Center on Health Policy at BROOKINGS

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Secretary Howard Lutnick
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

**Re: Comment on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket No. 250414-0065, XRIN 0694-XC120)**

Secretary Lutnick,

Thank you for the opportunity to comment on the Section 232 investigation into the national security implications of pharmaceutical imports. The resilience and security of pharmaceutical supply chains are vital to the health and safety of Americans. These global supply chains are vulnerable to geopolitical forces disrupting the flow of prescription drugs. Addressing such risks is essential, so I commend the Department of Commerce for gathering input on how to proceed.

The comments I submit here are based on over a decade of studying the economics of drug supply chains, the lack of supply chain resilience that results from such economic forces, and drug shortages that often follow. Much of my recent work has been around geopolitical risks and how the U.S. government should address them to maximize the impact, while minimizing the cost. Most recently I published a thorough analysis of how tariffs are likely to affect different types of drugs. I enclose three relevant analyses with this letter.

The views expressed in this letter are my own and do not necessarily reflect the views of The Brookings Institution or anyone affiliated with The Brookings Institution.

I make three critical observations about the interplay between tariffs and national security:

1. **China-only tariffs incentivize Indian manufacturers to move away from Chinese active pharmaceutical ingredients (API).** Such tariffs should be further strengthened through legislation, after evaluation for drug shortage risk and appropriate mitigation strategies.
2. **Imposing tariffs on India may have the opposite effect.** Tariffs on India will not only eliminate the incentive described above but create incentives for Indian manufacturers to rely more on China for drug inputs, including API and key starting materials.
3. **Imposing tariffs on India would also exacerbate shortage risk for certain generic drugs.** In fact, the higher the tariffs, the faster manufacturers will drop out of the market because of low margins coupled with contractual and regulatory barriers to passing on tariffs. This in turn would likely result in drug shortages – a consequence that President Trump certainly did not intend.

For these reasons, the U.S. government should proceed with tariffs cautiously, supplementing China tariffs with other policy tools to reshore more of generic drug manufacturing and then supporting its growth and sustainability.

The remainder of this letter provides further support for the claims presented above. I also provide a brief discussion of policies that the U.S. Government should undertake to further enhance the national security of U.S. drug supply chains.

I focus on China and India, presuming that Europe and other OECD countries pose lesser national security risk. But the dynamics described here also apply to those countries vis-à-vis China.

***Observation 1: China-only tariffs incentivize Indian manufacturers to move away from Chinese API***

China-only tariffs, or for that matter a sizable wedge between tariffs applied to China and other countries, have a unique impact on drug supply chains—they drive API demand away from China to other locations.

This dynamic is a result of a long-standing U.S. Customs and Border Protection (CBP) stance that mixing ingredients into the final drug form (FDF) does not substantially transform the API and therefore the country of origin is the API source. There are exceptions to the API-based country of origin, either because substantial transformation takes place elsewhere in the supply chain or because of trade agreements. But for most drugs with a single chemically synthesized API, the country of origin is where the API was made.

This CBP stance means that a chemically synthesized FDF drug coming from India will pay the Chinese tariff rate if it contains API made in China. Notably, the Chinese tariff rate will apply to the declared value of the FDF drug, increasing the effective API cost for the Indian manufacturer.

The following example illustrates this dynamic. Suppose an Indian manufacturer buys API for 20 cents to make a 30-day supply of a drug that has a declared FDF value of $1. Under the current tariff regime, there is a 20% tariff on Chinese pharmaceuticals, meaning the Indian manufacturer must pay 20 cents per 30-day supply for having sourced from China—an effective API cost increase of 100% and a strong incentive to source API from elsewhere if high volumes are involved (as there usually are).

What makes tariffs unique as a tool to incentivize Indian manufacturers is the fact that China does not currently have a significant footprint in API, with about 8% of chemically synthesized generic drug volume using Chinese API. But China's capabilities to make API is increasing, as can be seen through their increased number of drug master file submissions to the FDA, submissions that indicate the manufacturer is ready to make the filed API. China-only tariffs could be effective at dissuading uptake of these new API sources.

Having said that, a China tariff raises shortage risk for select generic drugs with a large share of FDF or API coming from China. For one, manufacturers will be unable to pass the tariff beyond the rate of inflation for drug sales are through Medicaid or the 340 program. Similarly, manufacturers may be under contracts that limit their ability to increase prices. This may lead them to exit the US market, triggering shortages. The U.S. government should study which specific drugs are at risk and then proactively apply mitigating measures, some of which I describe at the end of this letter.

One dynamic working against the effect identified here is uncertainty regarding whether of China-only tariffs and the potential for India tariffs will remain in place for more than a short time. The first one could be addressed through legislation that could eliminate much of the uncertainty. The latter would require a set of commitments from the administration regarding other policies to secure supply chains.

