APhA
American Pharmacists Association

May 7, 2025

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
United States Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

RE: Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket No. 250414-0065, XRIN 0694-XC120)

Dear Director Astle,

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments to the Department of Commerce's (Department) notice of request for comments on "Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients." APhA shares the Department's belief that the quality and safety of pharmaceutical products and the global pharmaceutical supply chain are essential to national security and public health. However, APhA is concerned that broad tariffs on pharmaceuticals and their ingredients could significantly impact patient access to medications and contribute to drug shortages.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Patient Access

Imposing tariffs on pharmaceuticals and their ingredients will create additional uncertainties and complexities within the pharmaceutical supply chain, possibly leading to disruptions in patient access to medications. At a minimum, costs across the supply chain will increase, and who will bear these increased costs is still uncertain.

Currently, "[g]eneric drugs make up 90% of US prescription volume" and come primarily from India.[1] Given the wide use of generic medications and the scale at which they are produced outside of the United States, it can be assumed that additional tariff-related costs will be introduced to the supply chain of many of the generic medications Americans take today. Tariffs also have the potential to impact the supply chain of branded pharmaceuticals. Over 40% of the active pharmaceutical ingredients (APIs) used in making branded pharmaceuticals come from the European Union.[2] While brand medications make up a significantly smaller portion of U.S. prescription volume, they account for 80% of prescription drug spending.[3] Studies show that over 8% of Americans prescribed medication do not take it because of costs.[4] Accordingly, passing these costs on to the patient could harm the patient's current health and increase the cost of care if patients decide to go without their needed medications.

As such, APhA encourages the Department, if it does decide to act under Section 232, to minimize disruptions to patient care. One approach would be to exclude certain medications and materials from additional tariffs to reduce their impact on patient medication access. For example, exemptions should include oncology and cancer treatments, radiopharmaceutical isotopes, equipment, and supplies that save lives or other "Essential Medicines, Medical Countermeasures, and Critical Inputs," as defined in section 7 of President Trump's Executive Order 13944, "to identify vulnerabilities in our Nation's supply chains for these products."[5]

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[1] Vimala Raghavendran, et al., *Over Half of the Active Pharmaceutical Ingredients (API) for Prescription Medicines in the U.S. Come from India and the European Union*, United States Pharmacopeia (Apr. 17, 2025). Available at: https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european.

[2] *Id.*

[3] Sonal Parasrampuria & Stephen Murphy, *Trends in Prescription Drug Spending, 2016-2021*, Assistant Secretary for Planning and Evaluations, U.S. Department of Health and Human Services (Sept. 2022). Available at: https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf.

[4] Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18-64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, Centers for Disease Control and Prevention (June 2023). Available at: https://www.cdc.gov/nchs/products/databriefs/db470.htm.

[5] *Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States*, The White House (Aug. 6, 2020). Available at:

While APhA urges the Department to make specific exclusions to prevent future disruptions and problems, these recommendations are not intended to serve as an exhaustive list. APhA recommends specifically excluding medications listed on the FDA's and the American Society of Health-System Pharmacists' (ASHP) drug shortage lists from additional tariffs to ensure that additional obstacles to their removal are not created. Generic medications make up most of the medications on drug shortage lists, and over half cost less than one dollar per unit.[6] Further, given the vast use of generic drugs and the concern that manufacturers may cease production of certain generics given their low-profit potential, at a minimum, APhA asks the Department to ensure any actions they take do not leave Americans without access to these essential, low-cost medications. Regarding APIs and starting materials, imposing tariffs on them may stall or create delays in manufacturing medications, leading to patient access issues. As discussed below, APhA asks the Department to consider any downstream implications, including future drug shortages and closure of domestic manufacturing facilities, when placing tariffs on APIs and starting materials.

Another approach would be to ensure the market incentivizes a strong, quality supply chain. This approach would require a commitment from policymakers, regulatory bodies, and those purchasing medications to establish protocols and payment models that value quality, resilience, and reserves, especially for drugs vulnerable to shortages and associated with patient care services. With the proper incentives, including leveraging governmental contracts, consistent access to the medications Americans need can be realized. APhA supports the development of strategies that ensure the availability, quality, and safety of pharmaceutical products and mitigate supply chain issues that provide the reliable and consistent availability of these products.

Passing the costs associated with potential tariffs onto the patient may also increase both patient and state and federal governmental spending. Not only is there the potential for Medicare and Medicaid beneficiaries to spend more on their copays, but government spending to operate these programs may also rise. One article estimates that "[a] 20-percentage point increase in the effective tariff rate on drugs could theoretically translate to approximately a 2.4% increase in overall health insurance costs, depending on how broadly the tariffs are applied and how much

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https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/.

