DEPARTMENT OF COMMERCE

Bureau of Industry and Security
[Docket No. BIS-2025-0022] [Reference Code XRIN 0694-XC120]
Comments on Section 232 National Security Investigation of Pharmaceutical and API Imports

Executive Summary

Demand Growth: U.S. pharmaceutical demand is expanding ~6 % annually—$806B now—and retail prescription outlays reached $450 B in 2023, underscoring the need for a secure supply chain.

Foreign Dependence: Over 60% of daily drug doses and two-thirds of generics rely on India/China; sterile injectables and DoD supplies face acute vulnerability to export restrictions and quality lapses. Tariffs would substantially increase costs and disrupt supply to the United States.

Economic Distortions: State-sponsored overproduction and subsidized pricing have depressed global prices for a number of generic products, eroding U.S. manufacturing output, jobs, and innovation. However, Tariffs would substantially increase the estimated $359M in annual hospital shortage-management costs.

Security Threats: Over 70 COVID-era export bans expose critical national health-security gaps.

Onshoring Feasibility: Significant idle capacity, continuous-processing, 3D printing, and public–private roadmaps make domestic scale-up practicable provided the right incentives and regulatory frameworks apply.

Public–Private Collaboration: HIRC's Resiliency Badge Program—evaluating 300+ critical diagnostic categories—aligns with HHS's MRAP proposal and provides a scalable model for true resiliency: prediction, prevention, and recovery.

Introduction

The Healthcare Industry Resilience Collaborative (HIRC) is a non-profit healthcare supply chain resiliency consortium representing 80 hospitals, health systems, medical manufacturers, distributors, and group purchasing organizations across 30 states. We appreciate the opportunity to comment on the Administration's Section 232 investigation into pharmaceutical and API imports and its implications for national health-security and healthcare costs.

The sections below align with the questions posed in the Federal Register notice (Docket No. BIS-2025-0022), addressing demand, foreign reliance, economic impacts, security vulnerabilities, domestic capacity, hospital finances, and collaboration frameworks.

#1. Current and Projected Demand

U.S. demand for pharmaceutical therapies continues to grow at an average annual rate of 6 percent, driven by population health, such as an aging population and a rising prevalence of chronic, age-associated conditions and also due to innovation, for example, new drug approvals and biosimilar expansion [1]. In 2024, total demand reached approximately $806B [1] and is projected to exceed 1T by 2030 [2]. Retail prescription outlays alone hit $450B in 2023 and are expected to keep rising at roughly 6 percent annually through 2032 [3][4]. This sustained expansion in both finished-drug and active-ingredient needs underscores the critical importance of a reliable, secure U.S. supply chain to ensure patient care and bolster health-system resilience [5].

#3. Role of Foreign Supply Chains

U.S. pharmaceutical supply chains—in particular, certain generic medicines—have shifted dramatically toward overseas producers. In certain markets, government-backed subsidies allow them to undercut domestic manufacturers—seizing market share and later wielding pricing power over American patients [6]. Targeted relief through antidumping and countervailing duty laws may be appropriate to address these issues. Today, the United States depends on imports for over two-thirds of its generic medications, with nearly 90 percent of generic API production facilities based abroad [16][17]. In particular, certain producers benefit from substantially larger state-supported financing—often through below-market loans—enabling them to expand aggressively into global pharmaceutical markets [7]. However, for the industry as a whole, other trade partners including allies such as Europe and India are a critical part of global supply chains. A recent GAO report found that, as of October 2022, more than half of the manufacturing sites supplying pharmaceuticals to the U.S. were located overseas [8]. More than half of all drug-product manufacturers supplying the U.S. market are located overseas—primarily in India and China—resulting in over 60 percent of U.S. daily drug doses (finished products and APIs alike) originating from those two countries [8][9]. While shortages are not primarily driven by global supply chains, but rather by U.S. market dynamics, the Department of Defense flags more than half of its pharmaceutical supply chain as “high” or “very high” risk—only 28 percent of its APIs are North American–sourced—underscoring the national-security stakes [10]. Together, these realities highlight the urgent need to expand domestic API and finished-product capacity and strengthen supply-chain resiliency.

#6. Economic Impact of Artificially Suppressed Prices

For certain generic products, U.S. pharmaceutical competitiveness has suffered as state-backed foreign manufacturers drive prices down to oust domestic rivals—only to hike costs once they secure market dominance [6]. The share of API Drug Master Files filed by U.S. facilities declined from 15% in 2000 to 4% in 2021, indicating a significant decrease in the number of domestic API manufacturing sites. [11]. U.S. market dynamics contribute significantly to depressed prices which result in supply-chain fragility: U.S. hospitals spend an estimated $359M annually in extra labor costs managing drug shortages and sourcing alternatives when supply breaks occur [12]. However, tariffs on medicines and inputs could

exacerbate this fragility given the considerable time and expense needed to expand manufacturing capacity in the United States. Persistently low generic drug prices—driven by market dynamics such as lack of transparency and purchasing consolidation—leave manufacturers with insufficient incentives to invest in redundant or resilient manufacturing and distribution networks, weakening the overall supply chain. [13].

