

September 7, 2022

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

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

Dear Chair Baldwin, Ranking Member Hoeven, Chair Bishop, and Acting Ranking Member Harris,

The undersigned members of the brain health community write to express our gratitude for the inclusion of \$3 million in funding and accompanying report language in support of the Neurology Drug Program at the Food and Drug Administration (FDA) in the Senate Committee's draft fiscal year (FY) 23 Agriculture, Rural Development, FDA, and Related Agencies Appropriations bill. As the House and Senate work together to negotiate final FY23 appropriations legislation, we strongly encourage you to maintain this critical funding and language, 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

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/>

conditions tracked by the Centers for Medicare & Medicaid Services (CMS) are related to the brain, at an 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. The draft Senate appropriations legislation would provide critical funding to create the Neurology Drug Program at FDA to better prevent, detect, and treat diseases and conditions of the brain. Accompanying report language encouraging the agency to develop policies and guidance that keep pace with scientific discovery in these areas will assist those living with these diseases, researchers, and providers in advancing promising treatments and cures. 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 strongly support the Neurology Drug Program funding and language in the Senate's draft bill and appreciate its inclusion. As the House and Senate work towards a bipartisan end-of-year funding bill, we encourage you to include this provision and ensure the program's applicability to the broad range of neurologic and psychiatric conditions affecting the brain, to advance innovative treatment options for all brain diseases, including mental health conditions, and brain injuries.

Thank you for your work on this important issue. 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.

Sincerely,

American Brain Coalition
Acadia Pharmaceuticals
Alliance for Aging Research
Alliance for Patient Access
American Academy of Addiction Psychiatry
American Academy of Neurology
American Behcet's Disease Association
American Brain Foundation
American College of Neuropsychopharmacology
American Epilepsy Society
American Society of Clinical Psychopharmacology (ASCP)
Anxiety and Depression Association of America
Association of University Professors of Neurology

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>

Avanir Pharmaceuticals
Baker Street Behavioral Health
Benign Essential Blepharospasm Research Foundation
Bobby Jones Chiari & Syringomyelia Foundation
Center for Law, Brain & Behavior, Massachusetts General Hospital
Coalition for Headache and Migraine Patients (CHAMP)
Charcot Marie Tooth Association
Cohen Veterans Bioscience
CURE Epilepsy
Cure PSP
Cure Sanfilippo Foundation
Depression and Bipolar Support Alliance
Down with Dystonia
Dystonia Medical Research Foundation
Eisai Inc.
EndBrainCancer Initiative (EBCI)
Epilepsy Alliance America
Epilepsy Foundation
FND Hope
Glut1 Deficiency Foundation
Harmony Biosciences
Huntington's Disease Society of America
Hydrocephalus Association
INADcure Foundation
International Essential Tremor Foundation
International Rett Syndrome Foundation
Karuna Therapeutics
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)
Lewy Body Dementia Association
Lundbeck Pharmaceuticals
M-CM Network
Mental Health America
Michael J Fox Foundation's for Parkinson's Research
Multiple System Atrophy (MSA Coalition)
National Alliance on Mental Illness (NAMI)
National Ataxia Foundation
National MS Society
National Organization for Tardive Dyskinesia
NBIA Disorders Association
Neuropathy Action Foundation (NAF)
NW Noggin
Otsuka Pharmaceuticals
Ovid Therapeutics
Parkinson's Foundation
Patrick Risha CTE Awareness Foundation
Phelan-McDermid Syndrome Foundation
QesGen Systems, Inc.
Sage Therapeutics
Schizophrenia & Psychosis Action Alliance

Sunovion Pharmaceuticals
Syngap Research Fund, Inc
SYNGAP1 Foundation
Takeda Pharmaceuticals
Teva Pharmaceuticals
The ALS Association
The Association for Frontotemporal Degeneration
The Brain Donor Project
The Headache and Migraine Policy Forum
The STARR Coalition
The Sturge-Weber Foundation
Tourette Association of America
University of Nebraska Medical Center
UsAgainstAlzheimer's
US Pain Foundation

cc:

The Honorable Pat Leahy, Chair, U.S. Senate Committee on Appropriations
The Honorable Richard Shelby, Ranking Member, U.S. Senate Committee on Appropriations
The Honorable Rosa DeLauro, Chair, U.S. House Committee on Appropriations
The Honorable Kay Granger, Ranking Member, U.S. House Committee on Appropriations