AMERICAN ACADEMY OF NEUROLOGY®

201 Chicago Avenue
Minneapolis, Minnesota 55415

Tel: (612) 928-6100
Fax: (612) 454-2744

AAN.com

March 16, 2022

The Honorable Anna Eshoo
Chair Subcommittee on Health
House Energy and Commerce Committee
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member Subcommittee on Health
House Energy and Commerce Committee
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 American Academy of Neurology (AAN), the world's largest association of neurologists representing 38,000 professionals, is strongly committed to improving the care and outcomes of persons with neurologic illness in a cost-effective manner. One in six people lives with a brain or nervous system condition, including Alzheimer's disease, Parkinson's disease, stroke, epilepsy, traumatic brain injury, ALS, multiple sclerosis, and headache.

The AAN thanks the Energy and Commerce Subcommittee on Health for hosting the upcoming legislative hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." Innovation in medicine is imperative, and we appreciate the Subcommittee's willingness to review key legislation that addresses this issue. More specifically, the AAN has endorsed H.R. 3085, the ENACT Act, and several key provisions included in H.R. 6000, the Cures 2.0 Act.

The ENACT Act: The Importance of Diversity in Clinical Trials

The AAN is committed to intentional action to be a fully inclusive, deliberately diverse, and anti-racist organization that respects and values our membership, our staff, and the communities we serve. We actively promote equity and social justice in neurology and the neurosciences. One action that can be taken to improve health care equity is making a deliberate effort to foster the inclusion of diversity in clinical trials. The AAN applauds the Subcommittee for including HR. 3085, the Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act to address the disparities in clinical trials. The ENACT Act would increase the participation of underrepresented populations in dementia clinical trials by expanding education and outreach, encouraging the diversity of clinical trial staff, and reducing participation burden, among other priorities.

Older Black and Latinx Americans are much more likely than White Americans to be affected by Alzheimer's and other dementias, yet many clinical research

studies focused on these diseases do not include sufficient data from these populations to be representative of the US population. The underrepresentation of these populations, along with Native American and Asian Americans, hampers our understanding about these health disparities and limits our knowledge of how potential therapeutics may affects populations that need them the most. This legislation aims to improve health care equity by taking deliberate actions to foster the inclusion of diversity in clinical trials. The ENACT Act would increase participation of underrepresented populations in dementia clinical trials by expanding education and outreach to these populations, encouraging the diversity of clinical trial staff, and reducing participation burden.

Cures 2.0 Key Provisions

Establishment of two additional Intercenter Institutes – Neurology Center of Excellence at FDA

The AAN supports Cures 2.0's efforts to establish two intercenter institutes at the Food and Drug Administration (FDA). Establishing the Neuroscience Center of Excellence at FDA has been a bipartisan, bicameral priority, and the AAN appreciates the leadership of Reps. DeGette and Upton on the 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 S. 3427, the Neuroscience Center of Excellence Act. Overall, the AAN supports the efforts of establishing an NCOE that is included in these bills. 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. We believe the creation of this center will enable several important goals, including 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 with psychiatric and neurologic diseases; and improving engagement between FDA and stakeholders and strengthening internal coordination within FDA.

The Creation of APRA-H

The AAN supports the authorization of an Advanced Research Projects Agency– Health (ARPA-H) that has been recently funded by the omnibus package. The omnibus provides $1 billion to establish the ARPA-H within the HHS. As highlighted by the administration, ARPA-H would have the potential to fund high-risk, high-reward research, such as new approaches to accelerate discovery of brain imaging and blood biomarkers. APRA-H could help contribute to the rapidly growing need to better understand the brain and nervous system. The omnibus legislation authorizes the President to appoint an ARPA-H director and allows the Secretary to transfer ARPA-H to any HHS agency or office, including the NIH, within 30 days of the omnibus's enactment.

While the funding has been secured, in addition to using DARPA as a model for ARPA-H, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative could also be a useful example in promoting collaboration and transformational discoveries. The BRAIN Initiative is a unique public-private partnership that involves the NIH, DARPA, the National Science Foundation (NSF), the FDA, the Intelligence Advanced Research Projects Activity (IARPA), and private organizations. One program funded by IARPA, the Machine Intelligence form Cortical Networks (MICrONS), uses a nimble, contract-driven approach to map the function and connectivity of cortical circuits to advance use of machine learning algorithms. IARPA collaborates with other BRAIN Initiative partners to share brain imaging data that can help inform additional neuroscience research. Many of these BRAIN Initiative projects focus on technologies and data analytics that could serve as a model for ARPA-H efforts. Given the existing success of the BRAIN Initiative and other innovative entities including NCATS and BARDA, ARPA-H should also have a clear scope of work to ensure synergy without redundancy.

Understanding the Implication of Long Covid

The AAN remains dedicated to reviewing research concerning the impact of Long Covid on patients. Since 2020, our knowledge of COVID-19 has significantly grown. With science at the forefront of policymaking, synthesizing research to formulate the best path forward is imperative. According to a recent study, one-third of patients diagnosed with COVID-19 developed psychiatric or neurologic disorders within six months, including depression, anxiety, stroke, and dementia. In that same study, researchers who evaluated more than 230,000 electronic health records, which includes anonymous data from 81 million patients, primarily in the US, found that among COVID-19 patients admitted to an intensive care unit (ICU), the incidence of developing a psychiatric or neurologic disorder rose to an unprecedented 46 percent. If left unchecked, post-acute sequelae of SARS-CoV-2 infection (PASC) could leave many unable to perform their jobs, severely impacting the workforce, and increasing costs of health care.

Given the number of COVID-19 cases across the US, the impact of neurologic symptoms is likely enormous, and without proper information sharing, patients could suffer devasting consequences and misdiagnoses. Additionally, understanding the core causes of PASC will make it easier for providers to identify patients who are more at risk of developing its chronic symptoms, and potentially taking measures to prevent them.

Mitigating COVID-19's Impact on Basic Research

The AAN also applauds the inclusion of the bipartisan, bicameral RISE Act (H.R. 869/ S. 289) in the Cures 2.0 legislation, which we believe would provide crucial funding to support NIH-funded research—to continue federally-funded research that has been stalled, delayed, or was even stopped as a result of the pandemic. The long-term consequences of the COVID-19 pandemic on the country's biomedical research enterprise are becoming clear: funds are being diverted to support COVID-19-related research to the detriment of research on conditions within the missions of NIH's 27 institutes and centers and the new COVID-19-related expenses incurred to run research reduced the buying power of existing grants. This provision authorizes $25 billion in funding for grants from multiple agencies to support scientific researchers and institutions, covering the costs of research disruptions related to the COVID-19 pandemic.

FDA Cell and Gene Therapy

With many gene therapies on the horizon with the potential to treat neurologic disease, the AAN supports the directive to submit a report on the current state of cell and gene therapy regulation. The first commercial gene therapy targeted to treat a neurologic disease, onasemnogene abeparvovec-xioi (Zolgensma), has revolutionized treatment options for children with spinal muscular atrophy, a previously untreatable and fatal neurologic disorder of childhood. However, insurance coverage of this life changing therapeutic remains a challenge due to its $2.1 million price tag. The report will also provide an opportunity to better evaluate current initiatives, including the National Institute of Neurological Disorders and Stroke's Ultra-rare Gene-based Therapy (URGenT) network. This new program will support the development of gene-based therapies for ultra-rare neurologic diseases.

The Inclusion of the Telehealth Modernization Act

The AAN has long supported the telehealth provisions included in the Cures 2.0 Act. Telehealth is essential to ensure that patients are able to maintain a stable relationship with their physician after the completion of the COVID-19 related public health emergency (PHE) declaration, regardless of their personal circumstances. The temporary extension of telehealth flexibilities after the end of the PHE provided in the recent omnibus legislation will provide more time for legislators and industry representatives to meet and solidify a long-term plan for telehealth coverage. Overall, we believe a

long-term solution is the Telehealth Modernization Act, which is included in the Cures 2.0 Act. It is imperative that telehealth services are accessible to all patients and that there are no restrictions on patient location or for conditions that are appropriate to be treated and monitored remotely. The patient's home is a critical originating site for many patients, but it can be inadequate for those without access to broadband, appropriate technology, or the space to have a private conversation with a health care provider. Maintaining telehealth coverage is essential to protecting Medicare's most vulnerable patients, as well as reducing health care disparities.

The COVID-19 PHE has made clear that providing access to care via telehealth is valuable in all communities, not solely rural areas, or communities with a shortage of health professionals. We thank the Subcommittee for its support on the permanent elimination of the statutory restrictions on Medicare telehealth care delivery based on geographic location. This change would benefit patients and providers and is a positive step towards removing limitations to health care access when telehealth is clinically appropriate. The AAN also supports the requirement that GAO report on recommendations to enhance Medicare coverage and reimbursement for innovative health technologies to better address the needs in the future.

In conclusion, we thank you for hosting this legislative hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." If you have any questions or require additional information, please do not hesitate to contact Derek Brandt, Director of Congressional Affairs at *dbrandt@aan.com* or Fred Essis, Congressional Affairs Manager at *fessis@aan.com*. We look forward to working with you as we all strive to improve care for all Americans with neurologic conditions.

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology