to accommodate Alison's concern with this, is there further discussion? Because generally it's understood to include the idea of a full range of supports to help an individual lead a self-determined life.

It's not something that is ever used to exclude that fact, that people really do need these types of support, so that's enough said. I think Sharon's here.

Ms. Lewis: I guess I would concur with both Ellen and Henry's comments and I would simply add that ADD has a fairly extensive investment in self-determination research and really, we are at a place where we are talking about scaling up. It is an accepted and valued concept, and the set of assumptions is that it is a means to an end. It is not an end to itself.

Self-determination is not the goal. The goal is that self-determination informs how we support people, so it includes people with the most significant and profound needs in achieving whatever it is they are trying to achieve, whether that's additional independence, whether that's employment, whether that's education and whether that's health.

And that we are respectful in the course of that discussion and in the course of those activities to understand that even people with very, very significant communication and neurological functioning challenges can direct and can make choices.

Dr. Insel: Denise.

Ms. Resnik: I just wanted to respond to Henry's comment. Alison is not alone in that concern, and I think many parents who have children who are more severely impaired in their autism hear about self-determination, it does require us as parents to read quite a bit before we might get it, and I do think the term "supported" would help our community a lot.

Dr. Insel: Geri, Lee and then Ari.

Dr. Dawson: Well, one thing I think would be helpful is if maybe at a later date, we actually had people come in and talk to us about the concept and about the movement and how this word is interpreted.

My sense of what's going on in the committee is that it is a semantic one in the sense that even best practices or empirically-supported practices now in interventions incorporate the concept of, you know, choice and preference and viewing the intervention process from the point of view of the child, even a very young child or a severely affected adult, and how by allowing that kind of self-determination in choices and activities, that one has a better outcome.

And I don't think that it's really meant to be interpreted as this individual no longer needs supervision or that parents wouldn't be making some decisions on their behalf in the same way that for typically-developing children, parents are always making you know, decisions on the behalf of their children.

So I think we need some education in this area.

Dr. Insel: Yes, given that, I guess a question that someone might wonder is whether this is ready or whether we need to, as a committee, learn more about this before it goes into the Plan. Lee?

Mr. Grossman: Yes, I just wanted -- I was sitting here trying to think if all the literature that we have and what some of the coalitions that we are involved in, if we have that supported self-determination in there. I believe we have struck it across the board.

We look at self-determination as I think the process is, is that it is a goal as well as a process, and my understanding is these are requirements by statute in our laws that we have self-determination. Am I correct there?

Ms. Lewis: Yes.

Mr. Grossman: Okay. And what we are talking about is human rights, civil rights and human dignity here and that it should be -- I mean, for us to even express it as a crosscutting theme almost sounds inconsistent with the law of the land, but it is here and we are putting it out.

So I would look at this as we should be setting the bar. We should be modeling others to follow us, and if -- and as a result, I think that the committee should take a strong stand in supporting self-determination and presenting it as such, and if we need to bring the community along and educate them, then we will use this as an opportunity to do so as well.

And Ellen mentioned -- dropped me a note saying that there are -- and we are aware of, she is aware of, others are aware of experts in the field, and we should have them.

Ms. Blackwell: Actually, I think --

Dr. Insel: I think, let's -- Ari go next and --

Ms. Blackwell: Can I just quickly point out, to finish what Lee was saying, is that we did have a presentation on self-determination at our November 8th Services Subcommittee workshop, so that's available online.

Dr. Insel: Ari?

Mr. Ne'eman: Well, I would say two things. First I think while it certainly does make sense for us to have more presentations on the topic of self-direction and self-determination, because they are topics that are important for the committee and the broader autism community to be aware of, and my hope would be that in doing that we might consider inviting to present to us individuals with significant impairment who nonetheless, with or without support, do live self-determined lives.

I do think it's important we include this as a crosscutting theme. I think it's ready and I think you know, and many people who have a tremendous amount of expertise in their field have reiterated this, the words self-determination carry, implied within them, with or without support.

So if we want to include somewhere in the language of the crosscutting theme, comma with or without support, or something to that effect, that's fine. But I don't think we should change the title of the crosscutting theme and I think it is very important that we see it included.

Certainly, to consider it and then to reject it would send a very negative message to the community that I don't think we intend to send.

Dr. Insel: But, so Ari, if I can just kind of clarify, because if you look at the first sentence, it says it is essential that ASD-related research incorporate and promote principles of self-determination, but an enormous amount of ASD research is being done in stem cells, is being done in cell culture, is being done in areas where there are often going to be breakthroughs that have really nothing to do with an individual's self-determination. There's not even an individual involved.

So I'm not sure if the, as you dig into this and start to really look at the language, I don't know that it is so obvious for many of the people on the committee how this would be an essential, crosscutting theme for the whole range of research that we are talking about.

Mr. Ne'eman: Let me speak to that because I think suddenly that's an important issue. When we talk about that research, with regards to stem cells and other areas of basic research, well, certainly that research has implications and one would think that those researchers that are embarking on those projects are considering the implications when they embark on it and in the spirit of touching on the community engagement crosscutting theme we had talked about previously, are also considering what community priorities their research relates to.

And with regards to both of those things, the selection of the topic and then the consideration of what kinds of implications and applications their research has, I think even basic is impacted by the principles of self-determination.

So I do think it's relevant across the broad scope of different types of ASD-related research.

Dr. Insel: Jim?

Dr. Battey: I don't agree with that. And I think this is not ready to go yet, and it needs a lot of work and should be deferred to a later year.

Dr. Insel: Geri.

Dr. Dawson: Well, I just want to weigh in that I actually do think it's very important to incorporate and I would advocate actually moving ahead to incorporate it now, but I do sense in the committee that there is a lot of different attitudes about this and so I respect that that is where the committee is now.

But I think this is a very important concept and it's an attitude that we want to infuse with all of your research and interventions and everything that -- the decisions that we make.

Dr. Insel: Alan.

Dr. Guttmacher: You know, I think it could be perfected but I think it's pretty good and I think we could get it in and then next year we could make it a little bit better. I am actually okay with the research.

It doesn't say that all research,

if it said all research then I would have hesitation. But I think the things like that -- I think the point is it's such an important one it really ought to be in our Strategic Plan, and maybe it's not, you know, I think, a perfect presentation of that, but little of the Plan is perfect, just as little in life is perfect, so to me it's good enough to get in there.

Dr. Insel: Yvette.

Dr. Janvier: I'm not sure why it needs to be a separate crosscutting. Why could it not be incorporated into the previous ethical legal and social implications? To me that's really a little bit more appropriate. When I think of research people are giving consent and it's a societal concern. I just don't see it standing alone. I agree with what Dr. Insel said prior.

Dr. Insel: Comments from others? Anyone on the phone want to weigh in here?

Dr. Fischbach: Neutral.

Dr. Insel: Neutral. Okay.

Ms. Redwood: Tom, I agree with Yvette as well. I don't know. I think we could incorporate this into the Plan I think it should be a goal. Self-determination should be a goal for individuals but I'm just -- I'm not certain with the way it reads that it's ready the way it's written to go into the Plan but --

Dr. Insel: Della.

Dr. Hann: So in listening to this discussion, one thing to think about, not to make it even more complicated, is the now sentence that Ellen has created, it might be useful to potentially think of that as the lead sentence. So the sentence I am referring to is the fourth line from the bottom, begins with, "People with ASD can, with educational supports and accommodations, acquire skills to lead self-determined lives."

And so that brings in the notion at the get-go, in terms of the breadth of what is now accepted as the definition but for those who don't understand necessarily what the breadth of the definition is, to have it up front, and then go into the definition by Wehmeyer, I guess that's how you say that individual's name, and go forward with the rest of the paragraph.

Dr. Insel: And then you'd take out the first sentence?

Dr. Hann: You could take it out or somehow use it in replacing the very last sentence, because it's redundant. Essentially the first sentence becomes redundant with the last sentence in terms of research needs to take this into consideration.

Dr. Insel: Alison.

Ms. Singer: The question about that sentence, maybe it's for Sharon. Does the Wehmeyer research indicate that all people with ASD can with educational supports and accommodations acquire skills to lead self-determined lives? Is that supported by the research?

Ms. Lewis: In my understanding it is. I think, back to Dr. Insel's comment, I think we need to have Dr. Wehmeyer and others folks come in and talk to us. But my understanding is yes, indeed, they have not found individuals who cannot improve the level of self-determination that they are able to exercise with accommodations and supports.

Dr. Insel: Well, I get the sense that there's sort of two streams here, one of which would say let's take it with a few modifications, which could be made next year; another which says let's wait until next year and get it right and then input it into the Plan. So Alan?

Dr. Guttmacher: Is there possibly a third way which is to have a small group of folks meet over lunch and try to perfect it, or is that not going to work?

Dr. Insel: I'm concerned we will still be on the same --

Dr. Guttmacher: Okay.

Dr. Insel: The same seesaw here, and we have other things we need to do after lunch. Let's put this out there as an option and see what the majority of the committee wants. Della? Seems like --

Ms. Redwood: Tom, could you add a third option too, which was Della's recommendation?

Dr. Insel: So, some wording changes?

Ms. Redwood: Yes, it's more logical the way it reads, by opening with that sentence, because I like that recommendation.

Mr. Ne'eman: I don't want to see the vote split so unless anybody on the include side has a concern, I would just suggest that we make it two and have Della's recommendation represent the proposal for including it as a crosscutting theme.

Dr. Insel: So one -- so one motion is that we take your language, which is reordering and have basically the same paragraph to include. The second would be to put this off until after lunch -- after 2010 plan and work on it next year and put it into the Plan we have heard from Wehmeyer and others about what the science actually demonstrates here.

So those are the two options. Della maybe we could take this to a vote and then we can break at that point?

Dr. Hann: Thank you. Okay, those in favor of the option of including most of this wording but leading with the sentence, "People with ASD can with educational supports and accommodations" et cetera.

Those in favor of that proposal?

We have one, two, three, four, five, six, seven, eight, nine -- wait a minute. I'm sorry. One, two, three, four, five, six, seven, eight, nine, 10, 11 in favor.

Dr. Insel: On the phone?

(No response.)

Dr. Insel: Okay. So --

Dr. Shore: Steve Shore in favor.

Dr. Hann: So then the vote -- it was 11 wait what did you just say Stephen?

Dr. Shore: In favor.

Dr. Hann: Oh, so it's 12. Does that carry? Okay. Then those in favor of holding on this completely until the next year's plan in terms of this idea of including something on self-determination as a paragraph, please raise your hands -- right, and hearing from speakers throughout the year.

I see one, two, three, four, five, six, seven in the room. Any on the phone in favor?

Ms. McKee: In favor.

Dr. Hann: Eight.

Dr. Insel: Motion carries to include it.

Dr. Hann: To include.

Dr. Insel: Okay. We are I believe

--

Dr. Briggs: Learning more about self-determination anyway, even those who voted for a paragraph, I think is important.

Dr. Insel: Let's hope that that doesn't make us take it out next year. I want to assume that that won't be the change. Sharon?

Ms. Lewis: And I guess, to that end, I would be happy to -- we have six who are involved in a project that is investing several million years over several years to demonstrate the concept and scale up self-determination and be happy to work them into the agenda as the committee sees fit.

Dr. Insel: I think you are on. We are going to put that on the agenda. Ellen?

Ms. Blackwell: And also the IACC website itself has two excellent presentations from Jim Conroy and Mike Head that are up already that anyone in the public or the members here in the room can refer to.

Dr. Insel: Okay. Lyn, anything else from the introduction that we needed to go through? We are done? We are determined. We are as a group determined to take a break at this point. Let's take -- we are a little behind schedule so let's take 45 minutes instead of an hour. We will catch up because we were -- we had scheduled some time to do additional discussion after lunch.

The part of the Plan we need to revisit after lunch will be looking at the recommended budgets, which I think we can do quickly.

So there's a cafeteria down the hall. For those of you who are on the phone, if you could just plan to rejoin us at 1:45 then we will reconvene. Thank you.

(Whereupon the committee recessed for lunch at 12:59 p.m. and resumed at 1:45 p.m.)

AFTERNOON SESSION

1:45 p.m.

Dr. Insel: It is 1:45 on the clock so we are ready to reconvene, and we are running a few minutes behind but I think we will be able to catch up. We have a public comment period here. We've got time for two public comments and then Henry Claypool has to leave at 2 and I want to make sure he has a chance to make a comment before he goes as well.

So let's start with the first public comment from Caroline Rodgers. Thanks for joining us.

Ms. Rodgers: Thank you. Good afternoon and I am very happy to be here today. Autism is thought to be caused by a complex interaction of environment and genetic factors.

This makes intuitive sense to us because we perceive ourselves as victims of exposure to an increasingly large number of toxins.

Yet time after time, when new public health issues have emerged, the cause has turned out to be simple, not complex.

Childbed fever, which was attributed to many different causes and claimed the lives of up to one-third of women delivering in maternity hospitals in the mid-19th century was virtually eliminated at one hospital when Dr. Emil Semmelweis ordered interns to wash their hands.

The disease rickets, which causes bone deformations, was accurately described in 1650 and for more than 200 years was blamed on everything from gland secretions to infections, bad diet, lack of exercise and even domestication, a term that embraced the collective slum conditions of confinement, foul air and unhygienic conditions.

It wasn't until the 20th century that scientists discovered rickets was caused by a simple vitamin deficiency.

In 1951, British epidemiologist Alice Stewart set out to discover why there was an increase in leukemia among children between the ages of two and four. She designed an extensive survey of possible prenatal factors and discovered, to her surprise, that just a single, low-dose fetal x-ray doubled the child's chance of pediatric cancer.

These are just three examples of how public health problems in the form of unexplained deaths, deformities and cancer, were each an effect that could be traced to a simple cause.

The remedies could not have been simpler, yet they were counter-intuitive according to the thinking at the time.

Is autism any different? In the case of childbed fever, Dr. Semmelweis noticed that women who gave birth in the streets had better survival rates than women who delivered in maternity hospitals. That didn't make sense to him, which is what led to his speculation about hand washing, a counterintuitive conjecture since the germ theory had not yet been proposed and doctors considered themselves gentlemen, whose hands, unlike common laborers, were clean.

Today, mothers who do not get first trimester prenatal care are less likely to have children diagnosed with autism than mothers who do. This also does not make sense according to our understanding of the value of prenatal care, suggesting that the reason is counterintuitive.

In the case of rickets, early investigators observed that fresh air helped prevent it, which made sense in the context of the times, since the importance of oxygen was well-established.

It would have been far less logical to suggest that sunlight was the operative factor since neither vitamin D nor the process by which the skin absorbs sunshine to manufacture it, had been discovered.

