



May 7, 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 *Angels for Change* (A4C), the only non-profit patient advocacy organization solely dedicated to ending drug shortages, I appreciate the opportunity to submit comments regarding the Department of Commerce's Section 232 investigation into the impact of pharmaceutical imports on national security.

Angels for Change is a volunteer-supported organization committed to ensuring patient access. Our mission is to end drug shortages through advocacy, awareness, and a resilient supply chain. We work across the healthcare ecosystem, connecting patients, providers, and manufacturers to prevent and resolve drug shortages.

My personal journey with this crisis began when my child experienced three life-threatening shortages during pediatric cancer treatment. No family should face a drug shortage. No child should wonder if they will die because there wasn't enough medicine made to save them. Yet drug shortages are at an all-time high. We continue to witness a fragile drug supply chain – one where minor disruption can lead to catastrophic consequences for patients and providers alike.

Tariff Concerns and Patient Impact

I write today to respectfully urge the Administration to exempt pharmaceutical products and ingredients – especially Generic Sterile Injectables (GSI) – from Section 232 tariffs. These are the medicines most vulnerable to disruption and most essential to everyday healthcare delivery. Tariffs risk compounding the already fragile economics of this sector, potentially leading to more frequent and prolonged shortages. This is the supply chain that fills the hands that save our people, and we must ensure patients have care.



Drivers of Drug Shortages

Drug shortages are driven by economics. The four drivers are:

- **Low pricing:** Lower-cost drugs are disproportionately at risk. In 2023, 85% of generic injectables in shortage cost under \$15.
- **Geographic concentration:** Both international and domestic over-concentration reduce resilience and increase shortages.
- **Quality failures:** Quality issues often recur and lead to shutdowns.
- **Complex manufacturing:** Injectable drugs are particularly vulnerable to production delays.

Generic sterile injectables make up the majority of drug shortages (56%) and are the backbone of routine and emergency treatments. Unfortunately, the GSI supply chain lacks the financial and systemic resilience to withstand additional burdens, such as tariffs. Many of these medicines are lifesaving yet sell for pennies, leaving extremely narrow margins which incentivize low investments and discontinuations. In fact, discontinuations of GSIs are on the rise, increasing 40% last year. Angels for Change is concerned that, given these broken economics, pharmaceutical tariffs would inadvertently cause permanent disruptions that could have devastating impacts on routine and critical health care in the United States.

Toward a Stronger Supply Chain

Improving supply chain security requires targeted incentives that address geographic concentration, as opposed to punitive measures. Solutions should:

- Encourage both domestic and international production of KSMs, APIs, and finished products.
- Support market entry for manufacturers
- Reward reliability and resiliency through increased reimbursement
- Promote multi-sourcing, just-in-case supply, and activate dormant capacity
- Include public-private partnerships to build long-term resilience

Through our *Project PROTECT* initiative, we've demonstrated how U.S. based 503B compounders can play a key role in emergency response – but they still rely on globally sourced ingredients as all manufacturers. Any policy that disrupts ingredient access will disrupt this brittle market that breaks too often.



Before the market is ready to withstand any changes caused by pharmaceutical tariffs, we need to fix some of the long-term challenges in the supply chain by efficiently changing purchasing behavior, moving the essential medicines market toward sustainability, incentivizing resiliency, and increasing patient access.

The Drug Shortage Hotline (DSH)

Angels for Change operates the nation's only Drug Shortage Hotline (DSH). Through our Global Supply Sharing Network (GSSN), we maintain a 98% success rate in resolving access issues during GSI shortages. As policy uncertainty has increased, we have already experienced a rise in calls looking for support. Many providers are considering proactive purchasing to relieve anxiety – a behavior that creates demand shocks and can itself trigger shortages.

I am concerned that, should Section 232 actions cause disruptions in the supply chain, the Hotline would experience further increased volume that we would be unable to keep up with. Strategies to mitigate the impact of drug shortages, such as the Hotline, only work in collaboration with efforts to prevent shortages before they happen. We respectfully request collaboration with the Administration to prepare our Hotline and broader GSSN infrastructure for any potential disruptions caused by Section 232 actions, and request to work with the Administration on initiatives to strengthen the essential medicines supply chain.

Conclusion and Recommendations

Drug shortages are a systemic threat to patient care and national health security. Any new policy such as pharmaceutical tariffs must be assessed in terms of its impact on an already fragile supply chain. Our recommendations for strengthening the supply chain include:

- Implementing payment reform to reward manufacturing reliability and resiliency.
- Supporting mitigation tools like the Drug Shortage Hotline (DSH) and *Project PROTECT*.
- Partnering with multi-stakeholder groups such as the Duke-Margolis Institute, the End Drug Shortages Alliance, and the USP Drug Shortage Task Force to build the resiliency.

Attached are our policy recommendations to Congress and the Administration, outlining near- and long-term practical solutions to end drug shortages for all patients. These policies would help build a stronger and more resilient supply chain for treatments our citizens rely on every day.



Thank you for the opportunity to share our perspective. We stand ready to support the Administration's efforts to build the supply chain of the future and ensure patients are protected from drug shortages for today's therapies and tomorrow's cures.

Sincerely,

Founder, Chief Change Maker

Angels for Change

(352) 200-0021 | laurabray@angelsforchange.org