# **Before The**

# UNITED STATES DEPARTMENT OF COMMERCE BUREAU OF INDUSTRY AND SECURITY 1401 Constitution Avenue, N.W. Washington, D.C. 20230

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In the Matter of:	) ) Docket No. 250414-0065
Investigation to Determine the Effects on the	) XRIN 0694-XC120
National Security of Imports of Pharmaceuticals	)
and Pharmaceutical Ingredients	)
	)
	_)
CENTER FOR INDIVIDUAL	FREEDOM COMMENT
<b>ADVOCATING JUDICIOUS APPLICATION OF S</b>	SECTION 232 TO SAFEGUARD AMERICA'S
Pharmaceutical	SUPPLY CHAIN

## I. <u>Introduction</u>

The Center for Individual Freedom (hereinafter "CFIF") hereby submits the following Comment to the U.S. Department of Commerce Bureau of Industry and Security (hereinafter

May 7, 2025

"Department") urging judicious application of Section 232 of the Trade Expansion Act of 1962 to safeguard our nation's pharmaceutical supply chain.<sup>1</sup>

CFIF is a non-profit, non-partisan organization established in 1998 for the purpose of safeguarding and advancing Constitutional rights and free market principles, as well as ensuring continued American welfare, innovation, prosperity, leadership and worldwide preeminence.

As a central part of that mission, CFIF advocates for public policies that preserve our nation's economic strength and our legacy of strong intellectual property (IP) protections that make the U.S. the unparalleled leader in pharmaceutical innovation and excellence.

Toward that end, CFIF commends the Department for proactively addressing potential vulnerabilities across America's pharmaceutical supply chains.

Simultaneously, however, CFIF also urges a strategically calibrated approach, because while the U.S. may be wise to reduce our dependence upon adversarial nations like China, it's equally vital to preserve and reinforce supply chain relationships with trusted and reliable allies who share our same goals and concerns. Overbroad trade restrictions imposed under Section 232 – such as tariffs on pharmaceutical supply chain imports from allied nations – would inflict unintended harm to American consumers, healthcare providers and pharmaceutical innovators who rely upon them. Potential consequences could include higher drug prices, reduced access to essential medicines for American consumers and impaired rather than enhanced U.S. national security.

CFIF therefore respectfully urges that the Department adopt a carefully targeted strategy that mitigates potential risks from adversarial nations without undermining the robust,

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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#print

collaborative, necessary supply networks on which America's world-leading pharmaceutical innovators and consumers rely.

### II. <u>Discussion</u>

America leads the world in pharmaceutical innovation, accounting for approximately two-thirds of all new drugs introduced to the world annually.<sup>2</sup> Moreover, most of those lifesaving and beneficial medicines on which American consumers rely are manufactured domestically.<sup>3</sup>

As noted above, however, America's pharmaceutical supply chain is deeply integrated into a global system that includes both friendly and unfriendly nations.

In that vein, the Department's expressed concern regarding the potential leverage that adversarial nations may exert is a well-founded one. As the leading example, China deliberately controls a significant share of the worldwide supply of active pharmaceutical ingredients (APIs), including a majority of key materials and APIs for our generic drugs on which so many depend.<sup>4</sup>

It also bears emphasis that China's control over pharmaceutical supplies is bolstered by its command-and-control economic regime, its overtly anti-American stance, outright theft of intellectual property, heavy state subsidies, disregard of environmental protections and strategic stockpiling.<sup>5</sup> That constitutes a genuine threat. In the event of heightened geopolitical tension, our dependence upon China could be weaponized, thereby threatening the availability of essential medicines for American consumers.

https://www.efpia.eu/media/412931/the-pharmaceutical-industry-in-figures-2019.pdf

<sup>&</sup>lt;sup>3</sup> https://advisory.avalerehealth.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-

<sup>&</sup>lt;u>us</u>

https://www.acsh.org/news/2025/04/22/prescription-risk-americas-hidden-dependence-china-life-saving-drugs-49427

<sup>5 &</sup>lt;u>https://www.fbi.gov/investigate/counterintelligence/the-china-threat</u>

Those concerns necessitate reasonable efforts to reduce supply chain risk from adversarial nation control.

