May 7, 2025

Bureau of Industry and Security
Office of Strategic Industries and Economic Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, DC 20230

RE: Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients; XRIN 0694-XC120

To Whom It May Concern:

On behalf of FMI – The Food Industry Association[1] and the tens of thousands supermarket pharmacies operated by our member companies, thank you for the opportunity to provide comments regarding the Department of Commerce's Section 232 investigation into the national security implications of imports of pharmaceutical products, ingredients, and supplies.

FMI represents the food industry, including grocery companies that operate retail pharmacies across the United States. These pharmacies play an essential role in ensuring access to medications for millions of Americans, often serving as a last point of care in communities facing provider shortages. We strongly support the Administration's goals of strengthening domestic pharmaceutical supply chains and increasing U.S. manufacturing of active pharmaceutical ingredients (APIs) and key starting materials (KSMs). However, broad-based tariffs on pharmaceutical imports – particularly without

[1] As the food industry association, FMI works with and on behalf of the entire industry – from grocery companies that operate retail pharmacies across the United States, to producers that supply food and other products – to advance safer and more efficient consumer supply chains for both food and pharmaceuticals. In total, FMI member companies, which range from independent operators to the largest national and international players, operate roughly 33,000 grocery stores and more than 12,000 pharmacies. Altogether, we are an $800 billion industry with nearly 6 million employees that touches the lives of more than 100 million U.S. households on a weekly basis. www.fmi.org

national security-based, targeted exclusions or implementation safeguards – would have serious unintended consequences for pharmacy operations, patient access, and public health. FMI urges the Administration to consider a more targeted, phased strategy – one that supports national security objectives, drives domestic innovation and industrial growth, and avoids disruption to pharmacy operations and patient access.

Drug Shortages and Supply Chain Fragility

Pharmacy operators are already navigating widespread drug shortages, particularly among generics and sterile injectables. Further disruption through tariffs would likely worsen this trend. Tariffs will almost certainly worsen these shortages, threatening the availability of many medications that patients rely on daily. In a March 2025 survey of FMI's Pharmacy Operations Task Force, 64% of retail pharmacy operators said they expect pharmaceutical tariffs would directly lead to shortages of critical products. None expected domestic production to scale quickly enough to prevent major disruptions.[2]

The generic drug industry, which accounts for 90% of all dispensed medications in the U.S., operates on narrow margins and depends on a highly globalized supply chain. Tariffs on APIs or finished dosage forms could erode these margins to the point that it disincentivizes manufacturers from remaining in the market, leading to additional shortages and higher costs across the supply chain, including for essential medications intended to manage and treat chronic disease.

While we support longer-term efforts to onshore production of strategic pharmaceuticals, doing so at scale will require significant time and investment. Building a compliant pharmaceutical manufacturing facility can take three to five years or more and cost upwards of $2 billion, with additional time needed for regulatory approvals and for sourcing and qualifying new API suppliers. Although long-term investments in domestic production are underway, they will not alleviate the immediate impacts of reduced access and rising prices. Even then, domestic production is not immune to disruptions, including natural disasters, labor shortages, equipment failures, and other risks.

The experience of Phlow Corporation – a U.S. manufacturer that received over $500 million in federal funding to support domestic API production – is instructive. Despite that level of investment, it took nearly four years to become operational and is expected to take more than five years before finished drug products are available to patients through downstream partners.

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[2] FMI Pharmacy Operations Task Force Survey, March 2025: 24 responding supermarket companies representing nearly 14,000 stores and 8,400 company-operated pharmacies. Responses collected between March 4 and March 28, 2025.

Supermarket pharmacies will not have the luxury of waiting years for new supply chains to materialize. As shortages increase and acquisition costs rise, patients will begin losing access to essential medications almost immediately – especially in communities that are already medically underserved.

