FEDERAL INVESTMENTS IN FRAGILE X-ASSOCIATED CONDITIONS & DISORDERS

NATIONAL **FRAGILE X** FOUNDATION

We are incredibly grateful for all the federal government has done to support research for Fragile X- associated conditions and disorders! Without this investment, we would not be able to make strides toward effective treatments for Fragile X. Over the past 21 years, our dedicated Fragile X advocates have helped to secure over $650M in research funding, which has led to significant advancements. These are just some examples of the remarkable impact of these federal investments.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

- The CDC funds the Fragile X Registry With Accessible Research Database (FORWARD), the largest resource of health, clinical, and social support information on people with Fragile X syndrome (FXS) in the United States.

- FORWARD includes over 10 years of longitudinal (changes over time) data accessible to researchers. 26 publications have been generated from FORWARD data with more to be released soon. Recommendations from many of these publications have been important for informing health management, identifying risk groups, gaps in care, and needs for intervention to improve the quality of life for individuals with FXS.

NATIONAL INSTITUTES OF HEALTH (NIH)

- The NIH has $104M in active awards specific to *FMR1*-related conditions and disorders.
- The NIH updated its Strategic Plan for Research on FMR1-Associated Conditions & Disorders in 2019. This plan shared goals for specific FMR1-associated conditions, including cross-disciplinarity goals that encourage innovative, impactful research in Fragile X.
- NIH supports The Centers for Collaborative Research in Fragile X Program, with the common goal "of facilitating the translation of basic research findings from bench to bedside and bedside to community." This grant supports research to improve the diagnosis and treatment of Fragile X syndrome (FXS) and its related conditions and disorders, aiding premier FX Centers in increasing their impact in line with the NIH Strategic Plan for Research on *FMR1*-Associated Conditions and Disorders. The current awardees are Emory University, Baylor College of Medicine, and Cincinnati Children's Hospital Medical Center.
- Notable NIH-funded impact includes genetic understanding of Fragile X, animal models, clinical trial support and infrastructure including intradisciplinary collaboration, and general education and awareness for Fragile X. And there’s still so much to learn.
- NIH funds multiple Career Development (K) awards, some of which have gone to up-and-coming professionals who are completing innovative projects in Fragile X. This pipeline of and for new researchers and clinicians is critical to advancements for Fragile X.

DEPARTMENT OF DEFENSE (DOD)

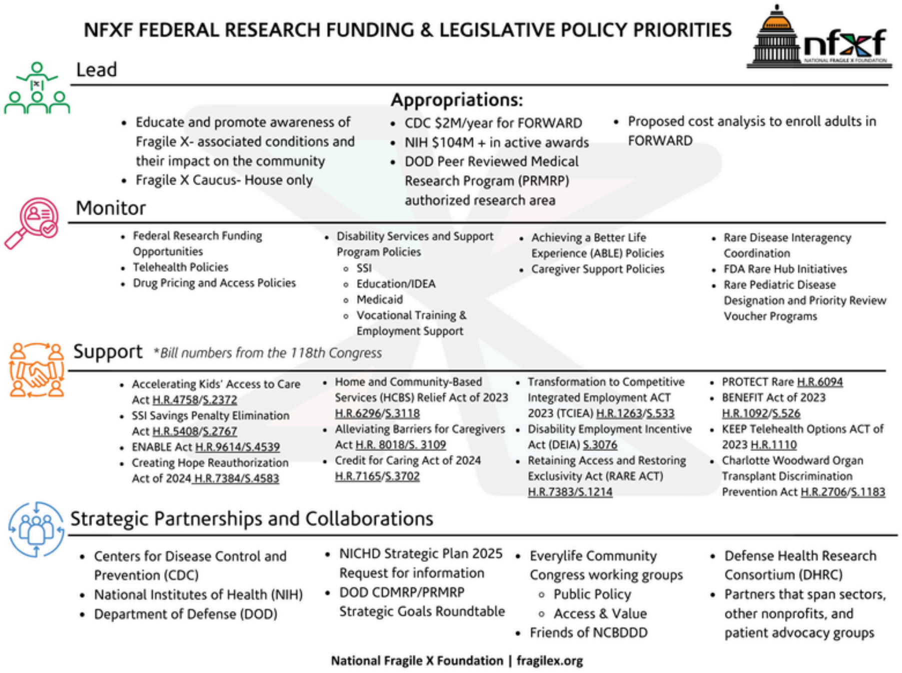
- Congress continues to recognize Fragile X as an authorized medical research area.

