May 6, 2025

Docket Number: BIS-2025-0022

Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, D.C. 20230

Re: Request for Public Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, XRIN 0694-XC120

Dear Deputy Assistant Secretary Longnecker:

The Association for Accessible Medicines (AAM) is pleased to provide comments on behalf of its members in response to the April 16, 2025 *Federal Register* notice.[1]

Executive Summary

AAM represents America's manufacturers and distributors of finished generic pharmaceuticals, biosimilars and bulk pharmaceutical ingredient companies. Generic drugs and biosimilar products play a critical and necessary role in the drug supply chain: they account for 90% of all prescriptions dispensed in the U.S., but less than 13% of the costs of prescription drugs. America's patients and the U.S. health care system have saved **nearly $3 trillion in the last ten years** due to the availability of safe and affordable generics and biosimilars.

AAM would welcome the opportunity to work with the Trump Administration to help secure those substantial savings—and more—for many years in the future. At the outset, AAM believes that it is important for the Trump Administration to consider three critical points about the generic and biosimilar industries as part of its Section 232 investigation before imposing any tariffs:

- The generic and biosimilar industries are **significantly different** from the brand industry in ways that are extremely meaningful for this investigation. While the brand industry

[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15,951 (Dep't of Commerce Apr. 16, 2025).

operates on as much as six-to-seven figure list prices and substantial profit margins, generics operate on razor-thin margins—sometime pennies-per-unit—that prevent them from absorbing tariffs in the same way as brands. Generics and biosimilars are also crucially important for patient access to affordable medicines. Tariffs, quite simply, have monumentally different impacts between the industries.

- While generic and biosimilar manufacturers have an important, ongoing presence in the United States, their continued presence is in jeopardy for reasons completely unrelated to tariffs. Indeed, tariff actions **would not address the issues that caused production to move overseas in the first place**, which include a broken reimbursement system and the monopsonistic behavior of large, consolidated generic purchasers. AAM would welcome the opportunity to work with the Trump Administration on incentives and reforms, detailed below in Sections I.A and VI, that would have more impact than tariffs in retaining and onshoring/nearshoring manufacturing and increasing American jobs.

- Because of these fundamental issues, imposing additional tariffs will not drive production to the U.S. and instead will likely lead to shortages or the discontinuation of many crucial essential generic medicines.

    - AAM members have identified **[[ ]] that will likely go into shortage or immediately be discontinued** (attached as **Business Confidential Appendix A**) if tariffs are imposed.

    - Given this serious risk of shortages, the current Administration should **exclude generic and biosimilar medicines as it did in the first Administration**.

    - To the extent that tariffs are considered, they should be carefully calibrated as detailed in Sections I.B and VII. The Trump Administration should consider a 180-day pause for countries willing to negotiate with the Administration to address unfair trade practices. The Administration should also consider exempting countries that have existing zero-for-zero pharmaceutical tariff treatment with the U.S. and phasing tariffs to prioritize retaining and onshoring/nearshoring fill-finish operations first.

We look forward to working with the Administration to help secure a resilient and reliable supply chain and providing patients and the healthcare system substantial savings for years to come.

I. Introduction

AAM is strongly aligned with President Trump's objective of lowering prescription drug prices in the United States.[2] Vibrant generic and biosimilar industries in the U.S. are key to achieving that objective. Generic medicines generated $445 billion dollars in savings for patients in 2023 alone and, in the last decade, have saved the U.S. healthcare system $3.1 trillion dollars.[3] These savings also have a profound effect on government spending. Medicare, the largest government healthcare program, realized savings of $137 billion dollars attributable to generic and biosimilar medicines in 2023 alone.[4]

As noted above, the previous Trump Administration chose to not apply tariffs to generic and biosimilar pharmaceutical products despite initially including Harmonized Tariff System of the United States (HTSUS) codes for such products in the list of goods slated for the first round of Section 301 tariffs.[5] Ultimately, through four rounds of such tariffs, no additional duties were imposed on any goods included in HTSUS Chapter 30, which covers finished pharmaceutical products. Likewise, the Administration determined not to impose such tariffs on numerous tariff codes covering Active Pharmaceutical Ingredients (API).[6]

AAM requests that the Trump Administration consider alternatives to facilitate onshoring and/or nearshoring generics and biosimilars in a phased manner that will benefit patients and the healthcare system. These alternatives, discussed in Sections I.A and VI below, would be more impactful than tariffs at driving production into the U.S.

A. Ensuring a Secure, Domestic Supply Chain

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2 *See, e.g.*, *Lowering Drug Prices by Once Again Putting Americans First*, Exec. Order No. 14273, 90 Fed. Reg. 16,441 (Apr. 15, 2025) ("Apr. 15, 2025 Exec. Order").

3 *The U.S. Generic & Biosimilar Medicines Savings Report*, Association for Accessible Medicines, (Sept. 2024), at 7, *available at* https://accessiblemeds.org/resources/blog/2024-savings-report/ ("Savings Report").

4 *Id.*

5 *China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation*, 83 Fed. Reg. 14,906, 41,910-13 (USTR Apr. 6, 2018) (notice of deter. and req. for public comment concerning proposed deter. of action pursuant to Section 301) (listing HTSUS codes 29146200 through 30067000, corresponding to API and finished pharmaceutical products). These tariff codes were proposed in the first tranche of tariffs to counter China's practices related to tech transfer and intellectual property protections, and as such were examined extensively as part of that process.

6 API are classified widely throughout Chapter 29 of the HTSUS, in some cases outside of provisions that expressly cover "Drugs." However, the Section 301 tariffs in large part avoided placing duties on these goods, and particularly those tariff codes that uniquely cover pharmaceutical API. While certain such codes were subjected to the additional duties (2933.19.35, for example), Section 301 tariffs were never applied to goods of HTSUS codes 2914.69.21, 2918.99.30, 2921.49.38, 2922.19.09, 2922.50.13, 2922.50.14, 2922.50.17, 2922.50.19, 2922.50.25, 2924.29.57, 2924.29.62, 2928.00.30, 2930.90.92, 2932.20.20, 2933.39.31, 2933.39.41 2933.49.20, 2933.49.26, 2933.59.21, 2933.59.22, 2933.59.36, 2933.59.46, 2933.59.53, 2933.99.26, 2933.99.42, 2933.99.46, 2933.99.51, 2933.99.53, 2933.99.55, 2933.99.90, 2934.30.23, 2934.99.30, 2934.99.47, 2935.90.29, 2935.30, 2935.90.32, 2935.90.33, 2935.90.42, or 2935.90.48.

In this submission, AAM details the key alternative steps that that the Trump Administration can immediately take to further the critically-important goal of a safe and diverse medicines supply chain in light of (1) the unique complexities of the generic and biosimilar industries, (2) current and projected future manufacturing capacity, and (3) the features of the medicines access and reimbursement market in the United States. As detailed below, the Trump Administration also has a unique opportunity to create and sustain U.S. jobs by immediately activating dormant capacity, summarized below, and incentivizing its use. These steps include:

- Improving Medicare reimbursement and coverage by:

    - Developing a Medicare condition of participation requiring providers to prioritize and plans to cover generic drugs and biosimilar products from resilient suppliers, which are either (i) suppliers that finish pharmaceuticals in the U.S., its Free Trade Agreement (FTA) partners, or its WTO Pharmaceutical Agreement partners, including any future partners of those agreements; or (ii) "Resilient Suppliers With a Significant Domestic Presence."[7] The Centers for Medicare & Medicaid Services (CMS) should solicit public comments on the definition of resilient suppliers before implementation. Resiliency standards should be driven by a public-private partnership. Additionally, AAM recommends that long-term, fixed-volume contracts should be prioritized for all federal procurements with resilient suppliers, defined above. This will help secure reliable domestic, near-shore, and friend-shore fill/finish operations.

