

March 24, 2023

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 undersigned members of the brain health community write to express our gratitude for the inclusion of \$2 million in funding for the Neurology Drug Program at the Food and Drug Administration (FDA) in Fiscal Year (FY) 2023 Omnibus Appropriations Act. **As the House and Senate work together to craft FY 2024 appropriations legislation, we strongly encourage you to provide \$3 million for the Neurology Drug Program, which will help speed the delivery of safe and effective treatments for brain diseases, mental health conditions, and brain injuries.**

As you may know, conditions of the brain impact more than one billion people worldwide and more than 100 million individuals in the U.S. live with psychiatric conditions or neurological diseases and disorders.¹ However, despite the tremendous burden of brain diseases, brain injuries, and mental health conditions, there remains a dearth of treatments for common and rare brain diseases. Research and development for conditions of the brain is hindered by high costs and associated risks², but more streamlined and transparent regulatory processes have the potential to help mitigate these concerns, facilitating speedier delivery of critical, life-improving treatments that individuals with psychiatric conditions and neurological disorders so desperately need.

The burden of brain conditions and diseases on the U.S. economy is also staggering. Brain conditions and diseases cost the U.S. economy more than \$1.5 trillion per year.³ Seven of the twenty-one chronic conditions tracked by the Centers for Medicare & Medicaid Services (CMS) are related to the brain, at an

¹ Gooch CL, Pracht E, Borenstein AR. The burden of neurological disease in the United States: A summary report and call to action. *Ann Neurol*. 2017;81(4):479-484. doi: 10.1002/ana.24897

² CSDD-Tufts Center for the Study of Drug Development. "CNS drugs take 20% longer to develop and to improve vs. non CNS drugs." *Tufts CSDD Impact Report*, September/October 2018. <https://csdd.tufts.edu/tuftscsddreports/>.

³ Information Technology & Innovation Foundation. "Brain Disorders and Diseases Cost U.S. Economy \$1.5 Trillion, Underscoring Scale of Opportunity for Greater Research and Innovative New Treatments to Improve Health and Drive Prosperity, ITIF Study Finds." <https://itif.org/publications/2016/07/11/brain-disorders-and-diseases-cost-us-economy-15-trillion-underscoring-scale/>

average annual cost of \$23,325 per Medicare beneficiary—higher than the average cost for other chronic conditions.⁴ Additionally, studies also show that the FDA approval process is 38 percent longer for central nervous system (CNS) drugs, which includes treatments for people living with mental illness, when compared to non-CNS drugs.⁵ The economic burden of brain diseases, combined with the emotional toll that patients live with as they deal with the longer regulatory approval timelines for CNS treatments highlight the need for swift action to accelerate the development and approval of new treatments for neurologic and psychiatric conditions. Increased funding for the Neurology Drug Program would allow FDA to better prevent, detect, and treat diseases and conditions of the brain. As we work together toward these goals, we also ask both Congress and FDA to ensure that the agency’s activities associated with the Neurology Drug Program, involve all areas of neuroscience, including brain diseases, mental health conditions, and brain injuries. The complex interrelationship of these maladies requires that they be approached with unity.

Again, our organizations are grateful for FY 2023 funding for the Neurology Drug Program and ask that you provide \$3 million for the program in FY 2024. We look forward to continuing to work together towards the goal of speeding the delivery of safe and effective treatments for individuals living with psychiatric conditions and neurologic diseases. 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
Alliance for Aging Research
Alliance for Patient Access
Alzheimer's Association
Alzheimer's Impact Movement
American Academy of Neurology
American Behcet's Disease Association (ABDA)
American College of Neuropsychopharmacology
American Epilepsy Society
American Neurological Association
Benign Essential Blepharospasm Research Foundation
Brain Aneurysm Foundation
Cerebral Palsy Research Network
Coalition for Headache and Migraine Patients (CHAMP)
Cohen Veterans Bioscience
CSNK2B Foundation
cureCADASIL
CURE Epilepsy
CureSHANK
Depression and Bipolar Support Alliance

⁴ Center for Medicare & Medicaid Services Chronic Conditions Utilization/Spending State Level: All Beneficiaries 2017. The average per capita spending for a chronic condition is \$22,099.

⁵ Tufts Medical Center. Incentivizing Drug Development for Serious Mental Illness. Institute for Clinical Research and Health Policy Studies. Jan. 25, 2022. <https://cevr.tuftsmedicalcenter.org/news/2022/smi>

Down with Dystonia
Dup15q Alliance
Dysphonia International
Epilepsy Alliance America
Epilepsy Foundation
FAM177A1 Research Fund
FND Hope
Glut1Deficiency Foundation
Hope for HIE
Huntington's Disease Society of America
Hydrocephalus Association
INADcure Foundation
International Alliance for Pediatric Stroke
International Essential Tremor Foundation
International Foundation for CDKL5 Research
Lennox-Gastaut Syndrome (LGS) Foundation
Lundbeck Pharmaceuticals LLC
M-CM Network
MdDS Foundation
Medical Technology Enterprise Consortium (MTEC)
Mental Health America
National Alliance on Mental Illness
National Aphasia Association
National Ataxia Foundation
National MS Society
National Organization for Tardive Dyskinesia
NBIA Disorders Association
Neurocritical Care Society
Neuropathy Action Foundation
Neurotech Network
Northwest Noggin
Patrick Risha CTE Awareness Foundation
Pediatric Epilepsy Research Consortium
Pediatric Epilepsy Surgery Alliance
Phelan-McDermid Syndrome Foundation
Schizophrenia & Psychosis Action Alliance
SMC1A Foundation
Sunovion Pharmaceuticals
SynGAP Research Fund
SYNGAP1 Foundation
The Brain Donor Project
The Headache & Migraine Policy Forum
The Michael J. Fox Foundation for Parkinson's Research

The Multiple System Atrophy Coalition
The STARR Coalition
The Sturge-Weber Foundation
U.S. Pain Foundation
University of Nebraska Medical Center

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 Kay Granger, Chair, U.S. House Committee on Appropriations
The Honorable Rosa DeLauro, Ranking Member, U.S. House Committee on Appropriations