

Revisions to Combating Autism Act – 11/9/05

United States Senate

S 843

Introduced in Senate

April 19, 2005

Explanation and Rationale for Changes to S. 843

The Combating Autism Act was introduced in the Senate as S. 843 on April 19, 2005 and in the House on May 18, 2005 as H.R. 2421. The autism community has worked since that time to agree on revisions that more particularly address the needs of the community in the areas of scientific research directed at cause and cure, prevalence studies, and early screening, diagnosis, referral, and comprehensive medical care. Set forth below are the major changes from the original S. 843.

Section 499A. NIH Director.

1. Moved (a) requiring annual identification of budget to end as it seemed less important and required public announcement. Changed title to “announcement of” and deleted 2005 in favor of “annually.”
2. In renumbered (a) (Strategic Plan), added “causes of and treatments for” in front of research to have more specific focus. This is similar to the directive for cause and treatment research for breast cancer, 285a-6(c). This language may be too limiting as there may be needed research on ASD that does not in some way relate to “cause” or “cure.” If so, then the language would be changed to “research on autism . . . , including research relating to the causes of and treatments for”
3. Replace autism research “matrix” with “roadmap” in (a)(2)(B) for IACC as roadmap suggests a direction forward while matrix suggests just an uninteresting spreadsheet. Made same change to 399AA(c)(4) relating to surveillance centers.
4. Move the requirement for annual updates to the Roadmap in the IACC section, 399CC(b).
5. Combine sections (b) and (c) dealing with budgetary authority to eliminate redundancy.
6. Remove (b)(3) [requirement for evaluation] as this is redundant and

- covered in more detail in (d) [Evaluation and Report], now (c).
7. Added “and the need for any additional appropriations to achieve the objectives of the strategic plan” in renumbered (c)(1) (report to Congress) to provide a way for the Director to justify any requests for added appropriations submitted with the annual budget (although this is somewhat redundant to the separately required budget request).
 8. Added activities of the ACES centers to the evaluate and report requirement of renumbered (c) to make the report more comprehensive on all the research activities relating to autism.
 9. Added “the specific research activities being funded, activities of the ACES centers, progress toward the objectives of the strategic plan” to the report and evaluate language of renumbered (c) to be consistent with other NIH reports to Congress, for example 285a-6(e) relating to breast and reproductive cancers, 284i(e) relating to autoimmune diseases, and 283g(f) relating to muscular dystrophy, and to make it a more useful progress report.
 10. Add a new section (e) to require public participation in peer review for funding decisions. We considered as a model the program of peer review mechanisms developed under the Congressionally Mandated Medical Research Program administered by the Army. This began in 1992 based on pressure from consumer advocates to fund breast cancer research, and is funded annually by Congressional appropriations (now covering about 30 research topics in eight core areas) now totaling about \$277.5m. That program describes the benefits of consumer involvement in peer review as follows: “Consumers' first-hand experience with a disease, augmented by the experiences of others from the group who nominated them, provides a perspective that is complementary to the scientific expertise. This perspective helps the scientists understand the human side of how the research will impact the community, and allows for funding decisions that will reflect the concerns and needs of patients, the clinicians who treat them, and survivors and their families.” That model could be copied into CAA with the following language: “Public participation in funding decisions- The Director shall develop and implement a program modeled on mechanisms used in the Congressionally Mandated Medical Research Program administered by the Department of the Army to include members of the public in all decisions relating to funding.” We also considered recent initiatives to implement public participation in peer review at NIH. Ultimately, we decided that more general language would be a more appropriate means of

implementing this mechanism. The section also lists the categories of persons to be included in the mandated peer review mechanisms, including experts in the relevant research areas: “The Director shall develop and implement a program to include individuals with autism or other pervasive developmental disorders; parents or legal guardians of individuals with autism or other pervasive developmental disorders; persons with expertise in the relevant research areas; and representatives of leading autism research and service organizations in setting priorities for research on autism spectrum disorders, and in participating in scientific and programmatic review of research proposals on autism spectrum disorders.”

