

DEONDRA DIXON INCLUDE PROJECT ACT OF 2024

MAY 14, 2024.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 7406]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 7406) 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “DeOndra Dixon INCLUDE Project Act of 2024”.

SEC. 2. DOWN SYNDROME RESEARCH.

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

“SEC. 404P. DOWN SYNDROME RESEARCH.

“(a) **IN GENERAL.**—The Secretary, acting through the Office of the Director of NIH, and in consultation with other Federal agencies and partners, shall carry out a program of research, training, and investigation related to Down syndrome to be known as the ‘Investigation of Co-occurring conditions across the Lifespan to Understand Down syndrome Project’ or the ‘INCLUDE Project’.

“(b) **PROGRAM ELEMENTS.**—The program under subsection (a) shall include research, training, and investigation related to—

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

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

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

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

“(5) the identification of biomarkers for the detection of risk factors, diagnosis, and customized interventions and treatments for conditions co-occurring with Down syndrome;

“(6) why several co-occurring conditions, such as Alzheimer’s Disease and autoimmunity, are prevalent in individuals with Down syndrome and how such conditions can be treated concurrently with Down syndrome; and

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

“(c) **COORDINATION; PRIORITIZING NONDUPLICATIVE RESEARCH.**—The Secretary shall ensure that—

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

“(2) such institutes, centers, agencies, and offices prioritize, as appropriate, Down syndrome research that does not duplicate existing research activities of the National Institutes of Health.

“(d) **TECHNICAL ASSISTANCE.**—The Secretary shall provide technical assistance to grantees and other involved entities, as appropriate, for carrying out activities pursuant to this section.

“(e) **BIENNIAL REPORTS TO CONGRESS.**—

“(1) **IN GENERAL.**—The Secretary shall submit, on a biennial basis, to the Committee on Energy and Commerce and the Subcommittee on Labor, Health and Human Services, Education of the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the Senate, a report that catalogs the research conducted or supported under this section.

“(2) **CONTENTS.**—Each report under paragraph (1) shall include—

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

“(B) a statement of whether the research is or was being carried out directly by the institute, center, agency, office, or entity or by multiple institutes, centers, agencies, offices, or entities; and

“(C) identification of any resulting real world evidence that is or may be used for clinical research and medical care for patients with Down syndrome.

“(f) **AUTHORIZATION OF APPROPRIATIONS.**—

“(1) **IN GENERAL.**—To carry out this section, there is authorized to be appropriated \$90,000,000 for each of fiscal years 2025 through 2029.

“(2) **SUPPLEMENT, NOT SUPPLANT.**—Funds appropriated to carry out this section shall be used to supplement, not supplant, other funds allocated by the National Institutes of Health for research and other activities relating to Down syndrome.”.

PURPOSE AND SUMMARY

H.R. 7406 reauthorizes the INCLUDE (Investigation of Co-occurring conditions across the Lifespan to Understand Down syndrome) Project at the National Institutes of Health (NIH), which is currently funded to promote the scientific understanding of Down syndrome and co-occurring conditions and improve the quality of life of individuals with Down syndrome and their families. This bill would also require reporting to Congress on the program's progress and related research. The legislation reauthorizes the program for five fiscal years from 2025 to 2029.

BACKGROUND AND NEED FOR LEGISLATION

People with Down syndrome have an increased risk of some medical conditions, such as congenital cardiac issues, autoimmune conditions, and early onset Alzheimer's-type dementia.¹ Over the past 50 years, average life expectancy for people with Down syndrome has increased by 25 years to the current average age of 60 years.² If an adult with Down syndrome develops Alzheimer's disease, the onset will often happen by the age of 40.³ Alzheimer's disease is the leading cause of death for people with Down syndrome.⁴ Further research would help improve the quality of life for people with Down syndrome, as well as other individuals who may be facing the same medical issues.

COMMITTEE ACTION

On February 14, 2024, the Subcommittee on Health held a hearing on H.R. 7406. The title of the hearing was "Legislative Proposals to Support Patients and Caregivers." The Subcommittee received testimony from:

- Andy Shih, PhD, Chief Science Officer, Autism Speaks;
- Corey Feist, JD, MBA, Co-Founder and CEO, Dr. Lorna Breen Heroes' Foundation;
- Joanne Pike, DrPH, President and CEO, Alzheimer's Association;
- Gordon Tomaselli, MD, Former President, American Heart Association; Marilyn and Stanley Katz Dean, Emeritus and Professor of Medicine, Albert Einstein College of Medicine; Adjunct Professor of Medicine, Johns Hopkins University School of Medicine;
- Michelle Whitten, President, CEO, and Co-Founder, Global Down Syndrome Foundation;
- Randy Strozyk, President, American Ambulance Association; and,
- Christina Annunziata, MD, PhD, Senior Vice President of Extramural Discovery Science, American Cancer Society.

¹ GLOBAL Down Syndrome Foundation, "GLOBAL Medical Care Guidelines for Adults with Down Syndrome", 2023. <https://www.globaldownsyndrome.org/wp-content/uploads/2020/10/Global-Down-Syndrome-Foundation-Medical-Care-Guidelines-for-Adults-with-Down-Syndrome-v.1-10-20-2020.pdf>.

² *Id.*

³ Fortea, et al., "Down syndrome-associated Alzheimer's disease: a genetic form of dementia", *Lancet Neurol*, 2022. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9387748/#:~:text=Adults%20with%20Down%20syndrome%20develop%20the%20neuropathological%20hallmarks,of%20therapies%20to%20prevent%20or%20delay%20Alzheimer%E2%80%99s%20disease.>

⁴ *Id.*

On March 12, 2024, the Subcommittee on Health met in open markup session and forwarded H.R. 7406, as amended, to the full Committee by a voice vote.

