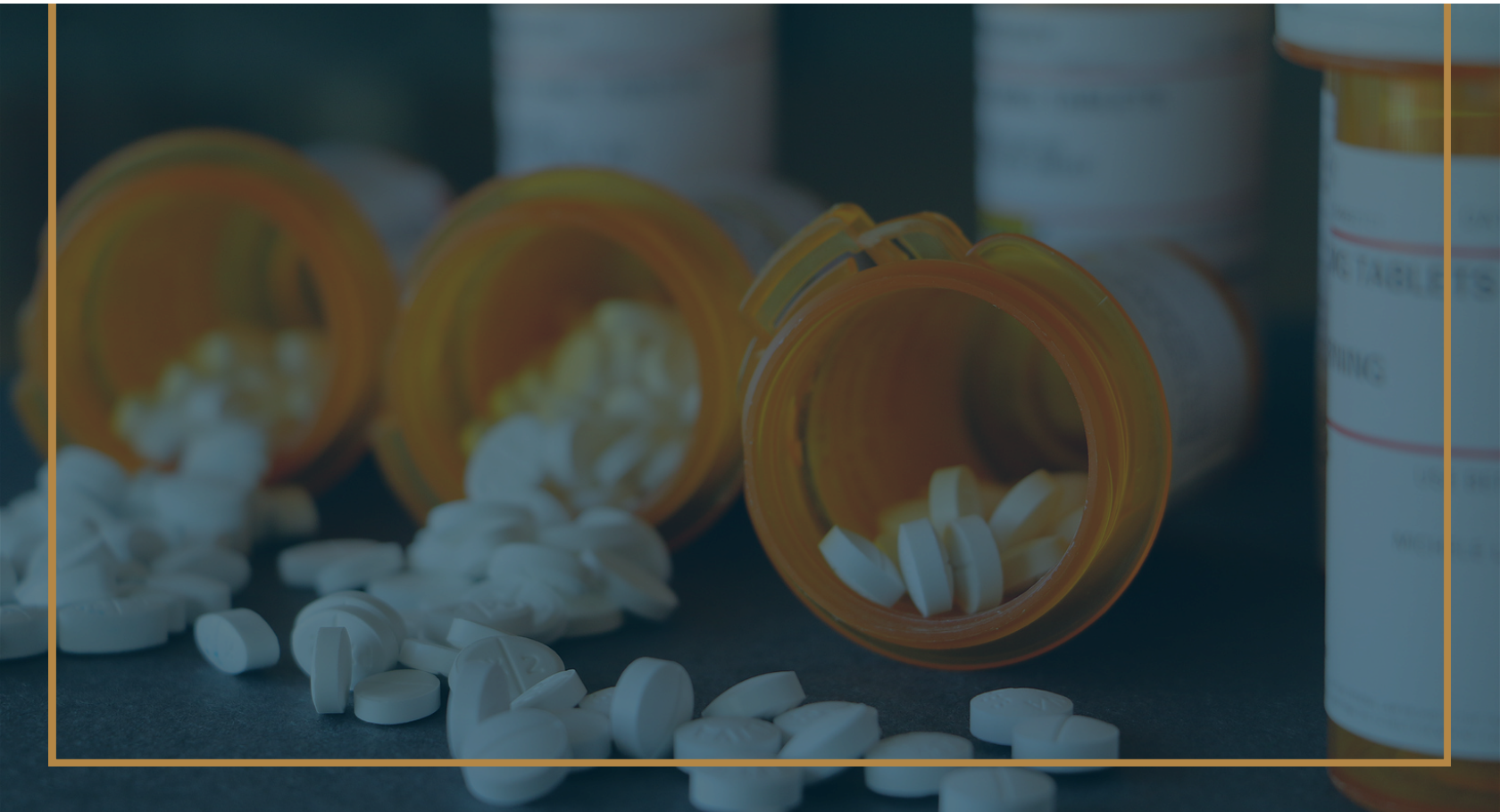
UNITED STATES SENATE

SPECIAL COMMITTEE on AGING

CHAIRMAN RICK SCOTT & RANKING MEMBER KIRSTEN GILLIBRAND

PROTECTING SENIORS' ACCESS TO ESSENTIAL MEDICATIONS:

SECURING THE FOREIGN GENERIC PHARMACEUTICAL SUPPLY CHAIN



KEY TAKEAWAYS

In this report, you will learn:

- Since 2002, pharmaceuticals manufactured in the us dropped by 46 percent.
- China manufactures the majority of some of the most common drugs Americans buy over the counter in the United States, including ibuprofen and acetaminophen.
- The U.S. is completely dependent on China for our pharmaceuticals. Approximately 90 percent of the Active Pharmaceutical Ingredients (APIs) for global antibiotics are of Chinese origin, and 83 percent of the top 100 generic drugs consumed by U.S. citizens have no U.S. based source of APIs.
- While India supplies approximately half of all generic drugs used in the U.S., Indian manufacturers rely on China for approximately 80 percent of the API that they use.
- According to a 2025 study, the occurrence of serious adverse events for generic drugs manufactured in India was 54% higher than for equivalent drugs that were manufactured in the U.S. Adverse events were hospitalization, disability, and death.

The following report was developed by the Majority and Minority staff of the United States Senate Special Committee on Aging at the direction of Chairman Rick Scott (R-FL) and Ranking Member Kirsten Gillibrand (D-NY). This document has been developed for informational purposes. It does not represent findings or recommendations formally adopted by the committee.

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INTRODUCTION

Generic drugs dominate the modern prescription drug market, accounting for 91% of all prescriptions filled in the United States. Older adults increasingly rely on prescription medications as they age. As of the publishing of a 2021-22 study from the Centers of Disease Control and Prevention, nearly every older American surveyed reported having been prescribed at least one prescription medication, with 88.6% of those aged 65 and older reporting this. This figure is even higher when looking at adults aged 75-84, with 91.3% reporting taking at least one prescription drug during the year.

Despite older Americans' reliance on prescriptions, the supply chain for these essential drugs remains vulnerable to disruptions, and issues persist with the quality of foreign drugs. Not only is the supply chain vulnerable, but it is almost entirely reliant on China and India. According to a study by Anthony Sardella at Washington University in St. Louis, 83% of the top 100 generic drugs consumed by U.S. citizens have no U.S.-based source of Active Pharmaceutical Ingredients, and another 11% have only one domestic source of APIs. This overreliance on foreign generic drugs, particularly those coming from China and India, poses both national security and public health risks to all Americans, but particularly to seniors. Compounding this problem is a decline in domestic manufacturing of generic drugs. Seniors who depend on medications are increasingly vulnerable to unstable, unreliable, and unsecured supply chains, raising concerns about the quality of the medicines they receive.

While there are additional underlying economic factors that have led to the offshoring of generic drug manufacturing, the scope of this report focuses on two separate but interlinked problems: (1) the decline of domestic generic drug manufacturing, which has resulted in an overreliance on drugs manufactured overseas, and (2) recurrent quality issues with foreign generic drugs entering the U.S. market. To secure supply chains and promote quality medications that are safe for American seniors, federal action is needed to implement policies that will create favorable market conditions for reshoring and friend-shoring manufacturing, incentivize quality in drug purchasing practices, bring about transparency in supply chains, and establish parity between domestic and foreign inspections of drug manufacturing plants.

As chairman and ranking member of the Senate Special Committee on Aging, we are committed to working with stakeholders across the supply chain to implement long-term solutions to create a secure generic drug supply chain for the United States. While there are additional actions that Congress can take to support overall market reform and short-term solutions for both our manufacturers and consumers, the scope of this report will focus solely on foreign manufacturing.

BACKGROUND

One of the most significant policies that pushed the generic drug market overseas is the *Hatch-Waxman Act of 1984.* This legislation was designed to facilitate generic drug approval and, in turn, lower prices and increase options for medications on the market. Under this bill, the Abbreviated New Drug Application (ANDA) process was established, exempting generic drugs from clinical trials. Generic drugs contain the same molecules as brand-name drugs that have been deemed safe and effective so manufacturers need only show the Food and Drug Administration (FDA) that their products are therapeutically equivalent. Generic manufacturers are also subject to pre-approval and post-approval inspections by the FDA. All generic drugs approved by the FDA since *Hatch-Waxman's* implementation have undergone the ANDA process.

The results of the *Hatch-Waxman Act* have lowered the cost of drugs for consumers through expansion of generics. The U.S. has gone from 19% market penetration of generic prescription drugs at the time of the *Hatch-Waxman Act*'s passage to 90% in today's market. Today, more than 80% of approved brand pharmaceutical drugs have a generic competitor as opposed to before the *Hatch-Waxman Act*, when only 35% of the top-selling brand drugs had a generic competitor.