    - Using existing authority, including under the Social Security Act's "inherent reasonableness" provisions and through Center for Medicare and Medicaid Innovation (CMMI) demonstration and pilot programs, to mitigate unsustainably low Average Sales Price (ASP) calculations and ASP-based reimbursement for generic drugs and biosimilar products payable under Medicare Part B. Additionally, the Administration could remove discounts to non-purchasers (i.e., GPOs, health plans, and PBMs, who do not take possession of product and

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[7] **"Resilient supplier with significant domestic presence"** means a company that:

- **Owns and operates** one or more U.S.-based manufacturing facilities producing significant, qualifying commercial volumes of finished dosage forms and/or APIs for the U.S. market. Research and development and packaging activities without manufacturing do not qualify.
- **Has made substantial qualified capital investments** in domestic production capabilities within the past five years, including facility construction or material expansion, new equipment installation, and workforce development.
- **Maintains a multi-year strategy** to ensure continuity in constructing or expanding the U.S.-based footprint or materially increase production as part of a broader security and resiliency plan.

therefore are not "purchasers" in the traditional sense of the word) from the ASP calculation. While none of these options constitutes a "silver bullet", when taken together, they constitute significant effort toward stabilizing the reimbursement of generic drugs and biosimilar products payable under Medicare Part B.

- Consistent with the Administration's Drug Pricing Executive Order[8] and Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicine,[9] working with Congress and agencies to take decisive action to eliminate regulatory burdens that slow generic and biosimilar approval, including:

    - Deeming biosimilars interchangeable upon approval, thereby eliminating the non-scientific distinction between biosimilar and interchangeable products;

    - Ensuring that the U.S. Food & Drug Administration (FDA) can provide important quantitative and qualitative information (Q1/Q2) to generic manufacturers developing generic drugs;

    - Accelerating user-fee funded facility inspections by better utilizing FDA's Remote Regulatory Assessment tools to increase the number of remote and virtual FDA assessments (including section 704(a)(4) document requests), and better leveraging mutual recognition agreements; and

    - Streamlining FDA's approval process including the ability to utilize a global comparator and removing redundant clinical studies.

- Directing the Federal Trade Commission (FTC) and Department of Justice (DOJ) to investigate and issue new guidance on anticompetitive monopsony practices by group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs) that have led to onerous contract terms and race-to-the bottom pricing in the generic industry.

- Building on the Administration's establishment of the U.S. Investment Accelerator,[10] to prioritize revitalizing the U.S. generic pharmaceutical industry and immediately creating and sustaining U.S. jobs. This could include creating a financing facilitation program for strengthening U.S. pharmaceutical security and resilience. Such a financing facilitation

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8 *See* note 2, *supra*.

9 *Regulatory Relief to Promote Domestic Production of Critical Medicines*, The White House (May 5, 2025) *available at* https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/ ("May 5, 2025 Exec. Order").

10 *Establishing the United States Investment Accelerator*, Exec. Order No. 14255, 90 Fed. Reg 14,701 (Mar. 31, 2025) ("Mar. 31, 2025 Exec. Order").

program could be modeled after existing government financing institutions like the U.S. International Development Finance Corporation (DFC) or elements of the Export-Import Bank of the United States loan programs.

- Consistent with the Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicine,[11] substantially reforming permitting practices, which currently can take a decade for a single project with overlapping state and federal requirements.[12]

- Capping the number of patents that can be asserted in patent litigation and preventing duplicative patents (so-called "double patents") from stifling generic and biosimilar entry.

These actions will immediately begin to correct the market distortions that have contributed to generic and biosimilar pharmaceutical manufacturing shifting away from the United States over the past several decades. Tariffs, by contrast, stand to cause additional shortages of critical essential medicines and, for the reasons detailed below, will not ultimately result in the reshoring of manufacturing, absent substantial changes in the incentive structure in the generic and biosimilar industries.

B. Generic and Biosimilar Medicines Should Be Excluded; If Tariffs Are Imposed, They Should Be Carefully Calibrated

As noted above, the current Administration should again exclude generics and biosimilars from tariffs and find that the harm to U.S. interests from tariffs would outweigh any benefits from additional duties on generic and biosimilar pharmaceutical products and the supply chains necessary to produce them. It would also be consistent with the longstanding, worldwide treatment of pharmaceuticals, which has largely been zero-for-zero.

While AAM and its members fundamentally disagree with tariffs, steps should be taken to carefully calibrate them if they are ultimately imposed. In particular, the Administration should take the following steps to ensure that tariffs do not immediately exacerbate drug shortages and raise costs for patients:

- For a 180-day period following the announcement of any tariff action, provide a pause for countries willing to negotiate with the United States to address unfair trade practices or barriers affecting U.S. pharmaceutical exports. The 180-day window would provide

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[11] May 5, 2025 Exec. Order.

[12] Dr. Christian Roberts and Suzie Heap, *Permitting: Streamlining delivery of today's infrastructure opportunity*, KPMG (Mar. 2023), *available at* https://kpmg.com/kpmg-us/content/dam/kpmg/pdf/2023/permitting-streamlining-delivery-todays-infrastructure-opportunity.pdf ("KMPG Permitting").

the Administration the opportunity to proactively address the practices that it has identified as unfair.

- Exempt or delay tariffs on products from allied countries, including by recognizing countries that currently have zero-for-zero tariff treatment for pharmaceuticals (Japan, Canada, European Union member states, Switzerland, Norway, Macao), and any countries that adopt that treatment during the investigation. The Administration could choose to delay tariffs on products of these countries while it looks to address other distortive trade practices. The Administration should also continue to apply an exemption for USMCA-originating goods, as the Trump Administration rightly did in the context of the International Emergency Economic Powers Act (IEEPA) actions with respect to Canada and Mexico.[13]

- Combined with other proposed policy changes here, provide for a phased approach that recognizes the differences between finished pharmaceuticals and their inputs, including but not limited to focusing on first retaining, reshoring, and/or nearshoring production of finished pharmaceuticals. A staged approach that protects finished dosage production (where capacity and workforce already exist for at least some portion of the industry) would be the most realistic and effective strategy for creating immediate progress on the Administration's objectives.

    - Many AAM members have well-established U.S. manufacturing capabilities, and they employ thousands of American workers and supply the U.S. healthcare system with a large range of domestically produced generic medicines. These companies have made, and continue to make, substantial investments in domestic generic pharmaceutical manufacturing and product development.

    - We recommend delaying tariffs on finished dosage form while AAM members look to deploy existing, idle capacity. [[

      ]] The Administration can reevaluate this phase-in based on changes to incentives and reports on the deployment of capacity.