Pharmacy Reimbursement, Viability, and Sustainability

Pharmacies operate under contract with pharmacy benefit managers (PBMs), which reimburse pharmacies at pre-negotiated rates for both brand and generic drugs. These reimbursement rates, which are negotiated annually, are typically tied to pricing benchmarks or indexes that do not adjust to reflect rising acquisition costs. In short, pharmacy reimbursement rates remain static even as drug costs rise, placing increased financial pressure on dispensers. In FMI's recent survey, 87% of responding FMI pharmacy members expressed concern about the price increases that tariffs would trigger on pharmaceutical products, ingredients, and supplies. Nearly 60% expect their pharmacy costs to rise by at least 6-10%, with one-third anticipating increases as high as 16-20%.[3]

These increased costs cannot be absorbed by most pharmacies and risk worsening the affordability challenges already faced by patients and caregivers. FMI members report that without corresponding increases in reimbursement, nearly all expect negative impacts on the financial sustainability of their pharmacies, while half of respondents said tariffs would impair their ability to continue offering competitive pricing to patients. Alarmingly, 29% indicated they would likely consider closing some of their pharmacy locations, while 36% said they may stop stocking impacted generic drugs if tariffs make them financially untenable.[4] At a time when cost and accessibility are paramount, we cannot afford disruptions that threaten medication adherence – particularly for patients managing chronic conditions.

We are already seeing a wave of pharmacy closures across the country due to a combination of low reimbursement rates and high operational costs. Imposing tariffs without corresponding policy adjustments will only accelerate this trend – particularly in underserved areas where pharmacies are already stretched thin.

[3] Ibid.
[4] Ibid.

The Case for a Phased, Targeted Approach

FMI urges the Department to consider a more nuanced strategy – one that supports national security objectives while avoiding disruption to pharmacy operations and patient access. Specifically, we recommend:

- Excluding generic drugs and APIs for essential medications dispensed by retail pharmacies from any immediate tariff actions;
- Delaying implementation of tariffs or staging them for several years, allowing time to scale up U.S. manufacturing and permitting the development of resilient domestic supply chains;
- Considering country-specific exemptions, particularly for trading partners like India, the European Union, Switzerland, Japan, and the United Kingdom that play a critical role in supplying affordable generics; and
- Advancing parallel policy reforms to incentivize domestic production without destabilizing existing pharmacy access. This includes:
  - Financial incentives and long-term contracts for U.S. manufacturers;
  - Regulatory flexibility to expedite generic drug approvals;
  - Public payer reimbursement enhancements for drugs made in the U.S.; and
  - Policies that encourage supply chain diversification, not just onshoring.

Importantly, while nearly all surveyed members said they would be willing to transition to domestically produced pharmaceutical ingredients if pricing remained competitive, 71% believe it will take at least three years before domestic production can replace what is currently imported.[5] These timelines should be fully accounted for before implementing any trade restrictions.

Additionally, given the complexity of the pharmaceutical product lifecycle and the wide-ranging implications of proposed tariffs, we strongly encourage the Department to convene a multi-sector industry dialogue before any action is taken. Engaging stakeholders from across the supply chain – including pharmacy operators, manufacturers, payers, and patient advocates – would help the Administration better understand real-world implications, clarify sector-specific impacts, and develop appropriately targeted responses that directly address national security concerns without compromising public health.

[5] Ibid.

Conclusion

We share the goal of building a secure and resilient pharmaceutical supply chain. However, broadly applied tariffs – especially if implemented without key safeguards – risk doing more harm than good in the near term. The risks are not theoretical: drug shortages are likely to intensify, patients will increasingly lose access to medications and face higher costs, and pharmacies will close. These are entirely foreseeable and avoidable outcomes. A more targeted, phased approach – coupled with meaningful investments and regulatory coordination – offers a more responsible and effective path forward.

We appreciate the opportunity to share these perspectives and welcome continued engagement with the Administration as this investigation proceeds. If you have any questions or wish to discuss the topic in greater detail, please do not hesitate to contact me at aharig@fmi.org or (202) 452-8444.

Sincerely,

Andy Harig
Vice President, Tax, Trade, Sustainability & Policy Development