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COMBATING AUTISM ACT OF 2005

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Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

**R E P O R T**

[To accompany S. 843]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 843) to amend the Public Health Service Act to combat autism through research, screening, intervention and education, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY

As part of the reauthorization of Title 1 of the Children’s Health Act of 2000 (P.L. 106–310), the purpose of S. 843, the Combating Autism Act of 2006, is to improve upon our previous activities with respect to autism. Specifically, the legislation focuses on expanding research and coordination at the National Institutes of Health (NIH); increasing awareness through the Centers for Disease Control and Prevention (CDC); integrating health, education, and disability programs; and ensuring that citizens have a voice in governmental activities.

With up to 1 in 166 children being diagnosed with autism within the United States, we need to understand more about the spectrum disorder to better differentiate the conglomerate of individuals identified with the disorder. In addition, given the increased demand on services for these individuals, we need to provide better integration of the health, education, and disability programs already available.

## II. BACKGROUND AND NEED FOR LEGISLATION

Autism spectrum disorder (ASD) is a group of developmental disabilities caused by atypical brain development. People with ASD tend to have challenges and difficulties with social and communication skills. Many people with ASD also have unique ways of learning, paying attention, or reacting to different sensations. ASD begins during early childhood and lasts throughout a person's life.

As the name autism spectrum disorder implies, ASD covers a continuum of behaviors and abilities. Individuals with ASD, like all people, differ greatly in their skills abilities, and talents. They also differ in how their disability impacts their social, emotional, behavioral, and academic domains. No two people with ASD will have the same symptoms. A symptom might have a mild impact in one person and a significant impact in another person. Some examples of the types of challenges and behaviors a child or adult with an ASD might have include:

**Social skills:** People with ASD might not interact with others the way most people do, or they might not demonstrate interest in other people. People with ASD might not make eye contact and appear to want to be alone. They might have difficulty understanding other people's feelings, talking about their own feelings, or picking up on non-verbal social cues. Children with ASD might not like to be held or cuddled, or might cuddle only when they want to due to sensory integration sensitivities or difficulties. Some people with ASD might not seem to notice when other people talk to them. Others might be very interested in people, but not know how to interact with others due to a lack of understanding of verbal and non-verbal social cues, difficulty integrating sensory information from multiple modalities, and lack of predictability.

**Speech, language, and communication:** About 40 percent of children with ASD do not talk. Others have echolalia, which is when they repeat something that was said to them. The repeated words might be said right away or at a later time. For example, if you ask someone with an ASD, "Do you want some juice?" he or she may repeat "Do you want some juice?" instead of answering your question. Or a person might repeat a television ad heard sometime in the past. People with ASD might not understand gestures such as waving goodbye. They might say "I" when they mean "you", or vice versa. Their voices might sound flat and it might seem as though they cannot control how loudly or softly they speak. People with ASD might stand too close to people (according to acceptable western culture social norms) they are talking to, or might stick with one topic of conversation for a long period of time. Some people with ASD are very articulate, but have a hard time listening to what other people say. They might talk a lot about something they really enjoy, or persevere on a specific topic rather than engage in a conversation with someone.

Repetitive behaviors and routines: People with ASD might repeat actions multiple times, such as rocking back and forth. They might want to have routines where things stay the same so they have a sense of predictability of what will happen, for how long, and in what sequence or to meet sensory-based needs they may have. If a person with ASD does not have an effective approach or tool to predict and prepare for transitions or changes in family routines, and a coping strategy to effectively cope with unexpected changes in their routine, he or she may engage in challenging behavior. For example, if a child is accustomed to washing his or her face before dressing for bed, he or she might become very upset if asked to change the order, by getting dressed first and then washing his or her face, if he or she was not prepared for the change, the reason why the change occurred, or if he or she does not have a strategy to effectively cope with changes in routines.

Children with ASD may develop at different rates from children without ASD or other developmental disabilities. Children without ASD or other developmental disabilities develop at about the same rate in areas of development such as language, cognitive, and social skills. Children with ASD develop at different rates in different areas of growth. They might have significant delays in language, social, cognitive, and gross motor skills, while their fine motor skills might be about the same as other children their age. They might be very good at activities such as putting puzzles together or solving computer problems, but have difficulty with activities most people think are easy, such as talking or making friends. Children with ASD might also learn a hard skill or task before they learn an easy one. For example, a child might be able to read long words, but not be able to tell you what sound a “b” makes. A child might also learn a skill and then lose it. For example, a child may be able to say many words, but later stop talking altogether.

Data from several studies that used the current criteria for diagnosing autism and autism spectrum disorder (ASD), such as Asperger’s disorder and pervasive developmental disabilities (PDD–NOS), found prevalence rates for ASD between 2 and 6 per 1,000 individuals. Therefore, it can be summarized that between 1 in 500 (2/1,000) to 1 in 166 children (6/1,000) have an ASD.

Currently, there is not a full population count of all individuals with an ASD in the United States. However, using the prevalence data stated above, it is estimated that if 4 million children are born in the United States every year, approximately 24,000 of these children will eventually be diagnosed with an ASD. Assuming a constant prevalence rate over the past 2 decades, we can estimate that up to 500,000 individuals between the ages of 0 to 21 have an ASD. However, many of these individuals may not be classified as having an ASD until school-age or later. Since behaviors related to the ASD usually present before the age of 3 years, it is important to make sure that young children are screened, and if the individual is at high-risk of developing an ASD that they receive an interdisciplinary, comprehensive evaluation to confirm or rule out the diagnosis. If the diagnosis is confirmed subsequently, the individual should receive evidence-based interventions as early as practicable.

In a study conducted by the Centers for Disease Control and Prevention, the Metropolitan Atlanta Developmental Disabilities Surveillance Program found the rate of autism for children ages 3 to 10 years to be 3.4 per 1,000 children which is lower than the rate for mental retardation/intellectual disability (9.7 per 1,000 children); but higher than the rates for cerebral palsy (2.8 per 1,000 children), hearing loss (1.1 per 1,000 children) and vision impairment (0.9 per 1,000 children) found in the same study.

Approximately 2 percent of children under the age of 18 have a significant developmental disability (DD) and these include intellectual disability, cerebral palsy, hearing loss and vision impairment. Of these significant DDs, intellectual disability (in the past referred to as mental retardation) is the most common. A genetic disorder often associated with having an intellectual disability (ID) that many people recognize is Down syndrome. Current information indicates that having Down syndrome occurs in 1 out of 800 births and is slightly less common than ASD. Approximately 17 percent of children have some type of developmental disability, including more mild challenges such as speech and language disorders, learning disabilities, and ADHD, which appear to be more common than ASD.

While developmental disabilities may affect a child's speech or language, physical growth, psychological growth, self-care, or learning, diseases that impact adults may also affect children's health. A common childhood disease, juvenile diabetes, is prevalent in approximately 1 in every 400 to 500 children and adolescents, which is in a similar range as ASD. However, ASD is more common than childhood cancer, which has a prevalence rate of 1.5 per 10,000 children (1 in 300 males and 1 in 333 females have a probability of developing cancer by age 20 according to the National Cancer Institute).

In 2004, approximately 166,424 children received supports, services, and intervention under the "Autism" classification for special education services. Not all children with an ASD receive special education services under the classification of "Autism," often they are classified as "other" health impaired (OHI), so the education data may underestimate the actual prevalence of ASD. Autism was added as a special education exceptionality in 1991 and is now the 6th most commonly classified disability in the United States. The most common disability classifications in 2004 were: specific learning disabilities (2,838,694 children served), speech or language impairments (1,151,260 children served), intellectual disability (567,780 children served), emotional disturbance (484,488 children served), and other health impairments, which often includes children diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) (511,869 children served).

Using current standards, ASD is the second most common significant developmental disability after intellectual disability, but is still less common than other challenges that affect children's development, such as speech and language impairments, learning disabilities, and ADHD. The impact of having a developmental disability is immense for the families affected and for communities that provide services, interventions and supports for these families. It is important that we treat common DDs, and especially ASD, as areas of urgent public health concern, do all we can to identify chil-

dren's learning needs, and begin intervention as early as practicable to enable all children to reach their full potential.

