



May 7, 2025

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Bureau of Industry and Security U.S. Department of Commerce Washington, D.C. 20230

Re: Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Doc. ID BIS-2025-0022) XRIN 0694-XC120

Dear Sir or Madam:

IPPI: The IP Policy Institute at the University of Akron School of Law appreciates the opportunity to submit comments on the above-referenced Section 232 National Security investigation. IPPI is a research institute based at University of Akron School of Law that promotes rigorous, fact-based research and policy discussions exploring how sound innovation policy supports flourishing economies, businesses, and individual lives.

We write to express our strong concerns that imposing tariffs on pharmaceutical imports would harm U.S. patients, undermine one of our most important and successful innovation industries, disrupt global medicine supply chains, invite harmful retaliation, and ultimately undermine, rather than enhance, American healthcare security.

### Introduction

Based on extensive research across multiple studies conducted over the past decade, we urge that imposing tariffs on pharmaceuticals and their ingredients would be counterproductive to U.S. interests. We particularly call your attention to a 2021 study¹ by Geneva Network, a think tank focused on international trade, innovation, and global health with which we frequently collaborate. This study modeled the effects of a 25% tariff on medicines with likely retaliation by trading partners.

<sup>&</sup>lt;sup>1</sup> Bauer, M., & Lamprecht, P. (2021). How tariffs impact access to medicines. Geneva Network Working Paper. <a href="https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/">https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/</a>

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The likely results are not good – neither for patients, nor for business.

This study and others demonstrate that such tariffs would:

- 1. Significantly increase prices for American patients through a compounding effect along the distribution chain
- 2. Exacerbate existing drug shortages, particularly for generic medicines
- 3. Disrupt global pharmaceutical supply chains that the U.S. healthcare system depends upon
- 4. Invite retaliatory tariffs that would harm U.S. pharmaceutical exports, innovation, and manufacturing and endanger national security
- 5. Create a regressive tax that disproportionately burdens those least able to afford it
- 6. Contradict longstanding U.S. trade policy and international commitments

We urge the Department of Commerce to conclude this investigation without recommending tariffs on pharmaceutical products or ingredients.

### Tariffs Would Increase Drug Prices and Reduce Access for American Patients

Research consistently demonstrates that tariffs on pharmaceuticals and their ingredients substantially inflate final consumer prices. A 2017 study by the European Centre for International Political Economy found that even modest import duties on medicines compound dramatically as products move through the distribution chain, resulting in final price increases many times higher than the original tariff rate.<sup>2</sup>

This "compounding effect" occurs because each intermediary in the supply chain (importers, wholesalers, distributors, retailers, hospitals) applies a percentage markup to an already tariffinflated base price. Bauer's research revealed that a nominal import tariff of 10% can lead to price increases of up to 80% for final consumers when all markups are considered.<sup>3</sup> This effect is particularly pronounced in pharmaceutical distribution, where multiple layers of markup are common practice.

Applying these findings to the U.S. context, modeling demonstrates that a 25% tariff on pharmaceutical imports – as has been discussed – would have devastating effects on medicine affordability and availability. The 2021 Geneva Network study modeled various tariff scenarios and found that if the U.S. implemented such tariffs, it would significantly reduce global pharmaceutical supply, with repercussions that would directly impact American patients.<sup>4</sup>

<sup>&</sup>lt;sup>2</sup> Bauer, M. (2017). The compounding effect of tariffs on medicines: Estimating the real cost of emerging markets' protectionism. ECIPE Policy Brief 01/2017. <a href="https://ecipe.org/wp-content/uploads/2017/09/Tariffs-on-medicines-final.pdf">https://ecipe.org/wp-content/uploads/2017/09/Tariffs-on-medicines-final.pdf</a>

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Bauer, M., & Lamprecht, P. (2021). How tariffs impact access to medicines. Geneva Network Working Paper. <a href="https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/">https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/</a>

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The impact of tariffs would be particularly significant for generic drugs, which account for over 90% of prescriptions filled in the United States.<sup>5</sup> A 2021 report found that there is no U.S. source for 83% of the top 100 generic medicines in the United States.<sup>6</sup> Tariffs would thus likely make a large proportion of drugs used by U.S. patients more expensive.

