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Public Comment on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Submitted To: U.S. Department of Commerce, Bureau of Industry and Security

Docket ID: BIS-2025-0022

Reference: XRIN 0694-XC120

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Date: May-06-2025

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On behalf of Rising Pharma Holdings, Inc., we appreciate the opportunity to submit comments in response to the Department of Commerce's Section 232 investigation into the national security implications of imports of pharmaceuticals and pharmaceutical ingredients.

We have addressed the ten criteria outlined in the investigation notice below:

(i) Current and projected demand for pharmaceuticals and pharmaceutical ingredients in the U.S.: Generic drugs make up approximately 90% of all prescriptions filled in the U.S., and this market is only growing due to the aging population, chronic diseases, and cost containment pressures favoring generics. The majority of generic products depend on 1) foreign-sourced active pharmaceutical ingredients (APIs) and precursors regardless of their country of manufacture, and 2) in many cases generic finished dosage forms are also manufactured in a foreign country before being imported to the US. Most of the APIs are coming from China (~40%), India (20-25%), Europe (15-20%), and US (~10%). Tariffs that affect the availability and cost of ingredient inputs and/or the finished dosage product will directly impact the ability to meet domestic demand, risking both price inflation and access challenges across the healthcare spectrum.

(ii) Extent to which domestic production can meet demand: Domestic pharmaceutical production, especially for high-volume generic oral solid products (e.g., tablets or capsules), faces fundamental cost disadvantages. Most generic oral solid products are produced overseas for less than $1 per 100 units --- a cost point virtually impossible to achieve in the U.S. due to higher labor, energy, and packaging costs. This cost disparity is even more pronounced in injectable manufacturing. Globally, the cost of producing sterile vials or ampoules can be well under $1 per unit. These same products, if manufactured in the U.S., often cost multiple times more, particularly for high-volume, low-margin products. Injectables also require specialized sterile facilities (which are capital intensive and highly regulated), shifting their production domestically without a clear cost-offsetting mechanism would dramatically increase drug prices and create drug shortages.

(iii) Role of foreign supply chains, particularly of major exporters: Foreign supply chains are essential for meeting current U.S. demand affordably. China plays a central role in supplying raw materials, APIs, and fermentation-based pharmaceutical intermediates to the global market. This dominance is driven by several structural advantages: relaxed environmental regulations, low-cost power, and abundant groundwater access, particularly important for fermentation-based APIs, e.g. anti-infective ingredients, that require reactor cooling. These advantages make it practically impossible to manufacture certain APIs in the U.S. at competitive cost or scale, unless the U.S. government intervenes to fundamentally revise environmental

and permitting standards.

(iv) Concentration of imports from limited suppliers and associated risks: The U.S. pharmaceutical supply chain operates through a globally layered and interdependent structure. According to the FDA, approximately 72% of API manufacturing sites registered to supply the U.S. market are located overseas. India and China play important roles - India in manufacturing generic finished dosages and APIs, and China in supplying key starting materials (KSMs) and chemical intermediates that are used globally.

The U.S. maintains meaningful domestic production capabilities, particularly for specialty APIs, controlled substances, and sterile injectables, with companies like Ampac, Cambrex, Albemarle, Thermo Fisher, and Mallinckrodt playing important roles, but they too rely heavily on global pharmaceutical supply chains to make their products. Instead of representing a single point of failure, the U.S. pharmaceutical supply chain reflects a distributed and collaborative model, where strategic dependencies span trusted partners.

(v) Impact of foreign government subsidies and predatory practices: While foreign subsidies may exist (although there is limited evidence), the primary drivers of offshore generic manufacturing are lower labor/operational costs, different regulatory/environmental standards (e.g., China's advantages in power/water for fermentation), and established infrastructure/expertise, enabling the extremely low prices demanded by the U.S. market. U.S. firms often focus on higher-margin specialty/branded drugs. The competitiveness issue for U.S. generic manufacturing is significantly impacted by unsustainably low U.S. reimbursement rates and intense domestic price competition.