- 11 Add a new section (f) to authorize \$100 million in appropriations for discretionary programs. This is similar, for example, to the earmark for a breast cancer study in 42 USC 280e-4(b), for fetal alcohol syndrome in 280f-2(a), and for breast and reproductive system cancers in 285a-8(b). Some special programs in public health use more general language such as “such sums as may be necessary,” for example the program for treatment and education relating to childhood asthma, 42 USC 280g(e), the data and surveillance program for childhood malignancies, 280g-2(e), research relating to autoimmune diseases, 284i(e), and the program in applied research relating to children’s health, diet, physical activity, obesity, etc., 280h-1(b). Similar general language can also be found in the program for research in SIDS, 300c-12(a), “the Secretary shall assure that there are applied to research of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate, given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.”

Section 499B. Autism Centers of Excellence

1. Combined 499B and 499C (to codify the National Institute on Child Health Collaborative Program of Excellence in Autism centers). This is pursuant to NIH notice NOT-OT-05-048 (May 17, 2005) (available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-048.html>) announcing the combination of STAART and CPEA programs into a single program of autism centers of excellence. I have moved the text of proposed 499C to the end for reference in case some or all of its language need to be in the CAA. But I think it

would be best to avoid duplication.

2. Change the research topics in subsection (b)(2)(A) to “shall be conducted in the fields of developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, endocrinology, gastroenterology, and toxicology” Add “public availability” to the directives regarding collection of data in subsection (b)(4)(C). Added a requirement to achieve the benefits of collaboration that the Director “shall ensure broad and expeditious data sharing among autism researchers, including those outside the centers.”
3. Original (b)(2) provided that the centers’ program shall be carried out through NIMH “in collaboration with” other centers. Given the seemingly equal and complementary roles provided by the various centers, I got rid of the “collaboration” language and made the Institutes co-equal partners.
4. Added “autism” in front of “centers of excellence” in (b).
5. Added (b)(2)(B)(iii) to reflect the specific need to fund “cause” research relating to vaccines and other biologics. Also, changed “environmental triggers” to “environmental factors” to be more general. There may be environmental causes as well as “triggers.”
6. Add “expedited basis” to (b)(6)(C)(ii) regarding the availability of collected tissues, etc.
7. Added a new section (c) to incorporate the centers of excellence in environment and autism originally contained in a separate section 463C. It seems consistent to put all the autism-related NIH programs in a single part for focus. The vaccine-related “cause” language was added to the research topics in (c)(2) consistent with its inclusion in other listings of research topics.
8. Added language to (c)(3) as in (b)(4) to ensure that data collected are made available on an expedited basis to the public and other autism researchers outside the centers.
9. Added language to (d) to protect money already appropriated for STAART centers.

Section 399AA – CDC’s Epidemiology Centers of Excellence.

1. Replace the kids to be counted language in (b)(1) with “for the purpose of collecting and analyzing information on the number, incidence, incidence trend over time, by birth year, retrospectively and prospectively, for autism spectrum disorder, classic autism, and PDD-

- NOS, correlates, and causes of autism and related developmental disabilities.” This will ensure that data reported are comparable over time and that any changes in diagnostic criteria will not complicate comparison of year-specific and trend data. Added language referring to the current edition of the DSM and diagnostic criteria in effect in 2005. Regarding birth cohorts, “retrospectively and prospectively” was added to ensure that prevalence reporting would be comparable over time even if diagnostic criteria changed.
2. Added vaccines and other biologics to (b)(3)(C)’s list of research topics to ensure that these are not excluded from the collection of epidemiology data relating to “cause.”
 3. Added “epigenetics” to (b)(3)(D) to reflect the development of this new field.
 4. In section (c)(1), added “The clearinghouse shall implement a data sharing program so that these data can be made publicly available on an expedited basis.” This implements the recommendations of the IOM 2/05 panel that focused on the need to make VSD data publicly available both to facilitate good and competitive science and to help ensure public confidence in the safety of vaccines.
 5. Added an “expedited basis” requirement in section (c)(3) to ensure that biological materials are quickly made available to researchers.
 6. Deleted the “updated as appropriate” language from (c)(4) as the Roadmap is now to be updated annually by IACC.

Section 399BB. Information and Education.

1. Expanded the “purpose” language in (a) to ensure that education and information address the life-long needs of those diagnosed with autism and their families. Clarify that programs will both address the needs of those with autism and their families and inform and educate the public about those needs. The section also makes more specific the types of health professionals that should receive information. Finally, the section emphasizes the need for early identification and prompt referral.

Section 399CC. IACC.