While the *Hatch-Waxman Act* lowered the cost of drugs through the expansion of generics, it has not been without consequence, as it has initiated a race to the bottom in pricing which often leads generic manufacturers to offshore their operations. As of 2023, the average generic copay is $6.16, and 92% of all generics have a copay of less than $20. Generics are not only relatively inexpensive for consumers, but they also generate savings for the entire healthcare system. Despite accounting for approximately 90% of prescriptions filled in the U.S., generics account for only 17.5% of spending on prescription drugs and account for only 1.5% of all U.S. health care spending.

While consumers are benefitting from lower drug prices, shrinking margins for manufacturers associated with the race to the bottom have pushed manufacturing operations overseas, particularly toward India and China. However, this has led to challenges with oversight and quality issues, as there are significant differences in the FDA's ability to inspect a foreign manufacturer as opposed to an American manufacturer. Due to policy failures with the FDA's inspection process and overreliance on generics from China and India, foreign manufacturers are not held to the same standard as domestic manufacturers, and foreign companies have often been able to cut corners on facilities. This stems from a multitude of issues, such as a shortage of qualified foreign inspectors, support staff, or chronically insufficient funding.

Since all generics approved by the FDA are considered therapeutically equivalent, Chinese and Indian manufacturers produce drugs without undergoing independent quality testing while manufacturing at a much lower cost and with less oversight than American manufacturers.

These quality control issues underscore why reshoring essential medicines should be a priority for the U.S. Government. There is debate around exactly what a resilient supply chain looks like and to what extent reshoring of manufacturing is needed in conjunction with nearshoring or friendshoring. To secure generic drug supply chains, the federal government should prioritize purchasing American-manufactured generics, particularly for medicines deemed essential. This means a drug would be manufactured in the United States and source APIs and Key Starting Materials (KSMs) domestically.

An important issue to understand when discussing reshoring generic drug production is the "Acetris loophole", named for the ultimate ruling in Acetris Health, LLC v. United States. The Acetris decision was a 2020 Court of Federal Claims (COFC) decision that rejected the Department of Veterans' Affairs (VA) interpretation of a "U.S.-made end product" under the Trade Agreement Act (TAA) and Federal Acquisition Regulation (FAR). Prior to this, the government had long held that the country of origin for pharmaceutical manufacturing was based on where the API is manufactured unless "substantial transformation" occurs. Acetris argued that despite their products using foreign ingredients, they could be considered a "U.S.-made end product" due to the fact that the finished dosage form (FDF) tablets were manufactured in New Jersey. Despite U.S. Customs and Border Protection (CBP) finding that the New Jersey tablet manufacturing process did not constitute "substantial transformation" with respect to federal procurement and the VA's longstanding interpretation of what constituted a U.S.-made product, the Federal Circuit ruled in favor of Acetris. This ruling changed the definition of what makes a drug considered "Made in America." Following this ruling, the definition shifted away from where the API was manufactured to where the FDF was assembled. This created a loophole where APIs could be produced overseas, but the FDF could still be considered "Made in America." This loophole must be addressed in relation to federal procurement and contracting.

THE DECLINE OF DOMESTIC MANUFACTURING OF GENERIC DRUGS

The decline of API manufacturing in the United States has been swift and thorough, presenting a distinct risk to both national security and public health. A 2024 report from the API Innovation Center stated that in the past decade, the number of facilities located in the U.S. that produce API has decreased by 61% (~1,951 API-facilities). The countries where API production has grown in recent decades are: Taiwan with 326% growth and 189 new facilities, India with 254% growth and 3,676 new facilities, Israel with 131% growth and 142 new facilities, and China with 55% growth and 531 new API-facilities. These countries are consistently subject to high levels of geopolitical risk, yet the United States remains almost entirely dependent on them for many essential materials. Together, China and India manufacture 60% of APIs globally. The FDA collected data on the prevalence of overseas manufacturing and found that as of 2018, 88% of the manufacturing sites making APIs and 63% of sites making FDFs were located overseas.

Pharmaceutical imports have increased dramatically since the turn of the millennium, particularly in the last ten years. Per the Observatory of Economic Complexity (OEC), pharmaceutical products were the fifth most imported product in 2024, valued at approximately $212 billion. By volume, pharmaceutical imports account for seven times the levels observed in 2000, or 828,000 metric tons. This compares to $94.4 billion in exports of pharmaceutical products (seventh most exported product) and is reflective of the rapidly and steadily increasing pharmaceutical trade deficit. Last year's pharmaceutical trade balance was at a record deficit of $118.3 billion. The two charts below depict the increase in pharmaceutical imports as well as the trade deficit going back to 2000. In 2024, the U.S. manufactured 37% of its consumed pharmaceuticals, a stark decline compared to just over 20 years ago in 2002 when that figure was 83%.

FIGURE 1: U.S. Pharmaceutical Imports (2000-2024)

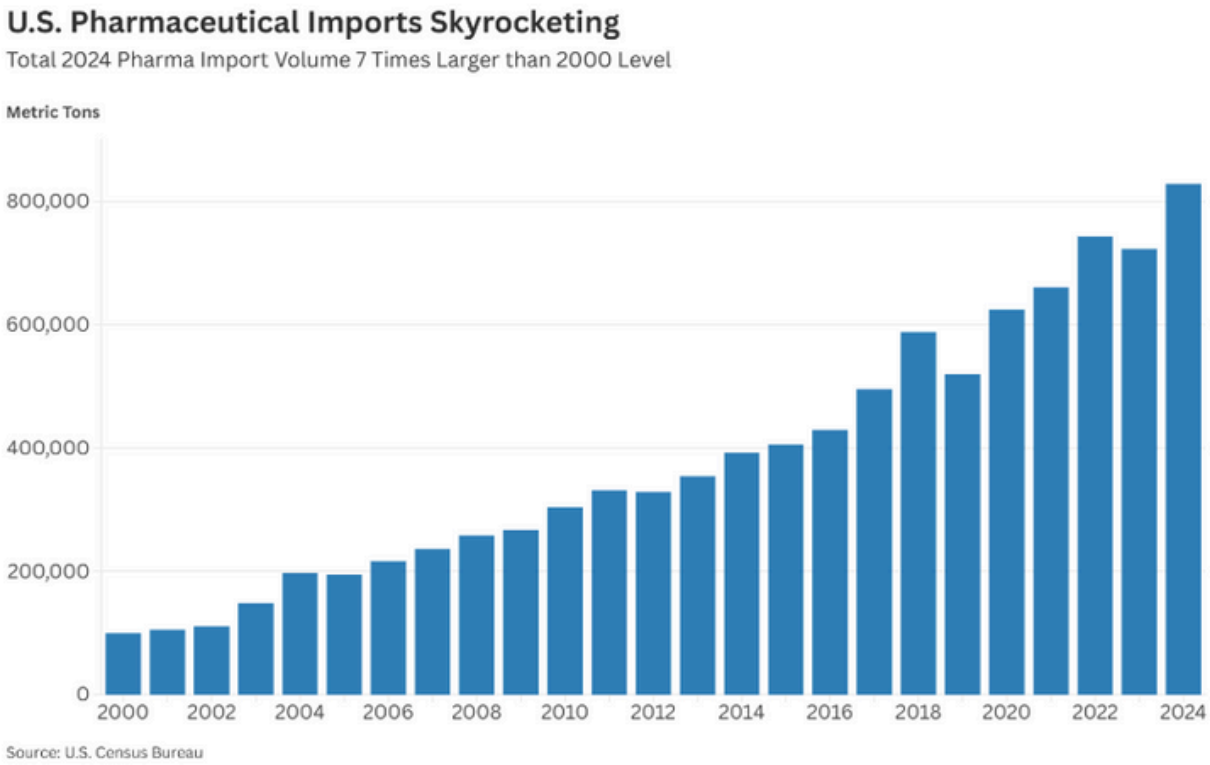
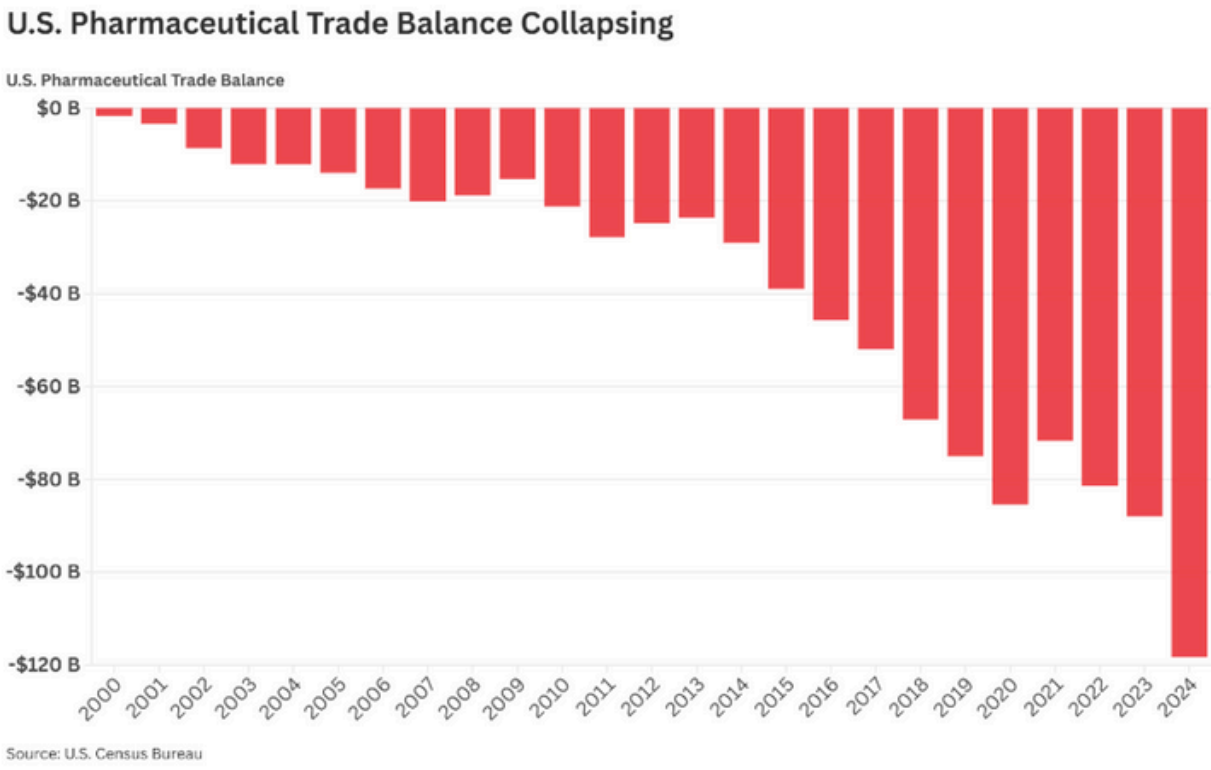


