WRITTEN SUBMISSION OF THE NATIONAL FOREIGN TRADE COUNCIL

Request for Public comments on

Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Docket No. 250414-0065 | BIS-2025-0022 | XRIN 0694-XC120

May 7, 2025

INTRODUCTION

This submission by the National Foreign Trade Council ("NFTC") is in response to the request for comments on the Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients ("the Notice") issued by the Bureau of Industry and Security ("BIS") of the Department of Commerce ("Commerce" or "DoC"). NFTC represents member companies with a significant foothold in the U.S., which have global operations, global customers and rely on global supply chains. Any actions that affect the importation of pharmaceuticals and pharmaceutical ingredients ("APIs") has the potential to impact a wide cross-section of NFTC members, not only leading pharmaceutical developers, but healthcare providers, medical device manufacturers, pharmacies and retailers, insurance providers, veterinary and animal drugs and supply chains, logistics firms, chemical manufacturers and food service companies. For this reason, it is imperative that extreme caution be exercised to ensure the scope of any actions be narrowly tailored to what is imperative to protect national security and that alternatives to tariff policies be considered and recommended.

About NFTC:

The NFTC, organized in 1914, is an association of U.S. business enterprises engaged in all aspects of international trade and investment. Our membership covers the full spectrum of industrial, commercial, financial, and service activities, accounting for over $6 trillion in revenue and employing nearly 6 million people in the United States.

OVERVIEW

NFTC and its member companies recognize the importance of evaluating vulnerabilities in critical supply chains and protecting national security in the face of growing geopolitical and economic uncertainty. The United States Government's rationale for launching this investigation, however, is not clearly articulated nor is the ultimate objective. We urge Commerce to approach this investigation with extreme caution, given the complex interdependencies that underpin the global pharmaceutical sector and the potential for unintended but significant harm to U.S. pharmaceutical development and manufacturing, to the American healthcare system and, most importantly, to the patients that rely on access to these life-saving medicines.

U.S. Pharmaceutical Market:

The U.S. pharmaceutical industry is a major driver of U.S. manufacturing, economic activity, and jobs. The pharmaceutical industry supports more than 1.7 million American jobs, and of the $393 billion in US consumer sales of finished pharmaceutical products, 64% or $251 billion is domestically produced and sold inside the United States[1]. The U.S. pharmaceutical supply chain is complex and intertwined with multiple reliable partners globally to enable the most optimal response to U.S. demand. Therefore, of the remaining 36% or $143 billion that are imported, nearly three-quarters come from Europe. Moreover, APIs made in the United States accounted for a majority (53%) of the $85.6 billion of API used in medicines consumed in the U.S.[2]

Scope:

We urge Commerce to avoid any restrictive import measures, in particular the application of import tariffs on any country with respect to:

- Branded or generic pharmaceuticals, including over-the-counter pharmaceuticals;
- Active pharmaceutical ingredients, including key starting material ("KSM");
- Medical devices, including any medical devices which may contain a pharmaceutical or API, as well as any product used in conjunction with a medical device, including contrast agents used in medical imaging procedures;
- Vitamins, dietary supplements, health-related products, or their derivatives;
- Veterinary and animal drugs, food, supplements, and their ingredients/inputs; as well as
- Chemicals, food ingredients, veterinary and animal supplements and drugs, or any other HS code which may relate to or be used as an input to an API but have non-pharmaceutical applications.

Furthermore, given the investigation is framed around pharmaceuticals and active pharmaceutical ingredients, we request that Commerce confirm that the following categories are respectively excluded from the scope of the investigation from the outset:

[1] Impacts of potential tariffs on the US pharmaceutical industry, Ernst and Young, April 2025

[2] US Makes Majority of API by Dollar Value in US-Consumed Medicines, June 2023

- Medical devices, including any medical devices which may contain a pharmaceutical or API, as well as any product used in conjunction with a medical device, including contrast agents used in medical imaging procedures;
- Vitamins, dietary supplements, health-related products, or their derivatives;
- Veterinary and animal drugs, food, supplements, and their ingredients/inputs; as well as
- Chemicals, food ingredients, or any other HS code which may relate to or be used as an input to an API but have non-pharmaceutical applications.

