American College of Physicians
Leading Internal Medicine, Improving Lives

May 6, 2025

The Honorable Howard Lutnick
Secretary
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]

Dear Secretary Lutnick,

On behalf of the American College of Physicians (ACP), I am pleased to share our response to the Department of Commerce's ("Department") Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. Prescription drugs are an essential component of a physician's toolkit for preventing mortality, treating chronic disease, and making America healthy. However, unsustainable price increases and unprecedented levels of shortages threaten adherence to patients' treatment regimens. Population health is critical to national security. As such, ACP urges the Department to consider as part of its investigation the public health impacts of prescription drug trade policy and commit to prioritizing maximal access to essential treatments.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

While drug shortages have been an issue throughout the history of modern medicine, they have recently reached record highs. Data from December 2024 identified 271 active drug shortages, down slightly from the historic high of 323 drugs in shortage experienced at the end

of 2023.[1] On average, each drug shortage affects over half of a million people, particularly older Americans.[2] These shortages have tangible negative consequences on the practice of medicine for primary care physicians and their patients' health. Patients may have delayed, inadequate, or foregone treatments; experience adverse reactions to alternative treatments; require increased monitoring due to inadequate treatment regimens; and be exposed to medication errors as physicians and pharmacists select less utilized options.[3] Beyond patient morbidity and mortality, hospitals face immense resource strain when managing shortages and identifying alternative treatment regimens, including financial cost upwards of $600 million per year[4] and 8.6 million labor hours.[5]

In a globalized pharmaceutical market, the American health care system is vulnerable to disruptions in prescription drug supply created by trade conditions. The prescription drug supply chain is incredibly complex, involving multiple steps and actors. Manufacturers of finished dosage form drugs are reliant upon inputs of active pharmaceutical ingredients (APIs), other bulk chemicals (i.e. binders, colorants), and packaging and other components[6] from numerous different sources located throughout the world. APIs may require between 2-5 starting materials, 1-3 catalysts, 3-10 solvents, and potentially enzymes, which may be combined with 3-10 excipients to produce the finished dosage form drug.[7] The origins of many drug ingredients are heavily concentrated, with India being the world's largest producer of generic drugs and China providing more than 70% of APIs for those drugs.[8] Most APIs for both brand name and generic drugs are produced outside of the U.S., with 32% produced in India,

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[1] National drug shortages: January 2001 - December 2024. American Society of Health-System Pharmacists; 2025. Available from: https://www.ashp.org/-/media/assets/drug-shortages/docs/2024/2024-Drug-Shortages-Survey.pdf

[2] ASPE report to Congress: impact of drug shortages on consumer costs. Office of the Assistant Secretary for Planning and Evaluation; 2023. Available from: http://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs

[3] Aronson JK, Heneghan C, Ferner RE. Drug shortages. Part 1. Definitions and harms. Br J Clin Pharmacol. 2023 Oct;89(10):2950-2956. doi: 10.1111/bcp.15842. Epub 2023 Aug 6. PMID: 37455356.

[4] Policy considerations to prevent drug shortages and mitigate supply chain vulnerabilities in the United States. Office of the Assistant Secretary for Planning and Evaluation; 2024. Available from: http://aspe.hhs.gov/reports/preventing-shortages-supply-chain-vulnerabilities

[5] Drug shortages and labor costs: Measuring the hidden costs of drug shortages on U.S. hospitals. Vizient; 2019. Available from: https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129

[6] Mulcahy AW, Kareddy V. Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships. Rand Health Q. 2022 Jun 30;9(3):7. PMID: 35837523; PMCID: PMC9242571.

[7] Wosińska M. Drug shortages: A guide to policy solutions. Brookings; 2024. Available from: https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/

[8] Årdal C, Baraldi E, Beyer P, Lacotte Y, Larsson DJ, Ploy MC, Røttingen JA, Smith I. Supply chain transparency and the availability of essential medicines. Bull World Health Organ. 2021 Apr 1;99(4):319-320. doi: 10.2471/BLT.20.267724. Epub 2021 Jan 21. PMID: 33953450; PMCID: PMC8085627.

20% in the European Union, 8% in China, 15% in undetermined countries, and 13% in other countries.[9]

Increasing reliance upon one (or few) source of an input reflects fragile supply chains. In such an environment, production disruptions caused by quality issues, business decisions, natural disasters, and increasingly fraught geopolitics create a production chokepoint and enhance the likelihood of shortages. Shortages can arise from shocks in any step of the supply chain, triggered by the availability of raw materials (like APIs, chemicals, and packaging), manufacturing facilities (including diversification of location), distribution, cost and negotiation of prices, regulation, tariffs, and trade barriers and restrictions. These shocks can be enhanced by supply chain factors, such as the co-location of production facilities and market concentration for a specific drug, which can produce shortages depending on the presence and ability of buffer measures to alter the impacts of the shock.[10] Hence, ACP advocates for a comprehensive, coordinated, and government-wide policy strategy to bolster drug supply chains. Such a strategy may include, but is not limited to, policies that promote geographic diversification of production, deter single-site manufacturing, increase redundancy within the supply chain, maintain a minimum number of manufacturers, incentivize the production of low-margin drugs, and invest in advanced manufacturing technology.

