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April 3, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Lina M. Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

**RE: Solicitation for Public Comment to Understand Lack of
Competition and Contracting Practices that May be Contributing to
Drug Shortages**

Dear Secretary Becerra & Chair Khan,

The American Academy of Neurology (AAN) is the world's largest association of neurologists and neuroscience professionals, with over 40,000 members. The AAN's mission is to enhance member career fulfillment and promote brain health for all. A neurologist is a doctor with specialized training in diagnosing, treating and managing disorders of the brain and nervous system such as Alzheimer's disease, stroke, concussion, epilepsy, Parkinson's disease, multiple sclerosis, headache and migraine.

The AAN thanks the Federal Trade Commission (FTC) and U.S. Department of Health and Human Services (HHS) for the opportunity to provide feedback on the agencies' Request for Information for public comment regarding factors contributing to drug shortages [FTC-2024-0018-0001], (February 14, 2024) (RFI). Drug shortages are pervasive challenges that impact prescribers' and patients' access across all areas of healthcare, and neurologists often rely on prescription medications faced with shortages, including stimulants, anti-convulsant, and anti-neoplastic medications to treat or manage their patients' conditions, making shortages an issue of particular concern for neurology practices. Further, the AAN is deeply committed to promoting access to generic medications as a strategy to reduce the high cost of neurologic medication. Accordingly, the AAN greatly appreciates the administration's interest in addressing drug shortages, with a particular interest in generic shortages.

Request for Information

The FTC and HHS requested information related to the causes and potential solutions to drug shortages and the impact of Group Purchasing Organizations (GPOs) and drug wholesalers. Specifically, the agencies are seeking input regarding these entities' impact on generic pharmaceutical and related markets.

Although the AAN believes that it is appropriate and necessary for the FTC and HHS to assess all aspects of the pharmaceutical supply chain in efforts to alleviate supply chain disruptions and shortages, the AAN believes that it is critical to acknowledge that manufacturer capacity and decision-making are the primary drivers of the available supply of a medication. The AAN is concerned that this RFI appears to be predicated on a conviction that there is inappropriate tension between a given GPO's ability to negotiate aggressively to achieve a lower price and patient access to medication. The AAN notes that high drug costs and associated cost-sharing for patients are directly linked to a higher likelihood of patients abandoning or rationing their treatments, which may result in permanent disability. When individuals are forced to ration therapeutics for chronic diseases, as is the case with many neurologic conditions, both patients and the healthcare system stand to lose as morbidity and mortality increase.¹

GPOs function to aggregate the hospital and healthcare providers' purchasing power to negotiate purchasing agreements and save on administrative costs when acquiring medications, yielding savings for patients and for the broader healthcare system.² Drug wholesalers purchase products from many different manufacturers and sell drugs to hospitals and pharmacies, which allows for financial efficiencies for the healthcare facility.³ A drug shortage may occur when the available supply of a product is low, when the demand for a product is high, or both. The pharmaceutical supply chain is complex and has many controls in place to ensure that patients receive safe and effective pharmaceutical products. GPOs and drug wholesalers are two resources a hospital, pharmacy, or prescriber may use to source drugs. Other resources, which may be used in place of or in addition to GPOs and wholesalers, include Patient Assistance Programs, the 340B Drug Pricing Program, grants, clinical trials, and discount programs through payers. Each of these resources can alleviate the strain on the supply chain during a drug shortage.

The AAN greatly appreciates the administration's interest in preventing lack of competition among GPOs and drug wholesalers from causing pharmaceutical supply chain disruptions; however, when a hospital, pharmacy, or prescriber experiences a drug shortage, the shortage is typically consistent across the healthcare system and not the result of any single GPO or wholesaler's practices. The AAN notes that working with a GPO is voluntary, and healthcare providers may work with multiple GPOs depending on their need and the value proposition each GPO offers. Hospitals, pharmacies, and prescribers will use all methods of drug procurement to secure drugs at the most efficient price. The AAN supports efforts to promote

¹ Prescription Drug Prices: an AAN Position Statement, *Neurology* 102:5 (Mar. 12, 2024), <https://www.neurology.org/doi/10.1212/WNL.0000000000209132>.

² James G. Scott, et al., "GPOs: Helping to Increase Efficiency and Reduce Costs for Healthcare Providers and Suppliers," *Applied Policy* (Oct. 2014), https://www.supplychainassociation.org/wp-content/uploads/2018/05/Applied_Policy_Report_2014.pdf.

³ "How Do Allocations Work for the Pharma Supply Chain?" *Fierce Pharma* (Oct. 26, 2020), <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>

price transparency throughout the drug distribution supply chain to better understand how the various components impact the price paid by patients.

When the supply chain experiences a drug shortage, wholesalers often employ the use of allocation to ensure the dispensers purchasing from the wholesaler receives a portion of the limited supply of the drug experiencing the shortage. Allocation prevents any link in the supply chain from hoarding product or receiving disproportionately less than others. The AAN believes that GPOs and drug wholesalers are integral parts of a stable supply chain and can be leveraged as effective tools to maintain drug affordability.

Conclusion

The AAN appreciates the opportunity to provide a response to the Request for Information. The AAN is committed to working with regulators to protect the pharmaceutical supply chain and ensure that generic drugs are readily accessible for all patients, especially those with complex neurological conditions. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com or Cale Coppage, the AAN's Senior Government Relations Manager at ccoppage@aan.com with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink that reads "Carlayne E. Jackson". The signature is written in a cursive, flowing style.

Carlayne E. Jackson, MD, FAAN
President, American Academy of Neurology