From here on out, unless specified otherwise, any reference to pharmaceuticals or pharmaceutical ingredients/APIs will refer specifically to:

- Branded or generic pharmaceuticals, including over-the-counter pharmaceuticals; and
- Active pharmaceutical ingredients, including key starting material.

Policy objective:

For the purposes of this investigation, we urge Commerce to focus the policy objective as narrowly as possible, and specifically to pharmaceuticals and APIs for the purpose of chemical, biological, radiological, and nuclear ("CBRN") national security threats. In doing so, the U.S. Government already has processes in place under the National Biodefense Strategy to prepare for CBRN threats. This includes the Strategic National Stockpile ("SNS") managed by Health and Human Services, which should be reviewed as a program in place that can mitigate such threats.

To the extent the government's objective is to incentivize the broader restructuring of pharmaceutical and API supply chains, there are a range of policy options that the government can consider, but there is no silver bullet.

It is not possible to utilize tariffs as a policy instrument to restructure pharmaceutical supply chains without irrevocable harm to drug manufacturing, to the health of Americans, and the American healthcare system. It will also be near impossible to avoid second-order effects on the out-of-scope products listed above. The application of tariffs risks weaponizing pharmaceuticals and APIs, which would further endanger the health, wellness, and lives of Americans and the industry trusted with protecting their health.

Risks of broad-based Tariffs:

Although the United States is a global leader in pharmaceutical development and a major pharmaceutical manufacturer, the United States does import APIs, KSMs, and finished products. This is for a number of reasons, including supply chain diversity, production efficiency, and cost control. If the United States were to apply tariffs on imports of pharmaceutical ingredients or KSM inputs, in particular from China, this would create new national security risks that are not present today. In response to other tariff actions, we have seen China utilize its export control regime and entity list, which, if applied in response to pharmaceutical tariffs on the sector, could create supply risks leading to drug shortages. This is why a positive supply chain agenda based on incentivizing U.S. investment and cooperation with allies over the medium-term to address national security vulnerabilities is advised.

Furthermore, given China supplies KSMs to a number of markets, it is essential that even a narrower application of tariffs on APIs and, in particular, derivative tariffs on KSMs are avoided. Tariffs on API or KSM derivatives will create increased costs of production among global trading partners that also source from China, including for finished drug imports and inputs. As a result, tariffs on pharmaceuticals and inputs will come at a cost to an American healthcare system that continues to be strained with higher insurance premiums, as well as costs for taxpayers through higher Medicare and Medicaid costs. A study conducted by Ernst and Young assessed the impact of a 25% tariff on the importation of pharmaceuticals, and found that it would increase costs by $50.8 billion, including $35.7 billion in increased costs for finished drugs and $15.1 billion increase in production costs to U.S. manufacturing through higher costs on inputs.[3]

These costs are substantial on the U.S. healthcare sector and patients, but if proper care does not fully exclude each of the bulleted categories above, the costs to U.S. consumers and the economy would rise dramatically; in particular if veterinary and animal medicines, non-pharmaceutical health and food products or other inputs or product categories are erroneously included. Depending on their scope, this could create risks and increased costs not only for the availability of medicines Americans rely on, but potentially for necessary veterinary drugs for livestock and companion animals, ingredients to foods themselves, in addition to broader supply chain and product risks. Finally, the costs of tariffs could also impact the availability of funding U.S. industry/companies have to invest in R&D for U.S. production.

Alternative actions:

Coordination with allies: U.S. national security is achieved not only through domestic manufacturing but also through diversified global manufacturing that avoids single points of failure.