1. Added “Interagency” to “Autism Coordinating Committee.”
2. Added a new section (b) to more specifically list responsibilities, including annual updates to the Roadmap.
3. Changed (c)(2) to make public members mandatory and have a minimum of six or 1/3 whichever is greater. Also, provided that at

least three of the public members are also on IACC. Also, provided that at least one member have an ASD diagnosis. This is a common feature in disease/disorder-specific oversight programs. The 1/3 public member requirement is consistent with, for example, the Coordinating Committee for Muscular Dystrophy, 283g(d)(2)(B), “1/3 of such members shall be public members, including a broad cross section of persons affected with muscular dystrophies including parents or legal guardians, affected individuals, researchers, and clinicians,” the advisory board for arthritis, 285d-7(b) (8 of 20 are public members), the advisory councils for each of the institutes, 284a(b)(3) (6 of 18 are public leaders), the national advisory board for medical rehabilitation research, 285g-4(f) (6 of 18 are public members), the advisory board for deafness and other communications disorders, 285m-4(b) (6 of 18 are public members), and the advisory boards for diabetes and digestive diseases, 285d-7(b) (6 of 18 are public members). Inclusion of public/consumer members on the IACC is innovative and somewhat unique as most disease-related inter-agency coordinating committees are limited to federal employees. Inclusion of these members on the IACC is efficient and avoids the need for duplication of public input used for some diseases and disorders via task forces and advisory boards, for example for diabetes and digestive diseases, 285c-4. A few disease-specific research program don’t seem to provide for any public input, for example the advisory program on women’s’ health, 287d(d) (18 scientific members, a majority of which are women).

4. In section (d), added (4) providing that all meetings shall be public and provide opportunity for public participation.
5. In section (d), added (5) to provide same compensation and expenses for IACC members as for Advisory Board.

Section 399DD. Screening, diagnosis, and treatment.

1. In (a)(2)(A), clarifying that “intervention” includes both referral to and the treatment and services provided by the relevant entities.
2. Adding the following language to (a)(2)(C) to more completely define “comprehensive medical care: “Comprehensive medical care shall include both evaluation and treatment of abnormalities identified during a complete history and physical examination and through appropriate laboratory evaluations. Areas should include, but not be limited to, developmental, psychosocial, behavioral, nutritional, neurological, immune, endocrine, gastrointestinal, metabolic, and

- toxicological parameters.” Adding “diagnosis” to clarify that “comprehensive medical care” includes diagnosis, evaluation, and treatment.
3. Adding “criteria in effect in 2005” to the diagnostic criteria language in (b)(1) to ensure data comparability among past, present, and future reporting. Regarding birth cohorts, “retrospectively and prospectively” was added to ensure that prevalence reporting would be comparable over time even if diagnostic criteria changed.
 4. Adding language to (b)(1) to ensure that diagnostic data can be compared over time: “to ensure quality monitoring of autism screening, diagnosis, and intervention programs and systems, including the reporting by birth year of the prevalence, incidence and trends in number of cases diagnosed by type of autism spectrum disorder as defined in the current edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association as well as diagnostic criteria in effect in 2005.”
 5. Add “medical care” to (b)(3) and (b)(5) relating to cost studies to be consistent with the purposes set forth in (a).
 6. Add “health status” to (b)(5) concerning metrics to ensure that overall health is also taken into consideration.
 7. Add “medical care” to (c)(2) and (c)(3) to ensure that policy guidance to federal and state agencies includes this subject.
 8. Section (d) has been deleted because the change has already been made. The proposed language would have required the Administrator of Medicare and Medicaid Services to assign a relative unit value to the diagnostic code for screening.
 9. The ratio of appropriations is changed in (e), now (d), to \$90 million for HRSA and states and \$10 million for CDC.

Section 399FF. Autism Advisory Board.

1. This is a new section responsive to the consensus concerns for greater oversight. It is modeled after advisory boards used for most if not all of the disease/disorder-specific programs at NIH. See the general language applicable to all such boards set forth below, 284a.
2. Composed of all non-federal employees, 12 scientists and 8 from the autism community.
3. It would have broad oversight over all autism programs, NIH, CDC, and HRSA, within HHS.

Section 399GG. Public Participation in Funding.

1. This is a new section identical to the authority granted the NIH Direction by new section 499e. See above (499A #10) for further explanation.
2. This would apply to all autism-related funding decisions made by CDC and HRSA.