***Observation 2: Imposing tariffs on India may drive Indian manufacturers towards Chinese supplies***

In turn, imposing tariffs on India is counterproductive to efforts to reduce reliance on Chinese APIs.

The first effect of India tariffs will be the elimination of the incentive highlighted in Observation 1—now the Indian manufacturer is impacted no matter where it sources the API.

Furthermore, the Indian manufacturer affected by tariffs will seek cost-cutting measures to preserve its profit margins that will drop because the manufacturer will be unable to fully pass on tariffs to U.S. buyers. To the extent that China offers price competitive API and other inputs (key starting materials and auxiliary chemicals needed in chemical synthesis of API), Indian manufacturers will have a further incentive to purchase from cheaper Chinese sources. This, in turn, would undo the recent efforts of the Indian government to derisk their supply pharmaceutical supply chains from China—efforts from which the U.S. benefits.

***Observation 3: Imposing tariffs on India would exacerbate shortage risk for certain generic drugs***

As already mentioned, there are structural barriers in the US market preventing drug manufacturers from passing on cost increases, tariffs included. As previously mentioned, government regulation mandates Medicaid rebates for price increases beyond the level of inflation, which at the time of publication was 2.4%, so less than a tenth of contemplated tariffs. Such rebates also spill over to the 340B program in which most U.S. hospitals participate. Other barriers are contractual, as with group purchasing organization (GPO) agreements that manufacturers sign for drugs sold in hospitals and clinics.

If an affected firm is unable to maintain profitability by cutting costs, it may instead leave the U.S. market. The higher the tariff rate, the more likely exits will happen. Shortages will then result if the drop in production is substantial relative to the market's ability to absorb the supply shock.

Historically, discontinuations have not been a major driver of shortages, partly because manufacturers have tended to decrease production before exiting, leaving a more vulnerable market but not triggering a shortage. But with tariffs affecting many manufacturers, discontinuations may correlate, magnifying the impact on each.

The ability of supply chains to bounce back from production shortfalls depends on the type of drug. Extensive experience in the generic sterile injectable markets suggests that those markets are particularly slow to adjust to supply shocks. In part is the lack of capacity in the short term and lack of fungibility in the production process—cancer drugs cannot be made on antibiotic lines or a drug that comes in vials cannot be put into IV bags. With long time frames to expand production and the lack of incentives to do so for generic sterile injectables, it is clear that—should supply disruptions occur—shortages will follow.

***Policy tools for derisking drug supply chains from geopolitical threats***

De-risking drug supply chains from countries such as China should not presume that onshoring is the only solution. This is particularly true for generic drugs with low profit margins, for which the math for building facilities in the U.S. simply does not work out. But onshoring can be a part of a comprehensive strategy that also encourages so-called friendshoring or "rerouting of supply chains to countries perceived as politically and economically safe or low-risk, to avoid disruption to the flow of business."

To improve drug supply chain resilience, the U.S. government should undertake the following actions:

- **Prioritize**. Prioritizing should include reassessing which drugs are critical, which have substantive research of footprint, and which supply chains are vulnerable. This strategic approach would update the essential medicines list to include drugs without which the healthcare system cannot function and use data analytics to monitor supply chain vulnerability.
- **Prepare and mitigate** against drug supply shocks that will inadvertently happen, whether they are geopolitical in nature or result from natural disasters. One element of preparation is having a ready assessment of a situation and a way to engage quickly with the right stakeholders—all aspects well suited for the highly underutilized role of HHS Supply Chain Resilience and Shortage Coordinator. The Strategic National Stockpile only focuses on pandemics and chemical, biological, radiological and nuclear threats, so it is important to consider buffers for other critical drugs, including through an API stockpile.
- **Invest** in domestic manufacturing, including through upgrades to the existing U.S. infrastructure, with it preventing further offshoring. The U.S. government has funded new industrial construction through grants, but partially forgivable, low-interest loans are also a promising pathway. Putting tariffs into law would create a "pay for" for such investments. Alternately, the administration could expand the use of Defense Production Act loans through the U.S. International Development Finance Corporation.
- **Support** domestic investments through subsidies if necessary. Here is where tariffs can be effective as syringe tariffs have shown. But Congressional action is warranted here to leverage Medicare's heft in the market. One mechanism is an update to add-on Medicare payment authorities that were previously used under the so called N95 mask rule. More broadly, restoring reliability of drug supplies for essential medicines requires further refinement and passage of the bipartisan Senate Finance Committee legislative proposal on drug shortages.

Thank you for the opportunity to comment on this important study.

Sincerely,

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Enclosures:

1. Wosińska (2025) Will pharmaceutical tariffs achieve their goals? *The Brookings Institution.*
2. Wosińska, Mattingly and Conti (2023) A Framework For Prioritizing Pharmaceutical Supply Chain Interventions**.** *Health Affairs Forefront.*
3. Wosińska (2024) Drug shortages: A guide to policy solutions**.** *The Brookings Institution.*