[6] *Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs*, Senate Committee on Finance (Jan. 25, 2025). Available at: https://www.finance.senate.gov/imo/media/doc/white_paper_preventing_drug_shortages.pdf.

of the added cost is passed through to payers."[7] These potential increases in drug costs may also deflate some of the savings the government or America's seniors expected to receive under the Medicare Drug Price Negotiation Program, as drug prices may increase following the implementation of tariffs on the pharmaceutical supply chain.[8]

Drug Shortages

Drug shortages negatively impact patient care. When a drug is in short supply, health care providers, including pharmacists, cannot give patients the medication they deem appropriate for treatment. As a result, patient behavior and outcomes change. When the patient's health care provider cannot acquire the medication in short supply, patients may skip doses or take the medication less than prescribed to ration doses out of fear that they will not be able to refill it.[9] If the patient is consistently unable to fill the medication, they may forgo taking it altogether.[10] In the long run, these behaviors, because of drug shortages, worsen health outcomes and exacerbate health care costs as the patient may now need to seek out more expensive treatments or surgeries at hospital emergency rooms, due to the inability to acquire or take their medication as prescribed. There is also the possibility that drug shortages lead to suboptimal care via medication selection. Health care providers aware of a drug shortage but still wanting to prescribe a similar medication may prescribe one that is not as clinically effective or more prone to adverse effects.[11]

Drug shortages also impact productivity and efficiency, as "[p]harmacists and nonpharmacist employees spend additional time procuring medications, identifying alternative therapies, and communicating with manufacturers about drug shortages."[12] Dealing with drug shortages has become so taxing that many health systems have hired pharmacists and pharmacy personnel solely to manage these issues.[13] Over twenty years ago, research estimated that the United

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[7] Katie Hayes, *The Medicare Paradox, Part 1: How Tariffs Could Undermine IRA Drug Pricing Reforms*, First Report Managed Care (Apr. 23, 2025). Available at: https://www.hmpgloballearningnetwork.com/site/frmc/blog/medicare-paradox-how-tariffs-could-undermine-ira-drug-pricing-reforms.

[8] *Id.*

[9] Mariana P. Socal & Joshua M. Sharfstein, *Drug Shortages – A Study in Complexity*, 7 JAMA Network Open (2024). Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2817213.

[10] *Id.*

[11] *Id.*

[12] Celeste R. Caulder, et al., *Impact of Drug Shortages on Health System Pharmacies in the Southeastern United States*, 50 Hospital Pharmacy 279, 280 (2015). Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4589883/#r9.

[13] *Id.*

States spent $99 million annually on acquisition costs alone due to drug shortages.[14] A more recent study estimates that hospitals spend $359 million annually to manage the implications of drug shortages.[15] These two studies highlight just a fraction of the additional costs of drug shortages on overall health care spending in the United States.

Accordingly, APhA reiterates the previous point that additional tariffs should not be imposed on drugs listed on drug shortage lists under this framework to mitigate barriers they may create in ensuring patients can timely access these medications. Placing tariffs on APIs and starting materials may contribute to decreased access to these medications when they cannot be obtained due to a shortage. In addition, compounders often rely on those outside the United States to supply them with the necessary components of medications to compound them, which would further limit a solution to address drug shortages and provide patient-specific medications "such as a patient who has an allergy to a certain dye and needs a medication to be made without it, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form."[16] Furthermore, APhA supports greater transparency in the pharmaceutical supply chain to prevent, mitigate, and resolve drug shortages more effectively. In conjunction with this greater visibility, APhA encourages appropriate agencies and bodies to establish a vulnerable medicines list, as recommended by the Task Force on Preventing and Mitigating Drug Shortages (Task Force),[17] that provides greater insight into medicines that are at high risk of becoming in short supply. This will allow for future improvements in the supply chain and reductions in the number of drugs on future drug shortage lists.

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[14] Amanda M. Baumer, et al., *National Survey of the Impact of Drug Shortages in Acute Care Hospitals*, 61 American Journal of Health-System Pharmacy 2015 (2004). Available at: https://academic.oup.com/ajhp/article-abstract/61/19/2015/5143798?redirectedFrom=fulltext.

[15] *New Vizient Survey Finds Drug Shortages Cost Hospitals Just Under $360M Annually in Labor Expenses*, Vizient (June 2019). Available at: https://www.vizientinc.com/newsroom/news-releases/2019/new-vizient-survey-finds-drug-shortages-cost-hospitals-just-under-360m-annually-in-labor-expenses.

