U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, JULY 16, 2010

The Committee met in the Congressional Ballroom of the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland, at 10:00 a.m., Thomas Insel, Chair, presiding.

PRESENT:

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

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

SUSAN DANIELS, Ph.D., Office of Autism Research Coordination, National Institute of Mental Health

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

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

JOSEPHINE P. BRIGGS, M.D., National Center for Complementary and Alternative Medicine

HENRY CLAYPOOL, Office on Disability

PRESENT (continued):

JUDITH COOPER, Ph.D., National Institute on Deafness and Other Communication Disorders

GERALDINE DAWSON, Ph.D., Autism Speaks

LEE GROSSMAN, Autism Society

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

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

LARKE N. HUANG, Ph.D., Substance Abuse and Mental Health Services Administration

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

JENNIFER G. JOHNSON, Ed.D., Administration for Children and Families

WALTER J. KOROSHETZ, M.D., National Institute Of Neurological Disorders and Stroke

CHRISTINE M. McKEE, J.D.

ARI NE'EMAN, Autistic Self-Advocacy Network

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

DENISE D. RESNIK, Southwest Autism Research and Resource Center

STEPHEN M. SHORE, Ed.D., Autism Spectrum Consulting

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

PRESENT (continued):

MARJORIE SOLOMON, Ph.D., M.B.A., University of California, Davis

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

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

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PROCEEDINGS

(10:03 a.m.)

Dr. Insel: Good morning, everyone. Just want to make sure we are good to go in terms of the conference call and videocast before we start. Getting the thumbs-up so let me welcome everybody to the summer meeting of the Interagency Autism Coordinating Committee.

The fact that you are here means that you survived this morning's earthquake and yesterday's power outage at Reagan Airport so thanks, all of you, for making it here.

Those of you who have come from California must wonder how you can have an earthquake when you get to Washington, D.C., but it happens -- not often, but it does happen.

We have got a different kind of meeting today. This is a meeting where most of the day will be taken up with presentations that you have asked for in previous meetings and we thought we would spend a good part of

the day just hearing from some of the people who have contributed important information about autism that we thought everybody on the committee should hear and it's also an opportunity for those listening in by conference call or watching by videocast to get updated on some of the new, exciting areas within both autism research and autism services.

This isn't comprehensive. There are additional people that we would have loved to have had but we just have run out of time. So we will continue to do this going forward and we will be looking for your recommendations about other people to include.

Couple of just administrative announcements and some other announcements that Della will make in a moment.

I first wanted to welcome Denise Resnik, who has been here on the phone at previous meetings but not here in person and Denise will be presenting later today, so you

will have a chance to hear much more about her background in SARRC but welcome to the meeting.

And I also wanted to let you know that we have another new member of the IACC, Sharon Lewis, who is from the Administration on Developmental Disabilities, will be joining us. Jennifer Johnson, who has served in that role in a very effective way, from the Administration for Children and Families, is here today because Sharon could not make the meeting.

But in the future we are looking forward to meeting Sharon, as well, and I assume that, Jennifer, you may still be involved with us as times goes on. Good, well, I am glad you could be here today.

We also have Josie Briggs, who is representing Dr. Francis Collins today, so welcome, Dr. Briggs.

And with that, let me turn this over to Della for some administrative notes.

Dr. Hann: Good morning. Just a few sort of housekeeping issues for those of us who are here in the room. First, I wanted to talk about the all-important lunch.

We have a very limited time slot actually, for lunch, given the amount on our agenda, and so we have worked out with the hotel and the hotel's restaurant -- you will find at your place, there is an express lunch menu, okay? And I am told by the hotel that if you select one of these items when you go to the restaurant, that it indeed will be express and it will happen quickly. So we highly recommend that as an option for you.

Also, for those of you who drove here and are parking, we do have vouchers for you to be able to exit. You will need your little voucher as well as your original card that you got when you came in, the little white, probably white or yellow, little slip of paper. You need both of them. You put the white one in the register first and then you

put -- the voucher will be blue -- and then you put the voucher in after that, okay? But you can pick those up at the front desk, at our desk here, at the registration desk.

The other thing I just wanted everybody to remember, I think Tom has sort of alluded to it already, the fact that this meeting is live. It is being videocast and it will be archived. In addition to which, it is completely open to the public, which also means it's also open to the press and there may be members of the press who are here in the audience and may wish to speak with you at some points during and throughout the meeting.

Then, the other thing I just wanted to remind everyone; the committee decided, I believe as a fact of the last meeting, that the start times now for the full IACC meetings will basically be at 10 o'clock in the morning.

That was a decision that was made, and in order to accommodate folks,

particularly who live here on the east coast or are flying in in the morning and so forth like that, to be able to be here.

So unless something changes and we have a super-packed agenda, the meeting will begin at 10 from now going forward, okay? So those were just some of the light housekeeping items to start the day.

Dr. Insel: Okay. Thanks, Della. We are going to start with just quickly looking at the minutes from the April 30th meeting and let me know if you have any corrections, changes, suggestions for those.

There have been a number, actually, that have already been submitted, that there are several typos and since these documents go to the Secretary's office, we want to make sure we refer to the Secretary appropriately so we are changing that in the minutes.

But let us know if there is anything else that is included there that needs to be changed. Anything? Can I have a

motion to approve with those edits that are -- I must say, since we haven't gone through them in detail, the edits that I have seen so far that have come through have been edits around typographical or references to --

Dr. Shore: I make a motion.

Dr. Insel: Yes. Okay. Second? In favor? Opposed? We are approved and we are going to move on then, to the first of several, what I think will be really outstanding presentations from -- the first is from Dr. Michael Ganz but I am not sure if Dr. Ganz has arrived yet.

Welcome. And we will make sure we can get your slides up on the screen. So while we are bringing the slides up, let me just introduce Dr. Ganz, who is an adjunct assistant professor of society, human development and health at the Harvard School of Public Health.

His primary research interest is in investigating the correlative healthcare

utilization and expenditures for children and families, especially for children with special healthcare needs.

I think almost everyone on the committee knows that in 2007 he estimated that the lifetime per capita incremental societal cost of autism is $3.2 million, a figure which we have used frequently. It's in our strategic plan and of course we have talked about this on several occasions here at this committee meeting.

Dr. Ganz, welcome. We are delighted to have you here and looking forward to your thoughts.

Dr. Ganz: Thank you very much for inviting me. My real day-job these days is working for United BioSource Corporation, which is a consulting firm that does work to support the life sciences industry, public and private, and I still retain an adjunct appointment at Harvard.

So this work actually started while

at Harvard but there have been some career changes along the way. Again, thank you very much for having me.

I am going to just go through slides that talk about my work in estimating the costs of autism, along the way just lay out some conceptual ideas about thinking about the costs of autism, and might be useful in the future for updating these estimates.

To place the estimates of the costs related to autism in current context and in past context, when I started doing this work, there is obviously a lot of policy activity involving insurance coverage for folks with autism and cost is a major policy driver for insurance companies.

There are also obviously large financial and non-financial burdens for families and society at large related to autism.

Given that and given the fact that there are currently considerable amounts of

resources used by families and again, society at large to support children and adults and their families with autism, there was a need to sort of formalize these cost estimates and that's why I did this work back a few years ago.

People ask what is so important about knowing these costs? Well, they are important to know, I think, what the costs are, when they are incurred along the lifespan and by whom -- again, families, local governments, federal government, employers, et cetera.

It's important to know these things because, number one, it does contribute to the sort of overall knowledge base about costs of different health conditions; but it's also important because having evidence about the costs allows advocacy groups to do their jobs, to advocate for coverage, for treatments, for example; and it's also important from a policy perspective to understand how to allocate

unfortunately scarce resources across the portfolio of different health support systems, for example, and to support individuals with autism in their families or to support research or to support other activities.

Understanding the current costs of autism, of caring for folks with autism is also important because there are current treatment strategies that are used and there may be future treatment strategies or future diagnostic strategies that have associated costs and have associated effectiveness, and to understand sort of the costs and benefits: what does a future treatment or diagnostic strategy cost and if that serves to sort of offset current costs of autism, it allows, again, policymakers to do the calculus.

And I think I already touched upon the second bullet-point here about extending insurance coverage to families.

So given all that context, the objective of the work that I did, and I think

the objective of going forward in estimating costs associated with autism would be to, again, estimate the cost of caring for these folks, the objectives for deriving these costs again, are important for policy perspectives, important to help raise awareness and I think the second-to-last bullet-point is valuable because, to understand the cost or the burden of autism or any condition now is in some sense the value of prevention.

I mean, if we can prevent or ameliorate a condition, their current cost is equal to the value of prevention. So it's, again, important to document these costs for policy purposes.

Back when I started this work three, four years ago and even now, the big problem is not much is known about these costs, not much is known about resources or healthcare resources that are used to care for individuals with autism.

Certainly, compared to other

conditions, there has been little work done and my focus is on the U.S. and there needs to be more work.

And in fact, last year, in Autism Research, there was an editorial titled, Where are the Autism Economists. And the point that the author made was that without quantitative estimates about the costs of autism, the cost of treating the condition, the cost associated with research to develop new treatments and diagnostics, we lack the value of advancing the field.

So, again, it's important to understand what these costs are and to refine them over time.

Okay. I don't know how detailed I should go into the methods for my work, and these are also generic methods that one might use to do a future study. At any point if it seems that I am boring you or I am running out of time I can always skip to the results.

But -- and that's why I put a

little green box there. If I click on it, I go straight to the results. Okay, so there -- this is a, I think you can consider this a primer on understanding the costs of illness but this is the framework I used for the autism work.

And in the health economics literature, we usually consider three components of cost: direct medical, so that's your physician visits and therapies and medications and it could be travel, as long as it's related to treatment; there are often non-medical direct costs -- childcare, adult care, respite care, special education, supported employment, those types of things that are not directly medical; and then there are indirect costs, and these are usually considered to be lost productivity and there's their own, the person's lost productivity and caregivers'.

In this case I considered parents although grandparents and aunts and uncles

might also be legitimately included but I didn't.

At least in the United States healthcare policy, usually the direct costs are important and in Europe, I know that some countries will explicitly consider indirect costs when they are doing healthcare policy decisions, but I just took a very broad perspective -- just, I think, I am on the next slide -- and considered all the components no matter who paid them -- paid for them.

In a cost of illness approach, ideally you would want to take an incidence-based approach, which would mean looking at people who are first diagnosed with the condition and then tracked over time, and an incidence-based approach is a close estimate of the value of prevention.

So, again, if we can prevent a condition, the incidence-based, lifetime cost is the value of that prevention. But in this situation, there are very formidable data

requirements. It would take me a long time, or one a long time, to enroll and track folks over time so I applied basically a cross-sectional approximation and if people are interested in more details I could tell them later.

But I think the bottom line is here that these are rough estimates that can be definitely improved but they are very, I think, formidable data requirements to do that.

So here's the perspective I alluded to a few slides ago. Since the impact of autism is felt anywhere from individual families across communities, employers -- again, people are missing work to care for children -- insurers, governments from the local to the federal.

I took a very broad societal perspective and I guess that different players in this field may want a more narrow or broader focus and that certainly can be done

and has been published.

Briefly, the work that I did looked at published and unpublished literature and tried to compute costs for higher- and lower-functioning individuals and I tried to do it as much as I can age- and sex-specific. More detail on this is available in the article, in the chapter that I wrote.

But again, since there's no large database that tracks these individuals, I had to cobble together what I could from the literature. Same thing for indirect costs, just took an assumption that average age- and sex-specific earnings rates can be used to approximate the indirect costs.

So for example, what will be the average earnings profile of a child over his or her lifetime and what would be the average earnings profile of adults of, you know, parents of some assumed age and that was used to estimate these costs.

The number that is quoted, the $3.2

million, these are incremental costs. So these are the costs that are specific to the condition.

So folks with autism or folks with asthma will incur costs over their lifetime or over a period of a year or whatever interesting time horizon you want to consider, but it's important to consider the incremental costs because people always experience some sorts of healthcare-related costs.

Under the assumption that someone goes to the dentist twice a year, that would not be an autism-related cost. If I found in the literature that kids went more often for doctor's visits -- they went more often, I would want to subtract out some assumed well visits that everyone might need anyway.

So, again, the $3.2 million that is quoted is the incremental costs above and beyond any other costs that would be associated with everyday life, as it were.

And I think it's important when

reading the literature to make sure that, if people are reporting overall or incremental costs, that can make a very big difference in your interpretation.

So some, again, methods. I took a lifetime perspective, so in summing up all of the costs at every age group, things were computed down to a present value using a three-percent discount rate.

For those of you who want more details, again, I can give it. We can talk offline or I could present the article but, again, the $3.2 million is a discounted value because money today is worth more than money tomorrow.

And again, I was able to compute an average per-person cost and then sort of the whole aggregate cost for an assumed cohort.

And if you want to make other assumptions about the number of children in a cohort, you can always take the $3.2 million -- that's a person cost -- and multiply it by a

different number of assumed children, a cohort, and have a different estimate if those legitimately suit your purposes.

So again, methods recap: everything I investigated, costs by age and severity, the lifetime cost is discounted and I was able to take the individual lifetime cost of a person and multiply it by cohort size to get sort of this national estimate.

Let me just stop for any questions or comments. Am I going too fast, too slow? Seems fine. Okay, yes.

Mr. Ne'eman: You know, and perhaps it would be better to wait for the end of your presentation, but I would like to drill down into this concept of indirect costs. Would you prefer that I wait until you finish your presentation?

Dr. Ganz: Maybe, maybe something--

Mr. Ne'eman: All right, that's fine --

Dr. Ganz: -- comes up that answers

it.

Mr. Ne'eman: I'll wait until the end.

Dr. Ganz: Sure, okay. So, the summary results are in this slide: that, again, there's the roughly $3.2 million per person and for the entire cohort that's $34.7 billion, I believe.

I found out that in the U.S. and in the U.K., billion is defined differently so this is a U.S. billion.

So over time, the direct medical costs are about $300,000 per person, non-medical are about three times that size -- and again this was composed of childcare, adult care, special education, those types of costs -- and lost productivity, about $1.9 million per person.

So at least in the work that I did, and this may not reflect reality for some folks here, the direct medical, which also includes therapies, is much less than the non-

medical.

And this is I think an artifact of the literature and the data that I had available and, you know, I would think that this is probably higher than it is now.

But, again, at the time I did this work there was very little data available on how much the behavioral therapies cost in the United States so I was estimating it from other sources. So this would probably require some updating. So again, this number is probably a lower bound.

I hope you have your glasses on. This graph, I mean this table, is summarized in an easier-to-read picture on the next slide, but it just sort of demonstrates that, you know, over time, the direct costs in different categories change.

So, you know, for younger folks, the direct medical is a large component of their lifetime costs because therapies are there. And as a person ages, the direct

medical costs go down and non-medical costs tend to go up because of -- well, around here, it's still special ed, but here you have adult care, supported employment costs.

So it's important to look at this distribution over age because, again, costs are distributed differently by category and that has implications for, I think, who is paying for it as well.

And indirect costs, you know, sort of go up and down. Here, parents tend to be missing a lot of work to care for their kids as they get older, you know, under the assumption that some of them are living in group homes or elsewhere, the parents may be going back to work, but around this age, the costs pick up again because these are sort of the costs associated with these folks who can't go to work themselves.

So, again, it is sort of interesting to examine this because this is sort of, the child as he ages and the parents'

costs sort of kick in and turn off.

And then this would be the overall costs and again, it's sort of high at a younger age, driven by these and then they kind of go down and go back up and then go down again because people at older ages, if they were working, tend to make less sort of as they age and approach retirement.

Dr. Insel: The assumption about life expectancy was what?

Dr. Ganz: Life expectancy was a little lower than normal life expectancy based on some literature. I am blanking on the name now. But yes, so the assumption was that the people with autism would have a slightly lower life expectancy than national health statistics would otherwise indicate.

Ms. Resnik: And I also, just a point of clarification, in terms of residential, where are you factoring and how are you factoring in residential? Are these adults living in group homes or with their

parents? What were your assumptions on --

Dr. Ganz: Not with their parents. It's, it would be external to the house because those are payments that are made to external sources and the literature was, again, I'd have to go back to my notes, but the literature came from whatever was available about adult care costs, so sort of --

Mr. Ne'eman: But are these people in home and community-based service provision settings, are they in ICFMRs, are they in developmental centers? There's a tremendous range of not just quality of life, but also costs associated with the different residential settings an individual could be in. How did you account for that?

Dr. Ganz: Well, I guess the short answer is yes, because it's everything. Whatever I found in the literature, which was not very extensive, basically took an average.

And a model of this type is not

meant to capture reality down to a granular level, so --

Ms. Resnik: I have another point of clarification.

Dr. Ganz: Well, she raised her hand first, sorry.

Ms. Resnik: Oh, I'm sorry.

Dr. Dawson: I am curious, under the medical costs, did you include the cost of a psychiatric hospitalization due to crises that occurred, whether it might be challenging behavior, suicide?

Dr. Ganz: I would have to double-check --

Dr. Dawson: Okay.

Dr. Ganz: the article.

Dr. Insel: Maybe we should let you finish.

Dr. Ganz: Yes. Let me finish and --

Dr. Insel: You know, we will get back to some of these things.

Dr. Ganz: Here's a picture that

displays what is going on here and again, direct medical, which is in green, is relatively high at younger ages and goes down, and the non-medical kind of spikes at some transition to adulthood then comes down.

And then the indirect, relatively low-ish, I mean these are again, this is mainly the parents' lost income and then as the age approaches, you know, starting employment, it goes up to reflect the fact that this is now a blend of the kids and their parents and then it goes down.

It is kind of hard to see, but just focusing on medical costs -- and here they are by category -- behavioral therapies, of course, the most expensive, and it dwarfs everything else.

So I did include hospital and emergency care. I am not sure if that's -- to what extent that includes psychiatric or not. Again, I would have to check my notes to see what was available in the literature at the

time.

Here is a picture of the non-medical costs, which are made up of childcare, adult care, respite care, home improvement, special education, supported work and -- what color is this -- adult care. Yes, so it's zero when kids are kids, and then when they become adults, it starts up there and decreases over time.

Special education again spikes at this young age group when they'd be requiring it and then you sort of get a picture of the relative importance of these compared to everything else.

And here is the lost productivity or lost income. Again, at the younger ages, it's the not-own, which is parental lost income that is driving the overall and then it sort of switches at the age when people would otherwise sort of enter the labor force.

You know, this is admittedly a crude model. Ari's question and my evasive

answer kind of underscores that. And so I did do some sensitivity analyses to see how much this -- this is the total cost, not the individual cost -- but I wanted to understand how some of the pieces of this puzzle influenced the overall estimate of the costs.

And I actually varied many, many components of the model to see what happened to the overall total. Here are some of the, sort of, main drivers. Again we are talking about the total costs, the aggregate cost. Of course that is very dependent on an assumed prevalence.

Prevalence doesn't make a difference for the individual $3.2 million but if you are trying to quote a number for all of the folks in the cohort in the United States, it is obvious that the prevalence is going to drive the overall cost.

Again, this is actually a mathematical truth. The discount rate that I used to compute a present value, of course,

makes a big difference. But, you know, things like the cost of adult care, which is not actually shown here, but the cost of adult care which is, you know, a pretty big driver of costs, you know, if I varied the cost of it by plus or minus 25 percent, which is pretty large, I mean it doesn't do much to the overall estimate. But this is a big driver, making assumptions about lost income is a big driver.

So this and other sensitivity analyses that I have reported in the literature and the article underscored the fact that this is a crude tool and the result is of course a function of assumptions and this article makes a lot of assumptions and I will argue that it's probably a lower bound on the cost.

Okay, so let me wrap up by pointing out some obvious and maybe less obvious features. Autism is expensive. It is not only a disorder or a condition of childhood but of

adulthood and it has implications for costs due to its effects in adulthood.

Based on some other literature that I have found about sort of average healthcare costs, you know, for the average person in the United States, the lifetime costs associated with autism are about twice as much as sort of the typical American's lifetime health expenditures.

And 60 percent of these extra costs are before 21, so it's weighted toward, obviously, the younger end of the age spectrum.

The work that I have done, along with some of the other work that I do cite are some of the first attempts at a comprehensive estimation of the societal costs of autism and I will be the first to admit that it is far from perfect and based on many assumptions, and relies on sometimes old data because that was what was available and I didn't have a budget to go out and collect new data.

And as healthcare technologies and standards of care change, have changed in the past three years and will continue to change, that will affect the validity of this cost estimate.

I argue that it is an underestimate. I didn't include legal costs that people incur to try to get coverage, which I don't think is going to be the case in many other conditions, for example you are not going to sue somebody to cover asthma medication.

I didn't include lost productivity of others, like grandparents, didn't include mental and physical stress, alternative therapies and diets. I did cover some, but not the full cost. Again, there was only a limited amount of available data at the time that I did this; certain behaviors, such as reproductive behaviors, genetic testing, counseling, immunization-avoidance behaviors, which may be not so relevant but was at the

time when I was thinking about this, are not included.

So again, I think that the estimate I have presented is an underestimate. It also lacks advocacy and research costs in the estimate and here is an -- as an example of how much the NIH research budget has grown and this is not included in my estimate, as well.

But on the other hand I feel that they have some validity, I mean, they are consistent with some other reports and the U.K. team that I cite in my original article has done an update. It came out I think this time last year.

It's roughly equivalent, these costs are roughly equivalent to some other conditions that have, well, that have sort of very different prevalences but can have to some extent -- present burden to a person in the family. So, you know, it's somewhat consistent.

And from a policy perspective this

estimate is equivalent to about five percent of the health component of the nation's GDP, just to point out that it has a large impact.

So, let me just wrap up by saying that, again, these are not very -- these are far from perfect estimates and to improve upon them I think we need -- if it's valuable to improve upon them -- a sort of more standardized approach to collect data on use and costs, as well as being very careful to catalogue out-of-pocket costs from families.

Again, that was not really reflected very much in the literature that I found to create my estimate. Prospectively tracking the life experiences of children with autism and their families can help to collect these data and perhaps thinking about other sources of costs that I didn't think about and link everything together to create a more complete picture.

Information on the costs can perhaps help provide families with greater

access to therapies if the costs can then sort of help increase insurance coverage and other coverage for services.

So I would like to wrap up my talk, which is financial costs of autism, with some quotes that I get via email. Some of these are older and some of these are newer.

And this is just to reflect some of the other, softer costs that I haven't included in my estimate. This is from a woman who left her country of residence -- Britain -- to come to the United States to have better services for her child and unfortunately experienced divorce and just shared this thought with me.

And this is definitely a cost that I am not including and this is probably something that people in this room know better than I do, but this sort of struck and resonated with me so I like to include this email.

This is a recent email I got. This

person works for California school districts and is trying to advocate for children with autism and deals with very thorny economic issues and wrote to me for some advice.

This is a very recent email. I think this was -- I think this resulted from my name being on the docket for this meeting. I am not sure. A woman writes to me about a child with autism and severe language delay, whose husband of 12 years, who is a physician, picked up and left because he considered therapy worthless and didn't want to pay for it.

And I don't have one here but I also heard from a lawyer in California who is trying to sue an ex-husband for increased childcare payments, again, to help cover these costs. And the lawyer had asked for a copy of my article to help convince the judge that this child is going to be more costly than otherwise thought.

So with that, I thank you and if

there is time I can be available for questions. Sure, thanks.

(Applause.)

Dr. Insel: We have got about five minutes. I see lots of hands up. So let's start with Stephen and we will go around the table.

Dr. Shore: This is more of a comment than a question. I appreciate all the hard work that has gone into putting together this information. It's badly needed information to help describe and emphasize the need for appropriate interventions for people with autism.

And I was wondering about looking at this information as the benefits of providing proper interventions for people with autism in the United States and making it more positive, because right now it sounds like a real disaster. Really, what is the disaster is that the interventions aren't being made.

Dr. Ganz: Well, I agree, and I

think that -- again, my day-job is for this corporation and part of our job is to help create evidence and value stories for why therapies and testing technologies are valuable because they help reduce suffering and they help reduce unnecessary or reversible or whatever word you want to use healthcare costs.

So you are right, I mean, there was a lot of doom and gloom here and economics is the dismal science but information like this can help, like you said, try to motivate folks to help and develop treatment or testing.

Dr. Shore: Yes, I agree. Thank you.

Dr. Insel: So Marjorie?

Dr. Solomon: As I note, look at your article, one of the things that is really striking to me is the huge bump up as children enter young adulthood. And picking up on the theme of positive and sources of potential growth, I was wondering, I think you made the assumptions based on Eric Fombonne's work that

it is about a 50-50 split between lower-functioning individuals and more higher-functioning individuals.

Did you make any different assumptions about the vocational potential of the higher-functioning individuals, or all individuals actually, because that would seem to me to be a way of potentially lowering costs to society as you have looked at them in your model?

Dr. Ganz: That is a good question. Off-hand I don't know. I mean it would seem reasonable that the lost productivity would be lower for higher-functioning folks.

Dr. Solomon: You know, and potentially a source of even making it lower still.

Dr. Ganz: Sure, I agree, again I would have to double-check and if you are interested in knowing I can certainly contact you right back.

Dr. Solomon: Yes that would be

wonderful. I will talk to you later. Thank you.

Dr. Ganz: Sure.

Dr. Insel: Ari.

Mr. Ne'eman: Thanks. You know, I appreciate you presenting on this and you know, insofar as your work can help improve access to services I think we all support it. I want to you know, sort of drill down into this concept of indirect costs that you have put forward, connected to what I think you referred to during your presentation as the value of prevention.

You know, and I wonder, you know, if you couldn't speak to some of the ethical implications here. I mean, correct me if I am wrong but isn't what you are saying here essentially these people are expensive, we have calculated exactly how expensive they are, now let's save that money by preventing them from existing?

How would you distinguish your

views from the views of say, the eugenics movement of the 20th century, which did a very similar thing?

Dr. Ganz: I don't want to insult anybody. I think that is a ridiculous statement. I think that the point of this work is to point out the lost opportunity costs associated with people who have a health condition that hopefully can be prevented, and I am not meaning that the folks should be prevented from being born.

I mean that they should be prevented from experiencing that condition, just like there is tons of literature on the costs associated with depression, with breast cancer, with overactive bladder; it doesn't mean that we want to prevent people from being born who might have overactive bladder.

We just mean that that's the cost, the associated opportunity cost, those costs can be going to something else, like playgrounds --

Mr. Ne'eman: What about in the example of, say, Down's syndrome --

Dr. Ganz: Right.

Mr. Ne'eman: I mean, that's an example in which, you know, you see very high rates of prenatal termination of fetuses that test positive for Down's syndrome. Now, according to your methodology, does that result in a net economic benefit for society? You know, does that represent part of the value of prevention?

Dr. Ganz: It might, but I'm not -- I really don't -- well, let's put it this way, that's not the perspective I am coming from. I am not coming from that perspective. I am coming from the perspective of a person is born, again, with a condition, can we treat it and what would you save if you treated it?

I think that reading too much into this from an ethical standpoint, certainly people are going to do that, but that's not what I set out to do. I set out to do an

accounting exercise.

Mr. Ne'eman: Let me phrase it a different way.

Dr. Insel: Ari, given our time, let me just jump in because I think we are going to --

Mr. Ne'eman: Well, let me ask one more follow-up.

Dr. Insel: Okay, very quickly, and then we need to go on, Lee still has a question.

Mr. Ne'eman: So, hypothetical situation, you know, there's a person on the spectrum or with another disability who requires, say, support, supported employment services, or reasonable accommodation under the ADA, or even, you know, just basic access to non-discrimination protections in order to work.

And one of the things you are measuring here are lost earnings, or diminished earnings in comparison to the

average individual.

And let's say that person does not get what they need in order to work. Would your model attribute those lost earnings, the cost of those lost earnings, to autism, to that individual's being on the autism spectrum, or would your model attribute the costs to lack of support or lack of accommodations or to discrimination? I mean, does your model distinguish between the two, and if so how?

Dr. Ganz: No, it's a simple -- I call it a simple accounting exercise. These are the costs, and it's not broken down by, sort of, more fine-grained reasons for why these costs arise. They arise because this person has that condition, not because they are being prevented from accessing supports that would otherwise ameliorate their --

Mr. Ne'eman: So part of the cost that you are representing here isn't the cost of autism at all. It's the cost of lack of

support and discrimination, is that correct?

Dr. Ganz: You might interpret it that way, but I haven't thought about that.

Dr. Insel: We are just getting the numbers. That's --

Dr. Ganz. These are the numbers, I mean, it is what it is.

Dr. Insel: Lee, last comment and then we are going to move on.

Mr. Grossman: Michael, I love your work. This has been great.

Dr. Ganz: Thanks, my mom says that too, so --

Mr. Grossman: I have talked to her about that, yes. No, I quote you in just about every presentation I give because I think this information is extremely important.

When you first published this we had a discussion, I guess it was in 2007 when it first came out, and we talked about the underestimation here of these figures, because it really doesn't account for many of the

alternative treatments that families and individuals employ because there is no way to account for that; it doesn't look at the lost -- as Ari was pointing out -- the lost productivity and many, many other aspects of it.

So I guess my question for you, and let me just put this out before the question is asked, there is a lot of resources out there. I agree with you, we don't have autism economists. I am glad that you are doing it. You are one of the few.

Recently we have identified some people that are now actively working on some updates in their states and they are taking it on a national level, so, and will be publishing some of that information soon at the Autism Society.

But my question for you is, what would you like this committee to do to assist you to get that, to get better data or more data, as well as to kind of bridge that gap to

show what, really, what are the true costs of this condition and what it's costing the U.S.?

Dr. Ganz: Wow, that is a good question. Unfortunately my, sort of, day job and my busy schedule prevents me from doing a lot of deep thinking these days outside of, again, my day job and my family.

But I think that from a methods perspective, this is not a population that is easy to capture in many data sets and professional health economists, health services, researchers, have lots of tools such as, again, large databases, whether they are public or private, to look at, to examine costs and other events associated with other health conditions.

This is very hard to capture that way especially since lots of the services are off the radars in terms of these databases. So I think that to the extent that there are families who enroll in sort of longitudinal studies or registries, if there could be a way

to think about expanding that, or creating a large registry where families with young kids who are first identified, can be established and tracked, and periodically fill out surveys or periodically bring in diaries.

I mean, there are many ways to think about collecting the data, and it could not just be very limited to financial data, it could be broader to accumulate more information on costs, on quality of life, on what therapies they are receiving, et cetera.

You know, I am thinking about work that was done at a previous company that I have worked for that was acquired by United BioSource, but we managed a large osteoporosis registry. It was one of a kind. And it gathered information that otherwise was unavailable.

So you know, that might be one thing to think about.

Dr. Insel: That's great. I think we are going to have to move on but let's thank

Dr. Ganz.

Dr. Ganz: Okay. Thank you very much.

Dr. Insel: Will you be able to stay around much of the day if people have additional questions? Perfect, so we can catch you at the break, hopefully. We are going to move on to the second presentation, which is from Dr. Isaac Pessah. This is actually relevant to the conversation we were just having about prevention.

Dr. Pessah serves as Professor for the Department of Molecular Biosciences at UC Davis's College of Veterinary Medicine and as Director of the UC Davis Children's Center for Environmental Health and Disease Prevention.

He is a toxicologist with research interests in the areas of molecular and cellular mechanisms regulating signaling in excitable cells and I think several of us have had a chance to hear you before, Isaac. It's great to have you back to talk about a sort of

progress report on where the center is going right now.

Dr. Pessah: Thank you again to the coordinating committee for the invitation. The UC Davis Center for Children's Environmental Health and Disease Prevention was established in 2001 through a competitive mechanism at NIH and EPA and then granted a competitive renewal in 2006.

So we are actually in our ninth year now and I want to give you the deliverables, what we have done. Because of time limitations, we really can only skim what we have accomplished in the last nine years.

I want to thank our funders, the NIEHS, the EPA and the UC Davis MIND Institute as well as Autism Speaks. I am sorry I didn't have that. I ran out of space.

So what is our goal? What are we trying to accomplish here with respect to understanding autism? Well, we want to evaluate the environmental factors that may

contribute to autism risk. We want to identify them.

We want to evaluate gene-environmental interactions that can contribute to autism risk, and we want to identify xenobiotic mechanisms of developmental neurotoxicity that are especially relevant to autism risk.

How are we doing this? Well, we have a truly interdisciplinary approach, which -- in many circles, interdisciplinary doesn't necessarily score you many points.

But in our case we think that interdisciplinary, integrated research is really essential for understanding the very complexities of gene-environment interactions and autism risk.

We have an epidemiology component, which is headed by Irva Hertz-Picciotto, that is inextricably tied to a community outreach component, which really is the basis for the very successful CHARGE study, which has now

enrolled almost 1,600 families; CHARGE-BACK, which has brought back some of those families, 300 of them, for additional analysis of immunological responses; and the MARBLES studies which we are now spearheading with about 160 women enrolled, which we are following from early in pregnancy all through the way through diagnosis of the children.

We have clinical and cellular immunology that is headed up by Judy Van de Water, and Paul Ashwood contributes to that quite a bit, studying autoantibody profiles and how they may be associated with autism, cytokines and now environmental chemicals, which I will talk a little more about, the polybrominated diphenyl ether flame retardants.

We are very interested in cellular and molecular mechanisms. We feel that these are very important to trying to understand how autism risk may relate to some exposures we already know quite a bit about in terms of

environmental chemicals.

Supporting our work in the projects, we have analytical chemistry through Bruce Hammock, molecular genomics through Frank Sharp, a statistical core that really services all of the above and a meager administrative cost -- core, which supports Rebecca Morrison, who truly tries to tie in all of the administrative loose ends.

So how do you actually assess risk in a complex disorder? Well, it is just as difficult to try to assess risk within the general population. You have to use good epidemiology, but epidemiology is very expensive. You have to know what to look for and what the outcomes are.

In vitro and in vivo models really contribute to our ability to extrapolate the risk. These include high-throughput screening, and I will show you some of that in some of the results and how they can be implemented in autism research, as well as animal models,

particularly mouse models that may have genetic impairments that are relevant to autism.

So, our epidemiological studies are rather complicated but I would like to go through them with you because it will sort of clarify some of the data that I will present in a few minutes.

The CHARGE study essentially looks at two- to five-year-olds. We take several types of samples including blood, hair, urine and these are collected from children within California that are in three diagnostic groups: autism, developmental delay without autism, and typically developing.

A subset of these kids are brought back in CHARGE-BACK, where we can do more thorough immunological assessments. And we also have the newborn blood spots that California banks, to actually go back in time, even though we don't have a longitudinal study here, to look for specific types of analytes

that might be of interest that emerge from the actual CHARGE study.

We have also launched, five years ago, the MARBLES study, which is extremely successful. It's amazing how we can get individuals doing everything we ask them to do in a longitudinal study.

We enroll women at high risk for giving birth to an autistic child as early in pregnancy as possible, follow them through time, collect blood samples in the first, second and third trimester but most often in the second and third trimester.

At labor and delivery we also collect cord blood and other tissues and then we follow their child out for two years and hopefully three years. And again, we can obtain blood from the children through consent.

So these are really the studies. I don't have any information about MARBLES at this point except that it is really going

along quite well. I am going to present some data that has emerged from the other components that I mentioned previously.

So what are some of the findings, what are some of the deliverables?

Well, very early on, we decided that we were going to take the mercury issue seriously and that we were actually going to try to make a contribution to our knowledge about mercury and environmental risk in autism.

And so, initially what we decided to do, because we were collecting blood samples from the kids from CHARGE, was to simply hypothesize what might be the most sensitive target in the blood if you assume that there is an immunological component to autism.

And so we looked at dendritic cells and there are several reasons why we looked at dendritic cells. They are the major player in the immune system that hone in on antigens and

in fact, use oxidative stress as their way of doing business.

So oxidative stress really drives the maturation and function of dendritic cells in the immune system.

What we found was that thimerosal was extremely toxic to dendritic cells. In the nanomolar range it altered their structure and it altered their function and it altered their interaction with T cells.

Now that was one, specific outcome but we also found that in fact through this work we contributed basic knowledge to how dendritic cells function because we actually could show that dendritic cells responded to oxygen tension and this was primarily driven by modulating class II of major histocompatibility complex expression.

And so this tells you how some applied type of research could lead to some interesting basic knowledge about biology.

Now, we expanded this study to a

mouse model and here we looked at an immune-compromised mouse and one thing I want to mention about this SJL mouse is that it doesn't really have an impairment in dendritic cells or antigen presentation; in fact, its immune-compromised through a complex series of events that occurred spontaneously.

But we chose this mouse because we wanted to either replicate or fail to replicate a previous study that indicated that thimerosal was especially toxic to SJL mice and produced symptoms that were similar to those seen in autistic children.

In fact, with this study, even though we had a very well-controlled study with thimerosal and vaccination antigens, we could not replicate the previous study.

So we moved on, and now we tapped into the epidemiological study to ask a very important question of concern to many parents: if their child is diagnosed with autism, does that necessarily mean that their blood mercury

levels are elevated relevant to comparison groups?

And here in the chart study -- again, this is a cohort within central California, or northern California, so it may not be expandable to all nationwide.

But certainly for this group, what we found was that blood mercury concentrations in the CHARGE kids were primarily associated with fish consumption.

Now that may not be surprising to most of us since mercury is in fact at high levels especially in certain kinds of fish and fish consumption is known to be a major source of mercury exposure.

So here we found that mercury levels were not different, at least the distribution of mercury was not different between the autistic kids and the general population, even though within each one of these populations, mercury levels could vary as much as 100- to 500-fold.

So that reflects the differential exposure to mercury but it does not necessarily say that children with autism have heightened mercury levels relative to the comparison groups.

It also does not say that mercury does not cause autism, because that isn't the point of this study.

So we didn't stop there. Frank Sharp actually took the same blood samples that we collected in this study and did a global transcriptional profiling on the boys that had autism and the comparison group that did not, and essentially found about 190 genes that were associated with mercury levels in the autism group that actually didn't change in the typically-developing group.

This suggests -- and again, needs to be replicated -- this suggests that in fact, as mercury levels increase in children with autism, their response to those mercury levels are different from those of typically-

developing kids.

So I want to change a little bit in directions and talk about some of the immunological studies that Judy Van de Water and Paul Ashwood have done.

Clearly there seems to be -- so about a year-and-a-half, two years ago, we reported that if you did a transcriptional profiling within the CHARGE cohorts, what you found was that there was an increased expression of natural killer cells expressed genes in the autism kids relative to the non-autistic comparison groups.

Paul Ashwood pursued this study a little further and actually showed that those markers were, again, elevated when you take the blood samples but when you culture those cells, they are very hyporeactive toward, essentially interacting with the T cells ex vivo, in other words in the dish, which suggests that they have a very different immunological profile in terms of natural

killer cells both in vivo and ex vivo, and this should be looked at a little further.

The maternally derived autoantibodies -- oh, and I wanted to point out that in this study here, what they really found was that when they looked at which genes were changing in the autistic children in association with mercury levels, they were primarily genes that influence cell structure, amino acid metabolism and one other group of genes that were very specific for functional signaling, like antigen presentation, which brings us back up to the dendritic cells.

So, in another immunological study, Judy Van de Water identified antibodies in maternal serum that recognize fetal brain proteins and this has actually gone quite far now.

She has identified what the antigens are and we are trying to develop mouse models using those antigens. But before we could do that, because we didn't know what

the antigens were, we actually took specific IgG fractions from maternal serum and exposed mice during gestation and those results are now being analyzed and we should have a report later this year.

So now I really want to change away from mercury and talk about persistent organic pollutants. These are pollutants that are very stable in the environment. We regulate certain kinds of persistent organic pollutants heavily because we know that they produce risk -- both neurodevelopmental risk but also risk for various types of disorders.

Dioxin-like molecules are heavily regulated but we have had an interest in non-dioxin like structures which we feel have gone under the radar screen, the regulatory radar screen, and are possible developmental neurotoxicants.

These include polychlorinated biphenyls, or PCBs that have particular chemical substitution with chlorine that make

them look kind of kinked rather than flat.

These chemicals have very low to no activity toward the receptor that has been identified for dioxin-like molecules and so we have been paying attention trying to understand their possible role in developmental neurotoxicity.

And so in doing so I want to highlight two papers that were recently published, one that shows that these non-dioxin molecules can differentially alter excitatory and inhibitory synaptic transmission, and that each of the congeners seem to have their own particular impact on this balance of excitation and inhibition in the nervous system.

When we take a look at what the developmental outcomes are in vivo, in an animal model, in this case weanling rats, we have identified that in fact that they alter experience-dependent dendritic plasticity and the mechanism is primarily through a set of

signaling molecules that we have previously identified and been interested in. And I will show you a little bit that data in a second.

Why is this important to neurodevelopmental disorder? Why is it important to autism? Well, there's a general agreement now that many developmental disorders, including autism, is a failure of proper networking during development of neuronal networks.

And this can happen a number of different ways, but in fact, a common convergence point may be that networks fail to produce the necessary complexity or maybe form too high a complexity, and that leads to behavioral impairments.

And so what we have been looking at was how the non-dioxin-like molecules affect the common currency in signaling, as a convergence point for producing impairments, and this is calcium-regulation.

Calcium in cells, especially

neurons, is extremely important for all of these processes, from interpreting environmental signals to adjusting the level of metabolism and the type of metabolism, to altering or influencing gene transcription, affecting dendritic growth and complexity, migration and, of course, cell death.

This is just a highlight, that very low levels of these non-dioxin-like compounds can actually produce dramatic effects in vitro. This is the normal pattern of firing of a hippocampal neuron in culture.

You can see it's very well timed. The frequency and the amplitudes are very characteristic at a particular day in vitro. This is as little as 100 nanomolar of a non-coplanar compound that actually is causing much higher frequency of firing and much higher amplitudes of firing.

And if you use a level of a PCB that is actually much lower than most people have used in published research, you see that

the neurons actually go pretty haywire.

This is actually with a 48-hour exposure. There is some criticism that this level of PCB may actually be partitioning with the neurons and accumulating in the neurons to very high levels and in fact we have measured it and in fact most of the PCB is in the plastic that these neurons are grown and very little of it is actually in the neuron, which means that these levels are probably an overestimate of toxicity.

And this is borne out in a more complex assay, where you actually take rat hippocampal slices -- and the hippocampus here can be seen very clearly -- and look at what happens, on a shrunk timescale, with inclusion of a non-dioxin-like PCB and culture and this shows that the excitability of the hippocampus slice, the synaptic connectivity, changes dramatically in a very short period of time.

In vivo, if you ask what could be the one consequence of such an exposure,

again, in a rat model, these mice show a camera lucida drawing of a cortical neuron before a learning paradigm.

This is the complexity of a cortical neuron after a learning paradigm. We are not the first to show that there is an increase in dendritic complexity with learning.

But those animals that were exposed to a low level of PCB actually already had an increased dendritic complexity before the learning task and after the learning task, instead of increasing further, you actually diminished the dendritic complexity.

So these PCBs, at low levels, tend to alter the trajectory of basal experience-dependent dendritic growth as well as learned -- post-learning dendritic complexity.

So PCBs are declining in the environment. They were banned in 1972. So through our UC Davis Superfund program, we actually took part in a rather large screen of

many different compounds to see if any of the compounds that we came across had similar activities as the PCB activity that I just showed you.

And this is a short list. This paper was published last year. We came up with a couple that actually when you look at the chemical structures, are not all that surprising.

They include the brominated flame retardants, the chlorinated diphenyl ether triclosan and derivatives of bisphenol A were active in our assay and so we pursued these to try to see if they are additive or somehow having the same effects on the end-points that I measured above.

Now why are brominated flame retardants important? Well, again, we went back to the CHARGE study where we actually measured PBDE levels in our participants and in fact we found that in the two- to five-year-old range, that in fact the PBDE levels

in these kids was about five times that the national average and about 10 times that of the Western European levels.

And so this is not the first report of this but this is the first report that actually includes a very well-defined autistic population and we are now looking more specifically at how the immune responses differ in kids with respect to the levels in their blood and those findings are yet to be published.

But this study was in fact published by Judy Van de Water where she actually cultured cells from typically-developing and autistic children from the CHARGE study and challenged them with one of the most abundant PBDEs in human tissues, PBDE or BDE-47 and found that in fact they have very different innate immune responses -- the kids with autism -- than do the control, suggesting that their response to environmental exposure is in fact different.

And finally, I am going to leave with this. I think that initially I had promised to talk a little bit about mitochondrial dysfunction. Again, we have these amazing samples from CHARGE-BACK and the paper is still out for review so I will just say that we think we have evidence of some mitochondrial impairments within the CHARGE kids and I will leave it at that. I will be happy to answer any questions.

Dr. Insel: Great, thanks very much. We have about five minutes for questions or comments. Larke?

Dr. Huang: I have a question on the CHARGE study, that was the one with the pregnant women?

Dr. Pessah: That was the MARBLES study.

Dr. Huang: The MARBLES study. And you said you took 100-something at risk women? How did you define at risk?

Dr. Pessah: They already had an

autistic child.

Dr. Huang: They had another child, okay.

Dr. Insel: Alan?

Dr. Guttmacher: For MARBLES, eventually how large do you think the cohort will be?

Dr. Pessah: Our trajectory is 200 women. We are probably about 150 now. But again, you know, the protocol requires quite a bit of time and so we are hoping to extend it past our --

Dr. Guttmacher: Thank you. That's the question I really wanted to ask. Thanks.

Dr. Insel: Geri?

Dr. Dawson: I wonder if you could comment on what you see as the potential value of the National Children's Study as shedding light on some of the mechanisms involved in environmental factors and their role in autism.

Dr. Pessah: I'm not up to the

minute on how the National Children's Study is changing, you know, how it selects, inclusion into the study, so maybe there are other people here that can comment.

But again, it's a relatively small study for trying to understand autism, even though it's got a very large population. I don't think it's particularly designed to look at autism, it's designed to look at a series, a broad series of impairments. Yes, eventually.

Dr. Insel: Linda.

Dr. Birnbaum: Oh, I think it's always fun to hear some of the work that you do. I was just wondering if you could tell me what other environmental compounds you might have been looking at or picked up by you and Bruce and Mike Dennison and so on in the high-throughput screen?

Dr. Pessah: Yes. Yes. So --

Dr. Birnbaum: What about certain pesticides, or -- ?

Dr. Pessah: DDE came up as a hit in our screen, which isn't surprising. We have looked at that structure. And again, there's a pattern that is emerging and the one that was really surprising was chlorpyrifos.

Dr. Birnbaum: Well, maybe not, given some of the data that is coming out.

Dr. Pessah: Maybe not. Maybe not.

Dr. Insel: Lyn.

Ms. Redwood: Isaac, I had a question about the mercury levels in children with autism. Since mercury in the blood is only going to reflect a recent re-exposure, like fish consumption or what's being -- what they recently were exposed to, was their any attempt to get to body burden issues with these different chemicals, because if children with autism do have lower levels of glutathione and they aren't able to excrete, then they are more likely to be bound in the tissue and the central nervous system.

And so I think if there would be a

way to get to body burden, that might be a more important question to ask than just what blood levels are. Is there any attempt to do that?

Dr. Pessah: Lyn, that's a very good question and in terms of how we couched the paper, that was one of the major limitations of this study, is that we didn't give body burdens. We basically just looked at blood levels and it was a single exposure -- I'm sorry, a single time point at which we examined the levels.

So we are hoping that the MARBLE level will give us more of a trajectory but again it doesn't get to the body burden, unless we look at some of the samples collected at birth. I think that that might give us a better idea.

Dr. Insel: Let me draw you out on two other questions. First is, do you collect DNA on all of the subjects so that you can genotype and look at the relationship of

genotype and -- ?

Dr. Pessah: Yes, we have DNA on all the kids.

Dr. Insel: And the second is, you quickly went over the autoantibody story, and you said that that's ongoing and there's lot more coming. Can you unpack that a little bit, because that just seems to be an extraordinary set of findings, if in fact there would be a biomarker for risk that we could begin to explore?

Dr. Pessah: Yes. So, I guess I can talk in generalities. I do have to go back to Davis and I think I have a meeting next week with Judy so I think she has a good lead on some of the antigens that these autoantibodies are recognizing, which would be a boon for us because then we could do highly-controlled studies in mice.

The autoantibody profiles are becoming a little more complex. There was a 73-kilodalton and a 37-kilodalton antigen and

now there's a 39 that seems to be involved as well.

In our mouse study with the IgG, we -- it was a very difficult study and I think we are finally to the point where we are doing the final data analysis because in fact, the IgGs can be very toxic.

Dr. Insel: Ari, you get the last question. Go ahead.

Mr. Ne'eman: I am curious, in respect to any of the at-risk children that were in the end diagnosed as on the spectrum, did you collect any data beyond whether or not a diagnosis occurred? I mean, did you collect -- is there any data available for example as to the particular traits, given the very broad degree of diversity within that diagnosis?

Dr. Pessah: Sure. Sure. So, I think one of the strengths of all of these studies is that we have very deep phenotyping on all of the kids. So initially in CHARGE, they are recruited through the California system, but

then they are brought to the MIND institute for evaluation and further testing.

And so, we do have very deep phenotyping for the children,

Dr. Insel: Well, this has really been terrific. Thanks, Isaac, for this presentation which I am sure we will hear more about it in the future. We are scheduled to take a break for -- it was going to be 15 minutes but we have encroached a little bit on that, so let me make sure everybody is back right at 11:30 and we will use that to go on to the next session. Thanks.

(Whereupon, the above-entitled matter went off the record at 11:21 a.m. and resumed at 11:44 a.m.)

Dr. Insel: We are just a couple of minutes behind schedule so I want to make sure we get everyone back in the room.

Thanks for, some of you, for being back in the room. It's a pleasure to introduce Dr. Philip Landrigan. Dr. Landrigan is a

Professor and Chair of the Department or Preventive Medicine at Mount Sinai School of Medicine and the Director of the Children's Environmental Health Center.

He has worked to develop the field of environmental pediatrics, which examines potential health threats to children, such as lead, pesticides, air pollution and plastics.

He has been consulted extensively by the World Health Organization and has been involved in the planning of the National Children's Study.

And we are just delighted to have you here, Dr. Landrigan. Let's make sure we can get your slides up and then we are good to go.

Dr. Landrigan: Somehow, an errant version of my talk was here so I am just going to take 30 seconds to load the correct version in and apologies.

Dr. Insel: Okay.

Dr. Landrigan: Sorry about the

technical difficulty. Well, thanks very much to the coordinating committee for inviting me here. It is a privilege to follow Isaac Pessah and I think you will see a certain intersection between what I have to say, which is more in the nature of commentary, and his deeply data-driven presentation.

So, start with a slide or two that contains material that is very well-known to virtually everybody in this room, I think, that the current incidence -- actually that's an outdated number, the most recent data of course from CDC indicates that it's one in 110 children, which is very much higher than a decade ago, no racial differences, but a clear gender difference with autism in its various forms being much more common in boys than girls.

Another set of facts that are well-known to people here, that there is very great variation in the clinical presentation of autism, which has led to the notion of the

Autism Spectrum Disorder and my own belief is that autism is probably not a single disease any more than cancer is a single disease. It's probably a family of diseases that share certain phenotypes which is why it's so important to do what Isaac Pessah referred to as deep phenotyping, because I suspect eventually we will come to understand that there are biologic differences underlying the various phenotypes of autism.

There's very clearly a genetic component to the causation of autism, and in fact some of the very elegant genetic work has come out of my institution, Mount Sinai School of Medicine.

Joan Buxbaum has been a leader in this work and has employed various strategies, most recently the search for copy number variants being associated with autism and the sense that genes that are involved in encoding the structure of synapses are perhaps particularly important.

But important and elegant as that genetic work is, I believe there are some shortcomings to it and let me outline those. These are not criticisms of the work per se, these are comments on the fact that it's important not to over-generalize the genetic research and ascribe all autism to a purely genetic causation.

So one of the problems is that none of the specific genetic abnormalities that have been linked to autism account for more than a very small percentage of cases and in the aggregate, these factors that have been identified don't account for more than 20 or 25 percent of the cases.

Some might say 30 or 40, but even if it's 40, that leaves a lot of territory uncovered by a purely genetic etiology and although one can invoke various permutations on genetic etiology, I find it's hard to stretch a purely genetic theory of causation to cover all the different clinical and

epidemiologic features of the presentation of autism.

And those shortcomings plus the emerging body of data that is going to constitute the rest of my presentation, create I think space in etiologic thinking here that gives us lots of room to consider environmental causation.

And by the way I should mention, those of you who want to read more deeply, I am sorry I didn't think to include it in the materials I sent to Roxann, but I had an article that summarized these arguments which appeared a couple of months ago, in March I believe, in a journal called *Current Opinion in Pediatrics* and I have actually arranged for that to be sent to Roxanne from my office so it can be distributed to the committee.

Here is some collateral evidence, too, for the notion that environmental factors are part of the story. There was an NAS report several years ago on neurodevelopmental

disabilities.

This report concluded that environmental exposures per se, by themselves, accounted for about three percent of neurodevelopmental disabilities. These are all disabilities, not simply autism.

