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How America Can Reduce Its Dependence on Chinese Active Pharmaceutical Ingredients (APIs)

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Heavy dependence on Chinese APIs creates risks to the drug supply and national security. To reduce dependence, U.S. policy should support domestic and allied production through the advanced manufacturing innovation, tax incentives, import limits, regulatory reforms, improved analysis, and targeted procurement, including strategic stockpiling.

KEY TAKEAWAYS

- In 1981, Europe produced 63 percent of APIs and the United States 25 percent. By 2024, China had produced 45 percent and India 43 percent, as the European and U.S. shares fell to 6 percent and 3 percent, respectively.
- U.S. dependence on China for APIs reflects decades of cost-driven offshoring and upstream concentration, creating structural vulnerabilities in the supply of essential medicines.
- Reducing dependence on Chinese APIs will require a multifaceted strategy that combines strategic stockpiling, increased domestic capacity, allied diversification, and manufacturing innovation.
- Advanced manufacturing technologies, such as continuous manufacturing, offer a pathway to restore competitiveness without replicating China's low-cost model.
- Strengthening oversight of foreign API manufacturing through expanded unannounced FDA inspections is essential to reducing compliance asymmetries and closing national security gaps.
- Demand-side tools, including advance purchase commitments, are important to making new API capacity economically viable and sustainable over time.

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INTRODUCTION

The COVID-19 pandemic revealed how exposed the U.S. healthcare system is to fragile global supply chains—particularly its heavy dependence on China for active pharmaceutical ingredients (APIs), the biologically active components in medicines that produce their intended therapeutic effects, and which are a foundational element of drug security and pharmaceutical innovation.[1] But the pandemic exposed more than fragility—it exposed the risks of allowing a geopolitical adversary to control critical pharmaceutical inputs. The core vulnerability is not geographic concentration per se, but dependence on a country that has demonstrated both the willingness and the capacity to weaponize industrial supply chains—creating risks that go well beyond ordinary market disruptions.

Disruptions during the pandemic highlighted how quickly dependencies on a small number of foreign API producers can translate into shortages, exposing vulnerabilities to supply chain resilience and national security. Trade restrictions and geopolitical tensions can similarly ripple through global pharmaceutical markets and contribute to drug shortages.

API dependence on China did not develop overnight, and cannot be solved overnight. Moreover, imposing tariffs on APIs to shift production back to the United States would not solve the problem. Building a more resilient pharmaceutical supply chain that is less dependent on China requires a multifaceted policy approach that combines reshoring and nearshoring/friendshoring strategies with other elements such as regulatory modernization, manufacturing innovation, and demand-side incentives. Such a strategy would address the challenges of not only where APIs are produced but also how resilient, transparent, and diversified the underlying supply chains are.

At the same time, the United States should not ignore the role of Chinese industrial subsidies in creating an uneven competitive playing field. Where Chinese API producers benefit from below-market financing, state land grants, energy subsidies, and preferential tax treatment, the United States and allies should consider targeted trade remedies—including offsetting duties—on APIs produced under such conditions. Addressing unfair trade practices is a complement to, not a substitute for, the broader supply chain strategy outlined in this report.

The Global Geography of API Production

Data from the U.S. Food and Drug Administration Drug Master Files (FDA DMFs) provide insight into the geographic distribution of API manufacturing. DMFs are filings submitted by API manufacturers to the FDA that document the facilities, processes, and materials involved in producing a drug ingredient.[2] Because every API sold in the U.S. market requires an active DMF, the distribution of DMF holders around the world can serve as a proxy for where global API manufacturing capacity is located—and how this distribution has changed over time.

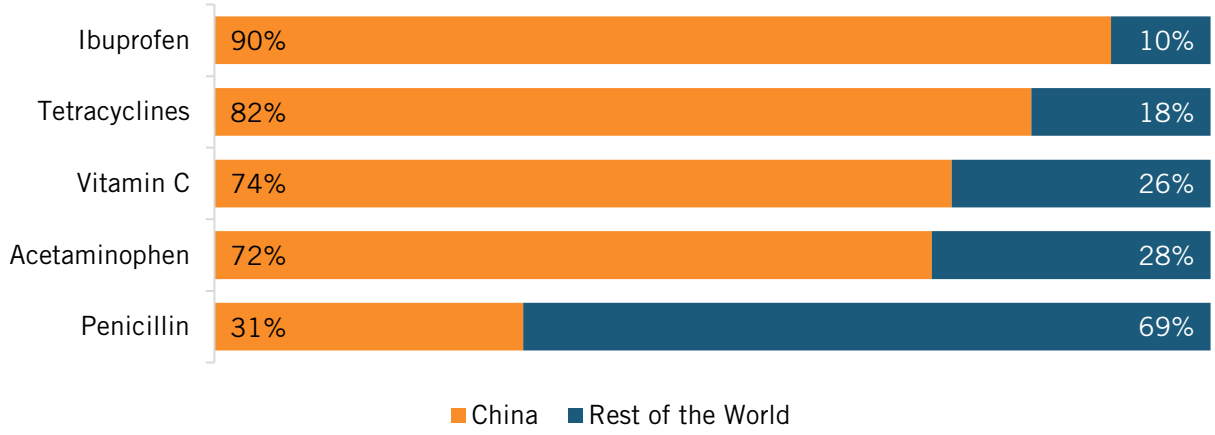
API manufacturing is highly concentrated in China and India, but this has not always been the case. In the early 1980s, most API production took place in Europe and the United States. Data compiled by the U.S. Pharmacopeia from the FDA's active API DMFs shows that, in 1981, Europe held 63 percent of the overall share of DMFs while the United States held 25 percent. India and China held a virtually zero share.[3] Yet, by 2024, that picture had reversed. Europe's share had dropped to 6 percent while the U.S. share had fallen to just 3 percent. Meanwhile, China and India accounted for 45 and 43 percent of active API DMFs, respectively.[4] Today, China plays a key role in the production of basic chemical precursors and key starting materials