Today parents who have observed their children regress into autism after vaccinations, believe that the vaccinations themselves, whether via the preservative, the number delivered at one time, or the increased number required caused it.

Yet virtually all of the vaccinated children who regress into autism had prolonged, high fevers first. Could it be that in vulnerable children, fevers cause autism?

Blaming fevers seems counterintuitive. After all, childhood fevers long predated the emergence of autism in the 1940s and usually are harmless.

Yet if regressing to autism is not caused by vaccines, and the scientific literature does not support that it is, the role fevers may play in causing autism deserves a closer look.

The link between low dose fetal x-ray and pediatric cancer is a reminder that diagnostic imaging, albeit bloodless and painless, is a biological intrusion with consequences.

In a world governed by cause and effect, why would anyone think that prenatal ultrasound, which has several bioeffects, would not sometimes alter fetal development?

Perhaps autism is caused by a perfect storm scenario that depends upon the combination of gestational timing, amount of heat generated by the soundwaves and genetic predisposition.

If this were the case, it would be fair to say that any genetic predisposition would be inconsequential if the fetus were not exposed to ultrasound.

Experiments don't always turn out the way scientists expect. Some results seem counterintuitive, yet make sense when more information becomes available.

When Dr. Stewart discovered that low-dose fetal x-rays increased pediatric cancer risk, she attributed it to the fact that low-dose x-rays were more likely to cause mutations than high-dose x-rays, but the scientific community at large did not buy it, or it would not have taken nearly 30 years for the major medical associations to recommend against routine fetal x-rays.

Today we have more information. A study published last year proved that double-strand DNA damage caused by low-dose ionizing radiation took weeks to repair, whereas the same type of damage caused by high-dose radiation was repaired in mere hours.

The reason why remains unknown, yet now cancer risks posed by low-dose fetal x-rays no longer seem so surprising.

It is natural to want to believe that an unsolved public health problem is caused by a complex interaction of environmental and genetic factors, yet the answer may not be complex at all, only counterintuitive.

Facts that don't seem to make sense could actually be the best clues we have, as inconvenient as they may be, upsetting our preconceived ideas. They deserve further investigation. They may even lead to a simple explanation. Thank you.

Dr. Insel: Thank you. We have a second person who signed up for public comment, was James Moody.

Mr. Moody: Thank you. Thank you Dr. Insel and members of the committee. I have a statement on behalf of the National Autism Association.

April of 2010, the National Autism Association brought a statement before this committee that called attention to the number of external causes of death within the autism population.

We outlined the need for research, preventive measures, mass awareness, resources and emergency interventions to help reduce and eliminate these fatalities.

Our statement focused heavily on wandering-related fatalities, the number one external cause of death within our population.

In October of 2010, we presented before the committee data that confirmed a higher risk of death among those with autism as well as a 2001 California study showing that drowning was among the top causes of death within the community.

Drowning often occurs following a wandering-related incident. In our presentation we shared case studies and outlined a sampling of deaths that occurred since our April statement.

Who can also forget the testimony at that meeting and public comment of Sheila Medlam, a loving mother who lost her son Mason just last summer to a preventable drowning.

We also made a number of recommendations, most of which have already been adopted by the Alzheimer's community, and we requested the formulation of a subcommittee focused solely on safety issues within the autism community.

While we extend our sincerest gratitude for listening to our requests and unanimously voting to initiate a Safety Subcommittee, we are extremely disappointed to see a shift in focus among subcommittee members who feel the right to live should not take precedence over one's right to independence and self-determination.

The concerns brought forth by subcommittee members are speculative, yet deaths associated with wandering disorder are very real.

The National Autism Association has worked extensively on civil rights and will continue to do so, focusing on reduction of abuse, seclusion and restraints, over the last two years, and the substantial increase in civil rights.

This issue however should not dictate whether an individual with autism has the right to be protected from injury or death associated from wandering.

Our recommendations still stand and it is our hope that the committee will take swift action in advising our Federal government to implement the same safeguards routinely available for the elderly population.

These safeguards are in jeopardy of being denied to the autism population based on hypothetical scenarios that should not overshadow the basic right to live.

Since our presentation in October we are pleased to report that there have been no deaths with in the autism population as a result of wandering. Know that we monitor these trends very carefully and colder months appear to represent a reduction of incidents and deaths.

However, these same trends assure us that wandering incidents and deaths will substantially reappear as warmer months approach.

You have been given a unique opportunity to help reduce these incidents and we hope you will accept that responsibility with the same sense of urgency you had following the October presentation.

Issues such as independence, self-determination, or speculation should not take priority over preventing these deaths, and we feel that certain committee members' waning sense of urgency is impermissible.

The right to live should be the priority. The right to quality of life was not the intended purpose of requesting a subcommittee focused solely on safety.

We ask the committee as a whole to address both issues with the appropriate sense of priority and urgency so that additional lives will not be lost.

I would only add that the tension between civil rights issues and safety is a false tension. The urgency and safety must be paramount and these kids need not be sacrificed on an altar of political correctness. Thank you.

Dr. Insel: Thank you. And we will circle back to both of these at the end of the meeting today so there will be a chance to discuss both of the public comments.

I want to make sure that Henry has a few minutes to chat with us because he had some specific concerns before he has to leave.

Dr. Claypool: So I guess it's very timely that we have in public comment addressed some of the actions of the committee that I'd like to take up.

My concern is that writing the Secretary at this time on this letter is probably not the best use of the IACC and I would ask that we get further research into this issue. I note that there are no deaths in the winter months and so perhaps we can use the next few months to formulate a stronger position and develop a course of action that is more comprehensive than simply writing a letter to the Secretary asking her to take action.

I think this body has been empowered to really begin to formulate some ideas around what the unique challenges that people with ASD face that result in this type of behavior, and there is an opportunity to do that.

I think there are resources here. It doesn't appear that there's a real broad consensus about what the next steps should be. My understanding of subcommittees' deliberations was that they weren't really able to reach a -- they did come up with a letter but there was no real galvanized consensus on this letter going forward.

My concern is that sending something to the Secretary at this point might not speak with the force that the IACC can garner if we give this another couple of months and some real time to look into what is behind some of the wandering.

Obviously people are pointing to trends. Do we have enough information on the prevalence among the population? These are some open questions for me. I could be persuaded and I have to leave at 2 o'clock, so I'm not running out the door. I really do invite more information on this, and I am just concerned that if we write the Secretary prematurely on an issue, that in some way it doesn't speak with the force that it can when we have more of a consensus amongst this group.

So with that I can stop and are we going to --

Dr. Insel: Yes I think rather than getting into this conversation now, because it's on the agenda for about half an hour from now, what we will do I think, we will take your comments to heart and when the discussion begins in a broader way, I think all of us can remember what you said and we will make that part of the discussion we have. Coleen?

Dr. Boyle: Henry, it would help me -- this is Coleen Boyle from the CDC -- if you could -- you addressed two issues. One was better data to identify the problem perhaps and the second one was maybe more well-defined actions, so if you were going -- because data will take some time, acknowledging that, do you feel like better defined actions would be helpful?

Dr. Claypool: Well, you know, we have reports of wandering. I am unclear and I haven't done the work that the subcommittee has, what is behind the wandering.

Are there incidences where families aren't getting the proper services and supports to supervise an individual? Are these families that are maybe inattentive to the individual and that we need to have more resources directed towards those families? Do they need additional education?

I am unclear on what the issues are. It's resulting in death and I think that's a very serious matter, but at the same time, if we are to go forward with something, I just think it -- I'm trying to answer your question so I don't want to avoid it. I really think that in terms of data, also I wonder about going into ICD-9 and trying to modify it, because I know the length of time that takes.

But can we do some analysis of the incidents among the population and how often it results in an extreme situation like death, and then start to formulate positions that respond to you know, taking an appropriate action to prevent this type of action?

Ms. Redwood: Excuse me, but I have a question. Were you here when the National Autism Association did their presentation on wandering and elopement?

Dr. Claypool: I don't believe so. I could have been on the phone but --

Ms. Redwood: Because I think that would have been important to hear and then also the several calls that the subcommittee on safety has had on this issue, and did you get a chance to read the letter?

Dr. Claypool: I did.

Ms. Redwood: Because we do talk in here about the importance of collecting data, and we are in the process of collecting data now. We had a meeting during lunch to work on a questionnaire to use the IAN database that the community has come together to fund to get this important data.

But I can't stress this enough. I cannot justify waiting for data when we know this is happening in our community and I would have a difficult time coming back to this committee and having a parent come in here and tell us that their child died from wandering and we were aware of this issue and we failed to act on it as quickly and as expeditiously as we said we would several months ago.

Dr. Claypool: I would be happy to broker a meeting between the group and the Alzheimer's Society to expedite any action on that part. I don't know as it takes a letter to the Secretary to move towards the types of outcomes that you are looking for. That's my primary concern, is that there are opportunities to work with other groups to learn from what they are doing and actually begin to make these options available to families that are dealing with these very serious issues.

Ms. Redwood: We would welcome that. I'm certain Alison would too. But as part of the Combating Autism Act, my understanding is that we are supposed to be informing the Secretary of important issues when they come to our awareness, so we were trying to fulfill our statutory obligations as members of this committee, so that was part of the reason why we felt as though writing a letter to the Secretary, to let her know this was happening and what steps we thought could be taken now to try to help these families and prevent another death.

Dr. Insel: I think we are going to get back into all of this in about half an hour or 45 minutes, and I promised I'd let Henry get out the door by 2 but is there anything else you want to say by way of final comments?

Dr. Claypool: I feel that it's unfortunate that I can't stay for the conversation and it puts me at a disadvantage in responding to some of the discussion that will occur.

Again, my offer is genuine and I would be -- I would happily work with the group to try and take steps that will I think end up basically achieving the same outcomes that you are looking for without having to go through a process of writing to the Secretary on something that arguably calls for more immediate action if this is where people are really concerned.

Perhaps it's trying to reach out to law enforcement to raise awareness of -- I note the use of AMBER Alert and items like that. So my concern is sending it up to the Secretary then there isn't an organ of the department that is responsible for implementation, it will come back down to which office and how much longer will it take for a bureaucracy to move into action that you would like to see.

I think it might be more expeditious for us to identify a few strategic activities, outline them and then empower ourselves as the IACC to take those actions.

Dr. Insel: Okay. That's helpful but as I say we will get back to this. Any way you could join us by phone? Is that an option?

Dr. Claypool: I'll be -- at 3 o'clock I'll be in a meeting.

Dr. Insel: Oh. Okay. Alison yes.

Ms. Singer: So I think all of the

things that you are suggesting are terrific, but why can't they happen in parallel with a letter to the Secretary, because this committee actually has very few power steps to take. There are very few actions we are able to take. The one in the statute is to be advisory to the Secretary, so why would we not want to do all of these items in parallel: advise the Secretary of this issue and simultaneously take steps to collect data, meet with the Alzheimer's associations and do other things?

Dr. Claypool: Because I don't think that there is a real consensus among this body that that action is appropriate. There is -- and again, there's a -- ASD is a very significant group in terms of a broader population of people that are living with other developmental disabilities.

The field of developmental disabilities has moved through things like wandering, like self-determination and has come to resolutions that are perhaps not as apparent to people that are just coming into the movement of other developmental disabilities.

And I just think that if we take the time to work together as a group, that we can benefit from the work that has already been done on behalf of people that are experiencing developmental disabilities like ASD.

And writing to the Secretary isn't going to change that reality. The hard work is going to need to be done still, of trying to bring together the interests of a group that is really struggling mightily to deal with a member of issues, determine what is the cause behind ASD, how best to deal with it in society.

We have a long history in the field of developmental disabilities, which has now kind of morphed into the identification of intellectual disabilities as part of its array and I think that is a healthy way to go.

And I am hopeful that ASD can begin to work with the broader disabilities community to start to resolve some of these issues and to work together to take actions that would address issues like wandering, instead of trying to take action aside or as a unique and distinct part of a broader community.

I think the issues that people with ASD are dealing with are again very similar to those that people with other developmental disabilities have dealt with, and I am just unclear on why the response is -- needs to be so different at this point in time for this population.

I do understand and hear clearly how passionate people are about stopping this behavior. But this behavior exists outside of any label and I'm struggling to try and think of a broader framework that builds a broader coalition of individuals that will allow a stronger agenda to move forward, instead of the fragmenting of this population, which is generally labeled as disability.

It's just a life's work of mine and so I feel strongly about it. I don't know as I'll be dissuaded from pursuing my work, but I would rather see us working together and trying to resolve these differences than having different groups go off and taking action on their own, and again, I understand the passion that people have.

We are trying to stop people from dying. I mean this is really a very important issue and I don't mean to minimize it by saying let's consider a different course of action at this time.

Dr. Insel: So we will -- we'll take all this into consideration at 3 o'clock. Sorry you can't stay with us, but appreciate your sharing those concerns.

We do need to go on with some of the business that we are obligated to complete and that has to do with the final votes on the Strategic Plan. There's an issue about now not the introduction, but the other seven chapters, where we have done all of the text and we have done all of the objectives.

What we hadn't done before were the budgetary requirements and Della will quickly take us through this.

Dr. Hann: Okay, so for our colleagues on the phone we are going back to the draft 2011 Strategic Plan and for everyone in the room that's where we are going as well. Hopefully it is still at your fingertips.

And I thought what we could do is simply walk through each chapter and sort of give everybody a moment to sort of orient themselves.

The comments that regard the budget issues that may have changed, where there was a response, are in green, green for money. So starting with the first chapter, that information is located on pages 6 and 7 of the hard copy. I don't know that it is in the electronic copy, but it's 6 and 7 in the hard copy and it's at the end of the first chapter.

There were one, two, three, four, five areas that were pointed out as potentially needing updates if you will or new information added to them.

Just as we have done in previous years, for those who are a little bit newer to the committee, the budget recommendations generally, we go to funders and ask them essentially if they were to launch an initiative on a given topic that's stated in the objective, what they estimate the costs to be.

So that's where this information is coming from and you will see here we have indicated which funder essentially provided the estimate, just for education purposes. That will be stricken in the final document, just as the green will go away in the final document.

So what I -- unless I hear a comment, what I would like to do is just take these en bloc and not necessarily do them individually.

So looking first at the first chapter, does anyone have any comments or questions with regard to the estimates that have been recently provided?

Okay. Hearing no comments or suggestions, can I have a show in hands of those who approve of the -- of what is stated here, which essentially, some of them have been changed, some have not.

Those in approval?

Okay. One, two, three -- I believe it is unanimous. Anybody on the phone?

Dr. Shore: I approve as well.

Dr. Hann: Okay.

Dr. Insel: Yes. Is anybody else with us on the phone at this point?

