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Public Citizen Comments re: Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients
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Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. As such, we and our members have an interest in preserving and strengthening pharmaceutical supply chains to deliver predictable access to medicines.

Our comment focuses specifically on generic drug supply and access, as these are especially threatened by potential import restrictions.

Maintaining the availability of and access to medicines should be a central consideration in any government action that targets pharmaceuticals.

Chronic drug shortages are a pressing concern for U.S. consumers.[1] The average shortage is estimated to impact at least half a million Americans and to disproportionately affect seniors.[2] Shortages can have significant consequences for patients, including interruptions to care, increased costs, and medication errors.[3] Shortages primarily impact generic drugs (which account for 90% of all U.S. prescriptions) and historically affect generic sterile injectables (among other drugs), including those used to treat cancer and used to deliver lifesaving emergency care.[4]

Concerns about supply disruptions and shortages extend beyond the general public. In a 2021 report assessing pharmaceutical supply chain risks, the Department of Defense (DoD) (whose servicemembers rely on commercial manufacturers for pharmaceuticals) noted the negative consequences of supply disruptions for public health and national security, finding that:

> …pharmaceutical supply disruptions could compromise the standard of care to DoD beneficiaries. A disruption of the supply of foreign-made APIs [active pharmaceutical ingredients] to domestic manufacturers could cause a drug shortage that affects every level of the U.S. health care system. Since the DoD is a consumer of the U.S. commercial pharmaceutical market, which is dependent on ingredients from foreign suppliers, these potential drug shortages could ultimately compromise the standard of care for Service members and DoD beneficiaries. Implementing measures to mitigate the risks of a pharmaceutical supply disruption would provide a defensive capability and mitigate public health and national security risks.[5]

While the causes of shortages are complex and often non-transparent, research finds that predictive factors can include a decline in suppliers and manufacturing issues.[6] Manufacturers reporting shortages to the U.S. Food and Drug Administration (FDA) cite causes including increased demand, discontinuation of manufacture, manufacturing delays or other issues, good manufacturing practices (GMP) issues, shortage of active pharmaceutical ingredient, and regulatory delays (though the majority of reported

shortages do not note a cause).[7] Reliance on a limited number of suppliers for some drugs also contributes to supply chain vulnerabilities. Recent research found that one-third of unique APIs produced for the U.S. market rely on a single facility and another 30% rely on two or three facilities.[8] Reliance on a limited number of suppliers is risky because the removal of one supplier can cause supply disruptions and impact the overall ability to meet demand.

Concerningly, pharmaceutical tariffs could exacerbate vulnerabilities in generic drug supply chains. Generics suppliers unable to accommodate the added cost pressures may exit the market or cut costs, including in ways that can adversely affect product quality and lead to shutdowns or slowdowns in production.[9] As a result, there may be fewer suppliers available to meet domestic demand and worsening drug shortages. Beyond these risks, tariffs could also worsen the drug affordability crisis in America—where many already struggle to afford needed medicines and 30% report not taking their medicines as prescribed due to cost.[10] Generics manufacturers or distributors that do not absorb tariff costs may instead choose to pass the cost on through higher prices.[11] This would yet further increase costs for consumers while at the same time undermining the goal of lowering prescription drug prices in the U.S.

Broad pharmaceutical tariffs would undermine domestic manufacturing and the ability to meet domestic needs.

We agree that bolstering domestic manufacturing for essential medicines and inputs is an important goal. However, broad pharmaceutical tariffs will make it more difficult to achieve this aim. A 2005 review prepared for the Commission on Intellectual Property Rights, Innovation and Public Health found that pharmaceutical tariffs were generally not structured in such a way to protect local pharmaceutical production and that they could adversely affect local production costs.[12] Indeed, broad pharmaceutical tariffs at this time would negatively impact existing U.S.-based producers. For example, a U.S. manufacturer that relies on imported API would pay a tariff applied to that import, adding costs that may make it more difficult to sustain its business.

