Duke | MARGOLIS INSTITUTE for Health Policy

May 5, 2025
Secretary Lutnick
United States Department of Commerce

Dear Secretary Lutnick,

The Duke-Margolis Institute for Health Policy appreciates the opportunity to comment on the investigation initiated under Section 232 of the amended Trade Expansion Act of 1962 regarding the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients.

This comment from Duke-Margolis researchers has been informed by the Duke-Margolis ReVAMP Drug Supply Chain Consortium, which consists of a group of experts in supply chain, manufacturing, regulatory science, national security, and drug shortages from academia, private industry, and additional relevant stakeholder groups[1]. The Consortium's mission is to generate effective policy solutions that promote a reliable drug supply chain with advanced manufacturing capabilities and, ultimately, to improve patient outcomes by reducing the frequency and severity of drug shortages.

Multiple interrelated policy aims are relevant to this Section 232 investigation, including addressing geopolitical risks arising from concentration of pharmaceutical manufacturing in high-risk countries, onshoring domestic pharmaceutical manufacturing capabilities, and providing protection from intellectual property theft and malicious use of advanced technology.

Many policy tools are available that could potentially help to achieve these aims, including tax policy, reimbursement and payment reform, domestic purchase preference, direct investment in industrial base expansion, tariffs, and restrictions on foreign use of critical technology. As described below and in our recent Health Affairs article, broad tariffs on pharmaceuticals are likely to be ineffective or counterproductive in many cases, while also causing negative impacts to patients through manufacturer discontinuations and drug shortages. **We urge a cautious, targeted, and step-wise approach that matches specific policy aims with the tools best suited to achieve them while avoiding negative consequences to patient care.**

In the remainder of this comment letter, we outline 1) the conditions that must be in place for tariffs to be successful in achieving policy aims, 2) details on proposed vulnerability assessments to enable effective targeting, and 3) other policy approaches that may be preferable to tariffs.

We look forward to engaging with the Administration as the path forward is considered. Please feel free to reach out to us at stephen.colvill@duke.edu or thomas.roades@duke.edu.

Sincerely,

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Mark McClellan

Disclosures

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Stephen Colvill serves as a board member for the End Drug Shortages Alliance and a volunteer advisor for Angels for Change.

Key Recommendations

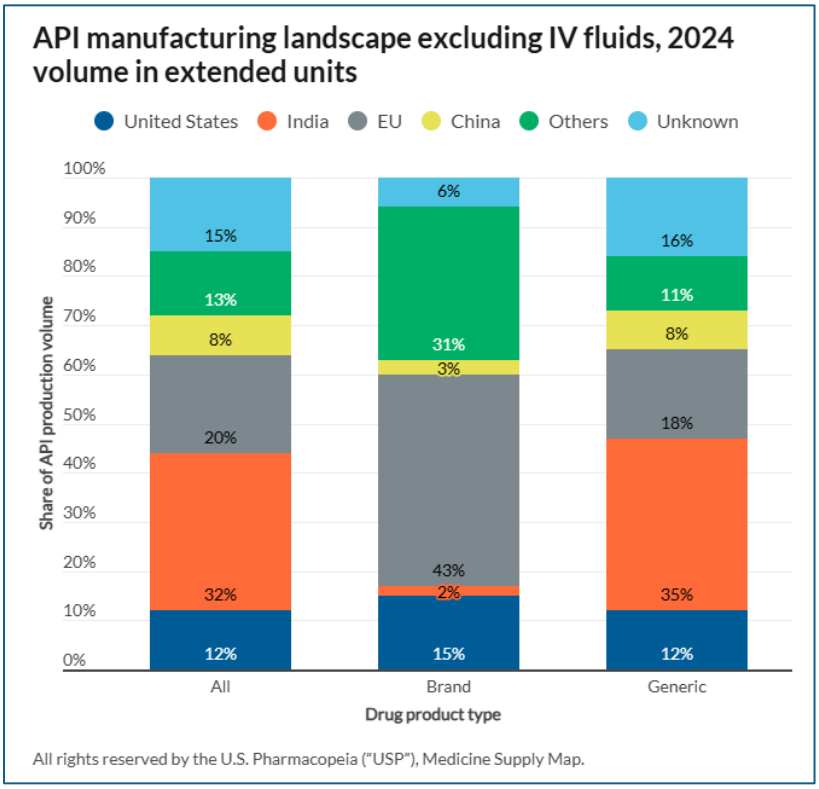
- The Administration should direct relevant agencies, including the Department of Health and Human Services (HHS), to conduct vulnerability assessments on critical pharmaceutical product categories to identify key supply chain risks. Importantly, a coordinating initiative drawing together federal expertise on medical product supply chains should be established at HHS to coordinate and lead these assessments and other similar initiatives.
- The Administration should pair these vulnerability assessments with focused and targeted supply chain policy interventions — such as investment in domestic industrial base and workforce expansion, tax policy changes, and reimbursement reform — both to bolster the domestic industrial base and reduce risk of shortages, barriers to access, and costs. Broad tariffs that include pharmaceuticals, especially vulnerable generic medicines, are likely to be ineffective in achieving other goals like increased U.S. manufacturing and well-paying manufacturing jobs, while also cause drug shortages.
- Policy actions should prioritize improving the resilience and reliability of supply chains for vulnerable generic medicines, since domestic manufacturing of all products used in the U.S. is not feasible or necessarily beneficial.
- Policy actions should also seek to expand domestic development and manufacturing capabilities for advanced biologics that involve highly sensitive intellectual property or protected patient health information. A review board to restrict offshore development and manufacturing of these advanced technologies on a case-by-case basis, contingent on the risk of theft or misuse, may be appropriate. Direct investment in advanced biotechnology can also help advance U.S. economic leadership and create well-paying manufacturing jobs.
- To complement efforts to increase domestic manufacturing, international partnerships such as the Bio-5 Coalition or trade agreements such as those described in the draft Medical Supply Chain Resiliency Act should be used to secure and diversify drug supply chains.

