talking, Johnny isn't pointing or whatever. That's been very specific. I would also urge you to look more at bringing in a wide variety of developmental disabilities, not just autism. I say that because I think we can enlist a lot more support from other various organizations. We all want to know, if we are parents, what's wrong with our child, if it's autism or any of the other neurological disorders we're all aware of. Thank you.

Dr. Insel: Thank you. Other comments?

Dr. Alsopp: That was a nice segue into a point I was make, and the point I was going to make is, the practice parameter that was a policy statement that was done by the AAP Committee on Children with Disabilities, we made the point that pediatricians need to listen to parents. So, in addition to these efforts where we screen every child, there's a very important message, which is parents suspect that there is something wrong, or they know there's something wrong, and if pediatricians and other physicians and healthcare providers would listen, I think we would do a lot

to promote the identification of these children at younger ages. The other point is that I notice that you didn't have a representative from the Department of Education on your Subcommittee, or maybe I missed that. I just want to put in a plug for Part C. So even before a child has a diagnosis that these children can be referred for early intervention services, and at that point, the child can start receiving services, even if the diagnosis hasn't been clearly defined at that point. There's a lot that we can do in addition to the recommendations that are already there, to make sure that these children get identified as early as possible and get the appropriate services.

Mr. Grossman: I was just wondering if there is any consideration by the Committee of just some hard core marketing efforts in public awareness. It seems as though there are a number of disorders or diseases that are now being detected more readily, just through public awareness campaigns, either through advocacy groups or even private and government agencies. Has there been any thought

given to that, and, if so, what; and if not, why not?

Dr. Hirtz: I think that clearly that was part of what we were talking about in terms of how do we disseminate the information? One option I mentioned was the Surgeon General, but that's part of the different examples of ways to mount a public information campaign. And that's clearly one of the objectives. I completely agree with reaching the parents, but we also hear that parents will say, you know, my child's not talking or not pointing, and the pediatricians or doctors will say, don't worry; he'll grow out of it; just wait another year or two. So, we have to get all of the aspects. We have to get the doctors, the nurse practitioners, and the parents. Clearly, that's a major public information campaign, and it's clearly doable.

Ms. Chase: I'm a parent of a child with autism. Your first information as a parent that you get is when you're leaving the hospital, they hand you a little booklet. SIDS is something that's mentioned in there. I remember being scared

to death. I had read about it ahead of time, and suddenly it was in my packet, and it -- I had to make sure my child was fine. But what's happened is, there was some type of developmental sheet and a fact sheet, talking about not only autism, but the various developmental disabilities that can occur. Prior to even visiting the pediatrician for the first time, the parent has that information sheet, and have a checklist of things to go through, month after month. And then they are more of an informed parent. I know that when my child first had symptoms, I had no idea what autism was. Then I heard the word, and I was too scared to find anything out about it. However, if I would have known about it at any time -- I did have a developmental study done my children from birth to 18 or 20 months old. I was able to go backwards from that, and was then aware of the various developmental disabilities. They can go to their doctor and not only say I think, they can say, you know what? I have a pretty strong conclusion that this is what my child has. Then the doctor, that's maybe not informed, or the doctor that doesn't

have time to fill out a sheet like that, has the fact sheet in front of them already, and they can go back through their records. That was my suggestion.

Dr. Insel: Time for one more question.

Dr. Zeph: That approach is actually quite effective. I used it a number of years ago during early intervention with rural families. I finally gave them summaries and instruments, so that they could be watching for the normal development of their child or the lack of normal development, and bring those markers, those developmental milestones to the attention of their pediatricians. At that point, we were seeing for children -- at that point, for children who had hearing impairments, there was a two-year gap, an average two-year gap between the time the parent had assumed there was a problem or suspected there was a problem, and the point at which intervention was happening. One of the reasons I did this was just to give the power to the parent, so that they had something to show their pediatrician, so that they would be able to say, well, how do you

explain this? Or, help me with this; I don't understand. And they had something more tangible than "I think." Forearmed, I think that's an approach from the hospital perspective, when families are leaving the hospital, or if you state has Well Baby follow-ups for every child. At that point, if there is a visiting nurse program or whatever, that that be introduced very early on. The pediatricians' first concern was not to scare families. Families don't understand that this is an average that they don't want to over- identify or have a lot of false positives. But I think it's easier to tell a family that there is no problem later, than to say that they missed something. I really think that idea may be a really viable one.

Dr. Insel: Thank you for your comments. It reminds me that a two-year lag in therapy here has tremendous consequences, so this is really a key issue for us to stay focused on. I appreciate the inputs of everyone on the Committee, and those who gave their suggestions as well. Steve?

Dr. Foote: Before we move on, could I just ask briefly, what next steps the Committee thought

were most important at this time? I mean, there's a process issue here of having gotten an initial take on this problem. What I think I heard was a diversity of activities that could possibly be undertaken, but unless we somehow -- and maybe it's simple to say the Subcommittee is going to meet again and go over this again, but we need to figure out what the process is for consolidating and prioritizing and making some selection among these possible activities in order not to lose momentum here. So I'd like to hear the Subcommittee's comments on that.

Dr. Hirtz: Certainly we do agree with you, and do not intend to lose the momentum. I think the summary of what I presented to you is kind of the agreement that these are all priorities, and they're linked. It's very hard to say, you know, we will work on dissemination of information and not work on linking that to referrals and services; it really does come as a package. We do have to explore mechanisms to implement this, but I think the next step is a very formal and very specific report from the Committee and decisions

need to be made about who is going to do this and how they can get it done. The one thing we would like to do is make sure that we don't just kind of leave this report to dangle somewhere, but that the Committee is actually responsible for what happens in these areas, and that we would like to assume that responsibility and supervise and monitor what efforts we are able to put in place. And so I think that's actually really key. Maybe we can end on that note and move forward as we think about how the Subcommittees are going to function. The idea of you providing us some action items, and then us going back to you and asking how you're going to make sure that they happen, is how we go from this being a group that talks about the problems, to actually having some impact. I think that was the original charge, really, of the Child Health Act, and something that we need to keep in the forefront here. This really ought to be a way to make things happen, not just to discuss them.

Mr. Shestack: There's a meeting in six months. Obviously, the plan of this Committee is that way

before that meeting, through e-mail and phones, to actually have a draft of what this Committee would think would be a good implementation plan with the timeline evaluation and preliminary budget, and then we can feel how we can get it into operation, but significantly before the next meeting, we will have a draft of what the possible plan and implementation is, and take it from there.

Dr. Insel: Go for it, great. We're going to move along. The next session here is a report on the NRC recommendations regarding educating children with autism and the Center for Training Children with Autism Spectrum Disorders. Dr. Houle, from the Office of Special Education Programs in the U.S. Department of Education will provide that report.

Dr. Houle: Good afternoon. I'm bringing you greetings from the Assistant Secretary. I've done PowerPoint, but I have never managed it myself from the podium before, so I might need a little help. [Slide.]

Dr. Houle: Not this past Summer, but the Summer before that, July of 2001 -- I do bring you

greetings from Bob Pasternak, who is speaking at a conferences at our Centers on Dispute Resolution today, so, unfortunately, he couldn't be here. July 2001, we were very happy to report that the National Academy of Sciences has finished a two-year study that we had commissioned them to do. As you probably know, they don't do their own research, but they synthesize research bases. And what we in the Office of Special Education have asked them to do was to synthesize the research base on educating children with autism from and educational viewpoint. They pulled together a study group or committee of people with national expertise, and did a thorough analysis, had numerous meetings, with and without the funding agents, and in the end, came up with what we thought was a really on-target task report. Some of you may have seen this. I know Lee's group has adopted it as a statement for use with parents. Lee, your group was using this report on autism.

Dr. Goodman: We've adopted that as our position on educating children with autism.

Dr. Houle: Very good, much stronger. One of the things we were really happy about -- and this is a segue form Lucille's comment, was that this did give parents a tool, and advocacy tool, so that when they went into their IAP or IFSP meeting, they were not only the only voice saying that my child has autism and a significant disability and it requires a significant commitment of intervention resources to make progress. But they also had some documentation from the literature on educating children by the National Academy of Sciences. This is available on the National Academy website, and also it can be ordered at the www.nap.edu, the National Academy Press website. One of the salient recommendations from that report had to do with the training and professional development of personnel to work with children with autism in the schools and at the next preschool and infant level. There was a feeling that the dearth of qualified personnel is one of the major stumbling blocks and impediments to ultimately children with autism making progress. There has to be the commitment of

resources, and there has to be the capacity of resources to be able to fulfill that commitment. So, we have, I think, four federal agencies. It didn't take us too long to get out a funding priority, which resulted in the Professional Development in Autism Center. The funding is to start in January of 2003. We're funding it at $1 million a year for five years. The purpose of the Center is to provide technical assistance and training to service providers in the field, either directly or through their local school districts, through their local service provision program, or through their state education agency. My first commission to this grantee was to develop a PowerPoint presentation by November 22nd, so I will be able to bring this to present to you. So, Ilene Schwartz, who is the principal investigator at the Center of the University of Washington, which will begin in January, has kindly provided me with this PowerPoint for you. [Slide.] Bob could not be here in person. But if he were here, he might say successful implementation of IDEA is perhaps the most critically dependent on the

quality of the people who implement the principles contained in the law. That is, the teachers, the para-educators, related service providers and administrators in cooperation with parents and students. [Slide.] The overall goal of this center is to conduct the training across the country so that every student with ASD can access high quality, evidenced based educational services in his or her local school district. [Slide.] The need for this center was apparent, and it's apparent to every superintendent of every school district. It's apparent to most parents whose children are receiving either early intervention or school services. It was apparent to the Committee at the National Academy that the number of students with autism is increasing dramatically, and while we don't do the prevalence and incidence data, we do get data on the number of children who are being served under the special education category as autistic or autism spectrum disorders. [Slide.] Many models of service delivery yield trivial outcome. That was the synthesis of Sally Rogers' work reported in the

National Academy of Sciences report. I'm not prepared to go into all of Sally Rogers' work in that synthesis right now, but the technology and skills necessary to implement sound programming is not widespread. That is an understatement. [Slide.] The science related to effective practices is expanding rapidly, not always accessible, and is often at odds with practices in general education. While the numbers of children identified with ASD are increasing, the numbers of highly skilled personnel are not. Some of the strategies that are effective with children with ASD are relatively complex and really demand a highly trained level of professional expertise or expertise. [Slide.] The center is located at the University of Washington. They have co-PIs in the following locations. We'll get into that a little bit more here. [Slide.] The PI has the asterisk for each center and these are representative of universities of child development centers and of parent advocacy consortia. [Slide.] The guiding principles of the center are that children with ASD are children first and have the same basic

needs as typically developing children in many ways. There is no single right way to educate a child with ASD. Children are individuals, and child and family characteristics must be considered in intervention planning which, you know, a lot of it is contextual. If there's one thing that was learned about interventions and intervention testing and intervention staging and implementation is that a lot of it contextual. Knowledge is power. One of the most effective techniques for empowering families is to provide them with accurate information. That is the main goal of OSEP. It's the main goal of things that we fund such as the NAS report and this Center. [Slide.] All interventions must be built on evidence-based practices and must include ongoing data collection and evaluation. This is what the center will do. They're going to be responsible for bringing their investigators together and administering the criteria for anything that they disseminate or that is on their Web site that they see built on evidence-based practices. Effective interventions must be comprehensive and of

sufficient intensity to yield educationally meaningful outcomes. That again, this is work that is based on our investment in the National Academy of Sciences report based on the conclusions in the report which actually do talk about the number of hours and the labor intensity and resource intensity that is necessary in intervention for children with significant impairments due to autism. Training of personnel is best conducted in an ecologically and socially valid setting, utilizing aspects of adult learning and providing ongoing follow-up and consultation. I'll tell you a little bit more how this will be operationalized, or we may get to it on the slide. [Slide.] Comprehensive training must include teams who participate in role specific and trans-disciplinary training. It must be individualized. Effective dissemination must include different types of activities, formats and materials to meet the needs of different consumers. To that extent, one of the partners here, the University of Kansas, already has a distance learning center in special education up and operational. So that will

be utilized to disseminate and to train in the most effective distance learning techniques available to teachers and school service providers. Just as intervention strategies need to be evidenced-based, so do all training and dissemination efforts associated with this center. That's one thing we've been doing for a while. In our earlier centers, we actually funded a component of every research center to do some research on the dissemination of the knowledge base and information the center produced, so we can then take dissemination a level further. I mean, a professional journal and publication is important, but it's not the way everybody gets the information that they need. [Slide.] The strategic plan for this center -- and this is how we will operationalize individualized team training. By "individualized", I mean a school district might fund a team. A state might find a team or several teams. They may request a training of the trainer kind of model whereby the center will train a state team who will then go out and train local teams. Parents will be invited to be included in

all the training teams as well, to the extent that they are willing and able to do that. Exposing district teams to a broad array of empirically based teaching practices rather than selling wholesale name brand models of service delivery. We, was you know, if you're at all familiar with the Department of Education, really are trying to pick out and package the empirically based, soundest intervention principles from the whole array of models of service deliveries that are out there, as opposed to picking up one particular brand name and marketing that, because we do believe in individualized education for children with disabilities. Providing families with easy-to-use tools that will help them to make unbiased judgments about the empirical strength of proposed strategies and how plans fit with the family needs and strengths. [Slide.] Then district teams. Say a school district sends a team. They would be provided with empirically validated strategies, the competency to reliably assess the intervention that they're going back and implementing for children and families and alternatives, should the

intervention outcomes fall short of expectations. School district teams will be taught to design and deliver educational plans that are comprehensive in development and curricular domain coverage, and of sufficient intensity to yield meaningful outcomes. This is testing. This center is putting into practice what is said in this report, intensity matters. Age of intervention matters. Intensity matters. There are some principles in intervention that really have been proven to make a difference if practiced. Members provide district team members with the opportunities to see practices delivered in settings like theirs, and providing opportunities for them to actually practice strategies with guided support and follow-up. Throughout the country, principal investigators may oversee training that is on site for state school district or early intervention programs. So they will actually do some traveling to sites. [Slide.] Training for educational teams and parents that is experiential, site-based and ongoing, have used literature that are applicable for students from the age of diagnosis through 21

and incorporate diverse educational models. One of the modes of practice that they're going to use and how they set it up is that because they have this report as a jumping off point, they are going to in the first year update the synthesis of the knowledge base and begin offering training for working with children birth through age eight. During that time, they are going to be synthesizing the intervention knowledge base for the next older age group of children and add that training to the training menu that's available and continue on through age 21, which is the age that the Individuals with Disabilities Education Act under which they are funded ceases to be the service delivery mode. A Web site they will have the provides basic classes and information, even if it links to the distance learning, which I see that it probably will, and serves as a clearinghouse for training opportunities and provides interactive follow-up support for trainees. We made it very clear to the grantee that what we were not interested in is actually funding dissemination of the co-PI's individual

work. It's fine. You know, that will be part of it, but we're also expecting them to serve as kind of a refereed clearinghouse to make a lot of information that has been screened for quality available to parents, families, teachers, educators, the public in general through their web-site linkages and also in their training. Capacity building activities, including participation in ongoing summer institutes and leadership symposia, a diverse and active National Advisory Board. Now the site-based training process. [Slide.] How if you are from a state or you're from a school district -- and believe me, being in the Department of Education, the demand is high. We are getting calls all the time from school districts to bring them in -- state education agencies, early intervention programs wanting the availability of training. So the center will recruit participants and match them with the staff throughout the United States on needs, interest and geography, and some of that will be age range. We have people on the staff of this Institute who are experts in adolescence.

