GLOBAL BUSINESS ALLIANCE | Investing in America

May 7, 2025

U.S. Department of Commerce
Bureau of Industry and Security
Office of Technology Evaluation
1401 Constitution Avenue, NW
Washington, DC 20230

Re: Section 232 Investigation on Imports of Pharmaceuticals, Pharmaceutical Ingredients, and Derivative Products (Docket No. BIS-2025-0022, XRIN 0694-XC120)

Dear Sir or Madam,

The Global Business Alliance (GBA) respectfully submits these comments on the U.S. Department of Commerce Notice of Request for Public Comments on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, as announced in the Federal Register on April 16, 2025.[1] GBA supports strengthening U.S. supply chain resilience and national security, encompassing both advanced and legacy pharmaceuticals.

GBA is pleased that President Trump recognizes that investments "by United States allies and partners can create hundreds of thousands of jobs and significant wealth for the United States." [1] GBA represents nearly 200 leading international companies, all of whom are major U.S. employers. On average, GBA members each employ 12,000 U.S. workers, and these companies are all globally headquartered in countries that are long-time friends and allies of the United States.

As you may know, international companies like these have invested over $5 trillion into the U.S. economy, employ 8.4 million U.S. workers and offer compensation that is seven percent higher than the U.S. private-sector average. Not only do they bring the capital necessary to create these opportunities, but they also import world-class know-how, which helps drive American innovation and more competitive U.S. workforce. In addition,

[1] https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of

these companies employ nearly one-quarter of all U.S. manufacturing workers and produce more than 20 percent of our nation's exports.

GBA advocates for fair, non-discriminatory treatment of international companies operating in the U.S. and promotes policies encouraging such companies to grow their U.S. operations, increase American employment and support U.S. economic growth. By representing this multitude of globally headquartered businesses across every sector of the U.S. economy, GBA is uniquely positioned to advocate on issues predominantly impacting inbound companies.

GBA members are integral to the global pharmaceutical supply chain, providing essential drugs, medical countermeasures and critical inputs that support U.S. economic and national security interests. Below, we address the specific criteria (i-xii) from the notice with technical detail and definitive positions to inform the investigation, incorporating updates to reflect the current date and refined recommendations based on stakeholder feedback.

Response to Specific Criteria

i. Current and Projected Demand for Pharmaceuticals and Pharmaceutical Ingredients in the United States

GBA members, primarily from close, non-adversarial nations, supply a significant share of the 80 percent of active pharmaceutical ingredients (APIs) for U.S. drugs that were sourced internationally in 2023.[2] These imports, including advanced biologics and legacy generics, are vital for U.S. healthcare systems, hospitals and defense applications, where domestic production cannot meet demand. The 2020-2021 global health crisis underscored the importance of resilient supply chains, necessitating targeted strategies to ensure continuity. Projected demand for critical drugs is also expected to grow by five percent annually through 2030, driven by an aging population and increased need for biologics.[3]

[2] Observatory of Economic Complexity, 2023 U.S. Pharmaceutical Trade Data, https://oec.world/en/profile/bilateral-product/pharmaceutical-products/reporter/usa.
[3] PhRMA, 2023 Global Access to New Medicines Report, https://cdn.aglty.io/phrma/global/resources/import/pdfs/2023-04-20%20PhRMA%20Global%20Access%20to%20New%20Medicines%20Report%20FINAL-1.pdf.

ii. Domestic Production Capacity Needed for Pharmaceuticals and Pharmaceutical Ingredients to Meet Projected National Security Requirements

U.S. pharmaceutical production capacity is limited, with only 28% percent of API manufacturing facilities for U.S.-market drugs located domestically in 2023.[4] Even with recent investments, domestic production is projected to meet less than 40 percent of critical drug demand by 2030, necessitating imports from key partner nations.[5]

iii. Existing and Anticipated Availability and Viability of Pharmaceuticals and Pharmaceutical Ingredients Fabricated at Foreign Facilities

GBA members operate advanced facilities in strategic partner nations, producing high-quality pharmaceuticals and ingredients, including vaccines and generics, for U.S. hospitals and defense needs. In 2023, global pharmaceutical sales reached $1.48 trillion, with friendly nation suppliers playing a key role in diversifying sourcing away from adversarial regions.[6] Access to critical raw materials, such as chemical precursors, remains essential for production, with anticipated stability from non-adversarial suppliers through 2030.

iv. Existing and Anticipated Gaps or Vulnerabilities in Supply Chains for Pharmaceuticals and Pharmaceutical Ingredients