Dr. Shore: Stephen Shore is. I

don't know if you can hear me.

Dr. Insel: Yes, we can hear you fine Stephen. Anyone else besides Stephen?

(No response.)

Okay. Thanks.

Dr. Hann: Okay. That's approved. Moving now to the question 2 or chapter 2 on page 14. There were two objectives with -- that have green that actually were recommendations by staff to not recommend any changes in the budget given the wording changes that were done to those objectives.

Jim?

Dr. Battey: Move to accept the recommendation.

Dr. Hann: Okay, we have a move to accept. Do we have a second?

Dr. Shore: I'll second it over the phone.

Dr. Hann: Those in favor?

And I believe it's unanimous except for one. So okay.

Dr. Shore: And I am in favor over the phone.

Dr. Hann: Okay. Motion carries. Third chapter. Going to page 24. There are some in the end that need some attention I think. So I think this pages 24 and 25 for chapter 3. Do we have a motion to accept?

Dr. Shore: So moved.

Dr. Hann: We had a second. I'll take that as a second. Those in favor of accepting?

Okay. It carried. It was not unanimous. There are two that didn't have their hands up.

Dr. Insel: Concerns. Lyn?

Ms. Redwood: I am just wondering about the budget for a workshop being 35,000, if that's really adequate, I'm thinking more in the neighborhood of 50 would be appropriate, especially if you are going to write up proceedings from the workshop and -- I mean -- I guess I thought that was a little on the low side.

Dr. Insel: These are austerity numbers, so we are in a new era where we are very careful about dollars, so yes I think if this was last year we probably would have said 50k but we are trying to do everything as frugally as possible.

Dr. Hann: Okay. Those in favor of the proposals for chapter 3?

Okay. Right

Dr. Shore: I'm in favor on the phone.

Dr. Hann: Thank you. It carries. Yes. Page 34 now for the fourth chapter, this was the interventions chapter and there are two, actually three, excuse me, there are three with recommendations. Give me a moment to orient. Okay. Do we have a motion to accept? Yes.

Second. Geri just raised her hand so I'm assuming he's a second. So those all in favor of these proposed changes?

Okay.

Dr. Shore: I'm in favor too.

Dr. Hann: Okay. Motion carries. Chapter 5. Where can I turn for services? Page 39 with a little tail on 40.

There's an issue with the long-term objective D where the budget is yet to be determined. The different funding agencies weren't quite clear on which one essentially would be responsible for this and as a result there is no budget. Ari?

Mr. Ne'eman: I actually also just wanted to call attention. We are also on 41 and there is also an issue with regards to E, where -- which I at least find somewhat concerning because it would appear that the people providing the budget numbers actually changed the language of the objective in a way that alters meaning, deleting adults and placing youth.

Dr. Hann: Right. So I believe you are correct Ari, there was a change and it has to do with the authority of the agency that was working on it, that that particular agency, reading the note here -- Peter, you may want to speak to this -- would not be covered by that particular agency.

Dr. van Dyck: Our authority under the Combating Autism Act is for children only so we, in turning our stuff back, we wanted to make clear that we do have money to do some of these things, but only for children, not adults.

Mr. Ne'eman: I think -- I understand that and I think the intent with regards to the objective wasn't exclusively with respect to HRSA programs and I guess my hope would be since the Strategic Plan is intended to be of use across the government and also with regards to private funders as well, that we could revert it back to its initial language, or at the very least use adults and youth, you know with the idea that hopefully other funders might consider the original intent of the language.

Dr. Insel: So just a procedural issue here. We really can't change the language at this point, based on the funding needs. We would have to go back to adults. And the hope would be that we can use your experience at HRSA with youth to make some estimate about what it would be for adults.

But it's -- unless the committee wants to go back and re-discuss and revote on this, we can make a decision about what the recommendations were going to be and we shouldn't be changing it at this point based on just the agency funding policies.

So all we are really looking for is a budget estimate as it calls for in the Combating Autism Act or that says budgetary requirement.

And perhaps we can hope that the number from HRA would also translate over broadly. It doesn't have to be perfect but it has to get us into the general ball park of what the cost or the budgetary requirement would be.

And likely that we could use the same number?

Ms. Blackwell: Yes, this is Ellen. I would say that what I would recommend is exactly what you just said Tom, make sure that the language stays the way it was, referring to adults, and people with ASD and then the budget assumptions look good so just leave them the way they are with just the dollar sign.

Dr. Insel: Okay, but for the committee I think it's important to know that the language as Ari says has to go back to where we started, not based on these kind of last-minute changes.

Okay, and then what about for the long-term objective D. So it says budget to be determined. Is that -- what's the plan for providing a number, since it's required to have some budgetary estimate?

Yes, so Susan is asking is there anybody here who could provide an estimate. Sharon you mentioned before that there is a whole research base for this kind of work. Is there -- again it doesn't have to be to the nearest dollar or even the nearest 100,000, but something that will give us a sense.

Ms. Lewis: Sure, well, right now we have a collaborative of six university centers and several other partners working together on a national training initiative that I think -- and I apologize, I'm doing this off the top of my head -- but I think it's $800,000 a year for five years, to develop a series of products related to demonstration of scaling up of self-determination practices across a variety of environments.

So I mean I think to look at two strategies or programs, I mean, I'm guessing, you know, $400,000, 500, I mean --

Dr. Insel: Geri.

Dr. Dawson: So I just want to point out that the -- I think the intent of this long-term objective is focused on health and safety and then we added the other phrase because as you address the issues on health and safety, it's important to keep in mind issues around self-determination and personal autonomy.

But it's not really a program on self-determination, right? So, and I think Coleen, you might have some ideas --

Dr. Boyle: I was just going to opt for $2 million over two years. That would be my -- if I had to guess.

Dr. Insel: So $2 million would be the total cost over two years?

Dr. Boyle: Yes, over two years.

Dr. Insel: Does anybody have a different sense of this?

Dr. Boyle: If you were going to use an existing structure, like the LEN or the UCEDD programs.

Dr. Insel: Okay. Sold. Done. Okay. Della, you could put that in as a budget.

Dr. Hann: Okay, so in terms then of considering for question 5, where can I turn for services, it's everything that is currently printed with the following exceptions: D under long-term objective would be $2 million over two years, and E would revert to its original language and, but use the current estimates for those studies.

So moved? Any second?

Dr. Shore: I'll second it.

Dr. Hann: Those in favor? It appears to be unanimous.

Dr. Shore: And I'll say in favor on the phone.

Dr. Hann: Great, thank you Stephen. Chapter 6. I think we run into some other issue.

Dr. Insel: Right. This is on page 48?

Dr. Hann: Yes. This is a similar issue to what we just discussed, in terms of what is on page 48, which is the budget estimate for long-term objective C.

Ms. Blackwell: I actually think that when we did this we were suggesting a particular item, so the budget estimate from the 2010 plan wouldn't be altered.

Dr. Hann: Any further discussion? Okay. Then to -- that's the only item, and so that would be to keep it as it was in the 2010 plan with the $6 million. No change. Okay.

Those in favor? Okay.

Dr. Shore: On the phone too.

Dr. Hann: Okay, thank you. Okay. Chapter 7.

Dr. Insel: This is pages 58 and 60.

Dr. Hann: Okay. So there is an item at the bottom of 58 and then on page 60 there are three items. So do I have a motion to accept?

Dr. Shore: So moved on the phone.

Dr. Hann: Okay. Those in favor?

It's unanimous in the room.

Dr. Shore: And on the phone.

Dr. Hann: Thank you Stephen. That concludes the budget update.

Dr. Insel: All right. So does that mean our Strategic Plan is good to go? There will be a few syntax issues that OARC will work with, but we can assume that this will go forward to the Secretary over the next very few days.

Congratulations. Ari?

Mr. Ne'eman: Just one question. Will we get a chance to look at the final language just to make sure that -- there are one or two areas where we were not looking at the writing in front of us. Will we get a chance to have this emailed out to us before this goes to the Secretary in case there are any --

Dr. Insel: Well, the issue with

that is there wouldn't be any other chance to discuss it, and because everything that we would determine on something like this has to be in an open session, in a public session, what you see here is what we will get.

I don't think there's going to be another opportunity unless the committee wants to meet an additional time before this goes forward, and it really needs to go out this week.

Mr. Ne'eman: I don't think that's necessary. The only area where I had a particular concern is I was wondering if Della could just read the language we approved on with regards to the self-determination crosscutting theme, just to make sure we are on the same page on that.

Dr. Hann: Okay.

Mr. Ne'eman: There were a lot of discussions about edits flying around at once and I don't think we ever read the final version out loud.

Dr. Hann: Yes. Yes. So I have that the group decided to start with this sentence: people with ASD can, with educational supports and accommodations, acquire skills to lead self-determined lives.

Second sentence would be the Wehmeyer sentence: Wehmeyer et al defined self-determined behaviors as human behavior that is caused e.g. determined by the person as opposed to being caused by someone or something else.

People leading self-determined lives make or cause things to happen, so that sentence stays as is. Then the last sentence will need to be modified slightly because the very first sentence, which is, "It is essential that ASD-related research incorporate and promote principles of self-determination" and the final sentence, "Self-determination must be promoted through various types of research," are very, very close in meaning.

So those two sentences will have to be melded essentially to produce a statement at the end.

Mr. Ne'eman: Could we just, in the interests of resolving now, just suggest that we keep the existing final sentence and unless anybody feels strongly about it, just get rid of the sentence that is currently the first sentence?

Dr. Hann: Works for me.

Dr. Insel: Is that okay by the committee? Done. Sold. Okay, we are going to circle back to -- Walter.

Dr. Koroshetz: I apologize, I just wanted to ask one thing. So on the budget on page 58, there is a note saying that to accomplish they three bullets would require an extra $50 million, and that is for a brain atlas of 50 people? Is that what the meaning there is? Because it sounds like maybe we should reconsider.

Dr. Daniels: I believe the 50 is

added already onto the 32, because if you add 50 to the 32, you get 82.

Dr. Koroshetz: But the 50 is for a brain atlas with 50 people in it? Is that what that was supposed to say? Or am I misreading it?

Dr. Insel: I don't think that piece will go into the Plan. It's just the final figure that would be in the Plan.

Dr. Daniels: It was just a note from the program staff to explain their decision.

Dr. Koroshetz: The question is, do we want to invest 50 -- I mean, if the meaning is as it says, it's $50 million for a brain atlas of 50 people. That's a million dollar per person -- I feel a little weird about that kind of money for that purpose, but --

Dr. Insel: So we just invested $35 million to do this already, but not in autism, but to get the control data with a transcriptional atlas, three-dimensional, cross-development, and it was -- not 100 -- it was a small number with probably -- actually I don't know what the final number will be, but it's going to be less than 50.

It's very expensive, but that will be our reference, and then from that there will be an opportunity to do more, hopefully. Good project for Simons Foundation or Autism Speaks to look at as well, by the way.

Okay. Speaking of Autism Speaks, we had skipped at the beginning of the day because both Geri and Alison were delayed because of the weather, so I wanted to make sure, since we have a couple of minutes now, more than a couple, we have about 15, if we could double back to the first part of the day and just get an update from Autism Speaks and the Autism Science Foundation.

So Geri, would you like to go first?

Dr. Dawson: So I wanted to report

on a meeting that we co-sponsored with Pfizer that was held last week. This is part of an initiative on translational medicine research and one of the meetings was focused on the development of outcome measures for clinical trials in autism, which as you know the IACC has identified as one of the areas that needs to be further developed.

There were 45 people who attended. It included parents, academics, scientists, industry leaders and NIH staff, as well as people from Autism Speaks.

The objectives of the meeting were to promote collaboration and cross-fertilization among the academic community, industry, NIH and other funders, to share ideas among both the industry and academic community about ways of optimizing success of clinical trials and then to begin to build a consensus among stakeholders regarding the appropriate outcome measures.

And this is something that has

been done in other fields, which is very important when you start to move towards FDA approval, and then to identify gaps and opportunities for future research and strategies for accelerating progress.

We had four sessions. The first was perspectives and lessons learned from industry and NIH-sponsored clinical trials.

The second focused on measuring core symptoms of autism: core constructs, measures of change and future needs.

The third focused on very early interventions, learning, plasticity and neuropsychological approaches.

And the fourth focused on outcome measures that address associated symptoms such as anxiety and irritability and so forth.

The recommendations at the end of the meeting were that there is a need to form consensus working groups that involves NIH and funders, industry and the FDA so that we get buy-in right from the get-go of what the endgame is and what the FDA will require.

That there is a need for greater cross-fertilization between the clinical researchers and the folks that are working at the preclinical stage of drug discovery, and we talked about different strategies for doing that.

And third the development of a white paper or a publication summarizing the meeting, where we stand, what do we need.

And then finally we identified three areas in need of research funding. One is funding specifically on measurement development, which is something that is sometimes hard to get funded, although some of the academic folks did point out that they were able to include that as a third specific gain to NIH and it had worked out, so it's possible.

The second is funding of studies that use innovative study designs and we talked about many different statistical approaches such as the smart designs, the adaptive designs, the use of biomarkers, innovative technologies, so we focused one part of the discussion was on using everything from iPads to other kinds of sensors to use as outcome measures.

And also some very interesting approaches that involved back-translation from animal models to humans, and then finally novel treatment approaches, particularly there was a strong interest in combining pharmacological and behavioral treatments in clinical trials.

Dr. Insel: Great. Any comments or questions? Alison?

Ms. Singer: Was there any consensus with regard to standardization of outcome measures or just --

Dr. Dawson: Well, one of the things that we did in preparation for the meeting, one of my graduate students from the University of Washington compiled a comprehensive list of the outcome measures that have been used in clinical trials, including also measures of side-effects and so forth, and we did talk about those measures and people shared with each other what had been you know, most sensitive to change, and issues around reliability and even issues like, we had folks from fragile X there who had done a lot of work on measurement development where they had tested what measures work with individuals who are nonverbal.

So it was a real kind of nuts and bolts kind of meeting like that. So it wasn't consensus but a lot of information-sharing and then a feeling that we need to work towards consensus and some areas there truly is just a gap in what is available.

Dr. Insel: Geri, maybe you mentioned it. Was the FDA at the meeting?

Dr. Dawson: Well it's interesting because we did invite the FDA, and but we were not successful in getting them there, but I know Sue Swedo was there and she talked about, in, I think it was schizophrenia, that there had been working groups that involved the FDA from the beginning and that that had been very effective, so that was definitely something that people talked about as necessary. But we weren't able to get them to this meeting.

