



May 7, 2025

Bureau of Industry and Security  
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).

ASHP (American Society of Health-System Pharmacists) appreciates the opportunity to submit comments regarding the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients.

ASHP supports efforts to strengthen supply chains by promoting investment in domestic manufacturing of pharmaceuticals and other critical medical supplies. However, establishing new drug manufacturing facilities is a long-term, capital-intensive process that generally takes 4-5 years. In the interim, imposition of tariffs must be carefully balanced with efforts to maintain a robust and resilient pharmaceutical supply chain for all Americans.

### **America's National Security Depends on Strong Pharmaceutical Supply Chain**

ASHP has long raised concerns about the national security implications of our nation's pharmaceutical supply chain.<sup>1</sup> Over the last two decades, ongoing and emergent drug shortages have created serious challenges for hospitals, health systems, and other providers.<sup>2</sup> In the first quarter of 2024, active, ongoing shortages reached an all-time high, impacting over 300 medications.<sup>3</sup> The majority of these shortages are for older, low-margin generic drugs, many of which are sterile injectable products that are essential to care provided in hospitals and health systems.<sup>4</sup> For example, vincristine, a drug used in regimens that can cure some pediatric cancers, has

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<sup>1</sup> See American Society of Health-System Pharmacists, "Drug Shortages as a Matter of National Security: Improving the Resilience of the Nation's Healthcare Critical Infrastructure" (Sept. 18, 2018), available at <https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-Security.pdf>. [Attached as Appendix A].

<sup>2</sup> M. Socal and J. Sharfstein, "Drug Shortages – A Study in Complexity," JAMA Network Open (April 5, 2025), available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2817213>.

<sup>3</sup> American Society of Health-System Pharmacists, "Drug Shortage Statistics," available at <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>.

<sup>4</sup> R. Gupta, U. Savani, K. Gatwood, and K. Culos, "The Recurring Problem of Drug Shortages—How Do We Overcome It?" Clin. Hemat. Int. (Mar. 18, 2018), available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC8432384/>.

been in critical shortage twice in the past 7 years.<sup>5</sup> Several dozen other chemotherapy drugs have also been in short supply over the past decade, along with critical sterile injectable products used for surgical anesthesia. Some medications that go into shortage, including chemotherapeutic agents, have no alternatives, resulting in delayed or cancelled treatments and/or rationing.<sup>6</sup>

Drug shortages are extremely disruptive for hospitals, health systems and other providers, forcing them to reallocate clinical and financial resources from patient care to medication sourcing.<sup>7</sup> The causes of drug shortages are multipronged, including a lack of incentives for manufacturers to produce low-margin generic drugs as well as quality and production issues. Even if drug manufacturers could quickly expand domestic production of medications, including low-cost generics, to meet American needs, key starting materials and active product ingredients (API) for generic medications are heavily sourced from other countries, with China and India being the largest sources. Imposing tariffs without addressing these underlying factors risks straining our pharmaceutical supply chain and increasing the risk of drug shortages that disrupt patient care.

Although ASHP supports efforts to enhance domestic manufacturing, broad tariffs could be counterproductive – leading to higher costs and drug shortages. Generic drugs, which are both the most widely-used medications in the United States and the most at risk of shortages, often have thin margins. Tariffs on API and key starting materials would further erode margins. Manufacturers may not even have the flexibility to raise prices, given that federal penalties are triggered when a drug's price increase outstrips the pace of inflation. As a result, generic manufacturers with little ability to increase prices and little margin to absorb higher ingredient costs may become unprofitable. These factors could result in generic manufacturers exiting the market, tightening supply and compounding the risk of shortages. Further, given that drug manufacturers are reliant on foreign sources for API and key starting materials for certain medications, if source countries were to impose retaliatory export restrictions, it could cause drug shortages, endangering patient health and safety.

### **A Strong Pharmaceutical Supply Chain Demands Diversification**

Preventing shortages and ensuring a robust medication supply is key to national security. In the short term, tariffs must be weighed against the likelihood that they will undermine supply chain stability, which would be counter to national security goals. Specifically, we urge the Administration to focus on the long-term project of building a highly diversified supply chain. Enhancing domestic supply is an element of robust supply chain, but it must be coupled with a recognition that positive incentives may be necessary to support cost-competitive domestic production of generic medications, their API, and key starting materials.

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<sup>5</sup> See American Society of Health-System Pharmacists, "Drug Shortages List," *available at* <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>.

