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

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. <sup>1</sup> 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.<sup>2</sup>

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%20condit ions.

<sup>&</sup>lt;sup>2</sup> https://foothillsneurology.com/neurological-breakthroughs-upcoming-2024/

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

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. 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

<sup>&</sup>lt;sup>3</sup> https://time.com/6509764/new-drug-compound-schizophrenia/

<sup>&</sup>lt;sup>4</sup> 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