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August 6, 2021

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 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, Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

While the science on SARS-CoV-2 continues to evolve, the threat posed by the delta variant heightens the stakes for health care providers who are at risk for breakthrough COVID infections. Frontline workers who become infected are unable to work and can potentially expose colleagues and patients creating a domino effect on our already strained workforce. We are already receiving reports of members who are infected and ill as well as those who are testing positive and out on quarantine.

Neurologists care for a patient population that is particularly susceptible to risks of COVID. With recent data from Israel showing fully vaccinated individuals carry a similar viral load as unvaccinated people¹, the risk of COVID transmission between health care providers and patients, vaccinated or not, is very real.

As the world enters a new phase in this pandemic, the AAN strongly encourages the FDA to consider the unique impact of the delta variant on health care providers while BNT162b2 is evaluated for emergency use authorization as a booster dose. Data indicate that immunity wanes with time, meaning the health care providers vaccinated six or more months ago have less protection as the delta variant becomes more prevalent. A third dose, or booster, would restore immunity levels for all individuals and health care providers, who continue to be at risk for mild or symptomatic covid breakthrough infections.

Approximately thirty percent of those infected with COVID are at risk of developing post-acute sequelae of SARS-CoV-2. Many of those with so-called *long-*

COVID, suffer from neurologic symptoms. As the delta variant poses new risks to even vaccinated individuals, an uptick in long-COVID would be expected.

Breakthrough infections among health care workers threaten the integrity of the US health care system, especially for the unvaccinated (voluntary and children at this point) and those that are immunocompromised, which include the elderly, renal and other transplant patients, those with cancer and diabetes, and those on immunotherapies, such as people with multiple sclerosis. Mental health concerns of health care workers are another challenge as the delta surge progresses. More needs to be done to protect US health care workers and medically vulnerable patients.

While vaccines continue to offer strong protection against severe illness, the virus transmissibility seen with the delta variant among fully vaccinated individuals necessitates swift action to protect those at greatest risk. We urge the FDA to offer prompt consideration of booster dose emergency use authorization. Please contact Amy Kaloides, Senior Director, Advocacy, at akaloides@aan.com, or Daniel Spirn, Senior Regulatory Counsel, at dspirn@aan.com with any questions or requests for additional information.

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

ⁱ Bergwerk MB, B, Gonen T, Lustig Y, et al. [Covid-19 Breakthrough Infections in Vaccinated Health Care Workers](#). *NEJM*, July 28, 2021. DOI: 10.1056/NEJMoa2109072