Dr. Insel: I would just second Sue's comment. We went through this about seven or eight years ago on cognitive deficits in schizophrenia. The two things we learned from that were first, get the FDA in at the beginning so they bless whatever it is the group comes up with, and the second is to make the transition from these experimental measures to real-world measures as quickly as possible, because yes, you want something that is very rigorous and quantitative and you can show change, but if it doesn't translate into somebody actually being able to function any better, it's not really helpful.

So, it took us a while to get around to that step and that turns out to be something that -- I think it was a lesson learned, that we should have done that at the beginning.

Anything else from the group? Alison, also, you are on the list for giving an update so the floor is yours.

Ms. Singer: Well, the Autism Science Foundation is a relatively new organization. We were founded 21 months ago and our mission is basically to fund outstanding autism research, predominantly in the areas of what causes autism and in developing and building the evidence base for treatments.

We are parent-led organization. We were founded by parents of children with autism and scientists who are working together. We are currently in our -- under grant review for our second round of pre-doctoral grants and post-doctoral fellowships and we expect to announce the recipients of these grants at the end of March.

Over the last few weeks we have also started working with other autism advocacy groups to organize the study and gather data on autism-related wandering through the IAN network.

We also have a program that we implemented last year that we are going to run again this year where we offer scholarships for stakeholders to attend the International Meeting for Autism Research.

Last year we gave scholarships to parents, to special education teachers, to individuals with autism, to siblings, to undergraduate students, bloggers. It was a great group and we plan to offer those scholarships again this year.

And we are also very active in disseminating science. We have programs that bring parents together with scientists, and not just parents but other stakeholders as well, both in-person meetings and online meetings, to talk about research, because we think that this give and take and sharing of information is really a critical part of the research process.

So we have several of those events coming up and I invite you all to participate and they are all listed on our website.

Dr. Insel: Great. Comments or questions for Alison? Okay. So as I said, we will be doing this at each meeting and we will be looking for volunteers for the next meeting to give just these three or four minute updates. Very helpful.

We are coming up on what was scheduled to be a break, but I would like to suggest that we continue to work, because we got a late start after lunch and unless anybody has a concern with that, let's keep going and move into the next topic, which is something we already began to talk about, which was the subcommittee on safety report.

So if I can have Sharon, Lyn and Alison get the full committee up to date on the Safety Subcommittee's work.

Ms. Singer: I'm happy to start off. Okay, as you heard today, the committee on safety really came together as a result of the presentation made at our last full -- two IACC meetings ago by the National Autism Association and particularly the public comments made by Sheila Medlam concerning the drowning death of her son.

The committee has been very active. Our first task from the IACC was to draft a letter to the Secretary outlining the issues behind wandering and we have met several times to work on that.

So first the committee met to discuss issues to include in the letter. That draft was then circulated by email prior to our last IACC meeting but many of the committee members felt that they needed more time to build consensus around the letter and to have additional input into the letter, so we did not at that time bring the letter to the full IACC.

Subsequent to that, the committee chairs met, the three of us met. Sharon became a co-chair of the committee. The three of us met to talk about the letter and to make revisions and Sharon gave us some great input.

We were really, I know I'm speaking for Lyn here, but we're very grateful for the input that Sharon gave. It really helped to strengthen the letter.

Subsequent to that, the full subcommittee met and the subcommittee basically agreed to the text that you have in front of you today, with the exception of one area where there were two different proposals submitted.

So, the -- really the differences between version 1 and version 2, if you look at the first one, two, three -- six lines, they are the same with regard to collecting data.

Version 1 really just gets more into the issue of the need for a specific medical sub-classification coding or general medical coding for autism spectrum disorder-related wandering, which would be similar to existing codes for dementia-related wandering and Alzheimer's with wandering.

The idea here is that the medical sub-classification would not only help us to collect the data, but it would also enable families to have greater access to wandering preventive devices.

I think right now those devices are available to families who have the means to purchase them, but there are families for whom it's not covered by insurance because no medical sub-classification exists and we didn't feel that it was appropriate for the decision to be made based on finances.

So that's really version 1. I'm going to ask Sharon to describe version 2.

Ms. Lewis: Well, version 2 is acknowledging kind of Henry's point around the fact that we need additional data and information before we make specific action recommendations and really that's the direction that that language came from, from a couple of members of the subcommittee.

I also wanted to just add by way of context the dynamic in the Safety Subcommittee was that we came forward to work on this task of the letter out of the October IACC meeting as requested by the full IACC.

And as the subcommittee chair, and Alison and Lyn know this, I have great reservations about elevating this issue as the only letter that the IACC has ever produced to send to the Secretary, in general, as a broader context.

And while we have worked hard to come to consensus with the letter, on the letter itself, and I think the letter is as -- is representative of the conversations within the subcommittee, I continue to have reservations and to reinforce Henry's point, around elevating wandering above all issues, and that's not to say that this isn't an important and urgent issue that the IACC needs to discuss and address and that the public has been very interested in.

I just wonder, in the broad context of the IACC, about elevating something as narrow as this issue of wandering as opposed to looking at health and safety more broadly, or the wide range of issues that are raised every time we meet at the IACC.

So I will open it up to discussion and have Lyn and Alison add any other comments that they have.

Dr. Insel: Or anybody else who is on the Safety Subcommittee who wants to chime in here. Ellen?

Ms. Blackwell: I am actually not on the Safety Subcommittee but I have been listening to its meetings and I share Sharon's concerns. I certainly agree with her that this is a serious issue, but my feeling is that if we send the Secretary a letter at all, it should be focused on overall health and safety issues, of which there are many.

So I think with that we should throw it out for discussion.

Dr. Insel: I want to go around the table. Lee, Ari and then Coleen.

Mr. Grossman: I just have a clarifying question. And what Federal agency is responsible or oversees the diagnostic criteria, the ICDs?

Dr. Boyle: So, we are working with NCHS in terms of the code itself, but that is part of CDC. There's a separate committee that is external but we are working through them. They are our --

Mr. Grossman: I guess, does the Secretary have influence over the diagnostic --

Dr. Insel: It's actually a WHO

classification, so -- and it is being redone but not until 2013, or `14 -- they just put it off another year.

Dr. Boyle: Or `14 -- just to put this in context, one of the reasons we moved quickly is the window was closing on January 7th for anything to be added to ICD-9. So we put the proposal in. We would have to actually wait until 2013 or `14, exactly.

This is a secondary code, this is not a primary code.

Dr. Daniels: And by way of just correction, in version 2, that should be ICD-9 not ICD-10 at the end of -- at the bottom of the page.

Dr. Insel: Ari.

Mr. Ne'eman: So, you know, I have to echo the concerns that were raised, that as important as this wandering/elopement issue is, I think if we are going to be communicating with the Secretary, we also need to look at the broader scope of safety issues including caregiver abuse, restraint and seclusion and a number of other areas.

But I also want to add another area of concern, that you know, leads me to feel that version 2 is the more appropriate option, which is namely, we haven't seen any research -- first we have seen very little research on this topic in general, but we haven't seen any research that suggests that it's best approached in the context of a medical issue rather than a behavioral issue, and that the -- and I think there are some fairly significant implications there, both as to what causes wandering, but also as to whether or not the more appropriate response is in the context of a diagnostic code or in the context of a human services or service provision response.

So you know, I guess the two things I would raise here are: a) I think there's definitely a substantial services component of this, so this is something that should probably be explored additionally by the Services Subcommittee; but b) and I noticed we actually have some public comment which speaks to this issue as well, in the written public comment, I think it may be premature to place this in a medical context when we don't have the research that would support that, as critical an issue as this is.

Dr. Insel: Coleen, you had your hand up.

Dr. Boyle: I guess I wanted to give a little context relative to another committee I sit on, where -- not that we want to be writing a lot of letters to the Secretary, but we have written a number of letters, and it's on newborn screening and it has a long acronym.

But the issue is on medical foods and the reimbursements for medical foods for children with PKU and other inborn errors of metabolism, so it's a fairly tight issue like this one is.

Again, I'm trying to draw parallels. We actually don't have a lot of hard data. It's more anecdotal data, similar to this one. But in the context of parent concerns, we have made some specific recommendations to the Secretary that she has helped facilitate action on.

And so again, even though I hear everyone's concerns about this being a fairly narrow issue without data there, I think that we know the urgency of the issue as with medical foods and inborn errors of metabolism, and we have some specific actions that we are asking of.

So again, just trying to draw on other experience outside this realm to maybe help the committee members put this into context.

Dr. Insel: Ari and then Alison, do you have your -- okay. Ari, Denise and then Geri.

Mr. Ne'eman: So I guess just to

respond to that, you know I understand the context with which you are placing it, but you know, I have to ask whether or not a diagnostic sub-classification, even a secondary one, is a wise option at this juncture, given that in the context of this issue, wandering, there are two very different potential ways of looking at it, two very different potential models of causation.

And if it is a medical condition, then it may very well make sense to create this medical sub-classification and to have these things covered by insurance in order to address them.

If it's primarily a behavioral issue, then I think that the recommendations that need to be made are still important recommendations to shift the burden from families to another payer, but the recommendations are more in the context of changes to Medicaid, changes in the way that residential service provision is approached, changes in the kinds of supports that are available to families.

And I would add that there is a wealth of different presentations and research and other things that exist in the broader field that we haven't heard presentations on, that go in that direction.

So once again, I do think it's important for us to keep in mind there are two very distinct ways of looking at this issue with hugely different implications and before we explore really either -- since we haven't really explored in detail either of them from a research-based perspective, it may be premature for us to endorse one.

Dr. Insel: Denise.

Ms. Resnik: Considering that safety is a broader issue, and considering the sense of urgency and the fact the committee has worked hard and that we do have a sunset clause as it relates to this body, in September, that my recommendation is perhaps we add something to the introduction of this that identifies safety, identifies some of the other areas, then this can be one of a series of forthcoming recommendations, just so we put it into context from a communications perspective and what -- we can manage expectations for what could be forthcoming from this committee.

And you go ahead and advance this but that we broaden the intro and then look forward to submitting future recommendations.

Dr. Insel: So, Lyn, when she was responding to Henry, said that it's one of the charges to the committee, is to send forward to the Secretary anything that we hear that we think is important for her to know as her advisory body.

Would it make sense to actually start the letter there and just say you know, writing to you in that context, this is a topic we have heard about which we feel you need to know about in the way that we have been hearing about it, something like -- to that effect, and you could put it into the broader context.

It struck me that the letter didn't kind of introduce where any of this came from or why we were letting her know this, and it is in fact part of our mandate. It's pretty explicit in the Combating Autism Act.

I think that -- Geri.

Dr. Dawson: Well I agree. I was actually going to make the same suggestion that I think if we put it in the broader context of issues related for example to health and safety, particularly because it is the Secretary of Health, I think that makes a lot of sense.

I would not be uncomfortable with sending a letter around a specific, targeted issue. I think that that's a very reasonable thing to do. I think your example is an example of that. I know that we do that a lot.

And I don't think it takes away from other letters or anything like that.

I guess the reason why I feel compelled for us to move forward is threefold. One is that I think it's important in terms of demonstrating the responsiveness of this group to the public voice and this was a, I think it's a kind of a high-profile, very compelling situation where we actually made a statement publicly that we were going to do this. We've had people work on it.

And I think that it sends maybe the wrong signal now to backtrack because no, now we have to have further deliberations about you know, the meaning, the context et cetera.

The second thing is that this particular issue has very important consequences, because we are talking about children who are being -- perhaps dying or other serious accidents, and I think the analogy would be when the AMBER Alert came, you could step back and say well you know, there's many things that children are struggling with in terms of you know, nutrition, and child abuse and so forth, but so we need to wait now and look at all those issues.

Now, there's a targeted issue, there was a feeling you could do something concrete about it. You could act quickly. So people did that, and I think that that is sometimes important to do.

And the third thing I think, just having functioned as a clinician for decades where I have seen many children that wander or run or -- I would say that you know, there is a character to this phenomenon when it exists, that is very different than someone simply trying to escape because they don't -- out of choice or self-determination, and I think it has to do with a combination of impulse control, a lack of awareness around danger and safety, and sometimes combined with an obsessive desire or need.

And when those things converge together, which is really part of autism, it's extremely hard for even the most attentive teacher or parent to deal with, and I've worked on cases like this and they are just extremely challenging, so if there's anything we can do, I think, to address it, I would like to see us move forward.

Dr. Insel: So in listening to this, it seems like there are two levels that we may want to consider. The first question is, do we send a letter at all, and you heard from Henry and Sharon to some extent and maybe Ellen having some reservations about sending a letter on this topic at this time.

The second would be what -- if we are going to do it -- what the letter says. Can we get a sense from the group about whether to send a letter on this topic at all? Where is the committee on that?

How many of you would like to see

us send something forward then we can worry about the details?

Dr. Hann: One, two, three, four, five, six, seven --

Mr. Ne'eman: It's a little bit hard for us to vote on a letter to be determined later.

Dr. Insel: Well, Henry was quite clear that he doesn't think we should send a letter and he is a member of the committee who works for the Secretary and has a pretty good sense of how this might be viewed or what would be -- what will happen with it.

So I would take his comments to heart and you know --

Ms. Blackwell: I would be okay -- I certainly don't want to speak for Henry -- if we delved a little deeper into sending a letter that looked at the array of health and safety issues, as Ari mentioned: abuse, neglect, seclusion and restraint, we had a very moving presentation from Kevin Ann

Huckshorn from the state of Delaware.

So we do have information on the Services Subcommittee about some of these other safety issues, so you know, that -- I'm reluctant to raise my hand or not raise my hand because I would be okay with that sort of letter.

Dr. Insel: Right, but if the majority of the committee felt we shouldn't send a letter forward at all then there would be no point in talking about what would go in it.

It's clear that, with a couple of exceptions, people would like to see something go forward and now we can figure out exactly how to scope that and what you want in it.

It sounds again like the two ranges of this are something very broad and then others who have said we could introduce a broad topic but then fairly quickly specify that this was an item that requires unique attention at this point in time. Sharon?

Ms. Lewis: And I want to be clear. I think communicating that this is an important issue is important. My question again is contextual in terms of the broad number of issues that we are concerned about that are high priority.

Having just spent several months and having met with over 700 individuals and families including many, many with autism across the country the last few months, I can tell you unequivocally of the hundreds of issues that folks brought forward to the Administration on Developmental Disabilities, wandering did not come up.

It was, you know, adult services and supports, it was abuse in both institutional and non-institutional settings. There was a whole range of health and safety issues and you know, I would be very supportive of considering a letter that acknowledges that this is but one of many issues.

But I am very concerned about elevating this at the cost of other priorities.

Ms. Redwood: I guess I don't see how it would be at a cost of other priorities, and if the safety -- excuse me, Services Subcommittee would want to send a letter too, addressing some of the concerns with services, I think we would welcome that.

