HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

Chester "Chip" Davis, Jr., President and Chief Executive Officer

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Mr. Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security, Bureau of Industry and Security
U.S. Department of Commerce
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Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, XRIN 0694-XC120

Dear Director Astle,

On behalf of the Healthcare Distribution Alliance (HDA), thank you for the opportunity to submit comments 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.[1] HDA represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.

HDA members safely and securely distribute 95 percent of medicines sold in the United States to approximately 330,000 sites of care daily.[2] In doing so, pharmaceutical distributors provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely. Importantly, pharmaceutical distributors' view of the pharmaceutical supply chain allows them to respond to the most pressing issues facing the nation, including drug shortages. Our industry is committed to improving access to safe, affordable pharmaceutical products for patients, providing an estimated $63 billion in cost savings to the U.S. healthcare ecosystem each year.[3]

We appreciate the Department of Commerce's leadership in determining the impact of import dependence on pharmaceuticals, their ingredients, and their derivative products on our country's national security. **In that context, it is vital to emphasize that a reliable and resilient pharmaceutical supply chain is itself a pillar of national security**. Ensuring uninterrupted access to medicines protects public health and enables our healthcare system to withstand disruptions, whether due to geopolitical challenges, natural disasters, or other unpredictable situations. Otherwise, supply chain instability risks patient care and our national security, which is why HDA supports federal investments that focus on increasing geographic resilience in the pharmaceutical supply chain.

We applaud President Trump for issuing an executive order just this week that takes meaningful steps to strengthen the domestic pharmaceutical manufacturing base. By streamlining regulatory pathways and directing key agencies to accelerate the development of new drug manufacturing facilities, the

[1] 90 Fed. Reg. 15951 (Apr. 16, 2025).
[2] HDA, https://www.hda.org/.
[3] HDA, Ensuring Safe and Affordable Healthcare for All Americans, https://www.hda.org/drug-pricing/.

administration is reinforcing its commitment to aligning national security priorities with patient access and pharmaceutical supply chain resilience.

Additionally, we are encouraged by recent reports that the Trump administration continues to make progress on negotiations with certain international trading partners following the recent reciprocal tariff announcements.[4] While these discussions are separate from this Section 232 investigation, they further reflect the administration's commitment to advancing U.S. strategic interests and ensuring the long-term security and stability of the pharmaceutical supply chain for the American public.

As the Department of Commerce proceeds with this investigation, we urge careful consideration of challenges that could undermine shared goals related to national security, pharmaceutical supply chain reliability and resiliency, and public health. Specifically:

- Tariffs on key starting materials (KSM), active pharmaceutical ingredients (API), and finished dosage form (FDF) medicines will not immediately increase domestic production capacity.
- Tariffs on KSM, API, and FDF medicines would likely exacerbate drug shortages and undermine national security goals.
- Tariffs on KSM, API, and FDF medicines would likely drive-up drug costs for pharmacies, providers, employers, health plan purchasers, payers – and, most importantly, patients – undermining affordability and access.

To avoid unintended disruptions to the pharmaceutical supply chain, HDA recommends that the Department of Commerce take a phased, strategic approach to any Section 232 action, including:

- **Exemptions** – Prioritize exemptions for pharmaceuticals currently in, or at risk of, shortage, particularly for essential generics relied upon by millions of Americans.
- **Stakeholder Engagement** – Conduct hearings and forums throughout this Section 232 investigation to fully assess the impact of potential tariffs and other actions on the pharmaceutical supply chain and provide mechanisms for companies to petition for relief or secure adequate phase-in periods.
- **Exclusions** – Establish an exclusion-based process to address KSM, API, or FDF medicines where domestic alternatives are unavailable or insufficient.
- **Investments and Incentives** – Pair any trade actions taken under this Section 232 investigation with targeted investments and incentives to strengthen domestic manufacturing that adds pharmaceutical supply chain reliability and resilience.

These recommendations reflect HDA's commitment to national security, pharmaceutical supply chain reliability and resilience, and most importantly, patient access and affordability.

I. HDA supports an increase in domestic production capabilities.

HDA supports federal investments to reshore production capabilities for pharmaceuticals of strategic importance to the United States.[5] As a key trading link in the pharmaceutical supply chain, distributors source products from upstream trading partners based on customer needs. In supporting these customer needs, expanding resilient pharmaceutical supply options is crucial to providing consistent and reliable sourcing. Additionally, it is equally critical to balance national security considerations with the reality of today's pharmaceutical supply-chain dependencies, ensuring immediate patient needs are

[4] Office of the U.S. Trade Representative, U.S.-India Establish Terms of Reference on Bilateral Trade Agreement (Apr. 2025), https://ustr.gov/about/policy-offices/press-office/fact-sheets/2025/april/fact-sheet-us-india-establish-terms-reference-bilateral-trade-agreement.