Supply chains from allied nations, governed by stringent regulatory standards like those of the International Council for Harmonisation (ICH), mitigate vulnerabilities by reducing reliance on geopolitically unstable regions. GBA members maintained stable U.S. supplies during the 2020-2021 global health crisis, demonstrating resilience. Applying trade remedies to imports from close partner nations could create shortages, delay treatments and increase healthcare costs by 10 to 15 percent, disproportionately affecting vulnerable populations.[7]

v. The Nature and Degree of Competition from Foreign-Produced Pharmaceuticals and Pharmaceutical Ingredients, Including Through Foreign

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[4] Observatory of Economic Complexity, 2023 U.S. Pharmaceutical Trade Data, https://oec.world/en/profile/bilateral-product/pharmaceutical-products/reporter/usa.

[5] PhRMA, 2025 Special 301 Review Comment, https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_2025%20Special%20301%20Review_Comment.pdf.

[6] PhRMA, 2023 Global Access to New Medicines Report, https://cdn.aglty.io/phrma/global/resources/import/pdfs/2023-04-20%20PhRMA%20Global%20Access%20to%20New%20Medicines%20Report%20FINAL-1.pdf.

[7] PhRMA, 2025 Special 301 Review Comment, https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_2025%20Special%20301%20Review_Comment.pdf.

Government Subsidies and Other Industrial Policies

Suppliers from key partner nations operate under market-driven principles, with R&D incentives driving innovation in biologics and generics that benefit U.S. patients. Unlike adversarial nations with distortive subsidies, friendly nation policies align with U.S. interests. GBA recommends cooperative transparency mechanisms with strategic partners to address subsidy concerns. Trade remedies on imports from non-adversarial nations could raise U.S. production costs and reduce competitiveness.

vi. The Impact of Foreign Competition on the Economic Viability of Domestic Production of Pharmaceuticals and Pharmaceutical Ingredients

Imports of advanced and legacy pharmaceuticals from close partner nations complement domestic production by addressing supply gaps. Trade remedies could force costly supply chain rerouting, increase operational costs and reduce GBA members' competitiveness. A 25 percent tariff on imported APIs could raise domestic production costs by 4.1 percent, impacting $101 billion in U.S. pharmaceutical exports in 2023.[8] This could deter FDIUS, which contributed $5.4 trillion to U.S. economic activity in 2023.[9]

vii. The Impact of Imports of Pharmaceuticals and Pharmaceutical Ingredients on U.S. Industries That Use Pharmaceuticals and Pharmaceutical Ingredients in the Manufacture of Other Products

GBA members enable U.S. production of medical devices, diagnostics, and biologics. The investigation's broad scope, including derivative products, risks constraining supply chains for critical healthcare products. A 10 percent tariff on imports from friendly nations could increase production costs for high-value medical products by $100-$300 per unit, eroding U.S. competitiveness and raising patient costs.[10] A narrower focus on CISA-defined critical functions would mitigate these risks.

viii. The Feasibility of Increasing Domestic Production Capacity for Pharmaceuticals and Pharmaceutical Ingredients as a Means to Reduce Import Reliance

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[8] PhRMA, 2025 Special 301 Review Comment, https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_2025%20Special%20301%20Review_Comment.pdf.

[9] PhRMA, 2023 Global Access to New Medicines Report, https://cdn.aglty.io/phrma/global/resources/import/pdfs/2023-04-20%20PhRMA%20Global%20Access%20to%20New%20Medicines%20Report%20FINAL-1.pdf.

[10] PhRMA, 2025 Special 301 Review Comment, https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_2025%20Special%20301%20Review_Comment.pdf.

Scaling domestic manufacturing capacity for pharmaceuticals and active pharmaceutical ingredients to address the projected U.S. demand shortfall represents a formidable challenge, necessitating investments of several billion dollars and timelines spanning five to ten years for facility construction, regulatory approvals, and ameliorating a projected deficit of 22,000 skilled workers by 2030. [11] Despite initiatives such as the Department of Commerce's Investment Accelerator program, domestic production is anticipated to fulfill less than 40% of U.S. demand by 2030, underscoring the necessity of sustained reliance on imports from strategic partner nations. [12]

ix. The Impact of Current Trade and Other Policies on Domestic Production and Capacity for Pharmaceuticals and Pharmaceutical Ingredients

Trade agreements and R&D incentives have supported domestic growth, but trade remedies on imports from non-adversarial nations could provoke retaliatory measures, harming U.S. pharmaceutical exports, valued at $101 billion in 2023.[13] Applying remedies only to adversarial nations would enhance resilience without harming trusted partners. Streamlined permitting through inter-agency coordination is critical for onshoring.