    - The Administration should delay or not impose any tariffs (sector-specific or reciprocal) on API, key starting materials (KSM), and necessary materials (excipients, packaging, and production equipment) needed for domestic fill-finish

[13] *Amendment to Duties to Address the Flow of Illicit Drugs Across Our Northern Border*, Exec. Order No. 14231, 90 Fed. Reg. 11,785 (Mar. 6, 2025).

operations at this time to ensure that existing domestic capacity is retained. Indeed, any tariffs imposed on imported production inputs and equipment would negatively impact U.S.-based manufacturing operations, reducing their ability to offer more affordable generic medicines to patients, mitigate drug shortages, and reinvest in further domestic manufacturing. Tariffs on inputs, packaging materials, and production machinery would compound cost pressures for these already low-margin medicines, leading to further supply contraction and fewer U.S.-based manufacturers of essential medicines. [[

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- To avoid risking serious drug shortages, exempt any generic drug or biosimilar product that is: (i) provided in the **Business Confidential Appendix A** submitted with these comments, which identifies [[ ]] that would likely be discontinued or go into shortage in the event that a tariff is imposed; (ii) currently "penny-priced" in the 340B program; or (iii) listed currently or within the past 100 days on the FDA's drug shortage list. This could be accomplished through a secondary HTSUS code for these particular products.

- Consistent with the recent Executive Order regarding the "de-stacking" of certain tariffs,[14] the Administration should ensure that any tariffs imposed on pharmaceuticals stand alone and are carefully calibrated to encourage U.S. investment, avoid unintended consequences, and support retaining and onshoring/nearshoring investments that may also require purchase of materials and machinery not yet produced in the United States.

- To the extent that the Administration wishes to address specific concerns with inversion and other tax issues, as the President recently indicated,[15] those issues can be addressed in the context of branded drugs alone——the primary locus of years-long tax inversion activity.

Below, we describe the successes and benefits of generic medicines for patients and the U.S. healthcare system a whole. Next, we describe pertinent differences between the brand and generic drugs industries, detail factors that have resulted in the current instability and fragility of the U.S. generic drug industry and explain why tariffs alone cannot resolve these factors

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[14] *Addressing Certain Tariffs on Imported Articles*, Exec. Order No. 14289, 90 Fed. Reg. 18,907 (Apr. 29, 2025).

[15] Chelsey Dulaney, *Trump Takes on Ireland Over Trade at St. Patrick's Day Event, The Wall Street Journal* (Mar. 12, 2025), *available at* https://www.wsj.com/politics/policy/ ireland-trump-tariffs-micheal-martin-3952bb43.

and, indeed, stand only to worsen them. We then identify specific, concrete actions that the Administration can take to address these factors and place the generic drug industry on a sound footing, consistent with U.S. national security interests. We also suggest features of a tariff action – should the Administration adopt one – that would calibrate it to minimize disruption and maximize the likelihood of supporting the domestic industry. Finally, respond to the specific questions posed in the *Federal Register* notice.

II. The Generic Drug Market is Highly Regulated and Has Delivered Affordable Medicine for U.S. Patients

The generic drug industry is different from other industries that have been subject to Section 232 investigations, both because it is highly regulated and because it is critical to the public policy goal of providing reliable and affordable medicine. The Drug Price Competition and Patent Restoration Act of 1984 stands out as a monument of federal legislation that produced lasting benefits for America's patients and taxpayers. Commonly known as the Hatch-Waxman Amendments, the law created a pathway for the introduction of lower-cost generic drugs.

To market generic drugs in the United States, generic drug manufacturers must first submit an abbreviated new drug application (ANDA) to FDA for approval to market. Before approval, FDA ensures that generic drugs contain the same active ingredients at the same strength and dosage form as their brand counterparts. In addition, the FDA ensures that the generic drug has the same route of administration (e.g., oral or topical), contains acceptable excipients, is bioequivalent, and is manufactured under the same standards as the brand version of the medicine.[16]

In the last ten years alone, the use of generic drugs and biosimilar products has saved patients and the U.S. healthcare system over $3 trillion dollars.[17]

III. The Brand and Generic Pharmaceutical Markets Are Fundamentally Different

While the supply chains for brand and generic drugs include many of the same stakeholders there are fundamentally different economic drivers and financial incentives at play. The brand companies, with their monopolies, have a greater ability to absorb tariffs than generic companies, with their highly competitive market and limited profit margins. That means that tariffs will have disparate impacts on the two markets. While tariffs may not reduce the

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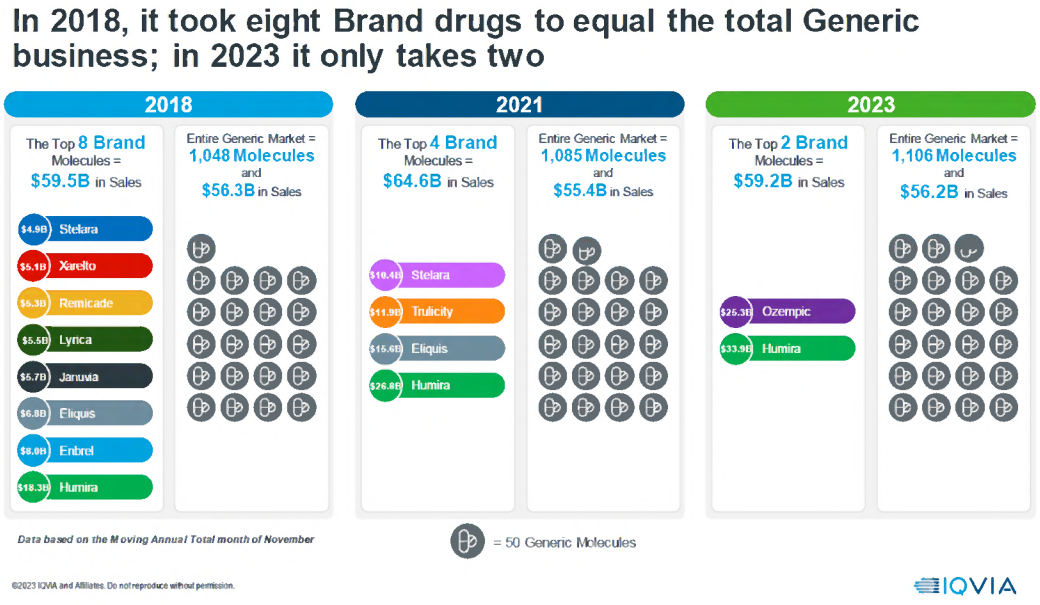
[16] Food and Drug Administration, *Generic Drugs: Questions & Answers*, *available at* https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers; Food and Drug Administration, *What Is the Approval Process for Generic Drugs?*, *available at* https://www.fda.gov/drugs/generic-drugs/what-approval-process-generic-drugs.

[17] Savings Report at 7.

availability of branded drugs, and may even incentivize investments in the United States, they will exacerbate generic shortages and hamper the ability for U.S. producers of generics to make investments.

Illustrating the disparity between the two markets, on a dollar-for-dollar basis, **the sales values for the United States' s top two branded products in 2023 equaled the sales values for 1,000 combined generic products**.[18]



Compounding these differences, an analysis by the University of Southern California's Schaeffer Institute noted that, while brand manufacturers have a net profit margin of 28.1%, the net profit margin for generics was significantly lower.[19] This submission focuses on the particular features and challenges of the generic pharmaceutical sector, while acknowledging that the brand market is characterized by higher margins and different incentives that may make tariffs more successful in incentivizing domestic manufacturing.

