



Neuroscience Working Table

Working Together to Achieve a Neuroscience Center of Excellence

February 15, 2022

Senator Susan Collins
413 Dirksen Senate Office
Washington, DC 20510

Senator Ben Ray Luján
498 Russell Senate Office
Washington, DC 20510

Dear Senator Collins and Lujan:

The Neuroscience Working Table (“Working Table”), which includes organizations and coalitions representing more than 100 million Americans with psychiatric and neurologic diseases, writes to express our support for S. 3427, “the Neuroscience Center of Excellence Act of 2021” introduced on December 16, 2021. We commend your leadership in authoring a bill that would require the establishment of a Neuroscience Center of Excellence (NCOE) at the Food and Drug Administration (FDA). 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.

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.

Given the success of the Oncology Center of Excellence,¹ the Working Table believes Congress should continue the model created by 21st Century Cures and enact S. 3427 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 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.

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>

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 can affect individuals' ability to function and work. Finally, under S. 3427, this NCOE would help promote equity and inclusion of traditionally underrepresented populations in the research and development of medical products.

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

As the bill moves forward through the legislative process, the Working Table would like to work with you to ensure the following: (1) the lists of neurological and psychiatric diseases and disorders included in the bill are as complete as possible and not seen as exclusive,(2) funding for the NCOE is at least \$25 million *per year*, and (3) additional opportunities for patient engagement and input into the NCOE are included.

Thank you again for your leadership. We look forward to working with you to advance S. 3427 through the legislative process.

Sincerely,

Acadia Pharmaceuticals
Alliance for Aging Research
Alliance for Patient Access
Alkermes
AfricanAmericansAgainstAlzheimer's
Avanir Pharmaceuticals
Cerevel Therapeutics
Coalition for Headache & Migraine Patients
CurePSP
Depression Bipolar Support Alliance
Eisai Inc.
The Headache & Migraine Policy Forum
Intra-Cellular Therapies
The Kennedy Forum
LatinosAgainstAlzheimer's
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)

Lundbeck Pharmaceuticals, LLC
Mental Health America
The Michael J. Fox Foundation for Parkinson's Research
Parkinson's Foundation
The Multiple System Atrophy (MSA) Coalition
National Alliance on Mental Illness (NAMI)
National Down Syndrome Society
Otsuka
Sage Therapeutics
Schizophrenia and Psychosis Action Alliance
Sunovion Pharmaceuticals
Takeda
UsAgainstAlzheimer's
U.S. Pain Foundation

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>