International Center for Law & Economics

Comments of the International Center for Law & Economics

RE: Section 232 Investigation into Pharmaceuticals and Pharmaceutical Ingredients

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1. Introduction

The U.S. pharmaceutical sector represents a cornerstone of both national public health infrastructure and critical national security interests, ensuring access to medicines and underpinning significant economic activity through innovation. This comment addresses the investigation into the national security impacts of the importation of pharmaceuticals and pharmaceutical ingredients pursuant to Section 232 of the Trade Expansion Act of 1962 by arguing that while addressing supply chain vulnerabilities and foreign trade distortions is necessary, any resulting policy actions must be phased, thoughtful, and precisely targeted at genuine trade distortions. Crucially, such measures must be implemented in a manner that avoids abrupt disruptions that could inadvertently harm U.S. pharmaceutical innovation, competitiveness, and the very security interests they aim to protect.

A. Trade Policy Uncertainty Depresses Investment

Addressing legitimate trade concerns must occur within a framework that recognizes the paramount importance of stability and predictability in trade policy. Maintaining technological leadership and fostering long-term economic stability, particularly for an innovation-focused economy like the United States, requires a predictable trade policy environment. Uncertainty surrounding trade policy acts as a distinct drag on economic performance, independent of the specific policies ultimately enacted.[1]

Studies employing diverse methodologies find that heightened trade policy uncertainty (TPU) leads to measurable reductions in investment and overall economic activity.[2] This negative impact is observed at both the firm level, where companies facing greater uncertainty reduce capital accumulation, and at the macroeconomic level, where aggregate investment and GDP growth slow.[3] For example, analysis of the surge in TPU during 2018 indicated a strong negative correlation between industry-level uncertainty and investment, even after controlling for the actual tariffs imposed during that period, isolating the detrimental effect of uncertainty itself.[4] Aggregate economic models predict that shocks to TPU, similar in magnitude to those experienced between 2017 and 2018, can depress the level of aggregate investment by 1 to 2 percent for roughly a year.[5]

The detrimental effects of TPU extend specifically to innovation, a critical driver of technological leadership and central to the pharmaceutical sector. Research indicates that eliminating uncertainty, particularly regarding tariffs, provides a significant boost to innovative activity, as measured by patent applications and R&D expenditures.[6] Uncertainty makes the long-term planning and significant

[1] *See generally* Dario Caldara et al., *The Economic Effects of Trade Policy Uncertainty*, 109 J. MONETARY ECON. 38 (2020), available at https://www.federalreserve.gov/econres/ifdp/files/ifdp1256.pdf

[2] *Id.* at 1-3.

[3] *Id.* at 12-14.

[4] *Id.* at 12.

[5] *Id.* at 13.

[6] *See, e.g.,* Duc Hong Vo et al., *The Role of Economic Policy Uncertainty in Environmental, Social, and Governance Practices: Evidence from Quantile Regressions*, 15 SUSTAINABILITY 49 (2023), *available at* https://www.mdpi.com/2071-1050/15/1/49

capital outlays associated with pharmaceutical innovation riskier and more difficult, potentially stifling the development and adoption of new therapies and technologies.[7]

The underlying economic mechanism driving these effects relates to the concept of real options. When future trade rules—affecting production costs, market access, and consumer demand—are unclear, firms perceive an increased value in delaying irreversible investment decisions and waiting for clarity. This "wait-and-see" approach applies to decisions regarding capital investment, hiring, and entry into new export markets. While the ability to delay might seem rational from an individual firm's perspective, when adopted widely across the economy, it results in suppressed investment, reduced firm entry into international markets, and ultimately, lower overall economic activity and innovation. Therefore, a stable and predictable trade policy framework is essential not only to avoid the direct costs of harmful protectionist measures but also to mitigate the chilling effect that uncertainty itself casts upon investment, innovation, and long-term economic prosperity, particularly within the vital pharmaceutical industry.

B. Avoid Disruptive Interventions That Threaten Pharmaceutical Innovation

In short, while the U.S. pharmaceutical sector is generally robust, innovative, and capable of meeting the nation's health and security needs, targeted vulnerabilities related to generic drugs and upstream supply chains must be thoughtfully addressed. Policymakers should carefully avoid broad, disruptive interventions such as sweeping tariffs or aggressive reshoring mandates that would impose substantial economic costs and hinder innovation. Instead, they should adopt a measured, strategic approach that clearly identifies and corrects specific foreign trade distortions—such as intellectual property violations, forced technology transfers, and targeted subsidies—through calibrated responses. This approach will sustain the substantial economic vitality and innovation-driven leadership of the U.S. pharmaceutical industry, thereby genuinely enhancing national security.

2. The Economics of the Pharmaceutical Supply Chain

The demand for pharmaceuticals and related ingredients within the United States has followed an upward trajectory, driven by fundamental demographic shifts, including an aging population, and the increasing prevalence of chronic health conditions requiring ongoing treatment. While specific quantification of this demand increase is complex, its effects are evident in the strain placed upon the supply chain, particularly during periods of crisis.[8] The supply chain for pharmaceutical components is likewise highly complex.

Active pharmaceutical ingredients (APIs) are the core components of medicines responsible for producing the intended therapeutic effects. They are the biologically active substances within a drug

[7] *See* Kyle Handley & Nuno Limão, *Trade Policy Uncertainty*, 14 ANN. REV. ECON. 363 (2022), *available at* https://www.nber.org/papers/w29672

[8] National Academies of Sciences, Engineering, and Medicine, GLOBALIZATION OF U.S. MEDICAL PRODUCT SUPPLY CHAINS, in BUILDING RESILIENCE INTO THE NATION'S MEDICAL PRODUCT SUPPLY CHAINS CH. 3 (C. Shore, L. Brown & W.J. Hopp eds., 2022), *available at* https://www.ncbi.nlm.nih.gov/books/NBK583730/.

product.[9] Key starting materials (KSMs), on the other hand, are the chemical building blocks or intermediates required for the chemical synthesis process that produces the API.[10] The complexity of the upstream supply chain – involving multiple steps from raw chemicals to KSMs to APIs before Finished Dosage Forms (FDFs) production – make comprehensive risk assessment and management exceedingly difficult.[11] Consequently, technical or economic disruptions occurring at the API or KSM manufacturing and distribution level can have widespread downstream consequences that are difficult to predict.

Evaluating the U.S. domestic pharmaceutical production landscape clearly illustrates significant strengths—particularly in innovation and high-value medicines—alongside certain vulnerabilities primarily in generic drug production and important precursors. The United States remains a global leader in the research, development, and manufacturing of innovative, high-value pharmaceuticals. Reflecting this, a substantial portion of U.S. medicine consumption by value—reportedly two-thirds—is manufactured domestically within a network of over 1,500 U.S.-based facilities.[12] This highlights a robust capacity for producing complex and cutting-edge therapies.

However, this strength in innovative drug production appears to contrast with the situation for many generic drugs and their important precursors. Analyses based on U.S. Food and Drug Administration (FDA) data focusing on the number of manufacturing facilities suggest a potential reliance on foreign sources, particularly for upstream components. As of 2019, only 26% of facilities manufacturing APIs for U.S. consumption were located within the United States.[13] However, it is important to note that a significant majority of APIs for innovative and high-value medicines are domestically produced or sourced from closely allied nations, reflecting substantial U.S. strength in these critical areas.

Similarly, only 40% of facilities producing FDFs—the final pills, capsules, or injectables—were domestic.[14] Furthermore, the observation that this domestic share of FDF manufacturing sites decreased from 44.05% in 2013 to 40.09% in 2019 might suggest a trend towards greater foreign production reliance for the final stages of manufacturing for certain products (primarily many generics).[15] Complementary analysis using Drug Master Files (DMFs), which often relate to generic

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[9] API Innovation Center, *Building a Resilient Domestic Drug Supply Chain* (2025), *available at* https://apicenter.org/wp-content/uploads/2025/03/APIIC-White-Paper-2025-Building-a-Resilient-Domestic-Drug-Supply-Chain.pdf

[10] *Id.*

[11] U.S. Pharmacopeia, *Supply Chain Resilience Policy Paper*, *available at*https://www.usp.org/sites/default/files/usp/document/public-policy/supply-chain-resilience-policy-paper.pdf (*last visited* May 3, 2025)

[12] Teconomy Partners, *The Economic Impact of U.S. Biopharma Industry* at 11 (2024), *available at* https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf

[13] *See* Yashna Shivdasani et al., *The Geography of Prescription Pharmaceuticals Supplied to the USA: Levels, Trends, and Implications*, 8 J.L. & Biosci. lsaa085 (2021), *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC8109232/.

[14] *Id.*

[15] *Id.*

drug components, may point towards a similar reliance on foreign API sources for generics. A 2021 review indicated that only 10% of active API DMFs supplying the U.S. market originated from U.S.-based facilities,[16] and the U.S. contribution to new API DMF filings was reportedly around 4% in both 2019 and 2021, possibly indicating limited growth in domestic API capacity relative to foreign competitors in these specific areas.[17]

This apparent bifurcation—strength in high-value innovative drug manufacturing alongside possible significant foreign reliance for APIs and many generic FDFs—underscores the need for nuanced policy approaches that support domestic innovation while carefully addressing potential vulnerabilities in important precursor and generic drug supply chains.

It is crucial, however, to contextualize the nature of this import reliance. While facility counts and API sourcing data point to foreign dependence, a significant majority of U.S. pharmaceutical imports by value originates from Europe. The European Union accounted for 73% of total U.S. pharmaceutical imports in 2023.[18] These imports predominantly consist of high-value finished medicines and complex biologics. Given the strong political, economic, and security alliances between the U.S. and European nations, reliance on these partners presents a different risk profile compared to reliance on imports from geostrategic competitors like China. Therefore, assessments of supply chain risk must consider not only the volume but also the source of imports and the geopolitical relationships involved.

Further, the economic factors driving offshoring are particularly potent at the API and KSM stages for generics. Manufacturing these materials often involves large-scale, capital-intensive chemical processes where economies of scale are paramount. Combined with lower labor and regulatory costs, and potential government subsidies in major producing nations, the cost differential compared to domestic production can be substantial.[19] This creates powerful economic disincentives for establishing or maintaining API/KSM production in the U.S. The "Commoditization Loop"[20]– where price pressures lead to offshoring, underinvestment, and increased shortage risk – applies with even greater force to these upstream components. This explains why domestic API and KSM capacity is generally weaker than FDF capacity and why reshoring initiatives face formidable economic

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[16] USP Quality Institute, *Geographic Concentration of Pharmaceutical Manufacturing*, USP QUALITY MATTERS (May 18, 2022), *available at* https://qualitymatters.usp.org/geographic-concentration-pharmaceutical-manufacturing.

[17] *Id.*

[18] Maggie Fick, *US Pharma Tariffs Would Raise US Drug Costs by $51 Billion Annually, Report Finds*, REUTERS (Apr. 25, 2025), https://www.reuters.com/business/healthcare-pharmaceuticals/us-pharma-tariffs-would-raise-us-drug-costs-by-51-bln-annually-report-finds-2025-04-25/

[19] *See* Andrew D. Mitchell, *Geography of Health: Onshoring Pharmaceutical Manufacturing to Address Supply Chain Challenges*, 22 WORLD TRADE REV. 344 (2024), available at https://www.cambridge.org/core/journals/world-trade-review/article/geography-of-health-onshoring-pharmaceutical-manufacturing-to-address-supply-chain-challenges/120B2E49D4D0CA475F00944F9ACE6172

[20] Anthony Sardella, *US Generic Pharmaceutical Industry Economic Instability,* Olin School of Business Center for Analytics and Business Insights (2023), *available at* https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf

challenges without significant policy interventions or fundamental changes to market structures. Dealing with this reality requires understanding how US domestic policy makes it less viable to manufacture certain goods at home.

It is also important to recognize that the current global distribution of pharmaceutical production, including the sourcing of certain inputs from abroad, reflects complex economic realities and rational decisions made by firms based on factors like cost, efficiency, and specialization.[21] While addressing supply chain vulnerabilities is valid, policy interventions designed to incentivize changes in these established patterns, such as reshoring, must be implemented carefully and thoughtfully to avoid unintended consequences and disruptions to the supply of medicines. Understanding the underlying economic drivers is critical for designing effective and sustainable policies.

With this as backdrop, this proceeding asks about "the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance."[22] Indeed, there are risks associated with foreign reliance on pharmaceutical inputs in *some* cases, as we discuss below there are many cases in which economic trade with friendly nations increases overall welfare in the United States. Moreover, attempting to accelerate reshoring of pharmaceutical production in excess of the speed at which private firms can stand up that capacity is likely to exacerbate supply chain issues, not remedy them.

Trade policy, even with a national security focus, needs to be carefully calibrated to allow firms to source and produce necessary pharmaceutical inputs in a wide variety of allied economies. And, where there are market distortions present in the economies of trade partners, the correct response in many or most instances is to work with those partners to reduce the distortion, not to severely attenuate or prevent trade at all.

3. Open Trade, Innovation, and Economic Prosperity

This comment proceeds from two foundational premises regarding international trade. First, open trade conducted on equitable terms generally yields substantial economic benefits for participating nations. Second, when trade relationships become imbalanced due to unfair practices or distortions, effective remedies require careful diagnosis of the specific market distortions at play, allowing for tailored and targeted policy responses rather than broad, potentially disruptive measures.

Open and competitive trade is a cornerstone of economic prosperity, particularly in innovation-driven sectors such as pharmaceuticals. While there are cases where market distortions can disrupt the gains from otherwise free trade, as discussed below, in general trade liberalization is widely

[21] See, e.g., Andrew D. Mitchell, *supra*, note 19 (Discusses economic factors influencing geographic distribution); *see also id.* (Highlights economic pressures, particularly in generics, contributing to sourcing decisions).

[22] Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 FR 15951 (Apr. 16, 2025), *available at* https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of

recognized to enhance economic performance by fostering competition within domestic markets.[23] Increased competition compels domestic firms to improve efficiency and can lead to a reallocation of resources from less productive to more productive industries, thereby boosting overall economic output.[24] Furthermore, integrating national economies into the global marketplace through open trade policies can stimulate foreign and domestic investment, facilitate the transfer and adoption of technological advancements, and expand export opportunities.[25]

A foundational economic principle justifying the gains from open trade is comparative advantage. This principle posits that nations benefit by specializing in the production of goods and services where they have a relative efficiency advantage compared to other nations, and then trading for goods where they are relatively less efficient. This specialization allows for a more efficient global allocation of resources, leading to increased overall production and consumption possibilities.

Traditional interpretations often view comparative advantage as stemming from relatively static factors like differences in technology, resource endowments, or labor productivity. However, contemporary research, particularly in the context of innovation-driven economies, increasingly emphasizes a more dynamic understanding of comparative advantage.[26] Trade itself can influence the direction of technological change. By expanding the potential market size for certain types of innovations, international trade creates powerful incentives for firms and researchers to direct their efforts towards developing technologies and products suited for global markets.[27] Consequently, a nation might develop a comparative advantage not only in producing certain goods but also in the *process of innovation* within specific sectors.

This dynamic interplay means that comparative advantage is not merely a given condition that trade helps exploit; rather, it is partially endogenous, shaped and reshaped over time by trade patterns and the innovation they induce.[28] Empirical estimates suggest that these endogenous adjustments in technology, driven by trade incentives, can account for a substantial portion—perhaps as much as half—of the observed variation in production-based comparative advantage across countries and industries.[29] This understanding reinforces the crucial link between trade openness, specialization, efficiency, innovation, and sustained economic growth. It highlights that openness fosters not just the efficient use of current capabilities but also the development of future economic strengths. While

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[23] Amrit Pathak, Shawn Leu, Mari L. Robertson & Mahinda Siriwardana, *Technical Efficiency, Scale Effect, and Trade Liberalization: Evidence from the Nepalese Manufacturing Sector*, 57(9) APPLIED ECON. 934 (2025), https://www.tandfonline.com/doi/full/10.1080/00036846.2024.2310524

[24] *Id.*

[25] Godswill Osuma & Ntokozo Patrick Nzimande, *Exploring the Dynamic Link Between Trade Openness, External Debt, and Economic Growth in Sub-Saharan Africa: Challenges and Considerations*, 12 Economies 283 (2024), *available at* https://www.mdpi.com/2227-7099/12/11/283.

[26] Mariano Somale, *Comparative Advantage in Innovation and Production*, Int'l Fin. Discussion Papers No. 1206 (May 2017), *available at* https://www.federalreserve.gov/econres/ifdp/files/ifdp1206.pdf.

[27] *Id.*

[28] *Id.*

[29] *Id*

the rise of complex global value chains complicates the measurement of traditional comparative advantage based on gross export data, newer methodologies focusing on trade in value-added confirm the continued relevance of comparative advantage principles in driving international production fragmentation.[30]

The positive effects of trade extend beyond static efficiency gains, which involve optimizing the allocation of existing resources. A significant body of research highlights the *dynamic* benefits of trade, particularly its role in spurring innovation and technological progress.[31] When firms face increased import competition or gain access to larger export markets through liberalization, they often respond by increasing their innovative activities, such as investing more in research and development, adopting new technologies, and seeking patent protection for their inventions.[32] This process implies that a country's technological trajectory and productivity growth are not fixed but can be positively influenced by its trade policies. This dynamic element is crucial for understanding how open trade supports prosperity, especially in high-technology fields where continuous innovation is paramount.

