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May 6, 2025

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
U.S. Department of Commerce
1401 Constitution Ave, NW
Washington, DC 20230

RE: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (XRIN 0694-XC120), April 14, 2025

Dear Director Astle:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Commerce's request for public comment on its Section 232 national security investigation on pharmaceutical and pharmaceutical ingredient imports. The investigation could form the basis for tariffs or other trade restrictions for pharmaceutical products; to date, these products have received exemptions from the administration's tariff policies.

The AHA shares the administration's long-term goal of strengthening the domestic supply chain for essential pharmaceutical products and recognizes the value of reducing reliance on international sources. At the same time, achieving this goal will require a significant amount of time, given the logistical complexity and resources involved in reorienting the pharmaceutical supply chain. In the short term, we are concerned that tariffs on pharmaceuticals and pharmaceutical products — and any retaliatory action from the countries on which tariffs are imposed — could inadvertently disrupt the availability of these essential care delivery tools, increase the complexity of delivering patient care and significantly raise hospital costs.

The AHA urges the administration to maintain tariff exceptions for pharmaceuticals and pharmaceutical products to minimize inadvertent



Director Stephen Astle May 6, 2025 Page 2 of 3

disruptions to patient care. It is especially critical to have these exceptions for products that are already in shortage and for which production in the countries subject to increased tariffs supplies a significant part of the U.S. market.

Each day in America's hospitals and health systems, the expertise of care teams comes together with a wide array of pharmaceuticals to deliver safe and effective care. The lives of patients often depend on the ready availability of drugs to respond to emergent conditions like heart attacks and infections, and other critical illnesses like cancer and organ failure. The supply chain for pharmaceutical products is highly complex and requires hospitals to draw on both domestic and international sources. It is also prone to significant disruption from a wide range of factors, including transportation interruptions, natural disasters, raw materials shortages and production issues. As of the first quarter of 2025, there are 270 drugs on the active shortage list, including lingering shortages of intravenous (IV) fluids stemming from the impacts of Hurricane Helene on a large North Carolina production facility. A recent Government Accountability Office analysis also found that the duration of drug shortages has increased, with nearly 60% of drug shortages lasting two or more years in 2024, compared to only one-third of shortages lasting that long in 2019.

Health care providers import many cancer, cardiovascular and immunosuppressive drugs, as well as antibiotics and combination antibiotics. For many patients, even a temporary disruption in their access to these needed medications could put them at significant risk of harm. Carefully planned chemotherapy treatments and antibiotic schedules are essential to giving patients the best chance of overcoming their disease. Similarly, the provision of necessary cardiovascular medications must be continuous to optimize both short and long-term patient outcomes.

Beyond the use of these finished products, many raw ingredients for pharmaceuticals come from international sources. These are commonly known as active pharmaceutical ingredients (APIs) and vital components for any pharmaceutical manufacturer's supply chain. The U.S. gets nearly 30% of its APIs from China. Furthermore, according to a 2023 Department of Health and Human Services estimate, over 90% of generic sterile injectable drugs — such as certain chemotherapy treatments and antibiotics — depend on key starter materials from either India or China. A recent US Pharmacopoeia analysis also found that over 50% of the APIs for non-IV drugs come from either India or the European Union. Shifting the sourcing for finished drugs and APIs would take a significant amount of time, and in some cases, may not be possible if a needed raw material is unavailable domestically.

Lastly, the AHA is concerned about the potential for tariffs to raise the costs of delivering care to hospitals and health systems. A recent survey found that 82% of health care experts expect tariff-related expenses to raise hospital costs by at least 15%, and 90% of supply chain professionals expect procurement disruptions. Given that hospital payments are set by government and private payer contracts, the costs would be borne by hospitals directly. As underscored by the AHA's recent Cost of

Director Stephen Astle May 6, 2025 Page 3 of 3

Caring report, such cost increases could further compound the broader financial headwinds challenging hospitals' ability to provide care to patients and communities. vi

Thank you for the opportunity to provide feedback on this notice. We welcome the opportunity to discuss with your team how to preserve access to essential pharmaceuticals and ensure that hospitals can continue delivering safe and effective care. Please contact me if you have questions at ademehin@aha.org.

Sincerely,

/s/

Akinluwa (Akin) A. Demehin Vice President Quality and Safety Policy

¹ https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly

ii Drug Shortages: HHS Should Implement a Mechanism to Coordinate Its Activities GAO-25-107110. Apr. 09, 2025. Publicly Released: Apr 09, 2025.

https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/

https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european

v https://www.beckershospitalreview.com/supply-chain/hospital-finance-supply-leaders-predict-15-increase-in-tariff-related-costs/

vi https://www.aha.org/costsofcaring