NATIONAL HEALTH COUNCIL

May 6, 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: Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket No. 250414-0065, XRIN 0694-XC120]

Dear Director Astle:

The National Health Council (NHC) appreciates the opportunity to provide comments on the Bureau of Industry and Security's Section 232 investigation into the national security implications of imports of pharmaceuticals and pharmaceutical ingredients.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, and sustainable health care. The NHC represents the people most affected by changes made to the pharmaceutical supply chain—patients. Made up of 180 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

The NHC understands the real-world impact trade decisions can have on the availability, affordability, and continuity of treatment. Over a century of experience bringing together patient organizations, caregivers, providers, and innovator informs our ability to advocate for policies that anticipate and address the needs of patients across the American health care system. Patients—particularly those with chronic, complex, or rare conditions—will bear the brunt of any disruption caused by pharmaceutical tariffs. For people living with these conditions, access to the right medicine at the right time is not optional—it is essential to survival and quality of life. Tariffs that increase costs or delay treatment put patients at serious risk, leading to worsened health outcomes, greater financial strain, and unnecessary suffering.[1] Policymakers must weigh the question: "How will this decision affect the people who need to access these treatments

[1] Sarah C. Van Alsten and Jenine K. Harris, "Cost-Related Nonadherence and Mortality in Patients With Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014," *Preventing Chronic Disease* 17 (2020): 200244, https://doi.org/10.5888/pcd17.200244.

every day?" Drawing on this critical perspective, we urge the Department to reject the use of import tariffs as a blunt instrument and instead pursue strategic, patient-centered approaches to advance national security without sacrificing patient care or biomedical progress.

Tariffs on medicines and pharmaceutical ingredients would be uniquely disruptive. Unlike many other industrial goods, medicines are not interchangeable—prescribed therapies are selected based on individualized clinical needs, not cost or supplier origin. Imposing trade barriers on these products risks introducing unpredictable delays, shortages, and pricing volatility into an already complex supply chain. These disruptions could cascade into postponed clinical trials, deferred FDA approvals, diverted research and development (R&D) budgets, and slower access to new treatments for patients. In areas such as rare diseases, oncology, or autoimmune conditions, where treatment options are already limited, tariffs could have life-threatening implications for patients who cannot wait for markets to adjust.[2]

From a national security perspective, meaningful resilience of the health care system cannot be achieved without addressing vulnerabilities in the pharmaceutical supply chain. These solutions will require long-term investment, international cooperation, and careful coordination—not policies that undermine patient access or deter domestic innovation. The absence of pharmaceutical tariffs in past trade policy reflects a bipartisan understanding that these products occupy a uniquely sensitive and high-stakes position within the US economy and public health infrastructure.

As the Department continues this investigation, we urge a strategic, measured response grounded in patient impact, health system resilience, and continued US leadership in biomedical research.

Impact of Tariffs on Patient Access to Medicines

Medicines are not discretionary consumer goods; they are essential components of clinical care, prescribed to treat serious, often life-threatening conditions.[3] Unlike commodities where alternative options may be substituted based on price or availability, prescription medicines are selected based on clinical efficacy, safety profiles, and individual patient needs—rarely is substitution viable in health care. Patients do not choose their illnesses and for many conditions— particularly serious, chronic, or rare diseases—the available treatment options are few, highly specialized, and not readily interchangeable. The imposition of tariffs on medicines would introduce new barriers into an already complex and fragile health care delivery system. It would increase costs across the supply chain, delay or disrupt access to medically necessary therapies, and ultimately reduce the availability of essential treatments, resulting in immediate and

[2] Hematology Oncology Pharmacy Association. "National Survey on the Effect of Oncology Drug Shortages in Clinical Practice: A Hematology Oncology Pharmacy Association Survey." *Journal of Oncology Practice* 18, no. 2 (2022): e314–e322. https://ascopubs.org/doi/pdf/10.1200/OP.21.00883.

[3] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains* (Washington, DC: The National Academies Press, 2022), 83–88, https://doi.org/10.17226/26420.

profound consequences for patient health outcomes, quality of life, and overall system sustainability.[4,5]

Millions of Americans rely on medicines that are manufactured outside the United States, particularly from close and longstanding allies such as Ireland, Switzerland, and the United Kingdom—countries whose regulatory frameworks for pharmaceutical manufacturing mirror the high standards enforced domestically.[6,7,8] These imports include critical biologics, advanced therapies, and specialty medicines that often represent the only clinically appropriate option for patients with serious or rare conditions.[9] Medicines manufactured abroad are often integral components of complex, multi-modal treatment regimens carefully calibrated by providers to address the individual and evolving needs of patients; substitution, when even theoretically possible, carries significant clinical risks—including reduced therapeutic efficacy, increased side effects, and potential disease progression.[10] Tariffs that disrupt the availability of these treatments or increase their cost to providers, insurers, and ultimately patients would endanger treatment continuity, compromise disease management strategies, and heighten the risk of adverse health outcomes.[11] Patients managing chronic conditions or complex treatment regimens may face missed doses, delayed refills, or disruptions in therapy—each of which can have cascading and potentially irreversible negative effects on their health.[12] The effects would be particularly acute for individuals with cancer, autoimmune diseases, rare genetic disorders, and other serious health conditions, for whom delays in initiating or maintaining appropriate therapy can lead to irreversible harm.[13]

