Neuroscience Working Table

Working Together to Achieve a Neuroscience Center of Excellence

July 16, 2021

The Honorable Diana DeGette
House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Fred Upton
House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton:

The Neuroscience Working Table ("Working Table"), which includes organizations and coalitions representing more than 50 million Americans with psychiatric and neurologic diseases, writes to express our support for Section 306 included in the "Cures 2.0 Act" released on June 22, 2021. This Section would require the establishment of additional centers of excellence at the Food and Drug Administration (FDA) and enable the creation of a Neuroscience Center of Excellence (NCOE).

The Working Table supports the creation of a NCOE at FDA with the mission of accelerating development, review, and approval of new medical products and achieving patient-centered regulatory decision-making through collaboration, engagement, and transparency. Below we outline some of the successes of the Oncology Center of Excellence (OCE), why there is such a need for a NCOE, and how the Cures 2.0 language supports its creation.

The Demonstrated Success of An FDA Center of Excellence

Under the 21st Century of Cures Act, FDA created the OCE. While we recognize the differences between oncology and neuroscience, FDA's OCE has been a robust success in coordinating the activities of the FDA's product centers related to oncology. The Center's internal collaboration and external engagement has been very positive, and the OCE has played an important role. Just last year during the height of the COVID-19 pandemic, the FDA (with OCE staff):

- Implemented an open and transparent stakeholder engagement process, including engaging those living with cancer;
- According to the FDA, between January 1 and November 1, 2020, the oncology review teams were involved in the approval of 15 new molecular entities and more than 80 efficacy supplements for the treatment of patients with cancer"[1]. Further, in 2020, they were involved in the review of 7 premarket approval (PMA) devices[2];
- Issued multiple guidance documents related to conducting clinical trials during the COVID-19 pandemic; and
- Held more than 10 listening sessions with patient advocacy groups with the Office of Oncologic Diseases.

[1] https://jamanetwork.com/journals/jamaoncology/fullarticle/2774311
[2] https://www.fda.gov/about-fda/oncology-center-excellence/oce-annual-report

The Need for a Neuroscience Center of Excellence

Given these successes, Congress should continue the model created by 21st Century Cures and establish a NCOE at FDA to tackle the significant unmet need faced by those living with psychiatric and neurologic diseases. Despite the large societal need, medical products for neurological and psychiatric diseases and disorders are approved by the FDA at a much lower rate than products for other disease areas. Additionally, in recent years, FDA reviewers denied more requests for (and granted fewer) breakthrough therapy designations among neuroscience New Drug Applications (NDAs) than they did for NDAs in other disease areas. Establishing the NCOE would accelerate development by:

- Placing a stronger emphasis on drug and device development tools for treatment and cures for psychiatric and neurologic diseases;
- Increasing utilization of patient-focused drug and device development for people living with psychiatric and neurologic diseases; and,
- Improving engagement between FDA and stakeholders and strengthening internal coordination within FDA.

The NCOE should leverage regulatory scientists and reviewers with expertise in drugs, biologics, devices, and diagnostics to expedite development of drugs and devices for psychiatric and neurologic diseases. Further, this NCOE would help address the needs of persons living with serious neurological complications resulting from contracting SARS-CoV-2, which may affect individuals' ability to function or work after the pandemic ends.

We agree with Former FDA Commissioner Scott Gottlieb who identified neuroscience as the next logical consideration for a Center of Excellence. When commenting about the possibility of future centers of excellence during testimony before Congress, Gottlieb said the OCE "is an organizational model that we seek to adopt in other settings" and "some of the areas under consideration are immunology and neuroscience."[3]

How the Cures 2.0 Legislation Supports a Neuroscience Center of Excellence

The NCOE meets all of the specific criteria set forth in the Cures 2.0 discussion draft:

SECTION 306 ESTABLISHMENT OF ADDITIONAL INTERCENTER INSTITUTES AT THE FOOD AND DRUG ADMINISTRATION

- **(b)(1)(A) "Negatively affects at least one major body system"**
    - The psychiatric and neurological diseases and conditions the NCOE would address include, but are not limited to: addiction; Alzheimer's disease and other neurodegenerative conditions that cause dementia; amyotrophic lateral sclerosis; autism spectrum disorder, Down Syndrome, and other neurodevelopmental disorders; bipolar disorder; brain aneurysms; cerebral palsy; anxiety and depression; dyspraxia; dystonia; the epilepsies; hereditary brain and CNS diseases; headaches and migraine disease; Huntington's disease; multiple sclerosis; pain; Parkinson's disease; parkinsonisms; personality disorders; psychotic disorders; traumatic brain injury and chronic traumatic encephalopathy; schizophrenia; as well as many rare diseases that impact the brain and CNS.

