

112TH CONGRESS
1ST SESSION

H. R. 2696

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 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 and the Centers for Disease Control and Prevention with respect to translational research and related activities concerning Down syndrome, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Trisomy 21 Research
5 Resource Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 The Congress makes the following findings:

1 (1) The father of modern genetics, Dr. Jerome
2 Lejeune, discovered the extra chromosome 21 re-
3 sponsible for the condition, known as Down syn-
4 drome, which he called Trisomy 21 in January
5 1959. His discovery has opened the doors of genetics
6 to new generations of researchers.

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

10 (3) Down syndrome is the most frequent ge-
11 netic cause of intellectual and developmental disabil-
12 ities and associated medical problems and occurs in
13 one out of 691 live births, in all races and economic
14 groups. Intellectual disability, formerly mental retar-
15 dation, is a disability characterized by significant
16 limitations both in intellectual functioning and in
17 adaptive behavior, which covers many everyday so-
18 cial and practical skills. This disability originates be-
19 fore birth and lasts a lifetime.

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

1 (5) Down syndrome occurs when, because of
2 cell division error, there are 3 partial or total copies
3 of chromosome 21 rather than the normal 2. Be-
4 cause of the extra copy of chromosome 21, people
5 with Down syndrome are more susceptible to dis-
6 eases including Alzheimer’s disease, leukemia, con-
7 genital heart disease, seizures, and diabetes. How-
8 ever, people with Down syndrome may be protected
9 from other common diseases including athero-
10 sclerosis, hypertension, and solid tumors such as
11 brain, gastrointestinal, and breast tumors. There-
12 fore, the study of Down syndrome may lead to novel
13 treatments of common diseases that affect millions
14 of Americans. Lead researcher, Dr. Bill Mobely is
15 quoted as saying “We’re not just asking what our
16 country can do for people with Down syndrome,
17 we’re asking what studies of people can do for our
18 country and the world.”.

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

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

1 (8) Life expectancy for people with Down syn-
2 drome has increased dramatically in recent decades,
3 but varies significantly across various ethnic groups.
4 People with Down syndrome attend school, work,
5 participate in decisions that concern them, and con-
6 tribute to society in many meaningful ways.

7 (9) The Children’s Health Act of 2000 (Public
8 Law 106–310) amended the Public Health Service
9 Act (42 U.S.C. 201 et seq.) and included a number
10 of provisions that addressed the research and sur-
11 veillance needs of many disabilities such as autism,
12 traumatic brain injury, Fragile X syndrome, juvenile
13 diabetes, asthma, epilepsy, and others. However, this
14 landmark legislation did not address the significant
15 research, surveillance, and clinical care needs of
16 Down syndrome and thus has been an impediment
17 to progress in the Down syndrome research commu-
18 nity over the last decade. This Act attempts to in-
19 corporate Down syndrome as an area of permissible
20 research and surveillance at the National Institutes
21 of Health and the Centers for Disease Control and
22 Prevention and will foster a better understanding of
23 Down syndrome.

1 **SEC. 3. NIH DOWN SYNDROME RESEARCH ACTIVITIES.**

2 Part B of title IV of the Public Health Service Act
3 (42 U.S.C. 284 et seq.) is amended by adding at the end
4 the following:

5 **“SEC. 409K. DOWN SYNDROME RESEARCH ACTIVITIES.**

6 “(a) EXPANSION, INTENSIFICATION, AND COORDINA-
7 TION OF ACTIVITIES.—

8 “(1) IN GENERAL.—The Director of NIH, act-
9 ing through the director of the Eunice Kennedy
10 Shriver National Institute of Child Health and
11 Human Development, shall expand and intensify
12 programs of the National Institutes of Health with
13 respect to research and related activities concerning
14 Down syndrome. The Director of NIH shall carry
15 out such programs in coordination with a working
16 group composed of representatives of the relevant in-
17 stitutes, centers, offices, and agencies of the Na-
18 tional Institutes of Health.

19 “(2) NIH RESEARCH PLAN ON DOWN SYN-
20 DROME.—The Director of NIH shall publish a Re-
21 search Plan on Down Syndrome, and update it every
22 five years or as appropriate.

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

25 “(1) BASIC, TRANSLATIONAL, AND CLINICAL
26 RESEARCH.—Building on the comprehensive re-

1 search plan set forth by the NIH Research Plan for
2 Down Syndrome published in October 2007, the Di-
3 rector of NIH may conduct basic, clinical, and
4 translational research on Down syndrome, including
5 research on the following:

6 “(A) Early detection, diagnosis, and treat-
7 ment of Down syndrome.

8 “(B) The biological mechanisms respon-
9 sible for structural and functional anomalies in
10 cells and tissues affected by Down syndrome.

11 “(C) The biological mechanisms respon-
12 sible for cognitive and behavioral dysfunction
13 resulting from Down syndrome.

14 “(D) Novel biomedical and pharma-
15 ceutical interventions designed to promote or
16 enhance cognition and related brain functions
17 and activities of daily living (ADLs).

18 “(E) Co-occurrence of and treatments for
19 associated medical and neurobehavioral dis-
20 orders.

21 “(F) Developmental disorders, interven-
22 tions for congenital heart disease, obstructive
23 sleep apnea, coronary heart disease, obesity,
24 and metabolism.

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

3 “(H) Identification of biomarkers for com-
4 plex phenotypes.

5 “(I) Noninvasive imaging in support of ef-
6 forts to identify other genotypes and
7 phenotypes of Down syndrome.