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[4] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, "Essential Medicines Fact Sheet," accessed April 29, 2025, https://aspr.hhs.gov/ibx/Pages/EssentialMedicines-2022.aspx.

[5] Kyle Munz, "Trump's New Tariffs Could Drive Up Health Care Costs, Experts Warn," *American Journal of Managed Care*, April 8, 2025, https://www.ajmc.com/view/trumps-new-tariffs-could-drive-up-health-care-costs-experts-warn.

[6] Avalere Health, *Majority of API in U.S.-Consumed Medicines Produced in the U.S.*, April 2023, https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us.

[7] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 83–88.

[8] Ernst & Young, *Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry* (Washington, DC: Pharmaceutical Research and Manufacturers of America, April 22, 2025).

[9] U.S. Food and Drug Administration, "Importing Biologics and CBER Regulated Products," accessed April 29, 2025, https://www.fda.gov/industry/importing-fda-regulated-products/importing-biologics-and-cber-regulated-products.

[10] Avalere Health, *Majority of API in U.S.-Consumed Medicines Produced in the U.S.*

[11] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 65–67.

[12] Timothy P. Hanna et al., "Mortality Due to Cancer Treatment Delay: Systematic Review and Meta-Analysis," *BMJ* 371 (2020): m4087, https://doi.org/10.1136/bmj.m4087.

[13] U.S. Food and Drug Administration, "Importing Biologics and CBER Regulated Products."

In addition to the direct clinical consequences, tariffs on medicines would deepen existing health imbalances across the United States.[14,15] Vulnerable populations—including individuals with lower incomes, residents of rural and medically underserved areas, and those managing multiple chronic conditions—already face disproportionate barriers to accessing necessary medical care.[16] These groups are least able to absorb the financial burden of higher prescription drug costs resulting from tariffs and are most at risk of nonadherence, delayed treatment initiation, or complete foregone care.[17] Moreover, the ripple effects of increased medicine costs would not be confined to individuals paying out-of-pocket; public programs such as Medicaid and Medicare, as well as private health plans, would face increased expenditure pressures, leading to broader system-level consequences including increased premiums, higher cost-sharing, restricted formularies, and further access limitations.[18]

From the patient perspective, these compounded clinical, financial, and logistical burdens could mean the difference between continued disease management and devastating setbacks in health. At a time when policymakers across the political spectrum are working to advance policies designed to improve the affordability, accessibility, and adequacy of health care, imposing tariffs on medicines would run counter to these objectives, erecting new barriers at the very moment when efforts to remove them are gaining critical momentum. It is essential that any policies emerging from this investigation carefully weigh not only theoretical trade or industrial policy benefits but also the very real and immediate impacts on patient care, health equity, and the overall functioning of the US health care system.

Impact of Tariffs on Domestic Pharmaceutical Manufacturing

The United States has long maintained global leadership in biopharmaceutical innovation and manufacturing—a position that reflects both the strength of its research ecosystem and regulatory infrastructure and sustained investment in domestic production capacity. Nearly two-thirds of all medicines consumed in the United States by value are manufactured domestically, across a network of more than 1,500 facilities

[14] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 65–67.

[15] Bharath Krishnamurthy and Megha Parikh, "Drug Prices and Shortages Jeopardize Patient Access to Quality Hospital Care," *AHA News*, May 22, 2024, https://www.aha.org/news/blog/2024-05-22-drug-prices-and-shortages-jeopardize-patient-access-quality-hospital-care.

[16] Rural Health Information Hub, "Healthcare Access in Rural Communities Overview," accessed April 29, 2025, https://www.ruralhealthinfo.org/topics/healthcare-access.

[17] Laryssa Mykyta and Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NCHS Data Brief no. 470 (Hyattsville, MD: National Center for Health Statistics, June 2, 2023), https://stacks.cdc.gov/view/cdc/127680.