Some are experts in early intervention. Some are experts with school age children. They will start out with online classes on the basics. Then the center staff will go out to the training sites where the implementation will actually occur and local school districts will compete, to the extent that we have money, we can keep putting money into the center to broaden the scope and the service that they're able to provide, and they'll get a short-term internship at the center or intensive training at their own site. Center staff complete follow-up visits and then they can also use technology to follow up. [Slide.] We can use model demonstration sites. We can use the participants' own programs. The participants get grounded within their context for training, and that's basically what we're saying here. It's individualized and it's contextual. [Slide.] Evidence-based practice throughout the age range that IDEA is responsible for. They'll also be doing topical areas on their Web site and documents for diverse audiences. [Slide.] This is what we expect out of their Web site. [Slide.] This would be some of their basic

classes that people would have a basic understanding level before they go in for the intervention training. [Slide.] Some of the benefits of having a broad Web site is that you can offer these services through Web and consultation. [Slide.] These are some of their capacity-building activities. [Slide.] The National Advisory Board. This is who they'll be looking for as representatives to serve on the National Advisory Board to get connected. [Slide.] And this will be officially starting January 1, 2003. The other I brought, and I won't go over it, I will only hand it out, is a summary, the study directorate NAS and I prepared at the close of the study, where we provided information to others at the National Academy. This summarizes that book that I was holding up and the report in terms of the salient recommendations. So I have copies of this. And hopefully if we run out, we can get more copies. It is a little aberrant. You'll notice it's folded over with page 1 here. I had somebody Xerox these for me at the last minute last night just doing it like that and I didn't realize it

was starting with page 2 and page 1 was on the back. So the best laid plans. How would you like me to disseminate these? Should I do it right now? Thank you so much. I'm finished.

Dr. Insel: While those are going around, are there comments or questions about the report? [No response.]

Dr. Cordero: Gail, thank you for a very nice presentation. I have two questions. One is, how do you see the coordination with the sort of non-educational groups, for example, the children have therapists and physicians, pediatricians, developmental pediatricians and perhaps some perhaps some that may be taking some medications and so on? And how are the medical aspects of the management of children with autism combined with what you're planning on the educational side? The second question is more how this project is going to address the issues of diversity in terms of children that may be, say, Spanish speakers or of other cultural groups, say, Native Americans or African Americans and so on?

Dr. Houle: Because they have not yet started I can't give you answer that they are doing it or that they're going to do it exactly this way, but bringing that to my attention, one way that comes to mind will be of course representation on the National Advisory Board. That will be one of the first steps. That representative will be responsible for providing the input and kind of the monitoring, how well are you doing with your non-English-speaking population of parents. We have the resources and we have the Whole Parent Network that is very interested in translation and providing information and training. They will be required to have diverse representation on the training team that come in for training among the parent groups that they go out to meet with as well as the Advisory Board, and we have a network for translation of materials. We also have a network from a multi- cultural clearinghouse that we've been funding that where parents and professionals from different cultures and cultural and linguistic groups review material for appropriate sensitivity to the population that

they represent. So we already have that in place from other projects, and we intend to leverage that for the Institute as well. And the non-education aspects. We are doing work in that area. Rather than be redundant, it's always an area that we are continuing to work on collaboration with our Part C program, which is Infants and Toddlers, mandates in the statute that the health-related professionals, including physicians, be equal partners in service deliver and service design systems, and they're funded to do that. We are aware of it. I'm not saying we'll be perfect, but we have some experience that we can leverage, and we will expect our center to leverage.

Dr. Insel: One more comment before we go on.

Dr. Kallen: My name is Dr. Ron Kallen. I'm a pediatrician in Chicago. I'm also a parent. In general, my experience with special education is probably like many parents. I've never met a teacher who doesn't know about autism. They've taken the course, they've been to the conferences. That doesn't mean they're implementing the optimal practices. So the piece that I'm wondering about

in the PDA is, how do you then go back and do whatever it is, quality assessment or outcomes measures, accountability? The people have been trained. Are they really accomplishing what we as parents hope they will do? Is there an accountability piece to this?

Dr. Houle: You brought up two things. We're grappling with a couple of things. One is the teacher in the regular education system. The law mandates that they are responsible for the education of the children. They're not special ed children, but they're children within the school system, so they will be part of the team. The teams will be responsible for going back out to the sites. This is a model of service delivery. A million dollars a year is not enough to provide trained up teams for every child with autism, but we don't want to see it continue to have to say that we don't have access to models. So states and locals will have to put some money in too. And how do we follow it up at the local level? Certainly the resources are there, and it's going to be most successful in school systems and schools that put

some comparable training money into ensuring that the team can come out and follow up or designate one person in their school system as the leader. There are several models for doing this, but the infrastructure will be there. It's a matter also of the will to commit the local and state resources to this. If your child is in a school, there's nothing that would prevent your child's school district from sending a team for training, and there is nothing that would prevent you from going with that team to train. And there's nothing that would prevent your school district from putting resources into continually monitoring, providing data back to the site. They can send a couple of people from their team to go out and monitor if the interventions are not successful. This is a technical assistance center as well. But we can't do it all from a top- down federal center. We have to have the will and collaboration from the school districts and the states as well.

Dr. Insel: We'll have to move on, if I can interrupt. I think the point that he's making, which is something that we should continue to

include in the record, is that the outcome of such a venture needs to be studied very clearly so that you know what actually is working and whether it can be generalized or not. That's something that will be an important part of any of these programs.

Dr. Houle: Right. And for the most part, the university-based PIs have a history and skill in being able to do that. So that's part of it. So it's as much a TA and training center as it is a research center. We feel like there is somewhat of a knowledge base already, at least birth through 8. But the big salient call in this report was that there aren't enough trained people to implement it successfully and monitor it.

Dr. Insel: One thing we can do is to make sure that the URL for that report is on our Web site so at least people who want to access it can do that. A lot of work went into that original National Academy of Sciences report, and it's something we should all take advantage of. Thanks, Gail, for that very helpful summary. The next session is an update on the other subcommittee that was set up

at that last meeting. We heard about the Screening Subcommittee already, and as you remember, one of their points was developing the links to referrals and services after the screening is done. So logically, this is the other subcommittee to hear from, which is the Services Subcommittee. We've got a panel of people who will be talking about that subcommittee meeting. Do you have slides as well? And who is going to take the lead on this discussion?

Dr. McPherson: Let me just make a few comments as the co-chair. I want to thank NIH for acknowledging the need to have the service agencies as part of this coordinating committee and setting up this subcommittee. We're very pleased with that. I also want to acknowledge that it is being co-chaired from SMSA and HRSA to once again acknowledge at the service level the need to bring the mental health resources and the health resources programs together so that we are co-chairing it. [Slide.] The other thing, we are two agencies that have very extensive programs out there that are involved in developing the systems

of care for children and families that were part of the presidential initiative in building on the promises. But we also have no targeted dollars directed towards autism as part of that effort. So what we're doing is really talking about our generic efforts and looking at where to build things. The other thing we would like to do at the end of the session is to come back to this question about what the roles and responsibilities and the scope of work of the subcommittees are. As you'll recognize, the service systems out there are huge and need to be brought together. So we'd like some focus on that. We elected to bring people in from the field to talk to you rather than us talking to you, because there are so many diverse perspectives from the services, and I'm going to turn it to Lee to take the lead.

Mr. Grossman: This is actually a continuation of what was presented at the last IACC meeting in May. [Slide.] This is part of our approach on the subcommittee to introduce to you the very, very critical and very important aspects of having service delivery as part of a national way of

approaching the needs of the autism community. When IACC started about a year ago it was heavily dominated by the research end, which is extremely important, and I applaud this committee for opening itself up to also include the service sector as part of what needs to be done to address this problem that we have today. In the next hour we have four presenters who will have about ten minutes each to talk about what they're doing in their local communities to give you a flavor of the array of services that are working in the community as well as they're going to talk about the needs that they have going forward. In the time that will be left, which will be about 20 minutes, we're going to engage in a panel discussion where we'll be entertaining questions from everybody here as well as providing you maybe next steps in the process. [Slide.] I am briefly going to go over where we are today and also lay the groundwork for where service delivery fits into this autism problem. What we know today is what you see on the screen. I'm not going to go through the whole thing, in the interest of time.

There are a couple of things that need to be pointed out today. All the figures up here are conservative. They are conservative figures. Today in the United States, one in 250 births will develop autism. The significance in that is not only what we have today, but that means in 20 years that one in 250 people in the United States will be entering the adult service sector, which is virtually nonexistent today and is flooded and overwhelmed today. In 20 years, as you can imagine, we have to start doing something now to be able to address what will be a tsunami of people entering into the system. As you can also see from some of the figures here that we can significantly reduce the amount of the service costs through early diagnosis and early intensive intervention. And one of the other key statistics that I find here that are very telling is that 90 percent of the costs for services are in the adult sector. [Slide.] In synopsis, I Just want all of us to take away from the figures that were just presented is that this is national emergency. It's an economic and social crisis. [Slide.] And autism

is an epidemic. [Slide.] There are four critical needs in the autism community as they're stated here. And as you can see, research is one and the rest are really centered around the service delivery model. [Slide.] The realities of autism today that we're all dealing with are as presented here, which again bring together the aspect of services working together with research at all levels across the lifespan if we're going to deal with the realities of autism. [Slide.] I presented this at the May IACC meeting what the needs assessments are. Here you can see that the service array is vitally important if we're going to adequately address this. [Slide.] And what's needed from the federal government is a coordinated and aggressive response. This includes multiple agencies. The presentation I gave in May I broke down those four critical needs and identified at least from my position what agencies would best respond in those various needs. In the interest of time, I didn't include that, but that might be something we do send out on the Powerpoint slides. [Slide.] Also, in dealing with

the puzzle of autism, as you can see, everything is interrelated, interconnected to address the needs of the individual with autism. I'm next going to call up Dr. Cathy Pratt from Indiana, and I'm going to allow the panelists to do their own self-introductions. Thank you.

Dr. Pratt: I'm going to ask neither Lee nor Gail to help me with Powerpoint. I can make the mistakes on my own.

[Laughter.]

Dr. Pratt: [Slide.] I thought it was going to be appropriate coming from the state of Indiana where sports rule that there should be an athletic picture up there, although probably should be basketball. I come to you in multiple roles, one is as Director of the Indiana Resource Center for Autism at Indiana University, and we're part also of the network of the University Centers for Excellence and also a member of the Board of Directors for the Autism Society of America, and as a past classroom teacher. We are a statewide training and technical assistance program that has been doing many things that Gail has talked about

in her presentation. But I just wanted to kind of go over some of the concerns. [Slide.] And I know this is very different, because we're really talking about services and what we see in the field. One is is that I see a trend towards generalized certification, and as a result of that, really a lack of trained personnel. At the same time, I feel the need to say that some of the people who I think do some of the best jobs with children are not necessarily the ones who go through Autism 3000, but they are the ones who are just tremendously wonderful teachers. We also see that there's a number of individuals teaching with limited licenses, and the reality of that is that oftentimes those teachers are relegated to working with the kids who have the most significant disabilities, and they are the least trained. We also see that there are a large number of individuals being served in general education classes and settings and that most professionals who go into the field of general education never receive even a course on autism. And then untrained paraprofessionals are taking an

increasingly active role, and are often left to do a lot of the education without very much support. I also see as I travel around the state of Indiana and nationally, increasing parent frustration because of so many issues: The lack of coordinated services, the lack of resources, the lack of trained personnel. As a result of it, I also see increased fighting between schools and families that are kind of making sure that we give a lot more of our limited resources unfortunately to those issues, and decreasing funds during a time when students are becoming more complex. And having been in the field of autism since the seventies, what I see is the changing face of autism. These individuals are much more complex than they used to be in the seventies and eighties, and a lack of interagency support for these students who are complex. And when school districts feel they no longer can serve children, they are oftentimes sent to highly restrictive settings. [Slide.] So here are just some of the things that I see needed. [Slide.] Funding for research that focuses not on clinical approaches,

but on those approaches, strategies and program components that lead to the greatest outcomes for students. I guess that I'm a little biased, because having the opportunity to see individual's live span, to me, the outcome for individuals with autism is that they leave school and they are employable. I think that our greatest indicator of success will be that we have individuals with autism who have jobs, who live in the community, who are not living at poverty level. And Anne will be talking about some of these issues. But many of the individuals that I know who go on for advanced degrees even are living at or below poverty level and don't have jobs. So I hope that we will focus on some of those outcomes, and in addition to that, those practices that are evidence- based and result in those outcomes for folks. [Slide.] Unfortunately, oftentimes these types of things are being decided in courts and not in educators getting around the table and having discussions. And so I'm really glad to see this effort from the Department of Education to put together a group of people to look at some of these practices.