- The DOD Peer Reviewed Research Program (PRMRP) has funded $21M in research projects related to *FMR1*/Fragile X-associated conditions and disorders.

2025 ASKS

NFXF FEDERAL RESEARCH FUNDING & LEGISLATIVE POLICY PRIORITIES

The ***NFXF Federal Research Funding and Legislative Priorities*** grid provides a summary of our key research and legislative interests, policies, and topic areas. It highlights the issues most important to the Fragile X community.



NFXF FEDERAL RESEARCH FUNDING & LEGISLATIVE POLICY PRIORITIES

Lead

- Educate and promote awareness of Fragile X- associated conditions and their impact on the community
- Fragile X Caucus- House only

Appropriations:

- CDC $2M/year for FORWARD
- NIH $104M + in active awards
- DOD Peer Reviewed Medical Research Program (PRMRP) authorized research area
- Proposed cost analysis to enroll adults in FORWARD

Monitor

- Federal Research Funding Opportunities
- Telehealth Policies
- Drug Pricing and Access Policies
- Disability Services and Support Program Policies
  - SSI
  - Education/IDEA
  - Medicaid
  - Vocational Training & Employment Support
- Achieving a Better Life Experience (ABLE) Policies
- Caregiver Support Policies
- Rare Disease Interagency Coordination
- FDA Rare Hub Initiatives
- Rare Pediatric Disease Designation and Priority Review Voucher Programs

Support **Bill numbers from the 118th Congress*

- Accelerating Kids' Access to Care Act H.R.4758/S.2372
- SSI Savings Penalty Elimination Act H.R.5408/S.2767
- ENABLE Act H.R.9614/S.4539
- Creating Hope Reauthorization Act of 2024 H.R.7384/S.4583
- Home and Community-Based Services (HCBS) Relief Act of 2023 H.R.6296/S.3118
- Alleviating Barriers for Caregivers Act H.R. 8018/S. 3109
- Credit for Caring Act of 2024 H.R.7165/S.3702
- Transformation to Competitive Integrated Employment ACT 2023 (TCIEA) H.R.1263/S.533
- Disability Employment Incentive Act (DEIA) S.3076
- Retaining Access and Restoring Exclusivity Act (RARE ACT) H.R.7383/S.1214
- PROTECT Rare H.R.6094
- BENEFIT Act of 2023 H.R.1092/S.526
- KEEP Telehealth Options ACT of 2023 H.R.1110
- Charlotte Woodward Organ Transplant Discrimination Prevention Act H.R.2706/S.1183

Strategic Partnerships and Collaborations

- Centers for Disease Control and Prevention (CDC)
- National Institutes of Health (NIH)
- Department of Defense (DOD)
- NICHD Strategic Plan 2025 Request for information
- DOD CDMRP/PRMRP Strategic Goals Roundtable
- Everylife Community Congress working groups
  - Public Policy
  - Access & Value
- Friends of NCBDDD
- Defense Health Research Consortium (DHRC)
- Partners that span sectors, other nonprofits, and patient advocacy groups

National Fragile X Foundation | fragilex.org

Support Fragile X Research Funding for Fiscal Year 2026

Between the NIH, the CDC, and the DOD, the federal government invests over $106M each year in Fragile X research. This amount can vary annually based on the research proposals funded through the peer review process.   There is still so much more to learn.You can support this in three ways:

- **Senate: Request that Fragile X be included as an authorized research area for the DOD's Peer Reviewed Medical Research Program (PRMRP).**
  - The Appropriations Committee authorizes the medical conditions, disorders, and diseases the program may research through report language each year. Which research is funded is decided by a peer review process.
  - Please include this in your appropriations request. We've been in communication with several offices to identify a champion to lead the letter. if you are interested in championing this effort, please email advocacy@fragilex.org.