[18] Kaiser Family Foundation, "The Effects of Premiums and Cost Sharing on Low-Income Populations," accessed April 29, 2025, https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.

operating under rigorous quality standards.[19] This manufacturing base also serves as a critical pillar of national health security, supporting approximately 1.7 million American jobs across a wide range of scientific, technical, and operational disciplines, and contributing substantially to the nation's R&D enterprise, economic output, and global competitiveness.[20,21]

Despite this robust domestic capacity, the imposition of tariffs on imported medicines and production inputs would impose severe financial burdens on US manufacturers.[22] Recent analyses estimate that a 25% tariff on imported pharmaceutical products and critical inputs would increase costs by over $50 billion annually—a figure equivalent to roughly 13% of total US pharmaceutical sales.[23,24] Tariffs on production inputs alone would add $15.1 billion in annual costs, disproportionately affecting domestic facilities that depend on the timely and affordable importation of active pharmaceutical ingredients (APIs), biological materials, excipients, and other specialized inputs essential to manufacturing operations.[25]

Such increased input costs would not only impair the competitiveness of US-based facilities in the global marketplace but also strain margins to a degree that risks reducing investment in new capacity, research and development, and workforce expansion. Rather than promoting reshoring or enhancing domestic resilience, tariffs on pharmaceutical products and inputs would have the opposite effect, diverting critical capital away from planned expansions and modernization efforts precisely when such investments are most needed. Building new pharmaceutical manufacturing facilities is inherently time- and capital-intensive, often requiring expenditures exceeding $2 billion per facility and timeframes of 5 to 10 years to achieve full regulatory licensure and operational readiness.[26,27,28] Imposing new, unpredictable financial burdens during this

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[19] Ernst & Young, *Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry*, 1.

[20] Ernst & Young, *Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry*, 10.

[21] National Association of Manufacturers, *Creating Cures, Saving Lives: The Pharmaceutical Manufacturing Industry's Impact*, report by Bradley Ward (October 2023).

[22] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 83–85.

[23] Ernst & Young, *Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry*, 1.

[24] Brookings Institution. "Will Pharmaceutical Tariffs Achieve Their Goals?" Last modified 2025. https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/.

[25] Number Analytics, "Tariff Effects on Biologics: Trade and Pricing Dynamics," accessed April 29, 2025, https://www.numberanalytics.com/blog/tariff-effects-biologics-trade-pricing-dynamics.

[26] U.S. Government Accountability Office, *Supply Chain Resilience: Agencies Are Taking Steps to Expand Diplomatic Engagement and Coordinate with Allies and Partners*, GAO-23-105534 (Washington, DC: February 2023), https://www.gao.gov/assets/gao-23-105534.pdf.

[27] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 83–85.

process would delay and potentially derail domestic projects already underway, deter new investments, and weaken the United States' ability to expand its manufacturing capacity at a pace necessary to meet future public health needs.

In addition, heightened production costs would place downward pressure on export activity—a key contributor to the sector's economic vitality. In 2023 alone, the US biopharmaceutical industry exported approximately $101 billion worth of pharmaceutical goods, demonstrating its critical role in sustaining American jobs in high-value, research-intensive sectors.[29,30] Increased input costs arising from tariffs would erode the price competitiveness of US exports, diminish market share abroad, and expose US producers to retaliatory trade measures that would further harm domestic employment and investment.[31] Ultimately, tariffs would threaten not only the immediate operational viability of domestic pharmaceutical manufacturing but also the long-term strategic interests of the United States in maintaining its leadership position in global health innovation and production.[32]

Recommendations to Ensure Pharmaceutical Supply Chain Security

The United States benefits from a robust and diversified pharmaceutical supply chain that is deeply integrated with longstanding allies, including the European Union, Japan, Switzerland, and the United Kingdom.[33] These partnerships provide American patients with access to a wide range of critical medicines manufactured to rigorous quality standards—medicines that complement, rather than compete with, domestic production.[34] Tariffs on pharmaceutical imports from these allies would not meaningfully reduce dependence on adversarial nations for certain essential generic medicines; instead, such tariffs would raise production costs, destabilize established supply chains,

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[28] Lisa M. Ellram, Wendy L. Tate, and Kenneth J. Petersen, "Offshoring and Reshoring: An Update on the Manufacturing Location Decision," *Journal of Supply Chain Management* 49, no. 2 (2013): 14–22, https://doi.org/10.1111/jscm.12023.

[29] Trading Economics, "United States Exports of Pharmaceutical Products," accessed May 5, 2025, https://tradingeconomics.com/united-states/exports/pharmaceutical-products.

[30] U.S. Bureau of Economic Analysis, "International Detailed Trade Data – Pharmaceutical Products," accessed April 18, 2024.

[31] Tax Foundation, "Trump Tariffs: The Economic Impact of the Trump Trade War," accessed April 29, 2025, https://taxfoundation.org/research/all/federal/trump-tariffs-trade-war/.

[32] BioWorld, "As Tariffs Threaten US Imports of APIs, Companies Reshore Manufacturing," accessed April 29, 2025, https://www.bioworld.com/articles/718195-as-tariffs-threaten-us-imports-of-apis-companies-reshore-manufacturing.