There is no known cure for ASD. However, early and intensive intervention is important to improving the outcomes so that individuals can grow and learn new skills. The goal of these efforts is to provide interventions and supports to individuals with ASD and their families to improve the individuals' language development, social interaction and play, learning potential, and activities of daily living skills. Medicines can relieve some symptoms and be helpful for some individuals with ASD, but interdisciplinary interventions that meet the comprehensive needs of individuals with ASD are currently the most effective intervention. The ideal intervention plan integrates therapies and interventions that target the core symptoms of autism: delayed social interaction, challenges with expressive and receptive verbal and non-verbal communication, sensory integration dysfunction, challenging behavior, and obsessive or repetitive routines and interests. There is general consensus among most professionals that the earlier implementation of interdisciplinary intervention, the better. For many children, autism symptoms improve with interventions and with age. Some children with autism grow up to lead typical lives.

During adolescence, some children with autism may develop, or show signs of depression, or experience a change or increase in challenging behavior. These changes may occur due to hormonal changes and increased social demands that typically occur during adolescence. Parents of children entering and throughout adolescence should be ready to adjust and alter the type, frequency and intensity of supports, services and interventions that their child receives as his or her needs change. One key fact to keep in mind is that oftentimes young adolescents with ASD, especially Asperger's Syndrome, will become more aware of the social relationships their non-disabled peers are forming with others and develop a strong sense of isolation, socially and emotionally.

According to data from the National Health Interview Survey, children with parent-reported autism were more likely than children without autism to have moderate or high levels of emotional symptoms, exhibit challenging behaviors, hyperactivity, peer problems, and overall difficulties. Approximately 83 percent of children reported with autism had moderate or high levels of overall difficulties compared with 15 percent of children without autism. The most notable differences were for peer problems (82.0 percent versus 15.9 percent) and hyperactivity (65.2 percent versus 11.9 percent). Substantially fewer children reported with autism had a high level of social skills (39.6 percent) compared with children without autism (82.3 percent).

The National Survey of Children's Health found that 93.8 percent of children with parent-reported autism were classified as having special health-care needs lasting or expected to last  $\geq 12$  months; 90.1 percent were reported as needing more medical, mental health, or educational services than usual for a child of the same age, or needing therapies or counseling for an emotional, developmental, or behavioral challenge. These percentages compared with 19.6 percent and 10.5 percent, respectively, for children reported without autism.

## NATIONAL INSTITUTES OF HEALTH (NIH)

NIH-sponsored research on autism spectrum disorder covers domains including: interventions, diagnosis, genetics, neurobiology, neuropsychology and services. In addition to individual grants for research projects, NIH sponsors training, small grants, career support, and program projects that involve autism research. NIH has also developed several networks of autism research centers.

There are several network activities in autism research sponsored by different Institutes including:

- Collaborative Programs of Excellence in Autism (CPEA) Network
- The Studies to Advance Autism Research and Treatment (STAART) Network
- Children's Environmental Health Centers (NIEHS)

In 1997, the National Institute of Child Health and Human Development (NICHD) and the National Institute on Deafness and Other Communication Disorders (NIDCD), started a 5-year, \$45 million, International Network on the Neurobiology and Genetics of Autism. The Network included 10 Collaborative Programs of Excellence in Autism (CPEAs) that would conduct research to learn about the possible causes of autism, including genetic, immunological, and environmental factors.

In 2002, the NICHD and NIDCD renewed funding for the CPEA Network, agreeing to provide \$60 million over a period of 5 years. The CPEAs link 129 scientists from 23 universities in the United States, Canada, Britain, and five other countries, and more than 2,000 families of people with autism. In fact, as a result of the CPEAs, researchers now have data on the genetics and outward characteristics of the largest group of diagnosed persons with autism in the world.

In 2003, the CPEA Network launched a Data Coordinating Center in Medford, Massachusetts, to provide data management and statistical support for Network activities. The Center will also maintain a Web site to ease communication and coordinate activities among the CPEAs. Three groups are managing different tasks in the Data Coordinating Center: DMSTAT, Inc.; the Boston University Statistics and Consulting Unit; and the Department of Biostatistics at the Boston University School of Public Health.

The Data Coordinating Center will provide combined support for the CPEA Network and for the eight sites of the Studies to Advance Autism Research and Treatment (STAART) Centers Program, a 5-year, \$65 million effort supported by five NIH Institutes, including the NICHD. Such support will increase the volume and speed in which data are processed and compared, which may increase the speed of uncovering findings resulting from these research efforts.

The STAART Network is comprised of eight centers across the country. Most of these centers are evaluating and treating patients, as well as enrolling them into NIH-funded clinical trials.

In 2001, the National Institute of Environmental Health Sciences and the Environmental Protection Agency jointly announced four new children's environmental health research centers that will focus research on childhood autism and attention deficit disorder.

The centers were funded at \$5 million, or approximately \$1 million per year for 5 years (fiscal year 01 through fiscal year 05).

#### CENTERS FOR DISEASE CONTROL AND PREVENTION

The Children's Health Care Act of 2000 required the Centers for Disease Control and Prevention (CDC) to establish Centers of Excellence. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at CDC funded five Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE).

The Centers have:

- Worked with the Autism and Developmental Disabilities Monitoring Network (discussed further below) to monitor the number of children with an ASD and other developmental disabilities.
- Improved community and service provider awareness of ASD and other developmental disabilities, or improved access to comprehensive, community-based, family-centered care for children with an ASD and other developmental disabilities.
- Conducted epidemiologic research related to ASD and other developmental disabilities. These studies will address topics such as what factors (genetic, environment, and others) make it more likely that a child will have an ASD, what other disabilities children with an ASD have, biomarkers, and the economic costs of ASD.

In addition to CADDRE, the CDC also funds 10 Autism and Developmental Disabilities Monitoring Network (ADDM) projects. These projects are developing or improving programs to track the number of children with an ASD in their States. The goal of the ADDM Network is to provide comparable, population-based estimates of the prevalence rates of autism and related disorders in different sites over time.

Other CDC-funded activities related to autism include the following:

- The Marshall University Autism Training Center, in West Virginia, is conducting an intervention study with families of children who have an ASD. Marshall University staff developed an in-depth program that helps reduce stress factors that have a negative effect on children with an ASD and their families. The program includes the development of family support plans. These plans coordinate the activities of the different professionals who work with the children, provide positive behavior support training for parents and teachers, and help create community partnerships, usually with another family who has a child with an ASD.
- CDC funds SAFE, Inc., in Pennsylvania, to enhance their community-based ASD outreach and educational activities to help individuals with ASD live a full and independent life.
- The Christian Sarkine Autism Treatment Center (CSATC) and Clarian Health Partners at Riley Hospital for Children have joined together to develop the HANDS in Autism (Helping Answer Needs by Developing Specialists in Autism) Program through a grant provided by the Centers for Disease Control and Prevention (CDC).

#### EDUCATION, EARLY DETECTION, AND INTERVENTION

Education: The NIH, CDC, and the Health Resources and Services Administration (HRSA) all provide a variety of activities to expand information and education to the general public and health care providers specific to autism spectrum disorder.

Beyond activities which have already been described, HRSA supports a program to train health professionals to work with children who have neurodevelopmental or related disabilities, such as cerebral palsy, autism or spina bifida, or who may be at high risk of developing such disabilities. The Leadership Education in Neurodevelopmental and Related Disabilities (LEND) grants provide interdisciplinary training to improve the clinical expertise and leadership skills of health professionals who serve children with disabilities. The grants encourage doctors, nurses and psychologists to work together to prevent disabilities in children resulting from genetic or metabolic conditions and to identify signs of disability early enough for effective intervention. In addition, social workers, speech pathologists, pediatric dentists, dietitians, occupational therapists, physical therapists and genetics experts promote practice models that encourage cultural competence by health professionals and the involvement of families in making decisions about their children's supports and services. Parents and youth consultants with disabilities provide leadership training through the program.

HRSA supports a network of statewide centers run by families of children with special health care needs (CSHCN) to help other families with special needs children. These centers, called Family-To-Family Health Care Information and Education Centers for Families of Children with Special Health Care Needs, will be designed and supervised by families in partnership with State Title V CSHCN programs and other providers.

They offer:

- Health and related information to families and providers for improving health decision-making;
- Assistance on gaining greater access to and making better use of services within communities; and
- Educational and leadership opportunities to family members.