Section 232 Investigation Considerations

1) As described in the recent "Will Pharmaceutical Tariffs Achieve Their Goals?" publication from the Brookings Institution, reducing geopolitical risks and onshoring pharmaceutical production are interrelated but also distinct policy aims. When considering tariff policies, policymakers should consider the conditions that must be in place for tariffs to be effective. In many instances, tariffs will be ineffective or counterproductive in achieving desired policy outcomes.

First, for a tariff to be effective in **reducing geopolitical risk**, a) the tariff must be applied to a product that has significant concentration of production in countries of concern, b) the tariff must apply to the right "link" in the supply chain, c) alternative sources of supply to meet demand must come online in a timely manner, and d) the domestic alternative must have clear support to enable financial viability over the long-term. In many cases, these conditions will not be met.

The below analysis from US Pharmacopeia (USP) identifies that 8% of active pharmaceutical ingredient (API) production is located in China. In aggregate, this is not necessarily a high level of concentration, but concentration can vary significantly when drilling into specific product categories. It is important to note that USP was unable to identify the source of 15% of API volume, and some of this volume could also be sourced from China. Experts frequently cite a high level of dependence on China for upstream "links" in the supply chain such as fine chemicals and other key starting materials used to produce APIs, but these "links" are too far upstream in the supply chain to be impacted by tariffs.



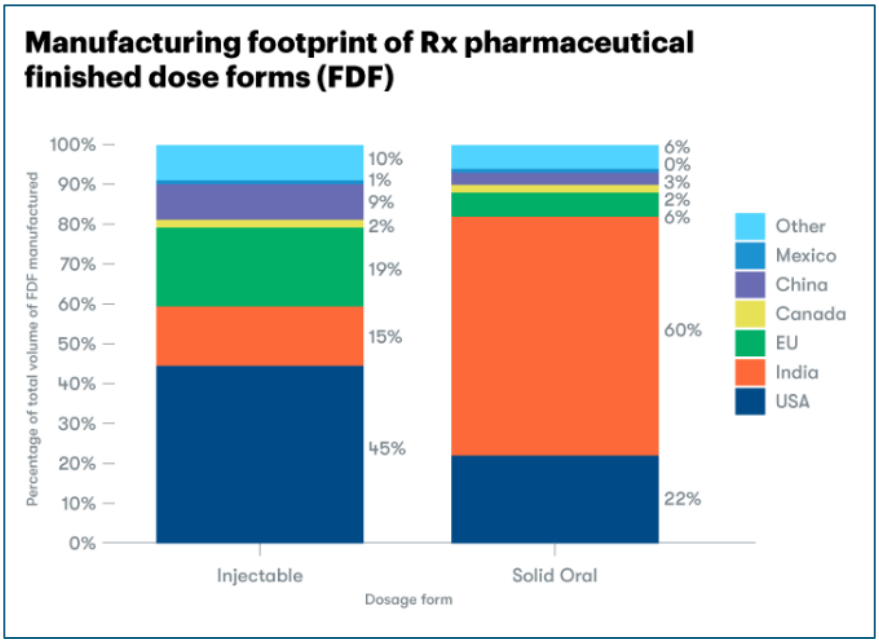
For many drugs, enabling enough new capacity to take on increased demand can take 3-5 years or more and cost billions of dollars. The President's recent Executive Order on Regulatory

Relief to Promote Domestic Production of Critical Medicines aims to shorten these timelines, though with reduced staff at FDA, speeding up review and inspections is likely to be challenging. Even if applications and inspections for domestic manufacturing can move more quickly, other factors may still discourage industry investments. Due to the uncertain nature of tariffs implemented by executive order, pharmaceutical manufacturers, particularly generic manufacturers, may not have the confidence needed to make significant long-term capital investments to bring on new capacity – especially as domestic manufacturing may be difficult to sustain over the long term without additional policy steps outside of tariffs. For example, Congress could authorize Medicare to provide additional payment to healthcare providers that source pharmaceuticals in a reliable manner, including from domestic manufacturers.