- Allied cooperative frameworks similar to what is proposed under the bipartisan Medical Supply Chain Resiliency Act, enable USTR to enter into preferential and trusted supplier arrangements with a range of countries that can advance U.S. national security for pharmaceuticals, pharmaceutical products, and inputs.
- The United States is in active negotiations around addressing trade irritants or towards preferential trading arrangements with a number of countries - including India, Japan, Korea, and the United Kingdom - which could provide opportunities to reduce barriers and further pharmaceutical and API cooperation.
- The investigation should recognize the integrated North American region for both trade in inputs and finished products and exclude goods covered by USMCA.

Domestic and foreign incentives: The United States should take a long-term strategy to further incentivize manufacturing of pharmaceuticals and APIs that are considered to be critical for U.S. national security.

- The administration and Congress should advance policies, taxation frameworks, and strategies to support the domestic manufacturing of pharmaceuticals and APIs that are key to U.S. national security.

[3] Impacts of potential tariffs on the US pharmaceutical industry, Ernst and Young, April 2025

- Congress and the administration must prioritize not only the National Biodefense Strategy, but also the Administration for Strategic Preparedness and Response ("ASPR"), the Biomedical Advanced Research and Development Authority ("BARDA"), and other relevant agencies.
- This government prioritization must include regulatory streamlining in order to facilitate onshoring, which can be supported by the May 5 Regulatory Relief to Promote Domestic Production of Critical Medicines Executive Order. This review provides the opportunity to review the regulatory framework for new facilities to ensure safety and efficacy are prioritized while shortening the overall timeline for market approvals. Nevertheless, supply chain realignments take time. Current timelines for post-approval changes for API manufacturing in the United States, as one example, can take 3-7 years. Whereas even an Abbreviated New Drug Application ("ANDA"), a request to the U.S. Food and Drug Administration ("FDA") to manufacture and market a generic drug, can take more than 15 months to be approved.
- Workforce Training and Availability: The skills gap in the U.S. manufacturing sector is a critical barrier. According to Deloitte and The Manufacturing Institute, this gap could result in 2.1 million unfilled jobs by 2030, including technical skills and expertise in pharmaceutical manufacturing processes. Significant investment in education and vocational programs, along with collaboration with companies and government agencies, is required to train a workforce capable of meeting these demands.
- The administration and Congress should utilize tools, including the Development Finance Corporation, created under President Trump's first term, to support the development of key pharmaceuticals and in particular APIs and KSMs in trusted countries, where it is not economically or otherwise viable to reshore that manufacturing to the United States.

Other factors – recommendations:

While NFTC remains extremely concerned and is opposed to any application of tariffs on pharmaceuticals, on APIs, or on their inputs or derivatives, should the imposition of very narrow tariffs become necessary to protect national security, NFTC offers the following recommendations to facilitate smooth implementation while mitigating harmful effects on industry:

- BIS should establish an exclusion process that allows the modification of any tariffs to rectify any market or drug manufacturing risk while continuing to meet national security objectives.
    - This may be warranted for a range of products, including for Biosimilars which as low-margin drugs are more susceptible to drug shortages. Given the impact on access and affordability, effective tariff exemption mechanisms should allow companies to seek tariff exemptions.

- BIS should create a duty drawback process for tariffs imposed on pharmaceuticals and pharmaceutical ingredients.

- The customs clearance procedures should be clear and simple. Specific information requirements, such as the declaration of country of origin and content ratio as seen with tariffs on aluminum derivatives, may create confusion and pose a significant burden on

companies without clear guidance and adequate time for companies to gather necessary information. Compliance challenges arising from complex customs procedures should be mitigated to the maximum extent possible, as they could cause an increase in operational costs and delays in procurement procedures, further reducing the competitiveness of related businesses.

Thank you for the opportunity to present our comments. NFTC appreciates your consideration of these comments and that concerns be heeded around the systemic risks this 232 investigation could have on Americans and their health. If you have any questions regarding our comments, please contact Brad Wood, Senior Director for Trade and Innovation Policy (bwood@nftc.org).

Sincerely,

Brad Wood