[Slide.] Being that I work at a university, I realize that there is a responsibility for those of us who are in higher education. And I would encourage this Committee also to kind of reach out their arms to those individuals who deal with higher education to look at how we prepare both general and special educators for the realities of dealing with these incredibly and increasingly complex students. [Slide.] And if there is a certification program, and I know that in some states parents are crying for teachers certified in autism, that it's not used as a means to exclude students from the least restrictive environment, which is what I see happening in some places in our country. [Slide.] If paraprofessionals are going to take a more active role, we have to put funds behind an effort and training behind training paraprofessionals so that they are really qualified and prepared to be doing the frontline work with our individuals. And perhaps there needs to be licensing procedures. [Slide.] Again, since many of our folks are living at poverty level or are unemployed, there needs to

be a more aggressive approach to preparing individuals for jobs, and there needs to be a very definite linking to adult services very early on. I know that that has also been an important part of the Department of Education. [Slide.] And so the personnel really need to be trained to better facilitate this transition process. Too often I see it happening where there is not a discussion held until the individual is 21 or so. [Slide.] Along with that, rather than just the one- shot training, we actually in Indiana have trained 180 teams in our state. Those teams consist of superintendents, principals. We've had bus drivers that have been trained, general special education folks, parents, a whole host of people that we bring together for training and then provide ongoing support for. But in addition that, what I see is really a need for a kind of cohesive state and regionalized personnel preparation programs. What we are finding in our state is that what is highly effective is if school districts actually hire autism coaches or mentors. Because the reality of it is, is that oftentimes people

receive a lot of training, but when they close the doors of their classrooms, they need ongoing supports to be able to implement those practices. So coaching needs to be available for those folks to be able to do their job effectively. [Slide.] We also need to have an expanded focus on intervention at the zero to three level. And unfortunately, too often, heavy services kick in when children hit the age of three, and we really need to be focusing earlier on kids. And that means that those providers need training. In some areas of the country, people who provide services to zero to three are not very well trained in providing services for young children. And oftentimes those services are not very integrated or coordinated for those children. [Slide.] When the educational system is unable to successfully educate these children, other agencies need to be willing and funded to step up and provide additional assistance. Another one of the members that I hope we start seeing at the table are people involved in the criminal justice system. Unfortunately, I am receiving phone calls from

families of children as young as five or six or seven or eight. And Jamie from TASH, you can probably talk about this, but children whose behaviors are being misinterpreted, and they are already getting in trouble with the court systems. And the courts are unprepared and uneducated about how to support these individuals. We also find that because of the complexity of these children, that oftentimes in addition to autism, they come to us with mental health issues. And the mental health community and educational community has to partner around these children. About six months ago I had the opportunity to speak at a conference, LRP, which is kind of the legal conference for special educators. One of the cries from the local directors of special education was the need for interagency agreements with all the agencies in their community to really partner up to come around these complex kids. Because the reality of it is that right now these kids, when the educational system can no longer support them, we are now looking for institutional places, places in the criminal justice system, and these

kids are failing dramatically. It is these kids who have tremendous potential but because of us not being coordinated in our efforts are really failing. [Slide.] Statewide parent training and resource centers. I hear from families when they first get the diagnosis, and oftentimes they call me and they say, how do we make sure that we don't mess our children up? How do we do the very best for our children? So we need to be there not just in major cities but in urban areas, in rural areas, and looking at families who have limited abilities themselves and also making sure that we're hitting minority populations, which are oftentimes underserved. [Slide.] Families need advocates who will help them interpret the system and negotiate the maze of services in a positive fashion. They will have to be interpreters of what's going on and help them to understand how the agencies come together. All of us work as separate agencies. They are dealing with one child. [Slide.] In addition to that, families need access to additional funding and support that allows them to supplement their children's school

program. Earlier, Merle, you talked about the fact that many of these children and their families lose insurance coverage when their child is diagnosed with autism. That is a very great issue for a lot of issues. [Slide.] And families need access to affordable and readily available training that will provide them with the tools to be able to effectively support their children. [Slide.] Currently there are efforts that are going on, and I hope that we don't duplicate efforts that are already happening. The Autism Society of America has for the last several years had a group of folks that are part of a nationwide network of training and technical assistance programs that can provide a mechanism for cohesive research, personnel preparation and training. We do a lot of training with physicians. We go out and spend a lot of time in the community and some of the states involved in that. [Slide.] In addition to that, since Indiana University, the Indiana Institute is part of AUCD, I would really encourage that you look at that group also, because that is a mechanism, and what we do in

every state is provide training, and it's a really good, coherent, cohesive kind of organization that can do some of these things. Okay.

Dr. Holmes: I'm Anne Holmes, the Director of Outreach and Support Services for the Eden Family of Services. Eden is somewhat of a unique program. It's a private, nonprofit agency that serves individuals with autism, basically birth to death. We have an infant and toddler program. Right now we seem to average about 3,500 three-year-olds at any given time. Our youngest is a 9-month- old. It's a sibling whom we're watching, which we have done for many families. We've been able to watch some siblings where the parents are concerned. We have a school-based program which serves 50 students from three to 21. Then we have quite a large adult program. Currently we have 10 group homes in the community where six of our adults live. We have three employment centers where 85 of our adults go. They are focused for employment, and I'm very proud to say that 100 percent of our adults receive paychecks, some very, very small, some enough that make their job coaches jealous.

So it's a nice problem that we have. I have the privilege of just in a short time to focus on this adults with autism. Thinking about the definition of autism, the third word is lifelong disability. I think we don't think enough about the adults. It seems at 21 they really do fall off the face of the earth. If you think about it, trying to do some rough statistics, but we're all going to spend about 75 percent of our lives as adults, maybe 60 years as adults. Right now I'm thinking that we'll give into the 80s, and with autism it's really good news. When I started in the field 26 years ago, the leading cause of death in autism was choking to death in institutions because of overmedication. That's not an issue anymore. Our adults with autism should live normal lifespans. So we're going to have, as Lee said, we're going to have a significant number of adults in that area as time goes on. Every year at 21, there's a new bunch of adults with autism needing services. Cathy alluded to individuals who maybe had gone through high school and secured a job, and the school system worked quite hard at getting that.

The hope is that this will somehow continue. I've sat on enough teams where, well, they'll just continue, individuals with autism that are quite high functioning can continue for a while, but often they fail because there are no supports. These individuals have gone to colleges, Cathy said, and can't get a job after that because of the real challenge to their social skills, and just keeping and maintaining a job. Then you have those that are more involved, those that have many more issues, which tend to be the individuals which we serve at Eden. We have had the pleasure of deinstitutionalizing half of our residents out of our state institutions. They have taught myself and our staff more about learning and about what adults need. Elizabeth Gould, who is a researcher at Princeton University, last spring, published her study on aging primates. And basically, what her research said is that aging primates, if stimulated, develop new neural pathways. We took the jump just mentally and said okay, if primates can develop new neural pathways from stimulation, absolutely our adults with autism can learn with

stimulation and with programming. This has I know for us been such a kick to say that learning doesn't stop at 21. In terms of service delivery it does, because we're challenged with no entitlements and no funding for programs. Most adults with autism are probably right now at home or in a state institution. We get called in often to look at an individual in a state institution. They want to know about diagnosis, and our team will go in. One hundred percent of the time we share with them, do you realize that half the other young men and women sitting in this room also have autism? So their mouths drop. Our institutions are filled with adults with autism, also in their home, their home with aging parents, their home with parents that are tired and have every right to be tired. As we always say at Eden, autism never sleeps, literally and figuratively. So you have the challenge of these parents trying to maintain these kids at home with no services. Some of the challenges, and there are many that face the adults with autism and service providers, one is just trying to interest specialization in

adults services and providing these services for adults with autism. Adults with autism, although parents and staff think they're cute, they're not cute. At 50 if they have a tantrum, it's not cute. There is not a desire for service providers to go into that field of residential services and adult services for autism. It's hard work. It's 24/7 as we say. On every holiday, the group homes are running, and it's been very difficult to get agencies to want to specialize. Adults with autism typically fail in your generic group homes and employment centers. They do not fit well with the mold in the population of mental retardation, cerebral palsy, you're looking at ratios of 40 to 1 for our population. They fail miserably. We have very few groups of individuals that want to provide those services. Another significant challenge we have in service provision for adults we have are workers. We provide extensive training, but at times when our economy is good, we are truly competing with McDonalds for staff. Those are the individuals, not just taking care of teaching our adults with autism 24/7. You know, as

I would say and my boss always says, you say to the parents, you know, mom, I'm going to go to school and I'm going to go to college and become a special educator, and your parents say that's great. Who goes to their mom and says, mom, I'm going to be a human service provider? I'm going to go work in a group home. We've got to professionalize that field. We have to have career tracks. And maybe they're in our county colleges where an individual can go and get a degree in human service provision, and then we have a pool to pull from, and that respect for that worker is just raised, which we need so significantly. Funding is an ongoing issue. The only reason why Eden can survive and offer our services is because we have an incredible fundraising division that supplements all of our funding. We have gotten zero percent increase from the state for several years now. And, you know, there isn't a zero percent in expenses. So we're looking at a serious funding issue. Another issue too that I think impacts -- we're talking about crossover agencies. The mental health issue came up, which is a

reality for adults with autism, just the whole medical care. Our population of adults, many of them have been on medications their whole life. We have a number of individuals right now that are suffering from serious liver issues and kidney issues because of medications their whole life. We've got those issues medically. We also have the challenge with autism that they can't tell you where it hurts. And it's so difficult to sit with a doctor and not be able -- you know something's wrong, but you can't say it because he's not going to grab the stomach here and the adult is not going to put his hand up here. So in terms of finding good medical care is an ongoing challenge. The issue that we struggle with, and I hope that all you will struggle with, is there are no entitlements for services for adults. So if there are no entitlements, money is not going to follow the entitlement. I would like to end. I have about two minutes. And it is a story because it's worth telling, a story about Larry, who was in the institution from when he was three to about 33. I'm not exactly sure how old he was when we were

able to take him out of the institution into our group home. He did nothing for those years, pretty much did nothing. All his records, I was reviewing his records, and he was nonverbal. All his records said he was nonverbal, and he pretty much was in the dayroom. And on his nights out, he would walk around the campus. We took Larry into our group home, and Larry is a big guy, so we very slowly took him off his medication, which was beyond a list you couldn't even imagine. It was every medication possible. Gradually took him off his medications, got a good balance of medications. Larry is verbal. Larry was just so drugged his whole life that he couldn't speak. Larry speaks. Not that he has huge conversations, but he definitely can tell us what he wants, what he doesn't want, where he wants to go. And he has a job, and he loves his group home, and he makes a paycheck. There are so many Larrys out there that I think if we can just pay attention to this end of the autism spectrum, we are really committing to that lifelong disability. Thank you.

Ms. Alfreds: I think our major accomplishment will be not destroying the audio/visual and technology of NIH. I will need the Powerpoint instruction. [Slide.] I'm Myra Alfreds. I'm the director of a public community children's mental health system in Westchester County, which is a county just north of New York City. We're about 923,000 people, about 200,000 kids under the age of 18, and I've been in the children's mental health field for about 14 years. I am also the project director for a children's mental health services grant and principal investigator and work with Columbia University Psychiatric Institute, and it's because of Sybil Goldman that I am here, and I said what do I know about autism? But I think what we're talking about here is children and families, and children also who come through a lot of different doors. [Slide.] Around three-and-a-half years ago as we were looking at children in the public mental health system, the majority of whom are using public services that come from a variety of systems, we noticed that about 20 percent of the children who were in the children's

mental health system also had co-occurring developmental disabilities, and we started to become very concerned that the families were coming forward but that the systems weren't necessarily coordinated and working together. We decided to do some looking together and analyzing what are the differences and what are the similarities in the system. I present this because these became some of our challenges in putting together a system that follows principles that I can highly recommend as organizing principles across systems. These are the child and adolescent service system principles. They are family-driven, individually strength-based, culturally competent, and I have yet to find a system that doesn't at least acknowledge that these are values and principles in their system as well. So it may be something that can bring people together. But we found, we are in New York State, that the developmental disabilities, which includes children with autism, is a state-driven system. The mental health system is a county-driven system. We have various services differences.

Children who have very serious behavioral issues, often who we find in psychiatric hospitals, need an intensive level of service that currently is only provided in the children's mental health system at a ratio of one case manager to eight families. The MR/DD system cannot replicate that. So these children are landing in the mental health system, and we are accepting them based on their mental health needs, but struggling very hard to serve them in a comprehensive way. We are finding that there is some difference in family support in our two systems. That is, in the MR/DD system, families are attached to programs. In the children's mental health system, we have a family movement that is separate and apart from any program, and these families find themselves in and out of all of these systems at any given time. So we want to try to work together with the MR/DD system to provide families what they need when they need it. You may be surprised to see that on the MR/DD side, we said many funded services, but when we looked at family support, recreation, community services, believe it or not, there is

much more available for kids with developmental disabilities in the communities than there are with kids with serious emotional problems. Again, we want to work together across these two systems to serve all of the children. We're finding in the MR/DD system, there is still a model of dispute resolution. Who does this child belong to? This doesn't always work well because there are many children that are between systems in gray areas that we want to come together. [Slide.] In Westchester County for the last 13 years we've had a model called Network. This is what it looks like. The child and family is in the center. They are in local communities, and together we are looking to engage all of the service systems. This works best when everybody can come with open hands and an open mind to really look at that individual child and family and puts their resources together on the table. We are now in Westchester County working at increasing numbers of very young children, children eight and under who are increasingly coming into emergency psychiatric services. In that population we are predicting

that, again, 20 percent are going to be children who have both mental health and developmental disabilities. These numbers are going up all of the time. We're looking for ways to come together across these two systems to serve these children. We are also looking at the other end of the spectrum in our kids who are now aging out, an even higher percentage of kids with developmental disabilities who have gravitated toward a system that has some peer support models. On the family support side and the peer support side, we're trying to have an open system to work across these two systems. [Slide.] What we have done in Westchester County so far that I believe is having some effect is that we are sitting together and have for the last three years in a cross-system planning group. We are looking through things like home and community-based services waivers to put together because that exists in both systems, and these are Medicaid waivers that states have available, that there are case managers in both of our systems, and yet there are children and families that need services at a high level of

case management. There could be work directed toward looking at Medicaid waivers as a way to bring together systems. We're doing it operationally. We would love federal support for this as well. We said even if we had all the money and all the services, we do not have a trained workforce. And last year we developed what seems to be the only cross-system training for workers in the mental health and developmental disabilities field. It's about 25 hours of training. People receive certificates that they've completed it, but we've found an inability in both of our systems to really understand how to work with these kids and families that have multiple challenges, and we are going to be repeating the training every year. We've contacted the National Association for the Dually Diagnosed to find out if there is and has been an emphasis on adults, almost nothing specific around children. We are really trying to encourage them to allow us at least to take some leadership in this and focus on the needs of children. Again, an advocacy issue with NADD to bring this to the forefront, and

dually diagnosed is mental health and developmental disabilities. As a result of training, again, we have searched through the United States to find that there really is not attention across these two systems on children. And as a result of our training, we've put together something of a resource book. Some of the challenges that I am thinking about, having attended this meeting, is we are missing an opportunity if we only think about screening with pediatricians and with medical people. What we found is, often the first people to enter these families are people from other systems. We're talking about child welfare workers. We're talking about other kinds of professionals. If we develop screening instruments, can I recommend that it goes broader than medical people? Because you are not always the first ones to know that there's a problem in the family. And I think that's all I'm going to say.