Similarly, tariffs on active pharmaceutical ingredients (APIs) would significantly increase production costs for domestic manufacturers, raising U.S. prices regardless of where the final drug is assembled. A study found that 72% of active pharmaceutical ingredients (APIs) on the FDA's list of essential APIs are manufactured outside of the U.S., with another 22% with only a single U.S. source.<sup>7</sup>

Given this diverse and globalized supply chain for U.S. drugs, tariffs would inevitably be passed on to patients either directly or indirectly. Furthermore, such tariffs would make finished drugs exported from the U.S. more expensive and thus less competitive in international markets, harming American pharmaceutical companies.

### Tariffs Cannot Quickly Shift Manufacturing to the U.S.

Proponents of pharmaceutical tariffs often argue that they will encourage domestic manufacturing. However, this assumption is flawed. Manufacturing of pharmaceuticals cannot be quickly relocated to the United States regardless of tariff levels. As noted in the May 5<sup>th</sup> Executive Order, "Regulatory Relief to Promote Domestic Production of Critical Medicines," industry experts have consistently noted that building pharmaceutical manufacturing facilities in the U.S. would cost billions of dollars and take 5-10 years to accomplish.

This timeline makes tariffs an ineffective tool for addressing immediate or even medium-term supply concerns. In fact, tariffs could disrupt existing supply chains before any new domestic capacity comes online, creating potentially dangerous gaps in medicine availability.

While the regulatory and permitting reforms set forth in the May 5<sup>th</sup> Executive order are laudable and much needed, building new biopharmaceutical manufacturing capacity could be done faster, but will never be done quickly. This kind of manufacturing requires significant investment, sophisticated equipment, and well-trained personnel. Even during the pandemic, with Operation Warp Speed de-risking investment and facilitating an increase in manufacturing, pharmaceutical companies had to search the world for partners with the ability and sophistication to make

<sup>7</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> FDA. (2022). Office of Generic Drugs Annual Report. <a href="https://www.fda.gov/media/165435/download?attachment">https://www.fda.gov/media/165435/download?attachment</a>

<sup>&</sup>lt;sup>6</sup> Sardella, A. (2021). The US Active Pharmaceutical Ingredient Infrastructure. CABI Olin Business School at Washington University. <a href="https://www.https://

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necessary doses of vaccines and therapeutics.<sup>8</sup> It sometimes took many months and a great deal of technology transfer to get such partners up to speed.<sup>9</sup>

## **Tariffs Would Exacerbate Drug Shortages**

The United States already faces persistent shortages of critical medications. The Geneva Network 2021 analysis<sup>10</sup> indicates that tariffs would worsen this situation by:

- 1. Reducing imports of finished drugs as foreign manufacturers redirect products to markets without tariffs
- 2. Disrupting the supply of APIs needed for domestic production
- 3. Potentially causing some manufacturers to exit market segments where tariffs make continued participation economically unfeasible

These disruptions would disproportionately affect generic drugs, which represent the vast majority of prescriptions in the U.S. When generics become less profitable due to tariffs, manufacturers may discontinue production, leading to monopoly conditions or complete absence of needed medications.

## The Government Would Pay More Than It Collects

While tariffs generate revenue, research by Geneva Network shows that for pharmaceuticals, the government can ultimately pay far more in increased costs for medicines than it collects in tariff revenue. This result has occurred in other countries that impose tariffs on medicines and occurs thanks to the compounding effect discussed earlier. This effect would likely occur in the U.S. because:

- 1. Government programs (Medicare, Medicaid, Veterans Affairs, etc.) account for approximately 40% of U.S. pharmaceutical spending
- 2. Crucially, in many of those instances, the government reimburses drug purchases (e.g., Medicare and Medicaid) rather than directly purchasing drugs, allowing various intermediaries to take a cut
- 3. A 25% tariff would thus increase prices by substantially more than 25% due to the compounding effect
- 4. The government would pay these inflated prices through its healthcare programs

