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House Committee on Energy and Commerce
Subcommittee on Health
The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight
March 17, 2022

Thank you for the opportunity to provide this statement for the record for the Subcommittee on Health's hearing on *The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight.*

I am the Frances & Edgar Reynolds Chair & Professor of the Department of Neurological Sciences; Co-Director of the Nebraska Neurosciences Alliance, and Director of Neurosciences Services at the University of Nebraska Medical Center. I am also honored to serve as the Chair of the American Brain Coalition (ABC). The ABC is a nonprofit organization comprised of the nation's leading professional neurological, psychological, and psychiatric associations and patient organizations. Together, the ABC seeks to advance the understanding the brain and reduce the burden of brain disorders for the millions of Americans who suffer from diseases affecting the brain and central nervous system (CNS). The ABC is reaching out today to urge the Committee to include provisions that will create a Neuroscience Center of Excellence at the Food and Drug Administration (FDA) within legislation that reauthorizes the prescription drug user fees.

Nearly one in five U.S. adults live with a mental illness. Neuropsychiatric disorders are also the leading cause of disability in the nation, making up 18.7% of years lost to disability and premature death.[1] 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.[2] Brain and CNS diseases also harm older Americans, with more than one in nine people over age 65 having Alzheimer's dementia.[3]

The enormous personal costs of brain and CNS conditions also translate to financial hardship for patients and their families and burden the U.S. economy. Brain disorders and diseases cost the U.S. more than $1.5 trillion per year,[4] 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 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.[5]

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[1] 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.
[2] S. Pal, Incidence and Prevalence of Major Neurologic Disorders. US Pharm, at: https://www.uspharmacist.com/article/incidence-and-prevalence-of-major-neurologic-disorders
[3] Alzheimer's Association, Facts and Figures, at: https://www.alz.org/alzheimers-dementia/facts-figures.
[4] 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.
[5] 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.

The high prevalence of these diseases means that nearly every family in the United States has either personally experienced a brain disease or watched a loved one struggle with the effects of diseases like substance use disorder, schizophrenia, multiple sclerosis, Alzheimer's disease, and hundreds of other diseases that impact the brain.

Despite the tremendous human and financial burden of brain and CNS diseases, disorders, and injuries, the discovery and approval of safe and effective treatments for these disorders lags behind other conditions. For that reason, the ABC and more than 100 other brain health partner organizations support the creation of a Neuroscience Center of Excellence (NCOE) at the Food and Drug Administration (FDA).[6] A NCOE will encourage innovation in the study, creation, and regulation of treatments and cures for brain diseases, disorders, and injuries.[7]

To respond to the unique challenges in the discovery and development of treatments for brain disease, and allow more neuroscience discoveries to directly benefit patients, it is vital that the federal government prepare the brain-specific regulatory tools and guidelines needed for fast, well-structured, transparent, and predictable product review. **To support this aim, ABC and the brain community urge Congress to create a NCOE at the FDA. While we understand that the existing authorities in the initial 21st Century Cures legislation allows for FDA to create such a center without Congressional direction, we believe that Congressional direction and funding for a center will provide the urgency needed for FDA to move quickly to establish an NCOE. We believe a NCOE will foster innovation in the regulation and development of treatments for brain diseases, disorders, and injuries.**

Several pieces of existing legislation address the need for a NCOE at the FDA. First, we are pleased that the Committee is considering H.R. 6000, the Cures 2.0 Act today. H.R. 6000 contains language (Section 306) to authorize a new intercenter institute at the FDA focusing on high prevalence and burdensome diseases, like those affecting the brain and CNS. As an option for authorizing a NCOE we encourage the committee to advance H.R. 6000, including Section 306.

The ABC also supports H.R. 5435, the Bringing Regulatory Advances Into Neuroscience (BRAIN) Act, a bipartisan bill that would establish, and authorize funding for, a NCOE and create Neuroscience Translational Working Group. The composition of the Working Group would reflect the entire stakeholder community, including patients and their families. The Working Group would provide invaluable "boots on the ground" community experience to help inform the NCOE's work and decisions on 1) translating neuroscience discoveries into approved treatments, 2) developing guidance documents to expedite novel approaches to cures and therapies, 3) creating useful and fruitful collaboration opportunities across governmental entities and public-private partnerships. The Working Group would provide vital information to the NCOE on patient preferences and patient-reported outcomes, along with real-world data for the development of and likely impact of treatments on patients' lives.

Importantly, the BRAIN Act follows the model of the 21st Century Cures Act, which led to the creation of the Oncology Center of Excellence, by giving the FDA the flexibility needed to respond to emerging science and patient input. Rather than delineating specific activities in legislative text, the BRAIN Act

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[6] Letter to Congresswoman Diana DeGette and Congressman Fred Upton regarding the creation of a Neuroscience Center of Excellence, at: https://drive.google.com/file/d/1gZ7wRPvdDqfiaYaZBGMv3oETAo45tENW/view.

[7] H. Gellis, et. Al. Incentivizing Drug Development for Serious Mental Illness. Tufts Center for the Evaluation of Value and Risk in Healthcare, at: https://drive.google.com/file/d/1OeNwcQ3H_YOTKX_QGBpVUEdR5eVFcLX1/view.

relies upon existing regulatory mechanisms for the FDA to obtain patient, researcher, and industry input on its activities, allowing the agency to adapt quickly to an evolving field of research and development. This structure, and its expansion to brain diseases and disorders, is supported by more than 80 organizations, former FDA Commissioner Scott Gottlieb and current FDA Commissioner Robert Califf.[8]

Related legislation has also been recently introduced in the Senate. Like the BRAIN Act, S. 3427, the Neuroscience Center of Excellence Act, would create, and authorize funding for, a NCOE. S. 3427 includes provisions that would help improve patient engagement and speed the delivery of treatments to patients who desperately need them. For instance, S. 3427 acknowledges the need for patient engagement with the inclusion of the Neuroscience Patient-Focused Drug Development Program and a study to assess the patient experience in medical products for brain and central nervous system diseases and disorders. Public input, including patient engagement, should be a requirement for all activities carried out by the NCOE.

ABC also supports the requirement in S. 3427 for the NCOE to hold annual public meetings to seek input from scientists, researchers, patient advocacy organizations, disease research organizations, and the drug and device industry. We recommend the issues discussed during these meetings be determined by FDA in partnership with patients and relevant industry and research partners. This will allow the agency to focus on emerging science and timely needs in the neuroscience space. Last, ABC supports the provision in S. 3427 requiring the FDA to issue guidance to industry on how to ensure greater diversity in clinical trials for medical products to treat diseases, disorders, and injuries of the brain and central nervous system.

As the committee considers proposals for inclusion in upcoming FDA user fee legislation, **ABC strongly encourages you to incorporate language to establish a NCOE**. Each of the existing legislative proposals contains provisions that would be of tremendous benefit to the millions of patients suffering from brain and CNS diseases, disorders, and injuries. Of most importance is ensuring that FDA has the flexibility to respond to advancing science and innovation as neuroscience discoveries emerge.

Again, thank you for the opportunity to provide this statement. The ABC looks forward to working together with the committee toward advancements that improve the health of all people living with brain and CNS diseases, disorders, and injuries.

[8] Letter to Congressman Earl Blumenauer, Congressman Bill Pascrell, and Congressman Don Bacon regarding the BRAIN Act, at: https://drive.google.com/file/d/1_cDLk1SlRhnWyNFjub907SXOQcyWp84i/view; shorturl.at/ltyMX