

**Department of Health and Human Services  
Interagency Autism Coordinating Committee  
Meeting Highlights  
November 18, 2005  
National Institutes of Health  
Bethesda, Maryland**

*IACC Members in attendance:* Thomas Insel, M.D. (Chair), Ann Wagner, Ph.D. (Executive Secretary), Duane Alexander, M.D. (represented by Alice Kau, Ph.D.), James Battey, M.D., Ph.D. (represented by Baldwin Wong), Carolyn Clancy, M.D. (represented by Padmini Jagadish), José Cordero, M.D., Elizabeth Duke, Ph.D. (represented by Merle McPherson, M.D.), Sybil K. Goldman, M.S.W., Barry Gordon, M.D., Ph.D., Lee Grossman, John Hager, M.B.A. (represented by Gail Houle, Ph.D.), Story Landis, M.D., Mark McClellan, M.D., Ph.D. (represented by Ellen Blackwell, M.S.W.), Patricia A. Morrissey, Ph.D., Jon Shestack, David Schwartz, Ph.D. (represented by Cindy Lawler, Ph.D.), Susan Swedo, M.D., Andrew von Eschenbach, M.D. (represented by Kathryn Carbone, M.D.).

## **Introduction**

Dr. Thomas Insel, Director of the National Institute of Mental Health (NIMH) and chair of the Interagency Autism Coordinating Committee (IACC), called the committee's seventh meeting to order. After the other members introduced themselves, Dr. Insel shared a few observations he had made at the 2005 meeting of the Society for Neuroscience. He observed that there was a striking increase in the number of posters and abstracts on autism at the 2005 meeting. In addition to the more than 100 such presentations, a satellite workshop was devoted to autism for the first time. These developments reflect the growing interest in autism. Reports from Federal agencies followed.

## **Health Resources and Services Administration (HRSA)**

HRSA representative Dr. Merle McPherson noted her agency's responsibility to develop community systems of services and support for children with special health care needs and their families. The agency's work on autism is supported through its existing appropriations and defined legislative and judicial responsibilities. It has no earmarked money for autism services, but supports them through State block grant and discretionary grant programs. Dr. McPherson said that HRSA is increasing its efforts to inform grantees that their programs may include children and youth with autism. HRSA has taken the lead in a work group that, since June, has been developing professional guidelines on autism spectrum disorders (ASD), as recommended in the autism services road map. Building on the work of professional organizations, such as the American Academy of Pediatrics, and such bodies as the Autism Treatment

Network, the work group is developing cross-cutting guidelines that provide a comprehensive set of core principles for an integrated service delivery system. In addition to its work on the guidelines, HRSA has a small research program and is supporting other projects related to autism. It funded a cooperative agreement, the National Medical Home Autism Initiative, with the Waisman Center at the University of Wisconsin, Madison. The focus is on improving the early identification of ASD children, enhancing coordination of care, and ensuring that the care is family centered and culturally responsive. In addition, issues related to ongoing care and follow-up are being addressed.

HRSA also supports the training component of another program, Leadership Education in Neurodevelopmental Science (LEADS). Eighty percent of the programs have a specialty clinic or a unit that focuses on autism. A survey of the 35 LEADS programs across the country showed that 10 to 25 percent of the enrolled patients have an autism spectrum disorder.

Dr. McPherson reported on the work of the IACC services subcommittee, which she chairs along with Ms. Sybil Goldman from the Substance Abuse and Mental Health Services Administration (SAMHSA). The subcommittee's two major issues are the need for financial and staffing resources and developing a framework for collaboration among Federal agencies. She said she anticipated hearing comments related to the subcommittee from the other agencies reporting at this meeting.

Dr. Barry Gordon asked Dr. McPherson if it is possible to ascertain how services are being delivered in any given State or city. Dr. McPherson replied that interagency efforts to learn about barriers and constraints at the community level have produced documentation on problems and their solutions. Despite the experience and efforts in every State, characterizing and coordinating services is enormously complex, she said. Dr. McPherson mentioned the problem of so-called silos of services. The question is how Federal and State governments take to support community inclusion in light of legislative and financial complications.

### **Agency for Healthcare Research and Quality (AHRQ)**

Ms. Padmini Jagadish, representing Dr. Carolyn Clancy said that AHRQ is working with the services subcommittee to enhance the Department of Health and Human Services autism web site to provide information on all Federal autism programs.

### **Centers for Disease Control and Prevention (CDC)**

Dr. José Cordero reported on developments in the CDC's autism activities, which focus on monitoring or tracking of autism; research and epidemiology; and an awareness campaign to foster knowledge of the science so that autism can be identified early.

The CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network, currently includes 16 sites in 17 States funded to do monitoring of the prevalence of ASD. The first six have completed their data collection, with the data expected to be available in early 2007. The Atlanta site, where the surveillance methodology was developed, will report its 2000 data in early 2007 as well. Another request for applications (RFA) has been issued for four developmental grants to generate ideas and processes to help identify young adults and children under the age of four.

The CDC's six Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) are finalizing the protocol for a large case-control study. Enrollment is expected to begin in early 2007.

The "Learn the Signs. Act Early" awareness campaign is directed at both providers and parents, with the aim of increasing knowledge about the early signs of autism and developmental disabilities, specifically early signs of developmental delay. Preliminary results from a small survey done a year after the campaign was launched suggest that pediatricians have become more knowledgeable about autism. Parents, too, are reporting that they are more aware of signs of developmental delay and discussing these signs with the children's physicians. Another hopeful sign is that fewer physicians are advising parents simply to "wait and see" how their children develop.

In response to Dr. Insel's request for more information on CADDRE, Dr. Cordero referred the question to Dr. Diana Schendel, also from CDC. She reported that the contract study was designed to examine several domains of possible etiology for ASD, the two of most interest being infection or immune function and hormonal and reproductive history. Data will be collected on the children, the biological mothers, and, where possible, the biological fathers. Results are expected in three to five years.

A discussion among committee members involved the best way to integrate data with other large-scale autism research projects. The CDC is following data-collection standards set within NIH, the National Center for Health Statistics (NCHS), and others, especially in the collection of biological samples.

Mr. Jon Shestack asked what had happened to data from the five sites in the CADDRE program started several years ago with the Children's Health Act 2000. Were the projects completed? Dr. Schendel replied that the projects had produced some 20 to 25 publications on completed studies, with another 15 to 20 coming out in the next year.

### **Centers for Medicare and Medicaid Services (CMS)**

Ms. Ellen Blackwell reviewed Medicaid and Medicare programs that serve individuals with autism. Although many children are served through the regular Medicaid State plan, CMS also provides services to special groups through waiver programs. Three

States, Wisconsin, Indiana, and Maryland, are operating under waivers that specifically mention children with autism. Waiver services not available under the regular State plan include for example, respite care services to families, and adult day care. In addition, in school settings, Medicaid provides support for such covered services as speech, physical, and occupational therapy, as well as mental health care. States elect these optional services. Through the New Freedom Initiative, CMS also supports Real Choice Systems Change Grants, which are aimed at increasing placement in the community for individuals with disabilities. These and other CMS programs serve persons with autism, although they are not specifically targeted to them.

Dr. Insel asked whether CMS could ascertain the number of individuals with autism who are served and the financial burden of such services. Ms. Blackwell said that the complexity of the CMS programs and the fact that disabled individuals are not usually categorized by type of disability would make it difficult to segregate the type of services they receive or the cost of those services. Ms. Blackwell indicated that she would speak with her colleagues to determine if additional information is available through Federal Medicaid sources.

Dr. Insel pointed out that some investigators are using Medicaid data to study services provided to persons with autism. They have documented such information as the number of visits required to get a diagnosis, the latency from the onset of symptoms to diagnosis, and health care disparities among ethnic groups. Ms. Blackwell suggested that such specific data may be provided by the States themselves, but perhaps not the Federal Medicaid program.

Dr. Insel asked how CMS knows whether the services being provided—at considerable expense—are based on sound evidence. The need for such data will become increasingly necessary with the implementation of Medicare Part D, which will pay for medications needed by many adults with autism. He suggested that this may be the time for different agencies to cooperate to assure that services provided have a scientific basis and are therefore cost effective.

Ms. Blackwell said that CMS looks carefully at the services that States propose to provide to make sure that Federal provider qualifications are met. Other than that, as of now, CMS does not currently require specific quality measures or oversight activities for its State plan services, but encourages States to use reliable and valid measures to assure and improve quality. Quality measures are built into some of the waiver programs.

Dr. Barry Gordon asked how one would go about studying the effectiveness of services such as speech therapy offered in the schools.

Dr. Ann Wagner said that NIDCD and NIMH fund studies on language interventions for autism. These are primarily early efficacy studies, not studies of how therapies are

being implemented in community settings. Studies on how best to implement interventions in the community are needed.

Dr. McPherson pointed out that many of the treatments are school based. It is difficult to separate educational funds from those that pay for medical care. The guideline and expert work groups had acknowledged the State-level conflicts between what schools require for evaluations and what modalities are educationally appropriate, as well as what is required through medical facilities and what is medically necessary. Families find themselves in the middle. Integrated efforts by Federal agencies could at least identify barriers and problems.

Mr. Lee Grossman said that it behooves advocates to organize at the State level to assure that CMS benefits are available to individuals with autism. He said that the same kind of activism is necessary with the insurance industry, which is highly regulated by the States.

Dr. Landis suggested putting together a matrix of what each State is doing for autism, a step that Mr. Grossman said is being done. After the matrix is constructed, Dr. Landis said, it could be determined if best practices are being followed. Mr. Grossman said that, because of the complexity of the issues involving State and local agencies, the Autism Society is polling those agencies. Some data are also coming from the state of Pennsylvania.

Dr. Insel noted that even when funds are available, there may not be an adequate number of providers with the expertise required to provide the types of services needed.

### **Department of Education (DOE)**

Dr. Gail Houle agreed on the necessity of working together at the State and local level to piece together financing streams.

She said that the Individuals with Disabilities Education Act (IDEA) statute had been reauthorized, and the regulations are being written in the DOE. Scientifically based practice standards are addressed in the new statute. In addition, new rules will reduce the amount of paperwork required of providers in the educational system, a step that may improve retention of providers.

Ms. Blackwell noted that the Medicaid program was empowered in 1988 to pay for services that are provided in schools. However, those services must meet all Medicaid requirements. Lack of understanding about the distinction between IDEA and Medicaid services causes some difficulties.

Dr. Landis returned to her suggestion of a matrix of State services and said that this model was developed for adverse event reporting and made it possible to examine the

complexities of such reporting. A similar exercise would illuminate the kinds of autism services offered; where the services are located; and how services can be accessed. Ultimately, the information gathered from this exercise may lead to uniform service offerings across the States.

### **Food and Drug Administration (FDA)**

Dr. Kathy Carbone reported that the FDA is supporting efficient review of treatments for autism. The agency's mission had recently changed from evaluating the safety, efficacy, and manufacturing of products used in the treatment or prophylaxis of autism to actually supporting and improving the efficiency of product development. Several FDA centers are involved in review of products related to autism. The Center for Drug Evaluation and Research reviews typical pharmacological drugs. The Center for Biologic Evaluation and Research would review novel therapies, such as gene therapy, if they were available. The Center for Food Safety and Nutrition and the National Center for Toxicology Research are involved in food and toxicology activities, and the Center for Devices and Radiological Health would be involved if there were new imaging techniques that were used, for example, either as part of the endpoints in the clinical study or as an actual potential for treatment.

Of particular interest to the FDA is maintaining manufacturing quality. The FDA also serves as an objective mediator and coordinator, encouraging dialogue among the public, sponsors, stakeholders, and those that may benefit from these therapies. The FDA helps to keep the focus on developing treatments or preventive measures. The FDA's research program includes intramural and collaborative research, and encourages high-priority research.

### **National Institutes of Health (NIH)**

Dr. Susan Swedo began her presentation with a report on the status of the STAART (Studies to Advance Autism Research and Treatment) and CPEA Centers (Collaborative Programs of Excellence in Autism) networks. Scientific advisors for the two networks concluded that the individual centers have been very successful in meeting their goals. The networks also continue to function collaboratively. Of special note is the imaging subcommittee, which is working on ways to combine data from all of the sites on the structural scans from nearly 800 children, adolescents, and young adults with autism, as well as typically developing controls.

Dr. Swedo addressed the transition of the two networks into the new Autism Centers of Excellence (ACE) network. Although resources are expected to be comparable to those invested in the STAART and CPEA networks, the ACE network is somewhat different. In addition to the traditional center mechanism for multidisciplinary research at one or two sites, grant applicants may alternatively propose research networks (e.g., neuroimaging networks, genetics networks, treatment networks). The ACE grantees will also be required to direct their research toward the IACC's research matrix,

particularly in the areas of etiology and treatment. To facilitate that effort, NIH has initiated the National Database for Autism Research (NDAR). Funding has been secured from the NIH Institutes to build infrastructure, acquire and modify software for NDAR use, and assemble individual components (such as the imaging module, clinical assessments module, etc). Standards are also being established for data acquisition and data-sharing. A beta-test of NDAR will commence in November 2006, and the database will be on-line in time to support the ACE network in spring 2007.

In another update, Dr. Swedo noted that at the last IACC meeting she had reported that NIH had issued a request for applications for large-scale molecular genetic research projects with the goal of identifying specific genes and gene variants in localized chromosomal regions that produce susceptibility to autism. Five grants representing three projects were awarded earlier in 2005. The five-year awards will total \$10.8 million.