<sup>6</sup> E. Santos, T. Oliver, et al., "Drug Shortages in Oncology: ASCO Clinical Guidance for Alternative Treatments," *JCO Oncology Practice* (Nov. 14, 2023), *available at* <https://doi.org/10.1200/OP.23.00545>.

<sup>7</sup> See American Society of Health-System Pharmacists, "ASHP Drug Shortages Report: Severity and Impact of Current Drug Shortages," 2023, *available at* <https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>; See also Vizient, "Drug Shortages and Labor Costs: Measuring a Hidden Cost of Drug Shortages on U.S. Hospitals" (June 2019), *available at* <https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/2904ca0ddec449b793fd3b39ff4bdf8b?v=9a739094>.

### Key Recommendations:

We urge caution in the broad application of tariffs and recommend the Administration take the following steps to support a healthy, diversified pharmaceutical supply chain:

- Targeted Exemptions: We urge the Administration to exempt API and key starting materials from tariffs until domestic manufacturers of generic medications are producing sufficient supply to meet all patient needs. Domestic manufacturers and 503B facilities cannot operate without these inputs, many of which are sourced from foreign countries – imposing tariffs on them will increase costs and potentially lead to market exits.
- Stay the Medicaid Inflationary Penalty for Multisource Generics: Tariffs on generic medications and their ingredients squeeze manufacturers' already slim profit margins. Because the pricing of generic drugs often approaches the price of production, generic manufacturers must be able to increase prices when the cost of ingredients increases to profitably manufacture essential medications. However, Medicaid inflation penalties prevent manufacturers from increasing prices faster than inflation. As a result, generic manufacturers caught between increased ingredient costs and inflation penalties are likely to stop producing some products, resulting in shortages. To safeguard manufacturing of generic medications, the Administration should stay the Medicaid Drug Rebate Program's inflationary rebate penalty for multisource, generic medications.
- Provide Positive Incentives for Market Entry: Entering the market to manufacture a generic drug is a multi-year process that requires investment in scientific, manufacturing, and regulatory functions. Tariffs may spur domestic production, but we urge the Administration to provide positive incentives as well. Specifically, we recommend that FDA waive generic drug user fees for generic drugs described in 506C(g) of the Federal Food Drug and Cosmetics Act, for which FDA may prioritize and expedite review of an Abbreviated New Drug Application (ANDA) or related supplement to mitigate a shortage. This fee waiver should only apply to manufacturers that commit to promptly market their generic drug if it is approved.
- Diversify the Manufacturing Base: While outside of the scope of this 232 investigation, we urge the Administration to consider other avenues for shoring up the pharmaceutical supply chain in tandem with any tariff imposition. Specifically, we recommend the federal government use its purchasing power to ensure that at least a minimum number of manufacturers remain in the market and maintain active manufacturing capacity for critical medications. While this would not prevent any given manufacturer from experiencing a supply disruption, it would increase the likelihood that another existing manufacturer would be able to respond, in the medium term, when a shortage occurs.<sup>8</sup>
- Improve Transparency into Manufacturer Quality: Healthcare providers and pharmacies currently have very little ability to select manufacturers based on the reliability of their supply chain. This undermines

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<sup>8</sup> For additional detail, ASHP's "[Policy Solutions to Address the Drug Shortage Crisis](#)" is attached as Appendix B.

their ability to source products from the most reliable manufacturers. Greater transparency could increase investment in manufacturing quality, which would strengthen supply chains.

- Create Reimbursement Policy Incentives: To encourage greater investment in manufacturing capacity and quality, the federal government (e.g., Centers for Medicare and Medicaid Services) should provide manufacturers of critical generic drugs who commit to producing large volumes of these drugs for hospitals and health systems (through guaranteed-volume contracts) with greater certainty of their ability to recover their investment and receive purchase volume for these products. This would also offer healthcare providers certainty that they can rely on the manufacturer to provide a particular level of supply at a guaranteed price, allowing them to consider quality and reliability rather than just cost when selecting products.

We look forward to working with you to ensure that patients have access to a safe and secure medical supply pipeline. As the Section 232 investigation continues, we would welcome the opportunity to act as a resource – please do not hesitate to let us know if we can answer any questions or provide additional information.

Sincerely,

A handwritten signature in black ink that reads "Jillanne Schulte Wall". The signature is written in a cursive, slightly informal style.

Jillanne Schulte Wall, J.D.  
Senior Director, Health & Regulatory Policy

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Appendix A - ASHP Report: Drug Shortages as a Matter of National Security: Improving the Resilience of the  
Nation's Healthcare Critical Infrastructure

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Appendix B – ASHP Recommendations: Policy Solutions to Address the Drug Shortage Crisis