FIGURE 2: U.S. Pharmaceutical Trade Balance (2000-2024)



Source: *Coalition for a Prosperous America, U.S. Census Bureau*.

Some of the primary drivers of shortages, such as market conditions and contracting practices, have driven manufacturers to offshore their manufacturing. In a 2019 report to Congress, the FDA inter-agency drug shortage task force identified three root causes as to why shortages occur. The causes identified were 1) lack of incentives to produce less profitable drugs, 2) the market does not recognize and reward manufacturers for mature quality management systems, and 3) logistical and regulatory challenges make it difficult for the market to recover after a disruption.

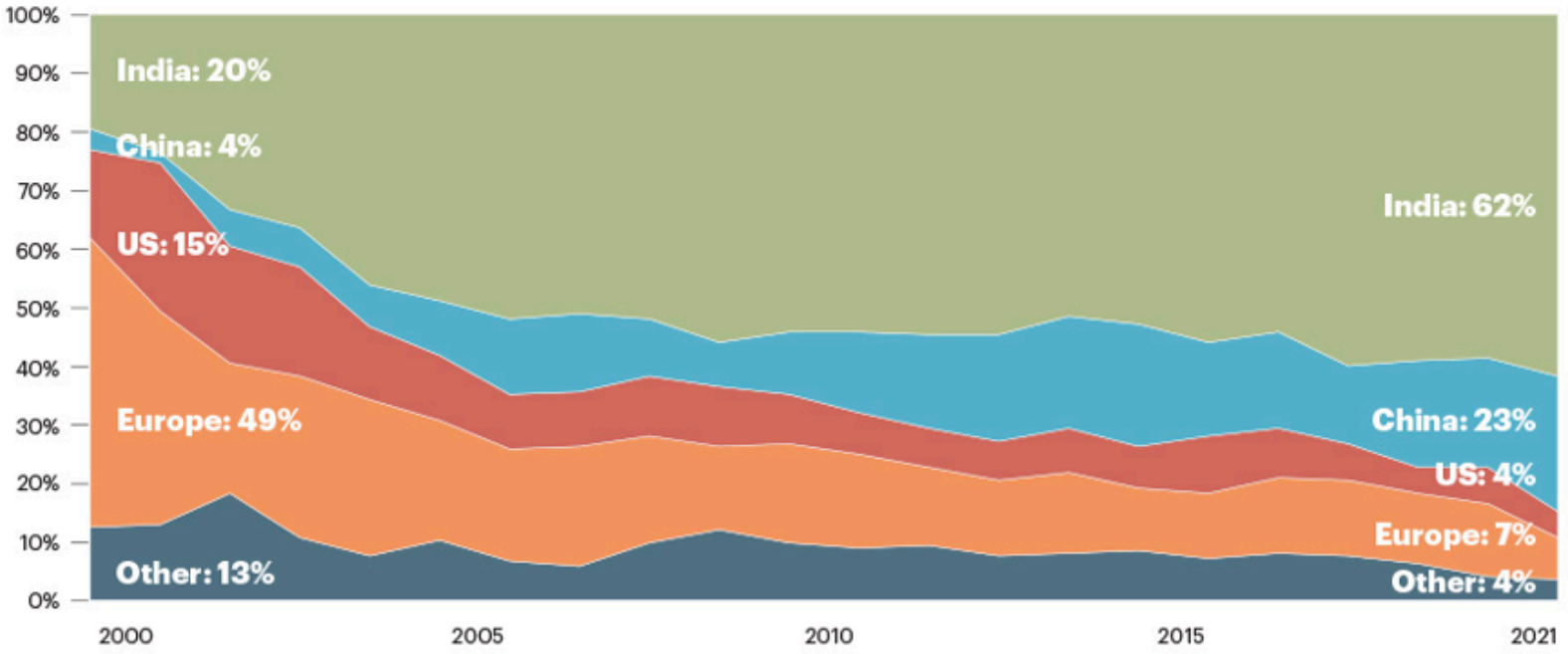
While introducing generic competition into the market has been an effective tool to lower drug prices for consumers, uncertain returns and thinning margins due to increasing price competition give some manufacturers little incentive to enter the market. Per a 2025 analysis by the Department of Health and Human Services' (HHS) Assistant Secretary for Planning and Evaluation (ASPE), the generic drug market continues to be extremely competitive, with prices falling drastically as more manufacturers enter the market. For example, for a generic market with three competitors, prices will fall approximately 20% compared to the pre-generic entry price. As more competitors join the market, the prices fall even more drastically, with price decline as high as 70% to 80% in markets with ten or more manufacturers following three years after the first generic entry to the market. These extremely low prices can dissuade companies from entering these markets. A study by the IMS Institute for Healthcare Informatics estimated that oral generics generally cost 80% less than the brand-name drugs they replace within five years. Even though these products can be sold at extremely low prices, there is still significant upfront investment for manufacturers. Coupled with limited potential return on investment due to price competition and uncertainty with contracting manufacturers with operations located overseas have gained an edge in the market due to their low production costs.

SUPPLY CHAIN VULNERABILITY

A key theme when assessing supply chain vulnerability is that the United States still relies heavily on foreign manufacturers, particularly China and India. The U.S.-China Economic and Security Review Commission found in its 2019 report that China is the world's largest producer of APIs, and that the U.S. is heavily dependent on APIs and KSMs that are sourced from China. India, on the other hand, supplies approximately half of all FDF generic drugs used in the U.S. However, Indian manufacturers rely on China for approximately 80% of the API that they use, per a March 2025 report from Exiger. This cycle highlights the vulnerability of dependence on foreign manufacturing for both FDFs and APIs. Of all FDA-approved API manufacturing facilities, 72% are located outside of the United States, with many of these facilities located in China and India.

Antibiotics are another prime example of China's dominance over the global API supply chain, with some estimates stating that 90% of the APIs for global antibiotics are of Chinese origin. This presents an unacceptable level of risk from a national security standpoint. In 2022, CDC data shows that 236.4 million antibiotic prescriptions were dispensed from U.S. community pharmacies.

FIGURE 3: Active API Drug Master Files by year of filing and country of manufacture, 2000-2021



Source: US Pharmacopeia Medicine Supply Map

Not only do China and India dominate the manufacturing of API, but their share of new API Drug Master File (DMF) submissions has steadily gone up since 2000. DMFs are submitted to the FDA by companies wanting to supply drug ingredients to another company, per U.S. Pharmacopeia. In 2000, China and India together totaled approximately a quarter of API filings. As of 2021, this combined total reached a staggering 85% of active API filings, with India being 62% and China being 23%. Figure 3 shows active Drug Master Files (DMFs) from 2000 to 2021. While India and China have seen the aforementioned immense growth to 85% of active filings, the U.S. and Europe have gone down from 15% to 4% and 49% to 7% of total filings.

While the FDA does list approved API suppliers and recently inspected API manufacturing facilities, there is currently no complete, centralized list maintained by the FDA on API suppliers, which places the onus of finding an API supplier, let alone a quality supplier, on manufacturers. The FDA did collect data on the prevalence of overseas manufacturing and found that as of 2018, 88% of the manufacturing sites making APIs and 63% of sites making FDFs were located overseas.

Much of the conversation with respect to pharmaceutical manufacturing centers around FDF and APIs. However, the precursor chemicals are often overlooked. These upstream materials have an even more concentrated market and are primarily made in foreign facilities. KSMs are the foundation of the entire supply chain. In addition to having higher risks of single points of failure, there is also a lack of data and understanding around the production of these materials. In a report written by the Administration for Strategic Preparedness and Response's (ASPR), one of the findings states that the U.S. government has limited information about KSM supply chains. This lack of data is due to confidentiality practices employed by suppliers of APIs and KSMs, making this supply chain more opaque to both the government and manufacturers attempting to source KSMs.

Finally, over 40% of generic drugs sold in the U.S. have just one manufacturer. Any disruptions to these vulnerable supply chains can result in shortages and a lack of access to medications for patients. With such limited options for critical medicines, potential shortages must be considered by the FDA when restricting imports or taking action against a manufacturer.

CASE STUDY

A chemotherapy drug used for several types of cancer, cisplatin, is a prime example of the lack of FDA-approved options for generic medications and the difficult decisions the FDA must make in the event of a shortage. Following FDA action over Intas Pharmaceuticals in 2023 to suspend imports into the U.S. market, a shortage arose. Intas accounted for 50% of cisplatin in the United States at the time, and there was a lack of supply that could account for Intas' market share. With a lack of viable options, the FDA decided to allow Chinese company Qilu Pharmaceuticals, which at the time had not received FDA approval, to sell its cisplatin in the United States.

While there was a need to import cisplatin, it is evidence as to how market conditions have led to vulnerable global supply chains and an extreme overreliance on critical medications from China and India. With no domestic options for critical medicines, the U.S. was forced to continue to rely on these extremely vulnerable supply chains and drugs without FDA approval.

Import data is also illustrative of Chinese dominance over prominent generics. China accounts for 95% of imports of ibuprofen, 70% of imports of acetaminophen, and up to 45% of penicillin, per a 2023 report from the Coalition for a Prosperous America.

QUALITY

Until recently, the prevalence of quality issues, particularly with foreign drugs coming from China and India, was relatively unknown. The central problems with generic drug quality can be attributed to market factors that have pushed generic drug manufacturing overseas, the assumed equivalence in quality of FDA-approved generics, and challenges and failures with respect to FDA oversight. Quality issues have been particularly significant with Chinese and Indian manufacturers, which have received the most FDA warning letters. Violations include, but are not limited to, the presence of carcinogens in medicines, destroying or falsifying data, and non-sterile manufacturing.

Due to a lack of parity in inspections between domestic and foreign manufacturing facilities, the "race to the bottom" is directly correlated with the quality issues seen with generic medications. Purchasers have limited information with respect to quality, which has led to market conditions that simply favor the lowest price over all other factors. Since the market does not reward quality, manufacturers lack incentives to invest in quality measures if they can sell drugs at a low cost. Manufacturers need only to adhere to the FDA's Current Good Manufacturing Practices (cGMP), but this merely sets a floor. As the FDA's interagency task force highlighted, without knowledge as to the quality management of a facility, back-up manufacturing capabilities, or risk management plans, purchasers have very limited information with respect to quality, which leads to a focus on price. The FDA's report also states that volume drug buyers, including Group Purchasing Organizations (GPOs) and large hospital or pharmacy chains, lack incentives to purchase drug products from reliable suppliers who might also be more costly. This pushes buyers toward low-priced drugs.

The FDA has recognized that there is a lack of information and incentives related to quality. Based on the FDA's report and recommendations from the Pharmaceutical Science and Clinical Pharmacology Advisory Committee, the FDA's Center for Drug Evaluation and Research (CDER) launched the Quality Management Maturity Program to encourage generic drug manufacturers to establish quality management maturity programs at their facilities. This program is a step in the right direction toward incentivizing companies to incorporate quality into their manufacturing practices, and also a sign that there is a quality deficit that the FDA is trying to address.

In her 2019 book, *Bottle of Lies*, Kathryn Eban exposed many of the fraudulent practices taking place primarily in India. These included falsification and destruction of data, subpar quality and safety measures, as well as efforts to falsely represent manufacturing plant conditions to inspectors. While this book brought attention to the issue of generic drugs, there was not a study that empirically demonstrated the issues associated with generic drug quality until the publication of *"Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events,"* a study led by Dr. Joon Noh of Korea University and co-authored by Doctors George Ball of Indiana University and John Gray of Ohio State University. The study matched 2,443 drugs manufactured in America with those manufactured in foreign countries, 93% of which were manufactured in India. The researchers found that the occurrence of serious adverse events for generic drugs manufactured in India was 54% higher than for equivalent drugs that were manufactured in the United States. Adverse events were hospitalization, disability, and death. According to the study, mature generic drugs, or generics that had been on the market for several years, exhibit greater quality risks and could be more vulnerable to production disruptions due to the attention on price.

Chairman Scott and Ranking Member Gillibrand have been tracking issues associated with drug quality, particularly as they relate to medications seniors rely on. In September 2025, the Chairman and Ranking Member wrote a letter to FDA Commissioner Makary expressing urgent concerns regarding the FDA's oversight of foreign drug manufacturing and importation and whether the drugs that are entering the U.S. market are safe and high-quality. This letter reflects the Aging Committee's commitment to securing generic drug supply chains and promoting access to safe, high-quality, and affordable medications for seniors.

Books like *Bottle of Lies* and studies like the Ohio State and Indiana University study are evidence that the FDA needs to increase its focus on drug quality. As part of its work with independent testing company Valisure, the Department of Defense (DoD) is already testing drugs based on quality metrics. Testing for quality is critical to protect against adverse health outcomes, but also to equip purchasers with information to incentivize markets towards focusing on quality.

The FDA relies heavily on self-reported manufacturer-submitted data. While companies must undergo the ANDA process and are subject to inspections, once production starts much of the data is submitted by the manufacturer to FDA. There are currently many proposals in Congress on how to best complement FDA's current work as they continue to face critical issues such as shortages of qualified foreign inspectors. Independent testing for quality like the partnership between DoD and Valisure would be a step toward understanding the broader picture of generic drug quality as well as work to prevent adverse and serious adverse health events.

CASE STUDY

In 2013, Ranbaxy, an Indian generics company, pled guilty to felony charges related to certain adulterated drugs made at two facilities in India. These included antibiotics and epilepsy drugs. The company pled guilty to four felony counts of knowingly making materially false statements to the FDA and three felony violations of the *Food, Drug and Cosmetic Act* (FDCA). The company kept incomplete testing records and an inadequate program to evaluate the quality of their drugs under real-world storage conditions. The company also failed to file timely reports required by the FDA for when drug batches failed certain tests.

Ranbaxy agreed to pay the Department of Justice $500 million due to false data submitted to the FDA among other violations. Relying on foreign companies with an incentive to keep costs as low as possible to adhere to an honor system of data submission is not an adequate substitute for independent testing.