[33] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 83–88.

[34] U.S. Food and Drug Administration, "Safety, Efficacy, and Quality Remain Top Priorities as We Continue Our Work to Expand Access to Cost-Saving Generic Drugs," accessed April 29, 2025, https://www.fda.gov/news-events/fda-voices/safety-efficacy-and-quality-remain-top-priorities-we-continue-our-work-expand-access-cost-saving.

and threaten the timely delivery of treatments on which millions of patients rely.[35,36] The resilience of this diversified pharmaceutical supply chain was demonstrated during the COVID-19 pandemic and other natural disasters, when longstanding international partnerships and advanced logistics systems allowed for the continued delivery of lifesaving treatments under extraordinary circumstances.[37,38,39] Rather than introducing new vulnerabilities through tariff-based interventions, federal policy should build upon these proven strengths — safeguarding public health by maintaining a stable, reliable, and patient-centered pharmaceutical supply chain.

Policies designed to strengthen the security and resilience of the pharmaceutical supply chain must prioritize the needs of patients—ensuring the uninterrupted availability of safe, effective, and affordable treatments for all individuals, particularly those with serious, chronic, and rare conditions. Rather than imposing tariffs that would increase costs, disrupt access, and destabilize supply chains, the Administration should pursue strategies that enhance domestic manufacturing capacity through supportive measures, while preserving strong international partnerships that have long contributed to patient access and health system stability.

Enhancing pharmaceutical supply chain resilience must be achieved through evidence-based domestic and trade policies that foster investment and innovation without harming patients.[40] Targeted incentives—such as research and development support, investment tax credits for advanced manufacturing facilities, and streamlined regulatory pathways—can promote the growth of domestic production in a manner that complements, rather than undermines, existing supply chains.[41] Similarly, sectoral agreements with trusted trading partners can strengthen collective preparedness and resilience by ensuring open channels for the movement of critical medicines and active APIs, while mitigating risks associated with geopolitical instability. Within this framework, any action resulting from the Section 232 investigation must be narrowly tailored to address discrete and demonstrable national security concerns—specifically,

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[35] Avalere Health, *Drug Shortages: Causes and Solutions to Safeguard America's Pharmaceutical Supply Chain*, January 2024, https://avalere.com/wp-content/uploads/2024/01/Drug-Shortages-Whitepaper-1.25.2024.pdf.

[36] Olivia Webb Kosloff, "A National Defense Strategy for Generic Drugs," *American Affairs* 8, no. 2 (Summer 2024).

[37] U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, *Public Health Supply Chain and Industrial Base One-Year Report* (Washington, DC: February 2022), https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.

[38] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 237.

[39] National Academies of Sciences, Engineering, and Medicine, *Strengthening Post-Hurricane Supply Chain Resilience: Observations from Hurricanes Harvey, Irma, and Maria* (Washington, DC: The National Academies Press, 2020).

[40] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 65–67.

[41] Internal Revenue Service, "Advanced Manufacturing Investment Credit," accessed April 29, 2025, https://www.irs.gov/credits-deductions/advanced-manufacturing-investment-credit.

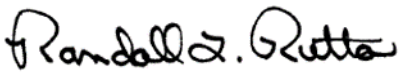
dependencies on adversarial nations for essential generic medicines critical to public health and national defense—rather than tariffs on innovative medicines and inputs sourced from allied countries.[42] A patient-centered approach, rooted in evidence and focused on genuine vulnerabilities, is essential to achieving the dual goals of enhancing national security and protecting the health and well-being of the American people.

Conclusion

The NHC strongly urges the Department of Commerce to avoid recommending tariffs on pharmaceutical imports and inputs. Such measures would compromise patient access to life-saving medicines, increase costs throughout the health care system, disrupt resilient supply chains, and hinder ongoing efforts to expand domestic manufacturing. In addition to limiting care access and affordability, these issues will negatively impact health care workers and potentially risk quality of care. Providers who do not have the treatments, devices, and equipment they need, such as diagnostic tools, infection control supplies, and more, may be unable to provide the best care possible. We encourage the Department to adopt a measured, patient-centered approach that prioritizes specific, demonstrated threats and promotes investment through constructive and collaborative policy tools.

We appreciate the opportunity to provide input on this important issue and welcome further dialogue to ensure that Americans retain timely access to safe, effective, and affordable medicines without unintended barriers that could compromise patient health. Please feel free to Kimberly Beer, Senior Vice President of Policy and External Affairs, at kbeer@nhcouncil.org or Shion Chang, Senior Director of Policy and Regulatory Affairs, at schang@nhcouncil.org for additional dialogue.

Sincerely,



Randall L. Rutta
Chief Executive Officer

[42] National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's Medical Product Supply Chains*, 65–67.