Understanding the Need for a Neuroscience Center of Excellence at the FDA

Central Nervous System (CNS) Diseases Afflict Millions and Cost Billions Each Year

As of 2020, nearly 100 million Americans suffered from psychiatric and neurological diseases, costing $760 billion annually.[i] The Centers for Disease Control and Prevention (CDC) 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),[ii] which Milliman estimated could cost $243 billion annually.[iii] CNS 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.

COVID-19 Worsened the Human, Social, and Financial Impacts of CNS Diseases

A large study published in *The Lancet Psychiatry* produced the staggering finding that one in five patients who contracted COVID-19 were diagnosed with a psychiatric disorder within 90 days.[iv] The study showed that anxiety, depression, and insomnia were the most common mental health problems that developed among recovered COVID-19 patients. Researchers also found significantly higher risks for developing dementia. More must be done to support the now-magnified need for research into treatments for CNS diseases and disorders.

The Need for Treatments and Cures for CNS Diseases Has Outpaced Development

Despite the tremendous human and financial costs CNS diseases place on Americans, CNS treatments face greater development challenges and approval hurdles compared to other therapeutic areas,[v] even though there is bipartisan agreement that more needs to be done. Challenges include the complex pathologies of the diseases, heterogeneity, difficulties in identifying and developing biomarkers and clinical endpoints, length of clinical trials, and regulatory processes that have lagged behind other therapeutic areas. CNS drugs take 20 percent longer to develop and approve than other drugs.[vi] The Government Accountability Office reported that, in recent years, FDA reviewers of CNS new drug applications denied more requests for breakthrough therapy designation (and granted fewer), when compared to other disease areas.[vii]

Neuroscience Center of Excellence (NCOE) Builds on Success of Existing Center

As part of the 21st Century Cures Act, Congress authorized the Food and Drug Administration (FDA) to establish Intercenter Institutes at the Agency for major diseases or other areas. One of the major stakeholders advocating for creating this authority was the cancer community, leading to the first Intercenter Institute – the Oncology Center of Excellence (OCE). FDA's OCE has been a robust success in coordinating the activities of the FDA's product centers related to oncology, even during the COVID-19

pandemic. In 2020 alone, the FDA (with OCE staff) issued multiple guidance documents related to conducting clinical trials during the COVID-19 pandemic; held more than 10 listening sessions with patient advocacy groups with the Office of Oncologic Diseases; and, according to FDA, between January 1 and November 1, 2020, the oncology review teams "approved 15 new molecular entities and more than 80 efficacy supplements for the treatment of patients with cancer."[viii]

Congress Should Establish an NCOE to Aid the Development of CNS Therapies

Given these successes, Congress should continue this model created by 21st Century Cures and establish an NCOE at the FDA to tackle CNS diseases and disorders. Such an effort brings together several different disease areas and their respective stakeholders, and accelerates development in the space by:

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

The NCOE Would Include Programs to:

- Address concerns over equity challenges in neuroscience research and development;
- Improve the understanding of the neuroscience-related impacts of COVID-19;
- Better integrate digital health technology into the neuroscience product review process; and,
- Inform the design and implementation of natural history studies to aid development for neuroscience therapies.

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