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[18] Doug Long, VP, Indus. Rels., *US Generics & Biosimilars Trends, Issues & Outlook for AAM*, IQVIA, (Feb. 6, 2024) presentation, *available at* https://accessiblemeds.org/wp-content/uploads/2024/09/Access-2023-Doug-Long-US-Generics-Biosimilars-Trends-Issues-Outlook.pdf.

[19] Neeraj Sood, PhD, Tiffany Shih, Karen Van Nuys, PhD, and Dana Goldman, PhD, *Flow of Money Through the Pharmaceutical Distribution System,* USC Leonard D. Schaffer Institute for Public Policy & Government Service (June 6, 2017), *available at* https://schaeffer.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/.

IV. The Generic and Biosimilar Markets in the United States Face Severe Sustainability Challenges

AAM applauds the Trump Administration for identifying the risks presented by a fragile supply chain and ecosystem for pharmaceutical products. The relative concentration of pharmaceutical drug production in certain foreign markets warrants this investigation, but it is a symptom of problems within the marketplace that go beyond trade practices. Without addressing those fundamental issues, the Administration risks taking action that will further drive production to the lowest-cost destination, while putting the sustainability of the U.S. generic and biosimilar industry in additional jeopardy.

Weakness in the U.S. generic drug supply chain is driven by several factors, including intense price competition and asymmetrical market power and negotiating leverage between many dispersed manufacturers and relatively few consolidated intermediary buyers. In the retail generic drug market, three buying groups account for nearly 80% of drug purchases.[20] Similarly, three major players dominate purchases for hospitals, accounting for at least 80% of that market.[21] If anything, the above figures understate the challenge. In the retail market, there has been extensive vertical integration between wholesale distributors and buying groups with equally consolidated PBMs—another market in which the three largest players (*i.e.*, CVS Health, Optum, and Express Scripts) control roughly 80% of the market. In some cases, all of these groups share financial and referral relationships, effectively owning the entire drug distribution channel. Studies have increasingly found that generics have recently experienced slower adoption than normal based on PBM behavior, with PBMs preferring high-priced drugs with high rebates over lower-list priced generics.[22]

This consolidation has enabled buyers to exert downward pricing pressure resulting in extremely low profit margins and one-sided contract terms including "most-favored-nation" clauses. These clauses allow a buyer to terminate a generic manufacturer's contract if a competitor in China, for example, can underprice by one cent, without regard to whether that Chinese competitor is a reliable supplier. This has driven purchases to the lowest cost producers, creating long-term disincentives for U.S. investments in manufacturing capacity. A similar contract term, "failure-to-supply", requires generic manufacturers to pay a substantial penalty that could significantly exceed the price of the drug if they are unable to supply the

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[20] Letter from AAM to Chair Fed. Trade Comm'n and Sec'y U.S. Dep't of Health and Human Servs., re: *Request for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages* (May 30, 2024) at 2, *available at* https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Response-to-FTC-HHS-RFI-on-Drug-Shortages-5-30-2024.pdf.

[21] *Id.* at 3.

[22] *Middlemen Increasingly Block Patient Access to New Generics,* Association for Accessible Medicines (Jan. 2023), *available at* https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Middlemen-Block-Patient-Access-New-Generics-2023-1.pdf.

market due to, for example, a shortage caused by tariffs. Because of that substantial failure-to-supply penalty, **manufacturers may simply choose to remove products from contracts and discontinue them if they have concerns about potential future shortages caused by tariffs**. Again, tariffs cannot solve the root cause of the problems in the generic market and instead could only worsen them. These practices below are the greatest impediment to manufacturing pharmaceuticals and pharmaceutical ingredients in the United States.

As the Administration has recognized in launching this investigation, downward price pressure driven by asymmetrical market power of U.S. purchasers has pushed production to markets which benefit from lower labor costs, reduced environmental and other regulatory standards, and distortive government subsidization. During the first Trump Administration, an interagency task force that included U.S. Department of Health & Human Services (HHS) (including FDA), CMS, Department of Defense (DoD), and FTC concluded that a primary "root cause" of drug shortages was the "lack of incentives to produce less profitable drugs."[23] The task force went on to conclude that "[m]anufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements all of which limit potential returns. Current contracting practices contribute to a 'race to the bottom' in pricing."[24]

The downward pressure on prices resulting from asymmetrical negotiating power of purchasers has also increased the risk of shortages, as discussed in further detail below. Most pharmaceutical shortages are found in the generic drugs market, particularly those with a per unit price of less than $1.[25] Many such shortages are a direct result of unsustainably low reimbursement for older, low-margin products, which may lead to their discontinuation. Indeed, there have been more than 3,000 generic product discontinuations since 2010.[26] Other countries, which generally pay more for their generic drugs, do not have as many drug

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[23] Drug Shortages Task Force, U.S. Food & Drug Administration, *Drug Shortages: Root Causes and Potential Solutions* (2019) (revised Mar. 11, 2020) at 6, *available at* https://www.fda.gov/media/131130/download?attachment ("FDA: Root Causes and Potential Solutions").

[24] *Id.*

[25] *Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs*, Senate Committee on Finance (Jan. 25, 2024) at 2, *available at* https://www.finance.senate.gov/imo/media/doc/white_paper_preventing_drug_shortages.pdf ("Policy Options").

[26] *Drug Shortages: Causes & Solutions*, Association for Accessible Medicines, at 1, *available at:* https://accessiblemeds.org/wp-content/uploads/2024/11/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf.

shortages.[27] Researchers have pointed to these structural features as a source of the fragility in the U.S. drug market.[28]

The biosimilar market also has significant challenges. Patent thickets are becoming increasingly prevalent, particularly in the context of biologics. A frequently cited example is Humira®, a biologic indicated for rheumatoid arthritis that resulted in 130+ issued patents, almost twice as many patent applications, and a litigation with 74 asserted patents.[29] Between 2015-2019 alone, "delayed entry of biosimilars due to patenting has cost the U.S. health care system an astounding $7.6 billion in lost savings."[30]

Given these large patent thickets, it is not surprising that biosimilars are made overseas. Indeed, if biosimilar manufacturers onshored their production, they would be immediately at risk of patent infringement lawsuits across hundreds of patents. This also highlights a separate but related concern—under current U.S. patent laws, biosimilar manufacturers cannot export to other countries without potentially infringing patent claims.

For all these reasons, the consistent supply of generic and biosimilar medicines for patients, uninterrupted by shortages, is in jeopardy.

V. Tariffs on Finished Generic Pharmaceutical Products, APIs and Other Ingredients Will Increase Costs and Lead to Shortages, Not Reshoring

A. Tariffs Will Lead to Higher Costs for Manufacturers

On their own, tariffs will increase costs for U.S. generic pharmaceutical manufacturers. In fact, a recent study commissioned by Ernst & Young found that a 25% tariff would increase costs in

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[27] *See, e.g.*, Tadrous, Mina, et al, *Differences in Drug Shortages in the U.S. and Canada*, JAMA (Oct. 31, 2024) *available at* https://jamanetwork.com/journals/jama/fullarticle/2825535; Ravela, Reko, et al, *National and Transnational Drug Shortages: A Quantitative Descriptive Study of Public Registers in Europe and the USA*, BMC Health Services Research (July 22, 2022) *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC9306441/; Cameron, Eliza E., et al, *Analysis of Drug Shortages Across Two Countries During Pre-Pandemic and Pandemic Times*, Research in Social and Administrative Pharmacy (September 2021) *available at* https://www.sciencedirect.com/science/article/abs/pii/S1551741120312067.