Across industries, tariffs on their own are insufficient to spur new domestic production. Public investment and support are needed to incentivize manufacturers and help balance the cost of establishing production in the U.S. Added costs from tariffs, on the other hand, would constrict funds, making it more difficult for generics manufacturers to invest in new production sites—which can cost hundreds of millions or billions of dollars and take several years.[13] Moreover, the complex, global nature of pharmaceutical supply chains—where components are often produced by different suppliers across different countries—makes relocating all production steps to the U.S. largely infeasible, particularly in a short timespan. This suggests that import restrictions would do more to disrupt fragile supply chains than to prompt relocation of production.[14]

Additionally, an estimated 40% of facilities that produce finished generic drugs and less than 10% of facilities that produce generic APIs for the domestic market are located in the U.S.[1516] An assessment of 118 essential medicines found that about half of these lacked domestic API manufacturing sites.[17] These data indicate that, apart from undermining the ability to establish domestic production, pharmaceutical tariffs would restrict imports without domestic capacity to supplement those supplies.

Recommendation: Promote resilience through support for stronger, more diversified supply chains, including via targeted approaches to bolster domestic capacity.

Given the interest in securing U.S. medicines supply, and given the potential for import restrictions to impair supply, we recommend that policymakers focus attention on strengthening supply chains, diversifying supply sources, and taking a strategic, long-term approach to increasing domestic capacity. Conversely to import restrictions, such actions will help lower vulnerability to supply disruptions.

Increasing domestic production capacity requires public funding and incentives to make relocation more cost-effective and sustainable. Previous recommendations from experts and the U.S. government include offsetting capital investment through loans, grants, and cost-sharing for critical medical infrastructure, investing in advanced manufacturing processes to improve efficiency, and creating a regulatory environment that facilitates qualification while simultaneously requiring practices that support quality, transparency, and resilience.[18] Investments should prioritize developing capacity to meet the U.S.'s most critical supply needs by targeting medicines based on assessments of clinical importance and number of suppliers to help insulate these from disruption. The U.S. government (including in response to President Trump's 2020 executive order on domestic medicines supply) has produced lists of essential medicines and inputs deemed particularly important.[19] Importantly, assessments of drug shortage drivers, supply chain vulnerabilities, and supply sources are severely limited by incomplete data.[20] As such, experts and government agencies emphasize the need for greater visibility and investment in data infrastructure to better understand vulnerabilities and match policy responses accordingly.[21] Additionally, existing literature and proposed legislation (as well as approved legislation) suggest public pharmaceutical production is a key initiative to increase competition and address shortages.[22][23] Similarly, government owned, contractor operated models offer structural advantages over other models of public-private cooperation.[24]

While increased domestic capacity is important, pharmaceutical supply chains will remain global, and U.S. medicines will continue to depend on global sources. It would not be feasible or cost-effective to produce all U.S. medicine supply domestically. Moreover, relying on a single or a few suppliers, or a single geographic region, for a drug or component is inherently risky whether those suppliers are based in the U.S. or another country. As such, addressing supply chain vulnerabilities requires efforts that support timely, affordable, quality-assured medicine production from capable facilities worldwide. The U.S. government can enable this through trade policies that support supply chain resilience and transparency. U.S. trade policy should also support flexible intellectual property rules to enable diversified global production that is more responsive to shortages and health emergencies.

Finally, recent cuts to staff and programs at the FDA that support inspections, product quality, and supply chain strengthening at home and abroad undermine the U.S.'s ability to bolster domestic production, diversify supply, and prevent shortages.[25] U.S. regulatory capacity must be sustained and strengthened in order to support efforts to increase resilience and reinforce medicine supply security.