Further, tariffs on allied countries threaten U.S. and allies' collective ability to differentiate supply away from high-risk countries. Instead, international partnerships could be established to reduce geographic concentration of production, including through supporting manufacturing in the U.S. and allied countries.

Next, for a tariff to be effective in **onshoring pharmaceutical production**, a) the tariff must be applied to a drug that is currently sourced primarily from outside the U.S., b) domestic sources of supply to meet demand must come online quickly, and c) the domestic alternative must be financially viable over the long-term. In many cases, these conditions will not be met.

Another USP analysis shown below identified that 45% of finished dosage form production of injectable drugs occurs domestically. U.S. production of some product categories such as certain brands, large-volume IV fluids, and others is likely even higher. A major effect of tariffs on these products may be to create fewer supply chain redundancies and reduce multi-sourcing opportunities.



As described above, domestic manufacturing sites generally face challenges in ramping up production quickly for many drugs. And without clear long-term financial support, financial sustainability is not

ensured, which in turn limits manufacturers' willingness to make these significant, long-term investments.

One goal of onshoring is to increase US economic growth and create well-paying domestic jobs. But the types of jobs created by different sectors of the pharmaceutical market vary significantly. Branded pharmaceutical manufacturers have a greater ability to make significant long-term capital investments in infrastructure and workforce, at least for investments in manufacturing capacity available through the duration of their patent protection. The most highly-skilled jobs most often exist in the branded pharmaceutical market.

2) As described above, in many instances tariffs will be ineffective or counterproductive in achieving desired policy outcomes. As a result, we recommend the Administration, importantly including HHS, conduct careful vulnerability assessments to determine a **focused and targeted approach** for various product categories.

Given major differences between various pharmaceutical market segments, including differences between brands and generics, and injectables and orals, different policy steps are required to achieve various goals within each market segment. In addition, significant risks may exist in certain therapeutic categories, such as small-molecule antibiotics or oncology, but not in others. Part of the vulnerability assessments we propose should include repurposing the USP analysis format above, drilling down on specific therapeutic categories to determine where the most significant geographic concentration exists. These vulnerability assessments should also include evaluating therapeutic categories against the conditions that need to be in place for tariffs to be successful.

In addition to geographic concentration, these vulnerability assessments should consider risks inherent to the technologies involved in certain advanced therapeutics and the advanced manufacturing methods used to make them. For example, some cell and gene therapies may involve using sensitive patient health information to tailor treatments, and some biotechnologies may have the potential to be used to create bio-weapons. As described in the table below, different steps are likely needed to address these risks.

These vulnerability assessments are likely to lead to the conclusion that broad tariffs are not the most effective policy option to achieve the desired goals. Instead, a tailored combination of policy interventions, potentially including some limited tariffs on certain therapeutic categories, could be deployed. The Administration should consider updates to the Harmonized Tariff Schedule that may be needed to enable this more targeted approach. These interventions will

enable a focused approach to ensure that limited available capital and workforce is deployed to bolster domestic manufacturing capabilities in the most impactful areas.

3) Many policy options are available that can help to build a robust domestic manufacturing base and increase the security and reliability of U.S. supply chains. Our white paper "Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of Geographic Diversification" details these options and related considerations, as summarized in the following table.

Policy Approach	When to Use This Policy Approach?
Demand-side supports – utilizing reimbursement reform or domestic purchase preference to incentivize purchasing from domestic manufacturers and/or those with demonstrated reliability	• Some domestic manufacturing capacity exists, but struggles to compete on price with international suppliers and/or those with less investment in reliability
Indirect investment – facilitating manufacturing in the U.S. or outside of countries with high geopolitical risk via tax credits, workforce development initiatives, support for tech transfers, etc.	• Some domestic manufacturing capacity exists, but struggles to scale up to meet demand due to cost barriers, limited skilled workforce, long timelines for tech transfers and regulatory approvals
Direct investment – grants, contracts, or loans from the government directly to manufacturers that meet conditions related to security and reliability	• Little to no domestic manufacturing capacity exists due to high start-up costs and other barriers to entry
Restrictions on malicious use of critical technology such as cell and gene therapies – establishing an expert board to oversee restrictions for use by high-risk companies or countries	• Significant expertise and intellectual property exists that could be misused by malicious foreign actors
Investment fund for emerging biotech research and development – ensuring enduring U.S. prowess in biotech discovery, invention, and entrepreneurship	• Early-stage technology areas have been identified as posing a potential future national security risk
International partnerships for supply chain security – cooperating with friendly governments to advance purchase commitments and other steps to support a shared manufacturing base	• Onshoring is likely to be very costly and bring few benefits in terms of economic impact or supply chain security

[1] As part of Duke University, Duke-Margolis honors the tradition of academic independence on the part of its faculty, researchers, and scholars. Neither Duke nor the Duke-Margolis Center takes partisan positions, but the individual researchers are free to speak their minds and express their opinions regarding important and pertinent issues. This white paper may not represent the opinions of every Consortium member. This publication is not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations.