

November 12, 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 Years (FY) 2023 and 2024. Support for this program will allow the FDA to gain the expertise to develop policies and guidance that keep pace with emerging brain science and speed the development of safe and effective treatments for brain diseases and conditions. As your subcommittees enter final negotiations for FY 2025 appropriation legislation, we ask that you provide \$5 million as proposed by the Senate Appropriations Committee for this important program. Funding at this level, an increase of \$3 million, 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. We continue to anticipate significant progress, particularly

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>

for conditions like Huntington's disease, Parkinson's disease, ALS, and Alzheimer's disease.² 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 Congress 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 brain diseases and conditions. 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 Clinical Neurophysiology Society

American College of Neuropsychopharmacology

American Epilepsy Society

American Neurological Association

American Psychiatric Association

American Psychological Association Services

American Society of Clinical Psychopharmacology

American Society of Neuroradiology

Association for Creatine Deficiencies

Association of University Professors of Neurology

BDSRA Foundation

BCI Pioneers Coalition

Black Women's Health Imperative

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

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/>

Brain Aneurysm Foundation
CACNA1A Foundation
Cerebral Palsy Alliance Research Foundation
Chronic Migraine Awareness
Coalition for Headache and Migraine Patients (CHAMP)
Coalition to Cure CHD2
Cohen Veterans Bioscience
CSNK2A1 Foundation
CTNNB1 Connect and Cure
Cure Brain Disease
cureCADASIL
CURE Epilepsy
Cure GABA-A
cureSHANK
Danny Did Foundation
Dravet Syndrome Foundation
DYNC1H1 Association
Dysphonia International
Epilepsies Action Network (EAN)
Epilepsy Alliance America
Epilepsy Foundation of America
Epilepsy Leadership Council
FAM177A1 Research Fund
FND Hope
GABA-A Alliance
GRIN2B Foundation
Hope for Hypothalamic Hamartomas
Huntington's Disease Society of America
Hydrocephalus Association
International Bipolar Foundation
International Essential Tremor Foundation
International Foundation for CDKL5 Research
KCNQ2 Cure Alliance
Koolen-de Vries Syndrome Foundation
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)
Lewy Body Dementia Association
LGS Foundation
Lundbeck Pharmaceuticals LLC
M-CM Network
Maternal Mental Health Leadership Alliance
MdDS Balance Disorder Foundation
Medical Technology Enterprise Consortium (MTEC)
Mental Health America

Mission MSA
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
Neuropathy Action Foundation
Neurotech Network
NORSE Institute
Northwest Noggin
NR2F1 Foundation
Otsuka America Pharmaceutical, Inc.
Pediatric Epilepsy Research Consortium
Phelan-McDermid Syndrome Foundation
PURA Syndrome Foundation
Rare Epilepsy Network (REN) Coordinating Committee
SLC6A1 Connect
SMC1A Foundation
STXBP1 Foundation
SynGAP Research Fund
SYNGAP1 Foundation
The Association for Frontotemporal Degeneration
The Bee Foundation for Brain Aneurysm Prevention
The Black Men's Brain Health Initiative
The Brain Donor Project
The Global Foundation for Peroxisomal Disorders
The Michael J. Fox Foundation for Parkinson's Research
The STARR Coalition
The Sturge-Weber Foundation
Treatment Advocacy Center
TSC Alliance
U.S. Pain Foundation
University of Nebraska Medical Center
v-ATPase Alliance
YWHAG Research Foundation

cc: The Honorable Patty Murray, Chair, U.S. Senate Committee on Appropriations
The Honorable Susan Collins, Vice Chair, U.S. Senate Committee on Appropriations
The Honorable Tom Cole, Chair, U.S. House Committee on Appropriations
The Honorable Rosa DeLauro, Ranking Member, U.S. House Committee on Appropriations