[3] Testimony of Scott Gottlieb, M.D., FDA Commissioner before the Health, Education, Labor & Pensions Committee. 2017 https://www.help.senate.gov/imo/media/doc/Gottlieb5.pdf

- **(b)(1)(B) "Represents a major disease burden in the United States and (b)(1)(C) [r]epresents a leading cause of mortality or disability in the United States"**
    - As of 2020, nearly 100 million Americans are living with psychiatric and neurological diseases, costing $760 billion annually. [4]
    - Multiple neuropsychiatric conditions, namely depressive and anxiety disorders, are recognized as leading causes of disability by the National Institutes of Health's (NIH) National Center for Complementary and Integrative Health[5] and the World Health Organization, among other authorities.[6]

- **(b)(1)(D) "According to the [NIH], affects at least an estimated 50,000,000 Americans each year"**
    - Neurological and psychiatric diseases and disorders are highly prevalent. According to the National Institutes of Health, neurological disorders affect an estimated 50 million Americans each year, and 51.5 million American adults live with a mental illness.[7]

- **(b)(1)(E) "Contributes to increasing health care (personal, familial, private sector, and governmental) expenditures and impacts the United States economy as a whole"**
    - The Centers for Disease Control and Prevention forecasts that the number of Americans with some form of dementia will double by 2060 to 13.9 million people (3.3 percent of the estimated 2060 U.S. population). Some estimate the 2021 cost at $355 billion (approximately $239 billion of that being Medicare/Medicaid) and the 2050 cost at $1.1 trillion. Such disease not only increases costs for private sector payers and government programs, but also places a heavy financial and social toll on many individuals, families, and caregivers.[8]
    - Across all ages, mental disorders are among the leading causes of ill health and disability worldwide. The World Economic Forum estimates that by 2030, the global cost of mental illness will rise to $6 trillion, more than double the total cost of cancer, diabetes, and cardiovascular diseases combined – and that is a pre-pandemic estimate.[9]

- **(b)(1)(F) "For which the SARS-CoV-2 virus exacerbates symptoms or causes serious complications"**
    - The National Institute of Neurological Disorders and Stroke has recognized that the SARS-CoV-2 virus can lead to serious neurological complications—such as anosmia, headache, impaired consciousness, and stroke—which may affect individuals' ability to function or work after the pandemic ends.[10]

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[4] https://www.brainfacts.org/diseases-and-disorders/mental-health/2014/global-burden-of-neurological-and-mental-disorders
[5] https://www.nccih.nih.gov/about/symptoms-matterleading-causes-of-disability
[6] https://www.who.int/news-room/fact-sheets/detail/depression
[7] https://www.nimh.nih.gov/health/statistics/mental-illness
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6333531/
[9] https://www.psychiatrictimes.com/view/mental-illness-will-cost-world-16-usd-trillion-2030
[10] https://www.ninds.nih.gov/Current-Research/Coronavirus-and-NINDS/nervous-system

- **(b)(1)(G) "For which medical products are approved by the [FDA] at a much lower rate than products for other disease areas, including in abbreviated pathways"**
    - Despite the large societal need, medical products for neurological and psychiatric diseases and disorders are approved by the FDA at a much lower rate than products for other disease areas. According to a 2018 study by the Tufts Center for the Study of Drug Development, central nervous system drugs take 20 percent longer to develop and approve than non-central nervous system drugs.[11]
    - The Government Accountability Office reports that, in recent years, FDA reviewers denied more requests for (and granted fewer) breakthrough therapy designations among neuroscience New Drug Applications (NDAs) than they did for NDAs in other disease areas.[12]

We appreciate your consideration of our input and look forward to working with you as Cures 2.0 moves through the legislative process.

Sincerely,

AfricanAmericansAgainstAlzheimer's

Alkermes

Alliance for Aging Research

Alliance for Patient Access

ALS Association

The American Academy of Neurology

American Brain Coalition

Cerevel Therapeutics

Coalition for Headache & Migraine Patients

Depression Bipolar Support Alliance

Eisai Inc.

Epilepsy Foundation

Headache & Migraine Policy Forum

The Kennedy Forum

LatinosAgainstAlzheimer's

LEAD Coalition

Lundbeck Pharmaceuticals, LLC

Mental Health America

The Michael J. Fox Foundation for Parkinson's Research

National Alliance on Mental Illness

National Down Syndrome Society

Otsuka

Sage Therapeutics

Schizophrenia & Psychosis Action Alliance

Sunovion

Takeda

UsAgainstAlzheimer's

Vradenburg Foundation

[11] https://www.globenewswire.com/news-release/2018/09/11/1569156/0/en/CNS-Drugs-Take-20-Longer-to-Develop-and-38-Longer-to-Approve-vs-Non-CNS-Drugs-According-to-the-Tufts-Center-for-the-Study-of-Drug-Development.html

[12] https://www.gao.gov/assets/gao-20-244.pdf