I don't think there's any limit. Someone mentioned about this letter where we are going to update the Secretary on several issues, but I'd just really hate to see us drag our feet on this any longer.

And I think we can accomplish -- we have worked hard on the letter, if you read the letter, we are updating the Secretary on what we have been informed are concerns, and we are asking for her guidance and consideration on these issues.

Mr. Ne'eman: Lyn, I think this is, at least to some degree, a services issue.

I mean I think the concern Sharon is raising is that there is a broader context if the first and so far the only letter we send is focused on this one issue.

I would suggest that perhaps we should give the Services Subcommittee a chance to review this letter and make edits to this letter, make additions on other high priority issues that should go into it, and then, when we have had that time for deliberation and for consideration of what the research really does say, that we should send the Secretary something.

And in part that is not just because of a disagreement as to what should go in here, it's because, when we send the Secretary something, I want her to take action and I don't think she is going to do that if we give an impression of lack of seriousness based on not having considered or included meaningful supporting research.

Dr. Insel: Walter.

Dr. Koroshetz: So, I feel that, hearing the stories that we heard, and the data that we heard, it seems hard to just let that lie, that the consequence is death. And even though it is maybe a small number, there are concrete things that are time-dependent that were brought out that might help.

So if, for instance, as Henry said -- I agree with him -- that we are probably going in with one arm behind our back when we go in on autism alone, and to think about partnering with other disability groups, because, as mentioned in version 1, the CDC is going in in March of 2011 to a meeting trying to propose that wandering be added to the ICD code for conditions with autism and other things.

So I think that the least we can do is get behind that action. I think -- I feel like it's our responsibility to do that, and I think also, the other thing that struck me, is the issue of there are systems that are out there working for similar conditions, and the fact that, I think it was made very poignantly, that if those systems cannot be activated for a child who is much higher risk of getting into trouble than a patient with Alzheimer's, it just seems like a disconnect.

So there seems to be some really -- I agree that there is -- we are not addressing all the safety issues. But I don't think that's necessarily what this is about. This is about a focal problem, potential solution, some time-dependent things going on.

So I feel good about trying to make a statement and getting behind the other disabilities.

Dr. Insel: I saw hands from Alison, Josie and Yvette and then we'll come around.

Ms. Singer: Well, I wanted to respond to something raised a few comments ago, which is the reason that the safety committee wrote the letter on wandering was because the full IACC acted with urgency to create the Safety Subcommittee, voted unanimously to do so, and charged the Safety Subcommittee with drafting a letter on wandering.

So we are sort of now revisiting an issue with which we acted with great urgency and saying well maybe it's not so urgent after all, which you know, I would argue that when children's lives are literally at stake, this is an issue over which we must act with great urgency.

I liked Denise's idea of beginning the letter by outlining that this is one of many safety issues that affect the autism community. But I also think that we need to move forward with this letter focused on wandering because this is the issue that the full IACC agreed, unanimously, was the one we should address first.

Dr. Insel: Josie.

Dr. Briggs: Just seconding some

of the points Walter made. I think the key reason this is an actionable recommendation comes down to the question of the ICD-9 or ICD-10 modification for wandering. And I would be interested in whether Dr. Claypool feels that there are strong arguments against that modification. It seems to me there is a -- I'm not sure if there's a debate here as to whether it's desirable to modify the ICD-9 codes or not.

But to me it sounds very sensible and very actionable.

Dr. Insel: Yes, so I'm not sure I can fully channel Henry, but I think what he would say if he were here is that it may be a good thing to do, but it's not something the Secretary is going to do and there's nothing she can do about it.

All she would do is to turn to the CDC and say go forth and do this, and yet if it's coming from the CDC anyway, so what's the point?

Dr. Briggs: I see.

Dr. Insel: So I think that's where -- what he was trying to imply and in fact he said that, that you know, she would just take these things and then look for who would do them in the department and she might very well turn around and say this is a great thing for the IACC to do, for all we know.

But I think that's what he was concerned about.

Dr. Briggs: We don't set ICD-9 codes. I mean --

Dr. Insel: Right, but for that matter actually, CDC doesn't either. It really comes down to WHO. Ari, and then Lee.

Mr. Ne'eman: Just again to provide some additional context. While I also can't channel Henry, I do know that there is debate on the issue of whether or not there should be a medical sub-classification coding and that the version of the letter put forward by Lyn and Alison currently recommends that there should be and the version of the letter put forward by Sharon currently recommends that there should not be.

So you know, that's the context -- that's just some additional context to respond to your question.

Dr. Insel: I think Lee and then Yvette and then Geri.

Mr. Grossman: I want the committee to please understand my sensitivity around this issue. My son wandered and wandered quite a bit unfortunately and we had to find -- we marched him around to various different school programs until we found a program that could adequately keep him from eloping.

So it is something I am very cognizant of personally, as well as having attended funerals of children that have died from wandering.

So it's in that context that this is a very important issue to me as well as to the autism community. The issue that I have, though, with the letter, is that I am still having a hard time understanding what in here justifies the letter to the Secretary.

The ICD-9 classification seems like that's something that we could just act on. There's action here for the Department of Education. The AMBER Alert, Silver Alert as far as I know are more of a jurisdiction and legislative activity that are, again, outside of the purview of the Secretary.

My organization has been working on safety issues for years. We have had committees, we have had conferences around that. We have tried a number of these things and I'm not really sure what the Secretary would accomplish in a letter like this.

Now raising the whole issue of safety concerns I think would be -- and also, from my recall, the first discussion we had about the safety committee was that they were going to -- there would be a review of all safety concerns in addition to wandering.

And I think if we put that in a context of raising it, which I think is important, that we should raise those concerns to the Secretary with more general concerns as well as actionable items, which would involve developing a better understanding of behavioral programs and understanding of what causes people to wander in the first place and what steps we can take to prevent it and improve services and support so that people can feel more comfortable in their environments, that would be a better use of a letter.

So I would suggest that we, as much as I hate to curtail this any longer, because it is an important issue, I think that this letter still needs a lot of work.

Dr. Insel: Geri, Yvette and then Denise.

Dr. Dawson: So I want to first respond to the issue of the letter implying that there would be an automatic change in the ICD-9 and you know, what it says actually is investigate the use of a medical sub-classification coding, right?

So it really does -- so let's say that the Secretary reads this and charges someone with thinking about that carefully, meeting with families, medical practitioners, reviewing the ICD-9, the Alzheimer's group et cetera, and then making kind of a decision on that, so I think that's important to point out.

And then I just want to respond to your comments Lee. I guess, why send a letter to the Secretary? Well, it is what you are charged to do, right? That is what the IACC is charged to do, is to make recommendations to the Secretary.

Why on this topic? I think issues around safety and health are of particular interest to the Secretary and this is one, I would hope, of many letters.

So we are starting with one letter that the committee felt needed to be addressed with urgency, and I think if it's put in the context of we have a number of issues we want to bring up, we are going to start with this one because it's timely, it's urgent, because of its urgency, but you know you will be hearing from us, so to speak. I think that's perfectly reasonable.

Dr. Insel: Yvette.

Dr. Janvier: I would like to echo some of what Walter had to say. I mean I've been on this committee three plus years and this is the only life-threatening issue that has come to our attention. I think our mission was to create a research plan. We have done that. Thank God we are struggling so much this year as we have in the past.

But this is truly the only life-threatening issue that has come to our attention, so I think it is reasonable to address it. This committee answers to the

Secretary. Why not send it?

You know I kind of get the sense that people are going to get a trickle-down effect in that department, but so what? I mean I live in a state where there's mandatory training for all law enforcement and first responders on autism.

Some of them are getting it face to face, some of them are getting it online, but there is mandatory training. I can't tell you how many kids come into my office with their little radio devices given out through the sheriff's departments. They pay for the batteries and that's it. If they can't afford the batteries they don't have to pay for that.

I probably am the only one here who does use the ICD-9 billing codes and diagnosis codes on a daily basis. It is not a big deal for me to code 299.00 for autism and then to have a 700 code for headache or constipation or wandering or whatever you would like to call it. I don't even know that wandering is the best conceptualization, to be honest with you, it's something they found and adopted from Alzheimer's.

But I do think it is important to come up with a code for these safety-affected behaviors and to advocate for that, absolutely. But again, I just don't see, why not send the letter? Maybe the letter isn't perfect but why not? We report to the Secretary and I think we should let her know this concern.

Dr. Insel: Denise.

Ms. Resnik: And I think to Alison's point earlier, in terms of setting up this subcommittee with the purpose of making recommendations, and truly I don't think this letter would stand out as much if on a regular basis we were doing this type of thing.

So I think let's set ourselves up for the New Year. Let's identify from the services workshop, Sharon, the outreach that you have done, I think there are a number of topics, one a month, through September, you know, where we could be informing the Secretary on issues that are of importance to this community.

So I would like to see us move forward with a safety letter.

Dr. Insel: Ari?

Mr. Ne'eman: I just, you know, with all due respect, I want to take issue to some degree with Yvette's comment that this is the first issue we have ever seen that has been life-threatening.

We heard presentations on restraint and seclusion during the Services Subcommittee. I have spoken with and worked with families whose children have been murdered as a result of restraint and seclusion.

We have heard presentations on housing. I would encourage you to spend some time talking with adults on the spectrum who have experienced homelessness and the life-threatening nature of experiences like that.

And you know, I think it's simply not accurate to state that this is the only life-threatening or critical issue that we are looking at, because the truth of the matter is, is that there are a lot of different areas where people's lives are on the line.

And I would hate for us to do something that would imply a lack of attention or lack of priority given to those other critical areas because of our desire to move forward fast on this one.

Ms. Resnik: My suggestion is those would be -- that would be the beginning of the types of recommendations that we would want to be and briefing, so we would want to provide for the Secretary those things that would be life-threatening.

I think if we put it in a broader context over the next few months, that you know, let's move on something, otherwise we just keep planning and I would really like to see something get to the Secretary so that we can honor our word in terms of what we are supposed to be doing.

And I think we can solve this -- some of this discussion if we spent some time talking about what those next topics are and teeing it up and moving forward.

Dr. Insel: Is there anything more to say? It sounds like there is a split in the committee and I am not sure we are going to get everybody on board, but the letter that goes forth doesn't go from the subcommittee, it goes from the full IACC.

So we do need to undertake this as a vote, and if it isn't a consensus, it's still possible to reflect that in the letter. Ari?

Mr. Ne'eman: The only query I have, and I'm not sure that I want to do this, but just as a point of order, I am just sort of curious. On other committees I've served on, when a document moves forward and is sent to the authorizing body, be it a legislator or public official, and there is not unanimity, it is possible to include a minority report which would be incorporated and sent with the majority document.

Is that something that the IACC - is there anything in the IACC's authorizing statute or other rules that would preclude members of the committee from doing that, regardless of how the vote goes?

Dr. Insel: I think what you are asking is whether the committee as a group would like to frame this report in such a way they would have both the majority report as well as a minority report that would be part of it. It wouldn't be possible for the IACC to send forward a separate document that represents only a small fraction of the committee.

Mr. Ne'eman: No, I recognize that. My question was only, with other committees, typically when a document is sent forward, it's possible for individual committees to attach a -- individual committee members, either collectively or individually, to attach a dissent from the majority document.

And once again I am not saying that that is my intent. I'd certainly have to think more carefully about it. But just as a procedural issue, I'm curious on the matter.

Dr. Insel: I don't think there's anything that precludes us from doing that but it's certainly not in the act itself, but this would be a conversation to have with your colleagues on the committee to see what they want to do.

One of the things I'm hearing, though, it sounds like there's a groundswell but not a consensus of sending something like this letter forward, is there are concerns about specific aspects of the letter.

So Denise had some recommendations about the introductory part. There is, in this, sort of two versions that the committee would have to choose between and others have wondered whether this is quite ready or whether there is still some work to be done here.

So I wonder how the committee wants to move forward on those three points. Lyn, what is your sense?

Ms. Redwood: Well, I was just going to say that we have had several phone calls and several meetings and we worked hard on the first draft of the letter and we didn't get a lot of input from some of the members of the committee until we were presenting it to the actual committee.

So we delayed it last time to have more conversations and more input and we have been diligently doing that and trying to reach consensus and so I hesitate to go back again and I would like to see the committee vote on this letter and what version they would like to send because my understanding is the vote we took previously was to move forward with sending a letter.

So I agree that we can send letters after this and this should be one in a series of letters, but I just really want to put forth, I believe Alison feels the same way, that we send something today and we make a decision today to act on this or not act on this and not delay it any further because it's reaching the point of being very unproductive.

Dr. Insel: Ellen?

Ms. Blackwell: If the committee in total elects to send the letter forward then I think that Denise's proposal should include language specifically mentioning other issues that relate to the health and safety of people with autism including seclusion and restraint, caregiver abuse to caregivers and from caregivers, issues related to the criminal justice system, bullying, abandonment, homelessness and if anyone else has any others -- I'm sorry, immunization.

Dr. Janvier: A paragraph certainly could be added addressing that but I mean I think the letter is excellent personally and I think the team did a great job working on it.

Ms. Singer: So I would like to move that we add that language that Ellen is describing, that Denise suggested as the introductory paragraph, also recognizing that we are sending the letter under our statutory authority under the Combating Autism Act to make recommendations and advise the Secretary on issues in the autism community, and that we vote first of all on whether or not to move this letter forward.

And then if there are still concerns, then we can talk about revising the letter but I would move to move forward with this letter with those -- with Ellen and Denise's revisions.

Dr. Insel: Second to that?

Mr. Ne'eman: Question. Would we

also be voting on version 1 or version 2?

Dr. Insel: We'll get back to -- we'll make that as the next step in the votes. We'll have to make a selection. But one of those two versions would go forward.

Or do we want to reverse order? Should we talk about version 1 versus version 2 so you'll know what the letter would look like?

Ms. Resnik: And can we also include in that that we will inform the Secretary of these other issues. I don't want to just throw them out there. I want to make sure that we follow up on those other areas that risk health and lives.

Ms. Singer: That's what I meant by including -

Dr. Insel: Okay. So before we -- I'm getting this impatience factor is coming through loud and clear. Could I get some direction from you about the two versions that the subcommittee put forward as a choice point. I'm not going to parse them any further than this, but it really comes down to the ICD issue and whether you want to include that, which is version 1, or whether you want to go with the more exploratory option, which is version 2.

Dr. Boyle: The way I read them, they both have ICB issues. I'm confused.

Dr. Insel: Sharon.