[5] HDA, Bolstering Resilience to Mitigate Delivery Challenges, https://www.hda.org/supply-chain-resilience/.

met. Thoughtfully aligning investment efforts with current pharmaceutical supply chain realities can help strengthen domestic resilience while continuing to support the availability of essential medicines for patients.

II. HDA urges the Department of Commerce to consider associated challenges that may undermine the reliability and resiliency of the pharmaceutical supply chain.

A. Tariffs on KSM, API, and FDF medicines will not immediately increase domestic production capacity.

Total U.S. consumer sales of FDF medicines were $393 billion in 2023, with 64 percent ($251 billion) domestically produced and sold inside the U.S. and 36 percent ($143 billion) imported.[6] Given the volume of imports, we are concerned that domestic capacity cannot scale fast enough to bridge any immediate disruptions. Further, expanding domestic pharmaceutical manufacturing capacity will take time and require substantial investment, infrastructure growth, and corresponding regulatory and workforce development. For example, industry data shows that building a compliant biopharma manufacturing facility costs up to $2 billion and takes five to ten years before the first commercial batches are available.[7]

In other instances, regulatory constraints at all levels of government (federal, state, and local), including the availability of domestic inspectors at the Food and Drug Administration (FDA), can further delay facility approvals and expansions.[8]

Given the short-, mid-, and long-term barriers to scaling domestic production, **HDA advocates for an exclusion-based process to mitigate these limitations and ensure continued access to KSM, API, and FDF medicines** that are currently (or may always be) unavailable or insufficient within the U.S. Maintaining diverse sourcing and production options is essential to preventing disruptions and supporting uninterrupted patient access.

B. Tariffs on KSM, API, and FDF medicines would likely exacerbate drug shortages and undermine national security goals.

Tariffs would likely pressure the channels that are currently preventing shortages from worsening, potentially leading to cost-driven disruptions in product availability, exacerbating existing shortages, and increasing national security risks. This is because manufacturers will likely pass along higher costs that come with tariffs to downstream trading partners, increasing both brand and generic drug prices. A recent analysis projected that a 25 percent tariff on imported pharmaceutical products and key inputs could raise industry-wide costs by more than $50 billion per year, which if passed on to the patient could raise drug prices by 12.9 percent.[9]

Importantly, generic manufacturers face unique economic pressures that may limit their flexibility in responding to added costs. These costs could inadvertently contribute to pharmaceutical supply constraints – particularly for widely used, lower-cost medicines – at a time when availability challenges are already growing. Many of the medicines currently experiencing supply issues are among the most

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[6] Ernst & Young, Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry, p. 3 (Apr. 22, 2025).
[7] Pharmaceutical Research and Manufacturers of America (PhRMA), Setting up a pharmaceutical manufacturing supply chain is a complex and lengthy process (May 14, 2020), https://phrma.org/blog/setting-up-a-pharmaceutical-manufacturing-supply-chain-is-a-complex-and-lengthy-process.
[8] Government Accountability Office (GAO), FDA Should Implement Strategies to Retain Its Inspection Workforce (Nov. 13, 2024), https://www.gao.gov/products/gao-25-106775.
[9] Ernst & Young, Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry, p. 12 (Apr. 22, 2025).

affordable on the market, and in some cases, pricing dynamics have made it difficult for manufacturers to sustain production.[10]

Given these considerations, continued access to these essential products will be critical not only to supporting patient care but also to preserving the stability of the pharmaceutical supply chain, an element that directly underpins U.S. national security. **Accordingly, HDA urges the Department of Commerce to prioritize exemptions for pharmaceuticals currently in, or at risk of, shortage particularly for essential generics relied upon by millions of Americans.**

In addition, key sources of API and KSM are not largely available in the United States, leaving manufacturers and ultimately distributors with few backup options should import costs rise dramatically. If a tariff policy does not include support for alternative pharmaceutical supply development, it may unintentionally limit pharmaceutical supply chain flexibility. Additionally, tariffs on API and KSM could undermine the competitiveness of the domestic FDF manufacturing capacity, especially for generics. This could contribute to future shortages or cost increases, which can impact the continuity of patient care and financially strain pharmacies, providers, employers, health plan purchasers, and patients alike. In the alternative, if the Department of Commerce contemplates quotas in lieu of tariffs, hitting a quota ceiling could trigger immediate pharmaceutical supply shortages and rationing, which is especially worrisome for generics.

C. Tariffs on KSM, API, and FDF medicines would likely drive up drug costs for pharmacies, providers, employers, health plan purchasers, payers – and, most importantly, patients – undermining affordability and access.

