DIABETES LEADERSHIP COUNCIL

DIABETES PATIENT ADVOCACY COALITION

May 6, 2025

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
United States Department of Commerce

Submitted via Regulations.gov

Re: Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket No. 250414-0065, XRIN 0694-XC120]

Dear Director Astle:

On behalf of the Diabetes Patient Advocacy Coalition (DPAC) and the Diabetes Leadership Council (DLC), we appreciate the opportunity to provide comments on the Bureau of Industry and Security's Section 232 investigation into the national security implications of imports of pharmaceuticals and active pharmaceutical ingredients (APIs).

DPAC is an alliance of people with diabetes, caregivers, patient advocates, health professionals, and others working together to support public policy initiatives to improve the lives of all 38 million Americans with diabetes. As an organization run by and for people with diabetes, DPAC seeks to ensure quality of and access to care, medications, and devices for people living with diabetes. DLC unites former leaders of national diabetes organizations, dedicated to securing effective, affordable health care for every person with diabetes.

We are extremely concerned that tariffs on pharmaceuticals and APIs will severely limit patients' ability to access the medicines they need at an affordable price, and will hamper the development of new, innovative medicines. Therefore, we ask that the Department focus its inquiry on specific, evidence-based national security risks and avoid tariffs that would have unintended and harmful consequences on patients and the U.S. health care system. Our specific concerns are outlined in more detail below.

Tariffs could interrupt patient access to medications by creating and exacerbating drug shortages. Medicines are critical components of patient care prescribed by licensed health care professionals to treat specific medical conditions that are often time-sensitive and life-threatening. Medicines are selected for a patient based on a number of factors including clinical efficacy, safety profile, and individual patient needs, so a patient cannot typically choose a substitute. For chronic conditions such as

diabetes, there are relatively few medicines, and those that do exist are highly specialized and not interchangeable.

The United States primarily imports medicines from allied countries such as Ireland, Switzerland, and the United Kingdom. While nearly two-thirds of all medicines consumed in the United States by value are manufactured domestically, the United States produces just 12% of the APIs used in Americans' prescriptions. More than half of these ingredients come from allies in Europe and India. [i]

As you know, pharmaceuticals have historically been exempt from tariffs, with all U.S. imports of medicines duty-free since 1994 under the World Trade Organization's Pharmaceutical Agreement. This exemption exists because of the extraordinary risks tariffs on medicines could pose to vulnerable patients.[ii] Quite simply, if companies are unable to import the necessary ingredients or drugs due to cost or availability, drug shortages are likely to occur.

Critical drug supply chains are already fragile and vulnerable, with 271 drugs currently in shortage. While this figure is down from a record 323 in early 2024, it is still alarmingly high. We have seen shortages of both diabetes and obesity drugs over the last few years, leading to patient delays in accessing the medications they need. Tariffs on medicines would further complicate and exacerbate these existing challenges, inevitably hurting U.S. patients by delaying or disrupting their access to medically necessary therapies, leading to immediate and significant impacts on health outcomes, diminished quality of life, and even death.

Tariffs could increase prices for patients and the federal government.
Estimates indicate that a 25 percent tariff would add $76 billion in costs to the economy[iii] and raise the price of medicines by as much as 10.5 percent.[iv] In one specific example, ING estimated that a 25% tariff could raise the cost of a 24-week generic cancer drug treatment by $8,000 to $10,000.[v] Uninsured patients would be most directly affected. However, these price increases would lead to higher premiums and out-of-pocket costs for insured patients in addition to restricted formularies and other methods of interrupting patient access.

Increased medicine costs would impact not just pharmaceutical companies and patients, but also the federal government. Public programs such as Medicaid and Medicare would face the same price increases.

Tariffs could interrupt manufacturer investment into research and development into new, innovative medications that help patients.
Tariffs would have a chilling effect on manufacturer efforts to develop breakthrough treatments and cures. Eli Lilly's CEO has already noted that absorbing some of the cost of any tariffs would necessitate cutting research and development.[vi] Other pharmaceutical companies have warned that they would be forced to absorb a large portion of tariff costs, with research and development efforts the likely first casualty.[vii] For patients with diseases that still have no cure, that is not an outcome we can afford.[viii] This interruption to innovation would further undermine America's pharmaceutical development and more important, would hurt patients by stifling innovation of new cures and treatments.

Tariffs could interrupt and disincentivize manufacturer investment in domestic production.
Nearly two-thirds of all medicines consumed in the United States by value are manufactured domestically, across a network of more than 1,500 facilities. This manufacturing base supports about 1.7 million American jobs. By value, America produces most medicines domestically and buys others mainly from Ireland, Germany, Switzerland, Singapore and a long list of allies, not from adversaries.

Tariffs would impose additional severe financial burdens on manufacturers already operating in the U.S. and would deter investments in additional manufacturing capacity needed to keep up with the health needs of Americans. According to some recent analyses, a 25% tariff on imported pharmaceutical products and critical inputs would increase industry costs by over $50 billion annually, which is roughly 13% of total U.S. pharmaceutical sales.[ix]

In addition to the increased cost, uncertainty about how long tariffs will be in place and the resulting inability to get needed supplies could actually disincentivize investment in long-term domestic production. If drug manufacturers are forced to contend with rising costs of ingredients, they may decide to reduce production as a cost-saving measure. That risk is exacerbated by the difficulty of restructuring supply chains on short notice. Eight in 10 U.S. biotech firms predict that it would take at least a year to find new, domestic suppliers in the event of tariffs, during which time their manufacturing capacity could be severely constrained.[x]

Higher production costs from tariffs would also erode the price competitiveness of U.S. exports, damaging our country's ability to export medicines, and would expose domestic manufacturers to retaliatory trade measures that would cause further harm.[xi] In 2023, the U.S. biopharmaceutical industry exported approximately $101 billion worth of pharmaceutical goods, demonstrating how critical this sector is in contributing to the country's overall trade balance.[xii] Damaging the competitiveness of U.S. manufacturers is the opposite of the intended effect of the tariffs. Ultimately, tariffs would threaten not only the immediate operational viability of domestic pharmaceutical manufacturing but also the long-term strategic interests of the United States in maintaining its leadership position in global health innovation and production.[xiii]

Conclusion: Protect a stable, reliable, patient-centered pharmaceutical supply chain.
Policies designed to strengthen the security and resilience of the pharmaceutical supply chain must prioritize the needs of patients, ensuring the uninterrupted availability of safe, effective, and affordable treatments for all individuals, particularly those with serious, chronic, and rare conditions. The Administration should pursue strategies that enhance domestic manufacturing capacity through supportive measures, while preserving strong international partnerships that have long contributed to patient access and health system stability.

Before implementing any tariffs on medical devices or drugs, we urge the Administration to:

- Conduct analysis on the impact tariffs could have on the pricing and shortages of drugs and the potential resulting impact this would have on patients; and
- Seek additional input from patient groups, physicians, manufacturers, and other experts to determine the impact these tariffs would have on patient access and care.

As a country, we should be focused on increased patient access and affordability of medicines, something the President and his Administration committed to prioritize in his April 15 Executive Order calling for lower drug prices.[xiv] Tariffs run counter to that commitment and should be focused on areas where there is a legitimate national security risk. Rather than introducing new vulnerabilities through tariff-based interventions, federal policy should build upon proven strengths, including safeguarding public health by maintaining a stable, reliable, and patient-centered pharmaceutical supply chain.

Thank you for your consideration of these comments. We stand ready to work with you to protect and strengthen patients' access to the critical medicines they rely on.

Sincerely,

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