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June 9, 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) is the world's largest neurology specialty society representing more than 38,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN has been strongly supportive of the Accelerated Approval pathway since its inception and credits this approval option with increasing access to life saving treatments for patients suffering from neurologic diseases such as MS, as well as for people living with HIV and cancer, who have benefited from hundreds of treatments being brought to market more quickly. However, the AAN has also closely monitored and engaged with the FDA, CMS, Congress, and other stakeholders regarding therapies that have been approved based on surrogate endpoints without our members, or their patients, having all the information they need to know how to most effectively incorporate these new drugs into their plans of care.

In the last year, a protracted controversy has played out over the approval, and subsequent National Coverage Determination (NCD) of aducanumab (brand name Aduhelm) for the treatment of Alzheimer's Disease. While the AAN has been incredibly supportive of the various companies that are working diligently to development treatments for this horrible disease, many of our members expressed concerns over the availability of evidence demonstrating adequate clinical benefit that they needed to determine how to best utilize this new drug.

That is why the AAN is very supportive of the measures included in Food and Drug Administration Safety and Landmark Advancements Act of 2022 that will modernize the Accelerated Approval pathway to ensure that novel treatments that address critical unmet medical needs can continue to be moved through the approval process quickly while also addressing the necessity for their timely and comprehensive post-approval study. The AAN is also encouraged by the inclusion of a director from the Office of Neuroscience on the Accelerated Approval Council as this will provide invaluable expertise in the evaluation of therapies aimed at the numerous neurologic diseases that people are suffering from today without adequate treatment options. **We strongly support the continued inclusion of these provisions relating to Accelerated Approval going forward.**

The AAN is grateful for the opportunity to engage with Congress on this important issue moving forward. 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 Max Linder, Government Relations Manager, at mlinder@aan.com.

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

cc: The Honorable Frank Pallone, Chair, House Committee on Energy and Commerce
The Honorable Cathy McMorris Rodgers, Ranking Member, House Committee on Energy and Commerce