(KSMs), while India primarily specializes in later-stage API synthesis and generic drug manufacturing, with much of India's raw material for APIs originating in China.[5]

China increasingly dominates production both of KSMs and APIs.[6] KSMs constitute the upstream building blocks used to manufacture APIs.[7] China is trying to corner production of these KSMs just as it is APIs. Across all medications, nearly 41 percent of KSMs used in U.S.-approved APIs are produced only in China, and 16 percent in India.[8] China controls the raw materials or KSMs for 94 percent of amoxicillin, 74 percent of heparin, and 70 percent of acetaminophen.[9] China also enjoys significant global concentrations for the following KSMs: angiotensin II receptor blockers (100 percent of APIs use China sole-sourced KSMs); blood glucose-lowering drugs, excluding insulins (94 percent); direct acting antivirals (83 percent); antineoplastics (71 percent); antibacterials (66 percent); statins (62 percent).[10]

With China dominating so much of the KSMs that represent the key inputs to APIs, it's no wonder that China is also coming to dominate global API production, making the United States increasingly dependent on China for API imports. Indeed, as figure 1 shows, the United States imports 90 percent of its ibuprofen from China, 82 percent of tetracyclines (a broad-spectrum class of antibiotics primarily used to treat bacterial infections, including acne and Lyme disease), 74 percent of vitamin C, and 72 percent of acetaminophen.[11]

Figure 1: U.S. imports of APIs, 2024[12]



This geographic concentration reflects several factors that have developed over decades. A key driver is cost. Traditional API production depends on capital-intensive facilities that must operate at high, predictable utilization rates to recover their fixed costs, which leaves plants (especially domestic ones) exposed to demand swings and underutilization.[13] Higher domestic labor, regulatory, environmental, and operating costs compound this problem, making offshore production far more economically attractive.[14] These cost differentials are substantial: an IQVIA report notes that API manufacturing costs are about 30 to 35 percent lower in India and 35 to 40 percent lower in China than in the United States.[15]

Moreover, price competition among API producers has at times intensified. Some Chinese producers have in recent years cut prices on key API starting materials by 40 to 50 percent, an aggressive pricing strategy that can squeeze other competitors out of the market.[16] This is not simply a reflection of efficiency gains—it is enabled by Chinese state support. Chinese API

producers benefit from a combination of direct production subsidies, below-market land and energy costs, preferential financing from state-owned banks, and more permissive environmental regulations.[17] State support extends to infrastructure and industrial clustering: government policy has subsidized the creation of dedicated pharmaceutical manufacturing zones, including API "super factories," and explicitly included biomedical technology on the list of high-tech fields supported by key financial subsidies policy.[18] This support allows Chinese producers to sustain prices that would be commercially unviable without government backing. The strategic objective appears to be consistent with predatory market consolidation efforts: by pricing competitors out, Chinese API producers can secure dominant positions in key upstream segments, reducing other producers' ability to compete and increasing global dependence on Chinese supply. This mirrors tactics employed in other sectors, such as solar panels and telecommunications networking equipment, wherein China has pursued national power industry dominance. (ITIF has identified 216 globally traded "national power" industries that serve as the bedrock of U.S. technological leadership, economic power, and national security.)[19]

By pricing competitors out, Chinese API producers can secure dominant positions in key upstream segments, reducing other producers' ability to compete and increasing global dependence on Chinese supply.

China's API Production

China has pursued a long-term strategy to build dominance in API production by leveraging scale, cost advantages, and coordinated industrial policy.[20] Beginning in the early 2000s, Chinese firms expanded rapidly in the production of chemical intermediates and KSMs, positioning China as a foundational upstream supplier not only for its own pharmaceutical sector but also for API manufacturers worldwide.[21] China's dominance in API production is not simply the outcome of cost competition—it is the result of a deliberate, state-directed strategy to build national power through control of critical industrial inputs.

As the Information Technology and Innovation Foundation (ITIF) has documented in its series on national power industries, China sees dominance in strategically important sectors not only as a commercial objective but also as a tool of geopolitical leverage—one that enables the nation to threaten supply disruptions, extract political concessions, and create leverage over trading partners in a crisis.[22] Pharmaceuticals fit squarely within this framework. Chinese leadership has explicitly targeted pharmaceutical and chemical manufacturing for strategic development under initiatives such as "Made in China 2025" and its successor industrial policies. The goal is not merely to capture market share, but also to establish the kind of upstream control over global supply chains that would give Beijing strategic influence over other countries' pharmaceutical supply chains. In an article in *Xinhua*, a Chinese state-run media agency, Beijing claimed that China could impose pharmaceutical export controls that would plunge America into "the mighty sea of coronavirus."[23]

As the Atlantic Council has noted, pharmaceuticals may be China's next trade weapon, following the pattern established in rare earths and other critical materials where China has leveraged market dominance to pressure trading partners.[24] The COVID-19 pandemic further demonstrated that API dependence is not an abstract vulnerability: supply disruptions had immediate

consequences for patients and health systems, and the United States had limited ability to respond.

State support through subsidies, preferential loans, tax breaks, and below-market land and energy costs—combined with more permissive environmental regulations—has enabled Chinese API producers to achieve economies of scale that competitors in higher-cost regulatory environments struggle to match.[25] As a consequence, many global pharmaceutical supply chains, particularly for generic medicines, have become structurally dependent on Chinese inputs, even when final API production occurs elsewhere.[26]

Disentangling genuine cost efficiency from state-subsidized advantage is difficult, but also important for policy. While public estimates of this are not available, marking a significant gap, what is clear is that China's government systematically subsidizes domestic manufacturers, and that this support contributes to both its success and driving other competitors out of key market segments. China's cost advantage likely reflects a combination of genuine efficiency gains and state subsidies—and America's policy response must address this challenge through trade remedies, manufacturing innovation, better analysis, and supply chain diversification.

API manufacturing costs are about 30 to 35 percent lower in India and 35 to 40 percent lower in China than in the United States, creating incentives for offshore API production.

POLICIES TO REDUCE U.S. DEPENDENCE ON CHINESE APIS

Reducing U.S. dependence on Chinese APIs requires more than reshoring production. It demands a coordinated strategy to strengthen supply chain resilience, domestic manufacturing capacity, and technological capabilities. Strategic stockpiling initiatives such as the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR), alongside investments in advanced manufacturing and public-private partnerships (PPPs), are beginning to address critical vulnerabilities. Together, these efforts aim not only to buffer short-term disruptions but also to build a more secure, scalable, and innovation-supportive domestic pharmaceutical supply chain over the long run.

Strengthen Strategic Stockpiling

SAPIR is an initiative the United States has undertaken to begin addressing near-term supply vulnerabilities. It is a federally supported effort led by the U.S. Department of Health and Human Services (HHS), including the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA), in partnership with companies such as Phlow Corp., which develops and domestically manufactures APIs and finished drug products that are essential for the United States. This PPP seeks to secure essential medicine manufacturing by building domestic API manufacturing capacity and maintaining a reserve of critical APIs to mitigate supply disruptions in times of emergency. Initial federal support for these efforts has totaled up to $800 million. SAPIR's vision is to serve as a national stockpile to secure key ingredients used to manufacture the most essential medicines in the United States, thereby reducing America's dependency on foreign nations.[27]

SAPIR is not designed as a passive stockpile. Rather, it represents an integrated system for pharmaceutical resilience. Its core components include domestic manufacturing capacity for

critical APIs and inputs, a distributed storage network for rapid response in times of crisis, analytical testing infrastructure to ensure ingredient quality, and conversion capabilities to rapidly turn stored ingredients into finished medicines. These activities are coordinated through a centralized platform for inventory, forecasting, and deployment, leading SAPIR to be a "living" reserve that combines stockpiling with production and logistics.[28]

Phlow's work is a critical part of SAPIR. Through its BARDA-supported contract, the company is working to build an innovative end-to-end domestic supply chain for essential medicines, including the production of chemical precursors, APIs, and finished drugs in partnership with other organizations.[29] This effort combines manufacturing scale-up with upstream research and development (R&D) and process innovation. In particular, Phlow is advancing continuous-flow and green chemistry manufacturing techniques to produce APIs more efficiently, and doing so at a higher quality and a lower cost than with traditional batch production.[30] Such technologies seek to make domestic production economically viable while reducing dependence on foreign suppliers.

At the same time, Phlow is helping to operationalize SAPIR itself by supporting the development, procurement, and storage of key pharmaceutical ingredients, which can be rapidly converted into finished medicines through a distributed manufacturing network in times of disruption. This work has already included supplying millions of doses of essential generic medicines to the Strategic National Stockpile during the COVID-19 pandemic response.[31]

Strategic stockpiling, as a complement to supply chain diversification through friendshoring and domestic manufacturing growth, can serve as an important buffer against disruptions while long-term production and innovation ecosystems are developed. It is important to acknowledge that stockpiling and near-term domestic capacity building are not self-sustaining solutions if the underlying cost difference between American and Chinese producers remains large. The viability of domestic reshoring at scale depends on either closing that gap through manufacturing innovation, offsetting it through policy tools such as advance purchase commitments and tax incentives, or accepting that strategic resilience for a defined set of essential medicines warrants ongoing public investment, much as the United States accepts the cost of maintaining other strategic reserves. Policymakers should be transparent about which of these mechanisms they are relying on for different types of API. Much of the effort depends on advancing new biomanufacturing processes for APIs—including continuous manufacturing and novel synthesis methods—which in turn requires sustained investments in R&D, specialized workforce training, and scale-up capabilities. Therefore, initiatives such as Phlow's work on SAPIR are critical not only for safeguarding near-term resilience but also for catalyzing the technological and industrial base needed for increased domestic production.

Enable Domestic Reshoring Through Manufacturing Innovation

Long-term resilience will also depend on whether U.S. and allied producers can compete technologically and economically with China. Advanced manufacturing technologies—including continuous manufacturing and advanced chemistry—are central to that effort.

Recent advances in biomanufacturing illustrate the potential. As Drew Endy, a member of the bioengineering faculty at Stanford University, has explained, novel bio-based and bio-fermentation processes now "make possible the biosynthesis of active pharmaceutical ingredients through bio-brewing-based processes … we can actually leverage yeast to create a set

of medicinal alkaloids," including for many key APIs.[32] Because these methods rely on engineered organisms such as yeast rather than traditional chemical synthesis, they can reduce environmental impact while drawing on feedstock that is often more readily available domestically.

At the same time, continuous manufacturing offers a pathway to disrupt the batch-based production model that has dominated API manufacturing. Rather than scaling production through large, capital-intensive batch facilities, continuous manufacturing based on flow chemistry enables smaller, more flexible systems that operate continuously and efficiently.

In addition to Phlow's work, other early efforts demonstrate the promise of this approach. CONTINUUS Pharmaceuticals, for example, is developing an integrated continuous manufacturing platform that takes raw materials, synthesizes and purifies APIs, and produces final dosage forms all in a single system that can operate 24/7. Whether advanced manufacturing technologies can help close the cost gap with Chinese production remains an open question. CONTINUUS's prototype results show that it reduces costs by 30–50 percent, solvent use by more than 60 percent, energy costs by 50 to 60 percent, facility footprint by roughly 90 percent, and lead time from months to less than 48 hours.[33] These cost reductions could help reduce the gap if replicated at commercial scale. However, achieving those results outside controlled pilot conditions requires solving challenges in process scale-up, workforce training, regulatory approval, and supply chain integration. The federal government should support independent techno-economic assessments of what cost parity between U.S. advanced manufacturing and Chinese conventional production would require, and at what production scale it becomes commercially viable.

The United States does not need to replicate China's low-cost manufacturing model to compete—it can instead compete through innovative manufacturing.

Even if manufacturing innovation helps to narrow the cost gap, it will not by itself shift procurement decisions. The pharmaceutical industry's purchasing decisions are driven primarily by price and buyers, including generic drug manufacturers and finished drug producers, that will not voluntarily pay a premium for domestically produced APIs absent policy incentives. A strategy to reduce dependence on Chinese APIs therefore requires not only supply-side investments in domestic capacity but also demand-side tools that give buyers a commercial reason to prefer allied supply chains. These include advance purchase commitments, formulary preferences for drugs sourced from non-Chinese API supply chains, and procurement criteria that reward supply chain resilience. Without such tools, new domestic capacity risks being underutilized.

Streamlining the development and deployment of these technologies will require deliberate policy support. PPPs and strategic federal funding for API manufacturing innovation can help move advanced production methods from the lab to commercial scale while strengthening domestic and allied supply chains. Achieving this will also require sustained investment both in R&D and in the scientific workforce—particularly Ph.D.-level researchers capable of developing and refining new biomanufacturing processes.

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) plays an important role in advancing U.S. innovation in biopharmaceutical manufacturing. Policymakers

could also consider establishing a new Engineering Research Center (ERC) or Industry-University Cooperative Research Center (I/UCRC) focused on next-generation biomanufacturing technologies. Such a center could support applied research to develop scalable API production methods such as continuous manufacturing and advanced synthesis, fund pilot and demonstration facilities to bridge lab-scale innovation to commercial production, and create industry-aligned training programs to develop a specialized workforce. It could also facilitate collaboration between universities, manufacturers, and federal agencies to accelerate technology transfer, standards-setting, and the adoption of new manufacturing platforms in domestic production.

Strengthening U.S. pharmaceutical manufacturing innovation and enabling effective reshoring will require coordinated policies across investment, supply chain diversification, and procurement reform.[34] Policymakers could expand the use of direct subsidies, advance purchase commitments, and guaranteed contracts to incentivize domestic API and KSM manufacturing, alongside tax incentives and streamlined permitting to lower barriers to new capacity. Federal efforts, including a 2022 executive order to advance biomanufacturing innovation, represent important steps, but scaling will require additional support.[35]

Consistent with recommendations from the API Innovation Center, reshoring strategies should prioritize modernizing underutilized domestic facilities, accelerating the adoption of advanced manufacturing technologies, and targeting essential medicines for domestic production. Such efforts should be reinforced by procurement reforms such as quality-linked reimbursement and preferential treatment for U.S.-manufactured drugs.[36] At the same time, reshoring must be paired with diversification across trusted partners, given persistent upstream dependencies on foreign sources.

Regulatory timelines also play an important role in determining where API manufacturing investment and innovation occurs. Lengthy or uncertain FDA review processes raise the cost of capital for new facilities, particularly for U.S. and allied producers attempting to develop innovative manufacturing techniques to compete with entrenched Chinese suppliers. As a result, regulatory friction can unintentionally reinforce geographic concentration in pharmaceutical supply chains. Expedited FDA review pathways for API facilities located in the United States or allied countries, paired with proactive FDA technical assistance to help manufacturers meet good manufacturing practice standards, could reduce time-to-market barriers. Recent federal efforts point in this direction. Executive Order 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines," directs the FDA to streamline review of domestic pharmaceutical manufacturing, including through initiatives such as the agency's PreCheck Program.[37] Such policies could support domestic manufacturing innovation.

More broadly, regulatory timelines are closely intertwined with the FDA's approach to overseeing pharmaceutical manufacturing innovation. As noted in a previous ITIF report, the FDA heavily regulates the manufacturing processes used to produce drugs to ensure safety. Companies seeking approval for a new drug are hesitant to propose new manufacturing methods that lack regulatory precedent. Even after production begins, the FDA must certify any changes to previously approved methods, even those aimed at enhancing efficiency. In part, as a result, pharmaceutical manufacturing has not experienced the productivity and quality improvements seen in other advanced industries.[38]

FDA leadership has acknowledged some of these challenges. Former FDA Center for Drug Evaluation and Research (CDER) Director Janet Woodcock has noted that many existing regulations were developed around "traditional batch manufacturing under a unified pharmaceutical quality system" and are ill-suited to emerging technologies such as continuous manufacturing and advanced chemistry.[39] To address this, the FDA has started working with stakeholders from across industry, academia, and Congress to identify and address regulatory challenges to the adoption of advanced pharmaceutical manufacturing approaches.

Congressional policymakers and the Trump administration should continue to work with the FDA on these issues and streamline and accelerate the FDA's capacity to evaluate and approve innovative pharmaceutical manufacturing processes. This could include expanding expedited review pathways, increasing FDA technical engagement with manufacturers, and ensuring that the agency has the resources and authority needed to evaluate innovative production methods quickly and predictably. Doing so would reduce investment risk while accelerating the diffusion of novel, cost-saving, and resilient manufacturing technologies.

Current U.S. efforts to onshore API manufacturing should be paired with strategies to diversify upstream supply chains, particularly the KSMs that serve as critical inputs for API production.[40] Failure to do so could risk reproducing a fragile dependency if API manufacturing remains reliant on Chinese-sourced precursors, as the United States continues to depend heavily on foreign suppliers for these inputs. Policy incentives should therefore extend beyond APIs themselves to include the domestic production of critical starting materials through efforts including targeted tax credits, investment incentives, or loan guarantees that would help strengthen supply chain resilience.

To bolster U.S. drug manufacturing, the Pharmaceutical Supply Chain Defense and Enhancement Act (sponsored by senators Elizabeth Warren (D-MA) and Tina Smith (D-MN)) calls for lowering the cost of domestic production by providing $1 billion a year for 5 years to BARDA to dramatically upgrade U.S. capacity to manufacture "critical drugs."[41] Funding would be used to contract with U.S. nonprofits and companies to help them invest in the facilities, manufacturing techniques, and drug development processes needed to produce the drugs, APIs, and starting materials included on the "critical drugs" list in the United States.

Support Domestic Reshoring in Puerto Rico

One underutilized opportunity for domestic reshoring is Puerto Rico, which offers a more competitive business environment for pharmaceutical and API manufacturing within U.S. jurisdiction. Under its Incentives Code (Act 60), eligible firms benefit from a 4 percent corporate tax rate, substantial property and municipal tax exemptions, and R&D tax credits of up to 50 percent for qualified activities, typically guaranteed over long-term incentive periods. These provisions are designed to attract capital-intensive industries such as biopharmaceutical manufacturing and have been cited as a mechanism to rebuild U.S. production capacity.[42]

Congress should also leverage the tax code to encourage greater levels of medicines manufacturing in Puerto Rico. For example, Congress should reinstitute Section 936 of the Internal Revenue Code, which, when originally enacted in 1976, released pharmaceutical manufacturers from taxes on profits made in Puerto Rico and other U.S. territories. Section 936 contributed to making Puerto Rico a pharmaceutical manufacturing powerhouse, and while the biopharmaceutical sector does still contribute 30 percent of Puerto Rico's gross state product,

the phase-out of the provision from 2006 to 2016 contributed to a shrinking of the sector and a 40 percent reduction in the territory's manufacturing job base. In 2024, the territory produced $48.3 billion in pharmaceutical exports, representing 74 percent of its total exports, with 60 facilities and 13,917 employees in the sector.[43] Yet this capacity exists despite, not because of, the federal tax environment. **Congress should restore the tax credit in Section 936 for biopharmaceutical production in Puerto Rico and other U.S. territories.**[44] Doing so would signal a federal commitment to expanding this domestic production base, generating additional API and finished drugs within the United States at a scale that no other domestic location could match in the near term.[45]