- **House: Request support for Fragile X at the NIH and the CDC.**
  - The CDC has an annual line item in their budget request for $2M for Fragile X, that supports the FORWARD project, which collects longitudinal data on individuals with Fragile X and makes it available to researchers. The numerous publications that have resulted from FORWARD data have been instrumental in shaping the widely used treatment recommendations for Fragile X.
  - Significant NIH-funded research has advanced our genetic understanding of Fragile X, supported animal models, facilitated clinical trials, provided infrastructure for interdisciplinary collaboration, and enhanced general education and awareness.
  - **Rep. Joe Courtney (maria.costigan@mail.house.gov) and Rep. Chris Smith (John.McDonough@mail.house.gov) are leading a letter. Contact either staff member for the latest draft and cosign.**

Join the Congressional Fragile X Caucus (House only)

The Caucus is committed to understanding the priorities of the Fragile X community. The Caucus does not require any financial commitment or agreeing to any policy positions.

Join the Fragile X Caucus by contacting Maria Costigan (maria.costigan@mail.house.gov) in Rep. Joe Courtney's office or **John McDonough (John.McDonough@mail.house.gov)** in Rep. Chris Smith's office

NFXF FEDERAL RESEARCH FUNDING & LEGISLATIVE POLICY PRIORITIES

Lead

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    - Public Policy
    - Access & Value
- Friends of NCBDDD

- Defense Health Research Consortium (DHRC)
- Partners that span sectors, other nonprofits, and patient advocacy groups

United States Senate
WASHINGTON, DC 20510

May 10, 2024

The Honorable John Tester Chair Defense Appropriations Subcommittee Committee on Appropriations Washington, DC 20510	The Honorable Susan Collins Ranking Member Defense Appropriations Subcommittee Committee on Appropriations Washington, DC 20510

Dear Chairman Tester and Ranking Member Collins:

As Senators committed to improving the health of children and adults living with intellectual disabilities in the United States, we respectfully request your continued commitment to sustaining federal investments in biomedical research focused on the treatment and cure of Fragile X syndrome and its related conditions.

Mutations of the Fragile X gene result in behavioral, developmental, cognitive, reproductive, and potentially life-ending neurodegenerative conditions across generations in families and impact affected individuals from cradle to grave. Fragile X syndrome and associated disorders result from a single-gene mutation, which is the most common, known inherited cause of intellectual disabilities and autism. In fact, research has shown that the Fragile X protein regulates nearly one half of the genes suspected of causing autism. Up to 100,000 Americans have Fragile X syndrome, and up to 1,500,000 Americans have a variation of the Fragile X mutation and as a result either have, or are at risk for developing, one of the conditions associated with Fragile X and passing the gene mutation to their children. The known premutation issues are Fragile X-associated tremor/ataxia syndrome, a condition similar to Parkinson's, and Fragile X-associated primary ovarian insufficiency, which causes infertility and early menopause.

The Committee's previous support of Fragile X as one of the research areas authorized for the Department of Defense's Peer Reviewed Medical Research Program funded some important research and has the potential to ease the burden of Fragile X and other intellectual and developmental disabilities on our military families. Military families are affected substantially by the financial and emotional costs of raising a child with intellectual and developmental disabilities, including Fragile X syndrome. This impact extends to the performance and readiness of service members and their units. Strides are being made towards effective treatments for Fragile X syndrome and other associated disorders while moving towards a cure. These treatments will help ease the burden on military families.

We are requesting that Fragile X be included as an authorized research area for the DoD's Peer Reviewed Medical Research Program for Fiscal Year 2025. While we understand the challenges the Committee faces in prioritizing requests, Fragile X has a significant impact on military families across generations in every state and district. The potential for effective treatments is within reach. We believe continued support for Fragile X research is imperative. The DoD's research has been a significant contributor over the past decade, and we hope it will continue be in the future.

We look forward to working with the Subcommittee on this important issue. Thank you for your consideration.

