

118TH CONGRESS
2D SESSION

S. 3981

To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to carry out a program of research, training, and investigation related to Down syndrome, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 19, 2024

Mr. HICKENLOOPER (for himself and Mr. MORAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to carry out a program of research, training, and investigation related to 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 “DeOndra Dixon IN-
5 CLUDE Project Act of 2024”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Down syndrome is the most common chro-
2 mosomal disorder. Each year, about 6,000 babies
3 born in the United States have Down syndrome, af-
4 fecting about 1 in every 700 babies born.

5 (2) Individuals with Down syndrome have a full
6 or partial extra copy of chromosome 21 that leads
7 to certain physical, intellectual, and developmental
8 challenges.

9 (3) Life expectancy of individuals with Down
10 syndrome in the United States has increased dra-
11 matically in recent decades. In 1960, the average life
12 expectancy was about 10 years. Today, the average
13 life expectancy of an individual with Down syndrome
14 is nearly 60 years.

15 (4) Individuals with Down syndrome can attend
16 school, work, make their own life decisions, have
17 meaningful relationships, vote, and contribute to so-
18 ciety.

19 (5) Individuals with Down syndrome are at an
20 increased risk for certain medical conditions, such as
21 autoimmune disorders, leukemia, congenital heart
22 disease, sleep dysfunction, and Alzheimer's disease,
23 but may be at a decreased risk for other conditions.

24 (6) Research and medical care supporting indi-
25 viduals with Down syndrome and their unique dis-

1 ease profile will improve health outcomes and may
2 potentially lead to treatments for individuals born
3 with or without Down syndrome who suffer from
4 diseases associated with that unique profile.

5 **SEC. 3. DOWN SYNDROME RESEARCH.**

6 Part A of title IV of the Public Health Service Act
7 (42 U.S.C. 281 et seq.) is amended by adding at the end
8 the following:

9 **“SEC. 404P. DOWN SYNDROME RESEARCH.**

10 “(a) IN GENERAL.—The Secretary, acting through
11 the Office of the Director of NIH, and in consultation with
12 other Federal agencies and partners, shall carry out, di-
13 rectly or through grants or contracts, a program of re-
14 search, training, and investigation related to Down syn-
15 drome to be known as the INvestigation of Co-occurring
16 conditions across the Lifespan to Understand Down syn-
17 dromE Project or the INCLUDE Project.

18 “(b) PROGRAM ELEMENTS.—The program under
19 subsection (a) shall include research, training, and inves-
20 tigation related to—

21 “(1) high-risk, high reward basic science studies
22 of the effects of chromosome 21 on human develop-
23 ment and health;

24 “(2) assembling and maintaining a large study
25 population of individuals with Down syndrome;

1 “(3) expanding the number of clinical trials
2 that are inclusive of, or expressly for, individuals
3 with Down syndrome, including novel biomedical and
4 pharmacological interventions and other therapies
5 designed to promote or enhance activities of daily
6 living;

7 “(4) the biological mechanisms in individuals
8 with Down syndrome responsible for structural and
9 functional anomalies in cells, tissues, and organs,
10 cognitive and behavioral dysfunction, and stunted
11 growth;

12 “(5) the identification of biomarkers for the de-
13 tection of risk factors, diagnosis, and customized
14 interventions and treatments for conditions co-occur-
15 ring with Down syndrome;

16 “(6) why several co-occurring conditions, such
17 as Alzheimer’s disease and autoimmunity, are preva-
18 lent in individuals with Down syndrome and how
19 such conditions can be treated concurrently with
20 Down syndrome; and

21 “(7) improving the quality of life of individuals
22 with Down syndrome and their families.

23 “(c) COORDINATION; PRIORITIZING NONDUPLICA-
24 TIVE RESEARCH.—The Secretary shall ensure that—

1 “(1) the programs and activities of the insti-
2 tutes, centers, agencies, and offices of the National
3 Institutes of Health relating to Down syndrome and
4 co-occurring conditions are coordinated, including
5 through the Division of Program Coordination,
6 Planning, and Strategic Initiatives under sections
7 402(b)(7) and 402A(c); and

8 “(2) such institutes, centers, agencies, and of-
9 fices prioritize, as appropriate, Down syndrome re-
10 search that does not duplicate existing research ac-
11 tivities of the National Institutes of Health.

12 “(d) TECHNICAL ASSISTANCE.—The Secretary shall
13 provide technical assistance to grantees and other involved
14 entities, as appropriate, for carrying out activities pursu-
15 ant to this section.

16 “(e) BIENNIAL REPORTS TO CONGRESS.—

17 “(1) IN GENERAL.—The Secretary shall submit,
18 on a biennial basis, to the Committee on Energy and
19 Commerce and the Subcommittee on Labor, Health
20 and Human Services, Education and Related Agen-
21 cies of the Committee on Appropriations of the
22 House of Representatives and the Committee on
23 Health, Education, Labor, and Pensions and the
24 Subcommittee on Labor, Health and Human Serv-
25 ices, Education, and Related Agencies of the Com-

1 mittee on Appropriations of the Senate, a report
2 that catalogs the research conducted or supported
3 under this section.

4 “(2) CONTENTS.—Each report under para-
5 graph (1) shall include—

6 “(A) identification of the institute, center,
7 agency, office, or entity involved;

8 “(B) a statement of whether the research
9 is or was being carried out directly by the insti-
10 tute, center, agency, office, or entity or by mul-
11 tiple institutes, centers, agencies, offices, or en-
12 tities; and

13 “(C) identification of any resulting real
14 world evidence that is or may be used for clin-
15 ical research and medical care for patients with
16 Down syndrome.

17 “(f) AUTHORIZATION OF APPROPRIATIONS.—

18 “(1) IN GENERAL.—To carry out this section,
19 there is authorized to be appropriated \$250,000,000
20 for each of fiscal years 2025 through 2029.

21 “(2) SUPPLEMENT, NOT SUPPLANT.—Funds
22 appropriated to carry out this section shall be used
23 to supplement, not supplant, other funds allocated

- 1 by the National Institutes of Health for research
- 2 and other activities relating to Down syndrome.”.

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