Finally, HRSA also supports the developmental-behavioral pediatrics training program that focuses on (1) supporting fellows in behavioral pediatrics to help prepare them for leadership roles as teachers, researchers, and clinicians; and (2) providing pediatric practitioners, residents, and medical students with essential biopsychosocial knowledge and clinical expertise. The purpose of the program is to enhance behavioral, psychosocial, and developmental aspects of general pediatric care. This program has three main aspects:

- Faculty and Fellows. Training grant funds support faculty who demonstrate leadership and expertise in behavioral pediatrics teaching, scholarship, and community service and fellows who have completed training to be board-eligible in pediatrics.
- Curriculum. The 3-year residency program curriculum includes course work and clinical exposure to psychosocial and biological sciences, growth and development, adaptation, injury prevention, disease prevention, and health promotion. Projects are also encouraged to cosponsor, with child psychiatry, an ongoing Collaborative Office Rounds (COR) group as a training experience for fellows and a continuing education experience for community providers.
- Continuing Education and Technical Assistance. Grantees must also provide continuing education activities for practicing

physicians and are encouraged to offer technical assistance and consultation to pediatric residency training programs that are in the early stages of developing their own behavioral program components.

To increase awareness about the early warning signs of developmental disabilities, such as autism, and help ensure that children get services at the youngest age possible, the Centers for Disease Control and Prevention (CDC), in partnership with Porter Novelli, developed a targeted social marketing campaign: “Learn the Signs. Act Early.” In its first year, this innovative campaign has educated parents and doctors about the developmental milestones that every young child should reach, the warning signs of a developmental delay, and the need to act early when a problem is suspected.

Recent studies have shown that developmental disabilities, such as autism spectrum disorder, can be diagnosed as early as 18 months; however, in an estimated 50 percent of children, disabilities remain unidentified until age 5 years, when most enter kindergarten. Why is this important? Although there are no cures for these disabilities, early detection and early intervention services have demonstrated significant improvement in outcomes and functioning for affected children. Early intervention is a child’s best hope for reaching his or her full potential.

The campaign targets parents of children ages 4 and younger and health care professionals, including pediatricians, family physicians, physician assistants, and nurses. These audiences tend to monitor a child’s physical growth—height, weight and milestones such as crawling and walking—but pay less attention to the social, emotional, cognitive and language milestones that mark a child’s overall development. To increase awareness of the milestones and the importance of early action when a delay is suspected, the campaign employed the following strategies:

- Build on the familiar physical developmental milestones, adding in information on social, emotional, language and cognitive milestones.
- Work with health care professionals to ensure they are able to initiate and respond to parent requests for information.
- Partner with trusted medical associations and leverage the CDC brand to build trust and credibility with providers.
- Distribute materials to parents through provider offices, empowering parents with questions to ask the doctor at the point of service.

The first phase of the social marketing campaign launched in October 2004 and focused on educating health care professionals, arming them with information and resources to initiate discussions and respond to increased queries from parents. The second phase, launched in February 2005, focused on increasing awareness among parents.

Evaluations have shown rather promising results.

#### EARLY DETECTION

Many children with developmental disabilities, such as autism spectrum disorder, are missing critical opportunities for early detection and intervention. In the United States, 17 percent of children have a developmental disability such as autism, intellectual disability, or Attention-Deficit/Hyperactivity Disorder. In addition,

many children have delays in language or other areas, which impacts school readiness, success in school and quality of life. However, less than 50 percent of these children are identified before starting school, by which time significant delays may have already occurred and opportunities for early intervention have been missed.

Recent surveys indicate that parents want information and guidance from their health care provider about their child's development, but studies sponsored by the American Academy of Pediatrics show that 65 percent of pediatricians feel inadequately trained in assessing children's developmental status. Although developmental screening is widely recommended, there are currently no national data tracking the state of this practice and how it is integrated into primary care. Developmental screenings such as the Modified Checklist for Autism in Toddlers (M-CHAT)—a brief assessment designed to identify children who should receive more intensive evaluation or assessment for autism spectrum disorder—can improve child health and well-being, especially for children with autism spectrum disorders and other developmental disabilities or delays.

Research has demonstrated that early detection of developmental disabilities and evidence-based intervention can significantly improve short- and long-term outcomes and reduce the need for life-long interventions. For example, children with autism spectrum disorder identified early and enrolled in early intervention programs show significant improvements in their language, cognitive, social, and motor skills, as well as in their future educational attainment and decreased need for special education services. Thus, the committee encourages the Department of HHS to develop and implement activities so that all children are screened for autism spectrum disorder and other developmental disabilities before their second birthday. Also, children with an autism spectrum disorder diagnosis or who are at high risk for autism should receive evidence-based interdisciplinary interventions as early as practicable. Interventions include referral and services provided by school and agencies (including community, consumer, and parent-based agencies), along with organizations and other programs required by the Individuals with Disabilities Education Act (which offers programs specifically designed to meet the unique needs of children with autism and their families).

Given this, the CDC has established the following goals to help children reach their full potential:

- Develop and evaluate community-based model programs in primary care settings (and potentially other settings that care for young children) to provide early screening for children to identify those at risk for autism and other developmental disabilities or delays, and ensure that children are referred to local and State resources, and receive evidence based interventions.
- Increase health care providers' knowledge and skills in developmental screening by incorporating developmental screening into professional health care training.
- Monitor the use of screening for autism and other developmental disabilities or delays in primary care settings.
- Raise awareness about the need for and benefits of developmental screening to identify and meet the needs for children with autism and other developmental disabilities or delays.

Complementing the activities at the CDC, HRSA administers the Maternal and Child Health Services Title V Block Grant (title V). The goal of the title V program is to improve the health of all mothers and children consistent with the applicable health status goals and national health objectives established by the Secretary of the U.S. Department of Health and Human Services.

The title V program has operated as a Federal-State partnership for more than 65 years. When the Social Security Act was passed in 1935, the Federal Government, through title V, pledged its support of State efforts to extend and improve health and welfare services for mothers and children. Title V has been amended many times over the years to reflect the expansion of the national interest in maternal and child health. It was converted to a block grant program as part of the Omnibus Budget Reconciliation Act (OBRA) of 1981. Congress later sought to balance the flexibility of the block grant with greater accountability by the States. Through the 1989 OBRA States were required to report on progress made toward key maternal and child health indicators and to provide other program information.

States and jurisdictions use title V funds to design and implement a wide range of maternal and child health programs that meet national and State needs. Although specific initiatives may vary among the 59 States and jurisdictions utilizing title V funds, all programs work to do the following:

- Reduce infant mortality and incidence of disability among children.
- Increase the number of children appropriately immunized against disease.
- Increase the number of children in low-income households who receive assessments and follow-up diagnostic and treatment services.
- Provide and ensure access to comprehensive perinatal care for women; preventative and child care services; comprehensive care, including long-term care services, for children with special health care needs; and rehabilitation services for blind and disabled children under 16 years of age who are eligible for Supplemental Security Income.
- Facilitate the development of comprehensive, family-centered, community-based, culturally competent, coordinated systems of care for children with special health care needs.

As part of title V's focus on children with special health care needs, the goal of that program is to support development and implementation of comprehensive, culturally competent, coordinated systems of care for the estimated 18 million U.S. children who have or are at risk for chronic physical, developmental, behavioral or emotional disorders and who also require health and related services of a type or amount beyond that required by children generally. Children with an ASD are specifically included within these programs.

#### IACC

The Children's Health Act of 2000 (P.L. 106-310), Title I, Section 104, mandated the establishment of an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department of Health and Human Services

(DHHS). In April 2001, Secretary Tommy Thompson delegated the authority to establish the IACC to the National Institutes of Health (NIH). The National Institute of Mental Health (NIMH) at the NIH has been designated the lead for this activity.

The IACC's primary mission is to facilitate the efficient and effective exchange of information on autism activities among the member agencies, and to coordinate autism-related programs and initiatives. P.L. 106-310 specifies that parents or legal guardians of individuals with autism or other pervasive developmental disorders be appointed to the committee. The Secretary retained the authority to select such public members. Such appointments are necessary and vital to the conduct of the committee's mission. Public members of the IACC will help bring to DHHS the concerns and interests of members of the autism community. The IACC will serve as a forum and assist in increasing public understanding of the member agencies' activities, programs, policies, and research and in bringing important matters of interest forward for discussion.

### III. HISTORY OF LEGISLATION AND COMMITTEE ACTION

On April 19, 2005, Senator Santorum and Senator Dodd introduced S. 843, the "Combating Autism Act of 2005." Since that introduction, the bill has been cosponsored by 40 other members of Congress. After accepting a substitute amendment offered by Senator Enzi and cosponsored by Senators Dodd, Frist, Kennedy, Burr, Clinton, DeWine, Harkin, Hatch, Gregg, Mikulski, and Jeffords, the Committee on Health, Education, Labor, and Pensions reported the bill favorably by unanimous voice vote on July 19, 2006.

### IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

The bill has a variety of provisions, the explanation of and committee views on which follow below:

Throughout the bill, the committee uses the term "intervention." In using this term, the committee believes that such a term encompasses a broad range of activities, including biomedical interventions (such as pharmaceuticals), behavioral interventions and therapies. Thus, it is the intent of the committee that the term "intervention" be very broadly construed as any activity which improves the overall health outcome of the individual diagnosed with autism spectrum disorder or other developmental disabilities.

In addition, the committee paired language related to "diagnosing" an individual with autism spectrum disorder with the need to also "rule out" a diagnosis. As with any determination of whether an individual has a particular disorder, it is important that the individual assisting with such process is able to distinguish between the particular disorder and other potential issues, hence, the need to pair "diagnosis" with "rule out."

Finally, the committee uses the term "evidence-based" at various points throughout the legislation. In doing so, the committee expects the term "evidence-based" to be the conscientious, explicit, and judicious use of current best evidence in making decisions about care and services for individuals. The practice of evidence-based care and services means integrating individual expertise with the best available external evidence from systematic research.

To increase the accountability and focus on autism spectrum disorder at the National Institutes of Health (NIH), the committee specifically authorizes a strategic plan related to autism spectrum disorder. In requiring the Director of the NIH to develop a strategic plan for autism spectrum disorder, the committee wants to ensure that this plan provides not only an outline of key research activities and questions but also ties those activities to specific budgetary outlays to improve the transparency of the planning process. The goal of this planning process is to ensure broader coordination of activities among the Institutes and Centers (ICs) within the NIH. This is particularly important given the number of ICs at NIH which have a role to play on research related to autism spectrum disorder. However, the Committee committee does not expect the strategic plan process to deviate from similar processes that NIH uses during the budgetary process by putting together their professional judgment of the funds required for particular activities, recognizing that those professional judgments cannot be tied to obligating such funds to the research outlined under the strategic plan.

In reporting on the expected spending and providing an analysis of what was previously expended, the committee strongly encourages the director to provide such dollar amounts using clear and consistent methods for determining the monetary allocation. At this point, various ICs have different policies for determining the budgetary allocation for a grant that has multiple disease impacts, and the committee would like the information presented for this report to use one consistent method for all of the information provided. The committee further encourages the director to use this information on the amount of spending on autism spectrum disorder for all of its dissemination purposes, including the information publicly available at <http://www.nih.gov/news/fundingresearchareas.htm>, regarding spending on specific disease categories.

Further, in crafting the specific strategic plan, the committee encourages the director to:

- Determine and establish priorities among critical scientific questions related to autism spectrum disorder;
- Specify the short and long-range objectives to be achieved, and estimate the resources needed to achieve these objectives;
- Evaluate the sufficiency of existing research programs on autism spectrum disorder to meet the specified objectives and establish objectives, timelines, and criteria for evaluating future research programs; and
- Make recommendations for changes to existing research programs on autism spectrum disorder, including potential consolidation of research activities if such consolidation would improve program efficiencies and outcomes.

In addition to the strategic plan, the committee requests that the NIH expand, intensify, and coordinate activities at NIH. The committee further authorizes two centers of excellence programs—the Autism Centers of Excellence and the Centers of Excellence in Environmental Health and Autism.

The committee is encouraged by the work that the NIH has already performed in the past 5 years with respect to Centers of Excellence. In providing updated authority for those Centers of Excel-

lence, the committee applauds the NIH for taking the proactive step to collapse two current Centers of Excellence programs (e.g., the Collaborative Programs of Excellence in Autism and the Studies to Advance Autism Research and Treatment) into one comprehensive Center of Excellence—the Autism Centers of Excellence (or ACE). This virtual network of centers across the Nation will build upon the work of the previous Centers of Excellence by focusing on treatment trials, neuroimaging, and the behavioral and biological components tied to genetic traits. In working with these centers, the committee expects the director to continue to coordinate activities with the directors of the National Institute of Mental Health, the National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, the National Institute of Environmental Health Sciences, the National Institute on Deafness and Other Communication Disorders, and any other agencies that the director determines appropriate.

Given that the Centers of Excellence can utilize their grant award for making individuals aware of opportunities to participate as subjects in research at the Center, the committee strongly encourages the NIH to provide appropriate oversight and accounting of these activities to ensure that those costs are reasonable and appropriate and tied directly to recruitment activities. The committee allows the NIH to request justification from grantees for such expenditures.

The committee also authorizes the collection of storage of data, including samples of tissues and genetic and other biological materials, to improve the availability of information to individuals examining questions related to autism spectrum disorder. Given that the NIH has already developed a genetic repository as part of the Autism Genome Resource Exchange, which includes DNA extracted from blood samples from families with a child with autism, the committee expects that the Centers of Excellence will have the opportunity to perform research on high-risk infant siblings.

The committee further commends the NIH for developing the National Database for Autism Research. This collaboration among sites allows for data sharing, additional analysis, queries across disparate systems and data stores, and additional data resources. By using common reference architectures of data standards, vocabularies, web services, and application solutions, this network can link the Autism Speaks Registry, the Autism Treatment Network, and the Centers of Excellence at the Centers for Disease Control, and other autism researchers. In making this information available to the public and other autism researchers, the committee expects the NIH to share this information using standard protocols to appropriately protect patient confidentiality.

Given that the NIH is already working to establish a virtual data center, the committee expects the CDC to share relevant data and samples of tissues and other biological material with the NIH so that there can be a single point of access within the Federal Government for all autism data-sharing purposes.

To ensure the maximum amount of efficiency, while still focusing on outcomes, the committee gives the NIH the authority to consolidate program activities under the direction of NIH if such consolidation would improve program efficiencies and outcomes. In pro-

moting any consolidation, the committee expects the NIH to retain a separate, distinct focus on environmental health factors as they potentially relate to autism spectrum disorder.

In addition, beyond the authorization of appropriations, the committee further clarifies that NIH can use up to 5 percent of the grant amounts for administrative and other expenses. Although the committee understands the need for the NIH to have such taps, the committee is concerned about those taps being too high and diverting scarce resources to administrative expenses.

In an effort to clarify the committee's intent that these provisions do indeed sunset at the end of the authorization period, the committee has provided specific sunset language. In providing this language, the committee intends to reauthorize this critical law within the timeframe specified to ensure that the committee provides appropriate oversight of these issues.

Except for the provisions related to biomedical research at the NIH, the committee does not separate autism spectrum disorder from other developmental disabilities because the committee recognizes how necessary it is to continue to provide such services and epidemiological research in a comprehensive manner. However, given how little is known about ASD in biomedical research, the committee consciously decided to focus solely on ASD in that particular context.

The committee appreciates the work that the director of the Centers for Disease Control and Prevention (CDC) has already done in implementing the provisions of section 1 of the Children's Health Act of 2000. Recognizing that, the committee updated the language related to the State epidemiological studies, as well as additional Centers of Excellence for Autism Spectrum Disorder Epidemiology.

In continuing to implement the State epidemiology program and centers of excellence for autism research focused on epidemiological questions, the committee encourages the CDC to examine specific trends of autism spectrum disorder over time. While examining the incidence and prevalence of ASD, the committee encourages the CDC to use the diagnostic criteria established within the current edition of the Diagnostic and Statistical Manual (DSM) of Mental Disorders published by the American Psychiatric Association. If there is a change in the diagnostic criteria over time, due to new insights into ASD, then the committee expects CDC to provide a sufficient crosswalk between the various definitions so that it is possible to still follow the trends over time. Further, to ensure that there are standard methods for data collection, the committee specifically requires the CDC to provide such guidelines, after consultation with relevant State and local public health officials, for both the State epidemiology program and centers of excellence.

The committee commends the CDC for continuing to coordinate the Federal response to requests for assistance from State health departments regarding potential or alleged autism spectrum disorder clusters. For instance, in late 1997, a citizen's group in Brick Township, New Jersey, told the New Jersey Department of Health and Senior Services (DHSS) of their concerns about what seemed to be a larger-than-expected number of children with autism in Brick Township. Because of the complexity of the disorder and the citizens' concern that environmental factors might play a role, the New Jersey DHSS contacted CDC and the Agency for Toxic Sub-

stances and Disease Registry (ATSDR) for help. CDC and ATSDR worked together on a project to find out how common ASD was in Brick Township and to study the possible relationship of environmental factors to ASD in the community. After much review, it was determined that the prevalence of autism in Brick Township seems to be higher than that in other studies, particularly studies conducted in the United States, but within the range of a few recent studies in smaller populations that used more thorough case-finding methods.

