May 7, 2025

Electronic Submission (https://www.regulations.gov)

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

Re: Trade Alliance for Health's Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket XRIN 0694-XC120)

Dear Director Astle:

The Trade Alliance for Health ("TAFH") submits these comments in response to the U.S. Department of Commerce's ("Commerce") and Bureau of Industry and Security ("BIS") in response to the request for public comments on the national security investigation of imports of Pharmaceuticals and Pharmaceutical Ingredients under Section 232 of the Trade Expansion Act of 1962, as amended ("Section 232").[1] TAFH appreciates Commerce's interest in increasing domestic production of and strengthen U.S. competitiveness in the pharmaceutical and pharmaceutical ingredients sectors. TAFH welcomes the opportunity to offer its expertise and insight for Commerce's consideration.

TAFH represents companies in the biopharmaceutical, medical devices and diagnostics, and logistics industries responsible for the research, development, production, and distribution the medical goods and services to improve health outcomes for U.S. patients. TAFH members employ hundreds of thousands of Americans and support millions more indirect high-wage jobs in the United States. TAFH members invest many billions to develop and manufacture advanced medical products across the United States and spend billions more to source American manufactured products, from laboratory equipment to trucks and large commercial aircraft, and export billions in finished products. TAFH members operate and support a broad network of U.S. manufacturing facilities, but imports of pharmaceuticals and pharmaceutical ingredients are crucial to meeting current and future domestic demand. By doing so, they partner with an array of suppliers, service providers, and retailers to provide a reliable supply of safe and effective medicines and devices.

TAFH agrees that overreliance on a single supplier, country, or region for manufacturing pharmaceuticals and pharmaceutical ingredients can pose a threat to national security, cause

[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15,951 (Apr. 16, 2025) (Docket No. BIS-2025-0022; XRIN 0694–XC120).

potential shortages, and result in disruptions. As such, TAFH supports reforming trade policy to enhance domestic production of pharmaceuticals and pharmaceutical ingredients. However, TAFH members are concerned that unilaterally imposing trade-restrictive Section 232 measures on imports of pharmaceuticals and pharmaceutical ingredients could jeopardize national security of the United States, drive up prices, make many basic medicines unaffordable for many low-income families, and prompt responses by foreign government that close off our export markets.

To prevent such unintended harmful impact, TAFH recommends BIS to consider carefully and thoroughly all information submitted by the industries, further engage with subject matter experts, and support the United States needs to a new trade strategy that ends overreliance on a single country for supplies of pharmaceuticals and pharmaceutical ingredients, ends foreign trade practices that harm U.S. manufacturing, and develops a network of trusted trade partners that enhance U.S. manufacturing capacity and our national security.

I. Tariffs May Impair National Security and U.S. Export Competitiveness

The pharmaceutical industry is a crucial part of the U.S. economy, playing a pivotal role in public health and global leadership. In 2021, the pharmaceutical industry contributed approximately $355 billion to U.S. GDP and generated $655 billion in total economic output, while supporting approximately 1.5 million U.S. jobs across the supply chain.[2] Further, according to the annual trade data released by the U.S. Census Bureau and the U.S. Bureau of Economic Analysis, U.S. exports of pharmaceutical preparations exceeded $90 billion in 2022.[3] Foreign direct investment in pharmaceutical industry attracted over $143 billion between 2019 and 2023.[4] Lastly, the industry invests an estimated $122 billion in research and development ("R&D") of new medicines.[5] In 2021, the industry's R&D intensity was 16.1 percent, significantly higher than the national average of 4.6 percent.[6] In the broader U.S. biopharmaceutical ecosystem, which includes development-stage firms that invest heavily in R&D before commercialization, R&D intensities may reach as high as 34 percent.[7] The average cost to develop a new drug in 2024 was approximately $2.23 billion and it took 10 to 15 years to develop, making the decision to invest in R&D highly sensitive to cost pressures.[8]

Considering the significant role of the pharmaceutical industry in the U.S. economy and its capital-intensive R&D/production processes, BIS should be cautious in using overly broad

---

[2] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 23.

