



July 15, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, D.C. 20515

Dear Congresswoman DeGette and Congressman Upton:

On behalf of the American Brain Coalition and the 107 undersigned organizations, we write to offer our strong support for Section 306 of the 21st Century Cures 2.0 proposal to authorize a new intercenter institute at the Food and Drug Administration (FDA) focusing on high prevalence and burdensome diseases, like those affecting the brain and central nervous system (CNS). The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, created through 21st Century Cures Act, has set the nation on a course towards unprecedented neuroscience discovery. Despite these advances, patients continue to lack access to enough safe and effective treatments for brain and CNS conditions due, in part, to the unique regulatory challenges facing treatments that target the body's most complex organ system. A Neuroscience Center of Excellence will allow the FDA to consolidate its neuroscience expertise to create the guidance and processes necessary to ease the review and approval of safe and effective brain and CNS treatments.

Brain and CNS diseases impose staggering personal and financial costs on Americans. Nearly one in five U.S. adults – more than 50 million – live with a mental illness, disproportionately impacting women, people reporting two or more races, and individuals under age fifty.¹ Neuropsychiatric disorders are also the leading cause of disability in the nation, making up 18.7% of years lost to disability and premature death.² Neurological conditions are troublingly prevalent as well - twenty million Americans suffer from a neurological condition, with 16% of households including an individual with a brain impairment.³ Brain and CNS diseases also harm older Americans, with more than one in nine people over age 65 having Alzheimer's dementia.⁴ The enormous personal costs of brain and CNS conditions also translate into financial hardship for individuals and families and burden the U.S. economy. Brain disorders and diseases cost the U.S. more than \$1.5 trillion per year,⁵ a significant portion of which is borne by the Medicare program. Seven of the twenty-one chronic conditions tracked by the Centers for Medicare and

¹ National Institute of Mental Health, Mental Illness, at: <https://www.nimh.nih.gov/health/statistics/mental-illness>.

² Office of Disease Prevention and Health Promotion, Mental Health and Mental Disorders, at: <https://www.healthypeople.gov/2020/topics-objectives/topic/mental-health-and-mental-disorders>.

³ S. Pal, Incidence and Prevalence of Major Neurologic Disorders. US Pharm, at: <https://www.uspharmacist.com/article/incidence-and-prevalence-of-major-neurologic-disorders>

⁴ Alzheimer's Association, Facts and Figures, at: <https://www.alz.org/alzheimers-dementia/facts-figures>.

⁵ Information Technology & Innovation Foundation, A Trillion-Dollar Opportunity: How Brain Research Can Drive Health and Prosperity, at: http://www2.itif.org/2016-trillion-dollar-opportunity.pdf?_ga=2.209915987.77733799.1607703298-1777725734.1607703298.

Medicaid Services are related to the brain, representing an average annual cost of \$23,325 per Medicare beneficiary – higher than the average cost for all other chronic conditions.⁶

Sadly, SARS-CoV-2 and the ongoing COVID-19 pandemic have only exacerbated the burden of brain and CNS conditions. During the pandemic, 40% of American adults have reported symptoms of anxiety or depression, up from 10% in 2019.⁷ The COVID-19 pandemic has also worsened the ongoing opioid epidemic, with monthly overdose deaths jumping from 6,638 in January 2020 to 9,362 in May 2020 – an increase of more than 40%.⁸ The SARS-CoV-2 virus itself also harms the brain and CNS in a variety of ways. A recent study found that nearly one third of patients diagnosed with COVID-19 were diagnosed with a psychiatric or neurologic condition within six months of contracting COVID-19.⁹ COVID-19 patients also report a wide variety of psychiatric and neurological symptoms, including strokes, psychosis, delirium, and loss of smell and taste.

Despite the enormous prevalence and impact of brain and CNS conditions, there remains a troubling lack of effective treatments that go beyond symptom mitigation to address the underlying disease. Product development is difficult for any disease or disorder, but brain and CNS conditions suffer from greater failures and more costly clinical trials than others.¹⁰ Brain-targeting drugs, devices, and other therapeutics reviewed by the FDA are approved at a much lower rate than those for other disease areas, with one recent study finding that the mean approval phase time for CNS compared to non-CNS was an astonishing 57% longer.¹¹ Another recent report indicated that the probability of a drug successfully making its way through a Phase 1 clinical trial to the point of approval is only 15% for brain and CNS treatments —compared to 32% for ophthalmology, 25% for cardiovascular problems, and 25% for infectious disease.¹²

To respond to these unique challenges and spur innovation in safe and effective treatments for brain diseases and disorders, FDA should establish a Neuroscience Center of Excellence using the intercenter institute authority proposed in the Cures 2.0 Discussion Draft. Building upon the successful implementation of the 21st Century Cures Act's Oncology Center of Excellence, a Neuroscience Center of Excellence will similarly create opportunities for innovation in the development and regulation of treatments for brain diseases and disorders, giving patients access to more effective treatment options. Creating a Neuroscience Center of Excellence could simplify regulatory review of brain-focused

⁶ 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.

⁷ N. Panchal et al., The Implications of COVID-19 for Mental Health and Substance Use, at: <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>.