Sincerely,

Debbie Stabenow
Debbie Stabenow
United States Senator

Roger Wicker
Roger F. Wicker
United States Senator

Ben Ray Luján
Ben Ray Luján
United States Senator

Tina Smith
Tina Smith
United States Senator

Sherrod Brown
Sherrod Brown
United States Senator

Jack Reed
Jack Reed
United States Senator

Cory A. Booker
United States Senator

Ron Wyden
Ron Wyden
United States Senator

Richard Blumenthal
Richard Blumenthal
United States Senator

Gary C Peters
Gary C. Peters
United States Senator

Amy Klobuchar

Amy Klobuchar
United States Senator

Chris Van Hollen

Chris Van Hollen
United States Senator

Alex Padilla

Alex Padilla
United States Senator

Kyrsten Sinema

Kyrsten Sinema
United States Senator

Elizabeth Warren

Elizabeth Warren
United States Senator

Kirsten Gillibrand

Kirsten Gillibrand
United States Senator

Chris Coons

Christopher A. Coons
United States Senator

Edward J. Markey

Edward J. Markey
United States Senator

United States Senate
WASHINGTON, DC 20510

DRAFT

XX XX, 2025

The Honorable XX
Chairman
Defense Appropriations Subcommittee
122 Dirksen Senate Office Building
Washington, DC 20510

The Honorable XX
Ranking Member
Defense Appropriations Subcommittee
115 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman XX and Ranking Member XX:

As Senators committed to improving the health of children and adults living with intellectual disabilities in the United States, we respectfully request your continued commitment to sustaining federal investments in biomedical research focused on the treatment and cure of Fragile X syndrome and its related conditions.

Mutations of the Fragile X gene result in behavioral, developmental, cognitive, reproductive, and potentially life-ending neurodegenerative conditions across generations in families and impact affected individuals from cradle to grave. Fragile X syndrome and associated disorders result from a single-gene mutation, which is the most common, known inherited cause of intellectual disabilities and autism. In fact, research has shown that the Fragile X protein regulates nearly one-half of the genes suspected of causing autism. Up to 100,000 Americans have Fragile X syndrome, and up to 1,500,000 Americans have a variation of the Fragile X mutation and as a result either have or are at risk for developing, one of the conditions associated with Fragile X and passing the gene mutation to their children. The known premutation issues are Fragile X¬associated tremor/ataxia syndrome, a condition similar to Parkinson's, and Fragile X-associated primary ovarian insufficiency, which causes infertility and early menopause.

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We are requesting that Fragile X be included as an authorized research area for the DOD's Peer Reviewed Medical Research Program for Fiscal Year 2026. While we understand the challenges the Committee faces in prioritizing requests, Fragile X has a significant impact on military families across generations in every state and district. The potential for effective treatments is within reach. We believe continued support for Fragile X research is imperative. The DOD's research has been a significant contributor over the past decade, and we hope it will continue be in the future.

We look forward to working with the Subcommittee on this important issue. Thank you for your consideration.

Sincerely,

XX
United States Senator

DRAFT

Congress of the United States
House of Representatives
Washington, DC 20515

April 30, 2024

The Honorable Robert Aderholt Chair House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies Washington, D.C. 20515	The Honorable Rose DeLauro Ranking Member House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies Washington, D.C. 20515

Dear Chair Aderholt and Ranking Member DeLauro,

As Members of Congress committed to improving the health of children and adults living with intellectual disabilities in the US, we respectfully request your continued commitment to sustaining federal investments in biomedical research and public health initiatives focused on the treatment and cure of Fragile X and its related conditions.

Mutations of the Fragile X (FX) gene result in behavioral, developmental, cognitive, reproductive, and potentially life-ending neurodegenerative conditions across generations and impact affected individuals from cradle to grave. Fragile X syndrome and associated conditions result from a single-gene mutation, which is the most common, known inherited cause of intellectual disabilities and autism. In fact, research has shown that the Fragile X protein regulates nearly one-half of the genes suspected of causing autism. Up to 100,000 Americans have Fragile X syndrome, and up to 1,500,000 Americans have a variation of the Fragile X mutation and as a result either have or are at risk for, developing one of the conditions associated with Fragile X.

The Committee's previous support for the important work underway at the National Institutes of Health (NIH) and Centers for Disease Control & Prevention (CDC) is advancing research towards more effective treatments and a cure for Fragile X. For instance, the CDC funds the FORWARD project, a natural history study. FORWARD is a longitudinal database that now includes 11.5 years of historical data of individuals with Fragile X and additional data on premutation carriers and other family members. This data gives researchers a view of Fragile X over the lifetime and across generations. These are resources that are not available anywhere else and are invaluable tools for educators and clinicians.

The NIH supports Fragile X research across multiple Institutes and Centers, with the primary one being the NICHD. This includes funding three national Fragile X research centers that focus on stimulating multi-disciplinary, multi-institutional research with a goal of translating basic research into treatments. We are seeing promising treatments for many of the behaviors associated with Fragile X syndrome – including several currently in various phases of clinical trials – and research that will also inform treatments and better understanding of autism. Fragile X is the most common, known, single-gene cause of autism.