[28] *See* Ravela *supra* note 29; Mui, K. Jane, et al, *Understanding Drug Supply Shortages in the U.S. and Canada*, JAMA (2024) *available at* https://jamanetwork.com/journals/jama/article-abstract/2825539?guestAccessKey=f2bf9b7c-bcc0-4fbb-a8cc-23d643b22ec1&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=olf&utm_term=103124&adv=

[29] Complaint at ¶ 1, *AbbVie Inc. et al. v. Boehringer Ingelheim Int'l*, No. 1:17-cv-01065-MSG-RL (D. Del. Aug. 2, 2017).

[30] *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients: Part I,* Biosimilar Council (June 2019), *available at* https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf.

the pharmaceutical sector by **$51 billion**.[31] That impact is particularly pronounced for generic drugs given the unique challenges that they face—compared to brands—in passing through any cost to purchasers.

Given the cost pressure created by the concentrated buyers' market, U.S. manufacturers have had no choice but to rely—at least in part—on imports to remain competitive. These imports include inputs, such as APIs, KSMs and other ingredients as well as vials and packaging. In addition, many U.S. producers complement their domestic production of finished pharmaceuticals with imports in order to maintain a competitive portfolio of products. New tariff costs will add to pressures that the industry already faces due to the reciprocal tariffs that affect inputs like vials, packaging, and other materials, as well as the existing 20% IEEPA tariff on all imports from China. Already, producers of finished pharmaceuticals in the U.S. face heightened inputs costs that foreign competitors do not.

B. Tariffs Will Exacerbate an Already Unsustainable Market

While one might think that tariffs would enable U.S. generic drug manufacturers to charge more and achieve sustainable prices, this is not the case. Given their lack of market power relative to large buyers, U.S. generic manufacturers would not be able to pass on the costs of tariffs on either finished drugs or on API/KSM, inputs, and equipment.

Notably, the generic pharmaceutical industry is subject to federal and state restrictions—both statutory and regulatory—that would impede any ability to increase prices **even for a fully domestic manufacturer**. These limitations include Medicare requirements, Medicaid requirements, State requirements, and 340B requirements.

Programs like the Medicaid Drug Rebate Program (MDRP), the 340B Drug Pricing Program (340B), and the Medicare Part B and D inflation penalties limit the ability of generic producers to increase prices, amplifying the concern that tariffs will cause substantial product discontinuations and shortages. If manufacturers attempt to raise the price of drugs to account for tariffs, their statutory rebate liability due to state Medicaid programs on Medicaid beneficiary utilization of their products will increase at a dollar-for-dollar rate for any increase greater than the Consumer Price Index. Manufacturers cannot simply opt out: they must participate in the MDRP in order to receive Medicaid coverage for their drugs.[32] These manufacturers must also

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

[32] *See* 42 U.S.C. § 1396r-8 *et seq.*

participate in the 340B program and sell covered drug products on the Federal Supply Schedule.[33]

The cost of these rebates has only increased recently. Prior to January 1, 2024, MDRP rebates were capped at Average Manufacturer Price ("AMP"), meaning a manufacturer's MDRP liability on a unit of drug product could not exceed AMP. However, under the American Rescue Plan Act of 2021, the AMP cap was removed, effective January 1, 2024. Thus, manufacturers are left to choose between two bad options: (1) attempt to increase prices increasing AMP and resulting in payment of ever increasing MDRP rebates on all Medicaid utilization of the manufacturer's drug; or (2) absorb a tariff that could exceed the razor-thin margins. Either option ultimately leads to discontinuations of essential medicines.

Medicare Parts B and D inflation penalties amplify these concerns further. Indeed, sole source generic manufacturers and biosimilar manufacturers—whose prices are generally lower—are more likely to face inflation rate penalties, because any increase constitutes a larger percent of its price, relative to price increases taken by brand manufacturers. By way of example, a $1 increase of a $100 drug is only 1%, whereas a $1 increase of a $10 drug is only 10%, and thus more likely to trigger inflation penalties.

The 340B drug pricing program serves as further confirmation. The statutorily prescribed 340B ceiling price is based on AMP and the Unit Rebate Amount (URA). When the URA equals or exceeds AMP, the price defaults to a penny (i.e., $0.01) per unit under Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) regulation (so-called "penny-pricing").[34] Imposition of a tariff on a 340B penny-per-unit priced product is not economically viable and will also simply lead to further discontinuations of essential medicines.

Consistent with the above, if a generic drug manufacturer opted to increase its prices, that price increase would likely need to be **more** than the cost of the tariff. For all products being provided through 340B, effectively, the manufacturer could **not** increase the price to account for the cost of the tariffs for those products. As such, the remainder of the products would need to incur the cost increase. This possibility is not economically viable.

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33 *See* Section 601 of the Veterans Health Care Act of 1992.

34 42 U.S.C. § 10.10(b).

340B Example:

340B Exposure	Declared Value/AMP	% Tariff	% units available for price increase	% Price Increase	$ Price Increase/unit
0%	$1/unit	20%	100%	20%	$0.20
20%	$1/unit	20%	80%	25%	$0.25
40%	$1/unit	20%	60%	33%	$0.33

C. Tariffs Will Lead to Shortages and Not Reshoring

Because of the conditions described above, tariffs will not lead to reshoring but instead will cause shortages of generic and biosimilar medicines. This concern is not merely hypothetical: This submission includes a **Business Confidential Appendix A of [[ ]] made by AAM members that are likely to either be discontinued or go immediately into shortage if additional tariffs are imposed.**

As detailed above, generics drugs operate on razor-thin margins[35] that substantially limit any ability to absorb additional cost in either the private or public sector marketplaces. Unsurprisingly, this causes problematic economic dynamics—a factor that was identified by President Trump's FDA in 2019 as a primary "root cause" of drug shortages.[36] The data confirm this: 56% of drugs in shortage cost less than $1 per unit.[37] Further, 84% of current shortages affect generics.[38]

While tariffs might normally be seen as a way to increase domestic producers' margins, and free up additional funds for them to further invest in U.S. production, that will not occur here. That is because, as discussed, purchasers have monopsony power that not only results in unsustainable pricing, but one-sided contracts that leave generic manufacturers with little ability to pass on price increases, including those caused by tariffs on inputs or final products. If generic producers are forced to absorb increased costs, even in part, those thin margins would disappear—heightening the risk of discontinuations and shortages.