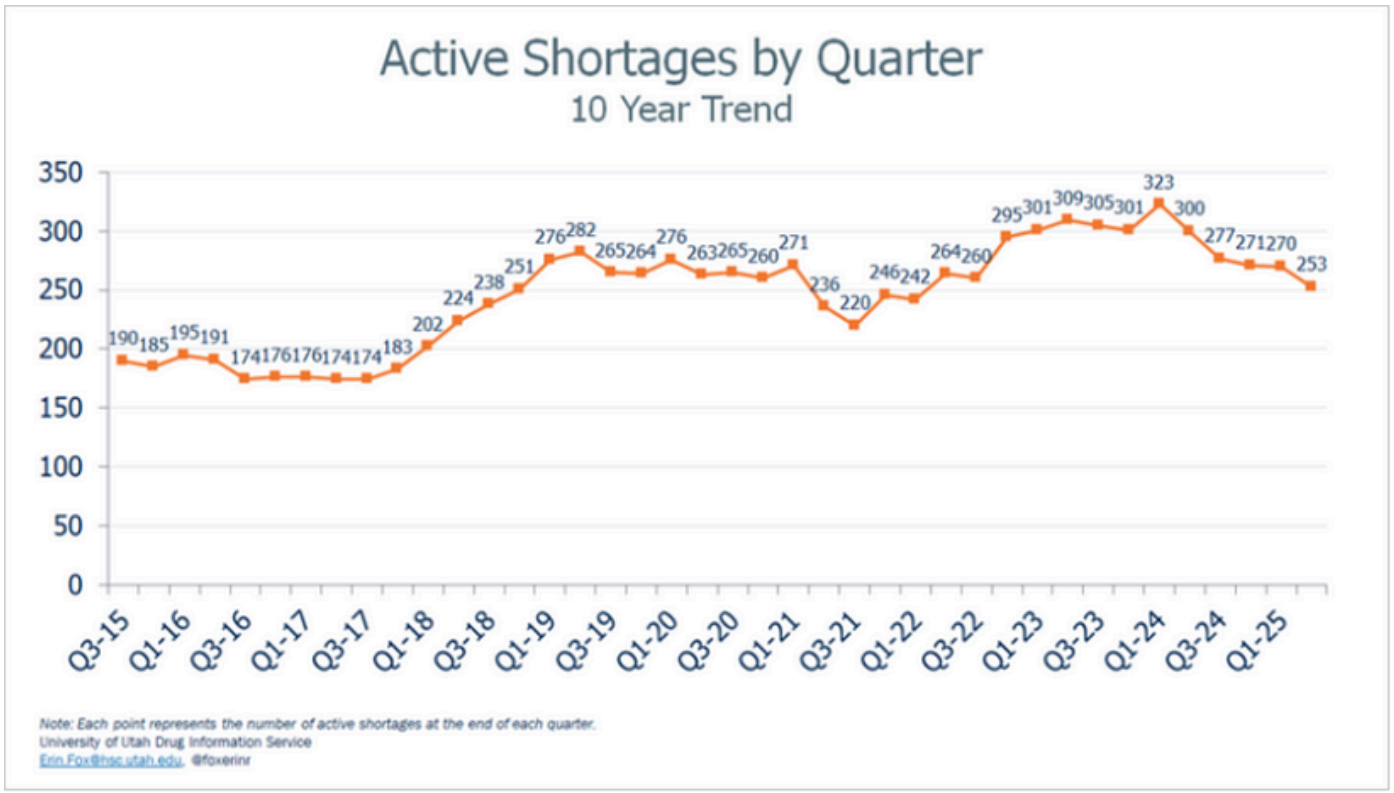
While the FDA utilizes many tactics to balance quality and supply, recent reporting regarding the FDA's practice of exemptions from import bans has been extremely concerning. Exemptions from import bans involve the reclassification or downgrading of an import ban. This could mean that a manufacturer that has documented safety violations can continue to import their product into the United States if there is a risk of shortage. The FDA does not maintain a comprehensive list of exemptions that have been granted and for what drug. A recent report from ProPublica identified over 150 exempted generic drugs, almost entirely from factories in India. Despite reports of adverse events being submitted for exempted products to the FDA's adverse event database, former Principal Director of the FDA Janet Woodcock has stated that the FDA did not actively look at the database for patterns of harm. While the FDA did say that the database is generally monitored weekly, the issuing of import bans without close examination of adverse event data, as well as the failure to notify Congress in any way of this practice until 2024, is a failure on the FDA's part to protect public health. The FDA has also failed to disclose the risk-based approach it employs to the testing of exempted drugs.

Although the FDA does not have direct purview over federal purchasing, it can inform purchasing decisions by incorporating quality into its inspections beyond the minimum standard of cGMP. The FDA can also enhance quality by conducting independent testing to decrease reliance on manufacturer data, or publicly report drug import exemptions and drug quality information for hospitals, GPOs, and other large buyers to use in their purchasing decisions.

SHORTAGES

For the first quarter of 2025, the number of active drug shortages is 253, down from the all-time-high of 323 in the first quarter of 2024 per data from the American Society of Health-Systems Pharmacists. Although this latest figure is the lowest number recorded since early 2022, shortages are still up from ten years ago in the third quarter of 2015, where there were 190 active shortages. Shortages can occur due to public health events such as the COVID-19 pandemic, a lack of global supply, or manufacturing disruptions. During an unforeseen circumstance, like a public health crisis, a country may decide to stop or restrict the exportation of drugs in order to provide supplies for its population. For example, Canada has enacted regulations to bar the exportation of drugs outside of the country if it could cause or worsen a shortage. These regulations have been enacted as a protectionist measure against bulk importation from countries with high demand, such as the United States. Figure 4 shows the 10-year trend of drug shortages, with a steady increase heading into COVID-19 in 2020 and 2021, followed by an all-time high in the first quarter of 2024.

FIGURE 4: Active Drug Shortages by Quarter (Q3 2015- Q1 2025)



Source: *American Society of Health Systems Pharmacists, Erin Fox, PharmD, University of Utah*

The COVID-19 pandemic is a prime case of how shortages can arise and how existing shortages can be exacerbated due to public health events. Due to concerns surrounding potential shortages during the pandemic in 2020, India restricted the export of 26 APIs and formulations out of concern for drug shortages within their own borders. The pandemic highlighted just how vulnerable the supply chain truly is, as even a massive producer of generics such as India was forced to balance its role as an exporter with a large population and reliance on Chinese APIs.

The FDA's responsibilities to prevent shortages and to ensure the quality of drugs entering the U.S. market at times conflict. Following the 2008 deaths from contaminated heparin from China, the FDA placed a focus on increasing the agency's oversight on manufacturers located overseas under then Commissioner Margaret Hamburg. Following this crackdown on overseas manufacturing, there was a period of unprecedented number of shortages. In 2012, the House Committee on Oversight and Government Reform published a report entitled "FDA's Contribution to the Drug Shortage Crisis." This report criticized Hamburg's FDA for dramatically increasing the number of warning letters issued, as in her second year as Commissioner, the number of warning letters increased by 156%.

CASE STUDY

Failing to ensure the quality and safety of medications can be deadly. One of the most notable and tragic examples of the consequences of failing to carry out adequate oversight were the approximately 100 deaths caused by dangerous and contaminated heparin in 2007 and 2008. Heparin is a commonly used and potentially life-saving blood thinner medication. It was later revealed that the FDA had approved the company Scientific Protein Laboratories–Changzhou (SPL-CZ) as a supplier for Baxter, the manufacturer of the adulterated heparin, without conducting a pre-approval inspection. This unfortunate mistake was made as the agency confused SPL-CZ with a different site in their database. In this instance, Changzhou SPL was a Chinese subsidiary of Scientific Protein Laboratories.

Deaths from unsafe medications like this contaminated heparin devastated families. LeRoy Hubley lost his wife of 48 years, Bonnie, and his son, Randy, just weeks apart. Bonnie and Randy died due to contaminated heparin that they relied on whilst undergoing dialysis treatment due to a genetic kidney disease. As a result of the FDA's failures to perform inspections and do routine testing, lives were lost, and contaminated drugs were allowed to enter the U.S. market.

The report cites regulatory action undertaken by the FDA that "essentially shutdown 30% of the total manufacturing capacity" as a large factor contributing to shortages at that time. This was due to simultaneous shutdowns of manufacturing lines and requiring major American producers of generic injectable medications to remediate their facilities. While quality was a primary focus for Hamburg's FDA, there was a growing feeling that regulators needed to incorporate shortages into decisions being made around quality and oversight. The report also identified a disconnect between FDA inspectors in the field and the career employees at FDA headquarters, stating that the FDA's field force did not consider the implications of their actions, including the closure of a facility or removing lines from production. This disconnect compounded existing issues. These criticisms of the FDA, however, did not reflect the conflicting position that inspectors and compliance teams faced since inspectors were only required to weigh safety and quality, not the potential downstream effects if they recommended a facility be subject to an import ban.

The FDA responded by elevating the shortage team within the CDER under Director Janet Woodcock. According to a ProPublica report, former FDA officials stated this elevation allowed the drug shortage staff to be part of deliberations involving the compliance team as they attempted to levy penalties on drug manufacturers because of bad inspections. This established a paradigm where career FDA officials deliberated on balancing shortage implications with quality concerns without notifying Congress.

Following the elevation of the shortage team, the practice of exemptions from import bans emerged. Manufacturers were granted exemptions to continue supplying to the U.S. market despite quality concerns from inspectors and the FDA's compliance team. Concerns around many of these exempted drugs were also expressed on the FDA's Adverse Event Reporting System Database (FAERS).

The practice of exemptions to import bans was unknown to the public or Congress, with the FDA not acknowledging the practice until 2024, when a report to Congress mentioned the practice in a single footnote. The FDA defended the practice of import ban exemptions on the basis that the agency might have been forced to source the drugs from China or an unknown source. Regardless of the veracity of this claim, failure to notify Congress of these issues as they occurred inhibited its ability to enact policies to address supply chain vulnerabilities.

CASE STUDY

In 2014, an FDA inspection of a Sun Pharma facility in Halol, India, found a number of infractions. The inspected product had "unknown impurities," and the factory was in disrepair with a leaking ceiling in a sterile manufacturing area. In 2015, the FDA declared the product "adulterated," which means it was produced in a manner that could compromise its strength, quality, and purity. However, only in 2022 did the FDA bar the import of drugs manufactured in that facility. However, this Sun facility immediately received an exemption from the ban for over a dozen medications and continued to import some of its drugs.

A 2025 study from researchers at the University of Illinois Urbana-Champaign, Indiana University, and Seoul National University shows that oversight and unfavorable inspection outcomes might be linked to more resilient supply chains. This joint study found that Official Action Indicated (OAI) inspection outcomes, the most severe classification, lead to reduced shortage risks. There can be a hesitancy to issue OAI outcomes due to the shortage team having concerns that OAIs could increase the risk of drug shortages. However, the stronger enforcement of OAIs has a higher likelihood of reducing shortages than Voluntary Action Indicated (VAI), second most severe classification, or No Action Indicated (NAI), which is the least severe classification, outcomes. OAI outcomes were found to reduce shortage risks by 96.4% per the findings. While more research is needed, this finding provides evidence that the linkage between inspection outcomes and shortages could be different from what was previously thought. If there is a general sense of consequences related to quality, the market would be incentivized to pursue quality to avoid penalties.

INSPECTION ISSUES

Inspections are one of the most powerful oversight tools available to the FDA as it works to move drugs through the approval process, as well as conduct inspections for quality. Despite the FDA's own reporting showing that more than 58% of established manufacturing drugs are located overseas as of 2022, the FDA has faced persistent challenges when trying to execute foreign inspections. These issues have not entirely been within the FDA's control, with COVID-19 affecting its ability to conduct inspections for an extended period of time. However, there are a number of fronts where reforms are needed to ensure that generic drugs coming from overseas, namely China and India, maintain the same level of quality as those from the United States.

Though the FDA has taken steps to increase foreign inspections in China and India, these efforts were largely derailed by COVID-19. While the FDA increased the number of foreign inspections it conducted, with the peak being in Fiscal Year 2016, a report from the Government Accountability Office (GAO) shows that this number decreased between 2016 and 2018. The FDA completed its largest number of foreign inspections in India and China in Fiscal Year 2019. However, most inspections were postponed in March 2020 due to the COVID-19 pandemic. The FDA then employed the use of "alternative inspection tools" such as relying on data from foreign regulators, requesting and reviewing records, and remote evaluation. While it is understandable that inspections would be disrupted during the pandemic, this only serves as evidence of the extremely vulnerable supply chain, and how reliance on China and India presents massive public health risks that are non-viable for long-term planning, resilience, and pandemic preparedness.

There are a number of challenges that make conducting foreign inspections difficult compared to domestic inspections. There is a stark difference between a preannounced and an unannounced inspection. Domestic inspections have almost always been unannounced, which allows for accurate viewing of the day-to-day operations of a manufacturer. In the case of foreign inspections, the FDA has adopted the practice of "announcing," or informing the manufacturer of an upcoming inspection, up to 12 weeks in advance. This is a significant window of time for manufacturers to prepare for these inspections, which can lead to a less accurate representation of the operating conditions of a manufacturing plant.

The FDA has struggled to establish parity between domestic and foreign inspections, particularly in China and India. The FDA's backlog as of May 2024 included 340 manufacturing plants in China and India. As part of establishing parity, the FDA announced in May 2025 that it will expand the use of unannounced inspections at foreign manufacturing facilities. This came shortly after an executive order from issued by President Trump on May 5th, which directed the FDA to increase fees for foreign inspections. That same executive order also directed the FDA to improve enforcement of API source reporting by foreign drug producers and to consider publicly displaying a list of facilities that do not comply.

Pilot programs for unannounced foreign inspections have been ongoing at the FDA. In 2014-15, the FDA ran a successful pilot program in India, leading to the accurate identification of quality issues. Inspections resulting in an OAI increased by nearly 60% under this pilot program. This program ended in July 2015 with little explanation from the FDA. Unannounced foreign inspection pilot programs were launched at the direction of Congress in March 2022 in India and in July 2023 in China. The May 2025 FDA initiative and executive order will presumably build on the existing efforts of these pilot programs.

Another issue the FDA faces with foreign inspections is its reliance on foreign translators provided by the manufacturers. Translators provided by the manufacturers present a conflict of interest, and FDA inspectors have questioned the accuracy of translators provided by foreign establishments. Unannounced foreign inspections can be made difficult due to the need for translators, particularly in China. While the FDA plans on implementing independent translation pilot programs, it has prioritized unannounced inspection pilot programs. This independent translation pilot program would utilize independent translators from the Department of State for select inspections in China and Hong Kong. The FDA has indicated that the independent translation program would begin after Fiscal Year 2024. While it is understandable that the FDA must prioritize unannounced inspections, the agency must address the issues surrounding translators provided by the manufacturers it is investigating to ensure the accuracy of inspections.

Recent initiatives like the expansion of unannounced inspections and the ability to collect increased user fees from foreign manufacturers will enhance the FDA's ability to conduct foreign inspections. Additionally, the FDA has persistent challenges regarding its inspection workforce. Per a 2024 report from the GAO, vacancies for investigators who inspect foreign and domestic manufacturers jumped from 9% to 16% from November 2021 to June 2024. These workforce issues have led to a large number of investigators with little experience entering the field, and have limited the FDA's ability to conduct inspections. The GAO report found that travel, pay, workload, and work-life balance were the primary concerns surrounding the inspection workforce. Investigators travel up to 75% of the time. The GAO has recommended that the FDA develop an action plan to address attrition issues in the inspection workforce. As of the publication of this report, HHS has agreed with this recommendation and said the FDA plans to establish a committee to address these issues, but the FDA has yet to provide an update to GAO.

TACTICS EMPLOYED BY FOREIGN COMPETITORS

It is no accident that China has had such significant growth in its pharmaceutical sector, but rather through deliberate, top-down policy efforts. In its 14th Five-Year Plan, which covers 2021-25, the Chinese Communist Party (CCP) designated biotech as a "strategic emerging industry." The number of biotechnology science parks in China grew from roughly 400 to 600 between 2016 and 2020. In addition to this, China has seen immense growth in its biopharma sector. The market capitalization of Chinese biopharma companies stood at $200 billion in 2020, a dramatic increase from a $1 billion market capitalization in 2016. While the number of biotech companies in the U.S., EU, and Japan declined from 2010 to 2020, in China, 141 new companies were established in the biopharma sector. Through domestic investment and subsidies, China has not only managed to grow its own pharmaceutical industry, but also undercut competitors. The CCP's approach to pharmaceutical manufacturing strongly resembles the approach it has utilized in other industries, including chemicals and telecommunications, per the U.S.-China Economic and Security Review Commission.

Lower labor costs have been utilized as a means of lowering production costs in China and India as opposed to the United States; however, there is some evidence that forced labor is being utilized by certain Chinese suppliers of APIs. A report from Exiger found that major Chinese state-owned entities that serve as indirect suppliers to the U.S. market, such as Sinopharm, Zhejiang Shindai Chemical Group, and Zhejiang Chemicals Export Corp., have connections to Uyghur forced labor in the Xinjiang Uyghur Autonomous Region. These are not small suppliers; Sinopharm is the largest Chinese state-owned pharmaceutical conglomerate and continues to have access to the US market by way of being an FDA-registered pharmaceutical importer. These forced labor practices are human rights violations and are used to undercut competition in the supply chain.

