Neuroscience Working Table

Working Together to Achieve a Neuroscience Center of Excellence

March 17, 2022

The Honorable Anne Eshoo
Chair
Subcommittee on Health
House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Statement for the Record on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight."

Dear Chair Eshoo and Ranking Member Guthrie,

The Neuroscience Working Table ("Working Table"), which includes more than 40 organizations and coalitions representing more than 100 million Americans with psychiatric and neurologic diseases, writes to commend you for holding this important legislative hearing. One of the bills under consideration, H.R. 6000, 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 the development, review, and approval of new medical products and achieving patient-centered regulatory decision-making through collaboration, engagement, and transparency. Establishing the Neuroscience Center of Excellence at FDA has been a bipartisan, bicameral priority. We appreciate the leadership of Reps. DeGette and Upton on the aforementioned H.R. 6000, *the Cures 2.0 Act*; Reps. Blumenauer, Pascrell, and Bacon on H.R. 5435, *the BRAIN Act*; and Senators Collins and Luján on S. 3427, *the Neuroscience Center of Excellence Act*.

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. 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. Consistent with the passionate pleas you heard at your July hearing entitled "The Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases", we cannot wait another five years.

Given the success of the Oncology Center of Excellence,[1] the Working Table believes Congress should build on the model created by 21st Century Cures and enact legislation to establish a NCOE at FDA to tackle the significant unmet need faced by those living with psychiatric and neurologic diseases. Establishing the NCOE would accelerate development by:

- Placing a stronger emphasis on drug and device development tools for treatments 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 (including patients) 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. Leveraging this expertise and enabling further collaboration, within the agency and with outside experts, will be essential as psychiatric and neurological diseases present challenging scientific questions due to the complex pathologies of the diseases and heterogeneity of symptoms, among other reasons. Further, this NCOE should help promote equity and inclusion of traditionally underrepresented populations in the research and development of medical products. Finally, Congress should not only establish the NCOE but also ensure it has the necessary funding, consistent with the Oncology Center.

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."[2]

The establishment of the NCOE will help FDA prepare for the likely explosion in medical product applications involving psychiatric and neurologic diseases, coming as a result of significant private and federal government investments in the area. In H.R. 2471, *the Consolidated Appropriation Act, 2022*, Congress enacted the following: $2.2 billion for mental health research, an increase of $113 million over Fiscal Year 2021; $620 million for the BRAIN Initiative, an increase of $60 million; $25 million for the ACT for ALS; and $3.48 billion for Alzheimer's and related dementia research, an increase of $289 million. The private sector, despite the challenges in development, has made an even larger investment for research and development. To prepare the FDA for the likely explosion in neuroscience medical product applications, Congress should establish and fund the NCOE, similar to what it did in the oncology space. FDA should not be put in a position of being under-prepared and trying to play catch-up. Putting FDA in that position would not only hurt the Agency

[1] Additional background on the success of the OCE and its connection to a potential NCOE can be found here: https://leavittpartners.com/wp-content/uploads/2021/11/Understanding-the-FDAs-Oncology-Center-of-Excellence-Neuroscience-Working-Table-October-2021.pdf

[2] 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

but also those living with psychiatric and neurologic diseases and disorders, due to the likely delays.

We appreciate your consideration of our input as you continue to develop the user fee legislation and look forward to working with you, other Energy and Commerce Committee members, and our Congressional champions on this important issue. Should you have questions, please contact Clay Alspach at clay.alspach@leavittpartners.com, Josh Trent at josh.trent@leavittpartners.com, or Mark Roberts at mark.roberts@leavittpartners.com.

Sincerely,

The Neuroscience Working Table