

US-China Business Council Comment on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

May 6, 2025

Bureau of Industry and Security, Department of Commerce

Docket Number: 250414-0065

XRIN 0694-XC120

The US-China Business Council (USCBC) welcomes the opportunity to submit comments to the Bureau of Industry and Security (BIS) on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

USCBC comprises about 270 US companies that do business with China. Many of our member companies play a leading role in the pharmaceutical sector and across related industries, including biomedical research, pharmaceutical transportation, clinical application, and the production of essential equipment and consumables that support pharmaceutical use within the United States. The biopharmaceutical supply chain is inherently complex and global in nature. While we recognize the vulnerabilities posed by reliance on foreign sources, the imposition of unilateral tariffs or import quotas—particularly in the absence of exemptions for manufacturing equipment and inputs and reasonable adjustment periods—can lead to serious unintended consequences. These include potential drug shortages, higher healthcare costs, and diminished incentives for innovation, all of which would harm American patients and the competitiveness of the US pharmaceutical industry. Moreover, such disruptions may significantly undermine the Administration's strategic objectives of reshoring pharmaceutical manufacturing, making it more difficult to achieve in a timely manner.

USCBC appreciates BIS' efforts to evaluate the national security implications "... of imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items." However, sectoral tariffs undermine US competitiveness and access to a diverse range of sources in the biopharmaceutical supply chain.

American biopharmaceutical companies have invested significantly in developing diversified, resilient, and cost-effective global supply chains. Data from USCBC's most recent annual membership survey indicates that 43 percent of respondent companies across different industries reported shifts in their suppliers or sourcing strategies, with many pursuing new supply chain configurations aimed at strengthening supply chain



resilience in the United States. In the pharmaceutical industry, the United States <u>sources</u> approximately 48 percent of its active pharmaceutical ingredients (APIs) from India, 22 percent from Europe, and 13 percent from China, while 10 percent is produced domestically. In 2022, the Atlantic Council <u>reported</u> that China accounted for only 6 percent of overall US pharmaceutical imports and 17 percent of API imports.

Nonetheless, China <u>remains</u> a critical upstream supplier of key starting materials and chemical precursors globally, which are often processed and exported to the United States through third countries such as India. As a result, major pharmaceutical manufacturing nations are structurally linked to Chinese-origin raw materials. If the Administration were to impose tariffs or quotas on pharmaceuticals or ingredients with Chinese-origin content, it would risk disadvantaging the US biopharmaceutical manufacturing relative to multinational competitors. Such actions would not only increase national healthcare costs but create advantages for multinational biopharmaceutical companies and undermine US competitiveness.

Impacts of stackable tariff rates and foreign retaliation should be taken into consideration

Blanket tariff measures on pharmaceutical imports risk triggering drug shortages and adversely affecting patient care across the country. According to a non-public report commissioned by PhRMA, the imposition of a 25 percent tariff on pharmaceutical imports would raise annual drug costs in the United States by nearly \$51 billion, potentially increasing domestic drug prices by as much as 12.9 percent if those costs are passed on to patients. While pharmaceutical imports are currently exempt from both the recently announced 10 percent universal baseline tariff and the accompanying country-specific reciprocal tariffs, the ongoing investigation should carefully evaluate the potential consequences of imposing additional tariffs. In particular, the cumulative effect of stackable tariffs—whether by product category, origin, or component—could severely undermine price stability, business certainty, and long-term investment in domestic healthcare and life sciences sectors.

• Tariffs should be scoped and risk-based

BIS should ensure the applicable scope of any resulting measures be narrowly defined and focused on addressing genuine national security vulnerabilities. Specifically, the investigation should differentiate between critical dependencies that present tangible risks and imports of low-margin pharmaceutical products from reliable local partners that are essential to the functioning of the domestic healthcare system. Unilateral tariffs are especially likely to disrupt the supply of generic drugs and biosimilars. These products are highly sensitive to cost pressures, and the imposition of tariffs would further strain their already-thin margins—particularly given that reimbursement rates are unlikely to adjust in tandem with increased input costs. Moreover, based on FDA's <u>definition</u> of "medical countermeasures," basic



personal protective equipment (PPE) may also be swept into the scope of the investigation, posing additional risks to patient access. BIS should establish a clear and effective exemption mechanism that allows companies to apply for temporary tariff exclusions or exemptions.

• Additional Policy Support Is Essential for Expanding Domestic Pharmaceutical Manufacturing

To effectively expand domestic biopharmaceutical manufacturing, the Administration should prioritize targeted policy support over broad trade restrictions. Above all, incentivizing investment requires robust exemptions for manufacturing equipment and critical inputs. These balanced, pragmatic approaches are more likely to advance national security goals while maintaining public health access and preserving the global competitiveness of the US pharmaceutical industry. Given the higher production costs and technical complexities involved, biologics and biosimilars should be evaluated separately in any assessment of supply chain resilience. We recommend that BIS conduct a dedicated vulnerability and capability assessment to analyze how unilateral tariffs could disrupt supply chains or hinder innovation and growth in these sectors. Such an assessment should also consider the financial and policy resources necessary to support expanded domestic manufacturing capacity.

While USCBC shares the Administration's concerns regarding specific national security objectives and unfair Chinese economic practices, we remain concerned about the effectiveness of tariffs in achieving these strategic goals. We urge BIS to take targeted approach to rulemaking. It is critical that any resulting measures minimize unintended consequences for US healthcare access, supply chain resilience, and business certainty.