

April 2, 2024

The Honorable Martin Heinrich
Chair
Subcommittee on Agriculture, Rural
Development, FDA, and Related Agencies
Committee on Appropriations
U.S. Senate
Washington, DC 20510

The Honorable John Hoeven
Ranking Member
Subcommittee on Agriculture, Rural
Development, FDA, and Related Agencies
Committee on Appropriations
U.S. Senate
Washington, DC 20510

The Honorable Andy Harris
Chair
Subcommittee on Agriculture, Rural
Development, FDA, and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Sanford Bishop
Ranking Member
Subcommittee on Agriculture, Rural
Development, FDA, and Related Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Chair Heinrich, Ranking Member Hoeven, Chair Harris, and Ranking Member Bishop,

The brain health community is grateful for the initial funding Congress has provided for the FDA's Neurology Drug Program beginning in Fiscal Year (FY) 2023. Support for this program will allow the FDA to gain the expertise to develop policies and guidance that keep pace with emerging brain science. As your subcommittees begin to craft FY 2025 appropriation legislation, we ask that you provide \$5 million for this important program, an increase of \$3 million. Funding at this level will help advance discoveries in all areas of brain health including neurodevelopmental, neurodegenerative, psychiatric, brain injuries, and more.

The National Institute of Neurological Disorders and Stroke reports that 1 in 5 adults live with a neurological illness. This figure suggests that a large population of Americans have direct experience with one or more brain health conditions. In the face of substantial challenges posed by brain diseases, injuries, and mental health conditions, the availability of effective treatments for both common and rare brain ailments remains notably lacking.¹ The potential to make innovative treatments for these neurological conditions available lies in the ability to conduct comprehensive research, develop innovative therapeutic approaches that target the underlying mechanisms of these brain disorders, and ensure regulatory approval channels are streamlined.

In recent years, the field of neuroscience has made remarkable advancements, and in 2024 we stand on the brink of significant breakthroughs committed to reshaping our understanding and treatment of neurological disorders. In 2024, we anticipate significant progress, particularly for conditions like Huntington's disease, Parkinson's disease, ALS, and Alzheimer's disease.²

¹ <https://dana.org/article/survey-finds-brain-health-is-a-top-priority-for-americans/#:~:text=The%20National%20Institute%20of%20Neurological,or%20more%20brain%20health%20conditions>

² <https://foothillsneurology.com/neurological-breakthroughs-upcoming-2024/>

Currently, the FDA is in the approval process of a breakthrough drug for the treatment of schizophrenia.³

The personal and economic tolls of brain diseases are immense. Brain diseases and conditions and diseases cost the U.S. economy more than \$1.5 trillion per year.⁴ This extends beyond direct health care costs and encompasses the societal and economic ramifications arising from disease and disability, the accessibility of medical services, and other public health challenges. Increased funding for the Neurology Drug Program would empower the FDA to advance products that better prevent, identify, and address diseases and conditions of the brain, improving the lives of many of these patients and their families.

Again, our organizations are grateful for past funding of the Neurology Drug Program and ask that you provide \$5 million for the program in FY 2025. It is imperative to the millions of Americans impacted by these diseases, and their family members. We look forward to working together towards the goal of speeding the delivery of safe and effective therapeutics for individuals living with diseases and conditions of the brain. If you have questions or would like further information, please reach out to the American Brain Coalition's Executive Director Katie Sale at ksale@americanbraincoalition.org.

Sincerely,

American Brain Coalition

A Nation of Hope

Alliance for Aging Research

Alliance for Headache Disorders Advocacy

Alliance for Patient Access

American Academy of Neurology

American College of Neuropsychopharmacology

American Epilepsy Society

American Neurological Association

American Society of Clinical Psychopharmacology

American Stroke Association

Anxiety and Depression Association of America

Association of University Professors of Neurology

BDSRA Foundation

BCI Pioneers Coalition

Benign Essential Blepharospasm Research Foundation

Brain Aneurysm Foundation

Cerebral Palsy Alliance Research Foundation

Cerebral Palsy Research Network

Chronic Migraine Awareness, Inc.

Cohen Veterans Bioscience

³ <https://time.com/6509764/new-drug-compound-schizophrenia/>

⁴ <https://itif.org/publications/2016/07/11/brain-disorders-and-diseases-cost-us-economy-15-trillion-underscoring-scale/>

CSNK2A1 Foundation
CTNNB1 Connect and Cure
Cure Brain Disease
cureCADASIL
CURE Epilepsy
Cure GABA-A
cureSHANK
Danny Did Foundation
Dementia Society of America
Dravet Syndrome Foundation
Dub15q Alliance
Epilepsy Alliance America
Epilepsy Foundation
FAM177A1 Research Fund
Focused Ultrasound Foundation
FND Hope
GABA-A Alliance
Headache Cooperative of the Pacific
Hope for HIE
Hope for Hypothalamic Hamartomas
Huntington's Disease Society of America
Hydrocephalus Association
IEEE Brain
INADcure Foundation
International Alliance for Pediatric Stroke
International Bipolar Foundation
International Foundation for CDKL5 Research
International Essential Tremor Foundation
International Neuroethics Society
Koolen-de Vries Syndrome Foundation
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)
LGS Foundation
M-CM Network
Maternal Mental Health Leadership Alliance
McLean Hospital
MdDS Balance Disorder Foundation
Medical Technology Enterprise Consortium (MTEC)
Miles for Migraine
My Kool Brother
National Alliance on Mental Illness
National Association of State Head Injury Administrators
National Ataxia Foundation
National Headache Foundation

National MS Society
Neurocritical Care Society
Neurotech Network
Northwest Noggin
Otsuka America Pharmaceutical
Patrick Risha CTE Awareness Foundation
Pediatric Epilepsy Research Consortium
Phelan-McDermid Syndrome Foundation
Society for Neuroscience
South Carolina Advocates For Epilepsy
Southern Headache Society
Spinal CSF Leak Foundation
SMC1A Foundation
SYNGAP1 Foundation
SynGAP Research Fund
The Brain Donor Project
The Michael J. Fox Foundation for Parkinson's Research
The STARR Coalition
The Sturge-Weber Foundation
University of Nebraska Medical Center