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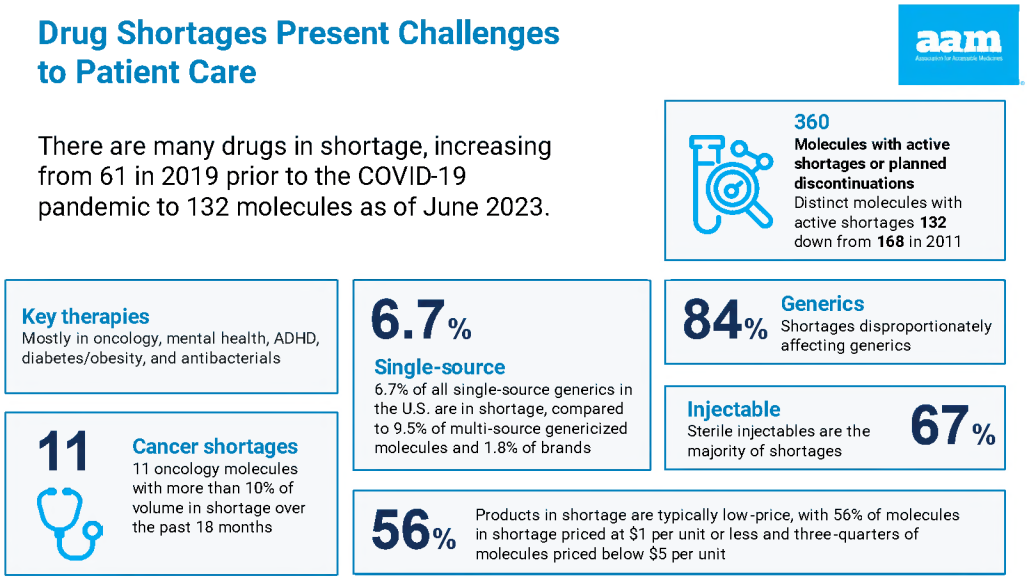
35 Anna Brown, *With Tariffs on the Way, Generic Drugmaking Woes Could Hinder Trump's Reshoring Plan, ENDPOINTS NEWS* (Mar. 15, 2025), *available at* https://endpts.com/new-pharma-tariffs-could-put-generic-drugmakers-under-pressure/.

36 FDA: Root Causes and Potential Solutions.

37 Policy Options at 2; Savings Report at 7.

38 Savings Report at 7.



The United States already faces a significant number of drug shortages.[39] And as the United States Senate Committee on Finance recently reported, shortages are concentrated almost uniformly in generic drugs:

> Generic drugs comprise the majority of medications in shortage at any given time. One recent analysis found that generics typically make up two-thirds of drug shortages, while other studies have produced estimates as high as 84 percent. . . . Shortages span a range of therapeutic classes, with oncology drug and antimicrobial access gaps attracting substantial media attention in recent months. Certain types of medications, like generic sterile injectables (GSIs) which include cancer drugs and saline solution used to flush IV lines provided in hospitals and physician offices, have proven particularly vulnerable, representing an estimated 67 percent of shortages overall.[40]

These shortages result from the economics of the industry, which leave producers unable to raise prices to either private or public sector purchasers. Given the industry's thin margins and inability to pass on increased costs, tariffs are likely to have negative impacts that are wholly out of step with the Administration's aims. Drugs will be discontinued. U.S. manufacturers will have less capital to expand investments if tariffs are imposed. Without significant reform to the

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39 FDA Drug Shortages: *Current and Resolved Drug Shortages and Discontinuations Reported to the FDA*, U.S. Food & Drug Administration Website (last accessed Mar. 10, 2025), available at https://dps.fda.gov/drugshortages.

40 Policy Options at 2.

existing marketplace, a tariff strategy alone will not succeed in strengthening the U.S. pharmaceutical supply chain.

VI. The Administration Should Tackle the Root Causes of Market Distortions and Unfair Foreign Practices

AAM would welcome the opportunity to work with the Administration on concrete incentives to spur domestic manufacturing of generic medicines and ensure a more resilient supply chain given the serious market dynamics discussed above. While tariffs can be a tool that drives the onshoring of manufacturing in other industries, tariffs in the generic and biosimilar industries would result in harm to patients and reduced availability of much-needed medicine, as noted above. And crucially, without other significant reforms—such as addressing reimbursement for pharmaceuticals—tariffs are unlikely to benefit U.S. manufacturing or exports of generic and biosimilar medicines given the economic dynamics in these industries. Instead, tariffs risk further incentivizing moves to lower-cost offshore destinations for production.

There are other policy tools that the Administration can employ that would be more effective at cutting red tape, correcting market failures and countering unfair foreign practices, which will increase generic production in the United States. We outline these key policies below.

1. Improving Medicare Reimbursement and Coverage

AAM has several recommendations to improve Medicare reimbursement and coverage for generic and biosimilar medicines First, a Medicare condition of participation could be developed that requires providers to prioritize and plans to cover generics and biosimilars from resilient suppliers, which are (i) suppliers that finish pharmaceuticals in the U.S., its FTA partners, or its WTO Pharmaceutical Agreement partners, including any future partners of those agreements; or (ii) "Resilient Suppliers With a Significant Domestic Presence," defined above. CMS can further solicit comments on the definition of resilient suppliers before implementation. Additionally, AAM recommends that long-term, fixed-volume contracts should be prioritized for all federal procurements with resilient suppliers, defined above.

Second, the Administration could use existing authority, including under the Social Security Act's "inherent reasonableness" provisions and through Center CMMI demonstration and pilot programs, to mitigate unsustainably low ASP calculations and ASP-based reimbursement for generic drugs and biosimilar products payable under Medicare Part B. Additionally, the Administration could remove discounts to non-purchasers (i.e., GPOs, health plans, and PBMs, who do not take possession of product and therefore are not "purchasers" in the traditional sense of the word) from the ASP calculation. While none of these options constitutes a "silver

bullet", when taken together, they constitute significant effort toward stabilizing the reimbursement of generic drugs and biosimilar products payable under Medicare Part B.

2. Streamline FDA Regulatory Process and Remove Regulatory Barriers

Consistent with the important steps announced in the Administration's Drug Pricing Executive Order[41] and the Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicine,[42] work with Congress and agencies to eliminate regulatory burdens that slow generic and biosimilar approval, including:

- Eliminating the non-scientific distinction between biosimilar and interchangeable products and deeming all biosimilars interchangeable upon approval;
- Ensuring that the FDA can provide important quantitative and qualitative information (Q1/Q2) to generic companies seeking approval for complex generic products;
- Accelerating user-fee funded facility inspections by better utilizing FDA's Remote Regulatory Assessment tools to increase the number of remote and virtual FDA assessments (including section 704(a)(4) document requests), and better leveraging mutual recognition agreements; and
- Streamlining FDA's approval process including the ability to utilize a global comparator and removing redundant clinical studies.

Commonsense reforms that ease the way for generic production will boost both affordability and access to medicines in the United States, as well as the competitiveness of U.S. manufacturers.

3. Crack Down on Anticompetitive Practices

To correct the broken generic and biosimilar marketplaces and asymmetric negotiating leverage between U.S. manufacturers and buyers, the FTC and DOJ should immediately issue new guidelines on monopsony power and anticompetitive contractual practices. Guardrails on the exercise of outsized market power would improve the long-term health of the generic and biosimilar industries, including their ability to obtain reasonable margins that promote high-quality, resilient supply, and prevent the discontinuation of essential medicines.

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41 Apr. 15, 2025 Exec. Order.

42 May 5, 2025 Exec. Order.

To further unleash competition and ensure the long-term viability of U.S. generic production, CMS should pursue corrections to Medicare and Medicaid formulary practices to ensure that generic and biosimilar medicines are appropriately covered on prescription drug formularies. Currently, many commercial and government plan formularies prevent access to generic and biosimilar medicines and prioritize continued "reference preference"— regardless of cost to the patient—due to program designs that create perverse incentives by favoring high-cost, high-rebate products.[43] When Congress created the generic drug market through passage of Hatch-Waxman (and the biosimilar market through the BPCIA) it intentionally signaled that competitive and lower-cost generic drug and biosimilar markets are important to the health of American patients and the U.S. economy. Practices like delaying coverage of new generic drugs and biosimilar products and negative tiering decisions not only destabilize the U.S. supply chain but ultimately act in direct conflict to Congressional intent in passing the laws creating these markets.