(vi) Economic impact of artificially suppressed foreign prices: Generic drug prices are low globally due to intense competition post-patent expiry. While U.S. prices for generics are among the lowest globally (U.S. generic prices are reported to be ~67% of OECD average), this reflects the highly competitive U.S. market and purchaser dynamics. Attributing low generic prices solely to "artificially suppressed foreign prices" overlooks the fundamental economics of the global generic market and the pricing pressures within the U.S. system. The cost benefits of global sourcing enable affordable access for millions in the U.S.; tariffs would reverse this, harming U.S. consumers and payers.

(vii) Potential for export restrictions by foreign nations: This is a valid national security risk. Weaponization of supply is possible. However, tariffs are unlikely to mitigate this risk effectively

in the short-to-medium term due to the time needed to build domestic capacity (5-10+ years). Tariffs could even provoke retaliatory restrictions. A more effective approach involves diplomatic engagement, allied partnerships, strategic stockpiling/reserves, and targeted investment in domestic capacity for the most critical/vulnerable medicines, potentially using dual/multi-sourcing strategies.

(viii) Feasibility of increasing domestic capacity: Building new, FDA-compliant API facilities or repurposing existing ones is complex, capital-intensive (often hundreds of millions to over a billion dollars per facility), and time-consuming (5-10+ years on average, including construction, validation, regulatory approvals, and inspections). Specialized capabilities (e.g., large-scale fermentation for antibiotics, high-potency handling) are concentrated offshore, often benefiting from lower labor, energy, and environmental compliance costs. Rapidly replicating this capacity and cost structure domestically is impractical without loosening environmental regulations and providing massive subsidies.

Transitioning to domestic suppliers requires investment in new and efficient production technologies, regulatory updates and approvals, and site inspections, all of which are expensive and time-consuming.

(ix) Impact of current trade policies and whether additional measures (tariffs/quotas) are necessary: Current trade policies generally facilitate access to lower-cost medicines via low/zero tariffs. Imposing new tariffs/quotas would cripple the cost-effectiveness of the U.S. generic market, risking retaliatory actions and severe negative consequences (shortages, higher costs, reduced access). Additional measures are needed, but they should focus on resilience-building (targeted incentives, partnerships, transparency) rather than trade restrictions like tariffs/quotas, which are ill-suited for the complexities of the pharmaceutical supply chain and risk significant harm.

(x) Other relevant factors

- Regulatory Burden: Complex FDA requirements for site transfers, approvals, and inspections add significant time and cost to shifting manufacturing locations.

- Generic vs. Branded Distinction: Policy impacts differ significantly. Tariffs on low-margin generics harm affordability and access. Supporting domestic production of higher-value, patent-protected branded/specialty drugs may be more feasible and strategically aligned with U.S. innovation strengths.

- Diversified/Hybrid Manufacturing Models: Models like ours provide flexibility and resilience. Tariffs could disproportionately harm these efficient, U.S.-based companies that strategically use global partners.

Supplementary Perspective - Focus on Generic vs. Branded Pharmaceuticals

It is important to distinguish between generic and branded pharmaceutical products when evaluating the impact of tariffs and potential reshoring strategies. The current reliance on imports for generic APIs and generic finished products underpins the affordability and accessibility of healthcare in the United States. Tariffs on generic medicines or their inputs will disproportionately harm U.S. consumers and increase the risk of shortages, especially for high-volume, low-margin products.

In contrast, branded pharmaceuticals and specialty medicines---many of which are protected by patents---offer a more practical and strategic avenue for domestic manufacturing. These products are often much higher in value, less sensitive to small cost increases, and can support the development of a more resilient U.S. supply chain.

Encouraging the domestic production of branded and specialty drugs through tax incentives, infrastructure investment, and streamlined regulatory support will enhance national security while avoiding the unintended negative consequences of broad tariffs on generic APIs and generic medicines.

Moreover, patent-protected drugs provide a built-in economic rationale for U.S. production, as these products are not subject to the same global price competition as generics. By focusing policy efforts on supporting U.S.-based manufacturing of high-value branded and specialty medications, the government can foster innovation, job creation, and supply chain resilience.

Thank you for considering our views.

Sincerely,

Vimal Kavuru

CEO

Rising Pharma Holdings, Inc.