Ms. Lewis: I think the distinction that we talked about in the subcommittee and where we had difficulty coming to consensus was that we felt that version 1 was really endorsing the CDC's position to move forward on the recommendation to include this as a secondary code, whereas version 2 was acknowledging the need for data collection, acknowledging the current efforts that are taking place, and leaving a specific endorsement around the ICD-9 alone and not making a specific endorsement from the IACC as to whether or not this should be a diagnostic code.

The process does include public comment and we had some conversation about the appropriateness of the IACC making a recommendation on a regulatory type of matter, when there will be opportunities for folks to comment through the Federal Register and for that process to go forward, since CDC has already put it out there on the table and it will be considered by the committee at the beginning of March.

And then secondarily, the other issue in terms of option 2 was again just acknowledging that I think there were some of us in the subcommittee who felt that we did not want to, if this letter were to go forward, to endorse a position that implies that this is something that should be looked at only as a medical issue, that this is -- that there are -- that this needs to be looked at holistically across systems and across settings, and that HHS can't do this alone.

This has to be looked at on a multi-agency basis.

Dr. Insel: So why don't we get this part of it resolved, and let's get a sense of the committee between these two versions, which was really the main question that the subcommittee was putting forward between option -- the version 1 and version 2.

Lyn, you look puzzled.

Ms. Redwood: Yes, I was just going to ask that the IACC committee members read them, because with regard to use of the diagnostic code, we are not endorsing it. We are asking that she investigate the use, so I think semantics, there's a difference there, so if the committee could actually just read the two versions I think that would be helpful to understand more clearly what we are putting forth.

Ms. Singer: Right, when we talked about this in the subcommittee, we came up with the word investigate because we thought that implied assign staff, as Sharon, I think, pointed out.

So that's really all we asked for. I mean there was a lot more that we had in this paragraph originally, that urged the Secretary to take much stronger action towards the medical sub-classification than what you see here.

And I think what you see here is really encompassing a lot of the feedback that Sharon provided.

Mr. Ne'eman: Even utilizing the word investigating, I think it does imply some level of an implied endorsement. I think the -- well you know where I stand -- but my feeling is that the version 2 language which simply makes note of the fact that a proposal has gone out on the ICD-9 with respect to -- from CDC, is the more neutral language.

Dr. Insel: Walter?

Dr. Koroshetz: Well usually the secondary codes are payment codes. They are just basically codes that are used so that you can actually mine data so I guess I am not clear about why would anybody object because all it's going to do is give you data on how many people get coded as wandering. So I don't see what's the downside?

Dr. Insel: Ari?

Dr. Boyle: The 700 series codes are symptom codes so it could be vomiting, diarrhea, headache, constipation, wandering, et cetera so it has nothing to do with billing.

Dr. Insel: So just to get clear, so Walter and Yvette, your point is that since most of this is about getting information, collecting data, trying to understand the scope of the problem, from your point of view, the ICD coding actually helps in that? It doesn't presume that it is already a problem.

Dr. Koroshetz: We had a problem with -- when we were trying to get information on how much TPA use there was, we got -- of hospitals treating people and sending them to a stroke center, we got them to put a 700 code in to try and collect data on how much there was, for the purpose of if we had enough we could get reimbursements.

Dr. Insel: I think one of the things that the group may be struggling with, is this document starts off by saying we don't know how big the problem is, so it is a little difficult to start asking for lots of action on something that you are still trying to understand.

But if what you are asking for action on is a way of quantifying the problem, that may be the answer that is implicit here.

Mr. Ne'eman: Let me just answer Walter's question on why there may be concern even on a secondary sub-classification code, and this is reflected in some of the written public comment as well.

When you medicalize a phenomenon it has implications for within what context it will be addressed, and the concern that I see and that I think others see, is that by identifying wandering as a medical rather than a behavioral phenomenon, it's going to make it less likely that the human services and service provision changes that could better address these things are going to be pursued, and it's going to privilege and serve as an implicit endorsement of going down the route of pursuing medical responses to this, be it through medication or chemical restraint, be it through the enhanced use of guardianship, which is a potential concern that public comment raises, and be it through potentially, because people who are subject to this coding, even if it's given in childhood, will eventually be adults, potentially medicalizing behavior that may not be medical.

So I think that's some of the concern that exists with placing this within a medical context, which it seems fairly clear making ICD-9 code does.

Dr. Insel: Geri, and then we are going to move on to making a decision here.

Dr. Dawson: So, when I think of the word medical, and I think this was illustrated in the presentations that we saw this morning on insurance coverage, it includes behavioral health and behavioral interventions.

So I don't see where having a way of classifying and monitoring and documenting what is an area of concern would automatically lead to a chemical or pharmacological intervention.

And I can say, having worked in the field around this behavior with physicians at my side, that that isn't actually the strategy even though I think by addressing it as a medical concern it also, I think, helps parents to understand that this isn't something that you can easily just say gee, if you were more attentive, or if you had done a better job and this and that, you wouldn't be having this problem.

It's as simple as that. I think it really does recognize that autism carries with it some particular behaviors that are very -- that put a child at risk in terms of their safety.

Dr. Insel: Okay.

Ms. Blackwell: Two things. One is that another issue that I know that the Safety Subcommittee discussed that I will raise very quickly is that the letter does not address at all adults who engage in this particular behavior and second, if we could add to my list of other health and safety issues neglect, which I neglected to mention when I made the list.

But this letter focuses solely on children, which is another concern that I have with it.

Dr. Insel: Yes, I think, again, that was what -- the problem that was brought to us. This is in response to what we heard from public comment, so, Sharon?

Ms. Lewis: Yes, Ellen, that was -- my comment was that the overwhelming number of stories were focused on kids. When we had conversations about particular actions, and the difficulties inherent in the questions around self-determination for adults, the Safety Subcommittee decided first and foremost to focus on children as the primary target of the actions that we were asking the Secretary to take, in part in deference to those difficult, ethical conversations that I think have kind of woven through our day today.

Dr. Insel: So version 1 versus version 2. Can I see hands for version 1?

Dr. Hann: Okay. One, two, three, four, five, six, seven, eight, nine.

Dr. Insel: And hands for version 2 and then we will take people on the phone as well.

Dr. Hann: One, two, three, four, five, six, seven.

Dr. Insel: And on the phone?

Dr. Shore: For version 1.

Ms. McKee: Version 1.

Dr. Hann: So, 11.

Dr. Insel: Okay, so version 1 passes. Now with version 1, in the document we have a recommendation that there will be a new paragraph added. So absent that, can we get a sense from the group about the rest of this document and whether you want to see this go forward with the addition of a new introductory paragraph? Ari?

Mr. Ne'eman: Two things very quickly. I would just add to Ellen's list, suggest the addition of infanticide, which is another concern, and then in addition to that, I would like to ask by what date would I or other committee members who wish to attach a minority document to the letter need to file such a document by?

Dr. Insel: Well I think the process here will be because we are not going to send something forward that the committee hasn't seen in final form. So I would guess that if the full committee decides to endorse something close to this, we will take this back to the subcommittee to actually give us the final document as they would like to see it and circulate it and look for an electronic vote, and that could happen within hours or within a couple of days I would think. It's up to the subcommittee.

But if that procedure works for the body here, then that is what we will do. So that could happen rather quickly. Alison?

Ms. Singer: So after that process takes place, would the final vote on the final document take place by email as the committee has done in the past?

Dr. Insel: Electronically, yes, we have done this in the past, when there is simply sort of a wording issue or something to be added like in this case. I don't see the wisdom of waiting until April or May for us to have another long conversation like this. I'm not sure anything will get better in the meantime. So I'd rather get it to some point that everybody -- most people would feel comfortable with.

So can I get a sense from the group about are we ready to do that, so that is the process would be to ask for the subcommittee to come back with a new introductory paragraph, and you have heard most of the parts of that already, the document as you see with version 1 included, and that is what you would then be asked to vote on electronically.

In favor of that process? Alison.

Ms. Singer: Can we vote now to approve the part of the letter that is already here since it's not going to be changed --

Dr. Insel: That's what I'm asking. Right, so --

Ms. Singer: And so all that has to be decided on after this vote would be the introductory paragraph.

Dr. Insel: Right. Right. We will not revisit the rest of the letter unless the group doesn't want to send this letter and it sounds like, just reading your body language, there's a lot of interest in this letter, but I must say not a consensus.

So the letter in front of you, in version 1 form, in favor of sending this forward knowing that there will be an introductory paragraph added?

Dr. Hann: Okay. One, two, three, four, five, six, seven, eight, nine, 10, 11, 12 are in favor.

Dr. Shore: And on the phone.

Dr. Hann: Thirteen in favor.

Ms. McKee: In favor.

Dr. Hann: Fourteen in favor.

Dr. Insel: Okay. And opposed? Okay.

Dr. Hann: Three. Oh, four, I'm sorry, I didn't see you.

Dr. Insel: Okay. I think we have a plan. So we are going to ask the Safety Subcommittee to revisit this, come up with an introductory paragraph, get it back to OARC as soon as you can and then this will be circulated electronically for your final approval.

And if there are concerns about the introductory paragraph, that can be changed electronically.

All right. We have some business to do. Do you want to take a break and stretch for five minutes? Denise?

Ms. Resnik: Yes, I'm in favor of a break but one thing is, and that is, in teeing this up, in having this go forward, then I would also like to know what it is we are going to talk about at our next IACC meeting and have it as thoughtfully presented as safety was just presented to us. I'd like to make sure that we do continue with this commitment to advise the Secretary on these pressing issues.

So I don't know if this is something that the Services Subcommittee takes on, or another group takes on, but I just want to know where the train is going.

Dr. Insel: You are asking a question of the Services Subcommittee, is that -- whether they want to come forward with -- if there is another issue that they feel really needs attention like this, as urgently, that they want to advise the Secretary about?

Mr. Grossman: I would think that would be a committee as a whole. I mean obviously anybody here can raise an issue and this one in particular on the wandering came from people outside the committee.

So if this issues that are presented are ones that the committee agrees upon are of such an urgent nature that the Secretary needs to act on it right away, then it could come from anybody, not necessarily just the committee.

Dr. Insel: But what Denise is asking about, since there was a concern and it began really with Henry's comments about the context for this and why send this letter forward with all the other things that are urgent issues for the autism community, what about the other 99 issues?

And so I think, if I -- what you are asking is who is going to take issue number 2 out of the 99 and bring that forward. Ellen?

Ms. Blackwell: Denise is on the Services Subcommittee and she knows that one of our activities, which was delayed for various reasons is that we will write recommendations to the Secretary regarding the issues that we heard about at our meeting on November 8th.

So our next meeting will focus on writing those and then we will bring them to the full committee, Denise.

Dr. Insel: So that may be --

okay.

Mr. Grossman: I think that in response to you Denise, there's a slew that are now biting at the bit to get in front of this committee to present their individual concerns, that affect the entire community, so I don't think that going forward that we are going to have any problem with people bringing important issues of an urgent nature to the committee. And we will address those. I'll certainly have some at the next full IACC.

Dr. Insel: And you know, just to manage expectations, sending a letter to the Secretary doesn't fix anything. All it does is, it is really our meeting our statutory obligation to let her know if we have heard about something that gets us excited enough to spend three meetings talking about it.

So we are at that point. We let her know. If there are other items like that, we should let her know as well.

And we need to do it relatively

soon, because as someone mentioned earlier, this committee, by statute, sunsets in September of this year, so if it's going to take us six months to come up with a new one, we are not going to get there in time. So it does need more urgent attention.

Let's break for five minutes, give everybody a chance to stretch and we'll come back and we have some additional business to take care of.

(Whereupon the committee took a brief break at 3:40 p.m. and resumed at 3:50 p.m.)

Dr. Insel: Okay, we are going to go back to work. IACC planning activity business and Susan Daniels is going to take us through this rather quickly and then we want to have some time to discuss public comment or anything else that is on your mind.

So Susan. Where are you? Okay. All right. Do you need slides?

Dr. Daniels: Wonderful. Good

afternoon. I wanted to give you a brief update from the OARC and then talk about some of the planning activities that will be coming up in the next few months.

For OARC update, I wanted to update you on our staff. As you know, Della will be leaving us soon and we have so tremendously appreciated all the guidance that she has given us over the past couple of years and wish her well in her new position, in building one.

I wanted to call to your attention that we have had two new people join our staff since the fall and you might not have had a chance to meet them yet.

We have Elizabeth Baden who is joining us from just finishing an AAAS fellowship on Capitol Hill, having worked in Senator Cardin's office on healthcare issues and small business and previously having done research at the Mayo Clinic College of Medicine.

And so Elizabeth is over here to my right. So say welcome to her. And then we have also had Sarah Dodson join us, and she is a current AAAS science and technology policy fellow, having joined us this fall from the Gladstone Institute in California, working on Alzheimer's disease.

And so we are really excited to have both of them joining us and helping us with our analytical work.

Next, I would like to talk to you about the Portfolio Analysis. There are a few of you in the room who have not been through the whole process of the IACC support Portfolio Analysis with us, and so I wanted to go over again what this activity is about.

It's an activity that assists the IACC in fulfilling its Combating Autism Act requirements to monitor Federal activities related to ASD.

And in fact it goes a little bit beyond the requirements in that it provides a comprehensive analysis of ASD research across both Federal agencies and private organizations.

And so with the cooperation of many private organizations we have really been able to get a much larger view of what is going on in the U.S. in autism research.

The reports that we put out using this information inform the IACC as well as stakeholders about the funding landscape and current directions of ASD research.

They help us to monitor the IACC Strategic Plan's progress and highlight gaps and opportunities that we can address in the Strategic Plan or through other activities of the IACC or for other Federal agencies or organizations to be able to understand what might be some important areas to address.

I wanted to give you an update on the 2009 Portfolio Analysis. In October we showed you a draft that the OARC had put together and you asked us to go back and do some verification of coding so I have checked off here the things that have happened. We did the data call, collected the information, got all the coding from the funders, generated the draft analysis and now we are in the stage of doing coding verification and final analysis.

So you did request the OARC go back and do a quality check of the coding and we actually did find several different coding errors and we have fixed those and we are going back and re-running the analysis and hope that in the next few weeks we can finally release the final version.

So you will have an opportunity to review electronically before it goes out if you -- in case you see anything that is an issue.

And then we will distribute it to the public by our website, so hopefully be looking for that in the next few weeks as we finalize that project.

So for 2010, we have to move on to

the new Portfolio Analysis and we are always a little bit behind. It's 2011 but we can't do the analysis of the previous year until the previous year is over, so that's why we are also behind.

But we are going to be doing the 2010 Portfolio Analysis and what I would like to propose to you would be potentially doing something similar in doing the data request, asking for the number projects, the total funding, the titles, the PIs, the institutions, project descriptions, and how these funding projects correspond to the Strategic Plan.