To accomplish this, CMS can pursue changes to Medicare Advantage, Medicare Part D, Medicaid (including Medicaid Managed Care), and Exchange plan formulary practices to ensure generic drugs and biosimilar products are quickly and appropriately covered, and that plan sponsors are able to immediately displace the associated reference product once the generic drug or biosimilar product is available on the market. Additionally, the Administration could consider "generics- and biosimilars-first policies" in the Medicare Advantage and Part D programs. Further, the Administration could clarify that switching a patient to a biosimilar does not violate the step therapy regulations in the Medicare Advantage Program. Finally, the Administration could ensure that beneficiaries are not required to step through reference products before accessing the corresponding generic or biosimilar product in any federal program (i.e., Medicare, Medicaid, or Exchange plans).

4. Accelerate Investment

The Administration could build upon the establishment of the U.S. Investment Accelerator[44] to prioritize revitalizing the U.S. generic pharmaceutical industry. This could include, for example, creating a government loan or financing facilitation program or entity for strengthening U.S. pharmaceutical security and resilience. Existing government financing institutions like the DFC or elements of the Export-Import Bank of the United States loan programs could provide good models here. Such a program could offer a mix of direct loans, loan guarantees, and low-interest financing to companies investing in U.S.-based API and finished drug production:

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43 *Medicare Plans Continue Trend of Restricting Generic Drugs*, https://accessiblemeds.org/resources/press-releases/medicare-plans-continue-trend-restricting-generic-drugs/

44 Mar. 31, 2025 Exec. Order.

- *Direct Low-Interest Loans*: Fixed-rate, long-term loans for generic and biosimilar manufacturers;
- *Loan Guarantees*: Covering a portion of private sector loans to reduce lender risk;
- *Public-Private Partnerships (PPP) Loans*: Co-investment models where the government funds part of the project and private investors finance the rest; and
- *Bridge Loans*: Short-term loans to help companies scale operations before securing private capital.

In the near term, federal grants or contracts, or other direct assistance, could target generic and biosimilar manufacturers with excess manufacturing capacity to upgrade and update existing manufacturing lines; build new lines in existing facilities; or build new facilities to provide additional capacity. These investments should focus on deploying already existing unused capacity, rather than new generic and biosimilar manufacturing that will take years to bring online, for generic and biosimilar medicines most vulnerable to shortages.

5. Reform Environmental Permitting

Consistent with the Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicine,[45] substantially reforming permitting practices, which currently can take a decade for a single project with overlapping state and federal requirements. Indeed, current restrictions imposed by the Environmental Protection Agency (EPA) slow down approvals for new manufacturing facilities and add to the cost burden that U.S. drug producers face as compared to their foreign competitors. In the United States, the National Environmental Policy Act (NEPA) permitting process takes an average of 3.5 years to 6 years to complete.[46] Between overlapping federal and state requirements, including under the Clean Air Act, the Resource Conservation and Recovery Act Permit Program, and the Clean Water Act, permitting for even a single project can take a decade. [[

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6. Streamlining Patent Litigation

Pharmaceutical patent litigation has become increasingly complex, particularly with large patent thickets. The Administration should work with Congress to cap the number of patents that can be asserted in patent litigation and prevent non-innovative double patents from stifling generic and biosimilar entry.

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45 May 5, 2025 Exec. Order.

46 KMPG Permitting.

VII. Unless Carefully Calibrated, Tariffs Will Exacerbate Existing Dynamics

Given the current dynamics affecting the U.S. generic and biosimilar industries, tariffs are unlikely to shift production of generic medicines to the United States in the near term and could instead lead to increased prices, drug shortages, and/or disinvestment in the United States. If the Administration decides to impose additional tariffs on generic pharmaceuticals, API and KSM, those tariffs must be carefully calibrated to further the Administration's objectives and avoid unintended consequences, including further driving production to low-cost sources and hampering the ability of the U.S. industry to revitalize. Below, AAM details strategies for ensuring that tariffs do not exacerbate current problems and further undermine U.S. national security, including a 180-day delay to allow countries to negotiate the removal of barriers to U.S. pharmaceutical exports, tariffs that distinguish between trade partners, a phased approach that recognizes the differences between finished pharmaceuticals and inputs, exemptions for drugs that are likely to be discontinued or go into shortage, tariff "de-stacking," and a recognition that inversion and other tax-related issues primarily affect branded drugs, rather than generics.

A. Provide For A 180-Day Negotiation Period

Should the Administration conclude that pharmaceutical imports threaten to impair the national security, it should not impose tariffs right away. Rather, it should provide a 180-day period in which the Administration can negotiate with willing trading partners to address trade practices, such as tariffs on U.S.-made pharmaceuticals and inputs and foreign subsidization of pharmaceutical manufacturing, that negatively affect U.S. generic and biosimilar production and exports. Such negotiations would boost exports, supporting increased investments in the United States, and get at the root of foreign government interventions that distort the global supply chains for pharmaceuticals. To the extent that a country reaches agreement with the Trump Administration, that country could be removed from the tariff action——which should incorporate both pharmaceutical product directly and supply chain inputs necessary to produce them.

B. WTO Pharmaceutical Countries and USMCA-Compliant Products Should Be Exempted

As discussed above, consolidation among purchasers of generic drugs has accelerated the shift away from primary manufacturing in the United States toward lower-cost locations. A uniform tariff applicable to imports from all sources will do nothing to shift production away from low-cost producers and may only enhance the drive toward those locations. Again, it could inadvertently disadvantage the producers currently in the United States.

Given market dynamics, generic drug manufacturers in the United States would have virtually no ability to renegotiate existing contracts to pass increased tariff costs on to purchasers in the near and medium term. To mitigate the impact of these increased costs, producers with operations the United States and other higher-cost locations like Canada and the EU would feel pressure to move production to lower-cost locations. Tariff costs may also lead to the discontinuation of drugs. Rather than increase the safety, reliability, and self-sufficiency of the U.S. pharmaceutical supply chains, tariffs that are not carefully calibrated stand to make a bad situation worse.

For these reasons, the Administration should consider differentiating among supplier countries and applying lower tariffs to markets with low incidence of distortive practices and zero tariffs on U.S. exports of pharmaceutical products and corresponding supplies. In particular, the Administration should consider exempting WTO Pharmaceutical Agreement countries, including signatories who join during the pendency of the investigation, that currently provide duty-free importation of pharmaceutical products, including both finished drugs and APIs. This differentiation would also give the United States greater leverage in trade negotiations with countries that undertake distortive trade practices.

Similarly, the United States should continue to apply duty exemptions for USMCA-compliant products, consistent with its approach in other tariff regimes. While Mexico is not a member of the WTO Pharmaceutical Agreement, under the USMCA, it provides duty-free treatment for U.S. pharmaceutical products. In addition, the USMCA rules of origin for finished pharmaceuticals and inputs like API and KSM require meaningful production operations such as chemically reactive processes and substantial value add. Given the close economic and security relationship between our countries, a pharmaceutical supply chain that capitalizes on each of our strengths and corrects for certain of the market failings mentioned in this submission could complement a revitalized U.S. industry.