To truly address the issues surrounding the need for additional education, early detection, diagnosis, and intervention for individuals with autism spectrum disorder and other developmental disorders, there must be an interdisciplinary approach, combining key resources from health, education, and disability programs. With that in mind, the committee made the largest number of changes in section 399BB autism education, early detection, and intervention to the original draft of S. 843. In particular, the committee included specific requirements for data coordination, as well as the designation by the Governor of a State lead agency.

The committee added language requesting the Governor to designate a lead agency to coordinate activities designated to provide information regarding risk factors, characteristics, identification, diagnosis, and interventions for individuals with autism spectrum disorder and other developmental disabilities and their families through specific Federal, State and local programs. Methods of delivery of such information may include websites, toll-free numbers, pamphlets and other means that the Governor may require. The committee recognizes that such activities are occurring throughout the United States, however, there are often multiple points of entry to access such information and families have indicated difficulties locating beneficial information in a timely fashion. Hence, the committee requests the Governor to designate a lead agency to seek, collect, and publicize information related to services that are available to individuals with autism spectrum disorder and other developmental disabilities, and their families.

The committee has modified the language from the original text of the Children's Health Act of 2000 to specify that the information should include information relevant to individuals with autism spectrum disorder and other developmental disabilities across the lifespan, especially transition age youth and adults, and with regard to college, vocational and labor accommodations. The committee further encourages that funding provided under this section include funding for information and education on advances in the early detection, diagnosis and intervention for individuals with autism spectrum disorder and other developmental disabilities as well as training and continuing education through programs for scientists, physicians, and other health professionals, social workers, and child care and education professionals and assistants who provide supports and services to, or are likely to come into professional contact with, people with autism spectrum disorder and other developmental disabilities, and their families. Activities under this section should place special emphasis on early identification of autism spectrum disorder and other developmental disabilities and those at high risk for ASD and other developmental disabilities, and prompt referral for appropriate services.

In addition to these activities, the committee specifically encourages the Secretary to develop evidence-based models for the comprehensive medical care of individuals with autism spectrum disorder. Comprehensive medical care models should include diagnosis and evaluation of disabilities identified during a complete history and physical examination and through appropriate laboratory evaluations. When outlining the comprehensive medical models, the committee encourages the Secretary to examine these models in the context of the individual, not just the potential diagnosis of autism spectrum disorder but in the context of the other potential co-occurring conditions and other health aspects. Therefore, evaluation and diagnosis could consider all of the health aspects of an individual, including developmental, psychosocial, behavioral, nutritional, neurological, immunological, endocrinological, gastrointestinal, metabolic, and toxicological parameters.

As part of the informational process, the committee requested that the Secretary, in collaboration with the Secretary of Education and the Secretary of Agriculture, provide culturally competent information regarding autism spectrum disorder and other developmental disabilities through a variety of Federal programs. In doing so, the committee recognizes that nutrition services are the mission of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and is concerned that placing additional responsibilities upon WIC that are not central to this mission may potentially result in a diminished quality of nutrition services. At the same time, the committee recognizes the access that WIC provides to a significant number of children up to the age of 5. It is the committee's intention that the information and education activities carried out through WIC under subsection (c) be limited to the basic provision and dissemination of information, such as providing pamphlets or other materials that can easily be passed along to or picked up by WIC clients, rather than activities that would require WIC staff to actively perform duties such as providing screening, education, interventions, administering information surveys, etc., for individuals with autism spectrum disorder, that are unrelated to the core mission of WIC.

The committee further re-examined the Interagency Autism Coordinating Committee (IACC). In particular, the committee wanted to increase the amount of public participation (from two individuals) to at least six. In addition, the IACC has been tasked to make recommendations to the Secretary regarding the public participation in decisions relating to autism spectrum disorder. For instance, the committee notes that the IACC may recommend providing other, additional, formal mechanisms, such as an Autism Advisory Board, to provide additional public feedback and interaction. Further, the Secretary may opt to provide such a mechanism without the recommendation of the IACC.

The committee expects that the IACC will be the primary mechanism for the coordination of all research, surveillance, and early detection activities within the Department of Health and Human Services. As agencies implement specific activities related to autism spectrum disorder, they should strongly consider those activities outlined in the Autism Research Matrix.

To provide the necessary information for an appropriate committee analysis of activities outlined in this legislation, the com-

mittee requires a specific report 4 years after the date of enactment of the “Combating Autism Act of 2006.”

Finally, the committee repeals sections of the “Children’s Health Act of 2000” that were updated by the “Combating Autism Act of 2006.”

#### V. COST ESTIMATE

Due to time constraints the Congressional Budget Office estimate was not included in the report. When received by the committee, it will appear in the Congressional Record at a later time.

#### VI. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

The committee has determined that there is no impact of this law on the Legislative Branch.

#### VII. REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has determined that there will be minimal increases in the regulatory burden imposed by this bill.

#### VIII. SECTION-BY-SECTION ANALYSIS

##### *Section 2—Activities to improve autism-related research*

Section 409C—This section authorizes the director of NIH to develop and implement a strategic plan for research related to autism spectrum disorder. The director will take into consideration the recommendations of the Interagency Autism Coordinating Committee (IACC). Oversight of the strategic plan and budget for research is based on the existing Autism Research Roadmap and Matrix developed by the IACC. The strategic plan shall require identification of the total expenditures of NIH research activities related to autism spectrum disorder.

This section promotes the expansion, intensification and coordination of activities at NIH related to autism spectrum disorder. It reauthorizes the Autism Centers of Excellence which were originally created in the Children’s Health Act of 2000. The funding may support both basic and clinical research in the fields of developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, psychopharmacology or toxicology. It will also support continued investigations into the causation, diagnosis, early detection, prevention, control, intervention and cure for autism spectrum disorder. Centers of Excellence will also receive funding for coordination of services and information for patients. The director of NIH shall promote research to determine evidence-based best practices for diagnosis and intervention strategies for individuals with autism spectrum disorder.

This section authorizes \$500 million for NIH research funding over 5 years (\$68 million for 2007, \$82 million for 2008, \$96 million for 2009, \$120 million for 2010 and \$134 million for 2011) and \$195 million for funding the Autism Centers of Excellence over 5 years (\$26 million for 2007, \$32.5 million for 2008, \$38 million for 2009, \$45.5 million for 2010, \$52 million for 2011).

This section promotes research initiatives for basic and clinical research of a broad array of environmental factors. The research will be coordinated through the Centers of Excellence in Environmental Health and will have the same requirements concerning coordinating, reporting and organization as applied to the other Centers of Excellence.

It authorizes \$45 million in funding for the National Institutes of Environmental Health over 5 years (\$6 million for 2007, \$7.5 million for 2008, \$9 million for 2009, \$10.5 million for 2010, and \$12 million for 2011).

This section also authorizes the Secretary to establish and provide funding for the collection, storage, coordination, and public availability of data generated from public and private research partnerships. It will also establish a program under which tissue samples, genetic material or biological materials are available for research.

*Section 3—Developmental disabilities surveillance and research programs*

Section 399AA—This section reauthorizes CDC's epidemiologic surveillance programs and establishes regional Centers of Excellence for collection, analysis and reporting of epidemiological data on autism spectrum disorder and other developmental disabilities. The Centers will also assist with the development and coordination of State autism spectrum disorder and other developmental disabilities efforts within a region. This section authorizes CDC to promote research to determine evidence-based best practices for diagnosis and interventions for individuals with autism spectrum disorder and other developmental disabilities. This section authorizes \$75 million for years 2007 through 2011.

Section 399BB—This section increases awareness, reduces barriers to screening and diagnosis, and promotes evidence-based early interventions for individuals with autism spectrum disorder and other developmental disabilities. It also promotes the training of professionals to utilize valid and reliable screening tools to diagnose and provide evidence based interventions. Information will be provided through Federal programs that target individuals and their families (such as Head Start, Early Start, Healthy Start and Medicaid and SCHIP). This section also requires the designation of a lead agency with demonstrated experience and expertise in autism by the Governor of each State to coordinate and provide comprehensive information, education and referral services regarding autism spectrum disorder and other developmental disabilities. It also promotes the development and implementation of valid and reliable screening tools for autism spectrum disorder and other developmental disabilities. Both the Secretary of HHS and the Secretary of Education shall collaborate to provide collection, storage, and coordination of screening tools, educational materials and other products used by Federal programs. The Secretary of HHS shall also expand the interdisciplinary training opportunities through the Health Resources and Services Administration (HRSA) grants to public and non-profit agencies and promote grants to determine the evidence-based practices for interventions for autism spectrum disorder and other developmental disabilities. They shall also develop guidelines for these interventions and disseminate such informa-

tion. It authorizes \$210 million in funding over 5 years (\$32 million for 2007, \$37 million for 2008, \$42 million for 2009, \$47 million for 2010, and \$52 million for 2011).