Dr. Noyes: Good afternoon. Can everybody hear me? My name is Donna Noyes. I'm the Director of Policy and Clinical Services for New York State's

Early Intervention Program. [Slide.] I'm here to talk to you today a little bit about our clinical practice guidelines for young children with autism, but I also want to start by telling you a little bit about Early Intervention. [Slide.] I'm sure that all of you know that Early Intervention is a national program under IDEA for children ages birth to three years with developmental delays and/or disabilities and their families, and the program provides for a broad range of evaluation, assessment and intervention services for children and families. [Slide.] In New York State, our Department of Health is the lead agency responsible for administration, financing and monitoring of the Early Intervention Program. We also have a very strong role for county governments. They're responsible for finding eligible children, developing IFSPs, contracting service providers and seeking reimbursement from third-party payers. The county governments actually share the cost of services with the state. [Slide.] Our mission at the program is to identify and evaluate as early as possible those

infants and toddlers whose health development are compromised and provide for appropriate intervention to improve child and family development. [Slide.] We as a Health Department have had a strong emphasis on early intervention in the medical home, a strong commitment to ensuring physician involvement in the Early Intervention program, surveillance of at-risk children in our Child Find efforts in IFSP monitoring of progress, and we have a number of activities to support that involvement, from medical home grants that was recently awarded to us, a strong parent involvement, committee of our Early Intervention Coordinating Council, and training and outreach program for physicians. [Slide.] I wanted to tell you a little bit about the scope of our Early Intervention Program in New York State. When we began in 1993, we had approximately 9,000 children receiving Early Intervention services in the first year of service delivery. We now in our most recent year with our current data have around 58,000 children and actually this year we're experiencing something

more in the neighborhood of 60,000 children and their families who are in our Early Intervention Program. And just to give you a sense of the cost, we're well over half a billion dollars at this point in service delivery expenses. Of these children, in 2000-2001, 519 were identified as having autism or pervasive developmental disorder with an actual diagnostic code. I would also say that when we look at the patterns of developmental delay status, it's probably true that there are another around 500 children just based on the pattern delay being cognition, communication and social and emotional delays. So that 519 is probably actually a bit of an under count. [Slide.] Our service delivery issues included obviously a high need population, parents seeking very intensive levels of early intervention services, a lot of questions from public officials, providers and families about what effective interventions are available. A real need for better data on our own service delivery system in terms of children with autism. A need to improve service delivery capacity, and obviously

funding is an issue. [Slide.] In 1997 we initiated a clinical practices guideline project to help us address some of these issues. The project in its total will actually result in six clinical practice guidelines. The first two guidelines that we tackled were autism and pervasive developmental disorders in part because of some of the issues I just addressed, and communication disorders, because obviously that's one of the most prevalent problems we find in Early Intervention. We also have completed clinical practice guidelines on Down's Syndrome, motor disorders, vision impairment and hearing loss. And these are all currently under our final review within the Department for release. [Slide.] We used an evidence-based methodology based on the Institutes of Medicine and the ARC methodology for development of medical practice guidelines. We had a project staff that included a methodologist and research teams, and we had six different multi-disciplinary consensus panels, all of which included parent consumers. And I just want to take a minute to say how important those parents were

on the panel. We actually were able to fund them to participate so they got a stipend that was comparable to the clinical and research experts who participated. We had four parents on the panel. The panel was chaired by a primary care physician from our Rochester area, and they were just really important to the effort in terms of helping us pinpoint the important issues for parents. [Slide.] We looked at 20 years of research. All of the panelists reviewed the evidence that met quality and clinical applicability criteria. We looked at studies that included children up to six years of age. We then had the panel develop consensus recommendations that would address their recommendations around practice issues related to assessment and treatment of children with autism. And we had a national and international peer review process. [Slide.] I wanted to tell you a little bit about the scope of our guidelines. They include a lot of discussion about developmental surveillance and screening and again, targeting physicians but also, as was mentioned earlier, the need to reach

other early childhood providers with information about autism. We looked at assessment and may have recommendations about assessment instruments, developmental assessments, and also health evaluations. We looked at the literature around MRI and SPECT and food allergies and diet assessment, and the guidelines include recommendations in those areas. [Slide.] The scope of the autism guideline related to interventions include general approach to intervention. Behavioral and educational approaches were among those found to be, based on the science that's available, the most effective for young children with autism. And we looked at what literature was available on intensity, and I would say across all six guidelines, the only place we found evidence on intensity was in the autism work, and the panel did recommend 20 hours a week, and also qualified that with factors that relate to individual child and family needs. [Slide.] We also addressed a number of other approaches, sensory integration. We found no evidence for any other approaches, at least in the science. The panel did recommend a

qualified use of sensory integration and the developmental model that's been developed by Dr. Greenspan. We couldn't find any evidence related to music therapy, touch therapy or auditory integration. And these were all areas that the parents felt very strongly we needed to address. [Slide.] In terms of the use of our guidelines and future plans, we have widely distributed our guidelines to our county officials, to physicians, to providers, to families. We have an ongoing program of training. Our plan is to update the guidelines as new evidence becomes available. And I would say with the autism guideline, that needs to happen relatively soon. There has been new research coming out that would I think impact on some of the recommendations. And we're considering strategies to evaluate the impact on the quality of care. I would just mention that I told you earlier that we had around 519 children in 2001 identified as having an autism. Prior to that, our early experience with Early Intervention, we had across a four-year period 77 children identified with that diagnosis. I don't think we were only

serving 77 children with autism, but I do think our efforts related to helping people recognize the importance of giving a diagnosis early has made a big difference. [Slide.] We are also in the process of developing standards and reimbursement rates for behavioral aides and paraprofessionals. This was raised as an issue, big issue for us in New York around capacity. [Slide.] And just to close, some recommendations that we would make is again, really the continued support for research is critical. And I would say services research is critical. That some of the issues that we are dealing with as states relate to the type and intensity of interventions that lead to good outcomes. I think the early identification area is very important too. And then I think it's really important to include state administrators and both early intervention and children with special health care needs administrators as target audiences for research. I'm very pleased to be here today. It was a wonderful experience for me to hear about the research, and I'd love to see that happen more regularly. To support

collaborative efforts across states, to develop guidelines and standards based on science, and I'm very, very pleased with the U.S. Department of Education's efforts to promote that. And to consider the funding needs of state service delivery systems relative to providing high quality care for children with autism and their families. Thank you.

Mr. Grossman: I want to thank all the presenters for surviving the technical difficulties we were all having. [Laughter.]

Mr. Grossman: In the next 15 minutes or so that we have allotted to us, I'm going to first open this up to the panel and then open it up to everybody to ask us questions. But the one question I have and what we saw as our role in presenting this panel was for these individuals here to present to the Committee what they thought as kind of the take-home message of what they believe is necessary for this Committee to respond to this powder keg that we're sitting on in terms of the service sector. So we'll start with I guess Donna.

Dr. Noyes: Do you want me to repeat the recommendations?

Mr. Grossman: What would be your main take-home point for this Committee, for the IADD Committee, in dealing with the service aspects of autism?

Dr. Noyes: I think my main take-home point would really be that we are at the state level increasingly under a lot of pressure to have evidence behind our work and to show that interventions can be effective. And I'm very pleased with the level of research that's going on. I think it would be important, though, to also think about how we can do more research that would interface with the service delivery systems for children with autism and possibly how we can make use of some of the data that states are collecting or have improved collaborative efforts among research teams and states to address some of the service delivery and practice issues related to children with autism and their families.

Dr. Holmes: I think for adults with autism, we have to look at the issue of entitlement which

would bring funding and support. We have to look at the adult population as learners still. So I think we just have to look at how are we going to bridge that from 21 when there's so much laws and regulations to provide appropriate education, what can happen after 21. And the other main goal that I would like you all to take home is that dilemma of how can we create career paths for those individuals that work with the adult population, and how can we approach that from the higher education standpoint.

Dr. Pratt: I think that all of us sitting here on this panel and probably several of you too feel this kind of ominous black hole that we're in. And I think that we're always overwhelmed by all the work there is to do, and I'm sure that families feel themselves in that black hole. So trying to think about in 30 seconds what's really needed, I think more of this and more funding. I'm happy to see that Thomas Scully from Medicare and Medicaid is on. I hope that we would get people involved with the insurance industry. I hope you would get people involved with juvenile justice system and

the criminal justice system. I would hope that education would partner with the mental health community to look at the complexity of these individuals' needs, and I hope that we would also access the resources that we currently have. We have a lot of energy. We have several family members here and several family members who are a part of this Committee to really kind of coordinate ourselves and coordinate our momentum to try to start digging us out of this very large black hole. I get phone calls every day, and I personally wish that I could write checks. But since I also have a government job, it just isn't possible to be able to do that. They'd be very small checks. But it is overwhelming. And I think one of the things, though, that I do want to say is, this is a ray of light, this Committee, for families and for us professionals who are out there getting those phone calls every day. So thank you for being here all day.

Ms. Alfreds: I have more than one point. One is that there is tremendous energy in the family movements, and it would be wonderful if they could

come together across disciplines. Again, these families tend to walk in a lot of different doors, particularly if their needs are complicated, which is what the public system sees. And there are so many gray areas, with all due respect to research and categories, but many of these kids and families through long histories of closed doors don't neatly fit anywhere. And really it's within our communities that we're trying to bring the best research, the best approaches, the best interventions. But it's complicated. It's individualized. And the more of us that are at the table together working on it, the better. One point that I didn't make: There is disturbing increases in medication of very young children in the mental health system. I think we all know that. We've seen the articles. And I think we need the research minds looking at what the implications are for children who are coming in, again, often the mental health door, because they are landing in psychiatric facilities and psychiatric systems.

Mr. Grossman: Barry?

Dr. Gordon: One of the reasons people use to deny services is there's no agreement on what services should be provided. And this is kind of a question for Anne and Donna but really for the entire panel. Do you actually think -- let's take in one area, say, education, that you disagree or agree with the New York report, the National Academy of Sciences report, the Eden model -- are they fundamentally in disagreement or are they fundamentally in agreement on what ideally should be done for children?

Dr. Holmes: I think they're generally in agreement. I think we're past that now. I think there's some subtle differences, but I think that the general strategies, behavioral strategies that are being used, they aren't being argued as they were ten years ago, 15 years ago. I find lack of people wanting to provide the services and in the public system that we deal with or that through Eden we deal with, is it's tough. And they sort of know that that's what they have to do, but it's really tough to do it, and it takes a lot of money, and it takes the training and it takes all

those pieces. But I don't see a lot of fighting about approaches anymore.

Dr. Noyes: I would generally agree. I would also just add that when we issued our guidelines in New York -- and they are science-based guidelines, looked at evidence and the panel made recommendations based on the evidence -- we had a series of dissemination and training sessions and we had some very strong supporters and some people who were very, very upset at the recommendations and the guidelines. So I agree that there probably is increasing agreement, but I do think that there probably still are some issues around approach and intensity that will continue to be discussed.

Mr. Grossman: One of the things addressing this question also is that these people here represent programs that are working. The reality is, is that 90 percent of the programs out there or what are called programs aren't working. And your question is a great question, because I think there is a consolidation of thought of what programs -- what is needed in the therapies for these children. In most places, those services are

denied. They're just not available for whatever reason, funding reasons, philosophical reasons, in many ways, and it's something that we tried to address a couple of months ago with the Psychosocial and Behavioral Interventions Workshop is that some of the service delivery programs will deny services because there's no scientific evidence behind discrete trial training, ABA, et cetera. So that's the problem that the vast majority are dealing with.

Dr. Insel: We need to wrap this up in a couple of minutes, but let's get some more comments.

Dr. Zeph: I think that we're in the same situation here that we started this morning in terms of the screening instruments. And what we said was, we have some adequate place to begin. I'll tell you, if there was a service out there that was doing it, that was having the kind of outcome that we all dream of, we'd all know about it and there wouldn't be this discussion. The fact is, we need more research that looks at the wide range of possibilities. I don't think we know what's possible. And as long as we put any kind of

blinders on ourselves, we're not going to know what's possible. We need to really tie together the research and the practice. We need to look at it. We need to remain open to all possibilities. We are our own worst enemies at that sometimes. And we really need to look at what or listen to what families are telling us in terms of what's possible. I know one thing as a diagnostician and as an evaluator that we don't find what we don't go looking for. And one of the questions that I use with families that I learned along the way is tell me about your child and tell me one thing that your child has done that you never dreamed they would be able to do and something that you might not even have told anyone about because you thought that they would think you were crazy. And I get the most incredible stories from families. Parents will break down in tears because of things that have happened and the reactions, if they've tried to tell this story to many professionals, which is you're being unrealistic, you're in denial, those things can't possibly be true. So there are little miracles that happen out there,

and what we need to do is really be open to them and really use them as the basis for opening our eyes and our minds. The combination of research and practice is probably the greatest area, from my perspective, that we need to deal with.

Dr. Insel: I think in view of the time, we're going to have stop in two minutes. If we could have just brief comments.

Dr. Cordero: Just a brief comment. I think that everyone would agree that there are more and more cases of autism that are being reported and that also they are aging. And one of the issues and I think another group that we need to look at that actually could be an important group is all the group of individuals with mental retardation or cognitive deficiencies. The Surgeon General's Report on Mental Retardation. If you look at the issues of access, and many of the issues that are in that report, I think echo what was described here. And really it is about the transition between childhood to adulthood. We have probably not a perfect but some sort of a safety net for children up to about 18. But in fact what we're

missing is almost like health care for individuals with special health care needs and special health care services in 18 and older. And I think that it is a generic issue, it is familiar issue for individuals with autism, but we need to look at it as sort of a national issue that needs to be on the national agenda.

Ms. Goldman: You began this session, Dr. Insel, with asking what was the role of the Committee. And I think that's something we are struggling with. When we put together this panel, it was to begin to show the complexity of these issues, that it involves multiple systems, multiple funding streams, multiple levels, from national, state and local across the age span, services, workforce, all of those things. And so one of our challenges as a Committee is to figure out how do we get a handle on this through this Interagency Autism Coordinating Committee. Right now on this Committee we have HRSA representatives, SAMSA, Lucille and Lee, from their perspectives and Anne from NIMH. But we do need other I think systems, federal agencies

involved. And I think we do need to either get some direction from the larger committee or really figure out how we get our hands around the broad scope that's implied with what you heard here, which is really just the tip of the iceberg. Dr. Insel: If we can end this session, I think that's a good place to try to sum it. And maybe, Rick, you can hear your comments later, because I'd like to. I think it's going to be critical to know what are the next steps and to come away with a process here that will be enriching and will take us one step further. I must say in listening to the presentations though I agree the challenge seems overwhelming and there is tremendous fragmentation and some horrendous situations, there's also a lot of hope in terms of some things that are happening in a diffuse way and some things that really do seem to make a difference. And it's a question of how to optimize those and bring them together. From what I'm hearing, I don't think the subcommittee is actually quite large enough. I mean, there are some other parties that need to be at this table. We haven't heard the Medicare

perspective, for instance, which would be an important piece. And that's something that can be developed. It would be helpful for us I think for you to, as we said for the Steering Committee, to come together with some kind of a written document. It doesn't have to be long, but it does need to have some action items that we can then all talk about. I don't think we have to wait six months to respond. These are things that we can begin to deal with electronically. Also, I'd really like to thank all of the presenters and ask if we could have your Powerpoint presentations again as something we could include on the Web site so people can refer back to them. It's an outstanding set of presentations and a very good discussion. I just wish we had more time. But I think in the interest of everyone here and the other presenters that are coming up, I'd like to take a break now for about 15 minutes -- let's say 10 minutes. Let's reconvene at 3:25. Thank you.

