112TH CONGRESS
1ST SESSION

S. 1841

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health and the Centers for Disease Control and Prevention with respect to translational research and related activities concerning Down syndrome, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 10, 2011

Mr. BROWN of Ohio (for himself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health and the Centers for Disease Control and Prevention with respect to translational research and related activities concerning Down syndrome, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Trisomy 21 Research Resource Act of 2011''.

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) The father of modern genetics, Dr. Jerome Lejeune, discovered the extra chromosome 21 responsible for the condition, known as Down syndrome, which he called Trisomy 21 in January 1959. His discovery has opened the doors of genetics to new generations of researchers.

(2) Down syndrome was named after Dr. John Langdon Down, the first physician to describe the syndrome.

(3) Down syndrome is the most frequent genetic cause of intellectual and developmental disabilities and associated medical problems and occurs in one out of 691 live births, in all races and economic groups. Intellectual disability, formerly mental retardation, is a disability characterized by significant limitations both in intellectual functioning and in adaptive behavior, which covers many everyday social and practical skills. This disability originates before birth and lasts a lifetime.

(4) Chromosomes are cell structures that hold our genes. Genes are the instructions that cells give that determine things such as eye color, blood type, and susceptibility to disease. Human cells normally contain 23 pairs of chromosomes, one pair from the mother and one pair from the father.

(5) Down syndrome occurs when, because of cell division error, there are 3 partial or total copies of chromosome 21 rather than the normal 2. Because of the extra copy of chromosome 21, people with Down syndrome are more susceptible to diseases including Alzheimer's disease, leukemia, congenital heart disease, seizures, and diabetes. However, people with Down syndrome may be protected from other common diseases including atherosclerosis, hypertension, and solid tumors such as brain, gastrointestinal, and breast tumors. Therefore, the study of Down syndrome may lead to novel treatments of common diseases that affect millions of Americans. Lead researcher, Dr. Bill Mobely is quoted as saying ''We're not just asking what our country can do for people with Down syndrome, we're asking what studies of people can do for our country and the world.''.

(6) There are more than 400,000 people living with Down syndrome in the United States.

(7) Down syndrome incidence increases with the age of the mother, but due to higher fertility rates in younger women, the majority of children with Down syndrome are born to women under 35 years of age.

(8) Life expectancy for people with Down syndrome has increased dramatically in recent decades, but varies significantly across various ethnic groups. People with Down syndrome attend school, work, participate in decisions that concern them, and contribute to society in many meaningful ways.

(9) The Children's Health Act of 2000 (Public Law 106–310) amended the Public Health Service Act (42 U.S.C. 201 et seq.) and included a number of provisions that addressed the research and surveillance needs of many disabilities such as autism, traumatic brain injury, Fragile X syndrome, juvenile diabetes, asthma, epilepsy, and others. However, this landmark legislation did not address the significant research, surveillance, and clinical care needs of Down syndrome and thus has been an impediment to progress in the Down syndrome research community over the last decade. This Act attempts to incorporate Down syndrome as an area of permissible research and surveillance at the National Institutes of Health and the Centers for Disease Control and Prevention and will foster a better understanding of Down syndrome.

SEC. 3. NIH DOWN SYNDROME RESEARCH ACTIVITIES.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409K. DOWN SYNDROME RESEARCH ACTIVITIES.

"(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES.—

"(1) IN GENERAL.—The Director of NIH, acting through the director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall expand and intensify programs of the National Institutes of Health with respect to research and related activities concerning Down syndrome. The Director of NIH shall carry out such programs in coordination with a working group composed of representatives of the relevant institutes, centers, offices, and agencies of the National Institutes of Health.

"(2) NIH RESEARCH PLAN ON DOWN SYNDROME.—The Director of NIH shall publish a Research Plan on Down Syndrome, and update it every five years or as appropriate.

"(b) ACTIVITIES.—In expanding and intensifying programs under subsection (a)(1):

"(1) BASIC, TRANSLATIONAL, AND CLINICAL RESEARCH.—Building on the comprehensive research plan set forth by the NIH Research Plan for Down Syndrome published in October 2007, the Director of NIH may conduct basic, clinical, and translational research on Down syndrome, including research on the following:

"(A) Early detection, diagnosis, and treatment of Down syndrome.

"(B) The biological mechanisms responsible for structural and functional anomalies in cells and tissues affected by Down syndrome.

"(C) The biological mechanisms responsible for cognitive and behavioral dysfunction resulting from Down syndrome.

"(D) Novel biomedical and pharmacological interventions designed to promote or enhance cognition and related brain functions and activities of daily living (ADLs).

"(E) Co-occurrence of and treatments for associated medical and neurobehavioral disorders.

"(F) Developmental disorders, interventions for congenital heart disease, obstructive sleep apnea, coronary heart disease, obesity, and metabolism.

“(G) Contributions of genetic variation to clinical presentation as targets for therapy.

“(H) Identification of biomarkers for complex phenotypes.