Now last year the committee mentioned possible interest in getting lists of publications from funders and I don't know if that's of interest, but I wanted to put this out to the committee to see if you have any other requests, concerns, comments about this proposal for moving forward with starting the 2010 Portfolio Analysis as we finish the

2009.

And by the way hopefully the 2010 will go much faster. We did run into a major technical barrier last year, which made this process slow down quite a bit, but hopefully this time we would be able to really have the final product by the fall.

Dr. Lawler: Susan, I just have a quick question. Remind me, when we code those, do we code existing grants, so non-competing renewals, as well everything that was funded in a given fiscal year or are we just coding new grants?

Dr. Daniels: You get a chance to review anything that has been coded previously and to update that coding, especially because we do add new objectives and sometimes something that didn't fit last year might now fit into something. So you do have the opportunity to review and recode.

Dr. Insel: But it would include non-competing.

Dr. Lawler: Okay.

Dr. Insel: Everything that NIEHS is investing in, in any given year.

Dr. Lawler: Because I guess my comment is, will the report be presented in a way that makes it easy to see what new funding we have done? Because it's -- you know you can subtract out what we had last year and then see what is new, but in terms of tracking how we are doing on the Strategic Plan, probably the year before last, it would be nice to very easily look and see what new grants have been funded by NIH and the others without the influence of sort of the continuing years for grants that were --

Dr. Daniels: We didn't do that for the 2009 but that is something if the committee is interested --

Dr. Lawler: It was just a thought.

Dr. Daniels: If the committee is interested in that, that is not difficult to do. We did for the 2009 break out the ARRA-funded projects because that was such a significant area and we actually did a special little analysis on ARRA.

But if you are interested in seeing kind of the comparison to the previous year, that is something that we could definitely work into the 2010.

Dr. Insel: Denise?

Ms. Resnik: I don't know if this has a place, but considering our economy and this age, I wonder if there is a return on investment or a potential return on investment that we could ask as we look at new data.

So what could the potential return on an investment be for this type of research that is moving forward?

Dr. Daniels: I don't know that the OARC is really poised to be able to do that type of analysis, to determine return on investment.

Dr. Insel: There's a whole area

that's becoming very popular now called value of information science, which does that. But I don't think we can do that as part of this. It would require each of the funders to run through that process, which is non-trivial.

I mean that by itself is a huge undertaking. We do it now for very large, especially public health-oriented projects, but I think it would be really hard to do and in some basic science areas, it's almost impossible to really identify a reasonable value of information number. So I'm not sure how we could do that. Geri?

Dr. Dawson: So one of the things that we did this year and we are just about ready to put this out, but we had this question come up, you know, we have made these investments, what is the impact, what is the return on the investment and so forth.

So what we did was there was no off the shelf program available so we developed our own web-based software program which goes out to the investigator when they have completed their grant and asks a whole variety of questions about everything from publications to how did you disseminate your results to actually talking about whether the finding was novel or just a replication or negative, and also what did they actually discover. Did you discover a new treatment? Did you discover any information that helps us individualize medical interventions et cetera?

And so we now have this wonderful data on the first set of 107 grants that have been completed since Autism Speaks' inception, and we have all this data about what were the main findings. We also have leveraged funding, which was amazing to see, that based on a $9 million investment, it actually leveraged $99 million in Federal funding.

So things like that, but you know, it's pretty easy. You just send it out to the investigator. They respond to a set of questions. We piloted it with investigators, got feedback and it works pretty well.

So if any organization would like to use this, we would love to share it and we could actually compare some -- across different organizations what people tend to be funding and what specific impact does it have, so we have a whole section on impact.

Dr. Insel: Alison.

Ms. Singer: I was going to ask if they could share it, but she answered my question. We would love to use it.

Dr. Insel: Lyn.

Ms. Redwood: And I think one of the things she mentioned was asking for publications -- and Geri that sounds wonderful. I would like to have a copy of it as well to use -- but as a proxy for not having that information, something that we could get would be publication. Is that doable and would that be worthwhile to the committee or not really?

Dr. Daniels: That's really the

question, whether you would find that information useful in terms of seeing kind of what's coming out of the grants. It would be additional work for the funders and so we don't want to put them through that if it's not going to be used, but if you can see yourselves really using that information, we would be happy to ask for it.

Dr. Insel: So, NIH collects that every year as part of its progress report, so --

Dr. Daniels: For NIH we have it.

Dr. Hann: We have it for NIH.

Dr. Daniels: We don't have it for other funders.

Dr. Hann: Through the reporter tool it allows you to do that, and you can identify the grant, if the investigator has identified the grant number and the grant.

Dr. Insel: But it sounds as if at least Autism Speaks is doing even more than that, so it would be maybe very feasible for them to provide, and others, the publications.

CDC, Coleen, would that be a problem or --?

Dr. Boyle: Collecting the publications?

Dr. Insel: Would the committee want to see that?

Dr. Boyle: We collect it anyway. I'd love to see it. I mean we collect for our grantees and I'd love to see what others are doing, yes.

Dr. Insel: Okay, so that could be something added to the Portfolio Analysis. The aggregate number would be interesting to see. It's too bad we haven't done that so we can't track it, but it would be interesting to look at. Maybe we can get some of this retrospectively.

Dr. Daniels: I'm not sure whether all of the organizations track their publications related to specific grants or kind of to the general portfolio. I know NIH does track to the specific grants so we would have to see kind of what type of data came in and how to best aggregate that. But if you are interested then we can go ahead and add that into our data call for next year.

So if you don't have any other questions and comments, are you okay with OARC moving forward with doing this in the next couple of months?

Dr. Insel: Walter.

Dr. Koroshetz: Did we talk about coding the grants that did not fall within specific --

Dr. Daniels: That's something that OARC will take a stab at doing that, and we are going to do that proactively so the first draft you see will have proposed tracking for the things that were not specific to objectives.

Dr. Insel: Okay. I think we are ready to move on.

Dr. Daniels: So these are the

funders that we went to last year so I assume that we would stick with the same funders. If there are any additional funders you can think of that we didn't address, we did have a longer list last year then found out some of them were not funding research and so we took them off the list, but this is the latest list. Autism Science Foundation was the only new organization that we added, and luckily, we are at seven outside organizations so we don't run into the Paperwork Reduction Act.

So the proposed timeline would be having the data call this spring, updating you at the April 11 meeting, doing data analysis over the summer, having a draft to you by July and a completed analysis by September before the reauthorization.

So that's my ambitious plan, hopefully we will not have technical difficulties this time and we will be able to stay on schedule with getting that to you by the fall before we sunset or continue.

Ms. Singer: When would the data be due to you? In April?

Dr. Daniels: So if we send out say -- if we send out our data call in April we usually give people about a month to get us the data, so if we get it back in May then we would start analysis in June. But we might get the data call out sooner. It depends. I need to work with our contractor and see what we need to do to get that rolling.

Dr. Janvier: I'm just curious if you had a bottom, a minimum amount of dollars that you are looking for, just because I'm thinking the New Jersey Governor's Council on Autism does fund I think, I want to say $4 million, $5 million and specifically on autism research and that they should be included --

Dr. Daniels: We didn't have a bottom dollar, however I'd worry about if we start going out to one state then we probably should be going out to all the states and then if we do that -- well, they're government so that wouldn't necessarily count under the Paperwork Reduction Act, but that would -- does it -- states? It's only Federal entities or -- so that would definitely yes, be a difficult thing, although a private organization could do it.

So then does it sound like everyone agrees then to go forward with this as planned?

Ms. Resnik: Is the Paperwork Reduction Act -- I hadn't heard of that before. Is that a real act or is that your sense of humor late in the day?

Dr. Daniels: No, it's not that humorous, really, it's a real --

Dr. Insel: She's actually funnier than that. She can do much better, even late in the day.

Dr. Daniels: Ellen knows the humor of that, very well, so -- and I do too from previous positions I've had, so we definitely don't want to get involved in that if we can avoid that. So we have a nice number. If we stay under nine outside funders we don't have to go through OMB to get permission, because then they have to review our entire data call and let us know whether we can even do it the way we want to do it. It's a long process.

So great. So then, it sounds like we have -- any objections? Okay. So, I'll keep moving. So the summary of advances, just to review this again for the newer committee members, it's required by the Combating Autism Act of 2006 that we develop and annually update a summary of advances in autism spectrum disorder research related to causes, prevention, treatment, early screening, diagnosis or rule-out, intervention and access to services and supports for individuals with autism spectrum disorder.

So the way that OARC has worked with the committee in the past, in 2009 we put out the summary of advances document that you have at your table in which the IACC identified 20 peer-reviewed articles that were published in 2009 that they felt reflected the most significant advances in ASD, biomedical and services research, and that these studies were very informative for the committee as well as the public.

So in 2010, earlier you voted to do a mid-year installment and start the work on the 2010 process. So this full document will include the 20 advances in the field, similar to 2009, and it's only published research. It doesn't include advanced ePubs.

The mid-year installment was completed in the fall. All of you nominated three to five articles each and gave us a total of 34 from which you chose 10 articles that were to be included in the summary, and so now we are ready to start part 2. Oh, by the way this is the mid-year list in slides and it's in your packet in case you need it as a reference and I would send it out to you again. So these are the 10 that are already a part of the summary of advances for 2010.

But, because now 2010 is finally closed we can go back and look at everything that came out in the year, so we need to identify 10 additional articles.

And so what I would propose is that we continue and use the same kind of process we did over the summer and fall to allow you to nominate three to five articles each and that we would redistribute the same articles form the mid-year ballot that were not already selected and then have you add on to that and then from the total pool, that you would vote and select the top 10 and those would be combined with the previous 10.

And the articles could have come out any time in 2010 in case you missed anything the first time around that was earlier in the year.

So this process would really mimic the one that you went through before, so do you have any comments, questions or concerns with going forward with doing something similar to what you did in the fall to complete the 2010?

Ms. Blackwell: Susan, when would you be requesting this?

Dr. Daniels: This request would probably come out within the next few weeks and we would have to work iteratively with you to collect the information, get the information back out to you.

But the goal would be for us to produce the final summary by April, by the time of our April meeting, and so the final product will be written by OARC. We will provide a collection of independent short summaries of each article, organized according to the topics that are covered in the Strategic Plan, and the timeline would be so winter, spring you will do your selection, and then the draft document will be presented to you on April 11th and then in the month of

April, which is World Autism Awareness Month, we would like to release the final version of the summary of advances.

So any questions or comments? Does that sound like an agreeable plan? Any objections to moving forward with that?

So then the next topic I wanted to talk to you about was future IACC activities, especially activities for gathering input from the research community and from the public.

So we have within our budget and our staff availability and so forth, the ability to run one workshop or town hall meeting between now and September 30th, before the reauthorization.

And so at the previous meeting, there had been a discussion about -- the Services Subcommittee brought a proposal to the full committee for another meeting on services and members of the committee said that they would like to talk about an array of possible topics for a workshop, or it could be a town hall meeting or you could even have a town hall component within a workshop but we could just do one event, and then whether the committee wants to do an RFI this year and the Safety Subcommittee is working on a draft RFI and if this is the RFI you want to do, but within our budget limitations, we really would want to stick with doing one RFI before September 30th.

Dr. Insel: Geri.

Dr. Dawson: I apologize in advance for this not being completely on target, but I have to leave in about two minutes and this is under the future IACC activities and it's something I just wanted to mention before I left.

Which is, you know, I think it would be great for the IACC to follow up on the presentation that we had this morning about the Affordable Care Act and actually maybe make a statement to the IOM committee about some of the issues related to healthcare.

I do see this as a real special opportunity for the IACC to have an opinion about some of these major issues that will have an immediate impact on healthcare and so I just wanted to throw that out as a possible item for a future IACC meeting that we could consider.

Dr. Insel: Maybe something we could put on the agenda for April, to follow up on that conversation from this morning. Ellen?

Ms. Blackwell: I just think we need to be mindful that some of us within the context of our work and our agencies are working on these items and they are still confidential.

So there might be a conflict of interest in having -- sitting on the committee and then making a recommendation. I don't know but I am not sure I am totally comfortable with that.

Dr. Insel: Yes, I'm not sure we're talking about making a recommendation, but there is further discussion to have based on what we heard this morning, in the same way that we have heard some other comments brought to the committee that require us to explore them a little further. Lyn then Ari.

Ms. Redwood: Yes, I just have a real quick question before Geri leaves. Last year we had discussed different workshops and one of the ones that came up was a treatment workshop and Geri you had said at the time Autism Speaks was having a treatment workshop I believe, and I was just wanting to follow up on that, to see if they did or --

Dr. Dawson: Actually I think what you are referring to is a second meeting that is part of the translational medicine initiative. So we are in two weeks having a meeting that is going to be focused on the preclinical phase of drug discovery, so animal models, drug targets, platform for screening, what is genetics telling us about different pathways that are involved in autism that might lead to treatments and so it's a very targeted focus on that type of treatment.

And I would be very happy to share that meeting in terms of what is discussed. But certain -- not the broader array of treatments.

Dr. Insel: Ari.

Mr. Ne'eman: Two things. First I actually in this context agree very strongly with Geri that it does make sense for the IACC to take up the issue of the essential benefits package, and you know if there are certain members that need to recuse themselves from that discussion, then I think that's certainly understandable.

But it probably is the most essential component of health reform in a lot of respects and I think we should take the opportunity to weigh in on it.

But then the other area as with

regards to the next workshop, I think there are a lot of options. But just to look at two possibilities, the one and the one I am sort of inclined to lean towards, is there were a lot of areas in the services workshop that we did not get to and that we could explore in greater detail and another possibility is our new Strategic Plan talks about a workshop on ethical, legal and social implications of autism research.

So to my mind either of those possibilities would be an extremely productive use of the committee's time and funding.

Dr. Insel: We talked about that when we were talking about the Strategic Plan, and you know there was a lot of discussion about what to do on the ELSI issue and what we decided ultimately was to hold a workshop but we didn't say when and Alan, when you came and discussed this with us a little bit, you were also of the opinion that this may be a place where it would be helpful to bring in people who have struggled with these issues in Alzheimer's or in other areas of medicine, to give us some advice about what the issues could be.

Dr. Guttmacher: Yes, I think that's right because I think there are two sort of dynamics here, one is just opening the eyes of those of us around the table and others in the autism community to some of the issues that others have trod before, so it makes sense to benefit from their expertise.

And then also I think to think about what are the aspects of autism -- there are probably very few that are actually unique but at least are distinctive in this and need particular attention et cetera et cetera.