[1] *See*, Congressional hearings and reports, including:
Legislative Proposals to Prevent and Respond to Generic Drug Shortages, Subcommittee on Health of the Committee on Energy and Commerce, https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-legislative-proposals-prevent-and-respond-generic-drug;
Hearing on Examining Chronic Drug Shortages in the United States, House Committee on Ways and Means, https://waysandmeans.house.gov/event/hearing-on-examining-chronic-drug-shortages-in-the-united-states/; The Health and National Security Risks of Drug Shortages, Senate Homeland Security and Governmental Affairs Committee, https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf

[2] ASPE, Impact of Drug Shortages on Consumer Costs (May 2023), https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf

[3] ASPE, Impact of Drug Shortages on Patients in the United States: A Case Study of Three Drugs (Apr. 2024), https://www.ncbi.nlm.nih.gov/books/NBK608930/

[4] ASPE, Analysis of Drug Shortages, 2018-2023 (Jan. 2025), https://aspe.hhs.gov/reports/drug-shortages-2018-2023; GAO, Drug Shortages: HHS Should Implement a Mechanism to Coordinate Its Activities (Apr. 2025), https://www.gao.gov/assets/gao-25-107110.pdf

[5] Department of Defense Office of Inspector General, Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain (DODIG-2021-126) (Sept. 20, 2021). https://www.dodig.mil/reports.html/Article/2784301/evaluation-of-the-department-of-defenses-mitigation-of-foreign-suppliers-in-the/

[6] Barber, Written statement, U.S. Senate Committee on Armed Services, Subcommittee on Personnel Hearing: The Department of Defense's efforts to ensure servicemembers' access to safe, high-quality pharmaceuticals (Apr. 30, 2024), at 3, https://www.armed-services.senate.gov/imo/media/doc/barber_statement.pdf

[7] *Id*, at 3 and 6.

[8] Socal et al. Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients, Health Affairs (2023), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.01120

[9] Wosińska, Will pharmaceutical tariffs achieve their goals?, Brookings, (Mar 27, 2025), https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/

[10] KFF, Public Opinion on Prescription Drugs and Their Prices (Oct. 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

[11] US consumers to be hit hardest by pharmaceutical tariffs, ING (Apr. 2025), https://think.ing.com/articles/us-trump-tariffs-pharmaceuticals-consumers/

[12] Olcay and Laing, Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation? (May 2005).

[13] Association for Accessible Medicines, The Quickest Route to U.S. Essential Medicines Production (2023), https://accessiblemeds.org/resources/blog/quickest-route-us-essential-medicines-production-existing-and-idle-production-sites/; Biopharmaceutical Manufacturing, PhRMA, https://phrma.org/policy-issues/research-development/manufacturing-supply-chain

[14] National Academies of Sciences, Engineering, and Medicine, Building resilience into the nation's medical product supply chains (2022), https://doi.org/10.17226/26420

[15] Beste Kaygisiz et al., The geography of prescription pharmaceuticals supplied to the U.S.: levels, trends and implications (Dec. 2019), https://www.nber.org/system/files/working_papers/w26524/w26524.pdf

[16] Socal et al. Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients, Health Affairs (2023), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.01120

[17] Barber, Written Statement, U.S. Senate Committee on Armed Services, Subcommittee on Personnel Hearing: The Department of Defense's efforts to ensure servicemembers' access to safe, high-quality pharmaceuticals (Apr. 30, 2024), at 9, https://www.armed-services.senate.gov/imo/media/doc/barber_statement.pdf

[18] Barber, Written statement, U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health Legislative Proposals to Prevent and Respond to Generic Drug Shortages (Sept. 2023),

https://democrats-energycommerce.house.gov/sites/evo-subsites/democrats-energycommerce.house.gov/files/evo-media-document/melissa-barber_witness-testimony_09.14.23.pdf; Essential Medicines Supply Chain and Manufacturing Resilience Assessment (May 2022), https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

[19] Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, FDA (May 2022), https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs; Essential Medicines Supply Chain and Manufacturing Resilience Assessment (May 2022), https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

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[22] The Affordable Drug Manufacturing Act, https://www.congress.gov/bill/118th-congress/senate-bill/3398/text; Brown and Morten, Public pharma is the best solution to the ongoing problem of drug shortages, Stat News (Aug. 9, 2023) https://www.statnews.com/2023/08/09/drug-shortages-public-pharma-option/

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