“(I) Noninvasive imaging in support of efforts to identify other genotypes and phenotypes of Down syndrome.

“(J) Pharmacological and other therapies for common features of Down syndrome including Alzheimer’s disease and other Down syndrome-related disorders.

“(K) Research related to improving the quality of life for individuals with Down syndrome and their families.

“(L) Research training programs aimed at increasing the number of scientists who are trained to carry out these research directions.

“(2) FACILITATION OF RESEARCH RESOURCES.—

“(A) CONTACT REGISTRY FOR INDIVIDUALS WITH DOWN SYNDROME.—

“(i) IN GENERAL.—The Director of NIH may award a grant or contract to an eligible entity for the purpose of—

“(I) identifying individuals with Down syndrome across the Nation;

“(II) collecting the names and contact information of such individuals; and

“(III) maintaining such names and contact information in a registry.

“(ii) CONSENT REQUIRED.—As a condition on the receipt of a grant or contract under this subparagraph, an entity shall agree that information about any individual will be collected or maintained pursuant to this subparagraph only if the individual has consented to such collection and maintenance.

“(iii) ELIGIBLE ENTITY DEFINED.—In this subparagraph, the term ‘eligible entity’ means a consortium including at least one national Down syndrome patient advocacy organization.

“(B) RESEARCH DATABASE FOR DOWN SYNDROME.—

“(i) IN GENERAL.—The Director of NIH may establish a database including the names, contact information, and each medical condition of individuals with Down syndrome.

"(ii) REQUIREMENTS.—The database under clause (i) shall—

"(I) be searchable by category of medical condition; and

"(II) be used exclusively to facilitate research.

"(iii) CONSENT REQUIRED.—The Director of NIH may include information about an individual in the Research Database for Down Syndrome only with the individual's consent.

"(C) BIOBANK FOR DOWN SYNDROME.—

"(i) IN GENERAL.—The Director of NIH may expand one or more tissue banks maintained or supported by the National Institutes of Health—

"(I) to identify any tissue harvested from a tissue donor with Down syndrome;

"(II) to include each medical condition of any such tissue donor; and

"(III) to allow searches specific to tissue identified under subclause (I) and by category of medical condition included under subclause (II).

"(ii) CONSENT REQUIRED.—The Director of NIH may collect and maintain information about an individual pursuant to this subparagraph only with the individual's consent.

"(D) RESEARCH RESOURCES.—In carrying out this paragraph, the Director of NIH may—

"(i) subject to the consent requirements of subparagraphs (A)(ii), (B)(iii), and (C)(ii), use information collected by the National Institutes of Health pursuant to other provisions of law or prior to the date of the enactment of this section;

"(ii) take into consideration the availability of other research resources;

"(iii) encourage the use of research resources for research on, and development of, therapies and treatments for individuals with Down syndrome; and

"(iv) encourage the inclusion of individuals with Down syndrome in clinical trials conducted or supported by the National Institutes of Health.

“(3) DOWN SYNDROME CONSORTIUM.—The Director of NIH may provide for the participation of agencies of the National Institutes of Health in a consortium to facilitate the exchange of information and to make the research effort on Down syndrome more efficient and effective by ensuring consistent communication, minimizing duplication of effort, and integrating the varied perspectives of partner agencies, organizations, and individuals. Such consortium shall include at least one national Down syndrome patient advocacy organization and may be the same consortium receiving a grant or contract under paragraph (2)(A).”.

SEC. 4. CDC DOWN SYNDROME SURVEILLANCE AND RESEARCH PROGRAMS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317T the following:

“SEC. 317U. DOWN SYNDROME SURVEILLANCE AND RESEARCH PROGRAMS.

“(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants and cooperative agreements to public or nonprofit private entities (including State health departments, political subdivisions of States, universities, and other educational entities) for the collection, analysis, and reporting of data on Down syndrome. In making such awards, the Secretary may provide direct technical assistance, including personnel support, in lieu of cash.

"(b) NATIONAL DOWN SYNDROME EPIDEMIOLOGY PROGRAM.—

"(1) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to public or nonprofit private entities (including State health departments, political subdivisions of States, universities, and other educational entities) for the purpose of carrying out epidemiological activities regarding Down syndrome, including collecting and analyzing information on the number, incidence, correlates, and symptoms of cases and the clinical utility (including costs and benefits) of specific practice patterns. In making such awards, the Secretary may provide direct technical assistance, including personnel support, in lieu of cash.

"(2) NATIONAL SURVEILLANCE PROGRAM.—In carrying out subsection (a), the Secretary shall—

"(A) provide for a national surveillance program; and

"(B) where possible, ensure that the surveillance program is coordinated with the data and sample collection activities of the National Institutes of Health under section 409K.".

SEC. 5. REPORT TO CONGRESS.

Not later than January 1, 2012, and each January 1 thereafter, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of the Congress a report concerning the implementation of this Act and the amendments made by this Act.

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