Thus, all else equal, the first instinct of policymakers when considering trade is how to enable it to work better for all parties involved. However, while the broad consensus among economists points to a positive relationship between trade openness, reduced trade barriers, and economic welfare, nuances exist. The extent and universality of these benefits, particularly for developing nations or specific sectors, remain subjects of ongoing research and debate.[33] Further, and particularly relevant for this inquiry, there are cases where foreign jurisdictions will engage in a variety of behaviors that distort trade and provide the basis for adjustments to US trade policy.

4. When All Else is not Equal: The Threat of Foreign Economic Protectionism

While identifying and addressing inefficiencies within the global trading system is a valid policy objective, the current approach may rely too heavily on general measures like tariffs. Tariffs may prove ineffective if they fail to account for the less conspicuous, non-tariff barriers that foreign jurisdictions employ to enact protectionist policies. The strategic value of a U.S.-imposed tariff is largely determined by the specific policy changes sought from the trading partner in exchange for its removal. Therefore, a critical element of effective trade policy involves identifying these distorting domestic policies and leveraging potential responses to secure commitments from foreign jurisdictions for their reform.

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[30] Josephine Wuri, *The Role of Comparative Advantage in Enhancing Trade in Value-Added Using a Dynamic GMM Model*, 12 ECONOMIES 187 (2024), *available at* https://www.mdpi.com/2227-7099/12/7/187.

[31] Wolfgang Keller & Stephen R. Yeaple, *The Gravity of Knowledge*, Nat'l Bureau of Econ. Research, Working Paper No. 22647 (Sept. 2016), *available at* https://www.nber.org/system/files/working_papers/w22647/w22647.pdf.

[32] *Id.*

[33] See, e.g., Godswill Osuma & Ntokozo Patrick Nzimande, *supra*, note 25.

Protectionist policies from foreign jurisdictions, broadly defined as government measures restricting imports through mechanisms like tariffs, import quotas, subsidies, and various non-tariff barriers (NTBs) such as complex regulations or standards, pose significant risks to international economic stability.[34] By their nature, these policies impede the free flow of goods and services across borders, which can disrupt established international collaborations and intricate global supply chains.

Beyond supply chain risks, protectionist policies have been long recognized as detrimental to overall economic efficiency and welfare.[35] By shielding domestic industries from international competition, protectionism allows less efficient firms to survive or maintain market share, leading to a misallocation of national resources away from more productive uses.[36] This lack of competitive pressure can dampen incentives for innovation within the protected sectors.

NTBs, such as complex regulations or standards, impose compliance costs on importers and exporters, which are often passed on to consumers in the form of higher prices.[37] The effect of these trade barriers is twofold. On the one hand, it hurts US firms that want to trade with our foreign partners. On the other, the cumulative effect of reduced competition, higher costs, resource misallocation, and potential trade conflicts is a reduction in overall economic efficiency, slower economic growth, and diminished national competitiveness for the foreign jurisdiction as well.[38]

A key challenge in evaluating protectionism is that its costs are often dispersed widely across the economy (e.g., slightly higher prices for all consumers, reduced opportunities for various export firms), while its benefits tend to be concentrated within specific, often politically influential, industries or groups that lobby for protection.[39] This asymmetry can make the less visible, aggregate costs harder to weigh against the more apparent, concentrated benefits in the political arena.

A. Anticompetitive Market Distortions as Trade Barriers

While we strongly caution against the generalized application of tariffs due to their inherent economic risks, if policymakers determine that tariffs are unavoidable, it is critical that such measures be narrowly targeted and precisely calibrated to deal with the quantifiable effects of protectionist policies. The concept of Anti-Competitive Market Distortions (ACMDs) provides a methodological framework to identify and quantify the specific harms arising from foreign

[34] *See generally* Walter E. Block, *Do We Need Protectionsim?* (2011), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1881052

[35] Jagdish Bhagwati, *Protectionism*, LIBRARY OF ECONOMICS AND LIBERTY, *available at* https://www.econlib.org/library/Enc/Protectionism.html (*last visited* May 3, 2025).

[36] Amrit Pathak, Shawn Leu, Mari L. Robertson & Mahinda Siriwardana, *supra*, note 23.

[37] Eric Fruits, *Non-Tariff Barriers*, International Center for Law & Economics (Feb. 27, 2025), *available at* https://laweconcenter.org/resources/non-tariff-barriers/.

[38] Jagdish Bhagwati, *supra*, note 35.

[39] Eric Fruits, *supra*, note 37.

government actions that disadvantage U.S. firms. This ensures tariffs and other trade sanctions are used strictly as targeted corrective measures rather than broad protectionist tools.

In essence, ACMDs are a way of understanding government actions that harm economic welfare by undermining competition. As defined by Shanker Singham, an ACMD is characterized as a government intervention in the economy that (1) substantially lessens competition, (2) cannot be justified by an overriding legitimate public policy objective (such as correcting a clearly defined market failure or ensuring public health and safety), and (3) empowers certain private interests or entities to obtain or retain artificial competitive advantages over their rivals.[40]

This definition distinguishes ACMDs from several other types of government actions. Unlike legitimate regulations designed to achieve welfare-enhancing social goals, ACMDs lack such justification and primarily serve to skew the competitive landscape in favor of specific players.[41] They also differ from private anti-competitive conduct, as ACMDs are fundamentally enabled, imposed, or maintained by government authority.[42] This government backing can make ACMDs more persistent and damaging than private restrictions. Furthermore, while standard trade policy tools like tariffs or broadly applied subsidies can distort trade, ACMDs encompass a wider range of interventions—including regulatory measures, discriminatory application of rules, or failures in governance—that specifically target the conditions of competition.[43]

The core economic harm arises from this deliberate distortion of competitive opportunity. In a well-functioning market, competition drives firms to innovate, improve efficiency, and lower prices, with resources flowing towards the most productive uses. ACMDs disrupt this process by insulating favored firms from competitive pressures or by imposing artificial disadvantages on their rivals. This prevents the market mechanism from efficiently allocating resources based on merit and performance, leading to systemic inefficiencies and reduced overall economic welfare.

The scope of practices potentially constituting ACMDs is broad, extending beyond traditional trade barriers. ACMDs can encompass various government policies and practices. Examples include:

- **Regulatory Barriers:** Regulations designed or applied in a manner that disproportionately hinders market access for certain firms (often foreign competitors) or raises their operating costs

[40] Shanker A. Singham, *Market Distortions and How Best to Deal with Them: Sugar Sector Case Study* (2024), *available at* https://shankersingham.com/wp-content/uploads/2024/10/Market-Distortions-and-How-Best-to-Deal-with-Them_-Sugar-Sector-Case-Study.pdf.

[41] Growth Commission, *2024–25 Growth Presidency Memo: A Research Report from the Growth Commission* (Nov. 13, 2024), *available at* https://www.growth-commission.com/wp-content/uploads/2024/11/Growth-Commission-Presidency-Report-for-Capitol-event.pdf.

[42] World Bank, *Unfair Advantage: Distortive Subsidies and Their Effects on Global Trade* (2023), *available at*https://thedocs.worldbank.org/en/doc/0534eca53121c137d3766a02320d0310-0430012022/related/Unfair-Advantage-Distortive-Subsidies-and-Their-Effects-on-Global-Trade-2023.pdf.

[43] Singham, *supra*, note 40.

relative to favored domestic entities. This could involve discriminatory standards, licensing requirements, or overly complex administrative procedures.[44]

- **Artificial Cost Reduction:** Government actions that artificially lower the production or operating costs for specific firms or industries, giving them an unfair advantage in domestic and international markets. This goes beyond general infrastructure support and targets specific beneficiaries.[45]
- **Failures in Property Rights Protection:** Inadequate enforcement or discriminatory application of intellectual property rights (IPR) or other property rights can undermine the investments of innovators and legitimate producers, effectively distorting competition by allowing others to unfairly benefit from their efforts.[46] Weak IPR protection, for instance, can discourage high-technology exports into a market or hinder domestic innovation.
- **Targeted Subsidies:** While not all subsidies are ACMDs, those that are specifically targeted to provide a competitive advantage to select firms or industries, distort market dynamics significantly, and lack a clear, overriding public policy justification fall under this category.[47] Distortive subsidies, particularly in manufacturing, have become a growing concern in international trade.[48]
- **Other Distortions:** The concept can also include interventions like discriminatory procurement policies, state-owned enterprise advantages not based on efficiency, or regulations that exempt favored firms from general competition rules.[49]

The common thread across these examples is a government's active role in manipulating market conditions to favor certain economic actors over others, thereby substantially lessening competition on the merits.

To be clear, our discussion of the ACMD framework should not be interpreted as advocating broadly for tariffs as a primary trade policy instrument. Rather, tariffs—if considered at all—must be narrowly tailored, rigorously justified by evidence of specific market distortions, and calibrated precisely to the level necessary to neutralize demonstrated competitive harms. The ultimate goal should always be to resolve trade distortions through international cooperation and negotiation, resorting to targeted tariff measures only when other approaches have been exhausted or clearly demonstrated as ineffective.

B. Focused Responses to ACMDs and Other Nontariff Barriers

The utility of using ACMDs as a framing device for looking at trade distortions is that it provides tools for policymakers to 1) assess what is out of balance and 2) make demands on trading partners.

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[44] Fruits, *supra*, note 37.

[45] Singham, *supra*, note 40.

[46] Growth Commission, *supra*, note 41.

[47] Singham, *supra*, note 40.

[48] World Bank, *Unfair Advantage: Distortive Subsidies and Their Effects on Global Trade* (2023), *available at*https://thedocs.worldbank.org/en/doc/0534eca53121c137d3766a02320d0310-0430012022/related/Unfair-Advantage-Distortive-Subsidies-and-Their-Effects-on-Global-Trade-2023.pdf.

[49] Growth Commission, *supra*, note 41.

Without some metric for judging the harm caused by trade distortions, broad tariffs are almost certainly doomed to being ineffective at deterring the harmful conduct of foreign governments.

Following diagnosis of particular ACMDs, Singham recommends a specific corrective measure known as "ACMD tariffication".[50] This approach involves applying a tariff to imports from the country imposing the ACMD, with the level of the tariff precisely calibrated to neutralize the estimated detrimental effect of the distortion.[51]

The core objective of ACMD tariffication is to discover the quantifiable harms generated by a trading partner's domestic policy and remedy those in a targeted fashion. To justify such a targeted tariff, the framework requires demonstrating: (a) the existence of an ACMD (a government intervention substantially lessening competition without legitimate justification), (b) a demonstrable anti-competitive effect resulting from the ACMD (potentially using tests analogous to merger analysis, such as the substantial lessening of competition or 'SLC' test), and (c) evidence of harm caused to the domestic industry by the ACMD.[52]

This methodology represents a conceptual departure from traditional trade remedies. Anti-dumping duties, for example, typically focus on comparing export prices to domestic prices or costs, without necessarily addressing the underlying reasons for price differences.[53] Countervailing duties target specific, legally defined government subsidies (requiring a financial contribution, benefit, and specificity), potentially missing broader regulatory distortions or failures in governance that constitute ACMDs. ACMD tariffication, in contrast, seeks to directly address the economic impact of the distortion on the cost base or competitive position of firms, regardless of the specific form the government intervention takes. The calibration of the tariff is linked directly to the measured scale of the distortion derived from the economic scoring methodology.

5. Specific Foreign Trade Distortions Impacting Pharmaceuticals

The U.S. pharmaceutical sector holds strategic importance, underpinning not only economic vitality through innovation and high-value employment but also fundamental public health and national security interests. Consequently, this industry is particularly sensitive to the impacts of foreign trade distortions. Practices originating abroad can undermine the competitiveness of U.S. pharmaceutical firms, hinder innovation by devaluing intellectual property, and create vulnerabilities in the supply chains that deliver medicines to the American public. There are two primary categories of trade distortion that are relevant to this comment: intellectual property violations and forced technology transfer, and the effects of foreign subsidies and price manipulations.

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[50] Singham, *supra*, note 40.

[51] *Id.*

[52] *Id.*

[53] *Id.*

C. IP Violations and Forced Technology Transfer

Intellectual property rights, particularly patents and trade secrets, form the bedrock of innovation within the pharmaceutical industry.[54] The development of new medicines is an inherently costly and high-risk endeavor, requiring substantial, long-term investment in research and development.[55] Patents provide a critical incentive mechanism, granting inventors exclusive rights for a defined period, which allows firms the opportunity to recoup their significant investments and fund future research.[56] Further there is a strong relationship between patent production and protection, and broader economic growth and innovation.[57] Trade secrets offer complementary protection for valuable manufacturing processes, formulas, and other proprietary knowledge that may not be patentable or for which patent disclosure is strategically undesirable.

Despite established international agreements like the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the U.S. pharmaceutical sector faces significant challenges from IP violations originating abroad, particularly from China. These violations encompass a range of activities, including the counterfeiting of medicines, patent infringement, and the misappropriation of trade secrets.[58]

The scale of this problem is substantial. According to the US Trade Representative, in 2022 China and Hong Kong accounted for the vast majority (over 83%) of counterfeit goods seized in the U.S..[59] Surveys have revealed that a significant percentage of U.S. companies report experiencing IP theft attributable to China, resulting in estimated annual losses to the U.S. economy reaching hundreds of billions of dollars.[60] While not exclusively focused on pharmaceuticals, this sector is inherently vulnerable due to the high value of its IP.

Specific concerns within the pharmaceutical domain include inadequate protection in some jurisdictions against the unfair commercial use or unauthorized disclosure of the extensive and costly test data submitted to regulatory agencies to obtain marketing approval for new drugs.[61] Furthermore, issues persist regarding the effective implementation of patent linkage systems (which

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[54] Adam Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, 98(2) ST. JOHN'S L. REV. 287 (2025), *available at* https://scholarship.law.stjohns.edu/lawreview/vol98/iss2/5/.

[55] *Id.*

[56] *Id.*

[57] Stephanie Nebehay, *In a First, China Knocks U.S. from Top Spot in Global Patent Race*, REUTERS (Apr. 7, 2020), https://www.reuters.com/article/us-usa-china-patents-idUSKBN21P1P9/.

[58] Gerald J. Krieger, *From "Made in China" to "Created in China": Intellectual Property Rights in the People's Republic of China*, JOINT FORCE QUARTERLY, (Feb. 16, 2024), *available at* https://ndupress.ndu.edu/Media/News/News-Article-View/Article/3679322/from-made-in-china-to-created-in-china-intellectual-property-rights-in-the-peop/.

[59] Office of the United States Trade Representative, *2022 Special 301 Report* (2022), *available at* https://ustr.gov/sites/default/files/IssueAreas/IP/2022%20Special%20301%20Report.pdf [hereinafter USTR 2022 Report].

[60] Commission on the Theft of American Intellectual Property, *The IP Commission Report* at 11 (2013), *available at*https://www.nbr.org/wp-content/uploads/pdfs/publications/IP_Commission_Report.pdf.

[61] *Id.*

prevent regulatory approval of generics while patents are valid) and patent term compensation mechanisms (to account for regulatory delays), despite legislative efforts in countries like China to address these areas.[62] These IP-related frictions contribute to broader trade tensions, notably forming a core component of the U.S.-China trade disputes.

Distinct from outright theft, forced technology transfer involves practices where foreign governments compel or pressure US companies to transfer valuable technology or intellectual property as a condition for accessing their market, obtaining investment or regulatory approvals, or receiving other governmental benefits or preferences.[63] Analyses have identified several mechanisms employed:

- **Conditional Market Access/Approvals:** Conditioning investment approvals, regulatory clearances (including for pharmaceuticals), government procurement eligibility, or other benefits on the transfer of technology to domestic entities, or on conducting R&D locally.[64]
- **Joint Venture and Ownership Restrictions:** Using foreign ownership limitations and joint venture requirements to pressure foreign firms into partnerships where technology transfer to the local partner is implicitly or explicitly expected.[65] Examples directly impacting the pharmaceutical sector include China's Human Genetic Resources Administrative Regulation and its Biosecurity Law, which stakeholders report create pressure to transfer technology when research involves Chinese human genetic resources.[66]
- **Administrative and Licensing Processes:** Leveraging opaque or discretionary administrative review and licensing procedures to exert pressure for technology transfer.
- **Cybersecurity and Data Localization Rules:** Employing cybersecurity regulations or data localization requirements that may compel disclosure of sensitive IP or discriminate against foreign-owned IP under the guise of security reviews.[67]
- **State-Sponsored Talent Recruitment:** Utilizing programs designed to recruit foreign experts and researchers, which can facilitate the transfer of sensitive knowledge and trade secrets back to the sponsoring country.[68]

It is important to note that China's official legal framework, including its Foreign Investment Law, explicitly prohibits administrative organs from using administrative means to force technology

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[62] Aaron Wininger, *China's State Council Releases White Paper: China's Position on Certain Issues in China-U.S. Economic and Trade Relations*, CHINA IP LAW UPDATE (Apr. 9, 2025), https://www.chinaiplawupdate.com/2025/04/chinas-state-council-releases-white-paper-chinas-position-on-certain-issues-in-china-us-economic-and-trade-relations-china-continuously-improves-ip-protection-and-prohibits-forced-technology/.

[63] Office of the United States Trade Representative, *2025 Special 301 Report* at 29-32 (2025), *available at* https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf [hereinafter USTR 2025 Report].

[64] *Id.*

[65] Office of the United States Trade Representative, *2018 Special 301 Report* at 44 (2018), *available at* https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf [hereinafter USTR 2018 Report].

[66] USTR 2025 Report at 25-27.

[67] USTR 2025 Report at 50.

[68] FBI, *The China Threat: Chinese Talent Plans Encourage Trade Secret Theft, Economic Espionage*, *available at*https://www.fbi.gov/investigate/counterintelligence/the-china-threat/chinese-talent-plans (*last visited* May 1, 2025)

transfer.[69] However, U.S. stakeholders and government bodies maintain that these practices persist through more subtle pressures and the leveraging of market access.[70]This discrepancy highlights a potential divergence between formal legal commitments and actual implementation or the use of informal pressures. The practices described often fall into a grey area where the line between voluntary business decisions made under duress and explicit coercion is blurred. Companies may face a difficult choice: transfer technology or forfeit access to a major market.

This description of the status quo that American firms face captures well the concept of ACMDs, discussed above, where government actions, even if not direct mandates, create conditions that disadvantage foreign competitors or compel certain behaviors.

The U.S.-China Phase One Economic and Trade Agreement, signed in 2020, attempted to address these concerns. It included chapters on Intellectual Property and Technology Transfer, with specific commitments regarding pharmaceutical-related IP, trade secrets, and prohibitions against forcing technology transfer in exchange for market access or regulatory approvals.[71] However, concerns about implementation and the scope of these commitments remain, and the agreement acknowledged the need for future negotiations on issues like data protection for pharmaceuticals.[72] The focus on pharmaceutical data protection specifically points to the unique value and vulnerability of clinical trial results and related datasets in this sector, suggesting that traditional patent and trade secret frameworks may not fully capture the competitive significance of this information.[73]

D. Foreign Subsidies and Price Manipulation

In the context of international trade, subsidies refer to financial contributions or other forms of support provided by a government or public body that confer a benefit to specific enterprises, industries, or regions.[74] These can take various forms, including direct monetary grants, loans at preferential rates, loan guarantees, tax credits or rebates, the provision of goods or services (like land or energy) at below-market rates, and income or price support mechanisms.[75] A critical distinction exists between general government support available broadly and specific subsidies targeted at particular recipients, which are more likely to distort trade patterns.[76]

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[69] George Tian, *The Political Economy Of Technology Transfer Rules Of The Us-China Phase One Trade Agreement: Competition Of Global Technology Leadership*, 32 IND. INT'L & COMP. L. REV. 531, 541 (2022), *available at* https://journals.indianapolis.iu.edu/index.php/iiclr/article/view/26852.

[70] USTR 2025 Report at 26.

[71] George Tian, *supra,* note 69 at 535.

[72] *Id.* at 560-61.

[73] *Id.* at 535.

[74] Lorenzo Rotunno & Michele Ruta, *Trade Implications of China's Subsidies*, IMF Working Paper No. 2024/180 (2024), *available at* https://www.elibrary.imf.org/view/journals/001/2024/180/article-A001-en.xml.

[75] *Id.*

[76] *Id.*

Evidence suggests that foreign governments created ACMDs by providing significant subsidies to their domestic pharmaceutical industries.[77] China, for example, officially designated pharmaceutical production as a "high-value-added industry" and has supported it through various means, including direct subsidies and export tax rebates aimed at boosting foreign sales.[78]

While comprehensive data on specific pharmaceutical subsidies can be opaque,[79] there are numerous mechanisms that indirectly subsidize inputs. For instance, China's policy of centralized volume-based procurement (referred to as "centralized band purchasing") for generic drugs, while primarily aimed at reducing domestic drug prices, may also function as a market-distorting mechanism.[80] Although it significantly lowers prices for consumers and the state, it channels funds (potentially including government subsidies) towards winning firms, while potentially compressing margins and hindering innovation for others disfavored (and largely foreign) firms.[81]

Indeed, this is not just a problem with China. Governments abroad routinely employ centralized negotiation and external reference pricing systems that artificially suppress pharmaceutical prices significantly below their market-driven value.[82] Countries such as Canada, the United Kingdom, France, Germany, and Australia operate national healthcare systems or single-payer models that leverage their massive buying power to negotiate or impose stringent price limits on medications. These practices ensure that foreign drug prices remain systematically low, well beneath what would naturally emerge under competitive market conditions.[83]

Foreign subsidies are frequently linked to the ability of exporting firms to engage in dumping or sustain pricing below their unsubsidized costs in foreign markets. In the pharmaceutical sector, there are allegations that Chinese companies, enabled by government subsidies and export incentives, have "dumped" low-priced APIs and generic drugs onto the global market, making it economically unviable for competitors in the U.S. and elsewhere to continue production.[84] This

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[77] U.S.-China Economic and Security Review Commission, *Growing U.S. Reliance on China's Biotech and Pharmaceutical Products*, in *2019 Annual Report to Congress* ch. 3, sec. 3 (2019), *available at*https://www.uscc.gov/sites/default/files/2019-11/Chapter%203%20Section%203%20-%20Growing%20U.S.%20Reliance%20on%20China%E2%80%99s%20Biotech%20and%20Pharmaceutical%20Products.pdf.

[78] *Id.*

[79] World Bank, *Unfair Advantage: Distortive Subsidies and Their Effects on Global Trade* at 32 (2023), *available at*https://thedocs.worldbank.org/en/doc/0534eca53121c137d3766a02320d0310-0430012022/related/Unfair-Advantage-Distortive-Subsidies-and-Their-Effects-on-Global-Trade-2023.pdf.

[80] Xinqing Chen et al., *The Impact of Centralized Band Purchasing of Pharmaceuticals on Innovation of Chinese Pharmaceutical Firms: An Empirical Study Based on Double Difference Models*, 12 FRONT. PUBLIC HEALTH 1406254 (2024), *available at* https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1406254/full.

[81] *Id.*

[82] *See, e.g.,* Council of Economic Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation* (2020), *available at* https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf.

[83] *Id.*

[84] U.S.-China Economic and Security Review Commission, *supra,* note 77 at 253.

strategy, if sustained by subsidies, can effectively drive out competition even if it doesn't meet the strict legal definition of predatory pricing required for antitrust action. This highlights a potential gap where subsidy-fueled pricing harms competitors but may evade traditional antitrust scrutiny, making trade remedies like countervailing duties (specifically targeting subsidies) or potentially frameworks like ACMD analysis (focusing on the cost distortion itself) more pertinent policy tools.

Foreign subsidies and associated practices like dumping significantly distort international trade flows and undermine the competitiveness of unsubsidized U.S. pharmaceutical firms. Economic analysis indicates that subsidies tend to increase the exports of the subsidized products from the granting country while simultaneously depressing imports of those products into that country.[85]An IMF study on China's subsidies found precisely these effects, noting that they were magnified through supply-chain linkages: subsidies provided to upstream industries (like chemical precursors or APIs) significantly boosted the exports of downstream industries (like finished pharmaceuticals).[86] This finding is particularly relevant given the structure of the pharmaceutical value chain, where subsidies to Chinese API manufacturers could indirectly enhance the export competitiveness of finished drugs produced elsewhere but reliant on those subsidized Chinese inputs.

These distortions make it difficult for U.S. firms, particularly in the highly price-sensitive markets, to compete against foreign rivals whose costs are artificially lowered by government support. The pressure from subsidized imports can lead to reduced market share, lower profitability, and ultimately, the exit of U.S. manufacturers from certain market segments. This contributes to the erosion of domestic production capacity, especially for important generic medicines and their APIs, thereby increasing U.S. import reliance. This pattern mirrors experiences in other advanced technology sectors where targeted foreign industrial policies, often involving substantial subsidies, contributed to a decline in U.S. competitiveness over time.[87] Consequently, foreign subsidies pose a dual threat: they directly challenge the competitiveness of existing U.S. firms and indirectly weaken national resilience by fostering the offshoring that creates supply chain vulnerabilities, linking the economic distortions discussed here to the security concerns addressed in the next section.

6. Recommendations and Conclusion

Addressing the national security implications of pharmaceutical imports necessitates a carefully calibrated strategy that acknowledges the significant economic benefits of open trade while decisively countering foreign practices that distort markets and create vulnerabilities. The U.S. pharmaceutical sector faces notable threats from ACMDs, including inadequate intellectual property enforcement, forced technology transfers, targeted subsidies, and discriminatory regulatory practices that disadvantage U.S. firms and threaten medicine supply chains.

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[85] Lorenzo Rotunno & Michele Ruta, *supra*, note 74.

[86] *Id.*

[87] Sandra Barbosu, *Not Again: Why the United States Can't Afford to Lose Its Biopharma Industry*, ITIF (Feb. 29, 2024), https://itif.org/publications/2024/02/29/not-again-why-united-states-cant-afford-to-lose-biopharma-industry/.

However, broad protectionist responses—such as expansive tariffs, sweeping reshoring mandates, or general "Buy American" requirements—carry substantial risks. Abruptly altering complex global pharmaceutical supply chains would likely increase healthcare costs, disrupt patient access, and ultimately undermine the very innovation and domestic production capacities these measures aim to protect. Moreover, it would introduce detrimental economic uncertainty, negatively affecting long-term investment and innovation within the pharmaceutical sector.

Therefore, policymakers should pursue a strategic approach that emphasizes cooperation and targeted corrective actions:

1. **Targeted and Conditional Tariff Measures**: To reiterate clearly, our discussion of ACMDs is not intended as a general endorsement of tariffs. Tariffs should only be considered as narrowly tailored temporary measures, rigorously justified by evidence of specific foreign trade distortions, and carefully calibrated to neutralize competitive harms. Such tariffs, if deemed necessary, should be temporary tools to incentivize trade reform, not permanent trade barriers.
2. **Phased and Targeted Domestic Enhancement:** Implement phased incentives and targeted support, potentially through public-private partnerships, to enhance domestic production capabilities for the most critical pharmaceuticals and their important components. This strengthens domestic capacity strategically without triggering destabilizing economic shocks.
3. **Allied Diversification:** Actively coordinate with allied nations to diversify supply sources for critical inputs and finished products, reducing over-dependence on any single nation, particularly potential adversaries.
4. **Measured Trade Actions:** Reinforce the importance of trade actions that are carefully measured and specifically targeted at identified ACMDs to maintain the U.S. pharmaceutical sector's innovation ecosystem, avoiding broad measures that could stifle beneficial trade.

In sum, a prudent, precise, and cooperative strategy, supported by rigorous analytic frameworks, will ensure the United States can effectively address genuine national security concerns without sacrificing the substantial existing economic vitality, production capacity, and innovative strength that characterize the U.S. pharmaceutical sector.