And using a very broad definition of the environment to include nutrition and micronutrients and infections, they concluded that another 25 percent of the whole gamut of neurodevelopmental disabilities are caused by interactions between environmental factors and individual susceptibility factors, presumably genetic. And therefore, doing simple arithmetic, that's 28 percent.

So, going forward, I would like to sketch for you four lines of argument that, I think, support the hypothesis that there are environmental factors that contribute to the causation of autism.

The first is the general knowledge that has been pouring in now ever more rapidly

in recent years about the vulnerability of the fetus to toxic chemicals, and specifically about the development -- the vulnerability of the developing human brain to toxic chemicals.

Thirdly, although the particular cases I am going to present here in no way can be thought of as driving the current situation with autism, the fact that certain prenatal exposures can cause autism -- and I will outline them in a few minutes, go over them in a few minutes -- is in my mind proof of concept or the principle that prenatal exposures, probably in early pregnancy, can contribute to autism.

And finally, the fact that there are hundreds, perhaps thousands of chemicals out there in today's world, synthetic materials, many of which did not exist in the 1950s and `60s, chemicals to which children are routinely exposed that have never been properly tested for toxicity, creates, again, a lot of space for pursuing the hypothesis

that chemical exposures contribute to causation.

So start with a little bit of history, going back to the `50s. There were a couple of early episodes, specifically thalidomide and DES, which made it painfully obvious that the placenta is not some sort of impervious barrier that protects the embryo and the fetus against toxic chemicals.

Instead, these terrible tragedies demonstrated with great clarity that chemicals can get across the placenta, can get into the fetus, and can cause devastating damage.

And then, more specifically the vulnerable of the developing nervous system to toxic chemicals was demonstrated most painfully in Minamata, Japan. I think most people in this room know the story, but for any that don't, let me quickly tell it.

Minamata is a fishing village in southwestern Japan, faces on a little bay and in the years after World War Two there was a

chemical factory there which was making polyvinyl chloride using mercury, metallic mercury, as a catalyst.

It was a not well run operation. A certain amount of the mercury escaped the plant and ran out and got into the bay which was basically just across the road, got into the sediments in the bay, where it was converted by marine microorganisms into methyl mercury and that methyl mercury went up through the marine food chain to bioaccumulate in species at the top of the chain.

The first clue that something was amiss was the cats, who presumably ate fish that had washed up on the shore. Cats began showing ataxia and other neurologic manifestations and people talked about the dancing cats.

And then babies began to be born like this little child here, microcephalic, blind, profoundly retarded, spastic, as a consequence of their exposure in utero to

methyl mercury that the moms had consumed in fish. The mothers themselves were physically unharmed.

And this tragedy showed the fundamental different susceptibility between the maternal and the adult brain and presumably this vulnerability of the developing brain is a consequence of the enormous complexity of early brain development.

The fact that the brain starts out, of course, as a strip of cells along the dorsal ectoderm of the embryo, those cells form up to become the tube which is the core architecture of the brain and spinal cord and then rapid multiplication of cells during the months of pregnancy and continuing into post-natal life, resulting in the formation of the brain with billions of cells, trillions of synapses, all of them precisely engineered.

And the price we, as a species, pay for that incredible complexity is that there's

an awful lot of vulnerability associated with brain development if something like lead or PCBs or certain pesticides get into the brain early on and interrupt cell division, interrupt cell migration, interrupt axon or dendrite formation, there may never be an opportunity for that missed opportunity at architecture to be repaired and the consequences are permanent damage.

And it's from this line of thinking has evolved the concept of windows of vulnerability in pregnancy, specific windows to susceptibility in early life that simply have no counterpart in adult life.

And there's been an awful lot of attention given over the past 20 years to understanding precisely why it is that children are different from adults in their susceptibility to pesticides and other toxic chemicals.

This is a report that I was involved in that came out -- it's hard to

believe, but almost 20 years ago now, in 1993, on pesticides.

And we concluded that there are several fundamental differences that account for the differential susceptibility. The first is difference in exposure.

Prenatally, you have the intrauterine exposures. Postnatally, dietary exposures and exposures that relate to children's behaviors: diminished ability to break down and get rid of chemicals, heightened biological vulnerability as I have just been describing, and finally the fact that kids have lots more years of life ahead of them.

So some of the disease and disability that may be caused by chemicals isn't necessarily disease and disability that shows up during childhood but rather, early exposures lay the seeds for conditions that show up years or decades later.

Now, moving on to autism

specifically, as I said a few minutes ago, I believe the strongest proof of concept evidence that certain -- that there may be certain factors in the environment that cause autism, is the fact that a small number of environmental exposures have been convincingly linked to autism and it is interesting that each of these exposures were exposures that occurred prenatally, in fact, very early in prenatal life, probably in the first trimester, when the fundamental architecture of the brain is still being established.

The first of these is thalidomide, the same pharmaceutical that was responsible in the 1950s and `60s for the epidemic of limb deformities. A certain percentage of these children, especially those that were exposed around weeks six to eight of pregnancy have developed autism. Stromland in Scandinavia and Patti Rodier have described this one.

Misoprostol is a medication not much used in this country but used overseas to

induce abortions in early pregnancy. Unfortunately, some of the women who take the drug in the effort to induce abortion don't succeed in causing abortion and they then carry through pregnancy babies who were exposed early on to misoprostol and there's a study from Brazil which suggests that babies who have had this exposure in the first trimester have increased risk of autism.

There are some old studies going back to the days when rubella was still with us suggesting that exposure to -- maternal infection with rubella in the first trimester is associated with autism in some cases.

Valproic acid, an anti-seizure medication, an anti-epileptic, has been linked to autism and in fact there's an animal model now been developed.

And then, most recently, some of the work that has come out of the Children's Environmental Health Center that NIEHS and EPA supports at Berkeley -- Brenda Eskenazi and

her group -- suggests that the organophosphate insecticide chlorpyrifos may be linked -- at least according to Maternal Report -- to pervasive developmental disorder.

The phenotyping in that study wasn't great, but it is nonetheless, it's a clue and certainly worth pursuing.

I also want to comment on the vaccine link. There have been an awful lot of studies that have looked very diligently at large numbers of children.

I will acknowledge that there is also the possibility that there are small groups of children who have particular susceptibilities. I don't think any of these studies can definitively exclude that possibility. It's awfully hard to prove that sort of thing through epidemiologic analysis.

But at least in any of these big studies that have been done, there is no evidence in my mind that vaccines or any of their components or in any of their

scheduling, can be linked to the current situation with autism.

I think one of the most convincing of these studies is the one, the third one down there, that was undertaken in Yokohama, Japan.

In the 1990s the public health authorities there were concerned about reported increases in rates of autism and so for about two years they suspended all administration of MMR in the health system there.

And it is a very top-down health system so when the minister of health speaks, things happen. So there was about a 24-month period when kids didn't get MMR. Rates of autism continued to increase unabated during that 24-month period at which point they said enough is enough and they resumed immunization.

But that said, the fact that vaccines don't seem to be linked to autism

certainly doesn't exclude the possibility that there may be other factors in the environment that are causally linked to autism.

We know that children today are surrounded by thousands of chemicals. Some of these, of course, convey great benefit, like antibiotics, like cancer, chemotherapeutic agents. But others are toxic and measurable levels of several hundred chemicals are routinely picked up in CDC surveys in virtually every person of any age group in this country.

These chemicals are not just out there in some mysterious cyberspace. They are in us. They are in our kids. And so to be sure the levels are low, but on the other hand, very little is about the toxicity of the chemicals considered individually, and less still about possible interactions and synergies among them.

Here is some actual data from EPA on the current state of chemical testing.

There is about 80,000 -- actually it is now closer to 85,000 chemicals -- registered with EPA for commercial use.

The ones that really matter are the roughly 3,000 that are considered high production volume chemicals.

Of these there is no basic toxicity information available, at least not in the public domain for about half these chemicals and for four-fifths of them there is no information available on developmental toxicity.

So the bottom line here is that all of us, including our children, are exposed daily to a wide range of chemicals whose potential toxicity has not been assessed.

Now we have got -- we have been building over the past century and most rapidly over the past decade, because research has accelerated and our tools have become a lot sharper -- we have been accumulating a list of chemicals that we now know with

various degrees of certainty can cause injury to the developing brain, chemicals that are developmental neurotoxicants.

Lead, of course, was the first of these. The first recognition of childhood lead poisoning goes back now more than 100 years to early recognition in Australia; methyl mercury, beginning in Minamata in the 1950s and `60s; PCBs with the work of the Jacobsons; arsenic with Joe Graziano's work in Bangladesh, manganese the same.

And then the pace is quickening: organic solvents, organophosphates, I just mentioned chlorpyrifos. But there are lots of other organophosphates in addition to chlorpyrifos: organochlorines; DDT, DDE; phthalates -- Stephanie Engel, my colleague at Mount Sinai, reported a few months ago that prenatal exposure to phthalates is associated with a phenotype that looks an awful lot like ADHD in seven and eight-year-old children.

So prenatal exposure produces

measurable injury seven or eight years later. And there was a paper I just read this morning on the plane coming down from Korea, in EHP, showing that prenatal exposure to phthalates is associated with diminished intelligence.

PBDEs, brominated flame retardants: Julie Herbstman from Columbia, the Children's Center there, the NIEHS, EPA Children's Center at Columbia, has reported that prenatal exposure to PBDEs is associated with diminished intelligence and some of Ira's work seems to converge on that.

And then beyond that little list there, there are another 200 or so chemicals that have been shown to be neurotoxic in adults, in human adults. These are for the most part workers exposed occupationally. These are solvents, metals, pesticides, plastics, chemicals.

And then there's a thousand more that are neurotoxic in animal species. So the big question is, are there other chemical

causes of autism among these 1,200 or so chemicals that have in some species, either human or animal, some demonstrated neurotoxic potential?

I think there is a lot of room here for some research. Fortunately, because of the investment that has been made over the past decade in the children's centers, we -- and also through the Superfund program and toxicologic testing, and at the NTP, we are beginning to acquire the tools to drill down into this.

So I think that going forward we are going to need a three-pronged strategy and actually I wish that I had preceded Isaac because the work he is doing is carrying out several of the prongs here.

First of all, we need enhanced testing of chemicals. We just can't continue to develop, produce and disseminate into the environment interesting chemicals that may have beneficial commercial properties but that

have never been tested for toxicity. It's just not wise biologically, if for no other reason.

And there is of course legislation wending its way through Congress that would mandate toxicologic testing if it is passed, but whether there is legislation or not, I think the approaches that Isaac discussed, that NTP is pioneering, for high-throughput toxicology, are terribly important.

We need to start whacking away at this backlog of untested chemicals. Fundamental research that looks at timing of exposure in pregnancy is going to be important. That's not my area, so I just put it there as a placeholder.

And then finally, something that I have been involved in, epidemiologic studies, especially prospective studies, multi-year studies, are very important.

Let me say a word for those who aren't epidemiologists, why it is so important I think to focus on prospective studies, even

though they are expensive, even though they are time-consuming.

The great advantage of prospective studies that recruit mothers during pregnancy and then follow mothers and babies longitudinally over the years, is that such studies are in a position to measure exposures in real time as they are actually occurring.

A lot of the chemicals that we are worried about as potential neurotoxicants and potential causes of autism, are chemicals that have very short half-lives in the human body: hours or days -- phthalates, many of the pesticides, for example, are come and gone.

Now people may be repeatedly exposed and so they maintain a level over the months and over the years, but the individual molecules don't hang around very long. They are very unlike lead, very unlike PCBs or DDT, which do last for substantial periods of time.

So what this means it that if exposure is not measured when it matters,

which is probably early pregnancy, then the chance to link exposure and outcome is degraded and that's, I think, the most fundamental argument for supporting prospective studies that incorporate careful measurement of chemicals, careful assessment of DNA and probably RNA and maybe look also at epigenetic changes.

And then finally, follow the kids prospectively, evaluate them and phenotype them as they grow up.

We are just starting something at Mount Sinai which actually looks uncannily like the MARBLES study that Isaac described to you. We are taking advantage of the fact that we have 6,000 deliveries a year in our institution.

We have strong genetics. We have a strong environmental group. And we are going to start enrolling moms during pregnancy and catching samples prenatally, catching cord blood and placental samples at delivery and

then following the babies out.

And also, of course, the National Children's Study. Now, the National Children's Study came up in the Q&A in the previous talk. Let me say a few word about the children's study for those of you who aren't familiar with it.

First, a word about our repository at Mount Sinai, though. It's a tissue bank. We hope to get at least 2,000 enrollees per year, that's a third of the babies and mothers that are born at Mount Sinai.

To the extent possible, we are going to use data collection instruments that have been pioneered in the children's study so that we can possibly link our findings to studies from the children's study.

I think I may need a little technical help here.

And we are going to follow the babies prospectively. One of the things that I feel rather proud of is that one of our young

scientists has invented a very clever device that looks a bit like an apple-coring thing, but ultra-sharp, for biopsying placenta.

And it means we can quickly do three or four punch biopsies on each placenta, pop them into liquid nitrogen and preserve them, which gives us the opportunity, I am told, to do epigenetic analyses on the DNA.

So here's the National Children's Study, supported by the Congress through the Children's Health Act of 2000 and directed by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, a study that the planning began in the year 2001. We took it into the field in January, 2009 so about 18 months ago.

We began the study in seven so-called vanguard locations and at latest count, 18 months in, the seven vanguard centers of which I am the principal investigator of one of those, which is Queens, New York, have recruited about 1,100 and some mother-infant

pairs.

And so it is moving along. Recruitment is proceeding a bit more slowly than expected. The systems are still being debugged. But the study is moving forward.

And just recently, NICHD has awarded contracts to another 30 academic health centers across the country which will be going into the field probably not this year, but hopefully rather early in 2011.

So by some time in 2011 we will be actively prosecuting the study in 37 locations across the country. I have listed the web address at the bottom there for those of you that want to read more about it.

So what is the study, for those who aren't familiar? Well it's a multi-year, prospective study, that will follow 100,000 mothers and their children from early in pregnancy out to age 21.

In fact it is hoped that roughly a quarter of the moms who participate in the

study will be recruited before they conceive pregnancy, and that is being done by going door-to-door, knocking on doors in selected counties and neighborhoods in the country, inviting women who are already pregnant today to join the study right then and there, but also invite women who think they might become pregnant over the next several years to be on a watch list where we are permitted to call them back periodically and catch them as soon as the blessed event occurs.

Also, the National Children's Study recognizes that even though it's large, with 100,000, it has limited power to look at certain rare diseases, like cancer, possibly autism, and therefore there's an active process through the World Health Organization to link to studies in other countries, like the Norwegian MoBa study, the Japanese children's study and other studies that are either under way or planned to be launched in the near future.

These are juts a few of the many, many questions that are incorporated in the study. It is hypothesis-driven. There are about 30 major hypotheses that we are -- and various sub-hypotheses that were very carefully crafted through a long and arduous committee process.

You can read about the hypotheses on the website. They are all listed there, in the background material to them.

These are the 105 counties in which the study will be conducted. These counties were selected by the statisticians at CDC, the National Center for Health Statistics, and the notion is that these 105 counties are statistically representative of the U.S. population.

The seven that have names attached to them are the seven vanguard centers, which you can see listed there, which you can see listed there, which span the country from New York to southern California.

And this is the way it works. I have already somewhat touched on this. Door-to-door recruitment, although that will probably be supplemented in the not-too-distant future by recruitment at prenatal centers and birthing centers.

And moms are signed up, they are consented, we get blood, urine and hair samples at several points -- two points during pregnancy.

Prenatal ultrasounds are recorded, very, very careful histories are taken, DNA is collected, nurses on beeper run to the delivery room when the baby is born, collect cord blood and placenta, do a quick examination of the baby and then there are scheduled examinations as the child grows up with detailed developmental assessments at several points along the way.

The model for the children's study was the Framingham Heart Study. Some of you probably know about this.

Framingham, Massachusetts launched in 1948 at a time when stroke and heart disease were epidemic in this country post-war, and the causes were not really very well-known, maybe suspected but not known; and Framingham identified the major risk factors, turned that scientific information into a blueprint for prevention and the consequence has been a 60 percent reduction, an amazing triumph of public health that doesn't get the attention it should get, driven by the scientific knowledge that was generated by Framingham.

We hope to do the same with the data that we will collect through the children's study and we hope to identify specific causes of disease in children and to achieve what we did back in the 1970s and 1980s in this country, when we took lead out of gasoline.

We took lead out of gasoline starting in the `70s because information was

beginning to build up at that time that even low levels of lead were toxic to brain development in children.

And starting in `76, EPA decreed that all future new cars needed to burn lead-free, so it was about a 10-year phase-out to get rid of lead in gasoline, came down step-wise.

And it was expected that there would be a one- or two-microgram decline in blood lead levels. In those days the average blood lead level on all Americans was about 17 micrograms and in kids it was about 20 micrograms, a level of course that would make a pediatrician's hair stand on end today.

So the predicted decline is represented by the white line; the actual decline is the yellow line.

There was this plummeting, this 50 percent decline in the first four years, which has continued since, with the result that over the past 25 years, thanks to David Rall's

prescience at NIEHS and bold action at EPA, we have brought about a 95 percent reduction in lead poisoning in this country and the economists -- and I was glad to hear Dr. Ganz this morning because it is always important when you go to Capitol Hill to put a dollar figure on these things.

And the economists reckon that the economic benefit to American society that has resulted from getting lead out of gasoline is $200 billion in each annual birth cohort.

And that is mostly due to the increased lifetime economic productivity of the children who were spared subclinical lead poisoning.

So let us hope that the children's study and other studies that parallel it will achieve as much. Thanks very much.

Dr. Insel: Thank you. We are encroaching on our lunch break but if there are questions people want to ask, or comments, we can take three or four minutes. Or if

people have, if their stomachs are growling we can go to lunch. Any comments, questions? Lyn?

Ms. Redwood: I just, I had one I wanted to share with the committee. With regard to the maternal rubella infection that you mentioned being associated with autism, when you look back historically, maternal rubella oftentimes had severe defects like cataracts and physical abnormalities and it really wasn't until the `60s with Stella Chess that we started seeing autism as an outcome of maternal rubella infection.

And at the same time, there was a treatment started where women who were exposed were given gamma globulin injections, which contained thimerosal, and a lot of people are not aware of that association.

I even know of a family whose -- the mother was exposed to maternal rubella infection during pregnancy. The son was born completely normal, no rash, no physical abnormalities and he went on to subsequently

develop autism and she was one of the mothers who had received the gamma globulin injection.

So I think historically, we link that with the infection itself and it might actually have possibly been related to a treatment to prevent the infection.

So I just wanted to throw that little historical caveat out.

Dr. Insel: Can I ask a quick question about how you think of this as a toxicologist. What we are talking about here is an increasing rate and much of what you -- many of the examples you used were either regionally very specific or, as in the case of lead, fairly stable for a period of time before any intervention was made.

So how do you think about that, the fact that the numbers we have, no matter whose numbers you look at, show a continuing increase. You made a good argument for why the genetics wouldn't support that. But from the toxicology perspective, does that tell you

that whatever it is that is driving this is accumulative, or is it getting worse and not better?

Dr. Birnbaum: Well, first of all it tells us that lead is not driving it. It tells us that PCBs are not driving it. They may be part of the story but they are certainly not driving it because we know that levels of PCB are slowly, slowly coming down in the American population.

The best answer I can give you, which is obviously pure speculation, is that some other chemicals that are presumably developmental neurotoxicants that haven't been properly assessed for neurotoxicity and that haven't been yet linked through toxicologic or epidemiologic studies to autism, may be the part of the story.

Could it be brominated flame retardants? Could it be phthalates? Could it be bisphenol A? All of those are chemicals whose production and environmental

dissemination have been increasing over the last 25 years.

I think it remains to be seen. I also don't think that it will be one chemical. I mean, it might be, but I think just as we now know that there are a whole sweep of chemical carcinogens that cause different cancers, there probably are various chemicals that contribute to autism and it depends on which child is exposed and when and in early development the exposure takes place.

I think there is room here for a lot of investigation, the kind of work that Dr. Pessah described has some very strong early steps on the journey and there is a long way to go.

Dr. Insel: Linda, do you want to have the last word about this?

Dr. Birnbaum: Well, I totally agree. Phil made most of the points I was going to make, that there are many chemicals that we are exposed to.

If you look at the CDC report card, the last one was 212 different industrial chemicals present in the blood of essentially all Americans. And that's what they measure. That doesn't tell you how many things they don't measure.

And for many of these things, levels are not going down but are continuing to increase but I think the most important thing is, it's probably not one single -- never mind that it's not one disease, it's also not one chemical.

And chemicals may be acting -- we know that some of them can act in additive and in some cases even synergistic fashion, at least certainly the animal studies are indicating that.

So I think there are a lot of possibilities here that deserve some investigation.

DR. INSEL: Well, on that note, let's break for lunch. We will reconvene

exactly at 1 p.m. for public comment.

(Whereupon, the above-entitled matter went off the record at 12:14 p.m. and resumed at 1:05 p.m.)

AFTERNOON SESSION

(1:05 p.m.)

Dr. Insel: We have two people who have signed up for public comment so we will start as soon as we have -- and we do -- one more member of the committee here.

The first person who we have on the list is Dr. Joseph Nyre and Dr. Nyre is here. You can either use that podium in the front or Dr. Nyre, if you are more comfortable, you can sit here and use the microphone.

So the routine here is that we ask people to introduce themselves and to hold their comments to close to five minutes. Since we have a little extra time, if you want to take an extra minute or two that would be okay.

Dr. Nyre: Well, thank you. My name is Dr. Joseph Nyre. I am the President and CEO of the Hope Institute for Children and Families and a clinical associate professor at the University of Illinois, Chicago School of

Medicine.

Chairman Insel and members of the committee, it's a privilege to address a group that has made such a significant impact on the system of care for individuals with Autism Spectrum Disorders.

Your work undoubtedly has not been easy. This committee, in collaboration with researchers and clinicians from across the country, has been charged with building a system to develop and sustain effective, evidence-based services for the future, while hundreds of thousands of individuals and families struggle with limited access on a daily basis.

Some, out of frustration, have argued that the IACC and the Combating Autism Act have ignored service needs. I take a contrary view.

I would argue that a careful review of Combating Autism Act funding priorities reveals a commitment to the type of research,

work force development and collaborative effort necessary to develop and sustain quality services at the local, state and national level.

Researchers, clinicians and families in Illinois have seen solid, progressive benefits of the Combating Autism Act and are hopeful that the reauthorization will integrate the research, work force and system development work funded in the past with service initiatives funded, and needed to be funded, in future years.

The autism program of Illinois that is governed by the Hope Institute supports a network of over 30 universities and agency partners committed to research, work force development and service for individuals with Autism Spectrum Disorders and their families.

The autism program of Illinois is the largest, statewide network of services in the country. Since its inception, during fiscal year 2003, the autism program has

provided more than 41,000 clinical contacts and trained more than 43,000 parents and professionals in Illinois.

The autism program partners at the University of Illinois, Chicago Institute for Juvenile Research and the Institute for Disability in Human Development have been involved in NIH research, training and system development funded through the Combating Autism Act.

The Hope Institute submitted and received one of the first HRSA state implementation grants funded under the Combating Autism Act.

Illinois, through state, national and foundation funding, has built an infrastructure with the capacity to advance a major service initiative.

My work as an administrator, clinician, educator and researcher at the Hope Institute, at Harvard Medical School, at Baylor University, the University of Kansas

and now the University of Illinois at Chicago, has given me a unique opportunity to experience the tremendous gains that are possible through integration of research, work force development and service.

Leaders in Illinois are calling for the IACC to build upon the strong foundation created in Illinois and other states as well, to advance services and link services to research.

Recent legislation, including the Autism Treatment Acceleration Act, expresses the clear call for service initiatives.

Illinois is an example of the early success of the Combating Autism Act's foundational work. The autism program state allocation provides a base of support for service programs. However service funding from Combating Autism Act is necessary to effectively link service to research and scale the service to the tremendous needs.

We are quite pleased about the

promising work of this committee. I look forward to the reauthorization of the Combating Autism Act and all the promise it holds for families across the country. I thank you for your time and for your commitment and all the work you do here and back in your professional lives outside of the committee. Thank you very much.

Dr. Insel: Thank you, and I will remind the committee that you should have a printed copy of all of the public statements as well as statements from people who aren't in attendance. Anything that has been submitted to the committee over the last few months since our last meeting has been included in your folder, so you should have a chance to review that.

Thank you very much.

Dr. Nyre: Thank you.

Dr. Insel: And our second person on our list for public comments, and of course we will come back and talk about public comments

later in the day. We have got some time later in the afternoon to discuss Dr. Nyre's statement as well as the one from our second public commenter, who is Carolyn Rogers.

Ms. Rodgers: Good afternoon. Everyone is searching for what is causing autism. Geneticists are studying gene arrays. Epidemiologists are looking everywhere, even under the kitchen sink. And others are seeking proof that would convince non-believers that vaccines are causing autism.

Meanwhile, emerging facts indicate that pregnant women who get first trimester prenatal care and/or the most ultrasound exposure are at the highest risk of bearing autistic children.

This is a surprising discovery that is showing up along ethnic, educational, age and economic divisions: four different categories that all wave red flags.

Along ethnic lines, by combining information from two CDC reports, we find that

white women, who have significantly more autistic children than black or Hispanic women, were much more likely to receive first trimester prenatal care. That is a red flag.

Another ethnic finding is that Hispanics, who had the lowest autism rate in both the 2002 and 2006 report, were 20 percent less likely to receive an ultrasound during a prenatal visit than white women. That is another red flag.

Several studies have shown that highly-educated mothers are more likely to have children diagnosed with autism than mothers without high school diplomas. A study published earlier this year showed that in the majority of 10 newly-identified, California autism clusters, the rate was four to one.

A CDC entry into prenatal care report reveals that the percentage of pregnant women without high school diplomas to not have first trimester care or skip prenatal care altogether was between three to four times

greater than for women with high school diplomas and some college. That is another red flag.

Maternal age is also a factor in autistic outcomes. A 2009 study found that for every 10-year increase in a mother's age, her risk of having an autistic child increased 38 percent. Since women over 35 average three or more ultrasounds than younger women, I think this deserves another red flag.

Economic differences also emerged. The only two states among those monitored in the 2006 Autism Prevalence Report to suffer cutbacks in Medicaid funding for prenatal care have the lowest autism rates. Another red flag.

On the other end of the economic spectrum, two studies regarding autism prevalence and socioeconomic status, one out of the Wisconsin School of Medicine and Public Health and the other from the CDC, found significant associations between higher

household income or socioeconomic status and autism.

This is the same group of people that can afford the best prenatal care and buy keepsake ultrasound image packages that cost hundreds of dollars. I believe this deserves another red flag.