Section 399CC—This section reauthorizes the “Autism Coordinating Committee” established in the Children’s Health Act of 2000. The Interagency Autism Coordinating Committee (IACC) shall make recommendations concerning the strategic plan for the Autism Matrix. The IACC will also develop and annually update advances in autism spectrum disorder research related to causes, early screening, diagnosis, intervention and access to services for individuals with autism spectrum disorder. The public member participation in the IACC will be comprised of 1/3 (or 6 members) of the committee. The IACC will be funded by such sums as necessary each year through 2011.

Section 399DD—This section requires a report from the Secretary of HHS in coordination with the Secretary of Education no later than 4 years after the date of enactment of this bill. The report shall be submitted to the Health, Education, Labor, and Pension Committee in the Senate and Energy and Commerce Committee of the House of Representatives on the progress of activities related to autism spectrum disorder and other developmental disabilities.

Repeals—The respective sections of the Children’s Health Act of 2000 are repealed.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

**PUBLIC HEALTH SERVICE ACT**

\* \* \* \* \*

**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE**

**PART A—RESEARCH AND INVESTIGATION**

IN GENERAL

SEC. 301 \* \* \*

\* \* \* \* \*

**PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN**

**SEC. 399W. [280h] GRANTS TO PROMOTE CHILDHOOD NUTRITION AND PHYSICAL ACTIVITY.**

(a) IN GENERAL.—\* \* \*

\* \* \* \* \*

**PART R—PROGRAMS RELATING TO AUTISM**

**SEC. 399AA. DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.**

*(a) AUTISM SPECTRUM DISORDER AND OTHER DEVELOPMENTAL DISABILITIES.—*

*(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants or cooperative agreements to eligible entities for the collection, analysis, and reporting of State epidemiological data on autism spectrum disorder and other developmental disabilities. An eligible entity shall assist with the development and coordination of State autism spectrum disorder and other developmental disability surveillance efforts within a region. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.*

*(2) DATA STANDARDS.—In submitting epidemiological data to the Secretary pursuant to subsection (a), an eligible entity shall report data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with autism spectrum disorder or other developmental disabilities.*

*(3) ELIGIBILITY.—To be eligible to receive an award under paragraph (1), an entity shall be a public or nonprofit private entity (including a health department of a State or a political subdivision of a State, a university, or any other educational institution), and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.*

*(b) CENTERS OF EXCELLENCE IN AUTISM SPECTRUM DISORDER EPIDEMIOLOGY.—*

*(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, award grants or cooperative agreements for the establishment of regional centers of excellence in autism spectrum disorder and other developmental disabilities epidemiology for the purpose of collecting and analyzing information on the number, incidence, correlates and causes of autism spectrum disorder and other developmental disabilities.*

*(2) REQUIREMENTS.—To be eligible to receive a grant or cooperative agreement under paragraph (1), an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including an agreement that the center to be established under the grant or cooperative agreement shall operate in accordance with the following:*

*(A) The center will collect, analyze, and report autism spectrum disorder and other developmental disability data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with developmental disabilities.*

(B) *The center will develop or extend an area of special research expertise (including genetics, epigenetics, epidemiological research related to environmental exposures), immunology, and other relevant research specialty areas.*

(C) *The center will identify eligible cases and controls through its surveillance system and conduct research into factors which may cause or increase the risk of autism spectrum disorder and other developmental disabilities.*

(c) **FEDERAL RESPONSE.**—*The Secretary shall coordinate the Federal response to requests for assistance from State health, mental health, and education department officials regarding potential or alleged autism spectrum disorder or developmental disability clusters.*

(d) **DEFINITIONS.**—*In this part:*

(1) **OTHER DEVELOPMENTAL DISABILITIES.**—*The term “other developmental disabilities” has the meaning given the term “developmental disability” in section 102(8) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15002(8)).*

(2) **STATE.**—*The term “State” means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, and the Trust Territory of the Pacific Islands.*

(e) **AUTHORIZATION OF APPROPRIATIONS.**—*To carry out this section, there is authorized to be appropriated, \$15,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011.*

(f) **SUNSET.**—*This section shall not apply after September 30, 2011.*

**SEC. 399BB. AUTISM EDUCATION, EARLY DETECTION, AND INTERVENTION.**

(a) **PURPOSE.**—*It is the purpose of this section—*

(1) *to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions for individuals with autism spectrum disorder or other developmental disabilities, and train professionals to utilize valid and reliable screening tools to diagnose or rule out and provide evidence-based interventions for children with autism spectrum disorder and other developmental disabilities; and*

(2) *to conduct activities under this section with a focus on an interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act) that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.*

(b) **IN GENERAL.**—*The Secretary shall, subject to the availability of appropriations, establish and evaluate activities to—*

(1) *provide information and education on autism spectrum disorder and other developmental disabilities to increase public awareness of developmental milestones;*

(2) *promote research into the development and validation of reliable screening tools for autism spectrum disorder and other developmental disabilities and disseminate information regarding those screening tools;*

(3) promote early screening of individuals at higher risk for autism spectrum disorder and other developmental disabilities as early as practicable, given evidence-based screening techniques and interventions;

(4) increase the number of individuals who are able to confirm or rule out a diagnosis of autism spectrum disorder and other developmental disabilities;

(5) increase the number of individuals able to provide evidence-based interventions for individuals diagnosed with autism spectrum disorder or other developmental disabilities;

(6) promote the use of evidence-based interventions for individuals at higher risk for autism spectrum disorder and other developmental disabilities as early as practicable.

(c) INFORMATION AND EDUCATION.—

(1) IN GENERAL.—In carrying out subsection (b)(1), the Secretary, in collaboration with the Secretary of Education and the Secretary of Agriculture, shall, subject to the availability of appropriations, provide culturally competent information regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, and evidence-based interventions to meet the needs of individuals with autism spectrum disorder or other developmental disabilities and their families through—

(A) Federal programs, including—

(i) the Head Start program;

(ii) the Early Start program;

(iii) the Healthy Start program;

(iv) programs under the Child Care and Development Block Grant Act of 1990;

(v) programs under title XIX of the Social Security Act (particularly the Medicaid Early and Periodic Screening, Diagnosis and Treatment Program);

(vi) the program under title XXI of the Social Security Act (the State Children's Health Insurance Program);

(vii) the program under title V of the Social Security Act (Maternal and Child Health Block Grant Program);

(viii) the program under parts B and C of the Individuals with Disabilities Education Act;

(ix) the special supplemental nutrition program for women, infants, and children established under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786); and

(x) the State grant program under the Rehabilitation Act of 1973.

(B) State licensed child care facilities; and

(C) other community-based organizations or points of entry for individuals with autism spectrum disorder and other developmental disabilities to receive services.

(2) LEAD AGENCY.—

(A) DESIGNATION.—The governor of a State shall designate a public agency as a lead agency to coordinate the activities provided for under paragraph (1) in the State at the State level.

(B) *INFORMATION.*—The Governor or a State, acting through the lead agency under subparagraph (A), shall make available to individuals and their family members, guardians, advocates, or authorized representatives, providers, and other appropriate individuals in the State, comprehensive culturally competent information about State and local resources regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, available services and supports, and evidence-based interventions. Such information shall be provided through—

- (i) toll-free telephone numbers;
- (ii) Internet websites;
- (iii) mailings; or
- (iv) other means as the Governor may require.

(C) *REQUIREMENTS OF AGENCY.*—In designating the lead agency under subparagraph (A), the Governor shall—

- (i) select an agency that has demonstrated experience and expertise in—

(I) autism spectrum disorder and other developmental disability issues; and

(II) developing, implementing, conducting, and administering programs and delivering education, information, and referral services (including technology-based curriculum-development services) to individuals with developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals locally and across the State; and

- (ii) consider input from individuals with developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals.

(d) *TOOLS.*—

(1) *IN GENERAL.*—To promote the use of valid and reliable screening tools for autism spectrum disorder and other developmental disabilities, the Secretary shall develop a curriculum for continuing education to assist individuals in recognizing the need for valid and reliable screening tools and the use of such tools.

(2) *COLLECTION, STORAGE, COORDINATION, AND AVAILABILITY.*—The Secretary, in collaboration with the Secretary of Education, shall provide for the collection, storage, coordination, and public availability of tools described in paragraph (1), educational materials and other products that are used by the Federal programs referred to in subsection (c)(1)(A), as well as—

(A) programs authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000;

(B) early intervention programs or interagency coordinating council's authorized under part C of the Individuals with Disabilities Education Act; and

(C) children with special health care needs programs authorized under title V of the Social Security Act.