C. Tariffs Should Be Phased In

As of October 2024, there were more than 23,000 prescription drug products approved for marketing in the United States. Given the sheer breadth of the finished drugs, APIs and KSMs consumed in the United States and the high volume that is currently imported, it would be impossible for the United States to onshore all of its pharmaceutical needs at once. As such, a tariff policy should be phased in to take into account the time horizons needed to bring new capacity online.

The *Federal Register* notice distinguishes between "finished generic and non-generic drug products" and "critical inputs such as active pharmaceutical ingredients." Finished dosage forms are where near-term progress can be made in promoting resiliency, while reshoring

production of API and KSM requires longer-term structural changes and significant new investments.

As previously described, the Administration should consider a phased approach, including but not limited to retaining, reshoring, and/or nearshoring fill-and-finish operations. As part of such a phased approach, and combined with other policy changes proposed, AAM recommends that the Administration delay tariffs on finished dosage form while AAM members look to increase idle capacity. [[

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The Administration can reevaluate this based on changes to incentives and reporting from the industry.

The Administration should also delay or not impose any tariffs (sector-specific or reciprocal) on API, KSM, and necessary materials (excipients, packaging, and production equipment) needed for domestic fill-finish operations at this time to ensure that existing domestic capacity is retained. Indeed, any tariffs imposed on imported production inputs and equipment would negatively impact U.S.-based manufacturing operations, reducing their ability to offer more affordable generic medicines to patients, mitigate drug shortages, and reinvest in further domestic manufacturing. Tariffs on inputs, packaging materials, and production machinery would compound cost pressures for these already low-margin medicines, leading to further supply contraction and fewer U.S.-based manufacturers of essential medicines. [[

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D. Products Likely to Be Discontinued Should Be Tariff-Exempt Until U.S. Supply is Established

To avoid risking serious drug shortages, the Administration should exempt from tariffs any generic or biosimilar drug that is:

(i) provided in the **Business Confidential Appendix A** submitted with these comments, which identifies [[ ]] that would likely be discontinued or go into shortage in the event of a tariff;
(ii) currently "penny-priced" in the 340B program; or
(iii) listed currently or within the past 100 days on the FDA's drug shortage list.

Tariffs stand to only increase such shortages until such time as domestic/nearshored/friend-shored manufacturing can be established. Establishing healthy manufacturing of these goods

is not something that can be accomplished through a tariff mechanism. Rather, it requires decisive action to reverse the market dynamics, including regulatory hurdles, monopsony power, and lowest-price purchasing practices that have driven U.S. manufacturing offshore while severely limiting U.S. drugmakers' ability to raise prices.

E. Pharmaceutical Tariffs Should Not Be "Stacked"

The Trump Administration has recognized that where multiple tariffs affect a single product, the "stacking" of the tariffs can produce unnecessary and undesirable distortions. For example, the Administration has exempted from reciprocal tariffs goods that are subject to Section 232 duties. Likewise, the Administration has taken steps to "de-stack" the separate Section 232 duties affecting automotive goods and steel and aluminum products and the IEEPA tariffs on Canada and Mexico.

If tariffs are imposed as a result of this investigation, the Administration should continue with its established practice of ensuring that reciprocal tariffs do not apply to goods covered by the duties on pharmaceutical goods. It should also ensure that the pharmaceutical tariffs do not stack with other duties. For purposes of these de-stacking efforts, the Administration should consider not only finished pharmaceuticals, API, KSM, and similar inputs, but packaging materials and production equipment needed for U.S. manufacturing of pharmaceutical products.

F. Tariffs Aimed at Tax Issues Should Focus on Relevant Products

To the extent that the Administration chooses to use tariffs imposed under this investigation or through other means to address concerns arising from inversion and similar tax issues, the Administration should recognize that generics and biosimilar drugs are not drivers of these problems. Unlike branded drugs, generic drugs are not being produced abroad for tax reasons. Instead, they are being produced abroad due to market dynamics that generic producers do not control, and which favor production in the lowest-cost foreign jurisdictions possible. Any tariffs that are meant to disrupt tax-driven manufacturing relocations should be aimed squarely where the problem lies—and not at generic and biosimilar drugs.

VIII. Answers to BIS's Specific Questions

Questions (i) through (iv) & (viii)

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;
(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;
(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;
(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

AAM conducted a third-party, blinded survey of its members, consistent with FTC-DOJ surveying guidance, to better understand the current supply chain and current used and unused domestic capacity. [[
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Questions (v) through (vii)

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;
(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;
(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

As noted above, we appreciate that the Trump Administration has identified specific foreign government subsidies that the Administration would like to address. We recommend that the Trump Administration utilize a 180-day pause, as noted above, to allow those countries time to negotiate for the removal of those subsidies. AAM is happy to work with the Trump

Administration to help facilitate a productive solution on these issues. We believe that removal of these subsidies could have far greater impact on counterbalancing trade practices than tariffs would.

With respect to the possibility of export restrictions, limits on a country's ability to impose such restrictions—particularly in the context of national emergencies—can also be negotiated with the United States. Additionally, taking the steps outlined above to immediately increase domestic fill-finish capacity could blunt the impact of foreign export restrictions.

Question (ix)

> **(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security**

As previously discussed, the current sustainability issues in the generic and biosimilar markets require multi-factorial solutions, including unique FTC/DOJ, CMS, FDA, and EPA reform. Trade reforms alone—without comprehensive reforms to the rest of the system—will serve to only exacerbate drug shortages and cannot solve the issue of domestic manufacturing. We look forward to working with the Administration on these issues.

IX. Conclusion

AAM's members provide essential medicines that improve the health of patients in the United States. Generic and biosimilar competition consistently reduces drug costs and expands patient access to needed therapies. While the United States must pursue an overall strategy for a secure, reliable, and safe pharmaceutical supply chain, tariffs are not the most effective means for achieving this worthy goal. By themselves, additional duties on pharmaceutical goods would tax the health and well-being of patients, cause disproportionate economic harm for U.S. patents and taxpayers, decrease the competitiveness of U.S. drug-makers, and would be unlikely to result in any changes in the trade practices of other countries. And crucially, tariffs will not make it more attractive to manufacture in the United States, as the greatest impediment to such manufacturing is the economic dynamics of the generic and biosimilar industries. Accordingly, AAM respectfully requests that the Secretary exclude finished generic and biosimilar pharmaceuticals, APIs, pharmaceutical ingredients, packaging, other components, and production machinery from the scope of any recommended tariff action in this investigation. To the extent that any tariffs are imposed, they should be carefully calibrated in the context of a larger approach to overturning the current market dynamics that disfavor U.S. production of generic drugs.

REQUEST FOR CONFIDENTIAL TREATMENT

Pursuant to 5 U.S.C. § 552(b)(4), AAM respectively requests confidential treatment of bracketed business confidential information in the attached submission. We certify that the information contained in brackets ("[[ ]]"), or is otherwise identified as confidential, is confidential in its entirety. The information for which business confidential treatment is requested pertains to sensitive commercial information of AAM and/or its members that would not customarily be released to the public. Disclosure of this information would cause substantial harm to AAM's and/or its members' competitive and commercial positions or limit their ability to provide the Department with similar information as part of this and future investigations.

Sincerely,

John Murphy
President & CEO

APPENDIX A

ENTIRE APPENDIX NOT CAPABLE OF PUBLIC SUMMARY