x. The Impact of Export Controls or Other Restrictions Imposed by Foreign Governments on the Availability of Pharmaceuticals and Pharmaceutical Ingredients

Key partner nations adhere to transparent export control regimes, ensuring reliable U.S. access, unlike adversarial nations with restrictive policies such as tariffs and price controls. GBA members prioritized U.S. deliveries during global supply disruptions, reinforcing reliability. Export control concerns should focus on adversarial sources, with industry-led initiatives like early warning systems to enhance supply chain transparency.

xi. The Impact of Imports of Pharmaceuticals and Pharmaceutical Ingredients on Domestic Employment

GBA members support a significant portion of U.S. the 300,000 U.S. pharmaceutical jobs

[11] Congressional Research Service, 2023 Pharmaceutical Industry Workforce Outlook, https://www.congress.gov/crs-product/IF11648.
[12] Ibid.
[13] Observatory of Economic Complexity, 2023 U.S. Pharmaceutical Trade Data, https://oec.world/en/profile/bilateral-product/pharmaceutical-products/reporter/usa.

(2023) through R&D, manufacturing and distribution investments.[14] Trade remedies on imports from friendly nations could reduce these benefits, forcing supply chain adjustments that limit job growth, redirect capital from R&D and deter foreign direct investment in the U.S. (FDIUS). Investments in workforce training are essential to address talent gaps.

xii. Other Factors Relevant to National Security

U.S. national security and public health rely on partnerships with non-adversarial nations. Collaborative R&D initiatives accelerate development of critical therapies, enhancing U.S. resilience. The investigation's broad scope risks duplicative reporting requirements, as pharmaceuticals in medical devices could overlap with existing Section 232 frameworks. Applying trade remedies only to adversarial nations preserves critical partnerships and would help facilitate other public health priorities, including the stated goal of making more medications available over the counter.[15]

Recommendations

To safeguard national security and public health, GBA recommends:

1. **Apply Trade Remedies Only to Adversarial Nations**: Limit tariffs or quotas to imports from foreign adversarial nations, as imports of advanced and legacy pharmaceuticals from close partner nations pose no security threat and are vital to U.S. healthcare.
2. **Leverage the Investment Accelerator**: Utilize the Department of Commerce's Investment Accelerator to expedite investments from strategic partners in U.S. pharmaceutical capacity, boosting FDIUS and resilience.
3. **Deepen Collaboration with Key Partners**: Establish U.S.-friendly nation programs for R&D, supply chain security and regulatory harmonization to enhance resilience.
4. **Promote Diversified Sourcing**: Incentivize production across non-adversarial nations to mitigate concentration risks without disrupting critical imports, ensuring access to chemical precursors.
5. **Maintain Industry Dialogue**: Establish a structured timeline for stakeholder engagement to ensure evidence-based outcomes, with clear Harmonized Tariff

[14] Congressional Research Service, 2023 Pharmaceutical Industry Workforce Outlook, https://www.congress.gov/crs-product/IF11648.

[15] https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first.

Schedule (HTSUS) codes and national security targets, as well as a well-defined timeline for stakeholder engagement to provide well-researched input.

6. **Narrow Investigation Scope**: Focus on CISA-defined critical functions to avoid unintended impacts on healthcare supply chains, particularly for legacy generics used in essential treatments and products used for rare or ultra-rare conditions that cannot sustain redundant overcapacity. [16]
7. **Streamline Permitting and Workforce Development**: Enhance inter-agency coordination to expedite permitting and invest in training to address the projected need for 22,000 additional workers by 2030.[17]

Conclusion

GBA and its members are committed to supporting U.S. national security and public health. Imports from close, non-adversarial nations, including advanced and legacy pharmaceuticals, are a cornerstone of U.S. healthcare capabilities, supported by efficient global supply chains. Broad trade restrictions would increase downstream product costs by 10-15 percent, raise operational costs, deter FDIUS and harm U.S. exports, impacting healthcare access. We urge the Department to adopt precise, evidence-based measures that strengthen partnerships with key nations and focus on CISA-defined critical functions. GBA stands ready to provide additional data or expertise and welcomes a clear timeline for engagement.

Thank you for considering our comments. Please contact me with any questions.

Sincerely,

Jonathan Samford
President and CEO
Global Business Alliance

[16] https://www.cisa.gov/topics/risk-management/national-critical-functions
[17] Congressional Research Service, 2023 Pharmaceutical Industry Workforce Outlook, https://www.congress.gov/crs-product/IF11648