

The Risks of Pharmaceutical Tariffs for Generic Drug Availability

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In April 2025, the Trump administration announced an investigation into the adverse effects of pharmaceutical imports on U.S. national security.¹ Under Section 232 of the Trade Expansion Act of 1962, the president has broad power to investigate and subsequently to “adjust” or restrict imports that threaten to impair national security. If finalized, the application of pharmaceutical tariffs under Section 232 would upend long-standing trade conventions that have protected medicine imports from tariffs, increase costs for public health care payers, and potentially reduce the availability of important generic medicines in the United States.

Under the World Trade Organization’s 1994 pharmaceutical agreement, the United States and several of its major trading partners — including the European Union, Japan, and Switzerland — reciprocally eliminated tariffs and other duties on pharmaceuticals and active pharmaceutical ingredients. This agreement, in addition to separately agreed-upon favorable bilateral trading terms between the United States and other markets (zero or low tariffs on most drug imports from India, for example), has liberalized global pharmaceutical trade. Because of accelerated offshoring of medicine production, only about 20% of generic drugs are manufactured in the United States.² In exchange for nearly tariff-free generic drug imports, U.S. consumers have benefited from generic drug prices that are the lowest among peer countries.

In April 2025, the Trump administration announced “reciprocal” tariffs on all imports into the

United States, which were then temporarily reduced to a baseline 10% rate. Pharmaceuticals were temporarily exempted from both the reciprocal and baseline levies; however, the relevant executive order and subsequent administration statements indicated that pharmaceutical products would be subject to separate tariffs (for example, in July 2025, Trump threatened to impose tariffs of up to 200% on pharmaceuticals).

Although the legal basis for the administration’s sweeping global tariffs is currently being challenged, the president independently has authority under Section 232 of the Trade Expansion Act to restrict sector-specific imports that threaten to impair national security. On April 16, 2025, the Department of Commerce opened a Section 232 investigation on the national security implications of imports of pharmaceuticals and pharmaceutical ingredients. The administration has used this Section 232 authority to launch multiple sectoral tariffs; for example, the first Trump administration increased steel tariffs to 25% in 2018, and the current administration raised them to 50% in June 2025. Previously, Section 232 investigations had not resulted in adverse trade decisions since this authority was used to embargo crude oil from Libya (1982) and freeze oil imports from Iran (1979).

The pharmaceutical industry was never previously subjected to Section 232 investigation. Generic drugs, which account for roughly 90% of total filled prescriptions in the United States, generally have low profit margins and are mostly manufactured overseas.³ Although the administration’s tariff policy

aims to promote domestic manufacturing and reduce geopolitical risks to medication availability in the United States, tariffs may have important adverse consequences that could affect patients and payers.

Given low margins, high competition, and variable reliance on imported active pharmaceutical ingredients, generic drug markets may be more sensitive to tariffs than markets for brand-name pharmaceutical products. Generic drug manufacturers, most of which produce only generic medications, generally have limited ability to pass on added costs to payers and consumers. In the Medicaid and Medicare programs, statutory rules require pharmaceutical companies to provide rebates when price increases exceed the rate of inflation; similarly, the 340B Drug Pricing Program applies Medicaid’s inflation-linked rebates to purchases by qualifying hospitals and health care organizations. For injectable and clinician-administered products, multi-year contracts may lock in generic product prices for buyers such as group purchasing organizations.

Although political pressure may be exerted in an attempt to discourage market exit, applying tariffs in this context would provide generic drug manufacturers with an incentive to markedly reduce or even discontinue product sales (for example, for generic drugs that are disproportionately purchased by public payers) rather than absorbing the full cost of tariffs. Such a reaction could, in turn, lead to decreased market competition, as smaller manufacturers and those that are more dependent on imports exit the U.S. market; the net

results of supply discontinuations and reduced market competition would probably be higher costs for public payers and increased risk of drug shortages. For example, generic drug shortages were found to be associated with higher prices for alternative therapies⁴; and a national shortage of norepinephrine was associated with increased mortality.⁵

In addition, broad tariffs on generic drugs are unlikely to achieve the policy intent of safeguarding national security from geopolitical threats to the U.S. medicine supply. Capital investments in domestic manufacturing require multiple years of lead time and presumably prioritize high-margin products, rather than low-cost generic medicines. Most U.S. generic drug imports are from Indian and European manufacturers (for example, more than 60% of generic oral drug volume comes from India).² Both these jurisdictions have been independently engaged in recent policymaking to reduce reliance on active pharmaceutical ingredients from China, for instance. However, U.S. tariffs on generic drug imports from India and Europe would reduce, not increase, those manufacturers' capacity to invest in alternative suppliers of pharmaceutical ingredients. Reciprocal tariff actions by trade partners could also undermine the in-

ternational competitiveness of U.S. generic drug manufacturers.

We believe that several changes to the administration's proposed policy on pharmaceutical tariffs are urgently needed to protect access to generic medicines. First, if it were not politically feasible to exclude all generic drugs, which would be the best solution, the administration could avoid shocks to the U.S. medicine supply by gradually phasing in targeted tariffs on generic drugs from specific countries that are deemed to pose geopolitical risks. Harmonization of such a policy with those of key trading partners, including Europe and India, could support parallel efforts to diversify suppliers of key active pharmaceutical ingredients.

Second, instead of tariffs, the Section 232 authority would be better used to pursue more direct policy mechanisms to stimulate generic drug markets, including grants and tax incentives for building generic drug manufacturing capacity as well as national stockpiles for essential medicines and the active pharmaceutical ingredients necessary for their production. Finally, any pharmaceutical tariffs should be time-delimited and require close monitoring of key outcomes, including effects on market competition, prices, and drug availability, to ensure that fu-

ture trade policy is grounded in empirical evidence.

Disclosure forms provided by the authors are available at NEJM.org.

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Goals for Opioid Use Disorder Medications — Protection, Remission, and Recovery

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Medications such as methadone, naltrexone, and buprenorphine are the first-line treatment for opioid use disorder (OUD),¹ yet most addiction treatment programs don't offer these

medications and most physicians don't prescribe them. The result is that only 20 to 25% of the patients who are at risk for overdose or other OUD-related harms receive medication for opioid use disorder

(MOUD) — and even those patients are usually prescribed medication only for short-term detoxification. Along with stigma and lack of regulatory clarity, important barriers to broader prescrib-