(3) *REQUIRED SHARING.*—*In establishing mechanisms and entities under this subsection, the Secretary, and the Secretary of Education, shall ensure the sharing of tools, materials, and products developed under this subsection among entities receiving funding under this section.*

(e) *DIAGNOSIS.*—

(1) *TRAINING.*—*The Secretary, in coordination with activities conducted under title V of the Social Security Act, shall, subject to the availability of appropriations, expand existing interdisciplinary training opportunities or opportunities to increase the number of sites able to diagnose or rule out individuals with autism spectrum disorder or other developmental disabilities and ensure that—*

(A) *competitive grants or cooperative agreements are awarded to public or non-profit agencies, including institutions of higher education, to expanding existing or develop new maternal and child health interdisciplinary leadership education in neurodevelopmental and related disabilities programs (similar to the programs developed under section 501(a)(2) of the Social Security Act) in States that do not have such a program;*

(B) *trainees under such training programs—*

(i) *receive an appropriate balance of academic, clinical, and community opportunities;*

(ii) *are culturally competent;*

(iii) *are ethnically diverse;*

(iv) *demonstrate a capacity to evaluate, diagnose or rule out, develop, and provide evidence-based interventions to individuals with autism spectrum disorder and other developmental disabilities; and*

(v) *demonstrate an ability to use a family-centered approach; and*

(C) *program sites provide culturally competent services.*

(2) *TECHNICAL ASSISTANCE.*—*The Secretary may award one or more grants under this section to provide technical assistance to the network of interdisciplinary training programs.*

(3) *BEST PRACTICES.*—*The Secretary shall promote research into additional valid and reliable tools for shortening the time required to confirm or rule out a diagnosis of autism spectrum disorder or other developmental disabilities and detecting individuals with autism spectrum disorder or other developmental disabilities at an earlier age.*

(f) *INTERVENTION.*—*The Secretary shall promote research, through grants or contracts, to determine the evidence-based practices for interventions for individuals with autism spectrum disorder or other developmental disabilities, develop guidelines for those interventions, and disseminate information related to such research and guidelines.*

(g) *AUTHORIZATION OF APPROPRIATIONS.*—*To carry out this section, there is authorized to be appropriated, \$32,000,000 for fiscal year 2007, \$37,000,000 for fiscal year 2008, \$42,000,000 for fiscal year 2009, \$47,000,000 for fiscal year 2010, and \$52,000,000 for fiscal year 2011, of which—*

(1) *\$5,000,000 shall be made available in each fiscal year for activities described in subsection (c); and*

(2) \$3,000,000 shall be made available in fiscal year 2007, \$6,000,000 in fiscal year 2008, \$9,000,000 in fiscal year 2009, \$12,000,000 in fiscal year 2010, and \$15,000,000 in fiscal year 2011, for activities described in subsection (f).

(h) **SUNSET.**—This section shall not apply after September 30, 2011.

**SEC. 399CC. INTERAGENCY AUTISM COORDINATING COMMITTEE.**

(a) **ESTABLISHMENT.**—The Secretary shall establish a committee, to be known as the “Interagency Autism Coordinating Committee” (in this section referred to as the “Committee”), to coordinate all efforts within the Department of Health and Human Services concerning autism spectrum disorder.

(b) **RESPONSIBILITIES.**—In carrying out its duties under this section, the Committee shall—

(1) make recommendations concerning the strategic plan described in section 409C(a);

(2) develop and annually update advances in autism spectrum disorder research related to causes, early screening, diagnosis or rule out, intervention, and access to services and supports for individuals with autism spectrum disorder; and

(3) make recommendations to the Secretary regarding the public participation in decisions relating to autism spectrum disorder.

(c) **MEMBERSHIP.**—

(1) **IN GENERAL.**—The Committee shall be composed of—

(A) the Director of the Centers for Disease Control and Prevention;

(B) the Director of the National Institutes of Health, and the Directors of such national research institutes of the National Institutes of Health as the Secretary determines appropriate;

(C) the heads of such other agencies as the Secretary determines appropriate;

(D) representatives of other Federal Governmental agencies that serve individuals with autism spectrum disorder such as the Department of Education; and

(E) the additional members appointed under paragraph (2).

(2) **ADDITIONAL MEMBERS.**—Not fewer than 6 members of the Committee, or 1/3 of the total membership of the Committee, whichever is greater, shall be composed of non-federal public members to be appointed by the Secretary, of which—

(A) at least one such member shall be an individual with a diagnosis of autism spectrum disorder;

(B) at least one such member shall be a parent or legal guardian of an individual with an autism spectrum disorder; and

(C) at least one such member shall be a representative of leading research, advocacy, and service organizations for individuals with autism spectrum disorder.

(d) **ADMINISTRATIVE SUPPORT; TERMS OF SERVICE; OTHER PROVISIONS.**—The following provisions shall apply with respect to the Committee:

(1) The Committee shall receive necessary and appropriate administrative support from the Secretary.

(2) *Members of the Committee appointed under subsection (c)(2) shall serve for a term of 4 years, and may be reappointed for one or more additional 4 year term. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office.*

(3) *The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.*

(4) *All meetings of the Committee shall be public and shall include appropriate time periods for questions and presentations by the public.*

(e) **COMPENSATION AND EXPENSES.**—*Members of the Committee who are officers or employees of the Federal Government shall serve as members of the Committee without compensation in addition to that received in their regular government employment. Other members of the Committee shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including travel time) they are engaged in the performance of their duties as members of the Committee.*

(f) **SUBCOMMITTEES; ESTABLISHMENT AND MEMBERSHIP.**—*In carrying out its functions, the Committee may establish subcommittees and convene workshops and conferences. Such subcommittees shall be composed of Committee members and may hold such meetings as are necessary to enable the subcommittees to carry out their duties.*

(g) **AUTHORIZATION OF APPROPRIATIONS.**—*To carry out this section, there is authorized to be appropriated, such sums as may be necessary for each of fiscal years 2007 through 2011.*

(h) **SUNSET.**—*This section shall not apply after September 30, 2011 and the Committee shall be terminated on such date.*

**SEC. 399DD. REPORT TO CONGRESS.**

(a) **IN GENERAL.**—*Not later than 4 years after the date of enactment of the Combating Autism Act of 2006, the Secretary, in coordination with the Secretary of Education, shall prepare and submit to the Health, Education, Labor, and Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives a progress report on activities related to autism spectrum disorder and other developmental disabilities.*

(b) **CONTENTS.**—*The report submitted under subsection (a) shall contain—*

(1) *a description of the progress made in implementing the provisions of the Combating Autism Act of 2006;*

(2) *a description of the amounts expended on the implementation of the particular provisions of Combating Autism Act of 2006;*

(3) *information on the incidence of autism spectrum disorder and trend data of such incidence since the date of enactment of the Combating Autism Act of 2006;*

(4) *information on the average age of diagnosis for children with autism spectrum disorder and other disabilities, including how that age may have changed over the 4-year period beginning on the date of enactment of this Act;*

(5) *information on the average age for intervention for individuals diagnosed with autism spectrum disorder and other de-*

*velopmental disabilities, including how that age may have changed over the 4-year period beginning on the date of enactment of this Act;*

*(6) information on the average time between initial screening and then diagnosis or rule out for individuals with autism spectrum disorder or other developmental disabilities, as well as information on the average time between diagnosis and evidence-based intervention for individuals with autism spectrum disorder or other developmental disabilities;*

*(7) information on the effectiveness and outcomes of interventions for individuals diagnosed with autism spectrum disorder, including by various subtypes, and other developmental disabilities and how the age of the child may affect such effectiveness;*

*(8) information on the effectiveness and outcomes of innovative and newly developed intervention strategies for individuals with autism spectrum disorder or other developmental disabilities; and*

*(9) information on services and supports provided to individuals with autism spectrum disorder and other developmental disabilities who have reached the age of majority (as defined for purposes of section 615(m) of the Individuals with Disabilities Education Act (20 U.S.C. 1415(m))).*

\* \* \* \* \*

EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES OF NATIONAL INSTITUTES OF HEALTH WITH RESPECT TO RESEARCH ON AUTISM

**[SEC. 409C. [284g] (a) IN GENERAL.—**

**[(1) EXPANSION OF ACTIVITIES.—**The Director of NIH (in this section referred to as the “Director”) shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism.

