AMERICAN ACADEMY OF NEUROLOGY®

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July 28, 2021

The Honorable Diana DeGette
US House of Representatives
Washington, DC 20515

The Honorable Fred Upton
US House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton,

The American Academy of Neurology (AAN), the world's largest association of neurologists representing 36,000 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 applauds you for the 21st Century Cures 2.0 discussion draft. As with other medical specialties, the COVID-19 pandemic has forced neurology practices around the country to dramatically reshape the delivery of care for the vulnerable populations they treat. The AAN appreciates that your legislation builds upon actions already taken by Congress in the first version of the 21st Century Cures Act.

Sec. 101: Improving the research, development of treatments and education about Long COVID

We recommend reviewing legislation such as, the COVID-19 Long Haulers Act (H.R. 2754), that will serve as a great reference for policy proposals that address long COVID-19. 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. The AAN recommends the creation of a patient registry that includes individuals experiencing PASC. The registry will be an important tool in the active surveillance of patients with PASC, collection of data for research, identification of symptoms, and establishment of effective treatment strategies.

Furthermore, PASC can be common even if the patient has a mild case of COVID-19, as reported by The George Washington (GW) University School of Medicine & Health Sciences' COVID-19 Recovery Clinic and Yale's Post-COVID Recovery Program. As the PASC symptoms occur, patients must be able to recognize these signs in order to seek out the quality care they need. The AAN hopes you will build upon this introduced legislation to help develop and disseminate information to the public regarding PASC, so clinicians and patients can access appropriate therapies.

Sec. 203: 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 efforts included in your legislation in this section, which focuses on this important goal.

Additionally, the AAN urges you to consider incorporating the Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (H.R. 3085) to further bolster this section. 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.

Sec. 303: 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.

Sec. 304 – 309 Food and Drug Administration

Although the AAN is supportive of innovative therapies and devices, we encourage a thorough review of drugs and therapies prior to approval to ensure both clinical efficacy and patient safety are the highest priorities. To that end, the AAN applauds your legislation for including the use of real-world evidence to evaluate the safety and effectiveness of drugs subsequent to their approval or licensing as breakthrough therapies.

The AAN recommends that Cures 2.0 helps lower the costs of prescription medications to the health care system and to the consumer. The AAN supports reforms that increase drug pricing

transparency, providing authority to the federal government to negotiate prescription drug prices under the Medicare Part D program, eliminating federal tax deductions for direct-to-consumer (DTC) advertising, and removing harmful step therapy protocols.

Section 306: Establishment of Additional Intercenter Institutes at the Food and Drug Administration

The AAN supports the inclusion of Section 306 in the legislation, which requires the Secretary of Health and Human Services to establish two intercenter institutes at the Food and Drug Administration (FDA). Specifically, Section 306(b)(1) outlines specific criteria connected to the establishment of an intercenter institute.

This language supports our priority in establishing a Neuroscience Center of Excellence at the FDA, and we are appreciative of its inclusion. 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.

Sec. 403: The Inclusion of the Telehealth Modernization Act

The AAN applauds the inclusion of the Telehealth Modernization 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. 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 you for your continued 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 recommends the inclusion of continued coverage of audio-only services, which we believe are essential to ensuring health care equity for patients. Access to audio-only telephone-based services is important for Medicare beneficiaries of limited means and is also vital for Medicare patients who live in communities that lack sufficient broadband cellular and internet connectivity. For these communities, telehealth services provided through internet-based visual platforms are not an option. The elimination of coverage for audio-only telemedicine visits would disproportionately impact underserved communities that may face barriers to accessing video technology, according to Lori Uscher-Pines, a senior policy researcher at RAND. Additionally, as much as 7 percent of the US population does not use the internet, including 25 percent of adults age 65 or older, according to a recent study from the Pew Research Center. Audio-only continuation is imperative and can allow for more equitable and personalized care.

Sec. 501-502: Establishment of an Advanced Research Projects Administration – Health (ARPA-H) and the Inclusion of the RISE Act

The AAN supports the authorization of an Advanced Research Projects Administration – Health (ARPA-H) that has been proposed by President Biden to pursue transformational breakthroughs in medicine. 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.

Whether or not this new entity is housed within the National Institutes of Health (NIH), appropriate oversight and transparency will be of the utmost importance. Although the AAN is in favor of innovative research with fewer bureaucratic barriers, scientific rigor must be maintained. As recent experience has shown with the development of the COVID-19 vaccine, appropriate promotion and communication of government-funded science is essential.

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.

Also as noted by many, the creation of ARPA-H should not interfere with consistent funding for the NIH. Basic science efforts to better understand the molecular and cellular mechanisms underlying neurologic disease is critical to discovering better treatments and potential cures.

The AAN also applauds the inclusion of the bipartisan, bicameral RISE Act, which we believe would provide crucial funding to support NIH-funded research—to continue federally-funded research that has been stalled, delayed, or 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; the new COVID-19-related expenses incurred to run research are reducing the buying power of existing grants; and we are in danger of losing a generation of investigators who are particularly vulnerable to career disruptions. The bill also authorizes funding for research grants from multiple agencies that support scientific researchers and institutions, covering the costs of research disruptions related to the COVID-19 pandemic.

Sec. 760: Education Programs and Training for Caregivers

The AAN recognizes the importance of improving the ability of families and caregivers to support their loved ones through health literacy, family training in specialized medicine, community resources to aid caregiver education, and enabling patients and families to be better informed of their treatment options and associated costs. Education for patients and their caregivers has declined in recent years as clinical time with patients has been more limited by administrative

hurdles, electronic medical record utilization difficulties, and reduced reimbursement rates. COVID-19 sadly exacerbated this issue; education has often been limited to paper handouts, which is an ineffective means of helping patients and families understand their diagnosis and improve therapy understanding.

Improving health literacy in a digital age requires digital options. Patients are increasingly utilizing the internet, where information is frequently unvetted, biased, and/or inconsistent with evidence-based care. Improving and providing digital options for patients (such as YouTube videos on seizure safety and epilepsy) would be low cost, portable, revisable, and easy to understand. Many private and academic healthcare networks have begun using digital options for patients and families with great success. Your legislation could propose trial studies to assess the efficacy and utility of digital educational material worked on by subject experts.

Conclusion

We appreciate the work you have done and will continue to do to advance treatments and cures for neurologic patients. 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 continue working to improve the quality of health care for neurologic patients and physicians.

Sincerely,

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