And some of them may in fact be truly unique. So I, just off the top of my head, that's the way I would think about the workshop, bringing people who have prior experience to help us look through that, but then having heard that sort of look at it through an autism lens to see are there other things specific that have not been so well-looked at before, or even if they have been looked at before, there is sort of no satisfactory conclusion or whatever in terms of how that touches the autism community.

Dr. Insel: And of course it has the advantage that we could check yet another item off of the Strategic Plan, since this is something that this committee is committed to do.

Other ideas? I mean this is something we could do this year or it could be trumped by something that you feel is more urgent. Alison?

Ms. Singer: I just wanted to point out that in the past, it's been very helpful in terms of fulfilling the responsibility to use these as an opportunity to gather information from the broader public.

To hold them at places where there are additional stakeholders, I think, when we held a town hall meeting at the ASA conference, that was extremely productive. We got a lot of great information.

So I don't want to volunteer Lee's conference but that might be a great place to solicit stakeholder feedback also. IMFAR is coming up. I don't know, Ari, if there are any other conferences where there's a large aggregation of stakeholders.

But I don't want us to lose sight of the point of getting information from the broader community.

Mr. Ne'eman: I think it's a great idea. The only concern that I would raise is if we want a workshop to be a meeting of a variety of different kinds of stakeholders, and this is perhaps more important in something like ELSI than it is with something like a second services workshop, both of which would be great priorities, it may make sense for us to try and look for neutral territory so to speak, where no one perspective would be able to dominate the conversation. So that's just one thing for us to keep in mind when thinking about location.

Dr. Insel: The other -- I'm just looking through the Plan. And the other workshop that we called for by 2011, was a workshop that explores the usefulness of bioinformatic approaches to identify environmental risks for ASD. And there may be some others in here as well.

I mean these are things you already said you wanted to do. Should we take that as the marching orders from the committee, what's in the Plan, both ELSI, environmental risks, there may be others. I haven't looked at it in a while, so --

Ms. Redwood: And I think we have to also look at what we are going to use the information for and if we are using it to sort of update the Plan and stay current, then I would think something on the bioinformatics would be really helpful.

Dr. Lawler: So just to remind you, NIEHS and Autism Speaks are moving forward with planning a workshop in the bioinformatics angle.

Dr. Insel: All right. We can check that off. Done. Is anybody doing an ELSI workshop we need to know about? Okay. Ellen?

Ms. Blackwell: I was just going to say I totally agree with Alison that we should always try to include all of our stakeholders and suggest that we explore electronic options to facilitate as many people participating as possible, perhaps using the HHS regional offices and you know, just thinking of creative ways that we minimize expense and maximize our exposure.

Dr. Insel: Great. Ari.

Mr. Ne'eman: One thing I wanted to add here is, not to speak against my own recommendation, but I do think it's important that we give, in addition to the stuff that is covered in the Strategic Plan, ample consideration to the recommendation of the Services Subcommittee for a second services workshop.

So once again, I don't know what my preference is, an ELSI workshop or a second services workshop, I think either would be great.

I just want to make sure that Lee and Ellen feel that they have had the chance to make that case as we are coming to a decision on this.

Dr. Insel: My read on this though is if the committee as a whole has put something into the Strategic Plan that they want to get done in a particular time period, that probably is your way of voting with your feet that says this is the highest priority. I hope that's what would end up in the Plan.

So if we said that we really think there's a need to look at ethical, legal, social implications, that sounds like a pretty strong recommendation that we ought to respond to.

I was just trying to find if there are any other workshops that trump that in the Plan. I didn't see them, but if there is anything we can look at that before we do the ELSI workshop. Walter?

Dr. Koroshetz: In the letter, we mentioned the issues of safety so, how they have to be kind of fleshed out more so I think that might be another one.

Ms. Redwood: I would second that too and if we have already had a services workshop last year, it seems sort of maybe we should spread the wealth somewhere else and cover another topic. We also need to from the RFI perspective, because this is the first time I've heard that the committee could only do one RFI per year.

So we need to find out from the committee whether or not we want to move forward with the RFI regarding safety. One of the things we discussed that we didn't bring up today on our last Safety Subcommittee call was combining -- there are several other tools that we are developing right now to collect that data.

One is what the CDC has been working on through the National Children's Health Survey -- correct Coleen? -- that has an aspect of wandering and several questions, and then there's also the IAN project that is being funded by private funders.

So we may be able to capture that data that way and use the RFI to really update the Strategic Plan.

Dr. Daniels: Just to explain a little bit. We, as a part of general Federal government, could potentially under budget cuts and so we need to be mindful of our budget and not to make grandiose plans that we won't be able to fund.

And so that is why we are being a little conservative. Also that we need to be reauthorized in September to continue our business and so we have a much more constrained time schedule. We can't really be planning things that will happen after September 30th until we hear that we have been reauthorized.

Dr. Insel: Coleen.

Dr. Boyle: Just to talk about a workshop that is going to happen which is not in the Plan. I just wanted to bring your attention to the flyer that is in your packet, evaluating the changes in the prevalence of autism, which is on February 1st.

Dr. Insel: And that will be where?

Dr. Boyle: It will be in Atlanta.

Dr. Insel: For people listening in, is that open?

Dr. Boyle: Yes it is. It is an open workshop.

Dr. Insel: Okay. Anything else on the RFI, workshop, town hall meeting? Lee.

Mr. Grossman: Yes, I would

advocate strongly that we have a second services workshop. It was the intent of such -- the broad basis of information that we had to cover that we would have two workshops, and certainly I believe that was the understanding of all those on the Services Subcommittee as presented to the full IACC.

And if need be, I certainly would be very open and think it would only add value to their workshop to have a portion of that devoted to safety issues. I think that's very important, that that be addressed there as well.

And then thirdly, if we have only the option of having the event, certainly having a town hall session at the workshop would kind of pull everything together.

Dr. Insel: Ellen?

Ms. Blackwell: I was just going to say these are the topics that were put off the table at the last meeting and many of them are in fact health and safety issues: managed care delivery models for services, diversity, cultural sensitivity, health homes, infrastructure, person-centered planning and policies and assessment, recreational services, family support, home- and community-based services, characteristics, mental health parity, family support, early childhood, quality measures, employment, vocational support and benefits counseling, criminal justice diversion, post-secondary education, rebalancing the services system, community asset building an environmental modification.

So we had quite a few topics that we were not able to address in our first day. Look at Lee. Obviously, we can -- again I think there's a lot of overlap with the issues that the Safety Subcommittee is talking about but certainly there is on deficit of issues on the services side.

Dr. Insel: So what's your pleasure on this? How do you want to proceed?

Dr. Daniels: So we have heard

three topics, ELSI, safety and services. Would people like to vote?

Dr. Insel: Well, and I think it's realistic that we are going to have to select at this point. I'm not sure that we will be able to do two.

Dr. Daniels: Don't forget that we can continue to do additional workshops once we have been reauthorized. This is just really talking about between now and September, what are we going to do?

Dr. Insel: Ari?

Mr. Ne'eman: You know, before we vote I actually want to weigh in because I was the one who proposed the ELSI workshop. It would seem to me that because we can sort of hit two birds with one stone and tackle some safety issues in the context of a second Services Subcommittee, that would seem to be getting us the most bang for our buck.

So that's why I'm going to be weighing in on and I think my organization is going to look with some other options into other possibilities for an ELSI workshop.

Dr. Insel: Okay. So I'm hearing interest in having a services workshop with the Services Subcommittee taking that list of 15 or so items and making it a list of three, so that there is some focus and some deliverables and it educates us about something we need to do, so it's actionable.

Dr. Daniels: We also have the possibility of forming a work group that could contain members of either the safety or Services Subcommittee who want to really focus on planning that workshop, so that's an option.

Dr. Insel: Ellen and Lee, thanks for volunteering and we will look forward to your leadership in pulling this together and if you need support from the rest of us, let us know.

Moving on.

Ms. Singer: Is it possible to

incorporate a town hall component, so that we are -- okay.

Dr. Daniels: Yes, we can do that.

Dr. Insel: I heard that from the group, that they would like to see this do double duty in some way so that it's not just a workshop but it's -- and to the extent possible, to leverage another meeting that is happening would be great, it's a great way to get a lot more people to the table.

Ms. Singer: And the feedback from the conversation earlier about the safety letter was that there are all these other issues that are also high priority. A town hall that focused on safety would enable us to identify and prioritize those issues so it's actually informative. So I think the town hall piece is really the critical component.

Dr. Insel: And you know there are a couple of large-scale meetings between now and summer or midsummer so there will be opportunities if you wanted to leverage one of those to bring more than a thousand people together, we can do it. Lyn?

Ms. Redwood: And if we also used the town hall meeting to focus on safety, then it would take away the need for the RFI because we could solicit information through the town hall meeting and then the RFI could be utilized for updating the Strategic Plan.

Dr. Insel: Ellen.

Ms. Blackwell: We have done a lot of town hall meetings at CMS completely electronically, so maybe that's another way to do this in a cost-effective way. The biggest cost is the number of lines, the telephone lines, but again, compared to bringing people to a place, it might be less expensive. So again I would urge that we look at the full array of -- that way we can do as much as possible with the money that we have.

Dr. Insel: Sounds good. Okay. Moving on.

Dr. Daniels: Does the committee

feel like they would want to do an RFI on the Plan similar to the last two years? Just to give OARC a sense of whether we should be thinking about this and if we should be convening the Planning Subcommittee to work on it.

Dr. Insel: Would it makes sense to wait until we know whether there will be another committee because at this point, we are out of work in September, so rather than spending a lot of either time, money or sweat equity on an RFI, for the update, and it could be that even if the CAA is reauthorized, it could be in a very different form with a different group running it.

So I would weigh in on let's sit tight on making any commitment to do that until we have a better idea of what that will look like.

Dr. Daniels: Okay. So it sounds like the decision is for the Services Subcommittee to take the lead on planning a workshop that would incorporate a town hall component that might address safety issues. So we will work on that and we also still may be able to form a working group so that other folks on the committee who would like to participate might be able to be involved.

Dr. Insel: Okay. Thank you Susan. So we are right on schedule for the last item on the agenda, which is to loop back to the public comments. We had two today. And any discussion you want to have about those or really anything else, this is open time to bring up other items.

Dr. Lawler: I have a few comments after looking at the public comments written and oral today. I see that we continue to get comments about many different exposures that I think we can all agree do merit investigation today, and in past meetings we have heard about medical exposures such as ultrasound, nutritional exposures, soy formula, and I think the good news is that typically, many of these exposures that are mentioned in public comments, are being explored in some of our ongoing studies, primarily the CHARGE, the large case control study of autism, environmental and genetic risks more recently plans in the early study, the high-risk pregnancy cohort.

And I guess the larger question that these comments raise is really the specificity of the Plan. From my perspective the suggestions are typically reasonable ones, reasonable candidate exposures to explore. The difficulty is probably in pursuing them in isolation. I think in many cases if you see effects they are going to be conditioned on other variables that need to be measured as well.

So I think our current Strategic Plan really reflects the need to consider a whole broad range of exposures which I think is consistent with the current state of our knowledge.

And I think this can be very frustrating, not particularly satisfying if you have a directed question, but I think it's also important to recognize that progress in answering some of these questions that come up isn't solely dependent on what we do with research under the Strategic Plan.

And it's just one example in the context of questions about soy, NIEHS has made a very large investment recently and really over the past five to 10 years looking at, trying to understand environmental endocrine disruptors and the information that emerges from that line of research, I think, will be very important in identifying mechanisms, thinking about windows of vulnerability, what happens when you are exposed to a mix of endocrine disruptors and that information can then be applied to help address questions about autism causation.

Then I think my final comment I just want to remind everyone again that NIEHS is planning a workshop with Autism Speaks to explore the use of potential bioinformatic and high-throughput screening approaches as a way to try to get a handle on this real problem that we have a universe of certainly chemical exposures out there and we don't have at present a good way to narrow down classes of exposures that we should particularly prioritize and we need to figure out how to do that efficiently and rapidly so that we can then sort of move those candidate exposures into human studies where they can be investigated as risk factors.

So I think that is in response to this sort of frustration about where should we look. We have so many different exposures that do merit consideration.

Dr. Insel: Thanks Cindy. We certainly do continue to get a lot of public comment about very specific hypotheses on exposures.

Other comments or reflections on

what you heard today? Walter.

Dr. Koroshetz: To follow up on the point that was just made, that there are studies going on to try and get at some of these things. There's a recent CDC study that looked at ultrasound in the Kaiser Permanente's databases and did not find an association with autism.

So I think these are really good ideas. The issue is how do you track them down best. Because there's so many different possibilities.

Dr. Insel: And this is one place where sometimes just having a global perspective, you can find opportunities in other countries that might point to different exposures and different outcomes.

But this is going to take a very broad approach, and the thing to remember, I think, as you look at the CDC epi data as well as the DDS data from California, there is no evidence, there is simply no evidence that the rate of increase has leveled off.

So whatever is the driver environmentally is still there and may be worse. Other comments or questions? Other thoughts?

Well I wanted to end with three reflections on the day, the first being that this was not an easy process, but that doesn't mean it wasn't a good one.

Unfortunately coming to agreement on things where there are real disagreements and coming to some common ground is painful and at times frustrating, but I think all of you did a great job in finally getting to a place where there is at least some consensus.

And we have now an updated Strategic Plan that is longer than one that we could have ever imagined two years ago, but I think at least has everybody's support behind it, and that is an accomplishment.

I also wanted to thank some of you who got here today with great duress. We don't plan these meetings around ice storms, or are around big northeastern snow storms, but sometimes that happens, and I really appreciate those of you who put up with a huge amount of hassle to get here including several cancelled flights and all kinds of challenges.

And finally, this is Della's last meeting, and she is going on to do other really exciting things. But I wanted to, on behalf of the whole committee, thank you for all you've done for us since 2006 and even before, and you have made this whole process much better and your wisdom and guidance and good judgment at all parts of this process have been appreciated by all of us, and we are going to miss you. But we wish you the very, very best.

(Applause.)

Dr. Hann: And I know some of you are going to chuckle, but I will miss you as well. This has been a great experience and I want to thank you all for giving me the opportunity. It really has. I've learned a lot. I've learned a lot about autism, many different facets that I probably wouldn't have known if I'd just been reading my journal articles.

And the other part of it too is just this whole experience. I think this is a great committee and I think the fact that there is a forum for people to have good, honest open discussion has really moved the field forward in a number of ways.

If you think back to where we were 3-1/2 years ago to where we are now, I think there is a tremendous difference essentially in not only the science that we are doing, but also the other issues that are being attacked by this committee.

So I thank you all, and I wish you all the very, very best.

Dr. Insel: And with that, we are adjourned. Thanks everybody.

(Whereupon, at 4:39 p.m., the

committee adjourned.)