<sup>&</sup>lt;sup>8</sup> Hopkins, J. S. (2021, August 20). Key staffers aid global vaccine rollout. Wall Street Journal. <a href="https://www.wsj.com/articles/pfizers-global-covid-19-vaccine-rollout-depends-on-two-expert-staffers-11629464010?page=1">https://www.wsj.com/articles/pfizers-global-covid-19-vaccine-rollout-depends-on-two-expert-staffers-11629464010?page=1</a>

<sup>&</sup>lt;sup>9</sup> Ibid.

<sup>&</sup>lt;sup>10</sup> Bauer, M., & Lamprecht, P. (2021). How tariffs impact access to medicines. Geneva Network Working Paper. https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/

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Geneva Network's economic modeling demonstrates that governments typically end up paying 2-6 times more in increased pharmaceutical costs than they collect in tariff revenue. <sup>11</sup> Thus, for example, a 25% tariff on a medicine that costs \$100 upon import would produce \$25 in tariff revenue but cost the government \$50 to \$150 in increased reimbursement costs, far exceeding the tariff revenue it collects.

Applied to the U.S. context, this suggests that any tariff revenue would be significantly offset by increased government healthcare expenditures.

# Tariffs Would Trigger Retaliation and Harm U.S. Exports, Innovation, and Manufacturing

Geneva Network's 2021 study also explicitly modeled the impact of retaliatory tariffs on pharmaceuticals. The findings indicate that if trading partners respond to U.S. pharmaceutical tariffs with their own, American pharmaceutical exports would face significant harm.<sup>5</sup>

The U.S. exports over \$100 billion in pharmaceutical products annually. These exports would become less competitive in foreign markets if subjected to retaliatory tariffs. Additionally, as Bauer's research demonstrates, U.S. pharmaceutical manufacturers that rely on imported inputs would face higher production costs, further eroding their global competitiveness. 12

Geneva Network's scenario modeling shows that global actions to increase tariffs merely to bound rates would significantly reduce export and import volumes for all types of medical goods. Such a scenario would leave many countries with shortages in the supply of medicines and active ingredients, with the U.S. pharmaceutical industry caught in the crossfire.<sup>13</sup>

Retaliatory tariffs may be disproportionately harder on U.S. pharmaceutical exporters than on companies selling drugs into the U.S. due to the inflexibility of pharmaceutical pricing in other countries. Most countries set or heavily influence drug prices through single payer healthcare systems, government procurement agencies that are monopsonies or have significant market power, price caps, and other measures. In such markets, U.S. exporters will more likely bear the cost of tariffs than purchasers. The resulting financial losses would harm investment in U.S. pharmaceutical research and development and threaten its position as a leading innovator.

In addition, China, Brazil, and the EU are considering suspending IP rights or imposing increased antitrust scrutiny on U.S. IP owners, among other countermeasures, in retaliation against recently imposed U.S. baseline tariffs. <sup>14</sup> Much as compulsory licensing of patents is used

<sup>&</sup>lt;sup>11</sup> Ibid.

<sup>&</sup>lt;sup>12</sup> Bauer, M. (2017). The compounding effect of tariffs on medicines: Estimating the real cost of emerging markets' protectionism. ECIPE Policy Brief 01/2017. <a href="https://ecipe.org/wp-content/uploads/2017/09/Tariffs-on-medicines-final.pdf">https://ecipe.org/wp-content/uploads/2017/09/Tariffs-on-medicines-final.pdf</a>

<sup>&</sup>lt;sup>13</sup> Ibid.