[Recess.]

Dr. Insel: Let's get started here. [Pause.] We have Redskins tickets for anybody sitting down. [Laughter.]

Dr. Insel: All right. We're running a little bit behind schedule, so I want to launch into the next session. There will be a few people who are having to separate from their cookies, but they will do that momentarily. The next presentation is a focus on the Pharmacotherapy in Autism Results. We're going to first talk about a sort of general Psychopharmacology in Autism, and Kathryn Carbone from the FDA will begin that presentation. Dr. Carbone, I'd suggest we wait about ten seconds until we see a few more people come through the door, and then we'll launch. [Slide.]

Dr. Carbone: I've been accused of talking too fast, so maybe that's a good thing this late in the afternoon. [Slide.] These slides will be up and available, I've been told, so I'm going to hit the highlights for time awareness here. Special issues in autism for treatment, of course, as I mentioned it had severe persistent symptoms. Symptomatic therapy is likely to be lifelong,

which raises significant issues in therapy. Side effects become a concern and adverse events when you are talking about treating people for upwards of 80 years. In addition, we have to have treatments that are safe for children as well as adults, and children are a special population that's under considerable focus right now at the FDA. However, the good news is, is that this is a disease which is clearly recognized to have a biological basis, and that if we knew what the basis was, we could significantly impact the course through prevention. As a developmental disease, intervention is by nature a possibility. However, it would be time critical. Throughout the talk I'm sort of going to go with the "what if". Because as was mentioned, if we don't keep the "what if" in mind, we sort of stagnate. So what if? What if prevention of a neurological disease, something early during birth, for example, or during gestation, fully therapy. Okay. Symptomatic treatment. Significant quality of life improvements. We could never overlook this. The last session emphasized that it's absolutely

critical. And its successful treatment of several of the core symptoms of autism could significantly improve the life of many people in the United States and elsewhere. However, we have to remember that symptomatic treatment may fail to address mechanism, it may fail to address cure. So in the what if portion of this slide, we must always keep those in mind. [Slide.] Quandaries in symptomatic treatment approach is that in autism specifically, there have been many promising therapies that have been suggested but no treatment when carefully studied in a critical way, and we'll talk about that, has really been as good as initially hoped. We'll talk about specific treatment at the end of the second talk in this section. But in general, that's true. In a behaviorally -- a disease, which is the good news, can be affected significantly by behavioral therapy. The bad news is that this often makes it difficult to study other kinds of therapy because of placebo effect. I'm going to go very briefly over how we make decisions about data and quality of studies when reviewing the issue, is a particular treatment safe and effective for a

particular disease or syndrome. And so data for treatment decisions can come in from case reports, case series and prospective studies, clinical trials, open cohort and double-blind randomized. And those are sort of listed in order of quality of the data. In other words, reproducibility and objectivity of the data. Just briefly, case reports. The good news is that many interesting therapies are identified initially by cases. The first fellow who thought to brew up willow tree bark for his headache was very perceptive, because that contains aspirin, essentially aspirin compound. However, the problem is, is what you get reported are obviously only the successes. So that case report is going to report a success, and then the linkage of actual causality of success needs to be determined. Case series are a little better in that you have a series of patients who appear to have responded to a particular therapy. The evidence strength of those data go up a little bit, but the problem is once again, one reports the successful cases. One reports what are usually retrospective analyses, and there's no consistency

of an analysis of the data. A prospective study has improved the quality of data because it's preplanned study. There's a routine measure of the outcome so that it makes comparability among groups easier. And in an open trial, which is often the first step in a new medical therapy, is that both the patients, the treated and the researchers, know the therapy that's given. And there's an inherent tendency towards a bias. It's not an accusation of deliberate misintent, but it simply happens. There have been studies that even show if a particular study may be funded from a particular source that there tends to be a bias that may enter. So being an open label study, difficulties can arise. However, in an open label study, there are issues of discontinuation. You treat, measure, stop treatment, look at the loss of effect, or treat, switch to another treatment and compare the two effects. There are ways of getting a little more comparable data. However, it's very important in using psychotropic medications to be aware of the washout. In other words, the discontinuation must be measured after

it's clear that the drug therapy has left the body at significant levels. Cohort study is a little bit of an improvement. Two groups. Typically one treated and untreated are followed prospectively. They can be open or blinded. We'll talk about blinded soon. However, as has already been mentioned at this meeting, whenever you get a placebo trial, a trial that involves a placebo, there's some reluctance to enter therapy. In a case where there is an effective therapy, many times a placebo trial is considered not ethical and a comparison of two therapies is used. [Slide.] And probably the best quality data comes from a double blind, meaning the patient and the practitioner are both blinded as to the particular treatment, randomized so that the group of patients are not selected but they are randomly sent to each group, and they're controlled usually with either another medication or a placebo. However, it's been noted that the specific comparator to the experimental medication should be a well -- it's best if it's a well-established, well-documented therapy. But of course there

aren't any really in autism at this juncture. And you can both look for equivalents between two therapies or probably a superior way of looking at superiority of one drug over another. And you can continue to use other designs. [Slide.] Special considerations in autism spectrum disorders is consent, because the individual even as an adult may not be competent to give consent, so they require a person to give consent. And then of course whenever you're doing a trial where the individual receiving the therapy is not the person giving consent, there are issues of risk. Perhaps a smaller risk is accepted when the person is not capable of giving informed consent themselves. Disabling behavioral symptoms and placebo use or placebo effect can affect being able to measure the outcome of the study. The language problems that have been mentioned earlier may affect the ability to provide feedback about internal state. In other words, is the child now less hyperactive because they're simply sedated, or do they actually feel less anxious? If they're not able to communicate, that's hard to determine. And of

course, the disorder is quite heterogeneous, so that the selection of particular subgroups and responses by particular subgroups based on differences in a biology that we don't understand are important considerations. So, as was mentioned in an earlier talk, I think that going to the direction of finding the correct subsets to test may be very important. [Slide.] What does the FDA do? Well, FDA has the ultimate responsibility for determining whether a drug or biologic or device is efficacious and safe for treatment of a specific disorder. There are many other features of the FDA, including potency determinations and purity determinations and inspection, et cetera. But basically, is this decision is this drug based on a risk/benefit analysis, is the drug effective enough and safe enough to be recommended for use for a particular disorder? I just want to make it clear that when we evaluate the data, be it animal toxicity data all the way up to clinical studies, we evaluate very carefully the design issues. There have been times -- what you see published and what actually is part of the review are

sometimes two different things. There have been times when specific studies may be cited and published, but they're not used for efficacy analysis because a flaw has been determined in the study and therefore the data aren't felt to be acceptable. All studies are basically reviewed for safety. Regardless of study design, safety is an issue. But for efficacy, if the study design is lacking, the data will not be used for efficacy. One example, I won't mention the product, but one example was a change in the clinical outcome in the midstream of the study. In other words, the clinical end point was determined to be X. The investigator said we want to change it to Y in the middle of a blinded study, and we said you can't do that, suddenly change an end point in a study and then consider it a blinded study, and therefore we won't use the data. And they changed it anyway. We don't control that. The FDA, in terms of reviewing for drugs, the FDA is an organization which takes in the information, the applications from the sponsors, and we review what is presented to us. There also is an arm in the

Center for Biologics, this is particularly true, which is here on the NIH campus, a research end, and efforts would also include in our particular area is we do research on animal models of neurovirulence, of virus neurovirulence, and actually have an animal model of autism. So there are research components where we try and contribute as well. When reviewing clinical studies, superior outcomes are preferred over equivalence trials, because small margins are difficult to prove statistically. If you have a big difference, then statistically that's easy to feel comfortable with accuracy. In addition, there tends to be, as with an IOM report, a summary of a consistent body of evidence that continues to support the use of the drug. In other words, evidence where you have yes/no, yes/no, yes/no in a series of trials suggests the ability to show that this drug is effective is limited. Several well designed trials that say yes, yes, yes, yes, yes, then confidence increases that the drug is going to be effective. However, you may or may not know that any drug that's once approved by the FDA

can be used by a physician in an off-label use, and I'm sure many of you are aware of that. In other words, it's used for a disease that has not specifically been -- it has not been studied for that disease. If you want to find out specifically about off-label use, literally read the drug label. Because the drug label will say this drug is approved for, and these are the studies as to why it was approved for that. So that's one helpful bit of information. [Slide.] I'm not going to go through these in detail other than to say in these sorts of issues where these are difficult and complicated syndromes, the ability to define the quality of evidence that must reach a certain threshold for approval has been fairly well discussed by many different groups. And how it basically works is that list that I went from sort of the least quantifiable data to the most objective quantifiable data, if you reverse that list and go from top to bottom, those are the kind of studies that lend the most credence for approval of a drug. [Slide.] In addition, as I was saying, the preponderance of evidence is often the

final positive step in approval of a drug in that if a meta-analysis of many, many studies comes up with a clear indication that the drug is efficacious and safe, the safety review is adequate, then that is probably the highest evidence for support of a drug. But there are others, and I'll leave the Web site for the details. [Slide.] I think clinical studies for autism treatments, the problems that are run into many times is clear specification of the sample being studied is a major limitation. Biological markers are wonderful. If you took a group of people with immunodeficiency and treated them all with AZT, some would respond, because some of those people will have HIV. But if you can't separate out the segment of people that are immunodeficient because they have HIV, you may completely wash out the effect within the larger group of people with immunodeficiencies, is an example. So being able to define subgroups or having a clear biological marker would be a tremendous boon to clinical study design. Clear specification of the treatment is very important.

Random assignment is critical. And metal analyses are unlikely to be helpful in the case of autism. I said in general they're helpful. In the case of autism data, they're not currently that helpful because -- with the exception of perhaps some very recent studies, several of which will be discussed after me -- there really are small numbers of controlled studies with small sample sizes, nonstandardized outcomes, people using a variety of tests. And I would like to emphasize the importance in the setting of a developmental disease that may occur very, very early, the ability to segregate subsets of children by even pre-verbal, very early infancy types of tests, one of which was sort of suggested in preliminary data with the eye attention test and the lights. The ability to, in the case of, for example, safety analyses, which are very important to the FDA, and continuing safety evaluation of even licensed products, you could imagine the benefit of being able to clearly categorize infants very young before and after vaccination to answer public concerns, for example. At this point, there are

very few therapies that you can say are unequivocally of major benefit for the treatment of autism in terms of symptoms. There is virtually nothing really in terms of prevention or cure. These are categories that people have come up with as ways of sort of categorizing data and treatments. Some may be unsupported but are potentially useful, possibly efficacious; [Slide.] Probably efficacious; [Slide.] And a well-established treatment. And the criteria for well-established are fairly strict. [Slide.] So I'm just going to briefly finish up by running through a group of studies or group of drug categories that have been tested in autism. Time doesn't permit a detailed discussion of one of the more interesting ones that will be discussed in detail following this talk, but in general, traditional antipsychotics have been used in treatment of children with autism or autism spectrum disorder. They probably fall into the probably efficacious. There have been improvements in hyperactivity aggression, social issues, learning, stereotypy, et cetera. Side effects include sedation. There

are other side effects which may be permanent with these medications. Forty percent of the children with sudden withdrawal may have movement disorders that's increased in girls and increased after long therapy, and long therapy of course being an issue in autism. And I think it's very interesting to look at that setting and ask the question, why would little girls be more susceptible to these side effects than little boys? [Slide.] There are atypical antipsychotics. These are newer drugs that have different mechanisms of action, or at least different chemical bases. They appear to have fewer movement side effects. They have better reduction of negative symptoms. A negative symptom is sort of a persistent social, absence of normal social behavior that occurs in schizophrenia in between episodes of acute psychosis, and they're somewhat reminiscent of the withdrawal and negative symptoms seen with autism. These fall again into the category of probably efficacious, but it's variable. It depends a great deal on which of the atypical antipsychotics are used, and have many of the same positive benefits, or have

reported the same positive benefits as the traditional antipsychotics. Sedation. Weight gain can be quite significant, cardiac changes and seizures. So of course when you talk about whether drugs are approvable for a license or for a particular treatment of a particular condition, there's risk and benefit and serious side effects in the lifelong therapy are of great concern. [Slide.] The serotonin reuptake inhibitors. Serotonin has been one of the neurotransmitter abnormalities that has been -- consistently seems to be popping up in many different studies of children with autism, both imaging studies in the brain as well as serological studies of neurotransmitters. And many of the behaviors that appear in autism are somewhat reminiscent of obsessive-compulsive disorder, for example, is treated with this classification of drugs. There is some -- and I'm generalizing here. You'll probably find exceptions to everything say. But in general, there is some feeling that older individuals with autism benefit from these drugs for improvement of repetitive thoughts and

behaviors, aggression, language. Children, the data are somewhat more conflicting whether they work. And there are variable side effects depending on each of the drugs. And I guess the finding that there are age-specific differences in outcomes should not be surprising in a developmental-type disease. [Slide.] Secretin has been mentioned. It's a peptide hormone. It does these various things. It was cited originally in a case report but has really, really failed to show efficacy in placebo-controlled studies and blind studies. It, however, is felt to have minimal side effects, but the question is if multiple injections of a foreign protein may result in an allergy which could be serious. [Slide.] Vitamin B6 is utilized in the synthesis of several neurotransmitters. Selective studies using selected individuals showed some positive results. Standard rating scales generally weren't used. There was at least one small double-blind placebo-controlled crossover study that failed to identify benefit, and the feeling is minimal side effects, potential benefit in this treatment. [Slide.]