When tariffs apply to imported KSM, API, or FDF medicines, the importer of record typically absorbs the initial expense but often passes it down the chain to its trading partners. Pharmacies may be particularly vulnerable to reimbursements that are not reflective of increased acquisition costs, which could create financial challenges and impact the availability of products and services. Not only will directly impacted products see price increases, but interchangeable products not subject to the tariffs may also rise in price as the market equilibrium adjusts upward. Even modest price increases can have an outsized effect on patients who rely on affordable generics for managing chronic conditions, potentially making it harder to achieve our shared goal of maintaining pharmaceutical supply reliability, resiliency, and patient access, which could also run counter to the administration's important effort to lower drug prices. Moreover, higher drug costs can erode patient adherence to prescribed therapies, which studies show results in poorer health outcomes and drive-up healthcare spending in other areas.[11]

III. Conclusion

We thank the Department of Commerce for its leadership in examining import dependence on pharmaceuticals, their ingredients, and their derivative products that are a strategic vulnerability to continuity of care. We also welcome the opportunity to support our shared goal of maintaining a reliable and resilient U.S. pharmaceutical supply chain. In alignment with that goal, HDA respectfully offers its *Supply Chain Resilience Principles* as a potential resource.[12] These principles are informed by the distributors' experience in managing availability of products during a range of disruptions. We hope

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[10] Association for Accessible Medicines, Drug Shortages: Causes & Solutions, https://accessiblemeds.org/resources/reports/aam-white-paper-on-shortages/; Pharmaceutical Tariffs: How They Play Out, Brookings (Aug. 30, 2023), https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/; IQVIA, Drug Shortages in the U.S. 2023 (Nov. 15, 2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023 .

[11] Rujittika M. Mairon, et al., Estimating the Clinical and Economic Impact of Medication Non-Adherence in the U.S.: A Review of the Literature, 8 BMJ Open e016982 (2018), https://bmjopen.bmj.com/content/8/1/e016982.

[12] HDA, Guiding Principles for Increasing Supply Chain Resilience, https://www.hda.org/getmedia/2d816602-0c28-46c6-a52f-d1d36c094cd9/Resilience-Principles.pdf.

these ideas may be helpful as the administration considers various policy tools, including tariffs, in the context of long-term pharmaceutical supply chain resilience and expansion of the industrial base.

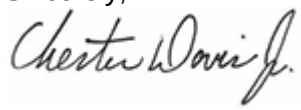
In addition, to address concerns around drug shortages, HDA has developed a *Policy Agenda on Drug Shortages* and *Drug Shortages Principles* that outlines practical, system-wide strategies to mitigate and address drug shortages.[13] Key recommendations include modernizing contracting practices, ensuring generic market sustainability and improving key partner communication to mitigate potential disruptions. We share these principles in the spirit of partnership, recognizing that pharmaceutical supply challenges must be addressed holistically alongside broader trade and industrial policies.

Finally, consistent with these approaches, we encourage the Department of Commerce to adopt a stepwise and measured approach should it move forward with any Section 232 action on KSM, API, and FDF medicines, including:

- **Exemptions** – Prioritize exemptions for pharmaceuticals currently in, or at risk of, shortage, particularly for essential generics relied upon by millions of Americans.
- **Stakeholder Engagement** – Conduct hearings and forums throughout this Section 232 investigation to fully assess the impact of potential tariffs and other actions on the pharmaceutical supply chain and provide mechanisms for companies to petition for relief or secure adequate phase-in periods.
- **Exclusions** – Establish an exclusion-based process to protect KSM, API, or FDF medicines where domestic alternatives are unavailable or insufficient.
- **Investments and Incentives** – Pair any trade actions taken under this Section 232 investigation with targeted investments and incentives to strengthen domestic manufacturing while maintaining pharmaceutical supply chain reliability.

We welcome the opportunity to serve as a resource to you and your team throughout this Section 232 investigation. Please do not hesitate to contact Patrick Kelly, Chief Advocacy Officer (pkelly@hda.org), and Kala Shankle, Vice President of Regulatory Affairs (kshankle@hda.org) should you have any additional questions.

Sincerely,



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[13] HDA, Policy Agenda on Drug Shortages, https://www.hda.org/getmedia/1457f7bf-d36f-4f28-8457-c06007a6ec53/HDA-Policy-Agenda-on-Drug-Shortages.pdf; HDA, Guiding Principles for Drug Shortages, *https://www.hda.org/getmedia/a6382b52-17f5-49b2-907b-7838847d867c/HDA-Drug-Shortages-Guiding-Principles.pdf*.