To ensure the rapid translation of ongoing research into near-term targeted treatments, we must continue these federal investments in the Fiscal Year 2025 Labor, Health and Human Services, and Education Appropriations bill. Specifically, we respectfully request your support for directives to:

- Expand the base of researchers and clinicians who are familiar with and trained in the Fragile X-associated disorders and promote collaboration between basic scientists and clinicians to enable researchers to better understand phenotypes, document variations in how the disorder presents itself, identify potential biomarkers and outcome measures, and develop new interventions.

- Maintain dedicated support for CDC's national Fragile X public health program.

To this end, we respectfully request the inclusion of the following report language regarding Fragile X syndrome:

CDC

Fragile X and Fragile X-Associated Disorders. -- The Committee commends CDC's efforts to identify and define the population impacted by Fragile X (FX) and all conditions associated with the gene mutation with the goal of understanding the public health impact of these conditions. To help this effort, the Committee urges the National Center on Birth Defects and Developmental Disabilities (NCBDDD) to support additional strategies to promote earlier identification of children with FX, such as voluntary newborn screening. The Committee also recommends the NCBDDD work to ensure underserved populations with FX conditions are being properly diagnosed and are aware of medical services available. Finally, the Committee recommends the NCBDDD support research across the lifespan of individuals living with Fragile X and the associated conditions and disorders.

NIH

Regarding Fragile X, the Committee notes the importance of expanding the base of researchers and clinicians who are familiar with and trained in Fragile X-associated disorders and promoting collaboration between basic scientists and clinicians to enable researchers to better understand phenotypes, document variations in how the disorder presents itself, identify potential biomarkers and outcome measures, and develop new interventions. The Committee commends the NIH for recognizing the ethical, legal, and social issues in premutation screening and testing and encourages to NIH to look at existing pilot studies that are looking at innovative ways to screen newborns, study Fragile X across the lifespan, and coordinate efforts and research with the CDC as they look at screening solutions for FMR1-related conditions.

While we understand the challenges the Committee faces in prioritizing requests, Fragile X has a significant impact on families across generations, on individuals throughout their lives, and on communities in every state and district. The potential for effective treatments is within reach, and continued support for Fragile X research and public health activities is imperative. We look forward to working with the Subcommittee on this important issue. Thank you for your time and consideration.

Sincerely,

Christopher H. Smith
Member of Congress

Joe Courtney
Joe Courtney
Member of Congress

Gerald E. Connolly
Member of Congress

Danny K. Davis
Danny K. Davis
Member of Congress

Mark DeSaulnier
Member of Congress

Jim Himes
Member of Congress

Darin LaHood
Darin LaHood
Member of Congress

Stephen F. Lynch
Member of Congress

Marcus J. Molinaro
Member of Congress

Bill Posey
Bill Posey
Member of Congress

Juan Vargas

Juan Vargas
Member of Congress

Ilhan Omar
Member of Congress

Josh Gottheimer
Member of Congress

Jason Crow
Member of Congress

Congreſs of the United States
House of Representatives
Washington, DC 20515

DRAFT

April XX, 2025

The Honorable XX
Chair
House Appropriations Subcommittee on
Labor, Health and Human Services,
Education and Related Agencies
Washington, D.C. 20515

The Honorable XX
Ranking Member
House Appropriations Subcommittee on
Labor, Health and Human Services,
Education and Related Agencies
Washington, D.C. 20515

Dear Chair XX and Ranking Member XX,

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Mutations of the Fragile X (*FMR1*) gene result in behavioral, developmental, cognitive, reproductive, and potentially life-ending neurodegenerative conditions across generations and impact affected individuals from cradle to grave. Fragile X syndrome and associated conditions result from a single-gene mutation, which is the most common, known inherited cause of intellectual disabilities and autism. In fact, research has shown that the Fragile X protein regulates nearly one-half of the genes suspected of causing autism. Up to 100,000 Americans have Fragile X syndrome, and up to 1,500,000 Americans have a variation of the Fragile X mutation and as a result either have or are at risk for, developing one of the conditions associated with Fragile X.

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