[3] Brian Picone, *U.S. biopharmaceutical exports support jobs, innovation*, PhRMA (Mar. 20, 2023).

[4] *Id.*

[5] *Id.*

[6] National Center for Science and Engineering Statistics, *Business R&D Performance in the United States Tops $600 Billion in 2021* (Sept. 28, 2023) (Official government data from the 2021 Business Enterprise Research and Development ("BERD") Survey).

[7] Amitabh Chandra et al., *Comprehensive Measurement of Biopharmaceutical R&D Investment*, 23 NATURE REV. DRUG DISCOVERY 652 (2024).

[8] Deloitte Centre for Health Solutions, *Measuring the Return from Pharmaceutical Innovation: 15th Edition* (Mar. 2025) at 6.

tariffs as they could not only challenge the industry's export, research, and investment ecosystem but also have substantial impact on the overall U.S. economy and welfare. For example, studies indicate that tariffs on pharmaceutical industry inputs could increase U.S. production costs by $15.1 billion, which will adversely impact the competitiveness of U.S. pharmaceutical companies that export their products to foreign markets.[9] Moreover, the cost of imported finished medicines would increase by $35.7 billion, seriously jeopardizing American lives and the overall wellbeing of U.S. citizens.[10]

The United States is a major exporter of high-value, innovation-driven pharmaceuticals.[11] It has been a global leader in pharmaceutical manufacturing. For example, in 2023, U.S. consumer sales of finished biopharmaceuticals totaled $393 billion, of which 64 percent was produced in the United States and 36 percent was imported, of which about three quarters came from U.S. allies.[12] The United States exported about 20 percent of domestic production, totaling $101 billion. It imported an estimated $60 billion of imported pharmaceutical products to use as inputs for domestic production. Any trade-restrictive measures imposed by BIS as a result of this investigation may prompt trade partners and others to respond with their own retaliatory measures. Countries may block imports of U.S. products or restrict exports of inputs critical to U.S. manufacturing competitiveness.

Retaliatory tariffs and trade-restrictive measures on U.S. exports of pharmaceuticals and pharmaceutical ingredients will also create burdens for U.S. companies. This could lead to decreases in investment in R&D and manufacturing capacity, purchases of new American-made equipment, and U.S. workforce. American companies, workers, and patients will ultimately face higher costs for pharmaceuticals and pharmaceutical ingredients as well as supply shortages. Restrictive measures could disrupt complex supply chains and lead to shortages for patients in need.

II. Boosting Domestic Manufacturing and National Security with Trust Allies and Trading Partners

The pandemic showed that in order to provide Americans the medical goods they need during times of supply chain disruption, the United States needs a new trade strategy that ends overreliance on a single country for supplies of pharmaceuticals and pharmaceutical ingredients, boosts domestic manufacturing capacity by stopping unfair foreign trade practices that harm U.S. pharmaceutical exports, and develops a network of trusted trade partners that complements both goals.

Following the pandemic, various studies and experts agreed that cooperation with trusted allies and trading partners is a necessity to secure supply chain resilience and mitigate the risks

---

[9] *Impacts of potential tariffs on the US pharmaceutical industry*, PhRMA (Apr. 22, 2025).

[10] *Id.*

[11] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 16; Niels Graham, *The US Is Relying More on China for Pharmaceuticals — and Vice Versa, Atlantic Council* (Apr. 20, 2023).

