HEALTHCARE
LEADERSHIP COUNCIL

May 7, 2025

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

RE: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Deputy Assistant Secretary Longnecker,

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit comments in response to the U.S. Department of Commerce's Notice of Request for Public Comment on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.[1] HLC shares the Administration's commitment to safeguarding national security and ensuring the resilience of critical healthcare infrastructure.

HLC is an association of CEOs and C-suite executives from all sectors of healthcare working to shape the future of the U.S. healthcare system. As the exclusive forum for the nation's healthcare leaders, HLC convenes hospitals, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, distributors, and other healthcare organizations to lead on cross-sector issues and advocate for high-impact policy solutions. Our diverse membership provides a unique perspective on how policies impacting the pharmaceutical supply chain affect the entire healthcare ecosystem. HLC strongly supports policies that promote a resilient, secure, and efficient pharmaceutical supply chain, which is critical to patient access, healthcare innovation, and public health.

Overview

The Healthcare Leadership Council also seeks to elevate the broader implications of this investigation, particularly with respect to patient access, innovation, and healthcare delivery. As you assess the national security implications of pharmaceutical imports, we urge you to consider the far-reaching effects on healthcare providers and patients, as well as the potential for unintended consequences on the pharmaceutical industry.

Tariffs and non-tariff barriers would critically harm patients and are not necessary to spur domestic production. Not only does our healthcare system depend on a globally integrated supply chain to create and access potentially life-saving treatments for patients, but imposing tariffs or other non-tariff barriers would further threaten patient access by increasing costs. Companies are expanding

[1] Bureau of Industry and Security, Department of Commerce (2025, April 16). Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

domestic manufacturing and will continue to do so, despite workforce challenges compounded by existing skill gaps.

Instead, we urge the Administration to consider other solutions and policy levers to strengthen our country's security. To bolster national security, we urge the Administration to consider meaningful solutions such as: expanding domestic production through long-term procurement contracts, tax incentives, and regulatory streamlining; supporting workforce development; encourage sourcing diversification; improving transparency and coordination across agencies; modernizing stockpiling and emergency preparedness, as well as proactively engaging stakeholders prior to instituting any import tariffs resulting from the investigation.

U.S. Healthcare Depends on a Globally Integrated Pharmaceutical Supply Chain and a Strong U.S. Manufacturing Base

The majority of finished pharmaceuticals consumed in the U.S. are manufactured domestically, with only about one-third imported.[2] This U.S. production is part of a globalized pharmaceutical supply chain, with both finished products and critical inputs like active pharmaceutical ingredients (APIs) and key starting materials (KSMs) sourced from a range of allied international and U.S. partners. This structure supports a steady, cost-effective supply of medicines and provides the flexibility necessary to respond to public health emergencies and sudden demand surges and impacts to existing supply chains. According to the FDA, approximately 72% of the manufacturing facilities producing APIs for the U.S. market are located outside the United States.[3] In 2024, 88% of all APIs are sourced outside the U.S., including 85% of brand API and 88% generics.[4] This global integration is not a weakness; it is a strength that enhances supply chain resilience, lowers costs for patients, and enables access to a broad portfolio of medications and therapies. U.S. manufacturing for both medicines and APIs is also growing.

However, imposing new trade restrictions or import barriers could unintentionally create shortages, delay treatment, and raise prices for both providers and patients. Because this investigation covers both finished pharmaceuticals and their inputs, such policies risk disrupting the affordability, availability, and timely production of essential medicines for American patients.

Tariffs Threaten Patient Access, Provider Stability, and Domestic Manufacturing

Imposing tariffs or non-tariff barriers on pharmaceutical imports risks harming U.S. patients by increasing the cost of essential medications and disrupting access to treatment. These added costs would further financially strain providers and hospital systems, many of which are already navigating workforce shortages, budget constraints and post-pandemic recovery pressures. Over time, such compounded burdens could erode the quality and timeliness of care creating ripple effects across the healthcare system.

Additionally, rather than strengthening national security, such tariffs could disrupt investments and stall momentum in U.S. pharmaceutical manufacturing capacity. This segment of the healthcare industry is already investing significantly to increase domestic production; however, tariffs introduce

---

[2] Why the Trump pharma import inquiry is pivotal | EY - US

[3] U.S. Food and Drug Administration. (2019, October 30). *Safeguarding pharmaceutical supply chains in a global economy* [Congressional testimony]. https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019

[4] https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european

additional uncertainty and costs, ultimately stifling growth and resilience in domestic manufacturing. Moreover, tariffs would divert resources from the R&D that drives America's leadership in developing new medicines. This would deny patients new treatments and cures.

Business Is Significantly Expanding Its U.S. Manufacturing Footprint

HLC member companies are making substantial investments to expand manufacturing capabilities within the United States. These investments reflect a commitment to strengthening domestic production and ensuring a reliable supply of essential medicines and helps advance the Administration's efforts to demonstrate America's industrial prowess and international leadership. Notable examples include:

- **Johnson & Johnson:** Announced a $55 billion investment over the next four years to bolster U.S. manufacturing and R&D, including four new advanced facilities – starting with a $2 billion biologics plant in North Carolina focused on cancer and neurological treatments.
- **Novartis:** Committed $23 billion to enhance its U.S. manufacturing footprint over the next five years, including the construction of six new factories and the expansion of three existing facilities.
- **AstraZeneca:** Invested $3.5 billion to expand its U.S. R&D and manufacturing footprint, including a next-generation biologics manufacturing facility in Maryland and specialty manufacturing operations in Texas.
- **Merck:** Invested $1 billion to build its first U.S. facility for producing Keytruda, its top-selling cancer drug, in Wilmington, Delaware, creating over 500 jobs.

These investments reflect a proactive approach to enhancing domestic manufacturing capabilities. However, establishing such infrastructure is a complex and time-consuming and resource intensive process, often requiring several years to complete. Even with the recent Executive Order from the White House intended to streamline and support U.S. pharmaceutical manufacturing, policies that impose sudden trade barriers or tariffs could disrupt ongoing efforts and undermine the progress made toward strengthening domestic production.[5]

Addressing the Workforce Gap to Support Manufacturing Expansion

A key challenge in increasing domestic pharmaceutical manufacturing capacity is the significant workforce gap across U.S. manufacturing sectors. As of March 2025, there were approximately 449,000 job openings in the manufacturing industry.[6] Projections indicate that up to 1.9 million manufacturing jobs could remain unfilled by 2033 unless the skills gap is addressed.[7] This labor shortage poses a substantial constraint on efforts to expand domestic production, including within the pharmaceutical sector.

Solutions to Strengthen the Pharmaceutical Supply Chain and Bolster National Security

HLC supports a proactive approach to strengthening the pharmaceutical supply chain—one that avoids broad trade measures like tariffs in favor of more targeted, strategic actions. In this vein, we urge policymakers to:

---

[5] Regulatory Relief to Promote Domestic Production of Critical Medicines – The White House
[6] Job Openings and Labor Turnover - March 2025 U.S Bureau of Labor Statistics
[7] ERI_8749837_DigitalSkills_POV_FINAL_040224

- **Convene Multi-sector Industry Dialogue**
  The Department of Commerce's Bureau of Industry and Security should convene a multi-sector industry dialogue given the complexities of the pharmaceutical life cycle before any action is taken. This will allow the Administration to better understand private sector concerns, clarify sector-specific impacts and develop targeted responses that address national security-specific concerns.
- **Expand Domestic Manufacturing Capacity Through Strategic Incentives**
  The innovative biopharmaceutical industry is already investing heavily in U.S.-based manufacturing infrastructure. However, scaling these capabilities takes time. Federal policy should support—not penalize—this momentum through public-private partnerships, long-term procurement contracts, tax incentives, and regulatory streamlining as the recent White House Executive Order recently announced and which will take time to implement. For example, provisions in the Tax Cuts and Jobs Act of 2017 enabled companies to reinvest in domestic operations and helped support resilience during the COVID-19 pandemic. Building on those types of strategic incentives is essential to expand sustainable manufacturing capacity and strengthen the pharmaceutical supply chain.
- **Support Workforce Development to Enable Manufacturing Expansion**
  With nearly 500,000 manufacturing jobs currently unfilled—and a projected gap of 1.9 million jobs by 2033—closing the skills gap is critical to realizing domestic manufacturing goals. HLC recommends federal investment in foundational STEM education (K–12), digital workforce development, and targeted training aligned with pharmaceutical production needs.
- **Encourage Sourcing Diversification Over Localization**
  A truly resilient supply chain is a diversified one. Policies should aim to mitigate risk through geographic balance in sourcing among allied trade partners, rather than creating new vulnerabilities through over-concentration—whether foreign or domestic.
- **Improve Transparency and Coordination Across Agencies**
  Federal coordination, including real-time supply chain monitoring and inter-agency data sharing, is essential for identifying early signs of disruption and deploying effective mitigation strategies.
- **Modernize Stockpiling and Emergency Preparedness**
  Stockpiling strategies must reflect real-world demand, shelf-life limitations, and the logistical realities of production and distribution. Partnerships with private-sector manufacturers and distributors can enhance the relevance and responsiveness of federal reserves.
- **Engage Industry Stakeholders Proactively**
  The private sector has deep expertise in managing complex supply chains and anticipating demand. Ongoing engagement with industry stakeholders will ensure that any federal action is informed, targeted, and aligned with both U.S. security concerns and patient needs.

Conclusion: Trade Policy Must Protect Innovation and Affordability

The U.S. biopharmaceutical industry leads the world in innovation, investing more than $100 billion annually in research and development. This innovation ecosystem is sustained by both domestic ingenuity and global collaboration.

Actions that disrupt international supply chains risks undermining this innovation pipeline and increasing costs, ultimately impacting U.S. patients who rely on timely access to life-saving medications. We appreciate the importance of national security concerns regarding pharmaceutical

imports, and we urge the Department to ensure that any proposed action in response to this investigation is narrowly tailored, supported by a robust risk-benefit analysis, and informed by private sector expertise.

Thank you for your attention to this critical issue. HLC is committed to continuing our partnership with policymakers to ensure the resilience of the U.S. healthcare system. If you have any questions, please do not hesitate to contact me at kmahoney@hlc.org or (202) 449-3442.

Sincerely,

Katie Mahoney
Executive Vice President and Chief Policy Officer