Unfortunately, a lack of supply chain transparency has allowed these state-owned entities to maintain their FDA-registered status and continue exporting their products to the U.S. market. Additionally, Aurobindo, the largest supplier of generics to the Medicaid program, procures products from at least six companies engaged in forced labor, per research from Exiger. In its research, Exiger also found that at least 12 manufacturers of API linked to 17 different drugs could be exposed to forced labor pharmaceutical products in their supply chains. Even more concerning is that this is not an isolated practice.

Lupin, the third largest prescription provider to Medicaid beneficiaries, was found to procure pharmaceutical products from at least four companies with ties to forced labor or CCP ownership. An investigative report found that at least two Xinjiang-based pharmaceutical companies are FDA-registered suppliers to the U.S. market and could potentially be linked to Uyghur forced labor.

Enforcement against these potential forced labor human rights violations would fall under the *Uyghur Forced Labor Protection Act*. It is critical that the FDA collaborate with the CBP to ensure Chinese entities in the supply chain are in full compliance with human rights practices, as well as for the FDA and CBP to act swiftly to remove those entities that are in violation from the U.S. market.

The money Chinese entities are making on these lower-cost pharmaceuticals is not being reinvested in quality in nearly the same way that occurs with U.S. companies. Chinese companies invest less than five percent of their sales revenue into research and development (R&D) costs as opposed to U.S. companies, which invest an average of 20 percent.

India, on the other hand, has allowed a significant amount of foreign investment through the liberalization of its Foreign Direct Investment policy. This has allowed for foreign manufacturers to partner with Indian manufacturers and benefit from lower manufacturing and labor costs. These policies, in addition to India's National Pharmaceutical Policy (NPP), are evidence that India is prioritizing investment in its domestic drug market as it aspires to transition from an economy that manufactures generics to one that develops new medicines. A major part of this strategy involves manufacturing APIs locally, as India currently disproportionately relies on China for APIs. India also subsidizes domestic manufacturers by way of the Production Linked Incentive (PLI) Scheme, which provides financial incentives based on domestic sales.

CHAIRMAN AND RANKING MEMBER'S POLICY RECOMMENDATIONS

There are several federal government actions needed to address the vulnerability of generic drug supply chains. Recommendations from Chairman Scott and Ranking Member Gillibrand to address these issues are as follows:

- **Establish a federal buyer's market for essential medications, while prioritizing American-made APIs and KSMs. If no American APIs and KSMs are available, prioritize TAA-compliant APIs and KSMs (nearshoring/friendshoring).**
  - **Allow a five-to-ten-year phase-in to allow for manufacturing capacity to be stood up before requiring federal purchasers to buy drugs manufactured in the United States using American-made APIs and KSMs.**

- **Map generic drug supply chains and require companies to disclose the country of origin for finished dose manufacturing, APIs, and KSMs**

- **Pass country of origin labeling legislation**

- **Utilize trade levers like the administration's 232 investigation**

- **Pass clarifying language to close loopholes associated with the Acetris ruling**

- **Support for U.S. biotechnology**

Establish a Federal Buyer's Market for Essential Medications that Prioritizes Drugs that are Manufactured in the United States and use American APIs and KSMs

To move toward reliable supply chains of safe, high-quality drugs, the number one priority for Congress and the administration should be establishing a federal buyer's market that incentivizes quality and prioritizes American-manufactured drugs. The federal government's role as a significant purchaser of medications has the power to incentivize the reshoring of pharmaceutical manufacturing. A federal buyer's market would prioritize purchasing generic drugs manufactured in the United States using APIs and KSMs that are sourced domestically. The federal government is the largest purchaser of drugs in the United States, either directly or via subsidizing federal health insurance programs. Federal agencies such as the DoD, the VA, the Centers for Medicare and Medicaid Services (CMS), and other federal purchasers of medications account for more than 40% of outpatient prescription drugs purchased as of 2018. Agencies such as the DoD and VA are direct purchasers of these drugs, whereas Medicare and Medicaid, under CMS, are indirect purchasers via reimbursement mechanisms.

Although the FDA does not have direct purview over federal purchasing, it can inform purchasing decisions by incorporating quality into its inspections beyond the minimum standard of cGMP. The FDA can also enhance quality by conducting independent testing to decrease reliance on manufacturer data, or publicly report drug import exemptions and drug quality information for hospitals, GPOs, and other large buyers to use in their purchasing decisions.

As a means of determining the best practices for implementing a federal buyer's market for domestically manufactured generic drugs, starting with a direct purchaser would provide the most control over the process and establish a model that can be expanded to other federal purchasers. Of the agencies that meet the criteria of being a direct purchaser, the DoD is the most logical choice to launch a federal buyers' market for domestic drugs due to the national security nexus surrounding the vulnerability of supply chains and the readiness concerns to service members if there is a disruption to the supply chain.

The Defense Logistics Agency is the primary purchasing arm for pharmaceuticals within the DoD, accounting for 2% of the total commercial pharmaceutical market in the U.S., or about $5.4 billion in annual procurement.

Not only would the DoD be a good starting point from a national security and readiness standpoint, it is already implementing quality measures for medications that would allow federal purchasers to incorporate quality as well as price into the decision-making process. Following an amendment authored by Senators Rubio and Warren and supported by Chairman Scott in the FY2023 National Defense Authorization Act (NDAA), the DoD entered into a Cooperative Research and Development Agreement (CRADA) with Valisure, a laboratory that independently tests the quality of pharmaceuticals. This study will assess the quality of drugs by testing products from DoD suppliers and scoring the National Drug Codes (NDC) of each supplier. Studying the quality-scoring model of NDCs has the capability to inform future pharmaceutical contracting and purchasing practices. The metric for this scoring is based off a collaborative study from individuals at the DoD, Long Island University, Yale University, Stanford University, Columbia University, Ohio State University, University of Connecticut, University of Utah, New York University Langone, and Cleveland Clinic, titled "A data-driven quality-score system for rating drug products and its implications for the health care industry."

The DoD and the VA engage in joint procurement efforts, meaning that the success of a program to purchase American-manufactured generic drugs at DoD will translate to the VA, another large direct federal purchaser. Further informing the logic of such a course of action is that most existing collaborative purchasing efforts between the DoD and VA have focused on generics. The DoD has implemented a recommendation from GAO to jointly procure all brand-name drugs when it is clinically appropriate and cost-effective by way of the Federal Pharmacy Executive Steering Committee. Considering approximately 52% of VA patients are over 65 years old, expanding federal purchasing of American-manufactured generics to the VA would be a first step in promoting access to safe and high-quality drugs for seniors.

Reshoring does not just include building new manufacturing sites, but also leveraging existing facilities and creating a market where it is profitable to utilize full manufacturing capacity. A study conducted by the API Innovation Center in conjunction with Washington University in St. Louis looked at 25% of the generic drug manufacturing infrastructure and found that only two out of 37 manufacturing sites in the United States are currently producing at full capacity. The study also found that 70% of sites are producing above 50% capacity and 30% of sites are utilizing less than 50% of their capacity. If a federal buyer's market were to emerge that prioritized drugs manufactured in the United States and sourced APIs and KSMs domestically and incentivized quality, existing manufacturing capacity could be repurposed within one to two years to expand manufacturing capacity for essential medicines and increase the resiliency of the supply chain. According to API Innovation Center findings, 60% of the generic manufacturers surveyed are already producing medicines on the FDA's essential medicines list. This manufacturing being stood up would significantly move the needle towards increasing essential and critical medicine supply chain resiliency and demand.

The process of reshoring manufacturing would take time and not be immediate. While existing manufacturing capacity exists, estimates suggest the timeline to build new manufacturing facilities could be as long as five to ten years. While the ultimate goal to best secure supply chains should be reshoring, nearshoring and "friendshoring" are immediate- to medium-term solutions to reduce dependence on China and India for generics. Nearshoring entails manufacturing in countries that are located in close proximity to the United States, while friendshoring places an emphasis on moving manufacturing to U.S. allies. In a federal buyer's market, if there is no domestic supplier available for either FDFs, APIs, or KSMs, the next best option would be to purchase drugs or critical ingredients that are either manufactured in or source their ingredients from TAA-compliant countries. There is data to support that under the right market conditions, countries in the European Union (EU) or nearby countries in Latin America could fill in gaps in the market.

Per a report from the FDA, 26% of all API manufacturing sites that supply the U.S. were located in the EU as of 2019. The EU has similarly identified a dependence on China and India and could serve as a key partner in identifying critical medicines, mapping supply chains, and manufacturing API should friendshoring purchasing practices be enacted.

In the generic space specifically, Latin American countries such as Mexico are already large exporters of generics and could be brought in as a near-and medium-term nearshoring solution. Mexico's own regulatory body reports that generics account for over 80% of the country's market volume. Mexico could not only serve as a partner for generic drugs but also APIs, as the country ranks 16th among API suppliers to the U.S. Mexico's pharmaceutical market is second only to Brazil in Latin America. As an immediate solution, increasing imports from Latin American countries could serve to secure supply chains due to geographic proximity and greatly decrease dependence on China.

Reshoring drug manufacturing would not only be beneficial to securing the drug supply chain but could also create jobs and contribute positively to the economy. A 2020 analysis from the Coalition for a Prosperous America showed that a reshoring program could create 804,000 U.S. jobs and add $200 billion to GDP in its first year. Even at a smaller scale with a focus on generics and essential medicines, the economic impacts of reshoring would be significant. A study conducted by Washington University in St. Louis found that establishing advanced API manufacturing in the state of Missouri is projected to generate between $49 to $51 million of economic activity for the development and commercialization of a single API and generic drug, including a projected direct impact of $22.2 to $23.2 million via job creation, production activities, and commercialization.

Map Generic Drug Supply Chains to Create Supply Chain Transparency

Reshoring efforts will be difficult, if not impossible, without supply chain transparency to understand where APIs and KSMs are being sourced. Mapping supply chains can identify areas of reliance, equip purchasers with information on sourcing, and bring attention to potential shortages. HHS' Administration for Strategic Preparedness & Response's (ASPR) website cites these challenges, stating, "Overall, insufficient data are available to the U.S. Government, due to confidentiality practices among API manufacturers and KSM suppliers, so it is difficult to properly understand and assess supply chain vulnerabilities." There is proposed legislation in Congress that would require mapping of the pharmaceutical supply chains from KSMs to the distribution of FDFs, which would be an important step toward a federal approach to securing the supply chain. With an understanding of the supply chain, vulnerabilities can be identified, which can best inform lists for shortages and essential medicines. The API Innovation Center emphasized the importance of supply chain mapping, stating that it could mitigate the effects of supply disruptions; this is critical not just to understand where suppliers are located geographically, but also to trace the volume of APIs and KSMs coming from these suppliers to build a resilient supply chain.

The DoD also identified a need to map supply chains in a 2023 review conducted pursuant to an amendment in the FY2023 NDAA. This review looked at 1,744 drug families from the FDA's essential medicines list, accounting for 10% of the U.S. marketplace, and found that 22% of drug families examined had unknown API sources. On top of this, DoD deemed 54% of the pharmaceutical supply chain to be either "high or very high risk" due to dependency on non-TAA-compliant suppliers such as China, India, or unknown sourcing.

In the FY2026 NDAA, the chairman offered Section 878 — an amendment to bar DoD from procuring any generic drug unless the seller of the generic drug discloses the country the generic drug was manufactured in and the countries of origin for all APIs and KSMs. Both Chairman Scott and Ranking Member Gillibrand supported the Senate's FY2026 NDAA, including this provision. This measure aims to incentivize supply chain transparency in federal contracting practices and provide DoD with information on API and KSM sourcing that is critical to national security.

Pass Country of Origin Labeling Legislation

Country of origin labeling is another promising solution that empowers stakeholders at all levels of the supply chain to make informed purchasing decisions. This type of labeling would be unreliable without coordinated supply chain mapping efforts. Current law does not require drug companies to list the API country of origin on product labels, leaving GPOs and consumers without valuable information when purchasing medications. Country of origin labeling would deliver transparency for consumers, equip them with information to consider safety and quality, and support American businesses and manufacturers.

Despite a recommendation from a congressionally commissioned report by the National Academy of Sciences, Engineering, and Medicine (NASEM) that the FDA require drug manufacturers to include manufacturing location and quality ratings on drug labels, no such reforms have been implemented. The implementation of these recommendations would serve to inform consumer behavior and bring awareness to issues surrounding foreign drugs and generic drug quality at all levels of the supply chain, particularly users who will be purchasing and taking these medications. A 2025 study entitled *"Generic Drug Transparency: Testing a Regulatory Policy Proposal"* by Doctors Sebastian Villa and Gloria Urrea of the University of Colorado at Boulder, as well as Doctors George Ball of Indiana University and John Gray of Ohio State University, supports the idea that location and quality factor into decisions made by consumers and pharmacists. This study found that when location, but not quality, is transparent, both consumers and pharmacists strongly prefer drugs manufactured in the U.S. and Canada over those manufactured in China and India. When quality and location information are both available, quality shifts the focus away from the manufacturing country for consumers. An interesting finding is that pharmacists were more willing to purchase low-quality U.S. drugs as opposed to consumers. While it is certainly important to have country of origin labeling, consumers must also be equipped with quality information to drive the market and American manufacturing toward quality. In the absence of readily available quality data or country of origin labeling, the only metric used in purchasing is price.

Utilize Trade Levers like the Administration's Section 232 Investigation

Trade is another lever by which the federal government can protect domestic manufacturing, particularly for essential medicines. In April 2025, Commerce Secretary Howard Lutnick initiated a Section 232 investigation into imports of "pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items." This investigation will examine the effects that the imports of generic and non-generic drugs as well as APIs have on national security. A Section 232 investigation occurs under the TAA in an effort to determine the effects of imports on national security. The Secretary of Commerce will then produce a report to the president within 270 days of the onset of the investigation, who then has the authority to impose tariffs should a national security threat be identified. As pharmaceuticals are such a critical commodity for both their impact on public health and national security, they were placed under a Section 232 investigation alongside semiconductors, critical minerals, steel, aluminum, auto parts, and more. Securing the supply chain for generic drugs, APIs, and KSMs cannot solely be accomplished via trade policy, therefore utilizing tools available to the federal government such as Section 232 investigations is a critical step to identify areas of overreliance and the role of adversarial nations in the supply chain.

Close Loopholes Associated with the Acetris Ruling

Another important step in the reshoring process is the consideration of closing loopholes associated with the Acetris ruling. Prior to this ruling, under TAA, the origin of a pharmaceutical product was based on the manufacturing location of the API unless "substantial transformation" took place. Under the current regulatory environment following the Acetris ruling, compounding, weighing, mixing, and measuring are included in the definition of having been manufactured in the United States. There have been several congressional proposals attempting to close this loophole. While the supply chain must be allowed time to adapt in order to prevent shortages, the ultimate goal should be for a drug to have been manufactured and sourced in the United States to be considered as having been manufactured in the United States.

Support for U.S. Biotechnology

It is imperative that the United States invests in emerging biotechnology to reduce reliance on foreign manufacturers. This research will help ensure that the United States has alternative methods for domestically producing the key ingredients that are necessary to manufacture high-quality, low-cost generic drugs. Investments in research and development will help create alternative means of synthesis for KSMs and APIs. Supporting this research to scale production in the United States will lead to a more reliable and stable drug supply chain, while also ensuring affordable prices for consumers.

The National Security Commission on Emerging Biotechnology (NSCEB), a congressionally chartered commission tasked with a thorough review of the biotechnology sector, has done a tremendous amount of work in this space. NSCEB has done critical research on how emerging biotechnology will support the current and future work of the DoD, as well as the benefits this technology will bring to health care, agriculture, and manufacturing. Ensuring that the United States continues to be a leader and pioneer in biotechnology development is critical to national security.

CONCLUSION

Securing the supply chains for generic drugs is a complex goal that requires a collaborative effort from both the legislative and executive branches of the U.S. government, particularly the FDA, the Department of Defense, and other purchasing agencies. Two key strategies to reduce U.S. dependence on generic drugs are: 1) having the FDA establish foreign inspection parity, and 2) implementing federal purchasing practices that prioritize American-made, high-quality medications.

While trade considerations and tools like the ongoing Section 232 investigation are important, they are not the complete solution. Additional measures such as independent quality testing, market reforms to prevent a race to the bottom, and the expansion of unannounced foreign inspections by the FDA can enhance the quality of medications entering the U.S. market.

The federal government must leverage all available resources to ensure that all generic drugs and pharmaceutical materials entering the United States are safe, effective, and affordable. A strong push towards domestic manufacturing of generic drugs, along with robust domestic sourcing of APIs and KSMs, is essential. This approach will strengthen our healthcare sector and national security while ensuring that Americans, including seniors, have access to affordable medications.

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