RETAIL INDUSTRY LEADERS ASSOCIATION

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Electronic Submission Via Regulations.gov

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (BIS-2025-0022; XRIN 0694-XC120)

Dear Director Astle,

The Retail Industry Leaders Association (RILA) appreciates the opportunity to provide comments in response to the Department of Commerce's "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients" (XRIN 0694-XC120).

RILA is the U.S. trade association for leading retailers. We convene decision-makers, advocate for the industry, and promote operational excellence and innovation. Our aim is to elevate a dynamic industry by transforming the environment in which retailers operate. RILA members include more than 200 retailers, product manufacturers, and service suppliers, which together account for more than $2.7 trillion in annual sales, millions of American jobs, and hundreds of thousands of stores, manufacturing facilities, and distribution centers domestically and abroad.

RILA appreciates the administration's interest in increasing domestic capacity of pharmaceuticals and pharmaceutical ingredients to bolster national security. To build such capacity, investment in domestic production is essential and requires considerable time, significant resources, regulatory and policy flexibility, and financial incentives. In contrast, imposing broad-based tariffs on pharmaceuticals and pharmaceutical ingredients will result in drug shortages and increased prices for Americans without delivering the kind of increased capacity the administration seeks. We therefore urge the administration to pursue a targeted and phased approach to boosting domestic manufacturing of pharmaceuticals and pharmaceutical ingredients to ensure the life-saving medicines that Americans rely on continue to be readily available. In addition, and to avoid supply chain brittleness, we urge the administration to partner with our allies to ensure the availability and affordability of pharmaceuticals critical to Americans' health and quality of life.

I. Broad-Based Tariffs on Pharmaceuticals and Pharmaceutical Ingredients Will Increase Drug Costs and Lead to Shortages

Retail pharmacies play critical roles in their communities, including dispensing prescription medications, selling over-the-counter medications, providing vital health information and advice, and serving as immunization and screening destinations for Americans. While the government has focused on increasing supply chain resilience for pharmaceuticals deemed critical for the acute care of patients, including sterile injectable medications, there also must be a commitment to foster a resilient, robust supply chain of pharmaceuticals dispensed by retail pharmacies. Each year, retail pharmacies dispense billions of prescriptions and over-the-counter medications. These drugs are essential for the treatment of common illnesses, severe illnesses, and chronic conditions, such as diabetes mellitus and chronic obstructive pulmonary disease (COPD).

If the administration imposes broad based tariffs on pharmaceuticals and pharmaceutical ingredients, it will increase costs throughout the supply chain, impacting retail pharmacies. According to a recent report from Ernst & Young, estimated that a 25 percent tariff on all imported medicines and critical inputs will increase costs by approximately $50 billion annually—or 13 percent of the U.S. pharmaceutical industry's yearly domestic sales. The costs would be borne by U.S. manufacturers, healthcare providers, taxpayers, and patients.[1]

Absorbing these additional costs will be a serious challenge for retail pharmacies, which operate on razor-thin margins. Pharmacy benefit managers (PBMs), who administer prescription drug benefits for insurers, reimburse based on contracted rates. If broad-based tariffs on pharmaceuticals and pharmaceutical ingredients are imposed as an outcome of this investigation, pharmacies will be placed in the untenable position of having to bear the increased costs until they are able to renegotiate contracts with PBMs – a process that could take up to two years. And while increased reimbursement may help sustain some pharmacies, it will require insurers to raise enrollees' premiums and impose higher copays, which may exacerbate existing coverage issues and could decrease patient access to essential medications. Layering tariffs on top of this unequal dynamic will likely force many retail pharmacies to close their doors – exacerbating an ongoing closures issue and impacting patient access to medicines essential to their health.

Most concerning is that broad-based tariffs on pharmaceuticals and pharmaceutical ingredients may lead to shortages that could pose grave health risks for patients and healthcare providers. Consider generic drugs, which represent 90 percent of total drug volume. Generics operate on extremely thin margins, which makes them vulnerable to manufacturing discontinuation. Reducing the availability of generic drugs would have significant patient access implications and lead to negative health outcomes. For example, active pharmaceutical ingredients (APIs) for the common antibiotic amoxicillin are not available in the United States, and 95 percent by prescription volume of amoxicillin comes from non-U.S. sources. Applying broad-based tariffs to amoxicillin or

[1] Fick, M. (2025, April 25). Exclusive: US pharma tariffs would raise US drug costs by $51 billion annually, report finds. *Reuters*. https://www.reuters.com/business/healthcare-pharmaceuticals/us-pharma-tariffs-would-raise-us-drug-costs-by-51-bln-annually-report-finds-2025-04-25/

its APIs may result in shortages of this important prescription medication for Americans, potentially leading to avoidable health emergencies across the United States.

Further, while some drugs may not be manufactured domestically, the pharmaceutical supply chain for generic drugs is considerably diverse. For example, India supplies 54 percent of generics by prescription volume. The United States manufacturers 26 percent of generics by prescription volume, and 21 percent of all generic products use a domestic API source. In addition, approximately 39 countries supply finished-dose generic products for the U.S. This broad diversification of the generics supply chain promotes resilience and security since a supply chain disruption in one region would not necessarily impact production in a different region.