In a study of prenatal ultrasound trends, differences in ultrasound exposure emerged according to healthcare payer type, with mothers who had private health insurance averaging three or more ultrasounds per pregnancy than economically-disadvantaged mothers who relied on Medicaid or those who had no health insurance. This is another red flag.

Geographical differences in autism and ultrasound exposure may be emerging. The prenatal ultrasound trends report found that by 2005 to 2006, southern women were 40 percent less likely to get an ultrasound scan during a prenatal visit than northeastern

women.

But since we don't yet have autism figures for children who were exposed to ultrasound during that time, it is too early to flag it but worth watching.

Studies regarding prenatal sound's effect on neurological health have waved red flags in the past. More than one Scandinavian study has associated children exposed to ultrasound with dyslexia. That's a red flag.

A 1993 Canadian study found that children with speech delays were twice as likely as controls to have been exposed to prenatal ultrasound. That's a red flag.

Plus, the studies have also found that boys exposed to prenatal ultrasound have a significantly higher incidence of left-handedness, considered a subtle marker for neurological damage when not inherited. That's a red flag.

Plus there's Yale neuroscientist Pasko Rakic's 2006 study that showed pregnant

mice exposed to ultrasound had offspring with changes in brain formation similar to those found in autopsies of autistic humans. Another red flag.

In view of these facts, it is worth noting that autism prevalence went from 2.4 children per 1,000 in 1994 to one in 110 in 2006, about the same period during which the odds of a woman receiving an ultrasound during a prenatal visit nearly doubled. I think that deserves another red flag.

Yet despite all these red flags, prenatal ultrasound is not being investigated as an autism risk factor. Many people expect that the National Children's Study and the Early Study, two prospective, longitudinal investigations currently under way, will yield answers.

But neither one is investigating prenatal ultrasound. Even more distressing, neither is collecting prenatal ultrasound data in a way that could lead to meaningful

research down the line.

Is prenatal ultrasound causing autism? Maybe not. But let's do whatever it takes to find out without further delay. Thank you.

Dr. Insel: Thank you, and as I said, we will come back to have a chance to talk about this later in the afternoon.

Ms. Rodgers: I won't be available to discuss it later this afternoon. If, I mean, if there's something you would like to discuss now, there is time in the schedule.

Dr. Insel: Yes, I realize that. On the other hand, I want to -- I have a feeling that we are going to get busy enough with the presentations that are coming up.

Ms. Rodgers: Okay.

Dr. Insel: So what we will do, I think, is -- since you can't stay we will make sure that you both have either the videotape or the transcript for the discussion so you will know what transpired and if there are

further questions I am happy then to follow up with you thereafter.

Ms. Rodgers: All right. Thank you.

Dr. Insel: Thank you very much. And again I want to remind the committee to review everything that has been sent in, not only the oral comments that we have heard today but there are a number of comments that were submitted from people who were not present at the meeting today.

We are at 1:15 so we are not too far off schedule. We are actually a little bit ahead to start on the rest of the agenda. So I wanted to invite our next speaker, who is Eric Courchesne, who is a Professor of Neuroscience at the University of California, San Diego School of Medicine, has done groundbreaking research on the neurobiology of autism and has produced important information about the structural, functional and genetic bases of the disorder.

In recent work with MRI scans to

investigate early brain development in toddlers on the spectrum has been particularly important and some of us got to hear the most recent part of this work at IMFAR recently and I think based on that, many of us thought that this was important for the whole committee to hear about.

So Eric, thanks for coming to share this with us.

Dr. Courchesne: Thank you very much, Tom, for the very gracious introduction. It's a pleasure to be here. I love D.C., whether it's super-hot outside or not. It's a great area to be in, live in and visit.

Many thank yous here, many thank yous to numerous organizations that have supported our research over the years.

Okay, so this pointer doesn't seem to be working. Maybe you can check into it.

And many thank yous to individuals who have worked with us over the years and are working with us on the many studies I'll be

talking about.

Of course, you all know that autism begins behaviorally in the first two years of life. This is individual data abstracted by Dr. Karen Pierce from work by Geri Dawson and by Lonnie Zwaigenbaum and Susan Bryson over the years.

We know that the symptoms are mild or not terribly observable by roughly six months of age, where you can see social engagement tends to be high in babies who later go on to be autistic.

But in these individual babies that went on to be autistic, symptoms came on at one stage or another until by 30 or 36 months of age, their symptoms were full-blown.

So it's a clinical disorder that begins in the first years of life. It's a neurological disorder, so neurodevelopment has gone awry and that's why the behavior has gone awry.

And yet the great majority of

studies on the biology of autism have actually not focused on the first years of life.

Out of almost 200 studies looking at functional imaging, structural imaging and post-mortem, fewer than just a bit over a dozen studies have actually studied autism in the first years of life.

So it's no wonder we don't know as much as we need to know about the underlying neurobasis and the molecular and genetic basis for this disorder.

So clearly if you were a little girl with autism you would want to change that picture, and you would hope people would start studying little kids with autism.

And so, about 10 years ago, we undertook a detailed and comprehensive investigation of brain structure as well as brain function in autism.

And in our first study, in 2001, we discovered an unusual brain growth trajectory in the early life of autism. This is brain

size. This is age. This is two years of age, eight years of age, 16 years of age.

And you can see in normal, the solid line, the rise of the size of the brain as compared to in autism, where the majority of individuals with autism, shown in green, have larger brain sizes than do typically developing kids. But then there's arrested growth and then a fall-off.

And this is plotted here. Individuals with autism as compared to normal, average, brain volume at two to four years of age. And you can see the majority have brain volumes that are larger than normal average.

So this is the first known growth defect or growth pathology that has been recognized in autism.

This child here is a three-and-a-half-year-old boy with a brain that weighs roughly 2,000 grams and that is about 50 percent bigger than any person in this room.

Our studies have been replicated by

Geri Dawson's group as well as other studies by Joe Piven and recently, a new study in our laboratory.

In order to find out when this early brain overgrowth actually does begin, a number of years ago, in 2003, we examined head circumference, because the size of the head at very early ages is a good index of the underlying brain size.

This is 50th percentile, normal average. At birth the kids in our cohort had had head circumferences at birth that were similar to or slightly below normal average. By one year of age that had jumped up to almost the 80th or 90th percentile.

So accelerated, early overgrowth seems to have been something that took place in the first year of life. So the onset of neuropathology, at least in this gross macroscopic fashion, appears to be in the first year of life, just about the time that the symptoms begin.

So we and others have surmised that this early overgrowth of the brain, shown here graphically across birth to 14 months of age, and this is head circumference, and you can see the CDC norms, you can see the blue line are autism head circumference, that this accelerated growth coincides with the emergence of autistic symptoms, the first autistic symptoms.

And it's not just our group, but many other groups have replicated this finding, including this finding for instance by Dementieva. They are individual cases as compared to our individual cases. Or this work by Geri Dawson and Sarah Webb. This is where their data fall compared to our data.

So it looks like early brain overgrowth in autism is something that can be identified and replicated across independent laboratories.

We wanted to know what parts of the nervous system were most affected and what we

discovered in our paper in 2002 was frontal and temporal lobes were most overgrown as compared to other structures.

Frontal and temporal lobes are the structures that are most important for higher-order human functions: social communication; language; and emotion processing. And you can see as compared to normal average, zero would be no difference from normal, it's this green bar and frontal lobes, that is most enlarged in autistic brains at the age of two to four and temporal lobes as well, but not parietal and occipital. Other people have since replicated that same finding. You can see there's a strong tendency. And then a new study by Cindy Schumann and myself.

As you can see across studies there's a gradient of neurogrowth pathology that is greatest in the structures that mediate the symptoms that are most prominent in the disorder -- the social, emotional, language and communication functions, whereas

structures that are least overgrown and not much affected, are those that mediate functions that are relatively spread such as visual information processing.

And it's not just the cerebrum, but it's also the amygdala. The first discovery of amygdala overgrowth was once again by Geri's group, Geri Dawson's group, back in 2002, recently also reported by Munson and Mosconi so now three, two different laboratories.

And then finally our group, in which we find as compared to controls, girls with autism over here have larger amygdala sizes. Boys with autism also have larger amygdala sizes. And that's true for both the right amygdala and the left amygdala.

So this pattern of early overgrowth and frontal, temporal and amygdala structures that mediate emotion, emotion memory, social, language and higher cognitive functions, that pattern is very striking, replicated across studies and seems to be emerging as a firm

finding within the area of autism.

So for the first time we are beginning to understand what the neural landscape is that defines and causes this disorder.

But look what happens when we look at the adult phase of autism. What we see in the adult phase in autism, when we look across the literature, is a pattern of neuron loss and reduced size.

There's decreases in neuron numbers as shown by David Amaral and Cindy Schumann, amygdala volume, as shown by Dr. Karen Pierce, reduced numbers in the fusiform, which is involved in face processing, or Purkinje neurons in the cerebellum and so forth, thinning of cortical regions, thinning of the corpus callosum and increases in what are called pro-apoptotic molecules. Those are molecules that promote cell death.

So the adult brain is demonstrating loss and change in function that is very

distinctively different from that in the child.

So because of this, Dr. Karen Pierce and I have proposed a new theory of autism that involves three phases of growth pathology as compared to normal growth and brain size and age.

We think the frontal, temporal and amygdala structures are key and that they are the ones that are undergoing abnormal growth and neural disorganization at very early ages. That is followed by arrested growth and then possible decline and degeneration.

Now, this is very exciting because for the first time there is a handle on what we should be trying to understand. We should be looking for genetic factors and environmental factors that can produce these types of specific growth defects in these particular regions if we are to understand the causes of autism.

We also know that not every child

undergoes exactly the same pattern of abnormalities. Statistically, most do, but some don't. Who are those individuals that don't? Who are those individuals that do? How can we better understand the heterogeneity of this disorder?

And it seems to me that the place to look is in the first years of life. So with funding from NIH for Autism Center of Excellence, we have investigated for the first time autism at a very, very young age, beginning at one year.

In order to get autism at one year of age we had to work with pediatricians and develop a close working relationship with them to institute a screen for risk for developmental disorders including autism, language delay and global developmental delay.

That screen is a screen that is administered by pediatricians to every baby that walks into their office from nine to 12 months of age on up.

That screen is the CSBS screen. It's not intended to be an autism screen because we didn't want to capture only autism. We wanted to capture individuals that had a variety of developmental delays, including autism, so that we could compare and contrast.

In addition, of course, we want to capture autism at a very early age. We wanted to do it in a way that was fast. The screen takes less than five minutes. It's easy, because mom fills out the screen. Mom knows baby best. Mom can do the best job of telling us what is going on with the baby, not a pediatrician in five minutes.

And then it investigates as it occurs in the general population. It's a really beautiful method of capturing autism, and not just simplex autism, but multiplex autism in exactly the same way.

Because there are some thoughts that perhaps simplex and multiplex autism might have different behavioral, neural and

genetic bases. But it's very hard to study this with any other method than this very early screening method.

There are many studies looking at baby sibs, but most of those are not comparing them to singletons, so how do we know they are the same? How do we know the findings for multiplex inform and generalize to the larger population who are, in fact, simplex autism.

This study involved Dr. Karen Pierce giving over 45 lectures to more than 150 pediatricians throughout San Diego County and developing the first autism pediatric network.

So the autism pediatric network, 150 pediatricians scattered throughout San Diego County, thereby producing what I think is one of the best-broadcast, ascertainment regimens that I know of. Thank you very much to all those folks.

In the last two-and-a-quarter years or so, we have inducted more than 400-and-

some-odd individuals into our study and we have imaged roughly 270 or 280.

We are doing a longitudinal study and what I am going to show you are data for our first analysis of brain volume in simplex and multiplex autism.

These are controls. This is birth, 10 months, 20 months, 30 months, 40 months and 50 months, brain growth and controls, brain growth in simplex autism and brain growth in multiplex autism.

So there's a distinct difference in the developmental growth trajectories between simplex and multiplex, indicating that the underlying neuropathology or function may not be the same and that there may be genetic differences between simplex and multiplex.

It's a cautionary note but it's an exciting note. It explains why it is that there's a lot of heterogeneity and we could better understand it if we knew how to look at the phenotype in a different way.

In addition to looking at autistic multiplex and simplex, we have also looked at language-delayed kids as well as global developmental delay kids and their growth curves, as you can see, are completely different from autism.

Autism is not simply language delay plus. It's not simply cognitive abnormality plus. Autism is its own distinct phenotypic and probably genotypic disorder.

Not only is brain different, but also function. Functional scores on the Vineland are better for multiplex, worse for simplex. Mullen is a cognitive score. Better, spare cognition in multiplex, worse in simplex. So a bigger brain is producing worse function and worse cognition and worse outcome.

So we should be able to find indicators of disordered operation of the brain in these frontal and temporal areas, if this overgrowth does indeed affect and alter

behavior and brain function.

Well, we all know that the red flags of autism in the first two years of life include reduced social interest, abnormal language development and lack of coordination of gaze and facial expression.

In reduced social interest, one of the key findings has to do with lack of response to name. In fact, everybody in the field of autism is very familiar with Geri Dawson's -- I usually show one of your slides from your first study of responding to objects as compared to responding to name -- so Geri was one of the first to show that in fact, there isn't a normal responding to name in autistic kids as compared to responding to other things.

I should show you a video afterwards that you will love to see. I don't have time to do it today, but I will afterwards.

And then abnormal language is

another red flag. Failure to develop an understanding and the ability to express language very early on is a striking red flag.

So we figured we should be able to investigate these red flags but no one has looked at the operation of the autistic brain at a very, very young age and that is because of course in an MRI scanner you have to be cooperative, you have to be awake and you have to perform a task.

But how many of you know of a single 12-month-old, no matter how wonderful he might be and how much you love that little 12-month-old as your dearest own, is going to sit still quietly in an MRI scanner and press a button every time he sees an oddball face?

Okay, probably zero. So most information on brain functioning in autism is based on high-functioning individuals who are adolescents and adults, people that are Asperger's and very high-functioning.

How do we know that has anything to

do with autism in general? So, since a large percentage of autistic patients are actually intellectually impaired, it means that there is some difficulty in trying to understand functional differences or similarities between high and low function.

Well, sleep is a level playing field. Normal kids sleep. Autistic kids sleep. We collect all of our brain imaging during natural sleep, and that means that I am typically sleep-deprived and so is my wife, Dr. Karen Pierce, because we do scanning as do six other individuals in my laboratory five nights a week.

We scan between eight o'clock at night and one o'clock at night. We are terrific at getting babies to sleep. I am well known as the baby whisperer.

So, the babies go to sleep and it turns out there is a literature on sleep versus wake fMRI and that even in studies of children and adults, it's been shown that

there is a great deal of normal and intact, functional operation in the sleeping brain, that is very similar to the waking brain.

And in fact, what our data and other data show, is that for those of you that either have babies or are going to be around babies or around anybody that is asleep, if your wife is asleep and you are sitting up in bed, muttering, she can hear you.

Her brain is processing what you say. Your baby is processing what you say. So be careful what you say when you are asleep.

Sleep activates the brain. We put headphones, $2,000 German headphones on the ears and put pads around it, the baby is in the scanner, we collect brain activation in response to things that baby would love.

What would baby love to hear?

(Whereupon, a pre-recorded selection from the children's book "Time For Bed" was played.)

Dr. Courchesne: This is brain

activation in normal babies and toddlers in response to that stimulus. It's a very beautiful, strong, clear stimulus that should activate anybody's brain. I am sure it did several of you in this room, for sure. I saw many smiles on your face. I know somebody here that has memorized that story.

And in the normal developing brain, both the right and left temporal cortices are activated. That's what this shows. I'll do that again. Both right and left temporal cortices are activated. And that's the way it normally is.

But what we discovered is that early in life, in like 12- or 13-month-old, typically developing kids, although the left cortex is more active than the right, the left is more active than the right, that difference is slight.

But with maturation and increasing skill with language, that asymmetry becomes stronger. So there is a gradual emergence of

language dominance on the left hemisphere. At the same time, there is a gradual emergence of pragmatics on the right hemisphere. Pragmatics is understanding social communication.

In autism, the story is different. They don't show that early leftward activation. They show rightward activation, not leftward activation. So they under-activate the left side, and as the years go by, they never develop left dominance for language. They remain right-dominant.

So it suggests that as they are gaining some language, it's on the right side, which probably is at the cost of the development of pragmatics on the right side.

So basic language skills may be developing slowly in the right side, but in so doing, compromising the capacity for the right side to also develop full-blown, social pragmatics.

We also know that the more activation on the right side an autistic child

has, even though it's the incorrect side, but at least if they are using right hemisphere, the capacity for developing language is increased, so the more activation, the better the language outcome.

So we think eventually it might be that fMRI is going to become a very useful tool for objectively identifying kids who are at risk for developing autism, and the degree of activation in response to language may be a predictor of later developmental language capacity.

Now, going back to Geri's experiment, Geri Dawson's experiment, social orienting, Dr. Karen Pierce, having grown up with Geri's work and other people's work on her mind, came up with the idea of presenting social orienting stimuli to sleeping babies.

So that last experiment I was talking about was Dr. Karen Pierce's and also Dr. Lisa Eyler's. This is Dr. Karen Pierce's.

Jamie is the child's name. We use,

whatever the child's name, we substitute the child's name in the speech episode. That was social orienting. This is non-social.

(Pre-recorded audio played.)

So that is speech without pragmatics.

(Pre-recorded audio played.)

And then this is a contrast.

(Pre-recorded audio played.)

It's amazing the kids don't wake up. When I don't have a cold I am actually a pretty good singer so -- maybe it's that singing them to sleep that does it, I mean, they're really resting.

Okay, so what we found is that normal kids, to social-orienting stimuli like, watch out, Jamie, and look over here, Jamie, watch me Jamie, or Billy or whatever the child's name is, activate, once again, strongly, the left temporal cortex.

But in autism that is not true. So in this slide, greater orange or red is

greater activation by typical kids as compared to autistic kids, so it's a different way of displaying than I had in the last picture.

And what you can see is greater activation in typical toddlers as compared to autistic toddlers on the left side.

So we are getting closer to identifying the fundamental structures that mediate these social and language functions that are the first red flags of autism.

It involves structures that are overgrown in very early life. And so naturally the question becomes, so, if those structures are enlarged, what is causing them to be too big?

If we knew something about the underlying cellular, molecular and genetic causes for the brain overgrowth, we might be a whole lot closer to understanding not only the emergence of autism, but how better to potentially intervene and maybe at some point correct.

So we want to know what causes this. We know where to target. We know frontal cortex and amygdala and temporal lobes are sites to target.

So what we have done in our recent studies, is we have examined brain overgrowth by considering what could be most plausibly causative.

Well, the brain is made up of a lot of different elements. It could be that there are too many brain cells. It could be that there are too many glia cells. Those are cells between brain cells that provide a lot of important supporting functions for brain cells.

It could be synapses. We know that brain cells communicate through synapses and synaptic connections. Maybe they have too many connections.

It could be through the development of too many cables. So up here I have got piles and piles of cables surrounding me.

Well, computers communicate with other computers via cables, as a for instance. Well, in the same way, a brain cell communicates with another brain cell by a cable called an axon. So maybe too many axons or too many connections are generated.

Or maybe the dendrites. So Isaac this morning was talking about dendritic development in autism and dendrites are those parts of a brain cell that receive information.

So imagine a brain cell like a tree, with branches and leaves, and imagine the leaves being like synapses and imagine information coming in, hitting those synapses and traveling down the dendritic arbor of a tree or a brain cell and then going out to another brain cell.

It could be that these dendritic arbors are overgrown in autism. It could be that the myelin is excessive in autism. Well, myelin is the protective sheath around a brain

cell's axon. It speeds communication and it prevents cross-talk, just as you have wrapping around electrical cables, so there's no cross-talk or short circuiting.

So, looking at this array, we have looked at several of these. We have looked at minicolumns. We have looked at microglia. But if you wanted to identify what really sets the whole ball rolling in the first place for overgrowth, what might it be?

Well, as a for instance, a good portion of you in this room -- not me -- but a good portion of you in this room are still putting myelin around your axons. Myelination continues on into the 30s and 40s, not quite up to my age.

But myelination is a long-term process. So if I examine myelination, and how much myelin is in the brain, I wouldn't be able to tell whether that was an early developmental defect or a later.

It's the same with axons. Axon

arbors change continuously and they are modifiable, especially the details of the arbor. And that is certainly true of dendrites.

Dendritic growth continues massively in the human brain at least through eight years of age or later. So if you have found large sizes of dendrites, that wouldn't necessarily tell you it was something early that took place causing the early brain overgrowth.

That's true of synapses. Babies are born with half as many synapses as they will have when they are three years old in frontal cortex. And the pruning back of synapses takes another three to 10 years depending on the study that you look at. Furthermore synapses come and go.

So if you quantified synaptic numbers, you might or might not be on target for whether they were involved in generating the early overgrowth. That doesn't mean that

they are not involved, it just means that you would be left a little but puzzled.

Brain cells. Every brain cell that you have in your brain, with the exception of the dentate gyrus and potentially, a small percentage of cells in your cerebral cortex, are prenatally generated.

There is some controversy as to whether there is ongoing neurogenesis in the young brain and the adult brain, but it's not very much. If there is some, it's not very much.

So most of the brain cells that you have in your cerebral cortex, you have had since before you were born. So if there are too many brain cells, that would help you mark the time of onset.

So in order to study overgrowth, one of the things we did is we started with a really young autistic boy. Mind you, out of over 40 or 50 post-mortem studies in the literatures, there is only one study that

exists that studied only young autistic individuals.

Every other study is of an adolescent or adult with an occasional pre-adolescent or an occasional child. So when somebody says we know what the neuropathology is in the child with autism, the answer is, we do not.

So I studied the youngest child on record, a three-year-old autistic boy. We counted the number of spindle neurons in mesial frontal cortex. That's right inside here, about an inch or so.

Spindle neurons are interesting to people because they are a type of brain cell that may be important in human social evolution. And without going into it, this is a very interesting brain cell.

At first when we did these studies, we thought, well maybe there will be too few spindle neurons or there will be something wrong with them.

But in fact what we found were 58 percent more spindle neurons in this area, a huge increase compared to what there ought to be.

Then when we counted all neurons within dorsolateral prefrontal cortex using stereological methods, we found 42 percent more total neurons in dorsolateral prefrontal cortex. This is the part of the brain that mediates higher-order cognitive, social and language functions. Forty-two percent more in this three-year-old boy.

There is no known molecular mechanism for generating such a tremendous excess in the number of neurons, that is post-natal. The only mechanisms known for generating such a tremendous excess must be prenatal mechanisms.

With help from Autism Speaks, we have gone on to look at a slightly larger, but still, I would consider it to be a pilot cohort of autistic and control kids, ages two

years to 15 years.

And what we have found is, in this small cohort -- and now we are replicating this -- 31 percent more neurons in dorsolateral prefrontal cortex. That's a huge increase that puts the time of onset for that neuropathology as being very early, indeed.

So what we are currently doing in our studies is we are trying to determine the type of cortical defects that must be consequent to having an excess number of neurons.

You would think, well maybe an excess number of neurons is a great thing. You know, you have more brain cells. We have more brain cells than a mouse. We are smarter than a mouse. So maybe even having more brain cells is a great deal.

No, it could be that that excess is of neurons which are not normal, neurons which have some type of defect. And so we are looking at cerebral cortex and we are

targeting frontal cortex because frontal cortex is where the greatest overgrowth is occurring, and we are looking for what signature might be there that could be related to this.

So at the present time we have clues and we are in the midst of replicating those clues. And then, if there's an excess number of neurons, you would think that there must be some molecular mechanisms that account for that excess.

And that excess and those mechanisms could be identifiable as well. So not only are we looking at the outcome that is caused by an excess, but we want to know what started that excess.

So we finished the study that is the first examination of that question, looking at those same kids and so we now have a pretty good idea of what are the genetic pathways that are potentially involved in producing those excesses.

And we also know in our studies that those pathways are not the pathways that show up in the adult autistic brain. Of course, because the adult autistic brain is 10, 20 years beyond the time of onset.

The signature of molecular pathology in the adult autistic brain in our studies looks very different from the signature of the very young child.

So theories about autism are probably going to shift as we focus attention on how the young, autistic brain ends up having this early overgrowth. Thank you very much.

Dr. Insel: Thanks. Let's take a couple of minutes for questions or comments. Lyn?

Ms. Redwood: Eric, I'm just curious in the post-mortem brain of the three-year-old, did you find any evidence of an inflammatory process like Vargas with regard to microgliosis?

Dr. Courchesne: Yes, in fact we did. So we have a paper that is now in -- I think it's beyond in press so it's probably out in Biological Psychiatry. And what we examined were microglia: their numbers, their size and their clinical characteristics.

And what we have identified is evidence that there probably is some activation of microglia at a pretty young age and if we look at the sort of nature of the aggravated inflammation of microglia, it definitely increases with age.

So by the time you get to a 20-year-old, it's really a classically activated microglia, much more so than at three.

Ms. Redwood: Would it be beneficial to target that activation? I mean, do we know if that's a beneficial response or if that's harmful?

Dr. Courchesne: We have gene expression data that makes it very clear that there is a strong, there are strong signals

that you could interpret either as inflammation signals in the adult brain, or you could interpret them as signals representing remodeling.

So it's kind of a puzzle. It could be either way. The complement system can either be signaling inflammation or it could be signaling very active, activity-dependent remodeling processes of synapses in the brain. Another question?

Dr. Insel: Well, lots of hands. I think Marjorie went up first and then we will go down this way.

Dr. Solomon: Following up a little bit on that, you started to speak about three phases of brain development. Given your thoughts about early overgrowth, could you talk about, then, the consequences for adolescent brain development and adult brain development?

Dr. Courchesne: Well, studies of the adolescent and adult brain show, as I

said, and as I showed in one of my slides, show that there is thinning of cortex, there are reduced numbers of neurons in fusiform, the amygdala, the cerebellum.

Some of those would definitely be pathological. So for instance in the Purkinje cells of the cerebellum, there is a flagrant loss so that in fact it's not just a reduction down to a normal level. The implications I think are really unclear.

Dr. Insel: Linda?

Dr. Birnbaum: It's a lot of beautiful data. As an experimentalist, are there any animal models you have for either, you know, rapid growth and then slow-down or vice versa that would provide insight and possibly some experimental matrix that we could look at intervention in?

Dr. Courchesne: I think that one of the remarkable things in my mind is that we originally identified this growth pathology back in 2001 and hardly anyone has really

grappled with the question of how genetic findings in animal models can be used to study this phenomenon.

It's one of the few, clear, anatomical, phenotypic characteristics in autism that could be studied with animals objectively. Social behavior and language are pretty tough to study in animals, aren't they? But anatomy is a little bit more straightforward and yet there is almost none.