[16] *Compounding and the FDA: Questions and Answers*, U.S. Food and Drug Administration (Nov. 11, 2024). Available at: https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[17] *The Drug Shortage Task Force*, United States Pharmacopeia. Available at: https://www.usp.org/supply-chain/drug-shortage-task-force.

Pharmacy Closures

Community pharmacies are closing at an alarming rate. Studies have shown that approximately one in three community pharmacies have closed since 2010.[18] Between December 19, 2024, and March 10, 2025, at least 326 pharmacies closed, 237 of which were independent pharmacies.[19] These closures lead to pharmacy deserts, leaving patients, often in rural or underserved communities, with limited access to their medications and the direct patient care services that pharmacists provide and patients depend on as a first line of care. These statistics highlight that pharmacies are already struggling to keep their doors open, as they operate with razor-thin to no profit margins on most medications due to harmful pharmacy benefit manager (PBM) practices.

The introduction of tariffs on pharmaceuticals and their ingredients will likely further strain pharmacy operations, as other more powerful players within the supply chain may seek to push these additional costs onto pharmacies. History shows that time after time, pharmacies end up getting the short end of the stick, and America's pharmacies are at their breaking point. Introducing these tariffs will further complicate the complexities of the pharmaceutical supply chain and pharmacy operations. Given the annual manner in which reimbursements are negotiated, the increased costs associated with tariffs were not considered under the current pharmacy contracts, potentially leading to pharmacies footing the bill for these additional costs due to reimbursement rates negotiated without these added costs in mind. As such, APhA urges the Department to implement a plan to protect pharmacies and ensure that any new tariffs will not jeopardize a patient's access to their local pharmacy.

Domestic Production

The President has stated that part of the goal of tariffs on pharmaceutical products is to encourage more domestic production of pharmaceuticals and their ingredients. APhA supports bolstering manufacturing capacity within the United States to prevent drug shortages and supply chain disruptions, ensuring Americans have access to the medications they need. However, onshoring pharmaceutical production is not an immediate solution, as this process will take significant time and financial investment over a number of years, well into the next President's term. It is estimated that onshoring a pharmaceutical manufacturing facility would

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[18] Jason Millman, *Nearly 1 in 3 Retail Pharmacies Have Closed Since 2010, Widening Health Disparities*, USC Leonard D. Schaeffer Institute for Public Policy & Government Service (Dec. 3, 2024). Available at: https://schaeffer.usc.edu/research/pharmacy-closures-united-states-health-affairs/.

[19] *326 Pharmacies Have Closed Since Elon Musk Tanked PBM Reform*, American Economic Liberties Project (Mar. 10, 2025). Available at: https://www.economicliberties.us/press-release/326-pharmacies-have-closed-since-elon-musk-tanked-pbm-reform/.

take at least three to five years, with costs expected to reach a billion dollars.[20] Currently, domestic manufacturers are still dependent on APIs and other starting materials from outside the United States, as only 12% of total API volume is made within the country's borders.[21] Accordingly, APhA asks the Department to ensure that any potential tariffs placed on APIs and starting materials, or the tariff framework overall, do not delay these necessary ingredients from getting to domestic sources. If these ingredients are delayed, production will lag, drug shortages will occur, and patients will go without their needed medications. Further, tariffs on APIs and starting materials will raise costs for domestic manufacturers, which will only be passed on through the supply chain. Any increases in the price of acquiring APIs and starting materials may strain the viability of businesses that manufacture pharmaceuticals in the United States, especially those manufacturing generic drugs with minuscule profit margins due to their low costs in the marketplace. As such, APhA encourages the Department to ensure that any potential tariffs placed on these vital materials do not result in the closure of these facilities, as ceasing their operations worsens access problems and lessens the United States' ability to manufacture pharmaceutical products domestically.

APhA appreciates the opportunity to provide the Department with additional insights into how implementing tariffs could impact pharmacists, pharmacies, and our patients and the prices they pay for their medications. APhA recommends that the Department take an approach to minimize the creation of new barriers and obstacles that potential tariffs may impose on keeping Americans healthy and trusted, local community pharmacies open. If you have any questions or would like to meet with APhA to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

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[20] Marta Wosińska, *Will Pharmaceutical Tariffs Achieve Their Goals?*, The Brookings Institution (Mar. 27, 2025). Available at: https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/.
[21] Vimala Raghavendran, et al., *Over Half of the Active Pharmaceutical Ingredients (API) for Prescription Medicines in the U.S. Come from India and the European Union*, United States Pharmacopeia (Apr. 17, 2025). Available at: https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european.