Naltrexone blocks the effects of opiates. Opiates are essential natural morphine derivatives, and believed to be released during androgenous, self-injurious, repetitive behaviors. The assessment may be possibly to probably efficacious in reducing hyperactivity and impulsivity, but there's some question of long-term benefit. Some studies actually showed worsening. It may be a function of the patient's age, and a side effect in this case, if it's material, it's very bitter. It's administered orally. [Slide.] Methylphenidate is used to treat ADHD, attention deficit hyperactivity disorder, and may have modest results. Statistically significant effect on hyperactivity. However, in a double-blind, placebo-controlled crossover study, just recently been reported, the response of methylphenidate in ADHD may be associated with increased phenylethylamine levels in urine. And what that means is that the children who responded showed this compound in the urine, and the children who did not respond -- this is with ADHD -- did not show it. Now that's one small study. It needs to

be repeated, et cetera. But these are the kinds of biological tests that may be very helpful in, again, subgroup type identification. Children can be given a test dose. If they metabolize the material and it's found in their urine, then maybe they'll be classified as a potential responder and more likely to benefit from the drug. But that's all in theory. Larger trials may seem warranted for certain indications for this drug. [Slide.] Anticonvulsants. One of them is a novel anticonvulsant with an unknown mechanism. It's a cognitive enhancer. There was an open label very small study and showed some interesting positive outcome, but again, requiring additional study to come to any conclusion. [Slide.] Immunoglobulin has been popular. There was some benefit in some small open label studies. There have been mixed response even within those studies. There appeared to be children who claimed to have clearly benefitted, children who did not. Clearly, more research is needed if this is going to be pursued as a therapy, because the question of the mechanism. And keep in mind that it's traumatic.

It requires IV treatment, transfusion of a human blood product, which is not an insignificant risk for an unsupported therapy. And then there are supply issues with obtaining this material, even for indicated and proven outcomes. [Slide.] Tetrahydrobiopterin has been used. It's a co-factor for tyrozine and hydroxylase in the biosynthetic pathway of neurotransmitters. It's used to boost the levels of serotonin in dopamine. An open label study that looked promising. A few side effects reported. But again, as you can see from the earlier discussion, this is a very preliminary type study. [Slide.] So limitations in autism clinical studies. And this is a big issue for the FDA, because remember, we review the toto of the work, the research. It's not study-by-study, but the body of the work that is our interest, although obviously we interface with each study as it becomes an IND. When we talk about review for licensing, it becomes the body of data, both safety and efficacy. And pattern of encouraging case reports in autism has typically been followed by unsubstantiated or modest

outcomes in much more rigorous studies. Even good studies tend to have very limited sample sizes. To remind you, this is public information that's been announced by the sponsor, so I can say it, we are currently undergoing a study involving 100,000 children for a trial of vaccine. We do that in part so we can pick up very rare adverse events and so that we can see efficacy. And contrast that to a study in autism which might have 250 children to try and make a determination. There tends to be, when there is a positive outcome, it's not in every subject. Obviously we discussed the heterogeneity of the disease, the placebo responses. Rating scales may not be specific to autism. Short-term studies for chronic disease. I think this should be highlighted as a real significant issue in autism. And then symptomatic versus curative or preventative. It's not an either/or. It's just that both sides of the coin need to be addressed. [Slide.] Treatment implications. To summarize, there's no evidence currently about any drug, although in the more recent data we will see that pharmacological

treatment dramatically changes the core symptoms or course of autism. However, we would hope that at some point to identify very early therapies with specific agents that may be preventative and eventually identify the subjects, the specific subjects that may be helped by each particular intervention. And we clearly need better work as well that the pharmacological treatments to improve function. That's probably where most of the strides have been made, but they're still modest. And it's difficult to associate a particular therapy with improvement of specific symptoms, and age dependence is a feature of efficacy. [Slide.] Future research directions. This is my big "what if" slide. Discerning mechanisms. Timing of the neurological basis for symptoms would permit direct treatment, and which is "what if". It tends to be for psychiatric diseases which for the most part are symptomatic treatments. This is a big what if to actually find a mechanism for this disease and treat that itself. Defining specific subgroups. I can't emphasize more from a point of view of review of

these studies and the data that having a biological marker for subsets would be phenomenally valuable. And that, as has been said before, the treatment should become as evidence-based as possible. Exposure to unsubstantiated treatments may have adverse effects, or even if they don't, reduce access to more efficacious treatments. Think laetrile. The big crime with laetrile was -- it had some bad side effects, but the big crime was if someone went in and had laetrile treatments instead of a proven therapy, that was the major disappointment there. [Slide.] So I'll just leave this slide up to let you read through it. This is what keeps me going in our darkest hours of granting and publishing and presenting at meetings. [Laughter.]

Dr. Carbone: But the message really -- and I left the one off about peer reviewed, because I didn't want to upset anybody here. But the message is encourage originality in research. True originality should be encouraged, but never, never, never neglect the quality and proof, because that's where the money is. Thank you.

Dr. Insel: Thank you, Kathy. Two points of clarification just so that we're all on the same page. Is any compound currently indicated by the FDA, or approved by the FDA for its use in autism? Point one. And point two is, is there any effort currently in light of your last point, to develop compounds that are specific for autism rather than just using compounds that are currently used for something else and trying to apply them off label to autism?

Dr. Carbone: I think what I'll do is, because -- on the second point, we're not really at liberty to discuss anything that hasn't been publicly released by the sponsor. And from a literature search, I couldn't identify anything I could really let you know about. So I have to defer that one, because I can only release information that's been public knowledge. The first question you asked, I will also have to defer that to my colleagues at CDR, because that's very complicated. I don't want to say no only to find out that one small list somewhere has been attempted for autism. So I'll be happy to get a

list that's very accurate and up to date. I don't want to do this off the top of my head. Sometimes it's buried in a label somewhere, and I don't want to be misleading.

Mr. Shestack: If you're asking if there's any concerted effort that we don't know about in pharmaceuticals to actively look for compounds for autism, I think the answer would be no, there is no concerted effort that any of us in the voluntary groups know or who fund research know about. There may be things that have off-label indications. And in the future as we look for like public-private partnership, if there ways for the federal government to encourage pharmaceutical investment in autism, given the numbers we have right now, and the lifelong condition. I mean, we spend a lot of time trying to convince people the obvious, which is that they could make some money if they served this market. And it would be good if they would hear it from you guys.

Dr. Insel: Just to underline that point, we've been listening all day to rather scary predictions of what the prevalence of this disorder will look

like in ten years. Big pharm is very heavily invested in creating yet another antipsychotic or another antidepressant, which is a market in both cases, both markets are relatively saturated. If what you're telling us is that there are no compounds currently that really show great promise here, one might ask why no one is really putting the best minds at big pharma into looking for this as a unique and new application for which actually there'd be no competition currently.

Mr. Shestack: Wait a second. One of the reasons is typically, among others, big pharma waits for academic -- for a big hit out of academia, whether it's going to come from neuroscience, from the imaging stuff we were talking about, or whether someone's going to find a couple of genes, that's what they wait for. And so honestly, I know you hate when somebody says like throwing money at a problem doesn't solve it, but actually a little bit more resources to get the first big biological hits is probably the most direct thing that the NIH could do to get pharma

to invest. I know that's not what any of us really want to hear.

Dr. Vitiello: Yes, but, John, we kept genes for rats syndrome. And I think it's extraordinarily difficult, and of course there isn't a lot of interest in private industry to develop genetic therapy for Fragile X.

Mr. Shestack: The point is, it's finding a pathway. And the other thing is, it's not a competitive sport. But there's what we now know is there is a much bigger market. There are a lot of people who have autism. So it still has to be encouraged.

Dr. Carbone: My sort of ignorant bias, being a neurovirologist backed into autism is that I think part of the problem is the lack of a good biological model in neuropsychiatric diseases in general. I had a discussion with someone very prominent in schizophrenia who said we don't need an animal model. I have 100 schizophrenic brains in my collection. And I said, when does schizophrenia develop? She said, I don't know. I said, what's the mechanism of damage? I don't

know. How do the drugs work? I don't know. What's the average age of the brain? Thirty-one. But you can't tell me if it develops -- is it a developmental disease in utero? I said, you know, I think you do need an animal model. And I think that drugs are the same thing. We actually have explored our model of disease virus using several different drugs and have found two things. One, that some are effective in the species- specific behaviors we measure. The second thing is we found genetic background effects. We have a couple of publications on that, that it used two different drugs in two rats with the same infection at the same time, that we have different outcomes because they come from two different strains of rats, and we're currently working on that. So I think it would be interesting if we could at least begin to look at some possible interventions based on some animal model systems, because that way you can explore a large number of drugs fairly cheaply. Clinical trials are very expensive, and obviously there are ethical issues.

Dr. Insel: Let's move along here. And the next presentation will be from Ben Vitiello focusing one specific finding recently around the atypical antipsychotic risperidone. Ben, your particular Powerpoint presentation here is not what any of us would have expected. [Laughter.]

Dr. Insel: If only we could hear it as well as we could see it. [Laughter.]

Dr. Vitiello: I am Ben Vitiello. I am with the Child Treatment Branch at NMIH, so what we do we basically are clinical trials to try to test the effects of treatment in kids. And research in autism is part of our program. I am going to report briefly on a study on the use of risperidone in children with autism and serious behavioral problems. Most of what I'm going to say has already been published in the New England Journal of Medicine in August. You might have already seen the paper. If not, if you are interested, I have copies there. You can just take a copy. The idea here is not basically to cure autism, because we don't think that risperidone unfortunately kept that promise. The study was

launched in order to see if risperidone could be helpful to alleviate the serious behavioral problems such as self-injury, aggression, agitation, severe compulsive behavior that impair the life quality of children with autism. As has already been presented by the previous speaker, agents that are called antipsychotics, meaning that are used to treat psychosis, have traditionally been used to control also behaviors such as self-injury, agitation, aggression in patients. And they have side effects and they are being replaced in the last ten years by the so-called atypical, which is a second generation of medication that is better tolerated not only, but it seems also to have efficacy on the so-called negative symptoms of schizophrenia. There are no good symptoms of schizophrenia, but basically the symptoms are divided into positive, which means hallucinations, delusions, and negative, which means social withdrawal, poverty of thinking, for instance, cognitive impairment. And it looks like the atypical are good also for the so- called negative symptoms. So it's very relevant to study

atypical in autism, because there is also some hope that it may also improve the ability to interact socially and to think more clearly for these patients in this condition. [Slide.] Now the study was conducted by the Research Unit on Pediatric Psychopharmacology, which is a network funded by NMIH through contracts that was established in '97, with the purpose to test medications that act on the brain that are commonly used in our communities off label without having data, good data to support the efficacy and safety. Dr. Carbone has pointed out that once the drug is approved, it goes into the community, clinicians start using it for indications that are not what was originally approved. So the purpose of RUPP, as we call it, was to try to fill the gaps for those conditions that were more important for kids. So there was a particular group of RUPPs that identified risperidone as being something of public health importance because it was commonly used to manage severe behavioral symptoms in the context of autism, is used off label. There was little interest from industry in this type of

research, and there were not enough data to support its efficacy or safety. [Slide.] This particular group of RUPPs included researchers at different universities, including also researchers at NIMH. It was monitored by the Data and Safety Monitoring Board of NIMH that review the data periodically every three months. [Slide.] Basically, the study enrolled subjects: children aged 5 to 17, with autistic disorder. So this is not autism spectrum disorder. It's just autistic disorder and severe behavioral problems such as self-injury, aggression or agitation: One hundred patients. Patients were randomized, and they were randomly assigned to receive either risperidone or a placebo for eight weeks. The main hypothesis was risperidone would be superior to placebo in improving the behavior by alleviating impulsive, aggression, agitation and self-injurious behavior. [Slide.] The design basically was a double-blind placebo controlled study, an eight-week double-blind control phase, followed by another period of four months for those patients who have improved. Basically it was double blind, and then there was

an open-label trial for those children who were assigned to placebo, and they didn't improve, just to be fair to everyone. So if you were randomized to placebo and you wouldn't improve on placebo, you were offered at random study eight weeks of risperidone in open label. And if you are a responder, you enter into a four-month, open-label extension, at the end of which there was a double-blind placebo substitution so that patients were randomly assigned either to receive placebo and continue risperidone. And the purpose of this was to see if you still needed to continue taking risperidone after having improved for six months. [Slide.] I'm skipping forward. The dose basically varied according to the weight of the child. So the study dose was 0.25 for very young kids with a weight below 20 kilos, was 0.5 for kids who are older, and the maximum dose, it was titrated based on efficacy, on clinical response and presence of side effects. The maximum dose was 2.5 for the younger children and 3.5 for older children a day on a BID, meaning twice a day schedule. [Slide.] It just shows the variables of the sample, and the

randomization actually did its purpose, meaning that all these variables were basically balanced very nicely like age, sex, ratio, ethnicity, tanner stage were quite comparable in the two groups, risperidone and placebo, which is what you want in a randomized clinical trial. [Slide.] And also the psychopathology as measured with this ABC scale that was developed really for kids with developmental disabilities was sort of comparable in the two treatment arms. That's really what we want. [Slide.] And other variables like family income, living situation, IQ were also comparable in the two groups. By the way, most of these children suffered from mild to moderate mental retardation in addition to autism. Only about 5 percent had normal IQ. [Slide.] This slide shows you the main result at eight weeks. This is the severity of the symptoms. If the symptoms go down, it's good. This is the actual curve with all the points. The straight line is the random regression line, so it would give you the average basically for the group. So the red is placebo. You see there is some decline, but not that much. And this

is the risperidone. So there is quite a huge difference between the two treatment arms that is highly statistically significant and also highly clinically significant. [Slide.] And if you want to plot the number of patients who are called the responders at the end of eight weeks, you see that about 80 percent in the risperidone were responders and less than 20 percent of the placebo were responders. [Slide.] Now clinical trials, unfortunately, present the data in a sort of a group mean, in a sort of probabilistic way, so it doesn't tell you too much. It doesn't give you a sense of how much the drug actually helped the individual patient. So what we are also doing now is doing another analysis of outcome data using the so-called target symptoms, which is an innovative system that we introduced for this study where basically if a child met all the inclusion criteria for the protocol, the parent was asked to identify the two major behaviors that were really of concern to the parent, and the improvement of these target symptoms was monitored throughout the study. So then we are able to see

what is the impact of the treatment not only on the average symptoms of a child but on those very top concerns and complaints, you will say a chief complaint if you're a clinician, that brought the patient into the protocol. This is a paper in preparation that we need to submit. But to give you just an example, just a flavor of the type of problem. So at baseline, tantrums twice a day lasting 10 to 15 minutes each. Throwing self on the floor, flailing arms, breaking furniture, hurting other child if in the way. Incidental damage to self. Parents won't take out in public. At random study for this particular patient who was a responder, tantrum twice in past week. So tantrum still present, but not every day now. Twice in the past week, lasting about five minutes each. Stomping and screaming without damage or injury. Stays off of floor. Parents now willing to take out. Just an example, so that it does make a difference. It does make a difference, improves also social withdrawal, improves stereotypies, improves hyperactivity and also inappropriate speech, very little. This is an effect side. The

