May 5, 2025

The Honorable Howard W. Lutnick
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, D.C. 20230

Re: Section 232 Investigation of Imports of Certain Pharmaceuticals and Pharmaceutical Ingredients

Dear Secretary Lutnick,

On behalf of the End Drug Shortages Alliance (EDSA), I write to express our appreciation for the opportunity to comment on the Department of Commerce's Section 232 investigation into the national security implications of imports of certain pharmaceutical products and ingredients. EDSA is an alliance representing diverse industry perspectives including patient advocacy organizations, group purchasing organizations, health systems, suppliers, and distributors dedicated to solving the pharmaceutical supply challenges that disrupt access to essential medications in the U.S.

We urge a cautious and strategic approach that considers the complex nature of drug manufacturing, distribution, and patient care to avoid unintended consequences for the availability of essential medicines [1],[2] for all patient populations in the United States.

On behalf of EDSA, we respectfully request an exemption from tariffs for pharmaceuticals and their ingredients. Generics form the foundation of our healthcare system, accounting for 90% of U.S. prescriptions filled, and only 17.5% of prescription drug spending.[3] Yet, generic medications already experience a disproportionate share of supply disruptions. Any additional financial or logistical barriers risk further compromising patient access to critical therapies.

Accordingly, we ask that the Administration not impose tariffs on medicines that are most essential to patients, particularly those identified as shortage-prone, or without viable therapeutic alternatives. A targeted, patient-centered exemption framework will help preserve the availability, affordability, and resiliency of the pharmaceutical supply chain, especially for the treatments that patients and providers rely on every day.

Drug Shortages: A Persistent and Growing Threat to Patient Care

America's vulnerability to drug shortages continues to highlight the importance of proactive supply chain resilience strategies. When essential medications are in short supply, hospitals, clinics, and pharmacies make difficult decisions that can delay or otherwise impact care. Drug shortages are particularly challenging in pediatric healthcare since an appropriate substitute specifically geared for

[1] World Health Organization. WHO Model Lists of Essential Medicines. 2023.
[2] U.S. Food and Drug Administration. Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs. 2022.
[3] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. (September 2023).

children might not be readily available, leading to increased rates of drug errors and detrimental impacts on their long-term health. These shortages strain the healthcare system, compromise treatment protocols, and increase the risk of adverse outcomes.

To mitigate these risks, we must invest in a more diversified, transparent, and geographically distributed pharmaceutical supply chain. This includes strengthening domestic manufacturing capacity, fostering strong international partnerships, improving coordination between federal agencies and the private sector, and incentivizing practices that prioritize quality and reliability. Without careful deliberate action, these vulnerabilities will persist—and the consequences will continue to escalate.

Tariffs Are a Risk to Medicine Availability

We understand that disruptions in pharmaceutical supply chains can threaten, at times, both public health and national security. Therefore, it is also imperative that efforts are made to avoid disruptions in the supply chain while considering policy approaches. As outlined in the Brookings article *Pharmaceutical Tariffs: Will pharmaceutical tariffs achieve their goals?* [4], the global pharmaceutical industry is built on specialized, interdependent production chains. Disruptions arising from Section 232 actions (particularly with generic manufacturers) could lead to cascading disruptions to patient care. Generic manufacturers supply the majority of essential, low-cost medications used in hospitals and outpatient settings. Shortages place pressure on hospital purchasers and health systems, who rely on stable, affordable access to generic medications, particularly for sterile injectables and other vulnerable product classes. Since reimbursement is prospectively set, hospitals and health systems, which are part of a critical sector and already operate on narrow margins, would be even more vulnerable financially if acquisition prices increased.

Similarly, we are concerned that tariff-related cost increases could erode the financial viability of generic manufacturers, leading to reduced manufacturing capacity, market exit, or product discontinuations. Establishing domestic manufacturing capacity can take a significant amount of time (three to five years or more). We cannot risk going without critical medications while the new capacity is being built.

Tariffs, which for pharmaceuticals have historically been based on the country where the active pharmaceutical ingredient was made, are likely to be ineffective at addressing foreign reliance on upstream manufacturing inputs such as key starting materials (KSM) and active pharmaceutical ingredients (API). Tariffs on allied countries threaten U.S. ability to differentiate supply away from high-risk regions.

The U.S. Pharmacopeia (USP) recently analyzed the geographic concentration of U.S. prescription API manufacturing (the substance in a medication that provides the pharmacological activity), by volume. The analysis found that major hubs of production are India and the European Union (EU); generic drugs come primarily from India and 43% of branded pharmaceutical API comes from the EU. The United

[4] Wosińska, Marta. (2025, March 17). Will pharmaceutical tariffs achieve their goals? Brookings, retrieved from https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/.

States accounts for 12% of total API volume analyzed. China contributes 8% of the total volume of API. However, there is case-by-case evidence of significant dependence on China for KSM.[5]

Tariffs intended to bolster the domestic industry may inadvertently weaken the generic manufacturer and healthcare sectors, reduce competition, and increase healthcare costs. We must carefully weigh these downstream effects when determining the appropriateness of trade measures, ensuring that availability of essential medicines for patient care remains a central consideration in any national pharmaceutical policy framework.

Recommendations for True Resilience

Reshoring without sustainable economic models and infrastructure will not change the ability to yield rapid or resilient supply. As USP's Medicine Supply Map illustrates, medicine supply risk is not evenly distributed; therefore, targeted interventions, particularly incentives, are recommended to stabilize access and address national security interests.

Given the risk of supply chain disruptions and drug shortages associated with tariffs, we recommend prioritizing positive financial incentives to support domestic capital investment, encouraging U.S.-based pharmaceutical manufacturing, and strengthening international partnerships with high-quality manufacturers that do not pose a national security risk.

Conclusion

As the End Drug Shortages Alliance has emphasized throughout this letter, addressing national security concerns must be carefully balanced with protecting the availability and affordability of essential medications. We urge the Department to consider policies that build long-term resilience without compromising patient access.

The End Drug Shortages Alliance stands ready to collaborate with the Department of Commerce and other stakeholders to develop forward-looking strategies that strengthen our pharmaceutical supply chain while safeguarding public health.

Respectfully,

April Giles
Executive Director
End Drug Shortages Alliance

[5] U.S. Pharmacopeia (2025, April 17). "Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union." Retrieved from https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european