#7. Export Restrictions on Pharmaceutical Supplies

During the COVID-19 pandemic, more than 70 export restrictions were imposed by over 45 countries, demonstrating this threat in action [14]. Awareness of dependencies and commitments with allies is a necessary priority. India and China together account for 57.6 percent of U.S. pharmaceutical imports by weight—nearly all generics, which constitute 91 percent of prescription drug volumes—further concentrating supply vulnerability [16][17]. Bottom line: with roughly 90 percent of U.S. prescription drugs either containing APIs sourced from or finished in India and China—and with key production in a handful of large, state-backed facilities—the nation faces substantial risk that these foreign governments could restrict supply chains in a crisis, in the absence of clear commitments not to do so. To mitigate this vulnerability, the U.S. must diversify API and drug-product manufacturing with allies and bolster strategic stockpiles.

#8. Feasibility of Increasing Domestic Capacity

While additional time will be needed to secure the needed regulatory approvals, the U.S. is well positioned to expand domestic pharmaceutical and API production by leveraging existing under-used capacity and embracing advanced manufacturing innovations—only two of 37 generic-drug sites operate near full utilization and nearly 30 percent run at 50 percent capacity or less, while FDA Task Force recommendations for continuous processing, 3D printing, Quality Management Maturity programs, and public–private partnerships lay out a clear roadmap to reduce import reliance and boost efficiency, cost-effectiveness, and product quality [18]. Despite possessing significant manufacturing infrastructure for finished dosage forms, much of it remains under-utilized [19]. In fact, half of U.S. generic-drug manufacturing sites operate below their full capacity [20]. However, utilizing this capacity and expanding US protection will take time, which is why broad tariffs will result in significant near term impacts on cost for hospitals and other providers. Building new cGMP API plants is capital- and time-intensive [21]—typically requiring five to ten years for construction and validation at a cost of $1–3B each [22]. Rather than tariffs, accelerate growth, federal actions such as streamlined regulatory approvals and permitting, direct subsidies, and targeted tax incentives will be essential to mobilize investment and scale domestic drug and API manufacturing.

Additional Considerations

Hospital Financial Vulnerability

Many U.S. hospitals continue to operate under financial strain, with 39 percent running negative operating margins in 2023 [23][24], and median margins stabilizing at just 6 percent by late 2024 [25]. According to a 2025 Becker's survey, 82 percent of hospital CFOs

predict a 15 percent increase in supply-chain costs if current policies persist, exacerbating this fragility and threatening care continuity [25]. Many community hospitals lack the capital to retool for domestic sourcing, underscoring the need for targeted financial support and the need to avoid broad tariffs on health products.

Public-Private Collaboration for Supply Chain Resiliency

True supply-chain resiliency goes far beyond simply "on-shoring"—it's the ability to predict, prevent, and recover from disruptions before they cascade into shortages. HIRC's Resiliency Badge Program, launched in 2024, delivers precisely that capability:

- Exhaustive Diagnostics (300+ Categories): Unlike narrow geographic diversification metrics, the Badge assesses more than 300 critical diagnostic categories—ranging from raw-material sourcing through final delivery—to uncover hidden single-points-of-failure.
- Proven Industry Validation: Deployed with five major healthcare suppliers (including a leading pharmaceutical manufacturer), the program has earned strong feedback on its rigorous methodology and actionable insights.
- DoD & VA Relevance: Its deep-dive diagnostics align with Defense and Veterans Affairs priorities for secure medical logistics, enabling military and VA hospitals to pre-emptively shore up at-risk nodes.
- GPO Integration: National group-purchasing organizations have already woven Badge metrics into strategic sourcing agreements, ensuring that resiliency scores directly influence procurement decisions.
- Alignment with HHS MRAP: Fully mirrors the Health and Human Services' Manufacturer Resiliency Assessment Program proposal, giving federal agencies a turnkey, scalable toolkit for monitoring and improving supply-chain health [5][26].

By partnering with the Commerce Bureau of Industry and Security, HHS, DoD, VA, and industry stakeholders, HIRC can rapidly expand this proven model across all U.S. healthcare systems—embedding predictive, preventive, and recovery capabilities into federal and private-sector practice.

Recommendations

• Expand domestic API and finished-drug manufacturing through targeted incentives and streamlined regulatory pathways.

• Provide financial support for at-risk health systems to enable capital investments in domestic sourcing and resiliency enhancements.

• Launch a public–private working group anchored by HIRC to scale the Resiliency Badge Program and elevate supply-chain resilience in healthcare.

• Increase federal funding for advanced manufacturing technologies.

• Avoid broad tariffs on medical products which will contribute to shortages and exacerbate cost pressures on hospitals.

Conclusion

We urge financial support for health systems to enable domestic pharmaceutical sourcing, robust incentives for domestic production, and the swift establishment of an HIRC-anchored public–private working group to expand the Resiliency Badge Program. We stand ready to convene the inaugural meeting within 30 days of approval to operationalize these recommendations and secure our nation's healthcare supply chains as an all-of-industry approach with our Federal partners.

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