And in fact the majority of studies that are coming out on genetic findings of autism don't even address the question of how genetic findings that have come out could help to explain this early overgrowth.

So there is a disconnect between what we absolutely do know from the studies of Geri's group, Joe Piven's group, our group and so forth and the studies that are coming out on potential genetic and environmental causes.

So we need to reconnect those, and I think the three new neuropathology studies

that we have will make the target even more crisp for animal model studies of autism, whether you are testing your favorite gene to find out if SHANK2 or SHANK3 or neurexin or ligand 3 or 4 can actually produce the kind of neuropathology that we have detected is a very interesting and important question.

And the same with the molecular defects that we have found. The question is whether those molecular defects that point to second trimester and third trimester events can be promoted by certain SHANK2 or 3 chromosome 15 models.

Dr. Insel: Yvette.

Dr. Janvier: I'm a developmental pediatrician. I work with a large number of young children with autism and you know, we certainly have kids that have large heads, macrocephaly.

But I was struck on your total brain volume slide of the range; it just appears that you have a large group of

children with smaller head and brain size and then a large group of kids with larger brain size.

You average it, it's about average, but it's just, that range really struck me, so it didn't appear to me, looking at this, that all children with autism have brain overgrowth or macrocephaly.

Dr. Courchesne: No, they don't. And that's the value of showing the slide that presents all the data. And so what would you think would be the neuron count in frontal cortex for the smallest autistic brain that we studied post-mortem?

We have an autistic brain that is seven to 10 percent smaller than normal average and we did neuron counts on frontal cortex on that autistic brain. The smallest number of neurons. The largest number of neurons. That's what it was.

So at some point, I am suspecting that there is such a huge increase that brain

growth essentially, to put it simply and in lay terms, collapses and you don't have excess size.

You have such a failure that you end up with a very different outcome. So what's very important to consider is that you could have more commonality in original, triggering events than you might suspect, and that what is key to understand, is that development is a process of change and you have 10,000 genes that are brain-interested and among those 10,000 genes you are going to have a great deal of variation from one autistic child to the next, and the variation of those genes will impact how the brain responds to that insult.

So if there is a very early, similar insult -- not in every autistic kid, but let's say there's a type of phenomenon -- the outcome growth trajectory will not be the same child after child because the genetics that come to play to respond to that defect

will differ from child to child.

And that's what makes it so complicated and so difficult. There are different strains of mice which are known to react in different ways in response to a similar type of insult. It's the genetics. The background genetics of an animal, can have a big impact.

Dr. Insel: So I think we are going to need to move on. Walter, did you have a question?

Dr. Koroshetz: Just wondering, you've probably thought about this, but the fact that the multiplex kids didn't have the same early growth -- what else -- you show the difference in severity, which I mean, that's a complicating factor, but in terms of your theories of causation, do you think there's -- what applies to the multiplex that -- or what applies to the simplex that doesn't apply to the multiplex other than just the MR stuff?

Dr. Courchesne: I don't know. I

have been puzzling about that now for almost a year. So I have got a lot of hypotheses but nothing that I think is ready for prime-time. But just consider that you can have a common, early defect that doesn't necessarily have, that doesn't necessarily mean a common cause.

So you could have equifinality, where you have multiple types of causes that lead to a common, early neural disorganization or disruption of certain pathways in molecular development that produce a characteristic early cortical phenotype which then spreads out again as you have other genetics coming to play on how other circuits, both genetic as well as neural circuits, operate in the context of that pathology.

Dr. Koroshetz: The cell number idea is not dependent on the brain size. You could, as you just said, you can see increased cell number without the brain size so that hasn't yet been examined, whether increased cell number is present in the multiplex.

Dr. Courchesne: We know that it is --

Dr. Koroshetz: It is.

Dr. Courchesne: -- in our post-mortem cases and you know, just leave it at that.

Dr. Insel: So, Eric, we are going to have to move on but before we do, I just feel like we have got an opportunity here and I want to make sure that we make the most of it.

You have given this committee some pretty important messages. It seems like the multiplex-simplex message, the issue about the animal studies tying in to anatomy, not just behavior.

I want to make sure we are getting a clear message from you about something else. You made a big point about saying that we had this, that it was really important to do the brain studies early in life, that almost all the literature, as you pointed out, was either

doing the imaging or post-mortem studies that were much later.

Do we have the resources that the field needs or is there a message for the committee in that as well, that we need to be thinking about having the biorepositories that are much, much earlier to the extent that it is possible than we what we have now?

Dr. Courchesne: Yes. Absolutely. You really need to do that. And I believe there are going to be markers in the blood that are going to be capable of detecting some of these effects.

And so, I just can't emphasize enough the need to have research that provides funding -- to have funding that provides research that enables novel methods of neuroimaging at a super-young age along with the context of early, blood-based markers, so that you can begin doing -- in fact we are designing a study like this in San Diego with a large group.

We are basically just going to be taking every child that comes through a large system and collecting all of imaging as well as early markers on every single child. It's very expensive.

Dr. Insel: All right. Thanks, very, very much. That's very, very helpful. Okay.

(Applause.)

The next presentation is from one of our own, Denise Resnik, who is going to be talking about Opening Doors, a discussion of residential options for adults living with autism and related disorders and Denise is co-founder and Board Development Chair of the Southwest Autism Research and Resource Center, SARRC, which is dedicated to autism research, education and community outreach.

And I guess perhaps maybe the thing to emphasize is also this is a group that has really been a flagship center for developing resources for youth transitioning to adulthood and for adults on the spectrum.

So I think we are going to hear a bit about that this afternoon.

Ms. Resnik: While they are getting this PowerPoint to work, at each of your place settings we have copies of two reports, actually one is our Opening Doors report. The other one is an executive summary from Advancing Futures for Adults with Autism.

And just yesterday we hosted a Congressional briefing in the Kennedy Caucus Room. We got about 200, 250 people there. The organization AFAA is represented by 14 national autism organizations across the country and the chairs of that are Autism Speaks and the New York Center for Autism.

And we are very proud of the work that this collaboration has done over the past few years that address the issues of housing, employment and community life.

And yesterday we heard about each of those areas and when you start considering those areas in depth, we also start

considering the road blocks, the unintended consequences and a system that is antiquated and needs to be fixed.

When you think about adults with autism who earn any dollars and would risk supplemental security income benefits when they have assets of more than $2,000, you begin to think about what incentive is there for individuals with autism, adults with autism, to enter the workplace.

Perhaps that's why we have a 90 percent unemployment or underemployment rate among adults with autism.

You also consider the $674 Medicaid reimbursement and who among us can live on $674 when there are not other mechanisms to pay for that? And where we need more support, and more opportunities for families to support their children through adulthood.

And then we think about the opportunities. We think about, as we heard yesterday, the group from Walgreens who talked

about their major distribution center which employs individuals with autism and those with other disabilities. And that distribution center is 20 percent more productive -- more efficient -- than any of their other distribution centers.

We recognize that individuals with autism do have value. They can be productive. They can be working members of our society and our communities and they can be tax-paying citizens.

What Tom didn't tell you about me is, I'm a mother. I'm a mother of Matthew, who, when diagnosed, we were told to love him, accept him and plan to institutionalize him because there is no hope for children with autism.

Today, what we would like to be told and what we would like other families to be told is that there are opportunities. There are opportunities for continuing education after they leave high school. There are

opportunities for jobs, for places for them to live, to have friends and to have communities that support them.

And that's what our organization, the Southwest Autism Research and Resource Center, has been dedicated to since 1997 and we have truly grown up with the kids.

We have not only been working on the services, but we have also been working on research and actually there is where we began.

The next two slides are going to orient you a little bit about SARRC and I thought this background might be helpful before I talked about the Opening Doors study to provide you with a context because the real estate of residential concerns is actually the easy part.

What is not so easy, are the services in the home and the community. When we think about quality of life, it's not just what we do in the kitchen or what we are doing to clean our homes, but how do we enjoy a full

and quality of life.

Our organization started in research and we continue with that. We are actually one of the most robust sites in the country in terms of the recruitment and enrollment in pharmaceutical trials through the autism treatment trials network and also in our molecular and genetic studies with the Translational Genomics Research Institute.

The reason for that recruitment and enrollment at such a high rate is because of the services that we offer and to provide an efficient mechanism for families to want to engage in the research and want to participate.

We started with early intervention. It remains a very robust program for us along with our parent empowerment. We are firm believers in early intervention. But not everything that happens through SARRC happens at our own facilities.

We have two facilities. One is

18,000 square feet. It's our campus for exceptional children. And last February, we opened a 10,000 square foot vocation and life skills academy.

But our feelings and our philosophy at SARRC is really to be a catalyst for community, to try to elevate the standards, so that those children can be schooled in their neighborhood schools, and it's not just about the teachers understanding how to interact with a child with autism.

It's about their peers. It's about starting on the playground, in the lunchroom, to make sure that this generation of kids better understand those who are different and the challenge and the courage it takes to be different.

And we had done a study just a few years ago about a program we call FRIEND, it's an acronym for Fostering Relationships in Early Network Development, and it actually helps teachers to facilitate the

relationships, in the playground and in the lunchroom and in other places on the school.

We demonstrated that the children with autism did progress in terms of their social skill development. The neurotypical peers did develop their better understanding and knowledge on how to interact with the child with autism.

But what we didn't expect was the call from the principal who said that there were fewer referrals from the playground because the typically developing peers better understood how to work with each other.

We also have a significant effort in terms of our educational initiative. It speaks to the physician committee. We have a wonderful collaboration with the Arizona Academy of Pediatrics.

We have reached out to 1,300 pediatricians and primary care practitioners throughout the state with our early screening kit and perhaps that's one of the reasons why

the CDC acknowledged Arizona has a slightly higher incidence of autism with one in 100 children being diagnosed.

We are also under way on a Think Asperger's study and early screening toolkit so that we can identify and actually have educators identify and help us identify Asperger's earlier in life. We do have some school programs at SARRC. They are for young children and what we are demonstrating there are how to interact, how to build a classroom where you have the typically developing peer and the child with autism.

And I am getting some great results. We have 36 kids enrolled in that program. But what's as important to us are the 800 educators who came through SARRC last year to learn what they needed to do in their school districts and in their classrooms.

I mentioned that we are just getting into the vocational training and life skills program and I will talk to you a little

bit more about that. And one of my favorite programs is actually our community works program, autism community works.

It's targeted for the teens because we want to be able to get to them while they are still in school to help them build their skills, build their resume so that they can better transition to those jobs.

Right now we have 225 teens ages 13 to 18. They are working in the library, at the zoo, at the Desert Botanical Gardens, at the Science Center, at 20 different non-profits.

And in the last two years, these teens have contributed more than 18,000 hours of volunteer, in-kind service. And it's not just about their building their resumes and making friends. It's about educating a broader community about what is autism and what it isn't and the challenges and the talents that these kids have to give and have to share.

We also have 135 adults with autism in our employment services program and we have

placed 46 in competitive employment. Now you know we are beating the national average on that one. We have 15 employers in our community that have been rolling up their sleeves and giving us a chance to succeed.

And we are just getting into the residential and that will lead me to the discussion of the report that I will be presenting to you today, because we have to think about what's next.

And what is looming for my family and so many others is who is going to take care of Matthew when he is no longer able to do so? And Matthew is more several impaired with the autism. The prospects of him living independently are very small and he does require quite a bit of support.

This last arrow that you see at the top is our working model and training hub and that is what SARRC has been aspiring to through the years.

We have been modeling these

programs, we have been packaging these programs, we are starting to license these programs, and we want other communities to be able to come to us at SARRC as we go out to other communities and to be helpful: to help them understand what they can do to bring a community together.

Because we can sit here and we can talk about a lot of policy, but we know we need to implement that at a local level, where our families live, and that is what we have been trying to and that is what we have been trying to demonstrate through the years.

We know the policy to set up the right infrastructure and I will tell you that we know what's working and what's not working.

This just continues with our core values, as you can see, continuing on with cooperation, collaboration and teamwork. I think the advancing futures with adults with autism was a remarkable example of, again, these 14 organizations getting together to

really make a mark and that is where we are heading.

You also have in front of you a summary of the public policy agenda that we presented yesterday during the Congressional briefing. We hope that you study that and I am almost hopeful that in our services workshop in November, we might be able to continue to address some of those issues.

I also want to acknowledge that through a community-based organization such as ours, we have also raised money from the local community. Since our inception in 1997, we have raised $40 million.

A few other criteria and actually strategies, if you would, for SARRC's approach. Family-centered: it's not just about a therapist coming into the home. We focus a lot on the parent education.

In our situation, our family has had about 82 therapists since Matthew was a child and sometimes when we go on long family

trips, we play the game, "Name That Therapist."

I can tell you the one that stayed with us for two weeks had long hair. Well, anyway. There are a lot of them that have come into our home, but it's the family that gets left behind, so we are insistent, through our SARRC programs to make sure that the parents and the extended family members have that access to the education and know what to do.

Also, you will notice too in all of our programs, they are inclusive, research-based, personalized; we all know that one size doesn't fit all. And we have collaborations with dozens of organizations locally as well as nationally.

And Arizona, truly, don't believe all the headlines, we are not self-destructing in Arizona but we do have a pioneering spirit about us and we believe that's embodied in SARRC.

Just a few summaries on some of the

points that I have made in our active collaborations with the schools, with the clinical programs and with the government agencies. We recognize that we cannot turn to just one entity. We need all parts of the community working together to support our children and our adults with autism.

Last year we provided services to more than 2,700 children, teens and young adults, 4,000 parents, family members and typical peers and 5,000 education and medical professionals. And I have mentioned a few of these other items.

And now getting to the Opening Doors study and the reason that I felt it was important to give you that backdrop is because when we talk about housing, and earlier today I mentioned group homes, we are really talking about a group community and we need to start early.

What we did through our Opening Doors study is to look at those pressing

questions that have concerned our family and so many others, for the more than half a million Americans' children who will be entering adulthood in the next 10 to 15 years.

Our study objectives in collaboration with the Urban Land Institute and with Arizona State University were to do what we could to bring the private sector to the table. And for those of you who are not familiar with the Urban Land Institute, it is to the real estate development and services industry what the American Medical Association would be to physicians.

So it is a well-respected organization that at this point is beginning to advocate for special needs populations and special housing. And yesterday we also heard from the executive director of the Urban Land Institute in Arizona and he quickly acknowledged that when we all look around at today's home-building community and the fact that many of our home builders are not as

active as they once were, the next few years may provide us with some ripe opportunities to truly make a difference in the housing options for individuals with autism.

So our first order of business, which is to evaluate what is out there, and we evaluated over 100 different residential properties in the U.S. and just outside the U.S. We were looking for best practices. We were looking for replicability, scalability and what would fit within the fabric of an urban, suburban or rural setting?

What we learned is that those highly-rated, very well-respected institutions -- and I say institutions broadly -- say residential opportunities, that there were waiting lists, 30, 40 years.

There were some organizations that at the age of 43, 46 they no longer would serve that individual because they didn't want to deal with senior issues. And so we have a lot of systems within residential options that

are broken and that will serve as roadblocks and do serve as roadblocks for our families.

We also wanted to set up goals for sustainable residential community design and you will hear about some of those goals today. We have 10 goals and a number of guidelines which are detailed in the report that I have shared with you.

We also recognize that to get the private sector to the table, we need to look at the financial options that are available. Right now, it is incumbent upon anybody who wants to go into this business to cobble together two, three, four sources of finance.

Yesterday we heard from Mardie Oakes, who is the executive director of Hallmark Community Solutions. They worked for about five years on the Bay Area housing project and we have actually noted that in the copy of your report.

It required seven different financial sources. That's seven different

attorneys and accountants working together for 14 units. So you do the math.

We are looking at, if you would, a tsunami of individuals who are going to enter adulthood where there is a patchwork of disconnected -- not even a patchwork -- just disconnected services that in some cases exist, in some cases don't exist.

And what are we going to do? And where are those families going to turn in terms of care and support for -- and service for those individuals?

We also recognize that different levels of service are going to be required, so consider we are looking at the financial framework, we are looking at the services in the home and we are looking at the actual real estate.

And another objective of the study was to increase public awareness and I want to thank you today for inviting me to make this presentation so we could advance that number

five objective.

I have mentioned the study process. We also selected 17 projects where we conducted on-site visits and further investigated trends in innovations in housing for other special needs populations.

And this is a situation that can't wait. It's here today. We heard yesterday again from our residential panel through the AFAA Congressional briefing that it takes about five years from inception to actual development of a residential project.

And my background is marketing and public relations, but primarily for real estate firms and I have been working in the real estate industry for nearly 30 years and I can tell you that that is, that trajectory of about five years from the early time of conceiving a project through actually delivering one is right.

And again, do the math, if it takes five years, and Hallmark Community Solutions

got 14 units, what's going to happen when we have a half a million knocking on our door?

We also demonstrate, and I know the slide is maybe a little difficult to read, but it is in your book, that 80 percent of adults with Autism Spectrum Disorder are living with their parents as compared to 32 percent without special needs.

And when you think about what Dr. Ganz shared with us this morning, the economic impact of our society of those families, when there isn't a day program or a program at all, for your adult child, what are you going to do and what happens to your job and your sources of income?

And this data was actually provided by our researchers at ASU in collaboration with the Harris Interactive and Easter Seals which produced a lovely report about a year-and-a-half ago.

So we know the pressing concerns are the cost of the system's failure to have

far-reaching implications. We heard from Dr. Ganz this morning the billions of dollars annually that is required.

I do want to pursue the discussion with Dr. Ganz about the cost. We indicated that 90 percent of the cost for carrying an individual are actually in adult services and when you think about, you know, the number of years of adult service versus the number of years of youth, that's something that I am interested in probing in terms of those numbers.

And the population represents a community of workers, many of whom can meet the needs of employers provided adequate supports are in place.

And we see this first hand at SARRC. We have adults in the program that are actually becoming stellar employees. Outback Steak House was quick to promote a 21-year-old -- it was his first job -- to train all the other bussers after just two months on the

job.

And one of our young men also worked in the kitchen of a local restaurant. He went on to the Scottsdale Culinary Institute and then just completed an externship actually at Disneyworld as a chef.

And so we recognize that those success stories not only inspire other employers, but they inspire us as parents and if you want to get into the issue of maternal depression and the outcomes of the child, give a mother some hope, give a dad some hope and I assure you, you will get some better results.

So that's what we are trying to do. We also recognize that the housing component can significantly reduce the cost for other services and that's, I think, at least we are hoping to interest Dr. Ganz in that study in the future too.

So if the right lifelong living opportunities are in place, I am hopeful that we can reduce not only that number but also

increase the quality of life for our families and their adults and children.

So the summary of our major findings: we recognized there was a lack of consistency in what we even call residential options and there is a void in market data.

We are currently under way in Arizona to conduct a study. It would be a study that would recognize what parents are interested in, what individuals with autism are interested in, and to quantify that in some way that we can actually take it to the capital markets and other sources of funding and we think that's a very important component for the business model ahead.

The lack of documented design guidelines was one of our major findings and we were trying to mitigate that with the report and provide some guidance to the private sector on what can be considered, and to give families some considerations.

The shortage of turn-key support

service models: we don't have the national standards, we don't have certifications in place. Consider that yesterday we heard from one of our presenters, she's the President of the National Association of Residential Providers for Adults with Autism, and she not only has 20, operates 20 group homes, she operates services also.

She acknowledged that she can provide one hour of speech therapy and get reimbursed at a higher rate than a full day of services for one individual in the residential home.

So when a residential service provider is being paid $8 an hour, you might to understand why there's a 50 to 80 percent turnover in service providers in those homes. And imagine if you had to run your business when you had a 50 to 80 percent turnover.

We need more career opportunities for service providers. We need to value them. We also need certification and standards and

right now we don't have any.

I have mentioned the limited and cumbersome access to capital and I know that there are critical short-term needs for adults with autism. We hear from those families every week, looking for options, looking for where they can place their adult and have peace of mind.

So the housing, the number of housing choices for adults, we know, is very limited and we are not only producing a study, we are also boots-on-the-ground and actually implementing some of those findings.

What we are looking for -- and this represents the residential models, you will hear, you can read more about that in terms of the study. I have to point out the photos.

This one at the bottom actually is from our summer camp program. Just two weeks ago we had 40 adults with autism at this camp program. In some cases it was the first time many of them slept away from home.

It is also at a ranch where there are 100-plus special needs. These animals have lost their caregivers. They have been abused. They have some physical challenges.

It's a wonderful interaction, but it's also another demonstration that children as well as adults should be able to enjoy what we all get to enjoy and that is what, again, we are trying to do in Arizona.

This young woman, Zoe, worked at one of our collaborating partner's restaurants and the customers didn't understand her at first because the restaurant and SARRC didn't acknowledge that there was something different about Zoe.

But once she had a little pin and once there was something on the restaurant menu that said that they were working in collaboration with SARRC, we had customers actually calling to make sure that they could be in Zoe's station.

So you know, when there is somebody

vulnerable among us, or someone who has special needs and when there is education in place, there is kindness in numerous ways.

These are the financing options that are currently available. I mentioned earlier the replicability concern that we had when we started the study. We found some lovely charitable models that are endowed with $20 million, $40 million, again, they are not replicable. And that's again our aim at SARRC.

The real estate community, particularly during this economic downturn has actually been quite receptive and we hope to continue that by creating a model in Arizona that would not only represent different financial options but also different forms of real estate.

We are looking at a multi-family project, at some set-asides in another project, at some surrounding group home opportunities and to be able to express many of the design goals and guidelines that you

will see in that report.

The housing is being situated near light rail, near locations where we already have a presence so the adults can get quickly to the downtown YMCA, the library, our community college and some of our employers.

I am going to go through this section quickly. These are the home design goals, again, giving the private real estate industry as well as families more to think about, when we know that one of our number one concerns that has been expressed over and over again is the safety and security of those adults.

And making sure that those transitions are in place and that's where we talk about familiarity, stability and clarity.

And I might add that I know the day is not going to come that I wake up and say it's time for Matthew to go live in a home other than this one, that we need those stepping stones and those transition plans for

parents, and we need them to experience what it feels like to have their adult living outside their own home.

And so transitional housing is also part of the mix and part of the model that we hope to create.

Minimizing sensory overload and simplifying that and you will see many guidelines on that; allowing opportunities for controlling social interaction and privacy: again it's what we all want and need when we think about where we want to live.

Providing adequate choice and independence: we know that there is not a one-size-fits-all and so that's why the model that we are talking about in Arizona is also one that provides many different choices and will express many of the different design goals and guidelines that you will see in that report.

And housing and residential that provides for health and wellness, and we are working in collaboration right now with St.

Joseph's Hospital and Medical Center on designing transition and adult medical care program that not only provides the services but also provides venues for us to volunteer and to actually work at the nearby hospital.

Enhancing one's dignity -- I don't think there would be any debate on that. Durability, affordability, which is critically important; and accessibility and support in the surrounding community, which again are criteria that we are factoring.

The home design guidelines, which are numerous, you will see, and they range and I think the ASU did a lovely job in terms of thinking about just everything.

But please keep in mind when you go through this report, the intent is not to factor every one of these design goals and guidelines in. That would make it not affordable.

And so our goal is to provide solutions, to provide good information as it

relates to the market, as it relates to the demand, and unlike so many of the presentations that you hear in terms of the scientific, this is a business proposition that we are talking about. It is really to get the private sector working with the public sector, with the non-profit community to make sure that we have choices for adults with autism, and quality choices.

So our next steps are to conduct the market survey. We are doing that -- I mentioned the survey we are doing in Arizona; our hope is to broaden that nationally, to create an interactive database of the outstanding pieces of information that we were able to secure during the study, and to test some of the soft infrastructure support models. Soft infrastructure means not the hard real estate.

I, of course, have to point out that that's another photo of my son working out at the YMCA where he is working out this

very moment.

Other recommendations and next steps are to develop prototypes to test best practices and new ideas and I believe that this works beautifully with the autism strategic plan, particularly chapter 5, that talks about the services, and to be able to respond to current and short-term demand. I have to say that it is heartbreaking for us when we receive those desperate calls and we don't have the answers and families don't know where else to go.

And to increase and systematize capital resources from public agencies and then to pursue the testing of some innovative options, and there are some wonderful things that are happening.

Through AFAA we have connected with more and more organizations that are going down this path and believe that there in short order will be some more innovative options and hopefully they won't have to cobble together

seven different sources of income and seven attorneys and seven accountants for 14 units.

So I again want to underscore that we are talking about public-private-nonprofit collaborations, and we are also talking about families.

Who I haven't mentioned yet is our daughter Alison and Alison is 20 now and she is actually heading to Israel in just two weeks to study abroad for her first semester junior year.

And she has got a very bright future. She is a very ambitious girl. She is a very compassionate sister. My concern also is that I don't want Matthew to be a burden in Ali's life and I want them to continue to have a healthy relationship.

I continue to be struck by an article, front-page article that was written by Clare Ansberry, front page of the Wall Street Journal, 2004.

And I remember it well, because I

was on vacation and I remember how hard I cried when I read it. And it was about Tim Tullis and his 87-year-old dad and dad would get Tim ready for that vocational bus every day and be taken to that vocational program and when Tim came home there was always popcorn waiting and something to drink and they would watch re-runs from the Lawrence Welk program.

And on weekends it was special for them to go into the country and a drive-through Wendy's and they had their routine and Tim's mother had died about five years prior.

And fast-forward as there was enough front-page Wall Street Journal article and this one was about the day that Tim came home and dad wasn't there and at 50 years old, Tim was living with his sister, and living in a home different from the one that he had known for 50 years.

And that story has stayed with me for a very long time. Clare continued to go on

and talk about the huge demands that are upon us and are upon us now, for not only adults with autism, but other developmental disorders and challenges.

And so our hope is that this report is not only going to lift our community and our stakeholders in terms of those individuals with autism, but those who have other special needs.

And I am open for any questions that you might have about the report or about our work with advancing futures with adults with autism and I thank you very much for all the hard work that this committee has done and the ways that you have been leading all of us and our communities.

Dr. Insel: Let's take a couple of minutes for questions or comments. Ari?

Mr. Ne'eman: Well, first, let me thank you for a very interesting presentation. Sounds like you folks are doing some fascinating things and in particular I liked

some of that data that you provided us which hadn't known was out there before.

I have sort of one question, just the process level. In the compilation of this, the Opening Doors report, and speaking more broadly, in SARRC's work in general, could you tell me specifically what level of involvement adults on the autism spectrum have in the compilation of materials and in making decisions as to what is going in here and in conducting planning as to types and approaches in service provision models?

Ms. Resnik: That's a very good question Ari. In the implementation phase, which we are in right now, adults with autism are being brought -- are involved but in terms of the compilation of the information, which you will read about, is primarily summarized on the service models, those were taken primarily from the Organization for Autism Research in collaboration with their work.

