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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]

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Department of Commerce to its docket: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. On April 1, 2025, the Secretary of Commerce initiated an investigation under section 232 of the Trade Expansion Act (19 U.S.C. 1862) to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products. This includes both finished generic and non-generic drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients (APIs) and key starting materials, and derivative products of those items.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care (LTC) services and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members employ 205,000 individuals, and provide an expanding set of health care services to millions of patients every day. Our members are small business owners who are among America's most accessible health care providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA supports the overarching goal of reshoring pharmaceutical manufacturing. Our experience during COVID exposed the country's vulnerability to shortages resulting from an international crisis or even foreign malevolence. However, tariffs on pharmaceuticals could produce similar risks to independent pharmacies and their patients. Tariffs on pharmaceuticals could lead to financial strain on small business independently owned community and LTC pharmacies because they could be forced to absorb resulting price increases. NCPA members procure their pharmaceuticals from drug wholesalers. The wholesalers will likely pass on any increase in the price of pharmaceuticals caused by tariffs. At the same time, pharmacies are unable to pass these increased costs to patients, as pharmacy benefit managers (PBMs) determine out-of-pocket costs for patients and dictate pharmacy reimbursement for the dispensing of medications. Should

pharmaceutical tariffs be enacted, it is imperative that the administration require PBMs to adjust reimbursements to pharmacies within 24 hours of price increases to account for increased drug acquisition costs should tariffs go into effect. These higher prescription drug costs would be borne by patients, employers, and the health care system.

Tariffs on pharmaceuticals could also exacerbate pressures on patient access from implementation of the Medicare Drug Price Negotiation (MDPN) program. Under the current Centers for Medicare & Medicaid Services (CMS) implementation pathway for this program, pharmacies are at a severe disadvantage, in essence floating the costs of this program while waiting weeks to be paid. This is unsustainable and increased costs to purchase drugs will only exacerbate this problem.

Tariffs on pharmaceuticals can also exacerbate drug shortages. There are multiple factors that contribute to drug shortages, many of which are beyond the control of pharmacies, including lack of raw materials used to manufacture drugs (both the active ingredients and inactive materials), consolidation in the generic pharmaceutical manufacturer industry, and the rationing of available products. In turn, drug shortages impact community pharmacy and can delay patient care.

Additionally, imposing tariffs on generics and biosimilars would likely exacerbate shortages of these drugs. According to the Association for Accessible Medicines, "The overall value of generic sales in the U.S. has declined by $6.4 billion since 2019, despite increased volume and new generic launches," and over 60 percent of generic drugs in shortage have a unit price of $1 or less.[1]

In sum, the administration should consider that tariffs on pharmaceuticals:

- Will not immediately increase domestic production capacity;
- Will likely exacerbate drug shortages and undermine national security goals; and
- Will likely drive up drug costs for pharmacies, providers, and patients alike, potentially impacting affordability and access.

NCPA notes that the previous Trump administration chose to not apply tariffs to generic and biosimilar pharmaceutical products, despite the initial inclusion of Harmonized Tariff System of the United States (HTSUS) codes corresponding to such goods in the U.S. Trade Representative's first proposal.[2] Ultimately, through four rounds of tariffs, no tariffs were imposed on any goods of HTSUS Chapter 30, covering finished pharmaceutical products. Likewise, the administration determined not to impose such tariffs on numerous tariff codes covering APIs after stakeholder feedback.

[1] The U.S. Generic & Biosimilar Medicines Savings Report. Association for Accessible Medicines, September 2024.

[2] Notice of Determination and Request for Public Comment Concerning Proposed Determination of Action Pursuant to Section 301, *China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation*, 83 Fed. Reg. 14,906 (USTR Apr. 6, 2018) at 14910-13 (listing HTSUS codes 29146200 through 30067000, corresponding to API and finished pharmaceutical products).

Therefore, we believe the current Trump administration should consider the potential harm to U.S. interests in refining its tariff policy. Any tariffs on the pharmaceutical sector should be carefully tailored to avoid increasing drug shortages and costs for patients.

Policies the Trump administration should pursue include:

- The following exclusions from any tariffs: generics, APIs, key starting materials (KSMs), and drugs on drug shortage lists. Domestic manufacturers and compounding pharmacies cannot operate without APIs and KSMs. Many of these materials come from China and India, so tariffs will likely increase costs and access issues.

- Implementing PBM reform to strengthen domestic supply chains. The administration, working with Congress and through agencies such as CMS and the Federal Trade Commission, must address anticompetitive PBM practices to strengthen domestic pharmaceutical supply chains, protect patients' access to medications at their local pharmacies, and safeguard the interests of American taxpayers; and

- Reducing U.S. reliance foreign production of APIs and KSMs by incentivizing U.S. manufacturing through supportive domestic and trade policies.

NCPA thanks the Department of Commerce for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association