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July 18, 2022

The Honorable Patty Murray
Chair, Senate Committee
on Health Education, Labor and Pensions
US Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, Senate Committee
on Health Education, Labor and Pensions
US Senate
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr,

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 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. To that end, we work to actively promote equity and social justice in neurology and neurosciences. It is for this reason that **the AAN supports two important provisions of H.R. 7667, Food and Drug Amendments of 2022, Section 503 and 506, that would provide guidance on diversity action plans for improving diversity in clinical studies.**

Several neurologic conditions have different rates of disease by demographic factors, such as gender, race, ethnicity, age, and geographic location. For example, older Black and Latinx Americans are much more likely than White Americans to be affected by Alzheimer's and other dementias. However, many clinical research studies do not include sufficient data from numerous groups to be representative of the US population. This underrepresentation hampers our understanding about these health disparities and limits our knowledge of how potential therapeutics may impact populations that need them the most.

The FDA Amendments of 2022 include several provisions that would help clinical trial sponsors to identify and implement strategies that will increase diverse enrollment. These strategies are preferred over requirements for enrollment proportions, which do not address the numerous systemic issues related to low enrollment such as trial site location, rates of health insurance coverage, and additional out of pocket cost for enrollees. Additionally, 19% of clinical trials have already ended early due to slow enrollment,¹ and additional requirements around enrollment could perpetuate this issue. As such, a focus on identifying and disseminating strategies to promote enrollment and provide robust support to researchers is preferred.

The AAN appreciates the focus on this important issue and specifically supports section 503 that creates public workshops to identify strategies to increase diverse enrollment,

¹ Carlisle B, Kimmelman J, Ramsay T, MacKinnon N. Unsuccessful trial accrual and human subjects protections: An empirical analysis of recently closed trials. *Clin Trials*. 2015;12(1):77-83. doi:10.1177/1740774514558307

and section 506 that will provide guidance on conducting decentralized studies. These methods can help to increase overall enrollment, with estimates of 60% to 80% of patients being more willing to enroll in a clinical trial if time and travel burdens were decreased,² which is a key benefit of decentralized trials. In addition, a systemic review of trials revealed that participation of Black and Hispanic individuals increased with video interventions and that cultural sensitivity is essential in tool development and content delivery.³ Promising practices to increase diverse enrollment such as these can continue to be identified and disseminated through the two provisions under consideration. Increasing diverse enrollment in clinical trials through these methods is an important step for neurologists to ensure the best treatments for their patients. **We strongly support the inclusion of these provisions related to the FDA Amendments of 2022 and encourage you to incorporate these policies into the final FDA user fee reauthorization package.**

If you have any questions or require additional information, please contact Madeline Turbes, Health Policy Manager at mturbes@aan.com, or Derek Brandt, Director of Congressional Affairs at dbrandt@aan.com. We look forward to working with you as we all strive to improve care for all Americans with neurologic conditions.

Sincerely,

A handwritten signature in black ink that reads "Orly Avitzur MD". The signature is written in a cursive, flowing style.

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

² Adams DV, Long S, Fleury ME. Association of Remote Technology Use and Other Decentralization Tools With Patient Likelihood to Enroll in Cancer Clinical Trials. *JAMA Netw Open*. 2022;5(7):e2220053. doi:10.1001/jamanetworkopen.2022.20053

³ Nolan TS, Bell AM, Chan YN, Leak Bryant A, Bissram JS, Hirschey R. Use of Video Education Interventions to Increase Racial and Ethnic Diversity in Cancer Clinical Trials: A Systematic Review. *Worldviews Evid Based Nurs*. 2021;18(5):302-309. doi:10.1111/wvn.12539