So I don't think I can address your

question directly. It was more of a reflection of what's out there and in collaboration with service providers and the providers who are members of the national association, NARPA, which you are familiar with.

Mr. Ne'eman: So as of the moment, there hasn't been any self-advocate involvement in the planning stages of this process?

Ms. Resnik: I want to be very careful in answering the question because I believe that there have been self-advocates who have been involved in the work that we have referred to and if you look at the reference material -- and we have involved our clients at SARRC.

We have a number of individuals with Asperger's who have been involved in discussions but -- that have led to --

Ms. Resnik: Could you talk a little bit more about the particular institutional mechanisms at SARRC that you use to ensure

self-advocate involvement? I mean is there something at the governing board level, is there an advisory panel or, I am just curious as to the specifics.

Ms. Resnik: I don't think I can give you those specifics right now.

Mr. Ne'eman: Okay, thanks. I was just curious. And again, there is really some very interesting and powerful materials in this report. I appreciate you giving us all a copy.

Ms. Resnik: Absolutely, and I want to clarify if I can. I am a volunteer co-founder and I do have a full-time business. I am not involved in the daily operations of SARRC, where we do have a clinical services director, a research director, a vocational director who work directly with the families. So the reason I can't answer your question is because I am not the person actually involved with them on a daily basis. But I will get back to you on that information.

Dr. Insel: Thanks. Ellen.

Ms. Blackwell: Thank you Denise. I did actually have the opportunity to visit with Denise at SARRC a couple of weeks ago, so you did a very nice job summarizing your efforts. I just have one correction. The $674 Medicaid reimbursement that you mentioned, that's actually the 2010 Social Security income monthly payment. We don't pay our beneficiaries at Medicaid yet. We do, under some circumstances, pay family members, but that is the amount that Social Security pays to individuals who are disabled.

Ms. Resnik: Thank you for that clarification, Ellen.

Dr. Insel: Okay. Marjorie, last comment.

Dr. Solomon: I was wondering if you could speak to any efforts you have had with the community college system or potentially just colleges and universities in general in your area, in helping individuals with autism

go to college?

Ms. Resnik: Absolutely. Actually it's a very timely question and we have meetings under way right now. We have been in the planning for a number of months in collaboration with the Maricopa community college district.

And there is a community college very close to the residential area that we are citing right now and we are looking at a pilot program at that community college that would provide additional resources through their office of special needs and providing an actual autism coordinator there and we are looking at full-time as well as part-time students.

We are looking for ways those students could become more engaged on the college campus. We are looking at drawing peer mentors from the colleges of education and social work and we are also looking at work opportunities on the community college campus

as well.

So a little early, but we do have discussions under way and I am very excited about the opportunities. Thank you.

Dr. Insel: Thanks Denise, that was a terrific presentation. And this question is a great segue to the next presentation, which will be given by Dr. Carol Quirk and it's on just this topic, about education.

Dr. Quirk is President of TASH, which is an advocacy organization dedicated to the inclusion and full participation of people with disabilities. She is also the co-Executive Director at the Maryland Coalition for Inclusive Education, which provides services for families in schools to promote the inclusion of children with ASD and other disabilities in their neighborhood schools. Carol, welcome, delighted to have you here.

Dr. Quirk: Thank you very much. Good afternoon everyone. My presentation will be brief and my message very specific, and my

message is that students with Autism Spectrum Disorders can be included, should be included and we are in desperate need of research on effective strategies that will lead to positive outcomes when students are included in their neighborhood school.

I am going to begin talking about including students with disabilities by grounding it in the law and not to bore you, but just to provide the framework and that framework, I hope, will help you to understand what some of the difficulties we have when we are in schools and talking about inclusion.

Most of the conversations I have in schools with teachers and often with parents and in the community is because there is confusion around the definition around inclusion.

And sometimes I will hear things like well, inclusion didn't work for that child, or inclusion doesn't work for these children under these circumstances.

And my response to that, if I need to respond at all, and sometimes I don't, is that if it didn't work, it wasn't inclusion. If it didn't work, it's because we didn't figure out what was going to work, it was because we didn't provide the supports and services to make it work.

And inclusion doesn't mean being someplace all the time, just for the sake of being physically present. So I am hoping that at the end of this you will agree with me that students with autism can be included, should be included and we desperately need research to tell us how.

So -- and I have to stay put. I'm used to moving. To begin with, as we think about inclusion, most people jump to the definition in the Individuals with Disabilities Education Act, which is called the Least Restrictive Environment or LRE.

And that definition, in different places in the law, says that children with

disabilities should be educated with children who are not disabled and then they have that to the maximum extent appropriate kind of qualifier.

In regulations it says the child should be educated in the school that he or she would go to if they did not have a disability, commonly referred to as the neighborhood school.

Now, if a child, sometimes families have daycare exceptions because their daycare provider is in a different neighborhood, that would be the school the child would go to if they did not have a disability.

So when we say neighborhood school, it's if the child didn't have autism, where would he or she go to school? The law says you determine that placement annually. You just don't keep the child there because the child was always there and justify it because that's what is working, but you revisit it and that revisiting should begin with the neighborhood

school.

It also says that school should be as close as possible to the child's home. It's interesting that the word removal is used in more than one location. It says that the child with the disability should only be removed if the nature or severity of that disability is such that they cannot make progress even when you provide supplementary aids and services.

What's interesting about the law is the SAS, or supplementary aids and services, are inadequately defined, and that's where we have teachers struggling to figure out what those are, what should we do.

And when they can't figure it out, the default is, send them to a place with a label, like the autism program. And so in some districts, it's the PAL program, something autism learning.

You know, you have these different names for different programs and what I call those is group EPs, group education programs,

not IEPs, individual education programs. They are places where students go because of their label and they are congregated.

The law also says that you cannot remove a child with a disability just because the program as it is, is not at their level or doesn't meet their needs.

In order words, if you have to significantly modify the program in order for that child to participate, you should do that. You cannot remove the child because any functioning level is different and the curriculum requires modification.

It does say that you can consider harmful effects to that child or other children. So in a really inclusive world, and we have worked with some really inclusive systems, when they are considering the LRE or the placement for that child, they consider any harm to that child or other children.

And so children, then, who may be excluded from their neighborhood school and

general ed classes are typically children whose behavior is such that it causes harm to themselves or others, or significantly impacts with other children's learning.

And when we have questions I will be glad to talk a little bit more about that.

Now how do we measure LRE and most schools and school districts do not know this data. This is data for students, every school, when a child has an IEP, they have to put in there the placement code that goes to the school district that goes to the state and it goes to the federal government.

The federal government's publication is generally about two years behind, just because of cleaning out the data. So this data is for the 2007-2008 school year and these are all of the states and jurisdictions.

Now, right here is New Jersey, okay? New Jersey's data is about 40 percent, this is all children with disabilities. So if

you live in the state of New Jersey and you have a disability, only 40 percent of those students will actually be included -- participate in general ed 80 percent of the time or more.

Now if you are over here in Oregon, almost 70 percent of the students with disability, North Dakota almost 80 percent. Where is North Carolina? Somewhere -- well there's Connecticut right there, so Connecticut is up there. Here's South Carolina and they are under 60 percent. This is Maryland in red, where you are located right now. Here is North Carolina and they are almost 65 percent.

So South Carolina and North Carolina are right next to each other. So why is that, in one state you are less likely to be included and in another, you are more likely to be included?

The children in one state are not significantly different than another state.

What this tells you is that there are different practices going on in terms of placement.

Now, this slide shows you the placement practices or the inclusion and how you measure that is when you are in general ed 80 percent of the time or more, specifically for students with autism.

Again, down here we have Delaware -- Vermont and New Hampshire the data wasn't there, they are probably more inclusive than most -- South Carolina, very low, a little over 20 percent. New York between 20 and 30 percent.

Massachusetts now, we are getting up between 30 and 40 percent. Nebraska, now, Nebraska is near 60 percent. That's still low. I mean, almost, just a little more than half of the students with autism get to be in general ed most of the time. Most of them do not get to be in general ed for even half of the day.

Nebraska however, which is up there in terms of being more inclusive than others, has made, the state Department of Education has made a significant effort to develop a training team and to make the education of students with autism a priority in their state.

So what this tells you, I hope, is that there are different practices in different states that are not based on children's needs. This has nothing to with the students. This has all to do with the adults. It has to do with their attitude, their knowledge and their expectations.

So, now, what is inclusion and inclusion is not placement. Those data slides are placement slides. All that tells you is where they are. Inclusion is about the acceptance, the belonging and the sense of community that children feel when they are in school.

It's a philosophy. It's how you

plan, how you teach and how welcoming the school is. The most significant factor that we have found in over 20 years of our work -- and this is not databased, it's all anecdotal -- is that the single most influential factor on a child's inclusion is the attitude of the principal. That will be it.

The second factor is the skills of the special ed teacher. But even if you have the most skilled special educator, if the principal is not structuring their school day and providing teacher supports, they are less likely to be successful including students with disabilities.

This circle has three parts: social, academic and physical. So just being there is not enough. You have to have social supports and academic supports and this is for all children. So inclusion is when you have an attitude and a philosophy that everybody belongs.

All children who live in my

jurisdiction for my school are welcome to be in my school and we will plan for them to be in my school and only when we cannot, through the best planning, figure out how to make it work for that child, will we consider other options. That's what inclusion is about.

So these are some pictures of some students we have included and the reason I have put them in there is because you can't tell in those pictures who the child is with the disability or whether or not that child has autism or another invisible disability.

What you see is children interacting together. These children here, that's a little guy with autism, all of these children in his neighborhood school are going to be with him in fifth grade, in middle school, in high school. They will be his neighbors. They will be his co-workers. They may be his support providers when he is an adult.

They may, with one percent of our

children being born with autism, they may have children with autism. They may have nephews or nieces with autism. They may have cousins who have children with autism. They will be better prepared in a future world to know how to interact with and be accepting of their peers with autism.

So being there is the first step and then there's the instructional part. So the green represents the instruction that teachers do for everybody. Hopefully they have been prepared in their pre-service program. Hopefully they are providing a high-quality instruction for all kids.

Students with IEPs, students with disabilities, will need more. They will need the interventions, the accommodations and they will need modifications to the curriculum.

And then some children need even more than that. We'll need to be looking at the embedded skills. When you are teaching a class and there's what we call hidden

curriculum, curriculum that some students with autism don't necessarily recognize. What are the social behaviors that are expected in different environments or in different social situations, what is embedded within that routine in the classroom, and then specialized instruction.

We do have research on applied behavior analysis. We know that as a science it works. But we don't have real good practical application in a general ed setting.

There is very little research on how to teach social skills or how to develop social relationships and they are two different things. You can have social skills but you may not practice them. Your social relationships have to do with the reciprocal nature of the interaction with your non-disable peers.

Scott Bellini is the only one that I know of in this country who has really taken the little research that is available to

develop an approach to look at how we can successfully engage in promoting positive social interactions and relationships among kids with disabilities when they are included in general ed.

So inclusion is not LRE. LRE is the way we measure where children go to school. Over here, we have the place. This is a high school cafeteria, and you know, in looking at that, and if you have ever been in high school cafeterias, you know how noisy they are. You also know that there are cliques. There are tables that are segregated. There's a lot going on in high schools.

That environment, for some kids with autism might not be a happy environment. It could be too crowded. It could be too noisy. The lights could be too flashy. There could be too much sunlight. There's any number of things that could be not so great about that environment. Does that mean you don't include the child?

No, it means that you look at how you might be able to modify the environment. If you can't modify the environment, maybe that's not a place at that moment in time for that child to participate.

Do we then say that he or she will never go in those environments? Maybe, but maybe not. There may be ways we can plan for that child to have some successes in a setting like that.

But in the planning process we don't automatically make an assumption of exclusion. We think about planning.

In this setting, and it's not real great, you have a student who is included in a general ed class. She needs significant academic modifications. Does that mean because she may be so-called functioning, at least based on what we see, on maybe a first-grade level, that she should not participate in fifth grade?

No, she can. You can modify the

materials. You can actually modify them very easily. One situation I was in, it was in a fifth grade, and they were studying science, earth science, and there was an aide. Here we have an aide next to the student.

And the teacher was trying to teach the class and the aide was saying, turn to page 57, come on, the teacher said page 57. And she was rapidly moving the pages because the student couldn't find page 57, couldn't read the little numbers, did know 57 but there was no way the student was going to get to that page in a timely manner.

They were taking turns choral reading, where one student read a paragraph, the other student read a paragraph. This student couldn't read. He could read sight words. He could read the, he could read plane, he had a few, very few, but some words that he could read that were maybe in the text. He kept raising his hand. He really, really wanted to read because he wanted to

participate, but he couldn't read, so he got passed over.

When they were doing a writing assignment, after they read about the earth, the crust, the mantle and the core, they had a circle where they had a cutout with three layers and they had to label crust, mantle, core, they had to say if it was hot or cold, dry or wet, I think hard or soft.

Well, so, the aide, because the student doesn't have those words, his handwriting was really bad, he could write a few things, she was trying to point to which, she was talking over the teacher, and the reason I was there was because they said this is so inappropriate. He can't really function here.

And I said, it is inappropriate. But he can function here. He can read the number 57, so you have a little post-it. If the teacher tells the aide, we are going to go to page 57 today, while she is walking down

the hall, she can pull her pencil out, write 57 on the post-it, stick it right next to that book and do that in every class.

Every time you open up a book, put that little sticky there for the page, so teach him, that sticky means page number. Now maybe you have to pull him out to teach him that. That's where removal might be okay because it's going to teach him an application in general ed, so that he learns when I see the sticky, I go to page 57.

Give him words and have him either match to sample or give him a C-R-U-S and then give him a T so he can participate in the lesson at his level if he's either matching or if he's copying the words, if he was doing something color-coded; there's lots of ways he could develop his own skills within that same assignment.

This is just an example, again, Scott Bellini, that I wanted to show, a diagram of how he is taking research and

trying to translate that research into an instructional strategy. We just don't have enough of these applications coming to our teachers.

My concern is that when we do have research at all we don't have enough application and we're not getting that application to teacher preparation.

So I have only a couple of slides left and I wanted to have you look at this slide and I have a question for this group, which is, what do you see about that slide? It may be in your book. I don't know if you can see here.

These two are in black and these are in red. Is there anything that strikes you about this slide as you look at it? It's not rhetorical. You can shout out an answer.

(Off-mic comment.)

Dr. Quirk: Yes. If you look up, if you Goggle research, if you Google research institutes, research education autism,

educating students with disabilities autism, inclusion autism research, any of those, you will pull up SARRC. Where is the woman who just spoke?

Your SARRC -- and I love Danny Openden and I really love your organization -- SARRC is one of the few institutes that will come up that has anything to do with any research that has any application; University of New Hampshire Institute on Disability, University of Indiana --

And then there's other research that are primarily medical in nature. I know SARRC does a fair amount of medical research. Almost all the research can fit into somewhere: medical treatments; gastro-related; developmental; etiology; they are all medical in nature.

And so what this tells me if you just look at what research is going on, is that we are focused on diminishing the amount of autism we see. If we have one in 100, we

want less. We want less people being born with autism. We want to cure the autism. We want to take away the autism. We want to stop the autism.

Well, we may be able to look at how to treat people or provide treatments that minimize the negative impact of autism. That is important. But what are we doing for that one in 100 people who are living today? What are we doing for that one in 100 children who are being born and who are going to now spend their lives, impacted by autism, in a world where 99 percent of the people do not have autism?

They need to have strategies where they can function in that society, where they can communicate their choices. Communication and social interactions are huge and I can't tell you how many times I am in schools where I have educators saying to me, that student with autism doesn't really need a communication device because he won't know how

to use it because he is not smart enough.

What they are confusing is intelligence and communication. Because the student has not acquired the ability to communicate in a formal manner, they are assuming that there's nothing to communicate. This is really big.

So research to practice is that we need to look at what are the strategies that will lead to these outcomes, where students with autism are participating in their neighborhood school and they are making progress on academic skills, social skills and communication skills, where they are developing relationships with peers who have disabilities and don't have disabilities, where they are employed, as you were speaking about earlier, and where they have meaningful access to the community things that everybody else has access to.

That's where I think we really are lacking in our research and we need to move

our focus. Thank you.

Dr. Insel: We've got about five minutes. Stephen?

Dr. Shore: Yes, great presentation Carol. And while all the work that we are doing here is very, very important, however as you remind us, it's also vitally important to look at what we need to do for people with autism today. So, thank you very much.

Dr. Quirk: Thank you, Stephen.

Dr. Insel: Ellen?

Ms. Blackwell: Hi, Carol, I have a comment and a question. I have to give a disclaimer here. I didn't know Carol was coming today and my son Robert was actually an MCIE client 20 years ago and I wanted Robert to go to kindergarten at his home school. This turned into such a contentious issue that the Washington Post wrote a story about it and MCIE was so successful in its efforts that Robert actually ended up going to kindergarten in the morning and the afternoon at his home

school.

So what I want to ask you Carol, is -- again, that was 20 years ago -- how have things changed over the past 20 years?

Dr. Quirk: There is change. If you look at the data -- and I am going back to the LRE data -- you will see over time, and the state of Maryland for example has probably increased by maybe 10 to 15 percent more students are included than before.

We see that in the field in general there is more knowledge of how to include students with disabilities. The but is I am really concerned that while we do have more practice and we do have more knowledge, there is a real gap in the education of the community and in the General Education and administrative preparation.

I will give you an example. One of the projects we have is a family leadership program. One of the assignments our family leaders had was to go into their communities

and interview one person with a set of questions who didn't have a child with a disability and wasn't really related to them, could be in their church or in the grocery store.

And it was basically asking questions about what people knew. More than one parent had the response, when the interview began, with something like what do you know about including children with disabilities or have you ever heard of it and what have you heard?

And the person responded, saying, you don't really want to talk to me, I don't have those kinds of kids. Or, I am not the right person to ask these questions because my kids don't have disabilities so I don't have to worry about that.

So I think the point, while I do see change, there's a big gap in the community understanding of disability in general and autism in particular.

Dr. Insel: Alison?

Ms. Singer: One of the things that I thought was so exciting at this year's IMFAR was that there really now is a lot of good research that is being done in schools and in communities and I agree with you that that is so important because our children don't live in the University clinical trial room. They go to school and they live at home.

So I think the issue that we are going to start to confront now, is, once the data from these studies starts to emerge, how are we going to focus on dissemination? How can we soften the ground now so that the school districts are receptive to this data once we have it?

Dr. Quirk: Is that a question?

Ms. Singer: Yes.

Dr. Quirk: I have the same question. I don't know. You know, I think that making folks receptive to data -- you probably have been in situations where, like, when I go

into schools and they will say, just around inclusion in general, show me the research.

We have no research to show that self-contained classrooms are better. There's no research. In fact, there's some research that shows that self-contained classrooms are worse.

But even when you talk about that, they will say, well that was just those kids or that was just at that time or that was just about that subject. So I think people generally are going to believe what they want to believe.

The dissemination piece is big. We have to get that information out there. Teachers are not being prepared. Teachers are really not.

Dr. Insel: So maybe we should follow up on this, because there is a very specific issue, I think, behind Alison's question. There are some really interesting new approaches to ensuring inclusion and

success for kids. But it's not clear how those are -- those specific interventions are being disseminated.

Do we know anything about that? Is there a -- I mean, what do teachers or school administrators read, for instance, that would inform them?

Dr. Quirk: There's no real good research on -- current research. There's some good old research on specific populations. For example in the 1990s, there was a lot of research on inclusion and it looked at things like the impact on -- change in IEPs for students with severe disabilities.

Or it looked at the impact on social skills for students with emotional disabilities or the impact on peer relationships for middle school students with intellectual disabilities.

So there is a wide variety of research on a small population on a specific kind of intervention or aspect of their

inclusion.

There is two studies in the 2000 decade that looked generally at the impact of inclusion as I described it, on students with and without disabilities and showed they made academic progress.

But in terms of strategies, there's not a specific strategy. There just isn't. It's really a whole way that you look at how you schedule teachers, how you schedule students, what you do about disability awareness, what teachers learn about how to modify instruction.

It's a variety of ways that they go about creating school environments and there is no research that captures that, now, with one exception that I am aware of, which is out of the University of New Hampshire.

They have a model called -- it's Beyond Access, that's the name of it. And that model looks at the variety of things that I have discussed as a package. But that's the

only research that I am aware of.

Dr. Insel: Well, we can maybe come back to this. There are some pretty interesting things that some of us are hearing about at scientific meetings. I am just not sure they are getting beyond the academic community. Ed?

Dr. Trevathan: Yes, thanks for a great presentation. Looking at this little graph you have here on Least Restrictive Environment, there is some -- I wonder if there are any insights into the differences between inclusion rates within the states that could be helpful and I know the sample size has got to be really small say in American Samoa and in Palau and Guam --

Dr. Quirk: Yes.

Dr. Guttmacher: But nevertheless, for those of us that know a little bit about those places, I would have thought they might be somewhat similar and yet if you look at American Samoa, it's greater than 90 percent

and I think these others. The font's awfully small, but some of these others are 30 percent or so.

So do you have any -- if those differences are real, which I am not assuming they are, but if they are, do you have any insights into what is being done well in places like American Samoa that other places could learn from?

Dr. Quirk: I do. Yes. Well, there's two things that I think influence this data. One is culture and the other is size and for example, Mississippi I think is up there. Mississippi never had buildings. Mississippi in 1975, when Public Law 94142 was passed, they didn't have schools for kids with disabilities.

Maryland, on the other hand, a more progressive state at that time, had buildings. So especially around the D.C. area and in the large districts. So in this state, the large school districts in Maryland that had more

money built buildings and they were considered to be progressive.

I mean, in Montgomery County, where we are right now, you had a building for kids with intellectual disabilities, a building for kids with physical disabilities, a building for kids with emotional, a building for kids with LD and so at that time it was progressive.

Montgomery County, where we are now, is the third most restrictive county in the state of Maryland, because they still have those buildings. Mississippi didn't have buildings, so once they were behind, now they are ahead.

So, that has something to do with it. The other is culture and I am not as culturally competent as I would like to be but in Latino cultures and many of the Asian cultures, family is important and keeping kids together is important and I think that also influences how we think about inclusion.

Dr. Insel: Gail Houle.

Dr. Houle: Hi, Carol.

Dr. Quirk: Hi, Gail.

Dr. Houle: It's good to see you again. Carol had a subcontract with one of our autism centers and they did a great job in working with the middle and high school components of inclusion for children with autism.

There are some caveats to that data, and one is that when you look at the first data, all the inclusion data, you have three through 21, okay?

There's very few states that have universal preschool, so if you look at young children with autism who spend 80 percent of their time in general education, you will not find a very high number.

There's more work being done with childcare centers and getting children involved but for the most part, three-, four- and five-year-old preschoolers who are

identified have no universal education component to integrate with.

So those are some problems whereas the other one is --

Dr. Quirk: No, these are both six to 21.

Dr. Houle: Six to 21?

Dr. Quirk: Yes.

Dr. Houle: Okay.

Dr. Quirk: This is six to 21, because the very thing --

Dr. Houle: Are you sure?

Dr. Quirk: Yes, I'm positive. The very thing that you said is absolutely true, that for the three- to five-year-olds, districts are struggling with how to include three- and four-year-olds where there is no present three- or four-year old to program.

Dr. Houle: And they have been doing that.

Dr. Quirk: Right.

Dr. Houle: And the other thing is

what Carol mentioned, that if you have got a structure, a highly-developed structure in place that you in essence have to dismantle for inclusion, it's much more difficult than a rural state that never had enough population in one place to have special education classes in schools.

So kids were included, historically had been included the whole time. So New Jersey, I mean, it's a highly-sophisticated, big structure to kind of dismantle, not much of a recent history of inclusion because the population was so dense and they considered themselves at that point in time as being well-developed in leadership to have special classes for children.

So those are -- and Carol mentioned that, and that is definitely a factor. Sometimes, too there are -- we have all this data on ideadata.org, which is our whole report to Congress every year. You can slice and dice it and it has all the disabilities.

And we are also working with states because sometimes there are some disincentives for -- financial disincentives. There are some states that fund more for children who receive more hours in self-contained special education classes so we are working to eliminate some of those disincentives at the state or local level.

Dr. Insel: Okay. We've got some committee business to do. Thank you Carol. But I think before we do that let's take a break for, let's say, 10 minutes and we will reconvene at 3:20 to get on with the rest of the agenda.

(Whereupon, the above-entitled went off the record at 3:13 p.m. and resumed at 3:22 p.m.)

Dr. Insel: We're ready to get started with the next session. So the next session involves some committee business and it begins with a Service Subcommittee and Lee Grossman is going to do that for us.

Mr. Grossman: And as all of you are just learning now, that I am giving this presentation, I found out about five minutes ago I was doing the same so please bear with me.

The gist of what we are talking about today is to provide you an update and to solicit input on what we are planning to do for this services workshop that is planned for November 8 in Rockville, Maryland.

And -- sorry, I am swallowing food at the same time -- I was trying to hurry, Della.

We had a conference call in June where we discussed what we were going to be doing in terms of putting this workshop together and since then Ellen and I have talked quite a bit about trying to formulate the opinions and input that we have received then into a tangible, day-long workshop.

As you can appreciate, that's quite an undertaking, to address the entire services

array related to autism in the course of a one-day workshop, is certainly a daunting task because it's -- I mean, we can probably, I mean, we have been working on this for decades and to try and put it into a very short aspect of one day is very, very difficult.

And certainly there are many, many different ways of approaching this and that is part of the struggle that Ellen and I have had as well.

So, this is our best attempt at putting a program together and we want to make sure that it resonates with you and as well, get your input on what we are trying to do.

We decided that it was probably in the best interest to take what has already been developed by the IACC and bring that as a foundation for how we would roll this workshop out.

And last year we did a -- we had an RFI that was sent out and we solicited input from the community and what came back from

that RFI were a number of topics that they felt were very important in addressing services.

And these were the top six issues that presented themselves and there was a huge gap between the top six and then the, I believe, the bottom other eight that were on there. There were a total of about 14 topics that came out.

Dr. Insel: Lee, since we just heard about housing, is that considered infrastructure or where is housing in this?

Mr. Grossman: It's adults, community, family support, infrastructure. It's built into all of that.

Dr. Insel: Okay.

Mr. Grossman: Would you agree with that Ellen?

Ms. Blackwell: Yes, I think there is a lot of room in these six categories for various topics.

Mr. Grossman: So what we felt were

important, and the outcome that we would like to come out of the workshop is that we would have a recommendation to the Secretary as mandated to the IACC and we were taking on the task that Tom had put forward to us that he would hope that whatever would come out of this workshop would impact public policy.

So we have taken that to heart as something that we hope will be a very definitive outcome and part of the recommendations that we will be making to the Secretary: we want to explore what is already out there.

We are in an environment now where autism is growing dramatically and the funding sources for it are decreasing dramatically and so we have to think of what new models are out there, what new ideas are out there, to address not only the growing need but the growing deficit in monies that we can spend to service this community and to take care of this crisis.

Lastly, we believe that we should be coming out of this with an idea, an envisioning of what we would hope the autism community would look like, and how we would serve that community in 20 years from now.

And based on that, we should be able to come back and also as part of our recommendations, put forth ideas that would move us in that direction so that we can meet what we had hoped to accomplish and what the community will look like in 20 years.

Some of the people that we are suggesting to bring into this and people that are very invested and involved and have great experience in the primary delivery systems that are now servicing people with autism across the country.

And one of the people that we have suggested is Nancy Thaler, who is the Executive Director of one of the two NASDDDS that we are suggesting to bring in. This first NASDDDS is the National Association of State

Directors of Developmental Disabilities Services and her organization represents all 50 states and the territories, state directors of developmental disabilities.

And she has extensive experience in that. She served as the Secretary of DD services in Pennsylvania, so she has extensive experience. She has also worked with the Autism Society in different capacities and is on the Coalition for the Promotion of Self-Determination, which is a coalition of multiple disability organizations that are looking at adult services as their primary goal.

So she has extensive background in that. The other person is Dr. Bill East, who is the Executive Director of the other NASDSE but this is the National Association of State Directors of Special Education.

Through his work in the past year this NASDSE has put together has put together core competencies and products that are

available to the special education community that they are rolling out now and he has been speaking quite extensively on autism services because he has found that this is an issue that all the state directors of special education are struggling with and it's become an extremely high priority for them.

So those are two of the people that we are putting up there. We also wanted to address the National Core Indicators and from that, the gentleman that has been identified, and Ellen has had quite extensive experience with, is Dr. Lakin, who is an expert on NCI data and would be able to address that.

So we felt like presenting these in a large, federal framework would be a good way to start the day and after that, we are still struggling and, again, want the input from all of you in terms of how we would structure the rest of the day.

We want to make sure that we are covering the cost-effective quality services

examples that do exist out there, that all of us are familiar with. We want to take advantage of the new technologies that are coming on board to provide more efficiency and higher quality of service delivery.

And as a result of these, we will be finalizing, hopefully in the next couple of weeks and we will have the program pretty much put together by our August 10 meeting where we will discuss that and then we will be issuing out more formal invitations for people to attend and get this workshop in place.

So, at this point, I will take any questions and I will invite Ellen to also help me address these. Geri. No, sorry.

Dr. Dawson: I just wanted to check about the section on adults and community. So is there some way to integrate the work that is being done on the advancing futures for adults with autism recommendations with the recommendations that would come out of this? Or perhaps have representatives from that

effort at this so it becomes an integrated set of recommendations rather than parallel?

Mr. Grossman: Well, we've discussed that. I think it came up on the meeting, the teleconference that we had in June, that I would believe that, yes, that has to be an important aspect of the dialogue.

There are other coalitions out there such as CPSD that is already moving forward on important legislation on employment and vocational needs and they have been meeting with various agency officials throughout the federal government on how to move those initiatives forward. So I think all of that should be in play and should be presented.

Dr. Insel: Alison?

Ms. Singer: I am also going to suggest that, based on the great presentation that we just heard from Dr. Quirk, that we look at including a component that looks at strategies for improving dissemination of

services research so that as we are building our body of evidence research, we can get it into practice more quickly.

Dr. Insel: I would love to see a goal of transforming services in 10 years instead of 20. Nice thing about that is the year 2020 has a certain ring to it. It's the year of perfect vision, so if we could make that the time at which we want to have a service system that is more effective, I think that would be, that would galvanize more response.

The other comment I had in looking at this is there are some opportunities right now with the CLASS act rolling out where you may want to include somebody like Richard Frank, who can talk to that from HHS in terms of what that will mean for long-term supports.

And there may be some other things like that which people from the disability community will know more about, that would really suggest that maybe now is the time to

think how should we position our community, what do we need from the autism community to make sure that we take advantage of some of these things that are just emerging.

And we still don't actually know exactly they will be implemented, so this would be the critical time to be in the conversation.

Mr. Grossman: Ellen and I have discussed 10 years versus 20 years and Ellen was the one that was talking about the 10 years. My idea for the 20 years was just that because of the systemic needs that are going to have to be addressed, that we probably need that amount of time. That's not to say that we shouldn't be looking at 10-year goals and I would hope that we would do that so that we can speed this up.

I think what you are bringing up about the CLASS act is very, very important. Those are the type of cross-cutting, overall disability systemic issues that we can and

should have addressed and I think that's a very, very good addition to this conference.

I think that it would have greater strength to whatever we are recommending to the Secretary is if we are presenting this as a -- not only addressing the autism-specific issues, but looking at how this will benefit the entire disability community.

Ms. Blackwell: I actually think it would be great if we could have Henry, one of our own members, give a presentation about the changes in health reform that impact the long-term services and support system. I love to volunteer people when they are not here. But I have heard Henry do this before, in fact he did it just the other day, and he does a great job summarizing.

Only some of the provisions impact -- a lot of them impact Medicaid but I think Henry could do a good job describing the larger picture.

Dr. Insel: Great idea, and maybe

Kareem Dale from the White House, who has continually wanted to be included and has expressed a specific interest in these issues. I am sure he would be interested and so that is an opportunity. Larke?

Dr. Huang: I agree with what Ellen is saying. I also think that perhaps, when we were looking at the parity law, and the parity regs, that autism kind of straddled both the physical issues and the mental health issues. And so there was a lot of confusion around that.

So I am wondering if somebody who is working on the parity regs might also be useful and also thinking about other funding sources that we are learning are sort of untapped and Ellen would know more about this than I and that is the money follows the person piece also, that we understand that there is huge resources there that are untapped yet for people with disabilities.

The second comment I had is around

the vision for that, the 20-year what should services look like. Twenty years does -- I mean, that's almost a generation, that sounds like so far out that you might want to have more immediate and then 20-year vision.

But I noticed the vision was in terms of services and I am wondering if we want to make the vision be more in terms of what do we want people with autism, what should their lives be like, more in the sense of -- as, we are so service-oriented, we are thinking what we want the services to look like.

But what do we want people with autism, the full lives that we want them to live, or the housing, whatever. So I am just thinking maybe the focus should be on the people as opposed to the services there.

And then, I am also thinking, in terms of the dissemination, that we talk about in terms of what CDC is saying is the prevalence rates now in terms of really almost

a public health crisis, that we might really think about this in terms of a broader public health approach, dissemination, communication, awareness being one part of that.

And we speak a lot about dissemination and about dissemination of the research. I think we miss a little bit out on that whole translation. As we were talking about, what are those practices that have been successful in terms of inclusion and maybe it's with children with autism, but maybe it's in a neighboring field like mental health, where they are not just looking at the effective practices but really the struggles around the uptake of those and the translation of those into the field.

And there are people that are working just on that translation piece, maybe in autism, but maybe in other fields, that we can learn from that.

And then if we think about this as a public health approach to this issue, that

gets into the social and the communication awareness piece, then that translation of both the prevention -- because I heard some discussion earlier about, are we just doing prevention? Ari was saying, are we preventing people? I don't think that was the intent of that initial presentation.

But there are prevention issues and then there are treatment issues. If we really came up with a broader, public health approach to this, and then there could be recommendations in each one of those areas, that might be a coherent way to present it to the Secretary.

What are the policies in each of those kind of arenas if we look at it from a public -- if we look at it as a public health crisis, which I think is what we are saying when we look at the prevalence data, we are not responding to it in a public health approach or we are not mobilizing in that same kind of way, and that would be a services

piece.

Then the final thing I wanted to mention is that I think the whole self-determination piece, and moving from a --

Mr. Grossman: There's a fly on you.

Dr. Huang: Okay, is that the quota? I have no more to say? But also, in terms of really looking at strength and a strength-based self-determination piece. I think it's something we strongly heard in the last two presentations, and how do we wrap that into a framework for service sand what we want the outcomes to look like.

Dr. Insel: Those seem like great comments. Could I just add one thing to that list, since, to go back to the first presentation we heard this morning, to also think about the economics of this, even in the way that this is presented.

I think we haven't done enough, especially if we are trying to advise the Secretary about what needs to be done, we

haven't done enough to explain the cost of not doing things, and what the enormous cost will be if we just continue with business as usual, and why sometimes you have to invest up front to save tremendous costs downstream.

So since we are beginning to get numbers, to have a business case or to have an economic argument in here would also be a powerful way of I think compelling the department that this is something really important to do.

Mr. Grossman: I guess one of the things that I would want to add here is what you just said, Tom, is exactly right. I think if we could show that there's a societal reward if we begin early treatment and we provide services, that will go a long way -- I would hope that would impress the Secretary and the public policy going forward.

What Larke was saying was, I think absolutely right on in terms of how we should approach this, looking at it as a greater

public health issue, looking at self-determination and building that out.

The issue that we have here folks is we have got from 8 a.m. to 5 p.m. to put all this together and that's what we are struggling with so these are all wonderful ideas and we really, Ellen and I and Susan, are going to need your assistance to really encapsulate this into that day so we can capture all these wonderful ideas and make something meaningful as a result.

Dr. Insel: Ari?

Mr. Ne'eman: Well, if I can just sort of jump off-of that. I think that's a very good point and I think one of the challenges here is, we are going to be holding this event but if it's going to be more than just an opportunity to highlight things, it's the follow-up that's really going to matter.

You know, I think one of the things many of the people on the committee now are feeling very strongly on is the need to

prioritize the services component as much as we have prioritized the strategic plan in the past.

So I am wondering, and I'm almost thinking out loud here, if we might consider, should the funding be available or should the logistics be possible, in the follow-up, in the months following the services workshop, putting together panels around each of those proposed framework topics, similar to what we do for the strategic plan, with the thought that there is the plan to put -- we do need to put together recommendations for the Secretary, we do need to put together this, maybe it's 2020, maybe it's 2030, I think 2020 but regardless -- we do need to put together this vision document.

And that's something that probably requires more of a deliberative process that drills down more specifically into each issue than we can necessarily have through simple -- through a one-day event, or even through

regular conference calls of the full Services Subcommittee.

So, again, I encourage us to start thinking very clearly and even before the services workshop occurs, especially before the services workshop occurs, how we are going to structure the follow-up from it so we can ensure that whatever we discuss there, it is meaningful and it has the opportunity to be translated into policy.

Mr. Grossman: Yes, that is an unknown right now for Ellen and I and we feel that is very, very important if we are going to get that process really moving. I am a firm believer that the time is ripe to take advantage of this. We have an administration that is listening and is being responsive and I think that they would like to do more and we just have to give them the direction to do this.

Now what we have been tasked to do at this point is just put together the

workshop, but I think that the aspect of the follow-up is very, very important and we haven't gone down that road in terms of what the support will be or how that logistically and financially would be funded by the full committee.

Mr. Ne'eman: Is that something that we can get more information on prior to the workshop? I just, I would hate to see us have this workshop and then for us to have to sort of sit for two or three months and figure out how do we, what do we do next?

Dr. Insel: So that's really, I think that's why we have the Services Subcommittee, you know, is to run with this and as Lee says, you are pushing on an open door. This is unprecedented in terms of the interest you have got all the way up through the White House.

So there's not a lot of reason I think to delay in coming up with a document that really lays out what the agenda should

be. Alison?

Ms. Singer: Lee, who was the audience for this workshop? In addition to inviting people to speak, are we inviting people to attend? Is it to advise this group? Is it open to the public? Who is the audience?

Mr. Grossman: We haven't gotten those details yet. We were of the assumption that it would be open to anybody to attend. It would be not unsimilar to what we did in October with the strategic plan, where would be a core group of people that would be the discussants and involved in the actual work, the work product.

But then the rest of the community would be open, but again, we haven't gone through those details, and those have to be worked out and finalized and decided upon by the time we walk out of that meeting which is, what, only in about three weeks, which will be an hour-and-a-half conference call, so --

Ellen, do you have, I mean, does

anybody else want to add to that?

Ms. Blackwell: There's just one thing that I want to always bring to the attention of the committee and I hate to bring gloom and doom into hope here, because I think there's a lot going on.

But, the system for children with disabilities in this country is for the most part mandatory and after age 21, the adult system, a lot of adults with autism and other disabilities are supported through Medicaid, which -- and the desired home and community-based services are optional on the part of our states.

So because of the state budget situation, there are a lot -- as Lee will attest and as I can certainly attest working in the Medicaid program -- a lot of things are playing out across the country that are not optimal.

So one of the things we talked about was a focus on how we could do more with

less. I mean, we all hope that things improve but I think that is really important to acknowledge, that the resources just are not readily available right now, so I think that is an important aspect of trying to look at what can be done and what streamlined procedures or systems can we find that can make things better, you know, overall.

Dr. Insel: Any other comments for Lee and Ellen about this? Larke?

Dr. Huang: I think Alison's question about the audience is really important and if it's going to be a targeted, strategically-chosen and invited audience, if you are looking for a federal program, your federal supports, what other federal agencies might be involved or rather there's a lot of different work groups going on.

I think, getting back to the cost piece, I think in terms of looking at the cost, as we heard in the presentations today, is one aspect but then another piece is really

looking at what are the sources for funding services.

I think that's different than looking at the cost of autism per capita or per population over time. You know, what are the funding sources that need now to be cobbled together. And I think we do have opportunities with health reform, you know, and expansions of Medicaid and various things that we need to really sort of see how do we take advantage of those opportunities.

I am wondering if some of it needs to be linked with the overall strategic plan where, and really linking it with perhaps some of the aspirational goals, particularly in the questions around services and all, so that it is not kind of flying independently but is linked with the strategic plan, but really goes deeper in, almost a strategic plan around the services piece that links up with the aspirational goals but really looking at the service piece that does that.

And I would strongly urge that we do a financing component to it, where are we looking at our block grants, our discretionary funding, health insurance is being revamped, so that might be a really important opportunity when we are seeing increasing burden on states as they are dealing with shrinking budgets. They are also looking at how are they reconfiguring their budgets also. So the timing might be right for that.

Dr. Insel: Geri.

Dr. Dawson: Well, one of the things that I am hearing and that I agree with very strongly is that the issues that we have been talking about here are really broad and complex, everything from economic analysis to a public health perspective on the development of services through the lifespan.

You know, it's a very broad agenda and it's one that we don't in some areas know a lot about. So my sense is that a one-day workshop is like a drop in the bucket, really.

And so to strategically think about how to use that day to really launch what probably needs to be a more thoughtful and systematic effort that does have some components to it. Maybe it is like a strategic plan or at least it's sort of a blueprint or something for thinking about each of these domains that I think you have listed here.

But I do think that a one-day workshop on something this important and complex and you know, at such an early stage in its development, is not going to be all that is needed.

So I do think it would be helpful, what Ari is suggesting, to kind of have a sense of a plan that goes beyond the workshop for re-implementation that is more than just a document that summarizes the workshop.

Mr. Grossman: Thank you. Great.

Dr. Insel: Okay. That's -- is there anything else you need from us, besides participation?

Mr. Grossman: Well, there is, I think there's quite a bit that we are going to need. We do have to identify really who our audience is and the logistics involved with this. I think that just the bringing together and formulating what the goals will be of this workshop will be determined, I feel strongly, by the type of follow-up that we plan out that will come out of the workshop. So those have to be talked through a little bit more as well, how all the logistics of that would work.

Dr. Insel: Very good. Thank you. We have got some other business which Della is going to take us through around the RFI update.

Dr. Hann: Thank you. Okay. So hopefully everyone in the room and hopefully those that are watching as well, know that we have released the RFI for information for updating the strategic plan.

It was released on June 18 and it

will close on July 30, so that's six weeks, essentially, out for public comment.

We have begun to receive some comments. Usually as these things go, we get the bulk of them towards the end. But we have received a few up to now.

We will, my office will be in charge of assembling the responses that we receive and those responses in turn will be given over to the planning committee in terms of their considerations for updating the plan.

So that's where we are with the RFI. Any questions? Okay.

Dr. Insel: So, update.

Dr. Hann: There we go. So about 10 days ago or so, actually it's been longer than that now, 16 days ago, I sent members of the committee a request for updating per discussions of the committee earlier at one of our meetings, it was decided that it would be very helpful if we could sort of have a mid-term update if you will in planning for the

summary of advances, and that that mid-term could then be used too in terms of possibly updating the strategic plan.

So I sent the request out the night of June 30 to be there for you on July 1 when you opened up your computers. It's due on the 22nd back to me and what it is requesting is that members of the committee identify up to five articles that you consider to be top advances.

And we are going through the exact same process that we did before in creating the summary of advances. I just truncated it to five as opposed to 10. When we did this exercise in January, it was 10 articles.

The articles need to be published and it's not an e-pub, they do need to be fully published in order to be considered. And as we did before, my office will compile the full list of nominations that we have received and send it back out to the committee for voting purposes to identify the top 10 out of

that list that will become sort of like the first installment, if you will, for the summary of advances.

Questions? Comments? Lyn?

Ms. Redwood: I have one, Della. Back a couple of weeks ago I was reading over the -- is this working? --

Dr. Hann: Yes, now it is.

Ms. Redwood: -- language in the Combating Autism Act and it says, quote, "Develop and annually date 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 ASD."

And I was just sort of concerned with the way we are going about this, when I looked over the updates that we just did for 2009. We didn't really address all those areas. We didn't have anything that I could find that related to services and supports for

individuals.

So I was almost wondering if we tried to target research that sort of went along with the different chapters in the plan, that that would be almost identical to what we are supposed to be turning in and that it might segue nicer to help us actually update the plan each year when we see what has been accomplished and what the advances have been to help us identify gaps.

So I just wanted to throw that out to the committee, in terms of just picking five articles that we actually try to find articles that relate to the different chapters of the plan.

Dr. Insel: Ari.

Mr. Ne'eman: The only thing that jumps out at me -- I think that's a great idea -- the only that jumps out at me there is I think it may sort of be a chance to highlight the real lack of research that is being done related to services and supports because in

that sense I think that's a mark in the favor of that format change because there's so little that is out there, I imagine many of us will struggle to find things to put in that category in terms of recent research.

So, you know, maybe that will assist us in looking at where there's been a dearth of finding when we get to the strategic plan as well.

Dr. Hann: I just wanted to remind the committee that back in January, February, when we went through this process, at the end of the year that comprises the summary of advances, there is two components now, the way that the committee has decided it.

There is a list of 20, essentially, advances that we summarize and put forward into now a nice document. But there also goes with that all of the nominations that are received as well as a listing that our office pulls together in working with the National Library et cetera, of all of the research,

essentially, that was published within that calendar year.

So that would include, I would assume and I would hope, that research in areas that may not be as strong, it would still be included in the final summary. It's just that that's the compendium that goes with it. It's sort of like the index that goes along with it but that the things that comprise the top 20 are those that the committee has decided really rise to the top in terms of notice.

So there really is two pieces to the actual summary. The request right now is just a mid-term for the one piece.

Ms. McKee: Did we ever put together the longer list for last year? I didn't see it yet.

Dr. Hann: It's in the process. It's still being compiled. We identified a number of errors when we had it pulled together, so we have to go through and cleanse it but we

are anticipating that hopefully within the next few weeks that that will be done.

Dr. Insel: Anything else on this? So, I mean, in response to Lyn's comment, I guess the encouragement would be for people as they look at the articles to submit, that they are mindful of the range of different kinds of progress that the Act calls for.

Ms. Redwood: And I guess, Tom, the other thing was when we submit the report, that we actually sort of tie the report to the strategic plan, so we can look at what advances we have made in those areas and then we could say, gosh, you know, we really haven't, it doesn't appear as though we have accomplished much in services.

So that was sort of my suggestion, and when I read the actual language for what we were supposed to be doing with this update, it seemed as though that was the intent, is to update in terms of what we have accomplished just not what, you know, the science has been

for the year.

Dr. Hann: Right, and it was my interpretation, and I could be wrong, that that was another reason why we wanted to do a mid-term, so that last year's science advances as well as the mid-term could be used by the planning committee to help update the plan.

Dr. Insel: Yes, but I hear Lyn saying something else, which is that this is one way to track success on the plan. So if we format it in such a way that you can see where the products are coming, you will know also where the gaps are. That's something we can do in the way that we produce it next year.

Right, yes, especially the mid-year will. Okay, anything else on the research advances? What about portfolio analysis?

Dr. Hann: Short update: we are in the midst of doing the portfolio analysis. We have had data calls out to the various organizations that provided information last year for the portfolio analysis. We are

preparing it and write this, just as a memory tool, these were the list of funders that provided information last year plus a new one: the Autism Science Foundation has been added.

You can see here we are in negotiations and will be receiving input from SARRC as well as Simons. We don't have it yet.

We are working still with NIH. It was a little more complicated this year working with NIH because of the ARRA funds. It kind of got our data runs a little messy.

So we are still in the process, but all of those, except for the Autism Consortium, we understand, will be providing us data that we will be able to have for the portfolio analysis.

And our goal is if we have the data time -- right, Susan? -- that we will be able to have a good chunk of it ready by September, in terms of the final portfolio analysis.

Dr. Insel: Ari?

Mr. Ne'eman: Very briefly, I found

the portfolio analysis from `08 continues to be useful so I very much look forward to the new one coming out.

I was wondering, you know, since we do have and this is public, these lists of specific funders we are collecting data for, can we also make available the break-down by funder for where each funder's research fits into the strategic plan?

Dr. Insel: We have that.

Mr. Ne'eman: Do we?

Dr. Insel: I think that's actually published.

Mr. Ne'eman: Really? Oh. My error.

Dr. Hann: It's a complex piece so it's quite all right. We have a brief overview on the web. That's probably the piece that you might be referring to, which is sort of the high-level summary.

But in addition to that, we have the data tables that support all of that and show where the data falls by each chapter of

the plan, for each funder, I mean, by all the funders.

Mr. Ne'eman: That would be great. If you could just show me how to find that later, I would really appreciate it.

Dr. Insel: Anything else on any of these items? Okay. Thanks, Della. The next item on the agenda is the discussion of the public comments and in addition to the two presentations we had this afternoon, I also want to encourage you to also comment on any of the things that came in through the web, which you have been provided with as well.

Lyn, you have that look.

Ms. Redwood: First, I want to acknowledge to everybody who submitted these that we have read over all of them and some of them are very thoughtful. Some of them were very redundant and I guess I am sort of at a loss with what to do with some of them. I think some of the ideas that come forward should be captured in our strategic plan.

So I am just sort of throwing out, I want to hear what other members of the committee think about the comments, except for the first one.

Dr. Insel: Yes, I was going to ask the same question. I think there is a lot in here and it comes from lots of different perspectives. But there are some very detailed -- very specific issues. One person for instance who says, you know, you guys really need an immunologist someplace in your committee because the lack of expertise in that area is hurting you.

So those kinds of comments, I think, are the sorts of things that I am hoping the committee will take into account and we should really think through whether there are things here that are action items for us.

Mr. Ne'eman: One comment I thought was particularly useful is, if you look on page 45, from Matt Carey. You know, this is --

he raises the issue that there are, that we mention in the strategic plan particular sub-groups that require more research, but we mention them sort of as examples. So that we need to explore particular phenotypes and he provides us the example, non-verbal individuals on the spectrum and those with cognitive impairments, intellectual disabilities, and he mentions that's in the strategic plan already.

But the fact that we don't specifically prioritize those may ignore the fact that -- as I think many of our presenters pointed out earlier today -- there's a lack of research with particular sub-groups on the spectrum.

So I think the comment that was made here makes that point very nicely and I think that may be really something to keep in mind in future iterations of the strategic plan, to really require digging down into particular sub-groups that research has just

not prioritized in the past for whatever reason.

Ms. Redwood: Tom, back to your question about adding additional expertise to the committee. I know we just added several new members. How would we go about expanding the committee more? Because several of the comments were asking for more focus on environmental factors and not genetics, adding immunologists, more environmental expertise, which I think there were a count of three or four that were along those same flavor of comments that were from separate individuals. So how would we go about doing that?

Dr. Insel: So, certainly there is also -- there's a possibility of adding in additional federal members at this point, if we decide to go that way, and that is something that is not that complicated to do although it could take some time.

What I had the sense from the community, and I may have read this wrong, was

that for many areas like that, what I thought you were wanting was to bring in the expertise the way we did today.

And it might be really helpful to bring in one or two people with specific expertise in an area of immunology that could be relevant to autism and I think you were the one that asked the question about microglia or inflammatory responses in the brain and that may be an area that we want to hear more about going forward.

I don't know if that means that we have to change the constitution of the committee as much as just making sure we have someone who can help to advise us. That's the great thing about being a committee like this, is that we can usually get people to help us when we need that, and there's a lot of expertise either at NIH or in the community that we fund in those sorts of areas.

I have the same issue, I keep bringing this up at every meeting, but I

happen to think that the whole explosion of work on the microbiome is highly relevant to us. There was a wonderful piece in the New York Times earlier this week about this.

And it's not something that is in the strategic plan. It's not something we have talked about. I do think that it would be good, even if we didn't have someone on the committee who does that, if we brought that expertise in for the committee to hear about.

Ms. Redwood: Tom, is there also a way to address -- because a lot of the suggestions we get are for specific environmental factors, to research whether it's XMRV virus, soy, formulas, ultrasound, that we could take that information and translate it over when we are updating the plan so to keep sort of a running list of things we have received from public comment for areas that the public thinks are important.

(Whereupon, official committee

business was temporarily suspended due to a power outage from 4:09 p.m. to 4:14 p.m.)

Dr. Insel: Okay, we are back online. Welcome back. For those of you joining by videocast, our apologies, we have had a power outage here but we are back running again.

And I think just before the power went out, Lyn Redwood was saying something -- there's no connection (audience laughter). We actually believe here that correlation and causation are unrelated in most cases (audience laughter).

Ms. Redwood: I just thought that if there would be a way to keep a list of the recommendations we get in terms of areas of research that we could use to refer back to when we are updating the plan, because we do get these specific requests for looking at things like ultrasound and you know, soy formulas and all the things that were reflected in these public comments so we could transmit that to the people who are doing the

updates.

Dr. Birnbaum: I will say that when some of that comes across my desk, I talk to people at our institute who are doing some of these things and we kind of put them on the list of things to think about. So we actually have an intramural program looking at soy-fed versus breast milk versus cow milk infants, a study that is just starting.

We are frankly having trouble recruiting children who are on 100 percent soy milk, since it's not a recommendation of the American Academy of Pediatrics anymore. But you know, there's no reason that they couldn't add certain neurological points into the assessment of these kids as they go forward.

Dr. Insel: But the more -- that's a great thing to know -- but I think the more general point of finding a way to incorporate this, just as we do the RFI, is really important. I mean, people have gone to the trouble to write this down and send it in,

sometimes multiple times.

So they come to this with a lot of passion and it's usually based on some experience and it should be possible for us -- I would think, right? -- to find a way to collate this and to provide it to the committee in a way that's very tractable so that when it comes time to think about the update of the plan, we have that in front of us, along with everything else that we are pulling together. Chris?

Ms. McKee: I had the same idea when it came to the non-verbal workshop. At the end of the presentation at the last meeting they had six bullets of what the next steps are and I didn't know how we would track those or don't lose track of them, as we head into revising the strategic plan.

So there is a lot of things that come before the committee and I don't know how we can keep a running list of that as well.

Dr. Insel: That's a great idea. So

I think one of the things OARC can do is to try to find a way to capture those, get them back to the committee at the time when we are starting to consider all the options, what we need to do. And if there are other sources of information like that, help us think about it and we will make sure it's there. Geri?

Dr. Dawson: The speakers made a number of recommendations today, just to add to the list of information.

Dr. Insel: Right, but we will have those. So those will be in your minutes, so you will get that before the next meeting, but we can also try to capture some of those and in this case, we had some very specific comments about what might be important for us to think about, going forward, and after all, that is why we are having many of these people here, is to help inform us about what we want to do. Alison.

Ms. Singer: We also talked at the last meeting about creating a calendar of

events of interest to the autism community. Is that moving forward? Is there a way we can help to move that forward?

Dr. Insel: OARC team?

Dr. Hann: What we have -- the quandary that we are in is sometimes we are notified of meetings that are not open to the public, and so I, while you all may be invited to it, it's not necessarily something that is open to the public. So therefore we are sort of in a quandary about how best to proceed in terms of that.

We are happy to gather the information when it is sent to us and to let you know that it is available, but in terms of tabulating it and keeping it in some sort of calendar format, if we do that, it has to be available to the public.

And since not all the meetings are, we are, I feel like I am caught between a rock and a hard place.

Dr. Insel: What about doing that

for meetings that are open to the public?

Dr. Hann: Sure, if you all let us know what those meetings are, we are happy to do that.

Ms. Singer: But I thought one of the other goals of having that calendar was so that we would know what meetings were taking place, even if they weren't open to the public or even if we weren't invited, so that we would have the opportunity to invite a representative who attended those meetings to come and present the way we did with the non-verbal workshop.

So in that sense, it would be useful to see all the meetings.

Dr. Insel: Yes, maybe we are talking about two different things. So I suspect that Della's concern, which I share, is that if we put onto the website a list of meetings and they in any way appear to be endorsed by IACC and yet they are not open, there's a conflict. That's a problem.

On the other hand, I think you are right, Alison, we would like to know what is going on out there so that we can be informed about what's happening.

The good news is that almost all the meetings that I think, at least many of the ones we know about, someone around this table is likely to attend and so one thing we can do is to ask you to help us, to inform the committee about anything that you have been a part of or that you are going to be a part of, which is actually coming up in the round robin. We are going to do a little bit of that today, even for meetings that are not open to the public.

Is that helpful? I mean, does that solve the problem? I think Gerry Fishbach brought this up last time as well, that he wanted to make sure there was some way to see the whole landscape of what was going on, because none of us knew about all the different meetings happening.

Anything else in terms of the comments we heard, presentations today, or anything that came in written?

If not, let's move on to the round robin. We have asked a few people to -- and remember last time we decided that we would kind of rotate, because we wanted to hear from everybody, but we may not have time -- actually today we may have time to hear from more than a few people -- but just to get some quick updates about the things that have happened, are about to happen or that you want to share with the rest of the committee.

And since Linda has a little bit of a schedule conflict, you wanted to go first.

Dr. Birnbaum: Thank you. Our institute is totally overwhelmed right now by the Gulf oil spill crisis and I have got to get a meeting at NIOSH by 5:30, so I just wanted to give you an update on an autism and environment brain-storming session that we are going to be holding at our institute September

8 from 8:30 to 4:30.

We are working together with Autism Speaks -- thank you -- to organize this session and the goal is to identify novel opportunities and mechanisms to accelerate research on environmental factors in autism.

And we are bringing together a mix of autism experts with those outside the field who can provide kind of a fresh, out-of-the-box look at tackling environmental contributors to disease.

The roster of invited experts and meeting agenda are being finalized as we speak and they will be shared with all of you next week.

We are hoping that the products of the workshop will include recommendations for highest priority areas of research that address the contribution of environmental factors for risk and phenotypic expression of autism, possible solutions for any barriers to progress identified in these areas and other

resources that we would need for increasing the pace of the research.

All the products of the workshop will be shared with the IACC and can be considered in the ongoing process of evaluating and refining the strategic plan.

Now, the space that we have for this meeting is relatively limited but we welcome any IACC member who is interested in attending. We will also be arranging for videocasting and webcasting for observers who would like to be able to hear and see what is going on.

So if you are interested in attending, please let me know or let Cindy Lawler or both of us, that would be fine, and we will make sure that you get in touch with the meeting organizers. I think it's going to be a great day. It's currently scheduled from 8:30 to 4:30. I may have said that.

Dr. Insel: Great. Ellen, you had a meeting as well? I should just say, by the

way, Linda, I know that you are working 80 hours a week on the Gulf oil spill, so all of us really appreciate your being here today and taking the whole day for this.

Dr. Birnbaum: No, I have to say I thought it was a great day, and I think having all the different people come in and present, I mean it was the environment this morning and then it was more the issues of taking care of our autistic friends and colleagues and relatives, you know, in the afternoon. It was a great balance.

Dr. Guttmacher: I would first of all second that, but then I would call your attention, thanks to Susan, there's a slide up there about the meeting about which I am going to be speaking, which in fact is somewhat inspired by the IACC.

I will actually read from the meeting website. "There is increasing evidence that Autism Spectrum Disorders are often diagnosed several years after the onset of

symptoms. This pattern of delayed and sometimes missed ASD diagnosis may be exacerbated among medically under-served racial and ethnic minorities.

"The Interagency Autism Coordinating Committee's 2009 strategic plan for research opportunities has identified improved screening and assessment as part of its research opportunities.

"The strategic plan documents the need to identify quote, `sensitive and efficient clinical diagnostic tools for diagnosing ASD in widely diverse populations, including under-represented racial and ethnic groups, females, younger and older age groups.' End quote.

"In response to this gap in research, this symposium will bring together experts in the field of ASD to discuss assessment with particular emphasis on children of diverse backgrounds."

So, if you are worried sometimes,

is anyone listening, yes, folks at the NIH, I can tell you, are listening.

This, as the poster says, is co-sponsored by NICHD and the trans-NIH autism committee. There are actually a couple of organizers of the workshop: Judith Cooper and Alice Keyl, both in the room now. We thank you for the workshop.

And it talks there about the folks who are going to be speaking, and at the end of the day, there is going to be a panel discussion about how you pull this together and how we kind of move forward in this area, which clearly I think is a very important one.

I have already heard from a couple of members of the IACC that are planning to attend. You can register on the web. It is open to the public. So we invite folks to come down. It's on the NIH campus, so come a little bit early so you can get through security, and we look forward to as many people as possible, both here and that are watching on the web

now, joining us for it.

I should mention, just to underscore, that the deadline for registering is August 6.

Dr. Insel: Thank you. Is there anything else from NICHD that we need to know about?

Dr. Guttmacher: I don't think so.

Dr. Insel: Okay. Ellen? I have got you on the list.

Dr. Guttmacher: Actually, Tom, can I take that back?

Dr. Insel: You just did.

Dr. Guttmacher: Thank you. Yes, something to make folks aware of, that if you keep an eye on our website we will have more information. We have some information up there now but in the near future we will have a lot more and we can maybe send to the whole committee information about this.

NICHD has just launched upon a more or less year-long visioning process to look at

what are the scientific opportunities across the broad mission of NICHD over the next decade or so.

This is not a program review, it's not the traditional kind of Soviet-style five-year strategic plan, it's really a scientific vision. And the idea is we are going to have a series of nine different workshops and then sort of a culminating workshop where we are going to have several dozen folks get together for a day-and-a-half or two days on various kinds of topics to help us really figure out what are the scientific opportunities.

I call that to folks' attention both because, as you will see, there are going to be opportunities to engage in the workshops, even if one is not physically there, we are going to use the web to get input from folks about these topics et cetera.

So pay attention to our website. There are several different of these workshops in which, I think, issues related to autism

will come up and certainly other ones where larger issues about developmental delays are going to come up.

So, sort of pay attention to that if you would and again, we will, as we have more concrete kinds of things about exactly dates for workshops, those kinds of things, we will be circulating information through the IACC.

Dr. Insel: Great, thanks. Okay. Ellen?

Ms. Blackwell: Okay, well, I was asked to give an update on one particular project but I have been jotting myself notes so I will add a couple of other things.

We at CMS are very excited this week to welcome our new administrator Dr. Berwick. Great timing, because we are all very excited and exhausted working on health reform, so that it's a good time to be at CMS.

Just a couple of things that I would draw to folks' attention. The Medicaid

director has issued two, what we call, state Medicaid director letters and they are on the CMS website at www.cms.hhs.gov that I think might be interesting to this group.

One of them sort of lays out or work in the area of Olmstead compliance and the Americans With Disabilities Act and then sort of discusses in very broad terms what CMS has done in the areas of promoting home and community-based services. So I think that's a good letter, especially for people who aren't terribly familiar with those efforts.

The second delves a little deeper into what Larke mentioned earlier regarding the money follows the person demonstration, which was reauthorized by the Congress in the context of health reform. This is a demonstration that seeks -- 26 states are currently participating in it and its goal is to get people out of institutions and into home- and community-based settings.

So not only was the demonstration

reauthorized, but CMS also has the authority to solicit the participation of new states. So the project has been a little slow to get up and running, but we are still really excited about it.

Although most of the states have elected to target older adults and people who are physically disabled, there are some states who are de-institutionalizing people with developmental disabilites and mental illness.

So if you are not familiar with that demonstration, I would take a look at the update letter that we issued just a few weeks ago.

And then, Susan, I think I had sent you a note about the Reinventing Quality Conference which is in Baltimore? That is the end of July or this August, and I absolutely forget the date right now. We have reached that point in the day. But that is another meeting that I would draw to folks' attention because, again, and it is something that is

open to the public, looks at quality in Home & Community-Based Services, so that's a good one.

Mr. Ne'eman: I think it's August 8 and 9.

Ms. Blackwell: Thank you, Ari, I knew he would know. Okay. So, the next thing I wanted to talk about really quickly is a plan or a project that we are administering at CMS which deals with one of our strategic plan goals, the State of the States project and it's in chapter 7 of the strategic plan, objective B, and this is a contract that we are actually administering at CMS. We have a couple of contractors, L&M has subcontracted to Thomson-Reuters, and these contractors have done good work for CMS in other areas.

So, what are we doing? I'm sorry, this slide is a little crooked here. We are first looking at quantitative data and I had to laugh when I looked at this slide this morning. This is a Freudian slip. I left out

Medicaid. Okay?

Okay. Although one might say that Medicaid is somewhat covered by institutional services and Home & Community-Based Services and ironically, we recently received the quantitative information from our partners at Social Security so we are looking at that data.

And the Medicaid data has been the slowest to collect and as anyone who has ever attempted to delve into the Medicaid MAX data will attest, that is probably not a big surprise.

So we are in the process of looking at the different data that we can glean from institutional systems, including the Education Department, which has, you know, pretty robust data on autism.

One thing I wanted to mention is that in Medicaid we are presently looking at redesigning our data collection systems. We are at the beginning of that process. It's

called MACBIZ (Phonetic) and I have been a strident advocate to include collection of data regarding people with autism, which I fervently hope will be part of the redesign of Medicaid data collection.

So, in upcoming years, we have to look at what we have now as far as this project is concerned, but I imagine in five or 10 years, we will have much better data coming out of Medicaid about people with autism.

So what are we looking at as far as qualitative data? We are looking at interviews with different state policy types in these areas and these are pretty much the agencies and the folks that we will be talking with.

We have to design a data collection tool, an interview tool, and what kind of questions are we looking at, and these are some of the questions. I think these are important. And what type of publicly-funded services and supports are available for people with autism, how many people get them, how are

states improving the diagnosis and services for people with autism, irrespective of payment source?

So those are the sorts of things we are looking at in terms of the qualitative data collection, and the tool is getting really close. We have to have it, because we are interviewing more than nine states, it has to be approved by the President's Office of Management and Budget.

We are finalizing that process or we are at least getting close. We can't alter the tool once OMB locks on to it so we want to make sure that we get it right and that it is something that will work going forward into the future.

We field-tested it last month and this month. We picked a couple of states that we thought were friendly Indians. Those states are Minnesota and Vermont and actually what we have, it worked pretty well, so we are feeling pretty good about how far we have gotten in

terms of finalizing this qualitative piece, which is really the most difficult.

We also have almost finished our interviews with stakeholders, except for the Autism Society of America, okay? So, thank you everyone who participated in those.

And if anyone has any other ideas about who we should be talking to, please send them my way. I am the project officer for this project.

We also formed a technical advisory panel and we convened this panel almost as soon as the project went into action. We brought the people to Baltimore for face-to-face interviews and it's a really nice group of folks. I put them up here because I think they deserve a lot of credit for helping us for practically nothing.

And they have been looking at the qualitative interview tool and -- I have put Nina on here twice, oops. But they have been looking at it and giving us their input as far

as telling us what they think should be on there.

So what are we doing now? As I said, we are finalizing the tool, we expect to have some real data by December. Our contractor will be giving us a mid-term report in December of 2010. And we should have the project, the first iteration, complete by December 2011.

I have to say that one of the other obstacles in the interview process is that, you know, I said before that states are stressed, that isn't just a fiscal stress area in terms of what services are provided. It plays out in terms of what state staff are available. You know, we have states furloughing employees, we have people working limited hours. We have California talking about, you know, putting its staff on minimum wage.

So that is, it's going to be a challenge for us. But we have had a lot of

cooperation so far, at least in the states that we field-tested, so we have high hopes.

And everyone is very interested in autism so, I am hoping that it won't be an obstacle. So that is where we are.

Dr. Insel: Great. Thank you. Comments or questions? Gail?

Dr. Houle: Yes, that sounds great, very good, Ellen, and if you need any help with the Department of Education let me know. I'll volunteer.

Maybe in future years -- the more I hear about it, the more interested I get in the initiatives that are being funded at the Department of Defense, in their schools and their TRICARE system.

They've got model demonstration projects. They've got collection data. Their school system does not come under the U.S. Department of Education. It comes under the Department of Defense. So we would have to go through them to get any information about

their autism program in the schools.

But they did get some additional funding for it -- as Lee knows; he tracks the legislation -- and for quite a few years now, to do demonstration projects and collect research data.

So that would be a goal for this committee and for a comprehensive assessment in the future.

Ms. Blackwell: Gail, I can't -- I vaguely remember that it came up in our technical advisory panel discussion so I think it might be on the docket but today I absolutely cannot remember where it is, but yes, I recall that it did come up.

Dr. Insel: So, Ellen, what is the prognosis with OMB? Could they delay this for months?

Ms. Blackwell: Here's the exciting thing about what is happening at CMS. We have so much leaving the building so fast right now that we actually do have accelerated venues

for OMB clearance, so I am really hoping to grow wings on this project and float it out of the building along with some of the other stuff that is leaving very quickly.

Because we -- CMS is tasked with so much in terms of health reform, especially Medicaid, we are just really moving things fast. So I have high hopes.

Dr. Insel: Okay. Well, it also raises the opportunity that if it becomes a problem, there are people, since we are advisory to the Secretary, there are people in the Secretary's office who could probably weigh in on this and try to help get this thing through.

Ms. Blackwell: That would be great.

Dr. Insel: Okay, but you will need to keep us informed about where it sits, because Della and I just went through this experience with something unrelated to this committee which took months at OMB for reasons that were hard to determine.

So, let us know if this becomes a problem. I think everybody here is really eager to have this, especially given what you just said about the loss of support in states. What we would like to have is a base line so we can begin to look. This is supposed to be an annual update, so we want to know what it looks like now and what it looks like in 2011, 2012, 2013.

Ms. Blackwell: Well, one of the things that's growing is waiting lists, as I am sure many of the people around the table are aware, and one of the problems we have is that we don't really have a way to look, because states treat waiting lists for Home & Community-Based Services so differently so we haven't really figured out -- no one has really figured out -- how to look at waiting lists, but I do think that's a place where we are going to see a change over the upcoming years.

Dr. Insel: Okay. Anything else for

Ellen and CMS? Geri, I think you were on the list as well?

Dr. Dawson: Yes, I wanted to let people know about a meeting that will be happening this September and it's part of a larger translational medicine research initiative that we have launched at Autism Speaks which will launch with three meetings, one this year and two in January, with the two in January being focused on drug discovery, drug targets and drug validation and also on refining and developing better outcome measures for clinical trials.

But the meeting that is the first one, that's coming up most quickly, is one on "Genetic Risk Factors, the Science and Communication of Translating Scientific Discoveries into Clinical Tools for Screening and Diagnosis."

So this meeting is going to be held on September 1 and 2 in Toronto, Canada. The purpose of the meeting is to offer a forum for

a wide range of stakeholders to share and explore the scientific, ethical, legal, communication and commercial aspects of translating research in autism genetic risk factors into clinical tools for screening and diagnosis.

The goal is to inform the participants of key relevant issues and to initiate a dialogue among stakeholders regarding the complex issues, challenges and needs pertaining to the translation of the science of risk factors for autism into clinical tools that can promote the well-being of individuals with autism.

So we are really bringing together many parts of the community, people affected with autism, basic and clinical scientists, people from the biotech and pharmaceutical industry, government represents -- I know Alan Guttmacher will be there, and Alice Keyl is coming -- and also ethicists and communication professionals. So this is not an open meeting

but it is a meeting that I think would be valuable to have someone, perhaps Alan, myself or someone really from the meeting would be better, to come and share what happens in that two-day meeting because I think it will be a very interesting one.

I do want to say, the meeting is co-sponsored by the NIH, the Medical Research Council, by Genome Canada and Autism Speaks, so really a wide range of organizations are funding this meeting.

Dr. Insel: Excellent. Anything else from Autism Speaks that we need to know about beyond that? Okay, if you think of something, we still have a few minutes. The other name I had on this list was Lee.

Mr. Grossman: Yes, the reason why we haven't been able to be involved in the stakeholder interviews is we have been a little busy lately and that's what I am going to report on. I am reporting out on the conference that we held last week. It's our

annual conference. It was in Dallas.

It was a big success in terms of our attendance. This year it was over the attendance that we had last year, which bucked the trend of most national conferences, and that was good.

We had a record number of papers submitted, over 500 papers submitted, which means that I had a record number of complaints from those that didn't get accepted. My email and my voicemail got full the day that we sent out the invitations to the speakers.

It was a very, very good meeting. We emphasized last year what we envision the future of autism to be and we started out the conference re-looking at that vision, but relating it to what we need to do today to make that vision real.

And the keynotes that we had, and many of the speakers that we had, reflected on that message of what we needed to do now so that we can deliver on our future hopes.

The three keynoters that we had, the first keynote was extremely well-received and it was an update from the Obama Administration on their efforts for autism.

We had Kareem Dale and Sharon Lewis present and they sat with me and Dr. Cathy Pratt in a town hall format, fielding questions from the 1,500 people that were in the audience and it was received extremely well and the feedback that we received from our attendees was extremely positive to the efforts of the administration. It really went well.

The second keynote was by Dr. Cathy Pratt, who discussed autism as a whole-family condition. We have talked for years about how this is a whole-body condition, but now we want to change and add to that and complement it, the fact that autism is a whole-family condition and that if we are to help people with autism, then we also have to look at their support mechanisms, which are the

siblings, the parents, grandparents, et cetera, and how truly they are impacted and how we cannot forget about them when we are talking about services and supports.

And our last keynote, on the third day, was individuals with autism that presented on their various social networking and blogging apparatuses and networks that they have and the impact that that has had on those with autism as a means to communicate and to find social connectiveness and that too was received extremely well.

We had presentations, we had about 120 presenters over the four-day conference that presented on virtually every aspect of autism. Some of the highlights were a panel discussion led by Dr. Cathy Lord on the changes that will be implemented in the DSM V and that was really well-attended.

Again, that was in a town hall format. The questions were very intriguing and it created quite a bit of buzz afterwards,

people responding to it. We had a blogger reporting from the session and within the hour after she was done, there were about 80 comments and others had been feeding into it with their own needs and that's obviously something that we will be discussing as we go forward.

We had a science symposium, a day-long science symposium that was part of the conference as well, and it was entitled "Environmental Exposures in Childhood Development." We did this symposium in conjunction with the LDDI group, which is a coalition of other disability organizations that also have an emphasis on environmental health.

We had a day-long continuing medical education program and that was titled "Addressing Chronic Problems and Improving Quality of Life" and again, that was extremely well-received.

We had a gala there which was very

much fun. It was a Texas theme, since we were in Dallas. And it featured a very live, longhorn bull named Jake and there are various pictures on the website with us sitting on top of Jake and enjoying his company.

Next year our conference will be in Orlando and will be the same week of July 6 and I would expect that much of what is being presented here and we are going to be talking about at the IACC, particularly on adult services, will be the emphasis of that conference since that and safety were perhaps the topics, even though we had a great deal of those being presented, were the ones that the attendees wanted much, much more of.

Thank you. Any questions? Any questions about Jake?

Dr. Insel: Stephen.

Dr. Shore: Yes, with Jake the bull I guess there was a lot of bull being flung around.

(Laughter.)

Dr. Shore: But aside from that, I think ASA should be commended for developing true partnerships with those of us on the autism spectrum in leading the way for making the world a better place for those of us with autism, the autism community as a whole and by extension, the community, the world community as a whole. So thank you for that.

Mr. Grossman: And for anybody that wants to see it, I do have the program guide here if you want to peruse through it I will leave it here since I've got --

Mr. Ne'eman: Does it have any pictures of you on the bull?

(Laughter.)

Mr. Grossman: No, but they got Tweeted.

Mr. Ne'eman: Well, all right.

Dr. Insel: Ari.

Mr. Ne'eman: Yes, I actually -- and maybe if anybody has a question for Lee, they should go first, but I have another upcoming

meeting to announce.

Dr. Insel: No, I think go ahead.

Mr. Ne'eman: Two things actually. First, I wanted to announce that, and I apologize for not putting this on the list, we just finalized the arrangements a few days ago, in conjunction with Self Advocates Becoming Empowered, or SABE for short, which is a large self-advocacy organization of people with developmental disabilities more broadly, ASAN will be holding a summit on defining community living arrangements and delineating true living in the community as compared to more segregated or restrictive settings that may be simply be going by another name.

It's going to be held in September at SABE's conference and we are going to be bringing together self advocate leaders from across the country to help define what is true community living setting, to provide guidance to policymakers, advocates, regulators at what

I think is a very crucial time, but for our discussions, in regards to the IACC Services Subcommittee, but also for some of the broader discussions that are occurring in the developmental disability community around this topic.

You know, one of the impetuses for this meeting which I should probably add, we are very grateful for the Administration on Developmental Disabilities providing the funding for, is that what we have often been seeing is as there's been increased focus on moving people out of institutional settings and into community living settings, very often states have attempted to place people in community living settings that are not deserving of the name, that may still be on the institution grounds and may simply have changed the size of the building.

So what we are really hoping to do is to really define the culture shift that has to occur, and the specific details to make de-

institutionalization and integration into the community meaningful and effective for all people with developmental disabilities.

You know, it's my hope that we will be able to report back on the findings and to have a very strong statement from the self advocate community to provide both to the IACC and to other relevant policymaking bodies.

Dr. Insel: Great. You said there were two meetings, though?

Mr. Ne'eman: Yes, I'm sorry. I also wanted to report on Autreat, which is the largest gathering of the autistic community, which occurred at the end of June, beginning of July, this past month. It was a resounding success, with topics on a wide array of areas.

Autreat is the largest gathering run by and for autistic adults in the country and, in particular, I want to highlight what we thought was a particularly successful this year, which was we had a representative from the Transportation Security Administration

present to hear from self advocates about challenges that many of us face going through airport security, particularly in the post-9/11 context, given that many of the suspicious behaviors that screeners use are, in fact, also diagnostic traits for the autism spectrum.

So we have engaged TSA in a broader discussion of which this was one part of and I am pleased to report that they are currently considering implementing a number of different specific steps to help address this issue, including, but not limited to, additional training for their screeners but also providing information for the autistic community about what kinds of existing and future accommodations can be requested while going through the airport security for both children and adults.

Dr. Insel: That's great to hear about. That's really important. Any other comments or updates? Jennifer.

Dr. Johnson: Thank you. I just wanted to share some information that isn't about a meeting but I think is important information for this committee and it's a recent publication of a funding opportunity that we had for National Autism Resource and Information Center.

This year Congress set aside money in our appropriations to establish this center so we will fund a center that is going to be designed to provide information and resources on autism and other developmental disabilities, and it's really going to focus on community-based services that support independent living and self-determination.

And it's going to essentially use a variety of strategies to collect and disseminate information when it is funded. So I just wanted to again share that with everyone that we are going to be funding that.

Dr. Insel: And that's available on your website, is that the place to find this?

Dr. Johnson: If you go to the ACF, Administration for Children and Families, their funding website, it's available there.

Dr. Insel: Great.

Dr. Johnson: And it is due August 16 -- yes, August 16.

Dr. Insel: Thank you. Anything else, Ellen?

Ms. Blackwell: You know, I got an email last week and I apologize again for being vague, from one of our AHRQ partners and I believe that AHRQ just posted something on its website regarding early intervention.

So you might want to just, everyone just might want to take a look at that because they had put out an RFI, oh gosh, about 18 months ago and I think that that's come in.

Dr. Insel: Yes, Rosaly at the last meeting, had mentioned this, from the Office of Disabilities, so she brought this up a little bit. But I think at that point it wasn't ready to go. So this is a different

initiative. Okay. Good. I know AHRQ has gotten a number of things going in the autism space, just in the last few months.

Anything else? Susan, Della, anything from the office?

If not, I think we have reached the end of our agenda. I want to thank all of you for hanging with us through the day, a day that started with an earthquake and somewhere towards the end had a little power outage, so eventful, in that sense.

Our next meeting is October 22 but, of course, before then we have got the Services Subcommittee efforts and there are -- as you have just heard -- lots of other things going on that are relevant but not sponsored by the IACC.

Thanks again for your attendance and participation and safe travels. We'll see you in October if not before.

(Whereupon, the above-entitled matter was concluded at 4:56 p.m.)