Dr. Swedo then turned her attention to the activities of individual NIH Institutes and Centers. Highlights follow:

- The Centers for Children's Environmental Health and Disease Prevention Research, which are sponsored by National Institute of Environmental Health Science (NIEHS) in partnership with the Environmental Protection Agency (EPA), have announced a new round of competitions for P01 research center grants. These centers will conduct multidisciplinary basic and clinical research using a community-based participatory approach to examine the effects of environmental exposures on children's health. The centers will also translate these findings to inform public policy, to address community needs, and to gain information for the health care community and the general public. The focus of this round of competition is on environmental aspects of neural developmental and/or endocrine disorders. The current solicitation provides an opportunity for the two existing NIEHS-EPA autism related centers (at U.C.-Davis and at the UMDNJ in New Jersey) to submit applications to continue their work; the solicitation also encourages applications from new centers. The NIEHS and EPA have set aside funds to support up to four centers, with up to \$1 million in direct costs per year for each center, for five years beginning in FY06  
<http://grants.nih.gov/grants/fuide/rfa-files/RFA-ES-05-004.html>.
- The National Institute of Neurological Disorders and Stroke (NINDS) is supporting a birth cohort study in Norway. To study genetic and environmental causes contributing to the development of autism, the investigators are following a cohort of more than 100,000 mothers from pregnancy; their children are now three or four years of age. Data collection is continuing, this time with a focus on identifying autism spectrum disorders and related conditions. Another NINDS-funded investigator found a link between autism and the genes that encode receptors for the common neurotransmitter GABA, an inhibitor of firing in nerve cells.

- As was reported last spring, the NIMH intramural program (IRP) has launched a new program focused on autism and related disorders. The IRP research program is taking a multidisciplinary approach to the evaluation and treatment of children, adolescents, and adults with autism spectrum disorders. The first protocols have been approved by the science committee and the Institutional Review Board, and recruitment of subjects has begun. The children will be screened at the Cedar Lane facility, a patient and family-friendly environment, and subsequent evaluations will take place at the NIH Clinical Research Center. The first year's research will be devoted to studies of the etiology and pathophysiology of regressive autism. Several treatment trials are also planned. One of the approved protocols is to look at Riluzole, which is a glutamate antagonist. In addition, other NIMH intramural investigators are conducting research on autism; for example, functional imaging studies in high-functioning adults with autism, and a clinical trial of a novel immunomodulatory agent. Dr. Swedo noted that the money for the new intramural autism program represents additional funding for autism, as it is drawn from the NIMH intramural budget and does not affect the extramural funding stream.

In answer to a question, Dr. Swedo noted that as soon as the study protocols are approved they are listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Mr. Shestack asked about the use of NDAR for NIH-funded research. Dr. Landis said that several NIH institutes have agreed to contribute to NDAR and that the budget for NDAR is \$1.6 million for the end of FY 05 and FY 06. Mr. Shestack also inquired about the progress in establishing a steering committee and consortium office, as well as the staff to administer the program. Dr. Swedo stated that Ms. Louise Ritz had been recruited to serve as liaison between the funding Institutes and the NIH Center for Information Technology (CIT), and that CIT had hired core NDAR staff and was continuing to build the development team. The NDAR Implementation Team, composed of staff from five NIH Institutes (NIMH, NINDS, NICHD, NIEHS, and NIDCD), also meet regularly. A Scientific Advisory Board will be established and will have their first meeting in early winter 2006.

Dr. Insel recalled that after the last meeting, public attendees expressed concern about the relative paucity of research on environmental issues. He asked whether the NIEHS centers and the large Norwegian study funded by NINDS would provide the kind of information the public wants. Dr. Lawler said that those studies would certainly help, and that applicants for the ACE network would be encouraged to propose studies of environmental risk factors.

### **Substance Abuse and Mental Health Services Administration (SAMHSA)**

Ms. Sybil Goldman said that SAMHSA has co-chaired the services subcommittee with HRSA since 2002. The agency does not target specific conditions, but its grants and technical assistance focus on persons with mental and substance abuse disorders or



those at risk. The grants fund research on best practices, and on building of state and community infrastructure for service delivery and capacity. Persons with autism are most affected by the congressionally-mandated Comprehensive Community Mental Health Services Program for Children and Their Families, which has funded 121 communities since 1993. Ms. Goldman noted the multiple organizations involved in the system serving children.

She reported that data from SAMHSA's national evaluation show that only 2.2 percent of individuals served by its programs are diagnosed with autism. "They tend to be in communities that have reached out to the developmental disability community and put some effort into how you can meet the needs of children with autism," she said.

In addition to its services programs, SAMHSA and other agencies are developing an action plan in response to recommendations for improving service delivery made by the President's New Freedom Commission on Mental Health. The action plan, which highlighted the work of the IACC, is bringing together Federal agencies to examine screening tools for children across the developmental age spectrum and for those with particular kinds of conditions. Results of those efforts will be disseminated widely.

SAMHSA will also increase its focus on research into effective services for children and the implementation of available evidence-based practices. Ms. Goldman said that evidence-based practices for children with complex needs have to be unbundled in order to receive financial support. Medicaid may pay for the medical components and the Department of Education may support some of the behavioral components. She said creativity is needed because very few funding streams pay for the whole package.

### **Administration on Children and Families (ACF)**

Dr. Patricia Morrissey began her presentation by noting that she, Ms. Sybil Goldman, and Dr. Merle McPherson, had discovered that little systematic attention had been given to the subject of services for adults with autism. A meeting is planned for December to generate ideas for an adult systems plan.

Dr. Morrissey reported that ACF funds a variety of grant programs, including 64 grants for university centers for excellence in developmental disabilities; approximately 34 of those probably have NIH grants or CDC grants that either directly or tangentially address problems associated with autism. Another grant program focuses on the needs of people who are having trouble with human service systems. Maryland, for example, has recently produced a guide on the State's autism Medicaid waiver. ACF has other grant programs as well.

Dr. Morrissey said that ACF has been actively involved with the hurricane recovery activities. Early on it became apparent that individuals with autism and their families were being treated differently than others. Dr. Morrissey said that she believes it is

imperative that people who come in contact with a person with autism in an emergency be educated about the condition.

She noted that the Federal Emergency Management Agency (FEMA) had given \$66 million to a consortium of volunteer agencies to do case management. ACF has educated the principal contractor about the importance of giving one of 12 grants to a group or groups that can assist families with members with disabilities. She said she and her colleagues are optimistic that such a grant will be awarded.

Mr. Grossman underscored the importance of planning for emergencies. He echoed Dr. Morrissey's view that this tragedy provided an opportunity to bring a number of the service agencies together to respond more adequately to future emergencies.

### **Autism Genetic Resource Exchange (AGRE)**

Dr. Insel introduced Dr. Clara Lajonchere, an experimental psychologist who is the director of AGRE, a repository of DNA from autistic individuals and their families.

Dr. Lajonchere said that since AGRE's inception in 1997, it has become a resource for both families and researchers. Its core competency is family recruitment and standardized data collection. Since 1997, Cure Autism Now has invested somewhat more than \$8 million to establish and maintain AGRE, including the establishment of the ISAAC system, the Web-based data management system. The original DNA collection from 100 families has grown to more than 1,200 families. AGRE, she said, has helped investigators realize the utility and power of collaboration. It has also set the stage for a larger initiative, the National Alliance for Autism Research (NAAR) Autism Genome Project (AGP), which created a consortium of investigators from this country and around the world. The largest whole genome scan done to date was performed on more than 300 families from the AGRE resource. AGRE is looking forward to the next release of genome scans on many more families.

The greatest stakeholders in AGRE are the families and the NIH, which has invested nearly \$3.5 million. AGRE has a scientific steering committee, and more than 140 researchers who access the AGRE collection, including students and young investigators. Since 2001, AGRE has been cited in 64 peer-reviewed scientific papers.

Dr. Lajonchere then explained how the families were recruited and how they contributed to AGRE. The families currently registered are U.S. residents, clustered bi-coastally; they have two or more children diagnosed with ASD—i.e., autism, Asperger syndrome, or pervasive developmental disorder (PDD); at least one biological parent must be available; and they are proficient in English. The team of phlebotomists, clinical raters, and pediatric neurologists conduct state-of-the-art assessments so that the families are very well characterized.

With the data obtained from the children and families, AGRE establishes cell lines, which are housed in a DNA repository at Rutgers University. In addition to the clinical data and biomaterials, researchers are given access to genetic data (e.g., zygosity, whole genome scan); flags for possible nonidiopathic autism (e.g., chromosomal abnormalities); and demographic data. Especially noteworthy are the 621 families with two, three, four, and five affected individuals (called multiplex families). Thus, researchers have the opportunity to study very large pedigrees, twin pedigrees, monozygotic twins, dizygotic twins, and a handful of trios or simplex families.

Dr. Lajonchere concluded her presentation by noting recent breakthroughs in autism that grew from the AGRE resource. All of the publications are on the AGRE web site ([www.agre.org](http://www.agre.org)), with associated PubMed IDs. She emphasized that AGRE and Cure Autism Now are devoted to collaboration and data-sharing, and for that reason, require researchers who use their resources to submit raw, unanalyzed data, including null results. In the future, AGRE will continue to expand its data-collection efforts. She appealed to attendees to direct families with two or more children diagnosed with ASD to the AGRE web site.

Mr. Shestack asked about the lack of Spanish-speaking families in the AGRE database. Discussion followed about the lack of standardization of assessment instruments in languages other than English. Dr. Lajonchere and Dr. Cordero noted that activities are underway that may provide reliability of Spanish-language versions of standardized instruments.

Dr. Cordero noted that CDC data on an Atlanta population indicates that multiplex families make up only about 10 percent of all autism cases. He asked whether AGRE had plans to include single cases to serve as subjects and as controls.

Dr. Lajonchere said that, at present, AGRE gives priority to families with more than one affected child. Other investigators are contributing data, including a Californian twin study that will involve some monozygotic twins, equivalent to simplex families. Such partnerships appear to be most practical, given the constraints on resources. She said AGRE is working with another agency to recruit a normal control population of typically developing children, though it is anticipated that those children may be reluctant to submit to the blood draw and assessments.

Dr. Cordero noted that the National Health and Nutrition Examination Survey (NHANES) collects DNA in a representative sample of normal children who have had full exams. That sample could potentially provide controls.

Dr. Insel concurred that the question of suitable controls is critical. As scientists move to whole genome association and SNP (single-nucleotide polymorphism) studies, they are moving away from the type of design used by AGRE to case-control designs. This change brings up the tough problem of the appropriate control group. Those control

populations can be stratified by genetic markers to match with the subject cases. This is being done for other diseases, and it does provide a great opportunity to move forward very quickly, he said. He pointed out that AGRE has provided the tools so that investigators can move very quickly. In answer to a question, he noted that singleton collections exist.

Dr. Insel compared the experience with juvenile diabetes, where real breakthroughs came at around 3,000 cases and 3,000 controls; for type-2 diabetes, it was about 10,000 cases and 10,000 controls. The NIMH Genetics Repository now includes more than 1,000 families of autistic individuals. If large-effect genes are discovered, many more cases and controls may not be necessary. Clearly, however, the current rate-limiting step is the sample size.

### **Psychopharmacology for Children with ASD**

Dr. Insel introduced Dr. Ben Vitiello, a psychiatrist with the NIMH extramural program, who has been involved in testing of medications with children with autism for the last eight years.

In his talk, Dr. Vitiello noted that, at present, there is no medication that can cure autism, that is, correct the core symptoms of autism. Many children with ASD, however, are treated with psychotropic medications. Community epidemiological surveys, which are probably an accurate representation of the national sample, indicate that between one-third and one-half of children with autism receive at least one psychotropic medication in the course of a year; that exceeds the figure for any other childhood condition. Children with autism spectrum disorders are most commonly given stimulants (e.g., methylphenidate, commonly known as Ritalin), antidepressants (notably, selective serotonin reuptake inhibitors), antipsychotics (e.g., risperidone), or alpha-2 agonists (e.g., clonidine or guanfacine). These medications are given to control hyperactivity, inattention, repetitive behaviors, aggression, self-injury, and severe tantrums.

Dr. Vitiello gave an update on the research activities of the NIMH-funded Research Unit on Pediatric Psychopharmacology (RUPP) Network. The RUPP autism network, which includes six sites, was started in 1997. Its purpose is to study medications that are used in the community without adequate evidence for efficacy or safety. In 2002, the RUPP network completed an eight-week study showing that risperidone is effective in reducing severe aggression, self-injury, and severe tantrums when compared with placebo; 69 percent of children treated with risperidone improved, compared with only about 12 percent of those who received placebo. A follow-up of extended treatment, up to six months, showed that the improvement persisted. However, treated children experienced weight gain twice that expected in normally developing children. When risperidone was discontinued, the problems recurred in roughly two-thirds of the sample.

Another recent study tested the safety and efficacy of Ritalin in children with autism, Asperger syndrome, or other PDD who had significant symptoms of ADHD. The design of the study allowed the investigators to control for individual characteristics. Of the 72 children who entered the study, six were not able to tolerate at least two doses of Ritalin, primarily because of irritability. Another seven children eventually dropped out of the study because of adverse events. The study showed a statistically significant decrease in hyperactivity, inattentiveness, and impulsiveness. On average, the improvement, as judged by parents and teachers, was modest—roughly half that seen in ADHD children who do not have ASD. Some children improved appreciably on this medication, some did not improve, and some got worse. Overall, the placebo response was about 12 percent. However, the placebo response was greater for children who had Asperger syndrome or another kind of PDD compared to children with autism. Less than 10 percent of the children with autism showed a response to placebo.

Children with autism spectrum disorders react quite differently to Ritalin, a commonly used medication. In children with ADHD alone, only about two or three percent cannot tolerate the drug. Another interesting finding is that at the highest dose, social withdrawal increased in children with ASD. There is no point in exposing a child with autism or PDD to more than a medium dose, Dr. Vitiello said. This, too, is different from treating other children with ADHD, whose response typically improves with higher doses.

Summarizing the study, Dr. Vitiello said that if ten children were given Ritalin, one could expect that five would improve, two would get much worse, three would show no significant change, and all would have some sort of side effect. He said he believes that this finding should be useful for clinicians to take into consideration and could be integrated into their practice guidelines.

As part of the RUPP study, a survey was conducted to determine what parents understand about participation in treatment research. Although the vast majority of parents understood most features of the study, including that their children might receive a placebo, only 72 percent were aware that treatment was assigned randomly. Instead, they believed that treatment was based on individual needs. The misunderstanding was more common among parents with lower educational levels. The researchers are now trying to be more attentive to this issue.

## **Regression and Development**

Dr. Insel introduced Dr. Catherine Lord, professor of psychology and psychiatry and director of the University of Michigan Autism and Communication Disorders Center in Ann Arbor. Dr. Lord is an expert on diagnostic instruments and longitudinal studies of ASD.

Dr. Lord's presentation was on developmental regression and early trajectories of development in ASD. She began her talk by acknowledging she would not be able to discuss all relevant studies but would instead report on those that seem particularly provocative or puzzling. Her research attempts to answer three different questions:

1. Is developmental regression in the second year of life a real phenomenon in autism?
2. Is there a regressive phenotype in autism?
3. Do patterns of regression provide insights into its causes or the pathophysiology of autism?

Dr. Lord described research that came from three different studies. The first was an NIMH-funded longitudinal study involving consecutive referrals of children, ages three to five, from the TEACCH (Treatment and Education of Autistic and Related Communication Handicapped Children) centers in North Carolina and a clinic in Chicago. Those children have been followed into their teen years. The second study involved follow-up interviews with parents of all the children in the CPEA sites who had reported a regression when they entered those studies, as well as case controls of children with autism whose parents did not describe regression. The third study involved checking medical records from birth to age two in children from the CPEA study.

Dr. Lord reported some of the complex findings from those studies. In the North Carolina-Chicago study, it appeared that parents first became concerned when the child was about age two, although the regression had started a few months earlier. Many parents who reported that their children had lost words also reported loss of social skills, and about a fifth of those who did not report word loss said that their children lost behaviors.

The CPEA study involved many more children than the Carolina-Chicago study. All of the sites reviewed the parent interviews conducted when the children first entered their studies. In most cases, the data were collected about six or seven years previously, before concerns were raised about the measles, mumps, and rubella (MMR) vaccinations. Of the 350 children with ASD, 132 had word loss. In subsequent parent interviews, the investigators found that a high proportion of parents of children with word loss said their children had also lost social skills. Compared to children with word loss, about 10 percent of children who did not have word loss had almost exactly the same pattern of loss (though more severe) of other skills, such as response to language. Children who had regressions were actually reported by their parents as doing better prior to their regression than those who did not show regression.

The group-level data showed no clear association between MMR vaccination and age of onset of the regression. However, vaccination coincides with the time when regression occurs in children with autism, and that may be why vaccination has been

associated with the onset of symptoms. Because children with regression have been reported to have more gastrointestinal (GI) symptoms, the issue was studied by examining medical records. Dr. Lord said that an association was found between regression and GI symptoms, as reported by the mothers. The group also found an association between regression and a mother reporting autoimmune or thyroid disease in herself or a relative.

With funding from CDC and the National Institute of Child Health and Human Development (NICHD), the investigators looked at medical records for the first two years of life of 75 children with ASD, 29 of whom had word loss or a cluster of losses in other areas. The sample was small and not representative, and the earlier finding of more GI symptoms was not replicated. It was not clear whether that result could be attributed to a power deficiency in the study or to other factors.

Because the earlier study had shown some increase in diarrhea, which can result from the antibiotics given to children with ear infections, Dr. Lord and her colleagues examined medical records for that condition. To their surprise, both ASD groups (i.e., with and without regression) were more likely to have had many different ear infections prior to the age of two than in the typical control group. Though not conclusive, this finding is suggestive and does replicate earlier studies that also suggested that children with autism had more ear infections. Because the ASD children had more infections, they also received more antibiotics.

The third study Dr. Lord reported was a longitudinal study of children at high risk for autism who were followed during the period when regression usually occurs. They were considered at risk because they had an older sibling with ASD or, during their first year of life, had experienced infantile spasms or some other seizures. Assessments were done monthly. Using the example of one boy to illustrate the findings to date, Dr. Lord noted very significant language delay even though the boy's nonverbal skills were average. His social skills were consistently low across time, and his repetitive behavior fluctuated but gradually increased after he started walking.

These and other observations from the study suggest that a more focused concept of regression may be needed, Dr. Lord said. The frequent assessments in this group used the baby version of the Autism Diagnostic Observation Schedule (ADOS), which has more subtle social probes intended for small children. The assessments are giving the researchers the opportunity to quantify regression in the expected one in ten children who have marked regression.

In conclusion, Dr. Lord provided information to address her three original questions:

1. Her group's work and that of others strongly suggest that regression in the second year of life is a real phenomenon. It is not usually the first sign of autism, since most children who showed regression were not totally developmentally on target before the regression.

2. Regression does appear to be relatively specific to autism. Whether there is a long-term regressive phenotype in autism is not clear. At age two, the children do seem to have been more competent early on and less competent afterwards. Whether that is associated with GI problems is also not clear.
3. These patterns of regression may provide some insight into what may be causing or contributing to the autism, though nothing definitive can be concluded at this point.

### **Individuals with Disabilities Education Act (IDEA)**

Dr. Insel reintroduced Dr. Gail Houle, associate division director for early childhood programs and parent programs in the Office of Special Education Programs at the Department of Education. In that role, she oversees departmental initiatives in the areas of early childhood special education, early intervention for infants and toddlers with disabilities, parent training, and community parent resources; these programs include children and families with autism spectrum disorders.

Dr. Houle presented an overview of the Individuals with Disabilities Education Act, the Nation's special education law, first enacted three decades ago. Its funds, which in 2005 totaled \$11.7 billion, provide educational opportunities for more than seven million children and youth with disabilities. The 2004 reauthorization of the Act authorizes Federal increases of \$2.3 billion a year through 2011 until Federal funding per pupil reaches 40 percent; that increase, though authorized, is not mandated. The 2004 reauthorization introduced a great number of changes to the Act. Dr. Houle emphasized that the most important for autism may be a new birth-to-age-six option. The change, initiated by the States, allows States to combine early intervention and preschool programs for young children with special needs; preschool programs must now promote school readiness.

Another relevant change was an expansion of the Act's Part C to include infants and toddlers with disabilities and their families who are homeless or wards of the State. Children under age 3 who are the victims of substantial child abuse or neglect are also included. States are, in addition, required to describe collaboration with Early Head Start and childcare programs.

The 2004 IDEA reauthorization strengthens the requirements that help children make the transition from one part of the Act's provisions to another as they become older. Another feature relevant to autism is the creation of the new National Center for Special Education Research within DOE.

A discretionary grant program, Part D of the IDEA Act, is aimed at improving the education of children with disabilities. The FY 05 appropriation for that program was more than \$341 million, \$83 million of which is not new money. New wording in Part D requires support for training service personnel in expertise in autism spectrum disorder.



Of the 36 projects currently funded under Part D, 26 support personnel preparation and 10 are research and demonstration projects. Part D investments in autism totaled nearly \$11.6 million in 2005; that figure includes a large one-year Congressionally-mandated project.

Every State has at least one parent training and information center or community parent resource center (see [www.taalliance.org](http://www.taalliance.org)). Those centers were in contact with families of children with disabilities almost immediately after Hurricane Katrina struck.

IDEA services for students with autism have increased steadily since 1999, although the increase declined a bit from 2003 to 2004.

Dr. Lou Danielson, director of the Research to Practice Division in DOE's Office of Special Education Programs, reported data from a set of four large-scale longitudinal studies conducted over the past several years that cover the entire age range from birth to 21. Because only aggregate data exist for the early intervention and preschool studies, however, he was only able to report autism-specific data for the two longitudinal studies in school-age populations. Those studies employ nationally representative samples of children for each of the 12 Federal disability categories. Dr. Danielson said that a report on the findings on children with autism is being prepared.

The first of the two studies, SEELS (Special Education Elementary Longitudinal Study), uses data collected in three waves over five years when the children are between the ages of 6 to 12; at the study's conclusion in 2006 the children will be 11 through 18. The second study, National Longitudinal Transition Study-2 (NLTS2) uses data collected in five waves over nine years in children who were 13 to 16 at the outset; these youth will be 21 through 26 at the study's conclusion in 2010.

The primary research interest was determining the following:

- Characteristics of students receiving special education.
- Educational programs and services they receive as they age.
- Their achievements in education, social adjustment, and independence.
- The services and experiences that contributed to better results.
- How programs, experiences, achievements, and beneficial factors differ for children and youth with different characteristics.

Data are collected through telephone interviews with parents and, for the NLTS2, with children who are able to answer or, alternatively, through mail surveys. Both studies include direct assessment of reading and math skills and in-person interviews to gauge self-concept. The secondary school children are also assessed for self-determination and content knowledge in social studies and science. Mail surveys are done with each student's teacher, as well as school staff and principals.

In presenting the findings of the studies, Dr. Danielson said it is important to remember that each disability category is very heterogeneous, even though children in each category share characteristics related to their disability. He emphasized that the studies provide a rich source of information, only some of which he could report at this meeting. Among the findings:

- Whereas speech impairment all but disappears in high school among most disability categories, children with autism have similar speech impairments in elementary and secondary levels.
- About three-fourths of the children in the SEELS study who carried the autism label were functioning in the lowest quartile in passage comprehensive, although about five percent were in the highest quartile and about 22 percent were plus or minus one quartile around the median.
- The performance of the secondary students with autism in the NLTS2 study was better on math calculation skills than on reading comprehension. Sixty percent did, however, score in the 0-25 percentile range.
- Despite these poor achievement scores, 53 percent of the secondary school children labeled autistic received A's or A's and B's. Children with emotional disturbances, by contrast, had higher achievement scores, but their grades were the worst of the categories. "One can imagine that those grades might have something to do with deportment," Dr. Danielson said.
- Grade retention was low among autistic children, and high school completion was high (86 percent).
- In the first wave of data collection, about 16 percent of the post-secondary youth with autism were receiving supplemental security income (SSI), whereas two years later 22 percent were receiving SSI.
- About 47 percent of the youth with autism were in a postsecondary school program, often a vocational technical school. The gradual disappearance of vocational education in high school—a reflection of the changing labor market—is of concern because it has traditionally been valuable for children with disabilities.
- Only about a third of youth with autism had been employed since high school, and on average, only about 10 hours a week. Less than half made more than \$7 an hour. A multivariate analysis of factors related to employment in all the disability categories showed that the more that disability affects multiple domains of functioning, the lower the likelihood of employment.
- About 19 percent of youth with autism had been arrested at some time, less than half the rate of those with emotional disturbances.
- Although only five percent of youth with autism were living independently, more were doing so than when the first NLTS study was done.

Dr. Danielson said that some questions were deliberately taken from other national longitudinal studies of youth so that comparisons could be made with non-autistic samples.

Dr. Cordero asked Dr. Houle whether paraprofessionals who could act as facilitators with autistic children were being trained. Dr. Houle replied that, although most of the money goes to training special educators, psychologists, and speech language pathologists to work with children with autism, some grants are aimed at training paraprofessionals.

Dr. Geller pointed out that the classifications used in the studies are not medical diagnoses and that many ASD children may be in other categories. Dr. Danielson said that the categories are assigned by the schools, and therefore, it is possible to generalize to the population of children labeled in this way. It is unlikely that the categories will be the same as those in a clinically identified population.

### **CDC and Denmark Collaboration**

Diana E. Schendel, Ph.D., an intramural scientist with CDC's National Center on Birth Defects and Developmental Disabilities, next described the collaboration CDC has underway with Denmark, for which she serves as principal investigator. The collaboration's goals are to establish the Danish National Autism Registry; complete case-control studies of perinatal risk factors and potential biomarkers measured in newborn blood; complete other registry-based epidemiological studies; identify biomarkers and risk factors in the Danish National Birth Cohort; and develop and apply laboratory microanalytic techniques, Luminex xMAP.

Dr. Schendel explained that these studies are possible in Denmark because its unique data infrastructure includes individual-level data on millions of people organized into many disease and administrative databases and registries, some of which go back for decades. Data systems are linked by unique personal identifiers. These registries and databases make it possible to do large population-based epidemiologic studies, especially those that would benefit from a longitudinal perspective. Another resource is a biobank of blood samples of newborns, collected to screen for metabolic disorders, which has samples dating back to the early 1980s. A third resource is the Danish National Birth Cohort, consisting of 101,042 pregnant women and their offspring. This databank includes blood samples, cord blood at delivery and newborn blood spots, and information learned during telephone interviews done before and after the birth. These comprehensive sources of data are not available in this country, and it would be prohibitively costly to replicate them.

Dr. Schendel said that in 1999 her CDC center established a collaborative relationship with Denmark as a mechanism for a variety of public health activities. The agreement is specifically with the Danish Medical Research Council, a unit in the Ministry of Science, Technology and Innovation. The primary research collaborators are at the University of Aarhus Institute of Public Health, headed by Paul Thorson, M.D., Ph.D. The core group

of researchers at the university and other Danish institutions has formed the North Atlantic Neuro-Epidemiology Alliance (NANEA).

The CDC-Denmark collaboration has devoted its autism efforts to several undertakings:

- Establishing a Danish national autism registry.
- Conducting case-control studies of perinatal risk factors and potential biomarkers measured in newborn blood using existing registry data and medical record data, as well as linkage with the biobank.
- Doing other registry-based epidemiologic studies focusing on data extracted from the existing registries and through linkage of those different registries.
- Developing a laboratory to take full advantage of the newborn screening biobank.
- Ultimately, looking at a study of autism related to biomarkers and risk factors in the Danish National Birth Cohort, taking advantage of the tissue samples collected from the women during pregnancy and looking more closely at factors as they arise during pregnancy.

In describing some of the efforts, Dr. Schendel noted that, to date, a validation study based on psychiatric records has shown that 85 percent of cases in the Danish autism registry could be confirmed as meeting criteria for an ICD-10 or ICD-8 diagnosis of infantile autism. Another 14.2 percent could be diagnosed with ASD/PDD. She said that more than half of the cases have been reviewed so far, and therefore it's likely that the reported diagnoses are reliable.

The study of biomarkers that is underway compares children in the autism registry with children identified through the Danish central person register.

Another activity involves protein assay, primarily an inflammation panel. It is of interest because it may shed light on the extent to which there is a difference in inflammatory reaction in newborns with autism as opposed to typically developing children. Although the analytes are primarily related to inflammation, a few markers for brain development are included.

Other registry-based activities include studies of time trends and seasonal variation in hyperkinetic disorder, obsessive-compulsive disorder, Tourette's syndrome, and autism spectrum disorder, and subdiagnoses within the spectrum. These are four of the most common neuropsychiatric disorders with onset in childhood; they have specific diagnostic criteria in ICD-10; they are often co-morbid; and data were retrievable for the Danish psychiatric register. Such a comparative analysis of multiple disorders within the same large population over the same time period eliminates the problem of confusing the comparability of the diagnoses within that study. For the time trends, the investigators are looking at two measures, the age-specific diagnostic rates, and the cumulative incidence proportions. The age-specific rates make it possible to identify changes in age of diagnosis over time.

Dr. Schendel said that she's hoping that this investigation will contribute to the understanding of the extent of the public health burden of problems in children's neuropsychiatric development, not just autism. "And that perhaps gives us a better understanding of the trends in autism in the context of other childhood neuropsychiatric conditions," she said.

In another study, the bloodspots are being used to do genetic analysis and further develop multiplex assays.

A planned next step is to initiate a case-cohort study of autism in the Danish National Birth Cohort. Laboratory analyses of the blood samples will be done since they are valuable sources for both protein gene and nongenetic protein analysis.

During the discussion period that followed, Dr. Insel asked whether consideration had been given to doing an actual proteomics analysis on the bloodspots and trying to measure tens of thousands of proteins. Dr. Schendel replied that the option is there and would be valuable, but there are no funds available to do the analysis. Dr. Cordero pointed out that the Luminex technology being developed allows for such an analysis. Dr. Insel cited biotech companies that have taken the approach, although the findings have not yet been published.

A participant asked what would be the implications for treatment or intervention if a biomarker were identified. Dr. Schendel said that the markers of inflammation, for example, would indicate disease exposure but wouldn't be useful for treatment. It could, however, be a first step in identifying predictive factors of autism risk.

### **Autism Diet and Nutrition Workshop**

Dr. Courtney Ferrell, chief of the individual fellowships and research education program at NIMH, reported on a workshop that had been held a month previously on diet and nutrition for individuals with autism. The workshop was sponsored by NIMH, NICHD, NIEHS, the Office of Dietary Supplements (ODS), and the National Center for Complementary and Alternative Medicine (NCCAM). Its purpose was to bring together researchers in autism, nutrition, and treatment evaluation to discuss potential issues involved with dietary supplementation.

The workshop was organized around four themes: evidence-based research; lessons from dietary supplement research; design and methodology; and examples of research methodologies exclusive to autism.

Evidence-based research about dietary supplement use and ASD is in its infancy. Although vitamin B<sub>6</sub>, magnesium, and dimethylglycine, along with vitamin C, are the most common vitamins and nutritional supplements that are currently used with children and adults with ASD, very limited empirical data are available concerning their safety

and efficacy. In addition, there are currently few guidelines for pediatricians regarding the use of these vitamins and nutritional supplements for youth with ASD.

The workshop examined potential lessons that could be learned from dietary supplement research focused on ADHD. Specifically, the discussion of design and methodology largely focused on the uniqueness of the placebo response in the autism population. Caregiver expectations and feeding practices were part of that discussion.

The workshop also discussed current examples of methodologies being used in the autism research community with respect to diet and nutrition. Information on a gluten-free and casein-free (GFCF) diet was used as an example of an innovative dietary challenge strategy.

The workshop participants agreed that several questions need to be addressed before planning further activities. For example, categorization of diagnostic groups should be determined prior to beginning the research (e.g., by genetic variability). Feeding and nutrition in the development of typical children needs to be understood better. It should be decided whether currently used supplements need to be studied. Finally, it was suggested that it may be too early to consider randomized clinical trials and that feasibility and pilot studies with use of single-case designs may be more appropriate at this stage. A summary of the meeting will be posted on the NIMH and ODS web sites.

In response to questions about the GFCG diet study, Dr. Wagner pointed out that a description of the study can be found on the public web site describing CPEA and STAART network activities <http://www.autismresearchnetwork.org/AN/>.

Mr. Grossman commented that ATN is doing a lot of work in this area and that pharmaceutical companies are developing pharmacological interventions. He suggested that such work might be of interest to metabolic and mitochondrial researchers, gastroenterologists, and others. Manufacturers have shown considerable interest in developing nutritional foods, and research in areas that are unrelated to autism show that nutritional interventions can be effective.

### **2005 International Neurotoxicology Meeting Update**

Dr. Cindy Lawler, from the NIEHS, reminded participants that at the last IACC meeting she had described challenges to identifying and understanding environmental influences in autism. NIEHS is encouraging neurotoxicologists and environmental health scientists to study autism. The 22nd international neurotoxicology conference held this year was one forum where scientists were being recruited into the field of autism research. The overall theme of the meeting was environment and development across the life span.

One of the main science sessions brought together clinical and basic scientists to present data and talk about the immune system function or potential dysfunction in autism. Presentations included a talk by Dr. Carlos Pardo, who had recently published evidence of increased inflammatory processes in postmortem brain from individuals with autism. His and other presentations, along with discussions that followed, produced a list of research needs.

At the top of the list was the need to support interdisciplinary meetings and partnerships. Another high priority need was basic science to identify and understand regional differences in the brain regarding immune system regulation. Also on the list were better clinical characterization of individuals with autism to determine or describe the immunophenotype; immune co-morbidities; and whether individuals with regressive autism were a subset that may be uniquely vulnerable to immune system disturbances. Finally, there was much discussion about the need to maximize existing resources, and there were many cohorts and populations in which additional measures could be added easily to examine immune markers.

In the ensuing discussion, Dr. Insel asked about progress in developing tool kits to look at environmental factors in autism and other disorders. Dr. Lawler replied that the new NIEHS Director is envisioning a large initiative that would develop the technologies needed to track environmental exposures. Currently, no single methodology can look at a universe of exposures within a single sample.

Dr. Jose Cordero pointed out that CDC has developed high-throughput analysis using tandem aspects for a whole series of metals. Part of the challenge is determining normal levels.

Dr. Insel emphasized the need to be creative in approaching the problem of environmental contributors to autism. The assumption is that if the environment is having long-term effects, it is probably through epigenetic modifications, which can now be tracked very well. Dr. Lawler said that NIEHS recently released a broad-based RFA on epigenetics and the environment. Along with others, the Institute sponsored a huge epigenetics/epigenomics meeting at Duke University a few weeks previously.

Mr. Grossman said that members from the Autism Society of America (ASA) who attended the recent neurotoxicology meeting came away very impressed with the progress that's being made in this area. ASA has made a strong commitment to continue to support activities related to environmental health and neurotoxicity. At the subsequent meeting of the Autism Treatment Network, people were talking about the same subject of genetic pathways, and mutations that could result in autistic symptoms. It became apparent that neurotoxicologists and the members of ATN studying medical models for autism need to sit down and compare notes, Mr. Grossman said.

Dr. Cordero, acknowledging that it is difficult and expensive to do high-throughput measures of exposure, historical exposure, said that what can be done is to use high-throughput methods to identify genetic or other markers of heightened sensitivity to environmental exposure. It may not be that the environmental exposures vary all that much, but that population differences in sensitivity may exist.

### **Update on Pending Legislation**

Mr. Lee Grossman, ASA president and CEO, reviewed some of the legislation now before Congress that affects the autism community.

- Combating Autism Act of 2005 renews and expands the 2000 Children's Health Act. It would increase Federal funding over five years to combat autism through research, screening, intervention, and education. It also reauthorizes the NIH Centers of Excellence Program.
- The Smith-Doyle Teacher Education for Autistic Children (TEACH) Act would provide funds for development of professional education, including tax credits for those going into special education. One provision would provide funds for an autism ombudsman's office in every State.
- A comprehensive autism services bill, which is in draft form now, would implement recommendations made by the IACC services subcommittee.
- The Kennedy-DeWine CLASS Act of 2005 would create a national insurance program financed by payroll deductions to help adults with severe functional impairments obtain needed services and support.
- Defense appropriations. Several Representatives are requesting an appropriation of \$10 million for autism research in the FY 2006 DOD appropriations bill.
- Family Opportunity Act would allow middle-income persons to buy into the Medicaid system.
- Improving Long-Term Care Choices Act of 2005 allows for states to offer home- and community-based services to those who are eligible under Medicaid without requiring a Federal waiver.
- Emergency Health Care Relief Act would extend Medicaid coverage for those affected by the hurricanes.
- The Medicaid Community-Based Attendant Services and Support Act of 2005 amends Title 19 of the Social Security Act. It requires the State Medicaid plan coverage for community-based attendant services.
- The Money Follows the Person Act is a demonstration project to encourage community-based services.
- Senator Paul Wellstone Mental Health Equity Treatment Act would expand the Mental Health Parity Act of 1996.
- The Independent Living Assistance Access Act would change the status of adult immigrants with disabilities so that they could receive in-home services.
- National Vaccine Injury Compensation Program Improvement Act of 2005 would amend the original provisions of the program to extend the statute of limitations



- for individuals filing claims and increase funding for the compensation program.
- Mercury-Free Vaccines Act of 2005 is directed at reducing human exposure to mercury through vaccines. The bill would eliminate the use of mercury in vaccines and biological products given to pregnant women.

Other legislation discussed by Mr. Grossman amended or extended current laws pertaining to education, including training of paraprofessionals and provision of services. He noted that some legislation may have negative consequences for the autism community. Of particular note is the Biodefense and Pandemic Vaccine and Drug Development Act, which would restrict the ability to seek legal recourse when injured by a pharmaceutical product. There are currently about 10 similar bills before Congress. Mr. Grossman said that details about the legislation can be found at [www.thomas.loc.gov](http://www.thomas.loc.gov).

Janis Guerney mentioned that the Reconciliation Bill being considered by Congress could have serious consequences for children with disabilities because it would allow States the flexibility to alter Medicaid benefits packages. In addition, the House bill would impose cost-sharing, particularly for prescription medications, on all but the very poorest Medicaid beneficiaries. To obtain more information, the best resources may be the Center on Budget and Policy Priorities, [www.cbpp.org](http://www.cbpp.org), and the Georgetown Center for Children and Families.

## **Public Comment**

Dr. Valerie Hu introduced herself as the mother of an 18-year-old son with Asperger syndrome and a researcher who is using genomics to try to identify biomarkers for autism in peripheral cells. She commended the AGRE organization for its resource of DNA from hundreds of families and the transformed cell lines, which she is using to try to identify biomarkers.

Referring to Dr. Houle's comments on the training of paraprofessionals, Dr. Hu suggested that perhaps a small amount of resources could go toward educating a child's peers in school and an adult's peers in the workplace about the milder forms of autism. Her own experience had taught her that peers who know something about "this more or less silent disorder" are much more understanding and much more willing to accommodate the ASD child.

Michael John Carley stated that he runs the Global and Regional Asperger Syndrome Partnership (GRASP). He said that, meager as the services are for children with ASD, it is much worse for adults. Adults born before 1994 when the diagnosis was expanded are now being diagnosed and some are languishing in jails or other inappropriate institutions. They are desperate for social services.

Dr. Linda Gellar, executive director of Asperger Foundation International, reiterated what Mr. Carley had said: Service support for adults is minimal. She said her organization's web site, [www.aspfi.org](http://www.aspfi.org), contains a report on a study of State resources for individuals on the autism spectrum.

Dr. Ricciardi, executive director of the National Autism Center (NAC), said his is a small agency being sponsored by the May Institute, which has been providing services for children with autism for 50 years. The founders were interested in learning the evidence for then-prevailing ideas about autism and its treatment. The National Autism Center has as its primary mission to guide families and practitioners toward evidence-based practice. The current focus is the development of a practice guideline in the area of behavioral and educational interventions for children with autism. To plan the program, the group recently brought together 19 researchers in the area of education, behavioral intervention, and descriptive elements of autism. Another project will look at programmatic outcome data across various models now being used in schools for children with autism. This project lends itself to a more rigorous adherence to the American Academy of Neurology (AAN) guidelines for practice statements.

Mr. Chase said that he was struck by a comment during the discussion of regression that often children with autism actually have made greater gains in their developmental stage than the children of typical peers or children who have not had regression. He and another participant had wondered whether the brains of children with autism are growing at an excessive rate. "They are developing quicker, and suddenly something almost like a sheet or break comes on that stops them from continuing their proper developmental stages to come." Mr. Chase suggested that researchers pursue such a possibility, including whether a protein could be involved.

He also suggested that nutrition researchers may wish to consult with pharmacists who are also herbalists, many of whom are knowledgeable about which nutritional and nonpharmaceutical interventions have worked.

Following these comments, Dr. Insel thanked the participants and adjourned the meeting.