II. Recommendations

A resilient pharmaceutical supply chain should prevent, prepare for, and recover from disruptions quickly. RILA supports policies that promote advanced manufacturing for APIs and key starting materials (KSMs), reducing reliance on certain imports that may pose national security concerns, and fostering innovation. However, potential tariffs on pharmaceuticals have extensive implications on the supply chain, insurance costs, and access to medications in the U.S. health care system. It also requires a targeted and phased approach to ensure that essential medicines continue to be available and affordable for Americans during this transition period. Accordingly, we recommend the administration pursue the following actions to onshore manufacturing capabilities for pharmaceuticals and pharmaceutical ingredients.

Incentives: We encourage the administration to consider policy alternatives to tariffs such as financial incentives that encourage increased investment and domestic manufacturing. This could include reduced taxes on manufacturing income, as well as preferred formulary placement for domestically manufactured drugs. Successfully onshoring and reshoring pharmaceuticals and pharmaceutical ingredients also requires environmental, technological, and investment strategies to support growing U.S. production.

The administration should also consider the purchasing power of the United States government to offer long-term, guaranteed volume contracts to help send demand signals to the market, as well as partner with the private sector to expedite the development of domestic manufacturing capabilities for pharmaceuticals and pharmaceutical ingredients. The Trump Administration did this successfully during Operation Warp Speed 1.0 and through its partnership with Phlow Corporation to expand pharmaceutical manufacturing in the United States for producing essential medicines and APIs needed during the COVID-19 response and future public health emergencies. While it has taken more than 5 years for that federal funding to see legitimate API manufacturing here in U.S., it is a strong example of how public-private partnerships can boost domestic production of pharmaceutical and pharmaceutical ingredients.

In addition, the administration could consider offering increased public payer reimbursement for generic medications that have an API manufactured in the United States. We also encourage the

administration to pursue more regulatory flexibility and enhanced support from the U.S. Food and Drug Administration (FDA).

Phased Approach: If the administration chooses to impose tariffs, we urge a phased-in approach so that manufacturers have time to ramp up domestic production and that the various participants in the supply chain – including retail pharmacies – have the needed time to renegotiate contracts and prepare for increased costs.

Onshoring APIs and KSMs is costly and takes time to scale up. It can take manufacturers 3-5 years to build a compliant U.S. pharmaceutical manufacturing site, and start-up costs can be close to $1 billion. Manufacturers also need time to acquire or train the skilled workforce needed for domestic production.

In addition, it can take more than 15 months for the FDA to approve a request to manufacture and market a generic drug. We appreciate that the recently published drug pricing executive order directs the FDA to explore how the agency can accelerate the approval of generics/biosimilars. This may lead to an eventual regulatory reform that could help speed up these processes to support generic drug manufacturing in the United States.

Moreover, changing API sources is a lengthy process requiring finished dose manufacturers to test the new API and confirm that it is safe and compliant for their processes. Typically, introducing a new API supplier takes 12-15 months, not including time for regulatory approval. It is also a costly process and, as a result, most price-sensitive generic medicines have only 1 to 2 qualified API sources. In short, it will take 5-10 years for new U.S. manufacturing capacity to develop and become operationalized.

Exclusions: Further, if tariffs are imposed on pharmaceuticals and pharmaceutical ingredients at the conclusion of this investigation, we urge the administration to implement an exclusions process. Eligibility for exclusions should include pharmaceutical ingredients where domestic production is non-existent today, as well as for generics and drugs on Drug Shortage lists. Without such exclusions, tariffs will increase costs for generic and brand drug importers – leading to increased costs and drug shortages. This can have a disastrous impact on public health.

Partnering with Allies: While increasing U.S. production of essential medicines is an important goal, we caution that onshoring does not guarantee reliability, as U.S. production disruptions are common, such as breakdowns in machinery, natural disasters, or labor disruptions. That is why actions to support a secure and resilient pharmaceutical supply chain will require purchasers to be able to source from diverse suppliers and geographies. We urge the administration to work with allies to increase our collective capacity to supply a diverse range of pharmaceuticals and pharmaceutical ingredients for the public.

III. Conclusion

We urge the administration not to impose across-the-board tariffs on pharmaceuticals and pharmaceutical ingredients that could lead to drug shortages and increased costs for patients. We strongly support efforts to promote national security, but these efforts should not come at the cost of Americans' lives and health, and the administration can incentivize additional manufacturing of pharmaceuticals and pharmaceutical ingredients through other measures. If the administration deems that tariffs are the appropriate next step in the investigation, we urge the administration to consider a phased and targeted approach to tariffs and to provide exclusions for generics and drugs on Drug Shortage lists. Finally, we urge the administration to work with allies to build a more diverse and resilient pharmaceutical supply chain.

Thank you for the opportunity to provide input on behalf of our membership.

Sincerely,

Blake Harden

Blake Harden
Vice President, International Trade
Retail Industry Leaders Association