8 “(J) Pharmacological and other therapies
9 for common features of Down syndrome includ-
10 ing Alzheimer’s disease and other Down syn-
11 drome-related disorders.

12 “(K) Research related to improving the
13 quality of life for individuals with Down syn-
14 drome and their families.

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

18 “(2) FACILITATION OF RESEARCH RE-
19 SOURCES.—

20 “(A) CONTACT REGISTRY FOR INDIVID-
21 UALS WITH DOWN SYNDROME.—

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

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

3 “(II) collecting the names and
4 contact information of such individ-
5 uals; and

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

8 “(ii) CONSENT REQUIRED.—As a con-
9 dition on the receipt of a grant or contract
10 under this subparagraph, an entity shall
11 agree that information about any indi-
12 vidual will be collected or maintained pur-
13 suant to this subparagraph only if the indi-
14 vidual has consented to such collection and
15 maintenance.

16 “(iii) ELIGIBLE ENTITY DEFINED.—
17 In this subparagraph, the term ‘eligible en-
18 tity’ means a consortium including at least
19 one national Down syndrome patient advo-
20 cacy organization.

21 “(B) RESEARCH DATABASE FOR DOWN
22 SYNDROME.—

23 “(i) IN GENERAL.—The Director of
24 NIH may establish a database including
25 the names, contact information, and each

1 medical condition of individuals with Down
2 syndrome.

3 “(ii) REQUIREMENTS.—The database
4 under clause (i) shall—

5 “(I) be searchable by category of
6 medical condition; and

7 “(II) be used exclusively to facili-
8 tate research.

9 “(iii) CONSENT REQUIRED.—The Di-
10 rector of NIH may include information
11 about an individual in the Research Data-
12 base for Down Syndrome only with the in-
13 dividual’s consent.

14 “(C) BIOBANK FOR DOWN SYNDROME.—

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

19 “(I) to identify any tissue har-
20 vested from a tissue donor with Down
21 syndrome;

22 “(II) to include each medical con-
23 dition of any such tissue donor; and

24 “(III) to allow searches specific
25 to tissue identified under subclause (I)

1 and by category of medical condition
2 included under subclause (II).

3 “(ii) CONSENT REQUIRED.—The Di-
4 rector of NIH may collect and maintain in-
5 formation about an individual pursuant to
6 this subparagraph only with the individ-
7 ual’s consent.

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

10 “(i) subject to the consent require-
11 ments of subparagraphs (A)(ii), (B)(iii),
12 and (C)(ii), use information collected by
13 the National Institutes of Health pursuant
14 to other provisions of law or prior to the
15 date of the enactment of this section;

16 “(ii) take into consideration the avail-
17 ability of other research resources;

18 “(iii) encourage the use of research
19 resources for research on, and development
20 of, therapies and treatments for individuals
21 with Down syndrome; and

22 “(iv) encourage the inclusion of indi-
23 viduals with Down syndrome in clinical
24 trials conducted or supported by the Na-
25 tional Institutes of Health.

1 “(3) DOWN SYNDROME CONSORTIUM.—The Di-
2 rector of NIH may provide for the participation of
3 agencies of the National Institutes of Health in a
4 consortium to facilitate the exchange of information
5 and to make the research effort on Down syndrome
6 more efficient and effective by ensuring consistent
7 communication, minimizing duplication of effort, and
8 integrating the varied perspectives of partner agen-
9 cies, organizations, and individuals. Such consortium
10 shall include at least one national Down syndrome
11 patient advocacy organization and may be the same
12 consortium receiving a grant or contract under para-
13 graph (2)(A).”.

14 **SEC. 4. CDC DOWN SYNDROME SURVEILLANCE AND RE-**
15 **SEARCH PROGRAMS.**

16 Part B of title III of the Public Health Service Act
17 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
18 tion 317T the following:

19 **“SEC. 317U. DOWN SYNDROME SURVEILLANCE AND RE-**
20 **SEARCH PROGRAMS.**

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Director of the Centers for Disease Control and Pre-
23 vention, may award grants and cooperative agreements to
24 public or nonprofit private entities (including State health
25 departments, political subdivisions of States, universities,

1 and other educational entities) for the collection, analysis,
2 and reporting of data on Down syndrome. In making such
3 awards, the Secretary may provide direct technical assist-
4 ance, including personnel support, in lieu of cash.

5 “(b) NATIONAL DOWN SYNDROME EPIDEMIOLOGY
6 PROGRAM.—

7 “(1) GRANTS.—The Secretary, acting through
8 the Director of the Centers for Disease Control and
9 Prevention, may award grants to public or nonprofit
10 private entities (including State health departments,
11 political subdivisions of States, universities, and
12 other educational entities) for the purpose of car-
13 rying out epidemiological activities regarding Down
14 syndrome, including collecting and analyzing infor-
15 mation on the number, incidence, correlates, and
16 symptoms of cases and the clinical utility (including
17 costs and benefits) of specific practice patterns. In
18 making such awards, the Secretary may provide di-
19 rect technical assistance, including personnel sup-
20 port, in lieu of cash.

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

23 “(A) provide for a national surveillance
24 program; and

1 “(B) where possible, ensure that the sur-
2 veillance program is coordinated with the data
3 and sample collection activities of the National
4 Institutes of Health under section 409K.”.

5 **SEC. 5. REPORT TO CONGRESS.**

6 Not later than January 1, 2012, and each January
7 1 thereafter, the Secretary of Health and Human Services
8 shall prepare and submit to the appropriate committees
9 of the Congress a report concerning the implementation
10 of this Act and the amendments made by this Act.

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