<sup>&</sup>lt;sup>14</sup> Negrao, F., et al. (2025, April 22). Brazilian Economic Reciprocity Law is published to safeguard Brazilian interests against unilateral measures adopted by other countries or economic blocs. Baker & McKenzie. <a href="https://sanctionsnews.bakermckenzie.com/brazilian-economic-reciprocity-law-is-published-to-safeguard-brazilian-eco

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by countries to attempt to boost domestic manufacturing, suspending pharmaceutical or other intellectual property rights could be used to try to boost domestic pharmaceutical and other manufacturing at the expense of U.S. manufacturing. Such actions, particularly by economies with such competitive pharmaceutical manufacturing capacity, would have a devastating effect on the U.S. pharmaceutical industry's ability to continue to lead in innovation.

Provoking a trade and IP war with respect to pharmaceuticals could cost the U.S. its place as the leader in pharmaceutical innovation. This in turn would threaten national security, as the U.S. would no longer be able to react swiftly to new public health threats the way it did to the COVID-19 pandemic.

## **Pharmaceutical Tariffs Are Regressive**

Research by Geneva Network and others consistently demonstrates that pharmaceutical tariffs function as regressive taxes. They take a proportionally larger share of income from low-income patients and place the heaviest burden on those who are already vulnerable due to illness.

As another Geneva Network research note highlighted in 2020, tariffs are "essentially regressive taxes" that are "doubly regressive as the hardest hit are poorer people suffering from disease." This regressive impact is particularly problematic given ongoing concerns about healthcare affordability in the United States.

## Tariffs Contradict U.S. Leadership in Zero-Tariff Pharmaceutical Trade

The United States has long been a leader in promoting tariff-free trade in pharmaceuticals, recognizing the benefits for innovation, affordability, and public health. In 1995, the U.S. and 21 trading partners agreed to the WTO Pharmaceutical Agreement (the "Zero-for-Zero" initiative), eliminating duties on approximately 7,000 pharmaceutical products.

This agreement reflects a bipartisan understanding that patients and healthcare systems benefit when essential medicines flow unencumbered by duties. Imposing tariffs now would contradict decades of U.S. leadership in this area and potentially encourage other nations to raise their own pharmaceutical tariffs, creating a negative spiral for global medicine access.

### **Conclusion and Recommendation**

interests-against-unilateral-measures-adopted-by-other-countries-or-economic-blocs/; Bao, A. (2025, April 16). China targets U.S. services and other areas as it decries 'meaningless' tariff hikes on goods. CNBC. <a href="https://www.cnbc.com/2025/04/17/china-targets-us-services-and-other-areas-after-decrying-meaningless-tariff-hikes-on-goods-.html">https://www.cnbc.com/2025/04/17/china-targets-us-services-and-other-areas-after-decrying-meaningless-tariff-hikes-on-goods-.html</a>; Figures, T., et al. (2025, April 10). Behind the EU's tactical response to US tariffs. Boston Consulting Group. <a href="https://www.bcg.com/publications/2025/eu-response-to-us-tariffs">https://www.bcg.com/publications/2025/eu-response-to-us-tariffs</a>

<sup>&</sup>lt;sup>15</sup> Stevens, P., & Banik, N. (2020). Abolishing pharmaceutical and vaccine tariffs to promote access. Geneva Network Working Paper. <a href="https://geneva-network.com/wp-content/uploads/2020/07/2020-tariffs-on-pharmaceuticals.pdf">https://geneva-network.com/wp-content/uploads/2020/07/2020-tariffs-on-pharmaceuticals.pdf</a>

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Based on the extensive research cited above, we strongly urge that the Section 232 investigation not recommend tariffs on pharmaceuticals or pharmaceutical ingredients. Such tariffs would significantly harm American patients through higher prices and reduced access to medications, while failing to achieve their stated security objectives.

Instead, we recommend that the United States:

- 1. Maintain its commitment to tariff-free trade in pharmaceuticals
- 2. Address supply chain concerns through positive incentives for domestic manufacturing, such as tax credits and grants and through permitting and regulatory reform to enable building new manufacturing capacity
- 3. Strengthen international cooperation to ensure diverse, reliable sources of essential medicines

Thank you for considering our comments. We would be pleased to provide any further information or analysis that may assist in this investigation.

Sincerely,

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