larger this number, the greater is the difference of the risperidone versus the placebo. So on hyperactivity is a big effect we say. On inappropriate speech is a small effect. [Slide.] However, the improvement has also several drawbacks. And one of the major drawbacks is that there is a significant weight gain. On average, these children gain almost 3 kilos, which would be six pounds, in the eight weeks, in two months of treatment. With the placebo, only one. There was also fatigue. There was drowsiness and there was tremor. The good news is that the so-called neurological extrapyramidal side effects were fairly mild, besides tremor. But kids didn't have dystonias, which are abnormal movements that sometime affect the neck, mainly the neck or the face or sometimes a finger. So that was the good news. But still there were side effects that were sort of worrisome. [Slide.] When the children were switched after improvement to placebo, there was a high incidence of relapse, you know, 62 percent relapsed. Interesting that 12 percent relapsed even if they stayed on risperidone. I call this

the nocebo effect, meeting the expectation of worsening. When you do a placebo control and you want to improve, you introduce a drug, there's an expectation of improvement, you've got a placebo. When you discontinue the drug there is an expectation of worsening, so everyone gets worse and starts reporting symptoms. And so this is the nocebo effect, which is interesting for us in the clinical trials. What is interesting is that there is about one-third at least of children who do not relapse. And so it will be interesting to know which ones are the ones that don't require long-term treatment with risperidone. Unfortunately, the study has a small sample size, a small sample size because the DSMB stopped the study because we had reached a significant result, and they didn't think it was ethical for us to continue randomized patient into placebo, and so they told us stop the study because you have reached a conclusion on the primary hypothesis, and the subgroup analyses are not the primary purpose of the study. So, unfortunately, we cannot comment on which subgroup of patients may be more likely to stay well

without the risperidone after having improved for several months. [Slide.] I think I need to stop. But the conclusion basically is risperidone works, it does make a difference. If you want to express in numbers, this is the NTT, which is sort of public health expression of how powerful a treatment is, is 1.7. It means that if you treat -- you need to treat only on average 1.7 children in order to add one to those who will improve regardless of a treatment. So if you imagine to treat 1.7 children, 0.7 will improve by itself without the treatment, and one will improve because of risperidone. That is a very high number needed to treat. That is much greater than an antibiotic, for instance. For instance antibiotic for an ear infection has a number needed to treat of 5 or 6. So of 5 kids you treat for otitis media, 4 will improve spontaneously. Without antibiotic, only one would be because of the addition of the antibiotic. There are significant side effects. Discontinuation results in relapse, but not in all cases. Unfortunately, we don't we know which subjects again. Again, you know, if you

want, you can take a look at the paper. You can stay tuned, because these analyses are also coming out and will be out in the next few months. Thank you.

Dr. Insel: Thank you, Ben. How about questions or comments?

Dr. Zeph: Are there any data around long- term use? I know in this particular study you said that you had to stop following them or you had to stop the study. Is there any attempt to follow in terms of long-term use?

Dr. Vitiello: Yes. When at the end of six months basically the patients were discharged to the community, so it was up to the clinician to continue treatment or not. We are in the process of rechecking these patients and reassessing them one year after discharge from the study to see how many are still in treatment, what their experience was, why they discontinued treatment. We have so far data on about 70 percent of them. So in the next few months probably we will -- we are trying to get at least 80, 90 percent of information on the subject.

Dr. Carbone: Now that you have these very encouraging clinical data, are there any plans to sort of advance to either something more mechanistic or trying to look for changes in markers of some sort, functional MRIs, serotonin metabolism, dopamine metabolism, anything that would lead you to a better feeling of mechanism? Typically, sometimes you start with Drug A and it's somewhat effective, but you can refine the drug with more information to become more effective the next generation.

Dr. Vitiello: We are not directly doing that because the purpose of RUPP basically is to test treatment that are used off label or in the community. But I think what you're suggesting is very important. It probably is the only way to go, meaning not to have a palliative improvement only but to go to the core of autism, and I'm very interested in that. Actually in about one year ago, we had a workshop here in Bethesda focused on Fragile X. This is connected back to the discussion we had before. And to say since we know for Fragile X what the gene is, we know what the

protein there, you know, what can be done with this information instead of just saying fine, you know, we have hit one disorder? How can we apply that information as a prototype for genetic therapy? And so we tried to steer activity in that. But again, I don't know how much is going on right now.

Dr. Insel: Just to follow up on that question, we know that the atypical antipsychotics differ in terms of their in vitro pharmacology. Is there any evidence that risperidone, for instance, would be different than any of the other compounds based on just even anecdotal clinical experience? Dr. Vitiello: There have been studies on alanzapine, for instance. As far as I know, no. I don't have. Certainly risperidone is probably the more typical of the atypical, and there are other atypical that are more atypical. But I don't know if this translates into a differential, more targeted efficacy for children with autism.

Voice: Along the same lines having to do with the side effects, could it be that some of the other atypicals might be less likely to cause the

obesity? Are there an interventions that are good for planning for that and trying to keep that side effect down?

Dr. Vitiello: Yes. There are atypicals that don't have the weight gain, like ziprasidone, for instance, already on the market, and aripeprizole is coming on the market now. So those drugs could be worth looking at just because they seem to have, not to have the weight gain problem.

Voice: Also, there was a paper just this month or last month in Developmental Medicine Child Neurology by Dr. DeLong at Duke about -- he's been studying Prozac or fluoxetine for a long time, and particularly in children whose families have a high incidence of other affective disorders. Children with autism whose families have affective disorders. And he feels strongly that there is a link there, in terms of getting back to the question about the genetics. And I think that's an interesting question.

Dr. Vitiello: I don't know the paper. I will take a look.

Dr. Insel: One final question. It's actually kind of a sensitive issue, but I'd like to maybe get both your thoughts and Dr. Carbone's thoughts about this. We know from the educational intervention perspective that the earlier you intervene, the more likely the beneficial effects will be and the more long-lasting. I don't know how comfortable people are in giving risperidone to children at a very young age, right after they have been diagnosed. But it looked like the mean age in the study that you cited is about 8 or 9 years.

Dr. Vitiello: Eight, yes.

Dr. Insel: So is there, again, experience at all with intervening at a much earlier time pharmacologically to find out whether there is a greater benefit or perhaps even a worse outcome by doing that? Dr. Vitiello: It's a very important question that can only be answered with long-term follow-up and treatment. On the short term, we look at age as a possible moderator of treatment, and we found it was not a significant moderator, meaning that both the young and the old kids

tended to respond pretty much in the same way, even though the younger for some reason have a slightly greater placebo response, but it was sort of a trend.

Dr. Cordero: A follow-up to your questions. I think one of the questions in a study like this is whether in fact the drug is having an impact or an effect on the disease itself, or really on the secondary conditions and complications that these children are having. Especially when I think you have something like 30 percent of this group have moderate to severe MR, one wonders whether this is really sort of a typical child with autism or it's just a subgroup. So I think that's really an important question to try to figure out.

Dr. Carbone: You probably know more than I do about this, but I was discussing with Dr. Lind at Hopkins, she had some interesting paradigms for pre-verbal testing, eye contact, et cetera. And the question would be -- there are sort of several questions. But one might be very simplistic of short term. In other words, load a child, give them enough drug to be confident that you'll have

an effect maybe even literally for days, and measure a short-term outcome. Do you get an improvement in a particular autism, pre-verbal autism indicator? Because I think that kind of a study -- now don't quote me that the FDA would approve that, okay? [Laughter.]

Dr. Carbone: I'm not speaking as an FDA person. But, for example, from a risk point of view, that may be perceived as a smaller risk than say a several month trial on an infant, at least to get some data that advancing to longer therapy might be of value. And I think the type of drugs one picks might be different based on trying to heal the damaged brain versus protect a being damaged brain. But I think we're well out of our understanding of autism at that point.

Dr. Kallen: I think the RUPP study is to be commended for the design and the execution of the study. This is exactly a model of how it should be done. Unfortunately, there may never be a treatment for autism in the medical sense. And one of the things that we really don't understand, because we don't understand autism, is really

what's happening at the micro level, the micro environment in the brain when you're using a psychopharmaceutical therapeutic agent in terms of receptor turnover, effects on synthesis of new transmitters, how they're released, effects on messenger RNA or whatever. There's so much there in a black box that we don't understand that could be very important in terms of how the brain is remodeled in terms of learning if one is using ABA or whatever. We're hoping that the network of dendritic processes or whatever are reinforced in those pathways that need to be reinforced and regressed, and others that are not the favored pathways. We are literally flying blind. But the cautionary note is what are the long-term effects of these medications on a young, developing brain, albeit a brain that has significant problems?

Dr. Insel: A last comment from Barry.

Dr. Gordon: Actually, this is in response to yours, not to comment on yours. Were you alluding, Tom, to the prophylactic treatment of schizophrenia development study? And if so, how has that been turning out, or is it too early to

say? Because that's the model in a sense you were bringing up. Namely, we think we have an effective drug. Maybe if we hit before the children become symptomatic, it'll be better.

Dr. Insel: That's the model. Actually I don't know what the results of that look like. Richard may know more about that than I do. I think that's at a very, very early phase. I don't think there are any results, certainly nothing has been published and a lot has been talked about. But I don't think we're at the stage of actually having numbers to look at.

Dr. Nakamura: NIMH has decided it would not sponsor those studies because of the ethical question about treating individuals who may not ever develop symptoms of schizophrenia. Most of the studies that we're looking at right now are trying to intervene as early as possible after the initiation of symptoms rather than that. Though I know there are individuals looking at the question of prodromal symptom evaluation.

DR INSEL: Would you like to comment, Ben?

Dr. Vitiello: Yes. There is actually a report in the archives of General Psychiatry I think this month or the previous month by Patrick McGrory from Melbourne in Australia. You randomize basically adolescents or young adults who have so-called prodrome, meaning that they get symptoms of you would say incipient psychosis almost because of their disorganization even though they didn't have fully criteria for schizophrenia. Randomize either to take a low dose of risperidone or just management in the community. And he is reporting on a trend toward a little better prognosis event of I think it was two years. But it's very subtle. The sample is small. I found that it was not really a convincing study yet.

Dr. Insel: Okay. I think we need to move along. The final session will be an opportunity for public comment. Rick Rollens is the first in line and perhaps not surprisingly, but we're all looking forward to hearing from you. You didn't have a chance to say what you wanted to earlier, so this is a good opportunity.

Dr. Rollens: I do appreciate that. I don't think -- we would be terribly remiss as an organization and I think as an autism community of all the people here today and parents throughout the country and everyone who is dedicated to finding the causes and cures for autism to not recognize the wonderful addition of Dr. Tom Insel as the new director of NIMH. I think one of the best things that's happened to this field is your taking that position. [Applause.]

Dr. Rollens: Now you'll let me talk when I get up the next time. [Laughter.]

Dr. Rollens: Secondly, another point I just wanted to make, I think all of us kind of take away from this meeting that we're not doing a very good job of really subtyping autism. And again, you know, we see these results from various studies and tests. It doesn't matter if it's a clinical intervention or a biological research program, but we keep getting mixed results. And I think a real priority for all of us, and I know at the M.I.N.D. Institute we're adopting this philosophy of doing a much better job of subtyping

and sub-classing autism. Thirdly, I just wanted to mention on the screening issue that we need to be doing a much better job getting people who are capable of diagnosing autism and pediatricians to diagnose autism when they see it and not to delay the diagnosis. This is a major problem in the community. Every day all of us see children that we know are on the spectrum or have level one autism, but there's a general feeling in many parts of the country particularly that if we just wait and see if this child grows out of this condition then it's better than telling the parents that the child might be at risk. And lastly, a little bit about the autism epidemic and its effect on services. During the break, one of the good things that happened when I wasn't able to speak when I was first up here is I got on the telephone during the break and called the director of the Department of Developmental Services in California to get an age breakdown of the number of cases of California and who are these cases. And I think you'll find these numbers absolutely shocking. Keep in mind in California we have an

early start program, zero to three kids are put in an early start program. We only have .07 percent of our total number of cases of kids zero to two, so we're not talking when we report these new numbers of cases of any children really under the age of three years old, a very small number of children in the zero to two groups. When you add up the numbers, 50 percent of all the cases of autism, level one autism, not including PDD, NOS or Asperger's, are under the age of nine years old. Fifty percent. You move it up the next notch, two out of three children are within the ages of zero to 13 years old. Move it up another notch, you move it to 80 percent of the folks who were born after 1980 or are under the age of 21. So in a system where we've had a difficult time up to this date of trying to provide services for adults, we only have less than 3,000 adults with autism in California. We're adding more than 3,000 new cases of children every year to California's developmental services system. This is one state and one set of a data from a system that's been around since 1969. So if we thought we had

problems providing services for adults today, the picture is pretty clear. Thank you.

Dr. Insel: Go ahead.

Ms. Ruppmann: I wanted to share some information and an invitation to you, and that's why I called ahead and said can I bring my stuff and they said yeah, but bring 80 copies. So I schlepped these on the Metro, and my husband dropped me off at the station at 7:30 this morning, and by gum, I'm handing them out.

