I

112TH CONGRESS
1ST SESSION

H. R. 2695

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

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2011

Mrs. MCMORRIS RODGERS (for herself, Mr. VAN HOLLEN, and Mr. SESSIONS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health 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 Centers of Excellence Act of 2011".

SEC. 2. 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 of the title 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 5 years or as appropriate.

"(b) CENTERS OF EXCELLENCE.—

"(1) IN GENERAL.—In carrying out subsection (a)(1), the Director of NIH shall award grants and 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 translational research on Down syndrome. To the extent and in the amount of appropriations made in advance, the Director of NIH shall provide for the establishment of at least 6 such centers of excellence.

''(2) BASIC, TRANSLATIONAL, AND CLINICAL RESEARCH.—Each center receiving funds under paragraph (1) shall contribute to a comprehensive research portfolio for Down syndrome building upon the recommendations set forth in the NIH Research Plan on Down Syndrome published on October 8, 2007, have a primary focus on Down syndrome, provide an optimal venue and infrastructure for patient-oriented research, and conduct basic, clinical, and translational research on Down syndrome, including research on one or more of 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 regarding other genotype 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 numbers of scientists who are trained to carry out these research directions.

"(3) SERVICES FOR PATIENTS.—

"(A) IN GENERAL.—A center receiving funds under paragraph (1) shall 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 receiving funds under such paragraph.

"(B) REFERRALS AND COSTS.—A program under subparagraph (A) shall, in accordance with such criteria as the Director of NIH 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.—In awarding grants under this section, the Director of NIH shall require the applicant to demonstrate, and shall take into consideration, the availability of and access to health and medical services described in subparagraph (B).

"(4) TRAINING PROGRAM FOR CLINICIANS AND SCIENTISTS.—Each center receiving funds under paragraph (1) shall establish or expand training programs for medical and allied health clinicians and scientists in research relevant to Down syndrome.

"(5) COORDINATION OF CENTERS; REPORTS.—The Director of NIH shall—

"(A) provide for the coordination of information sharing among the centers receiving funds under paragraph (1) and ensure regular communication among such centers; and

"(B) require the centers to submit periodic reports to the Director on their activities.

"(6) ORGANIZATION OF CENTERS.—Each center receiving funds under paragraph (1) shall use the facilities of a single institution meeting such requirements as may be prescribed by the Director of NIH, be formed from a virtual consortium or network of such institutions, or both.

"(7) DURATION OF SUPPORT.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Director of NIH may not provide support to a center receiving funds under paragraph (1) for a period of more than 5 years.

"(B) EXTENSION.—The period referred to in subparagraph (A) may be extended for 1 or more additional periods not exceeding 5 years if—

"(i) the operations of the center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH; and

"(ii) such group has recommended to the Director that such period be extended.

"(c) DOWN SYNDROME CONSORTIUM.—In carrying out subsection (a)(1), the Director of NIH may establish a Down Syndrome Consortium to facilitate the exchange of information and to make the research effort on Down syndrome more efficient and effective by assuring consistent communication, minimizing duplication of effort, and integrating the varied perspectives of partner agencies, organizations, and individuals.

"(d) 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 section.

"(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $6,000,000 for each of fiscal years 2012 through 2017.".

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