While Puerto Rico is unlikely to become a full substitute for Chinese API production at scale—as China's dominance over global APIs reflects decades of infrastructure investment and industrial agglomeration—for a defined set of essential medicines, especially those at highest risk of supply disruption, Puerto Rico could plausibly supply a meaningful share of domestic needs. A targeted assessment of which APIs are most critical and amenable to production in Puerto Rico, given its existing capabilities, and what federal investment would be required to bring about that capacity would help policymakers prioritize.

Puerto Rico's advantages extend beyond tax policy. As a U.S. territory, it provides legal and regulatory alignment with the FDA, use of the U.S. dollar, and an established pharmaceutical manufacturing base. Together, these features lower operational and compliance risks relative to offshore production and make Puerto Rico a viable nearshore location for APIs and finished drugs. Federal assessments have highlighted Puerto Rico's existing role in U.S. drug manufacturing and its potential to expand capacity with appropriate policy support, while still being mindful of its vulnerability to natural disasters, such as hurricanes, that may cause damage to manufacturing facilities and thus lead to disruptions.[46]

These incentives make the territory a compelling alternative to foreign API sourcing for certain products, especially complex or high-value APIs and finished drugs. By attracting investment through tax preferences and supporting R&D activity domestically, these measures can help the United States reduce strategic dependence on China for APIs while building resilient capacity within the U.S. jurisdiction.

Expand Nearshoring and Friendshoring to Diversify Supply Chains

The preceding sections have outlined domestic reshoring strategies—including manufacturing innovation, the SAPIR initiative, and Puerto Rico's underutilized capacity—that could expand API production in the United States. These efforts are necessary but not sufficient, as even such a fully executed domestic reshoring agenda would leave the United States short of the supply chain independence needed to withstand a major disruption or a deliberate Chinese supply cutoff. Nearshoring, friendshoring, and allied coordination could complement U.S. production by diversifying supply chains without requiring every stage of manufacturing to occur domestically, while reducing concentration risk through expanded production across trusted jurisdictions.

A U.S.-Mexico collaboration for API and precursor material manufacturing, for instance, could build on Mexico's growing chemical and manufacturing sector while maintaining proximity to U.S. markets, leveraging existing industrial capabilities and strengthening regional resilience.[47] Such a partnership could involve several factors: i) a bilateral working group to identify priority APIs for joint production; ii) financing through the U.S. Development Finance Corporation for

Mexican pharmaceutical manufacturing facilities; iii) harmonized FDA-COFEPRIS (Mexico's health regulatory authority) inspection protocols to streamline market access for Mexican-produced APIs; and iv) joint infrastructure investments in dedicated pharmaceutical manufacturing zones near the U.S.-Mexico border, reducing logistics costs and enabling just-in-time supply chains.

Similarly, friendshoring with allies—such as India and South Korea—could support diversification in both production and innovation.[48] South Korea represents a compelling friendshoring partner not primarily because of cost, but due to its advanced manufacturing capabilities, strong IP protections, and proven capacity in pharmaceutical production. While South Korean wages tend to be higher, meaning that South Korean API production would not be as price-competitive with Chinese production, South Korea's value proposition lies in higher-value, technically complex APIs and advanced manufacturing partnerships—areas where quality, reliability, and innovation matter more than unit cost. Bilateral cooperation should focus on APIs where technical complexity or quality requirements make South Korean producers competitive, and on mutually supporting R&D to develop next-generation manufacturing platforms. South Korea possesses established capabilities in pharmaceuticals and advanced manufacturing, and bilateral cooperation between the two countries could include joint R&D initiatives, coinvestment in emerging manufacturing technologies, and improved data-sharing to map and understand shared supply chain vulnerabilities. These partnerships would help reduce dependence on concentrated sources—especially China—while preserving efficiency and scale through coordinated production across trusted allies.

Nearshoring, friendshoring, and allied coordination could complement U.S. production by diversifying supply chains without requiring every stage of manufacturing to occur domestically, while reducing concentration risk through expanded production across trusted jurisdictions.

The United States should also increase its reliance on India through a coordinated combination of procurement, financing, and regulatory tools. Indeed, drugs and APIs have been identified as a key opportunity for U.S.-India collaboration as part of the U.S.-India "TRUST" initiative.[49] **On the demand side, federal purchasing authorities, including BARDA, the Department of War (DOW), and the Centers for Medicare & Medicaid Services (CMS), could deploy advance market commitments to provide Indian API producers with the revenue predictability needed to justify capacity investments.** A White House determination under the Defense Production Act in December 2023 expanded BARDA's authority to issue such commitments for essential medicines and medical countermeasures, providing a legal avenue for this approach.[50] In parallel, CMS reimbursement policy could prioritize medications for preferred Medicare formulary placement for drugs that source APIs from trusted Indian suppliers.[51]

On the supply side, U.S. development and industrial finance tools could support India's API capacity expansion. **The U.S. International Development Finance Corporation (DFC), which has approximately $3.8 billion already deployed in India—making it the agency's largest single-country market—could provide loan guarantees and political risk insurance for API facilities and chemical-intermediate plants in India, particularly those aligned with U.S. essential-medicines priorities.**[52]

Regulatory cooperation is also critical: expanded FDA technical assistance, faster inspection scheduling, and early scientific engagement can lower compliance costs and shorten time-to-market for Indian producers scaling advanced or continuous manufacturing. Finally, joint U.S.–India initiatives to localize KSM production—supported by tax credits, export-import financing, or allied coinvestment—could reduce India's starting material dependence on China. India currently imports most of its API KSMs from China, with roughly 87 percent of India's imported antibiotic ingredients by value coming from China, meaning that a simple shift in final API assembly without addressing upstream inputs would leave the supply chain exposed.[53] Diversification that includes these materials, not just finished APIs, would be key to turning procurement reorientation into durable supply chain resilience.

Align Demand-Side Incentives to Support Domestic and Allied Production

Demand-side policy tools—some of which have been mentioned in preceding sections—are essential steps in complementing supply-side incentives, as they create predictable revenue streams that reduce risk and improve investment viability. In particular, advance purchase commitments for APIs and essential medicines produced through non-China-dependent supply chains could provide manufacturers with the long-term demand certainty needed to justify investment in new capacity building. These commitments could be deployed by federal U.S. purchasers through multiyear contracts that guarantee minimum volumes or revenues for qualifying suppliers.[54]

The SAPIR strategic stockpiling example discussed earlier is itself a form of demand-side intervention, as BARDA's contracts with Phlow effectively function as advance purchase commitments that secure demand for domestically produced APIs. Broadening this approach across more products and producers requires identifying the appropriate federal buyers and funding sources. The primary federal purchasers with authority to deploy such tools include BARDA and the Department of Defense (DOD) under the Defense Production Act, the Department of Veterans Affairs (VA) for the VA formulary, and CMS through Medicare Part D and Medicaid reimbursement policy. Funding for these commitments should be explicitly appropriated by Congress, potentially through a dedicated pharmaceutical supply chain resilience fund, rather than rely on discretionary emergency authorities that may not be available in noncrisis conditions.

To be effective, such purchase commitments should be tied to clear criteria, including diversified or allied sourcing, strong compliance records, and, where relevant, the adoption of advanced manufacturing technologies. Implementation would require cross-agency coordination. For example, BARDA and DOD could focus on essential medicines and national security priorities, while CMS and the VA could reinforce these signals through reimbursement and procurement policies that favor resilient supply chains. Standardized contracting frameworks could also reduce uncertainty for manufacturers. Together, such demand-side tools could help ensure that new API capacity is not only built but also remains economically sustainable over time.

The proposed Pharmaceutical Supply Chain Defense and Enhancement Act seeks to facilitate development of a market for domestically produced pharmaceuticals by requiring DOW, VA, HHS, and Bureau of Prisons to purchase American-made drugs and providing funding to subsidize the purchase of these drugs. Under the legislation, those agencies would together

receive an additional $1 billion over their current procurement budgets to purchase drugs that utilize ingredients produced exclusively in the United States.[55]

Strengthen Oversight of Foreign API Manufacturing

Another enduring challenge in global pharmaceutical supply chains consists of asymmetries in inspection and enforcement across jurisdictions. While the FDA applies current Good Manufacturing Practice (cGMP) requirements to all facilities supplying the U.S. market, oversight of foreign facilities—particularly in China—has historically been more limited and subject to greater operational constraints than for domestic manufacturers.[56]

Prior to the COVID-19 pandemic, FDA inspections abroad were often pre-announced and conducted less frequently than domestic inspections. The pandemic further disrupted these processes, reducing foreign inspections and increasing dependence on host-country regulatory oversight, resulting in a backlog that constrained U.S. visibility into foreign manufacturing conditions and practices. Although inspections have since resumed, structural factors, including limited staffing, logistical barriers, and broader geopolitical frictions, continue to affect the FDA's ability to maintain consistent, on-the-ground oversight of facilities in China.[57]

The inspection regime's limitations in China are not merely logistical; they reflect a structural information asymmetry with China that is difficult to remedy under current conditions. Unlike domestic U.S. facilities, which can be inspected with no warning, FDA inspectors in China must obtain a business visa and schedule inspections in advance, providing facilities with effective forewarning of oversight visits. This advance notice creates opportunities for facilities to stage compliance by concealing deficiencies, updating incomplete records, and coaching workers before inspectors arrive.[58]

Structural factors, including limited staffing, logistical barriers, and broader geopolitical frictions, continue to affect the FDA's ability to maintain consistent, on-the-ground oversight of facilities in China.

As Rosemary Gibson, author of *China RX* and a witness before the U.S.-China Economic and Security Review Commission, has commented, the FDA faces a regulator's dilemma: it must choose between allowing potentially defective medicines from noncompliant suppliers to remain on the market or exacerbating drug shortages by banning these suppliers. The dilemma was created because the United States allowed itself to become dependent on a single adversarial source.[59] This cannot be solved through better inspection protocols alone. **Congress should require that all inspections of foreign facilities be unannounced, and that no APIs or finished drugs may be imported from any facility that hasn't passed an FDA inspection within the preceding three years.**

In May 2025, the FDA reported expanded use of unannounced inspections at foreign manufacturing facilities that produce essential medicines intended for American patients. This followed a FDA pilot program in China and India that aimed to ensure that foreign plants are subject to the same level of regulatory oversight and rigor as domestic companies. The FDA also announced that it would evaluate its policies and practices for improvements to its foreign inspection program to ensure that the agency is the gold standard for regulatory oversight.[60]

These inspection asymmetries have important implications. They could affect competitive dynamics, as differences in inspection frequency and enforcement intensity can translate into

variation in effective compliance costs across jurisdictions. At the same time, they could contribute to reduced supply chain transparency, limiting regulators' ability to carefully assess quality risks, production vulnerabilities, and dependencies in upstream inputs such as KSMs.

Addressing these challenges requires greater consistency in how regulatory standards are applied globally. The FDA's own data shows that prior to the pandemic, many foreign facilities had never received in-person FDA inspections.[61] **Congress should authorize and fund a substantial increase in FDA foreign inspection capacity, set a statutory inspection frequency floor for foreign facilities of, at minimum, once every three years for any facility actively supplying the U.S. market, and appropriate funding sufficient to achieve that target.** Also, the FDA should leverage inspection-sharing agreements with trusted regulators such as the European Medicines Agency through its Mutual Recognition Agreement and Japan's Pharmaceuticals and Medical Devices Agency to extend oversight reach.[62]

Complementing physical inspections with remote monitoring tools and improved access to manufacturing data could further enhance visibility into Chinese production facilities specifically.[63] In parallel, greater transparency around inspection outcomes, along with incorporating compliance track records into federal procurement decisions, could help align market incentives with quality and supply chain resilience goals.[64] More importantly, inspection enforcement is itself a supply chain diversification tool. When the FDA bans imports from noncompliant suppliers, buyers must source elsewhere, prompting a shift toward domestic and allied producers that the supply-side policies discussed throughout are designed to support. Incorporating compliance track records into federal procurement decisions would reinforce this dynamic. Therefore, a more rigorous and consistently enforced inspection regime does not merely protect patients from potentially defective drugs—it actively supports the broader goal of reducing U.S. structural dependence on Chinese pharmaceutical production.

Collect Better Data

The United States needs to collect better data regarding U.S. foreign supply chain dependencies for KSMs, APIs, and drugs more broadly. As such, **Congress should pass the Pharmaceutical Supply Chain Defense and Enhancement Act**, which calls for the FDA commissioner and the secretary of Defense to develop a confidential list of drugs critical to the public health or national security, and in doing so identify all APIs and KSMs required for the manufacture of those drugs.[65] The list would be updated every two years. The legislation would further require drugmakers to annually report to the FDA information about the source of APIs and starting materials used to make drugs consumed in the United States; require drugmakers to provide to any federal agency they supply drugs information on the foreign manufacturers that produce those drugs and components; and require the FDA to issue both public and classified reports to Congress on the strength of the U.S. supply chain.[66] The legislation further would require the U.S. Federal and Trade Commission and the Treasury Department to study the role of foreign investment in the U.S. pharmaceutical industry within one year of the act's passage.

CONCLUSION

China is systematically building dominance in biopharmaceutical production, starting with KSMs and APIs, the focus of this report. But as ITIF has written, this dominance is extending along the entire value chain, including in new-to-the-world drugs. The United States and allies cannot continue allowing this to happen.

The United States faces a China problem in pharmaceutical supply chains. The dependence on Chinese API production is not the result of neutral market forces—it reflects decades of Chinese state-directed industrial policy aimed at achieving dominant upstream control over critical inputs the rest of the world relies on. That dominance now gives Beijing leverage over U.S. healthcare: the ability to threaten supply cutoffs, introduce substandard ingredients, or use pharmaceutical access as bargaining in a crisis. Addressing this requires acknowledging that it is a national security challenge that demands a strategic response. Efforts to reduce dependence on China must be grounded in a broader strategy that strengthens resilience across the entire pharmaceutical supply chain.

A robust approach will require aligning supply- and demand-side policies to support investment in domestic and allied production while accelerating the adoption of advanced manufacturing technologies that could improve cost competitiveness. At the same time, regulatory modernization and expanded inspection capacity are necessary to ensure consistent standards and to reduce barriers to innovation. Nearshoring and friendshoring strategies can further diversify risk, particularly when paired with upstream diversification of KSMs. The objective of this multifaceted strategy is to build a more diversified, transparent, and robust pharmaceutical supply chain that is able to withstand future disruptions.

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