Dr. Insel: Can you identify yourself so we'll all know –

Ms. Ruppmann: Yes. I'm Jamie Ruppmann and I'm the parent of a 31-year-old son who has autism, and I'm Director of Governmental Relations for TASH, which is a 25-year-old organization, an advocacy and human rights and civil rights organization representing people with the most significant levels of disability. I'm also the past Government Affairs Director of the Autism Society of America, and the past president of the Virginia Autism Society of America chapter. So I'm an old mom who's been around a very long time. We

received funding, TASH did, from the Nancy Lurie Marks Family Foundation to bring together a group of adults who have the label of autism, some who have verbal communication, some who use various forms of augmentative communication, some, yes, who use facilitated communication and require support for typing. We met with them in May of this year in Boston, and it was quite an interesting and powerful day. The subject was public policy and how it affects the lives of individuals and the growing increasing power of people with disabilities in making public policy and in utilizing public policy to improve their lives in ways that they direct, and were in fact people with autism interested in becoming part of that movement, and did they have something to say about that. And we found that they had a lot to say about that. And the outcome of that is in our TASH Connection, which we tried to report out. If you'll hand those around -- we tried to report out as to just as fast as we could get things written down and recorded and said, what folks had to say about their lives, because they had very

meaningful and as you can imagine, very poignant things to tell us. And that was not a surprise. I have to in full disclosure I will tell you that this nice looking guy right here that says choose to work, that's my son Stephan. That's at an employment rally summer before last, and he was asked to be a speaker. This man here, this handsome man, 31-year- old man, didn't have verbal language until he was almost eight years old. He was eight years old and he had never come to us and asked us a question or made a declarative statement. So it's a big day for us when he stands up in front of a large group of people on the grounds of the Capitol to talk about what it means to him to be employed and how he feels about that and what his feelings are about a self- determined life. We are following up -- this is the point of introducing myself to you -- we will be following up at our TASH National Conference with two more meetings. John O'Brien is coming up to meet with our folks who have autism, and we've increased that group. This is a larger group of adults now. He's going to be working with them on Tuesday,

December the 10th, and they're going to be finalizing and really firming up some of their vision that they worked on in May. And then on Wednesday, I'd like to invite everyone here, because I know of your commitment, as many of you who might be able to come or come to represent your organizations or agencies, to a meeting that we're going to have to really set up a dialogue to talk about what are the barriers to people with autism really becoming part of that self-determining group of adults with disabilities who are making such a difference in terms of the direction that our government and our Congress is taking when they start looking at services and supports. And I think because of the emphasis today and our concern about our adults, their futures, their retirement, and our young adults coming out of our school settings into relatively a void for services, I think the idea that they could partner with us to begin to set that agenda, to begin to help us as their parents and researchers and service providers to set that agenda on what those services should look like and

what they really need and want in their lives. I think that we probably think we know all that they want and need, but they told us in no uncertain terms that they felt that we were underestimating them. And I think there have been many stories here today about expectations. And we had a very interesting sort of a revolution among that group of folks. I think this is a conversation you would enjoy, and we encourage you to think about coming. That was my message today and also to thank you so very much. I'm a very old mom, and some of this I've heard, and some of this we've been working on a very long time. It encourages me, on the one hand, but discourages me on the other hand and almost makes me feel like I need to apologize maybe to the younger families to say that, you know, we've worked very hard over these years since our children were diagnosed, and still so much of it we haven't fixed. Still so much of it we're discussing. Still. And yet we know what the potential can be for our kids. So, on the one hand you have a feeling of sadness, and on the other, great hope for the future. Because this parent

movement has become extremely powerful. I was part of that generation of parents who did the first knocking on the door to say parents are your partners. Parents are the power here. Parents and people with disabilities are going to make the difference. You need us. And I think today is really proof that we were right. That the partnership and the collaboration between the research and practice and families and people with disabilities is going to be what makes the difference. So I have no doubt in mind that within ten years we'll be having a completely different meeting. So, God bless all of you in your endeavors, and thanks so much for having such a good meeting today. And here are some more invitations. Thank you.

Dr. Insel: Thank you. I think we need each other actually. Other comments?

Ms. Polinsky: Hello. My name is Bernice Polinsky. I'm from Long Island with Pat Schissel. And I'm nervous because I'm not used to standing in front of a microphone. But anyway, I just wanted to continue with the discussion about 3,000

people who are adults in California with diagnosis and just to explain the reason why there's only 3,000 people with that diagnosis is because they're getting the wrong diagnosis or they're not getting diagnosis. And people are afraid to give the diagnosis or they're in hospitals with a mental health diagnosis. They're dropping out of colleges. They're not getting jobs. I co-facilitate with Linda Geller from the Cody Center a support group for parents of older teens and adults, and every day we're getting phone calls from parents of adults and teenagers who just got that diagnosis. They're falling through the cracks. The numbers are increasing immensely, and it's because of the increase in these children and adults that we're seeing large numbers in addition to every other reason that we're hearing. That's one of the major reasons. And we're very, very happy that you're doing this research. And we're very happy to explain also that great numbers are because of the adults that are being diagnosed.

Dr. Insel: Thank you.

Ms. Chase: Again, thank you. As everyone else said, this has been quite an eye opener for me, because this is I guess one of my very first opportunities to be among the professionals that are doing the research, and I thank you so much.
Dr. Insel: For the purposes of our tape, it would be good if you could identify yourself.

Ms. Chase: I'm so sorry. Hi. I'm Shari Chase. And as I mentioned before, I'm the mother of a six-year-old boy who is diagnosed with autism, and there are three points I just wanted to make. One, I'm hoping that there will be more emphasis put on the environmental issues. My son, my whole family was poisoned by arsenic through a lawn product, and as I said before, his development had been completely followed up to, I had said 18 months before, but it actually was 20 months. And through testing of myself, we all started off by losing our reflexes and our feeling in our hands and feet which normally children with autism don't have that experience. It's been four years now and last May he finally got his reflexes back. But as a result, he was developing normally, he has autism.

There are many skills that he has that are atypical of a child with autism, as his doctors have said, that he does have. That said, I just really would like to emphasize that I hope the environmental issues such as heavy metals and pesticides is not overlooked in the research, because that's something we could do. We would work on that. That isn't something where we have to look into an animal's brain. I mean, I guess we do. We have to see the effects. But if it's proven or if they look into the fact that children, the reason we're having such high increases is by having exposures to pesticides and heavy metals, then we can stop that exposure, and then we could look and if there's anything, any pathways that can be changed in those children's brains to try to improve them. And I think it would lessen the amounts of research that has to go in and we could get to the heart of the crux of the problem. So, again, I would hope that you all as researchers will look towards that and not only put all your eggs in one basket with the genetics. I'm not saying that my son possibly was genetically

predisposed. I think there is a straw that breaks the camel's back. So that said, that was one thing I wanted to mention. The second thing with the diagnosis, I think there's a lot more children that we're not hearing about that had the diagnosis of autism, and the reason we're not hearing about it is, such as my insurance company. I had a phone call from my insurance company when my son's medical records went into them that I needed to go back to the doctor and get everything stripped from his records that were autistic because they would stop covering him for any medical coverage such as speech therapy, occupational therapy, developmental. So I did that. He's still autistic. He's no different than he was the day before, but the assistant to the medical director of my insurance company was kind enough to do that, because she said, you know what? I have an autistic son, and you will not be able to pay for this out of your pocket. And I think that there's a lot more children that are autistic. So that's a second issue I wanted to bring up that something needs to be changed with

the insurance companies. And the third item I wanted to bring up is I'm not exactly sure -- did you say this? That if you do not search for it you will not find what you don't look for? Lucille had said that. Well, in addition to that, if we as parents, researchers, teachers do not appreciate what it's like to be autistic, then it's very difficult for us to appreciate what needs to be done for them with the interventions. And there was a fabulous video, and unfortunately, the name of it escapes me, but I would be more than happy to find out, that in Howard County, Maryland, the teachers are required to observe. And what it is is there is a group of teachers who are put in a room and they are put through different types of work skills, such as -- Fat City. That's exactly what it is. Every single person needs to see it. I think we need to all go through that training. But if we all see it, we could suddenly appreciate what it's like to be autistic. One example is I went to a seminar and they had us all put on snow gloves, and we had to button and unbutton our jackets. You can't button and unbutton your jacket

with snow gloves on. If you can relate that your brain, looking at instructions on a sheet, and if the processing, everything is going like that, that child can't focus on that. Well, anyway, that said, if all of you can somehow get your hands on Fat City, and that might be a very good public information source, because if that's required not only for the teachers to see and health care providers to see, but if it's something that's put on TV, maybe CNN could put it on or whatever, it will just suddenly open a lot of people's eyes. So with all that said, I thank you again so much. I'm new to this, but you will see me for the rest of my life campaigning and trying to find whatever funds I can to help you all do your work, and God bless you all.

Dr. Insel: Thank you. Other comments? [Pause.] This is a surprisingly quiet and non-contentious group.

Voice: Well, since you asked.

Dr. Insel: That was a challenge. That was a challenge.

Ms. Schissel: One of the problems that I find, I run a support group also, but for the school-age kids, if you can take one child, send them to four different doctors and you'll have four different diagnoses, which is very confusing. I don't know what any of you can do about that. But there's not any consistency. And it makes it very difficult and very confusing within all of the communities. We're on Long Island, and the school classification has to be autism. It's most helpful for a school classification. In New York City, that's absolutely a classification you can't have, because you'd be going into a class for mentally retarded. I don't know what happens in other states, but there's no consistency across the country. So we're in Washington, and I work with a bureaucracy in a school system, and I feel as a Board of Education member I have a lot of, you know, control at that level. So I have no idea at this level what you can do. But the consistency is so helpful. On Long Island, on a state level I know it's difficult. On a national level I'm sure it's that much more difficult. But if there's some

consistency that can come top down in terms of diagnoses, in terms of school classifications doing that would be so helpful to parents. First of all, obviously the A word is like the C word was in the fifties, which is a big problem. So what we do on the support group level is stop that immediately and help parents get used to the word autism, so that's helpful and we're all doing that here. And those are the kinds of things. Okay. So I wasn't quiet.

Dr. Insel: Thank you very much. Barry?

Dr. Gordon: I'd like to comment on that. I'm a physician and I'm also a parent, and we run into issues of coding all the time. And frequently we discovered that the physicians often agree on what's there, but they disagree on just how to weight it and how to force it into some of the categories they have. So some of that difference that you hear often doesn't exist at the level of data description and behavior. It differs I think at the level of just how much weight and how much confidence or unconfidence the person will have in telling you something, giving an answer. And we

also saw that the medical diagnosis doesn't have anything to do with the educational/social/political diagnosis at all. And as one of the I think you mentioned the coding where somebody was told to strip it out from the diagnosis for the insurance not covering it, I think we've seen the same thing in the education level where different educational systems will take the same medical records and code them somewhat differently, much to our surprise. And I don't know if there is a solution for that except to recognize that it occurs at several different levels. That there's a medical level where there's disagreements and there's an educational coding level where there's also disagreements, and then there's an insurance level that will probably disagree with everything.

Dr. Vitiello: But there are the technical instruments to solve this disagreement. There are validated interviews with the parents that has been found to be reliable and valid. It requires training, like autism diagnostic interview that was developed by Michael Ratar and another

researcher here in the United States like Ettie Lord. In some ways, if one wants a good quality diagnosis that has good validity, it is possible. The means exist. It's just a matter of applying them to the community.

Dr. Gordon: I wasn't denying that. In fact, I know that the ADOS, the ADI have tremendous reliability and stability and in fact have been extended down to a fairly young age. The problem of course, and I would let others address that, is it doesn't seem practical for people to use them. It takes an intensive training session to become reliable in them. Nobody has such people waiting around for the autistic individual to show up. And I don't know what mechanism the U.S. health care system would have for funneling all the potential children that might be diagnosed into specialized centers where that could be done with a greater reliability.

Dr. Rice: I'd like to speak to the issue. In terms of the data, it's certainly one thing –

Dr. Insel: Could you also identify yourself?

Dr. Rice: Oh, I'm sorry. Cathy Rice from the CDC. In terms of getting consistency within community diagnosis, that's certainly a challenge. We may have some data in the CDC surveillance studies that we're doing that can speak to this issue int he future as we collect surveillance data on the incidence and prevalence of autism. We're looking at behavioral descriptors. We're using diagnostic codes and educational classifications as a way of identifying kids. But we're not only looking at kids who have a previous autism spectrum diagnosis or classification, then we can look at kids that clearly have the behavioral patterns associated with autism but weren't labeled that. So in the future, we should have some data that will help at least inform this discussion a little bit.

Dr. Rollens: In a system in California that's been in place since 1969 in dealing with developmental disabilities such as mental retardation, cerebral palsy, autism and epilepsy, there's always a concern about is the diagnosis correct. And again, in our system, it's an

exclusive system. That is, if you don't meet what is considered level one autism, which is the DSM for autism, then you are not qualified for services. You're not added to the system. That does not include PDD, NOS, Asperger's or any of the other autism spectrum disorders. So the $1 million, three-year study that was just released a couple of weeks ago out of the M.I.N.D. Institute went back as one of the factors to look at are we getting this diagnostic issue right? Are in fact these numbers that the Department of Developmental Services is producing every quarter about the number of new cases, is it in fact autism or are we calling it something else or called it something else in the past? They went back and rediagnosed these kids using ADI and ADOS and in fact found an 85 to 90 percent accuracy rate on in fact the kids that were called level one autism cases were in fact kids with level one autism according to ADOS and ADI. So if anything, I think we're missing -- the numbers out there are clearly larger I can say in our state when you're not including the entire spectrum of autism, including

PDD, NOS and Asperger's in these numbers, and these horrific numbers that we're seeing which now autism is the number one disability coming into California's developmental services system. It's gone from a 3 percent of the total number of intakes to 40 percent over a 20-year period. This is like absolutely shocking to the folks in our system and in our state who've been around since the inception of our system in 1969.

Dr. Insel: I'm beginning to feel that it's been a very long day. People are starting to look a little bit worn at the edges. It may be time for us to wrap this up. I think in summary, if I can take just a moment, I found this discussion really very hopeful, but I think as the day went on, it became clearer that we have the makings here of really a working group, not just a group that will be convened based on some mandate. I think there's a real interest here in getting some things done. And it sounds to me like the subcommittees will be a very helpful part of that process. The next meeting is tentatively scheduled for May 13th. We may need to reschedule because of a possible

conflict with the CPEA meeting. But if we can do it, we'll shoot for May 13th. In the interim, the hope is that the subcommittees will continue to work together and that we can use that meeting really just as an update on their progress. We're available to help in any way that we can. We'd like to be able to use the Web site to at least provide the records of everything that's taken place at this meeting, including the Powerpoint slides and any of the documents that are relevant we'll try to maintain some links to. It would be helpful in the next few weeks if you have particular items that you would like to have on the agenda of the next meeting if we could have those brought up fairly soon and we can try to schedule that. And any other suggestions you have. In fact, if we have a minute now, if there are suggestions you have for the format of the meeting, we might take a moment to listen to that as well and try to make this meeting as useful as possible. Any particular strong feelings about that? Should we plan the next one much along the lines of this one with updates, progress reports

and some new findings as they come out so people know about them? [No response.]

Dr. Insel: And then the real challenge is to make sure, particularly in the services arena, that we have people talking across agencies that we know about what the options are for things that can be done collaboratively. We will try to make sure that next time we have someone from the Medicare/Medicaid program from CMS who can help us with some of the details of that as well. If there are no other comments, I'd like to thank everyone who participated today, and particularly those of you who came from far away. We really appreciate your taking the time and the effort. And those of you who were available for public comment, extremely helpful. That's right. I think Lee Grossman gets the record for coming the furthest.

Mr. Grossman: I always win this and the prize always is a round trip to Hawaii. [Laughter.]

Dr. Insel: There has been a recommendation that the next meeting be held in Hawaii.

Mr. Grossman: It definitely works for me.

Dr. Insel: Maybe it will be a subsequent one. Thanks to everyone for participating. [Whereupon, at 4:55 p.m. on Friday, November 22, 2002, the Interagency Autism Coordinating Committee Meeting adjourned.]