**[(2) ADMINISTRATION OF PROGRAM; COLLABORATION AMONG AGENCIES.—**The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

**[(b) CENTERS OF EXCELLENCE.—**

**[(1) IN GENERAL.—**The Director shall under subsection (a)(1) make awards of grants and contracts to public or non-profit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism.

**[(2) RESEARCH.—**Each center under paragraph (1) shall conduct basic and clinical research into autism. Such research should include investigations into the cause, diagnosis, early detection, prevention, control, and treatment of autism. The centers, as a group, shall conduct research including the fields of developmental neurobiology, genetics, and psychopharmacology.

**[(3) SERVICES FOR PATIENTS.—**

**[(A) IN GENERAL.—**A center under paragraph (1) may expend amounts provided under such paragraph to carry out a program to make individuals aware of opportunities

to participate as subjects in research conducted by the centers.

[(B) REFERRALS AND COSTS.—A program under subparagraph (A) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such subparagraph, referrals for health and other services, and such patient care costs as are required for research.

[(C) AVAILABILITY AND ACCESS.—The extent to which a center can demonstrate availability and access to clinical services shall be considered by the Director in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

[(4) COORDINATION OF CENTERS; REPORTS.—The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.

[(5) ORGANIZATION OF CENTERS.—Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director.

[(6) NUMBER OF CENTERS; DURATION OF SUPPORT.—

[(A) IN GENERAL.—The Director shall provide for the establishment of not less than five centers under paragraph (1).

[(B) DURATION.—Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

[(c) FACILITATION OF RESEARCH.—The Director shall under subsection (a)(1) provide for a program under which samples of tissues and genetic materials that are of use in research on autism are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

[(d) PUBLIC INPUT.—The Director shall under subsection (a)(1) provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism and through which the Director can receive comments from the public regarding such programs and activities.

[(e) FUNDING.—There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are in addition to any other amounts appropriated for such purpose.]

**SEC. 409C. AUTHORITY OF THE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH RELATING TO AUTISM.**

(a) *STRATEGIC PLAN FOR AUTISM RESEARCH.*—

(1) *IN GENERAL.*—The Secretary, acting through the Director, shall develop and implement a strategic plan for the conduct and support of research related to autism spectrum disorder.

(2) *REQUIREMENTS.*—The strategic plan developed under paragraph (1)—

(A) shall—

(i) be updated annually;

(ii) take into account the research recommendations of the Interagency Autism Coordinating Committee under section 399CC; and

(iii) using professional judgment, outline the proposed budgetary requirements of the strategic plan, including specific funding expectations for continued multi-year program activities, as well as new and complementary program activities, subject to the availability of appropriations; and

(B) may include investigator-initiated research.

(3) *REPORT.*—Not later than April 1, 2008, and annually thereafter, the Secretary, acting through the Director, shall prepare and submit to the appropriate committees of Congress a report that contains—

(A) the strategic plan under paragraph (1) that will be applicable to the upcoming fiscal year; and

(B) a description of the actual dollar expenditures for autism spectrum disorder during the previous fiscal year.

(b) *EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.*—The Secretary, acting through the Director, shall, subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to autism spectrum disorder.

(c) *CENTERS OF EXCELLENCE.*—

(1) *AUTISM CENTERS OF EXCELLENCE.*—

(A) *IN GENERAL.*—The Secretary, acting through the Director, shall, subject to the availability of appropriations, award grants or contracts to public or nonprofit private entities to assist such entities in paying all or part of the costs of planning, establishing, improving, and providing basic operating support for centers of excellence concerning research on autism spectrum disorder.

(B) *RESEARCH ACTIVITIES.*—A center of excellence that receives funding under this paragraph shall conduct basic and clinical research into autism spectrum disorder. Such research shall—

(i) be conducted in the fields of developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, psychopharmacology, or toxicology; and

(ii) include investigations into the causation, diagnosis or rule out, early detection, prevention, services, supports, or intervention of autism spectrum disorder.

(C) *SERVICES.*—

(i) *IN GENERAL.*—A center of excellence that receives funding under this paragraph may expend amounts provided under a grant or contract under such para-

graph to carry out a program to make individuals aware of opportunities to participate as subjects in research conducted by the center.

(ii) REFERRALS AND COSTS.—A program carried out under clause (i) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such clause, referrals for health and other services and reimbursement of care for individuals as are required for such research.

(iii) AVAILABILITY AND ACCESS.—The extent to which a center of excellence that receives funding under this paragraph can demonstrate the availability of and access to clinical services shall be considered by the Director in making decisions concerning the awarding of grants or contracts to applicants that meet the scientific criteria for funding under this section.

(D) COORDINATION OF CENTERS OF EXCELLENCE.—The Director shall provide for the appropriate coordination of information among centers of excellence that receive funding under this paragraph and ensure regular communication between such centers.

(E) ORGANIZATION.—A center of excellence that receives funding under this paragraph shall use the facilities of a single institution, or be formed through a consortium of cooperating institutions, that meets such requirements as may be required by the Director.

(F) DURATION.—The term of a grant or contract awarded under this paragraph shall not exceed a period of 5 years. Such period may be extended for 1 or more additional periods not exceeding 5 years if the operations of the center of excellence involved have been reviewed by an appropriate technical and scientific peer review group established by the Director and the group has recommended to the Director the extension of such period.

(G) GEOGRAPHIC DIVERSITY.—The Director shall consider geographic diversity in awarding centers of excellence.

(2) CENTERS OF EXCELLENCE IN ENVIRONMENTAL HEALTH AND AUTISM.—

(A) IN GENERAL.—The Director shall, subject to the availability of appropriations, award grants or contracts to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding environmental health and autism spectrum disorder.

(B) RESEARCH.—A center of excellence established under this paragraph shall conduct basic and clinical research of a broad array of environmental factors that may have a possible role in autism spectrum disorder.

(C) COORDINATION AND ORGANIZATION.—The Secretary, acting through the Director of NIH, shall apply to the centers under this paragraph the same requirements concerning coordination, reporting, and organization as the requirements applied to the centers of excellence under subparagraphs (D), (E), (F), and (G) of paragraph (1).

(d) COLLECTION AND STORAGE OF DATA.—

(1) *IN GENERAL.*—The Secretary, acting through the Director and in coordination with the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, establish and provide funding for mechanisms and entities that provide for the collection, storage, coordination, and public availability of data that is collected by the centers of excellence under this section, under section 399AA(b), and under section 409C(c) and, to the extent possible, data generated from public and private research partnerships. In establishing such mechanisms and entities, the Secretary—

(A) shall ensure that there is data sharing among autism spectrum disorder researchers; and

(B) may utilize existing facilities.

(2) *FACILITATION OF RESEARCH.*—

(A) *ESTABLISHMENT OF PROGRAM.*—The Secretary shall establish a program under which samples of tissues and genetic and other biological materials that are of use in research on autism spectrum disorder are donated, collected, preserved, and made available for such research.

(B) *ACCEPTED SCIENTIFIC STANDARDS.*—The program established under paragraph (1) shall be—

(i) carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples; and

(ii) conducted so that the tissues and other materials saved, as well as any database compiled from such tissues and materials, are available to researchers at a reasonable cost and on an expedited basis.

(e) *CONSOLIDATION.*—The Secretary, acting through the Director, may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

(f) *AUTHORIZATION OF APPROPRIATIONS.*—

(1) *IN GENERAL.*—There is authorized to be appropriated—

(A) \$68,000,000 for fiscal year 2007, \$82,000,000 for fiscal year 2008, \$96,000,000 for fiscal year 2009, \$120,000,000 for fiscal year 2010, and \$134,000,000 for fiscal year 2011, to carry out subsections (a), (b), and (d);

(B) \$26,000,000 for fiscal year 2007, \$32,500,000 for fiscal year 2008, \$39,000,000 for fiscal year 2009, \$45,500,000 for fiscal year 2010, and \$52,000,000 for fiscal year 2011, to carry out subsection (c)(1); and

(C) \$6,000,000 for fiscal year 2007, \$7,500,000 for fiscal year 2008, \$9,000,000 for fiscal year 2009, \$10,500,000 for fiscal year 2010, and \$12,000,000 for fiscal year 2011, to carry out subsection (c)(2).

(2) *GENERAL USAGE.*—Of the amounts appropriated under subparagraphs (B) and (C) of paragraph (1), not to exceed 5 percent of such amounts may be utilized by the National Institutes of Health for administrative and other expenses.

(g) *SUNSET.*—This section shall not apply after September 30, 2011.

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