ACP is especially concerned that generic drugs would be particularly susceptible to a tariff-induced shortage. Generic drugs function as safe and affordable treatment options for millions of Americans and play a critical role in reigning in national health care expenditures. Disruptions to generic drug supplies would reverberate throughout the country, as an estimated 90% of all prescriptions in the U.S. are for generic drugs.[11] These drugs are generally low-cost and typically have very slim profit margins. An analysis of FDA drug shortage data found that 84% of all drugs in shortage were generic, while an estimated 56% of all drugs in shortage had a list price of less than $1 per unit.[12] The lack of profit motive can lead to market consolidation that produces the conditions associated with fragile supply chains and shortages. Research suggests roughly 80% of generic drugs are finished abroad, with even more utilizing APIs sourced from abroad.[13] If

[9] Raghavendran V, Drucker P, Duman E. Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union. U.S. Pharmacopeia; 2025. Available from: https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european

[10] Wosińska M. Drug shortages: A guide to policy solutions. Brookings; 2024. Available from: https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/

[11] 2024 U.S. Generic & Biosimilar Medicines Savings Report. Association for Accessible Medicines; 2024. Available from: https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf

[12] Aitken M, Kleinrock M, Pritchett J. Drug shortages in the U.S. 2023: A closer look at volume and price dynamics. IQVIA; 2023. Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023

[13] Van Beusekom M. Report details where top 100 brand-name Rx drugs are made. University of Minnesota Center for Infectious Disease Research & Policy; 2022. Available from: https://www.cidrap.umn.edu/report-details-where-top-100-brand-name-rx-drugs-are-made

generic drug manufacturers were to face increased costs due to tariffs or other trade restrictions, they would likely be less able to absorb the increase, especially compared to brand name drugs. As a result, generic drug manufacturers may have to cease production and exit the market if they are no longer economically viable, causing shortages and impairing patient access.

Beyond shortages, ACP is also concerned about the risk for increased prescription drug prices that may be caused by trade restrictions and tariffs. Given competition and the lack of patent protections and market exclusivity, generic drugs often have a sale price that is close to the import price, leaving slim profit margins.[14] This means that any external factors that increases the cost of imports, such as the imposition of a tariff, would particularly impact generic drugs and require retailers to increase the sales price. Patients who pay for drugs directly, or who have prescription drug coverage with cost-sharing, could see higher out-of-pocket spending. In circumstances where an impacted drug may be in shortage, patients may incur higher cost-sharing expenses in switching to a more expensive available, alternative treatment option. Overall increased drug expenses throughout the health care system could also lead to increases in insurance premiums in future years. It is established that a substantial proportion of the American public engages in cost-related medication nonadherence, especially those who are of older age and/or have chronic conditions.[15,16,17] Failing to adhere to prescription drug treatment regimens can result in increased morbidity and mortality, poorer health outcomes, increased national health care spending, and lost productivity, the sum of which represents a stark threat to national security.

With an increasingly globalized pharmaceutical supply chain, trade policy has a significant role in determining the quantity, quality, and variety of treatments patients have access to. Trade conditions imposed by governments, while promoting one important objective, may have undesirable secondary and tertiary effects. As the Commerce Department conducts its investigation into the pharmaceutical market, ACP urges the Department to take into consideration and prioritize the goal of maintaining and expanding patient access to critical treatments in any action it takes. The College highlights the potential for unintended negative

[14] Lynch E. Who's gonna pay? The impact of tariffs on pharmaceutical products. The Petrie-Flom Center; 2025. Available from: https://petrieflom.law.harvard.edu/2025/04/14/whos-gonna-pay-the-impact-of-tariffs-on-pharmaceutical-products/

[15] Dusetzina SB, Besaw RJ, Whitmore CC, Mattingly TJ 2nd, Sinaiko AD, Keating NL, Everson J. Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022. JAMA Netw Open. 2023 May 1;6(5):e2314211. doi: 10.1001/jamanetworkopen.2023.14211. PMID: 37200029; PMCID: PMC10196872.

[16] Nekui F, Galbraith AA, Briesacher BA, Zhang F, Soumerai SB, Ross-Degnan D, Gurwitz JH, Madden JM. Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. Med Care. 2021 Jan;59(1):13-21. doi: 10.1097/MLR.0000000000001458. PMID: 33298705; PMCID: PMC7735208.

[17] Van Alsten SC, Harris JK. Cost-Related Nonadherence and Mortality in Patients With Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000-2014. Prev Chronic Dis. 2020 Dec 3;17:E151. doi: 10.5888/pcd17.200244. PMID: 33274701; PMCID: PMC7735485.

consequences that may arise from import restrictions and tariffs that target medications produced abroad and urges the Administration to balance the need for affordable and accessible lifesaving and life-enhancing drugs alongside the need for robust, reliable, and resilient domestic supply chains and inventories. Please contact Josh Serchen, Associate, Health Policy at jserchen@acponline.org if you have any questions or need any additional information.

Sincerely,

Jason M. Goldman, MD, FACP
President