[12] Ernst & Young, *Impacts of potential tariffs on the US pharmaceutical industry* (April 2025)

associated with overreliance on a single country for supplies of goods, instead of relying solely on onshoring.[13] Further, this option may not even be practically feasible as a single country's ability to support supply chains in their entirety is limited. As such, experts agreed that solely shifting supply chains domestically "could leave the very supply chains we are trying to protect more vulnerable to disruptions," and recommend the United States to engage in bilateral, multilateral, and plurilateral trade agreements.[14]

We ask BIS to support medical sector trade negotiations with allies and partners as the primary means of addressing national security concerns related to the imports of pharmaceuticals and pharmaceutical ingredients. The action would build on increasing attention by the Trump Administration and Congress on the prospect for medical sector trade negotiations. On January 20, 2025, President Donald Trump directed the United States Trade Representative (USTR) to recommend "countries with which the United States can negotiate agreements on a…sector-specific basis to obtain export market access for American workers, farmers, ranchers, service providers, and other businesses." In March, Senators Thom Tillis (R-North Carolina), Chris Coons (D-Delaware), John Cornyn (R-Texas), and Michael Bennet (D-Colorado) and Representatives Nicole Malliotakis (R-New York) and Brad Schneider (D-Illinois) responded to the President's directive by introducing ***the Medical Supply Chain Resiliency Act***, which proposes a framework for medical sector trade negotiations. During hearings in April, Rep. Malliotakis and Sen. Bennet asked Ambassador Jamison Greer to review the bill. Ambassador Greer replied that he will use "all appropriate trade negotiations to pursue more secure and resilient medical supply chains for the United States and to expand market access for innovative U.S. pharmaceutical and medical technologies. Sectoral arrangements could be one avenue to secure these supply chains and increase U.S. production."[15]

The Administration should work with Congress to enact the Medical Supply Chain Resiliency Act. The bill would empower the United States to negotiate Trusted Trade Partner Agreements that would eliminate trade barriers and harmonize regulations with U.S. allies and trusted partners that meet high standards. This will not only support Administration's national security goals, but also ensure that millions of Americans will have access to affordable prescription drugs. To be eligible to be a trusted trade partner, countries must meet high standards, including adhering to existing trade agreements, adopt and enforce laws that provide intellectual property, and promote good regulatory practices related to medical goods.

---

[13] *See, e.g.*, *Securing Medical Supply Chains in a Post-Pandemic World*, OECD Health Policy Studies (Feb. 23, 2024); *Diversifying Medical Supply: Lessons From COVID-19*, Johns Hopkins University (Feb. 2021); *US and European Strategies for resilient supply chains - Balancing globalization and sovereignty*, Chatham House (Sept 14, 2021); *Why we need global cooperation on critical mineral supplies*, World Economic Forum (Dec. 4, 2023).

[14] *Building Resilience into the Nation's Medical Product Supply Chains*, The National Academies of Sciences, Engineering, and Medicine (2022); *see also* Barthélémy Bonadio et al., *Global Supply Chains in the Pandemic*, Journal of International Economics (Nov. 2021).

[15] Jamison Greer, United States Trade Representative. *The President's 2025 Trade Policy Agenda.* April 8, 2025. Response to Question for the Record.

The bill directs USTR to negotiate agreements that achieve multiple objectives that would enhance American competitiveness and national security, including:

- reducing or eliminating any trade barriers that undermine the national security and public health of the United States;
- diversify and expand supplier networks;
- increase access to government procurement markets;
- provide U.S.-level IP protection;
- exempt parties to the agreement from trade-restrictive measures during a public health emergency.

Trusted Trade Partner Agreements will allow the Administration to create and promote a diverse and expansive network of suppliers offering U.S. companies, workers, and consumers access to a reliable supply of pharmaceuticals and pharmaceutical ingredients by reducing or eliminating trade barriers that undermine U.S. national security and public health.

III. Conclusion

TAFH welcomes BIS's commitment to increase domestic production of and strengthen U.S. competitiveness in the pharmaceutical and pharmaceutical ingredients sectors. TAFH urges BIS to consider the harm trade-restrictive measures would have and prioritize policies that promote a more pro-growth, cost-effective, and efficient domestic pharmaceutical manufacturing environment. TAFH is committed to working with the Administration and encourages BIS to consider TAFH as a resource in its national security objectives. Thank you for the opportunity to comment and your consideration.

Sincerely,

Trade Alliance for Health