The integrated global supply chain under investigation, however, also includes trusted allies like Switzerland, Ireland, other European nations, Japan, South Korea, India and Canada. Those cooperative nations manufacture critical APIs as well as finished medicines according to stringent regulatory standards comparable to those practiced by the U.S. Food and Drug Administration (FDA). Indeed, one-third of ingredients of pharmaceuticals used by American consumers are sourced from the European Union alone.<sup>6</sup>

Those collaborative supply chain networks enhance supply chain resilience by ensuring redundancy and alternative sourcing options. They also promote innovative collaboration in the development of new drugs, they strengthen quality control and mutual regulatory confidence to assure high standards of pharmaceutical safety and they help rather than hinder the continuous supply of lifesaving medicines across the U.S. market.

Moreover, the supply chains on which America relies would require years to remake.<sup>7</sup>

Domestic manufacturers cannot simply begin sourcing necessary ingredients and medicines from domestic suppliers, regardless of price.

Accordingly, American pharmaceutical security is bolstered, not threatened, by reliable trade with allied nations. And strengthening those alliances, rather than potentially disrupting them via sweeping trade disruptions, remains essential to securing our pharmaceutical preeminence.

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https://www.uschamber.com/international/ipef-and-biopharma-supply-chains-facts-goals-and-action

https://www.reuters.com/world/us/trump-faces-pressure-us-industry-over-china-tariff-medicines-2025-02-06/

If we needlessly impose Section 232 tariffs or other counterproductive restrictions on imports from those friendly nations, it would immediately disrupt supply chains for essential medicines, thereby potentially triggering widespread shortages that endanger patient care, especially for chronic and rare diseases. It would also increase costs for consumers and U.S. healthcare programs like Medicare and Medicaid that are already under fiscal stress, and it would counterproductively incentivize production of critical supplies in adversarial nations.

That would obviously undermine the very goal of the instant national security investigation.

Accordingly, rather than imposing overly broad tariffs under Section 232, CFIF respectfully encourages the Department to instead pursue a multifaceted strategy. That wiser, more tailored strategy would include selective de-risking by focusing any new restrictions specifically upon adversarial nations that practice systematically unfair trade practices or that create geopolitical risk.

A wiser, more tailored approach under Section 232 would also include initiatives to actually strengthen cooperation with allied nations via bilateral and multilateral trade agreements to deepen supply chain integration with those trusted nations with whom we face common adversaries.

Domestically, a tailored Section 232 approach would bolster U.S.-based manufacturing of critical medicines and supply components via tax credits, procurement agreements to enhance economic confidence and streamlining of regulatory burdens and timelines.

Developing and maintaining comprehensive supply chain plans to identify vulnerabilities and improve strategic responsiveness also offers a key opportunity, as does strategic stockpiling of reserves of critical drugs and APIs to hedge against potential disruptions at home and abroad.

A balanced approach that includes those new incentives can strengthen national security without sacrificing public health, our fiscal stability or our pharmaceutical leadership.

### III. <u>Conclusion</u>

For the reasons set forth herein, CFIF welcomes the Department's investigation under Section 232. Assessing and counteracting critical pharmaceutical supply chain vulnerabilities, particularly those relating to American dependence upon adversarial nations like China, constitutes a priority of the first order.

Meeting that challenge, however, demands precision and strategic wisdom lest we needlessly disrupt our world-leading pharmaceutical sector, undermine our fiscal stability and harm American consumers. CFIF therefore respectfully urges the Department to recognize that strategic trade with U.S. allies constitutes a pillar of national security, not a threat to it. We cannot impose overbroad tariffs that would only harm American patients and pharmaceutical innovators, and must instead pursue tailored measures that reduce supply chain risk and fortify domestic resilience.

Thank you very much for your consideration on this critical matter.

Respectfully submitted,

/s/ Timothy H. Lee

Jeffrey L. Mazzella, President Timothy H. Lee, Senior Vice President of Legal and Public Affairs CENTER FOR INDIVIDUAL FREEDOM

3050 Chain Bridge Road Suite 200 Fairfax, Virginia 22030 (703) 535-5836

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