On March 20, 2024, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 7406, as amended, favorably reported to the House by a record vote of 46 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE # 19**

BILL: H.R. 7406 DeOndra Dixon INCLUDE Project Act of 2024

AMENDMENT: A motion by Chair Rodgers to order H.R. 7406 favorably reported to the House, as amended (Final Passage)

DISPOSITION: AGREED TO, by a roll call vote of 46 yeas to 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone	X		
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette	X		
Rep. Guthrie	X			Rep. Schakowsky	X		
Rep. Griffith	X			Rep. Matsui	X		
Rep. Bilirakis	X			Rep. Castor	X		
Rep. Bucshon	X			Rep. Sarbanes	X		
Rep. Hudson	X			Rep. Tonko	X		
Rep. Walberg	X			Rep. Clarke	X		
Rep. Carter	X			Rep. Cárdenas	X		
Rep. Duncan	X			Rep. Ruiz	X		
Rep. Palmer	X			Rep. Peters	X		
Rep. Dunn				Rep. Dingell	X		
Rep. Curtis				Rep. Veasey	X		
Rep. Lesko	X			Rep. Kuster	X		
Rep. Pence	X			Rep. Kelly	X		
Rep. Crenshaw	X			Rep. Barragán	X		
Rep. Joyce	X			Rep. Blunt Rochester			
Rep. Armstrong				Rep. Soto	X		
Rep. Weber	X			Rep. Craig	X		
Rep. Allen	X			Rep. Schrier	X		
Rep. Balderson	X			Rep. Trahan	X		
Rep. Fulcher	X			Rep. Fletcher	X		
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks							
Rep. Cammack	X						
Rep. Obernolte	X						

03/20/2024

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 7406 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to establish a research program focused on investigating comorbidities of Down syndrome, with the goal of utilizing research findings to improve the quality of life for people with Down syndrome.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 7406 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 7406:

- On February 14, 2024, the Subcommittee on Health held a hearing on H.R. 7406. The title of the hearing was “Legislative Proposals to Support Patients and Caregivers.” The Subcommittee received testimony from:
 - Andy Shih, PhD, Chief Science Officer, Autism Speaks;
 - Corey Feist, JD, MBA, Co-Founder and CEO, Dr. Lorna Breen Heroes’ Foundation;
 - Joanne Pike, DrPH, President and CEO, Alzheimer’s Association;
 - Gordon Tomaselli, MD, Former President, American Heart Association; Marilyn and Stanley Katz Dean, Emeritus and Professor of Medicine, Albert Einstein College of

Medicine; Adjunct Professor of Medicine, Johns Hopkins University School of Medicine;

- Michelle Whitten, President, CEO, and Co-Founder, Global Down Syndrome Foundation;
- Randy Strozyk, President, American Ambulance Association; and,
- Christina Annunziata, MD, PhD, Senior Vice President of Extramural Discovery Science, American Cancer Society.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 7406 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the “DeOndra Dixon INCLUDE Project Act of 2024”.

Section 2. Down syndrome research

Section 2 directs the Secretary of the Department of Health and Human Services, acting through the Director of the National Institutes of Health to establish and oversee the implementation of a research program focused on Down syndrome. This section also specifies certain topics that should be investigated within the research program, as well as implements Congressional reporting requirements.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

* * * * *

SEC. 404P. DOWN SYNDROME RESEARCH.

(a) *IN GENERAL.*—The Secretary, acting through the Office of the Director of NIH, and in consultation with other Federal agencies and partners, shall carry out a program of research, training, and investigation related to Down syndrome to be known as the “INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE Project” or the “INCLUDE Project”.

(b) *PROGRAM ELEMENTS.*—The program under subsection (a) shall include research, training, and investigation related to—

(1) high-risk, high reward basic science studies of the effects of chromosome 21 on human development and health;

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

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

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

(5) the identification of biomarkers for the detection of risk factors, diagnosis, and customized interventions and treatments for conditions co-occurring with Down syndrome;

(6) why several co-occurring conditions, such as Alzheimer’s Disease and autoimmunity, are prevalent in individuals with Down syndrome and how such conditions can be treated concurrently with Down syndrome; and

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(c) *COORDINATION; PRIORITIZING NONDUPLICATIVE RESEARCH.*—The Secretary shall ensure that—

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(2) such institutes, centers, agencies, and offices prioritize, as appropriate, Down syndrome research that does not duplicate existing research activities of the National Institutes of Health.

(d) *TECHNICAL ASSISTANCE.*—The Secretary shall provide technical assistance to grantees and other involved entities, as appropriate, for carrying out activities pursuant to this section.

(e) *BIENNIAL REPORTS TO CONGRESS.*—

(1) *IN GENERAL.*—The Secretary shall submit, on a biennial basis, to the Committee on Energy and Commerce and the Subcommittee on Labor, Health and Human Services, Education of the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the Committee on Appropriations of the Senate, a report that catalogs the research conducted or supported under this section.

(2) *CONTENTS.*—Each report under paragraph (1) shall include—

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

(B) a statement of whether the research is or was being carried out directly by the institute, center, agency, office, or entity or by multiple institutes, centers, agencies, offices, or entities; and

(C) identification of any resulting real world evidence that is or may be used for clinical research and medical care for patients with Down syndrome.

(f) *AUTHORIZATION OF APPROPRIATIONS.*—

(1) *IN GENERAL.*—To carry out this section, there is authorized to be appropriated \$90,000,000 for each of fiscal years 2025 through 2029.

(2) *SUPPLEMENT, NOT SUPPLANT.*—Funds appropriated to carry out this section shall be used to supplement, not supplant, other funds allocated by the National Institutes of Health for research and other activities relating to Down syndrome.

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