⁸ J.C. Baumgartner & D.C. Radley, The Spike in Drug Overdose Deaths During the COVID-19 Pandemic and Policy Options to Move Forward, at: <https://www.commonwealthfund.org/blog/2021/spike-drug-overdose-deaths-during-covid-19-pandemic-and-policy-options-move-forward>.

⁹ M. Taquet, et al. 6-month neurological and psychiatric outcomes in 236,379 survivors of COVID-19: a retrospective cohort study using electronic health records. *Lancet Psychiatry*, at: [https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366\(21\)00084-5/fulltext](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(21)00084-5/fulltext).

¹⁰ J.A. Dimasi, CNS drugs take 20% longer to develop and to approve vs. non-CNS drugs. Tufts Center for the Study of Drug Development.

¹¹ See Bio, Clinical Development Success Rates and Contributing Factors 2011-2020, at: <https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020>; J.A. Dimasi, CNS drugs take 20% longer to develop and to approve vs. non-CNS drugs. Tufts Center for the Study of Drug Development.

¹² C. Heem Wong, et al. Estimation of clinical trial success rates and related parameters. *Biostatistics*, kxx069.

products, allowing federal and private investments in brain research to more quickly translate into safe and effective treatments for brain and CNS diseases and disorders.

In authorizing of a Neuroscience Center of Excellence, Cures 2.0 will build upon the successes of the 21st Century Cures Act by creating an environment for regulatory innovation that speeds access to safe and effective treatments and cures for brain disease. Doing so will relieve stress on an overburdened Medicare program and spur innovation – both in biomedical research and the regulation of brain and CNS treatments. We thank you for including the authority to create an additional intercenter institute focusing on high prevalence and burdensome diseases in Cures 2.0 and look forward to the enactment of this important provision as the bill moves through the legislative process.

Sincerely,

American Brain Coalition
Alliance for Aging Research
Alliance for Patient Access
ALS Association
Alzheimer's Impact Movement
American Academy of Addiction Psychiatry
American Academy of Neurology
American Association for Geriatric Psychiatry
American Brain Foundation
American Brain Tumor Association
American College of Neuropsychopharmacology
American Epilepsy Society
American Headache Society
American Neurological Association (ANA)
American Parkinson Disease Association
American Psychiatric Association
American Society of Clinical Psychopharmacology
American Society of Neuroradiology (ASNR)
Anxiety and Depression Association of America
Association of University Professors of Neurology
Autoimmune Encephalitis Alliance, Inc.
Brain & Behavior Research Foundation
Brain Aneurysm Foundation
Brain Injury Association of America
Brian Grant Foundation
Bridge the Gap - SYNGAP Education and Research Foundation
Caregiver Action Network
Center for BrainHealth
Center for Law, Brain & Behavior at Massachusetts General Hospital
Child Neurology Foundation
Childhood Brain Tumor Foundation
CJD Foundation
Cohen Veterans Bioscience
Cure Alliance for Mental Illness
Cure Alzheimer's Fund
CURE Epilepsy
Cure Sanfilippo Foundation
CurePSP

CureSHANK
Davis Phinney Foundation
Dementia Society of America
Depression and Bipolar Support Alliance
Down with Dystonia
Dup15q Alliance
Dyspraxia USA
Dystonia Medical Research Foundation
Epilepsy Foundation
FND Hope
Focused Ultrasound Foundation
Hawaii Parkinson Association
Headache and Migraine Policy Forum
HFC
Hope for HIE
Huntington's Disease Society of America
Hydrocephalus Association
Inadcure Foundation
International Alliance for Pediatric Stroke
International Bipolar Foundation
International Essential Tremor Foundation
International Rett Syndrome Association
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)
Les Turner ALS Foundation
Looms for Lupus
Lundbeck Pharmaceuticals LLC
Lupus and Allied Diseases Association, Inc.
M-CM Network
MdDS Balance Disorder Foundation
MLD Foundation
Movement Disorders Policy Coalition
National Alliance on Mental Illness
National Aphasia Association
National Association of State Head Injury Administrators (NASHIA)
National Ataxia Foundation
National Headache Foundation
National MPS Society
National Multiple Sclerosis Society
National Organization for Tardive Dyskinesia
National Tay-Sachs & Allied Diseases Association (NTSAD)
NBIA Disorders Association
Neurocrine Biosciences, Inc
Neuropathy Action Foundation
NORSE Institute
Northwest Noggin
One Mind
Oregon Health & Sciences University
Parkinson and Movement Disorder Alliance (PMD Alliance)
Parkinson Association of the Rockies
Parkinson's Foundation

Patrick Risha CTE Awareness Foundation
Phelan-McDermid Syndrome Foundation
QuesGen Systems, Inc.
RARE-X
Ring14 USA
Sage Therapeutics
Schizophrenia and Related Disorders Alliance of America
SLC6A1 Connect
Spina Bifida Association
Sturge-Weber Foundation
SynGAP Research Fund, Inc.
Teva Pharmaceuticals
The Association for Frontotemporal Degeneration
The Brain Donor Project
The Brain Recovery Project: Childhood Epilepsy Surgery Foundation
The EndBrainCancer Initiative (EBCI)
The Gerontological Society of America
The Michael J. Fox Foundation for Parkinson's Research
The STARR Coalition
United Cerebral Palsy