

SHORING AGAINST DEPENDENCE ON CHINESE DRUG MANUFACTURING

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DECEMBER 2024

EXECUTIVE SUMMARY

From the beginning, Texas has been an independent maverick. Today, more than ever, that spirit of independence, non-conformity, and self-reliance is needed to tackle the host of problems facing the Lone Star State and America as a whole. The COVID-19 pandemic and the Russian-Ukraine war exposed Texas' and the nation's vulnerabilities to global supply chain disruptions and the world's dependence on China for critical supplies, particularly for drug manufacturing. As the People's Republic of China continues to grow into the most significant economic, military, and ideological threat that the United States has seen in decades, Texas must take action to break its dependence upon China and restore its domestic drug manufacturing capability.

Due to a dearth of data and immeasurable opaqueness over pharmaceutical manufacturing and drug supply chains, this brief was developed and designed using a literature review focused on accounting for significant reports on drug manufacturing, historical developments, international drug manufacturing trends, and state policy capabilities. The subsequent information gathered was used to generate a series of policy recommendations that Texas and other states can take into consideration when drafting reforms intended to taper dependency on Chinese drug-making and incentivize drug manufacturers to build out infrastructure in America.

The subsequent policy recommendations for states to weigh are:

1. Truth in origin labeling.
2. State drug quota compacts.
3. Curtailing nonsensical price inflation rebates and regulated opaqueness.
4. Supply chain vulnerability analysis.

This brief is intended to provide a snapshot of international drug manufacturing, to articulate the danger of relying on Chinese drug components, and to think through state-level reforms to incentivize manufacturers to pursue operations on American soil.

INTRODUCTION

Understanding the Consequences of Foreign Manufacturing Dependency

In the early months of the COVID-19 pandemic, the United States experienced a major disruption in the delivery of healthcare due to a profound shortage in personal protective equipment (PPE), such as hospital gowns,

face shields, and N-95 respirator masks (O’Keeffe et al., 2020).

The disruption ensued when domestic demand skyrocketed, following America’s reaction to the novelty of the COVID-19 virus. Everything came to a head when domestic production capability shuttered once Chinese manufacturing facilities halted production and exports, with China claiming that there were quality concerns in January and February of 2020 (O’Keeffe et al., 2020). The following bottleneck consequences were dreadful and manifold. Approximately 500 healthcare worker protests occurred throughout the nation, with the protesters citing hazardous work conditions and low pay (Jacobi, 2024). Overall healthcare access plummeted and federal trusts hemorrhaged as U.S. spending increased to cover the 200% to 1000% price increase of N-95 respirators (Nicas, 2020).

Unsurprisingly, following the end of the pandemic, the international PPE market value nearly doubled from \$52.7 billion in 2019 to a projected \$92.3 billion in 2024 (Statista Research Department, 2024). However, upon further analysis, 33.4% to 55% of the PPE manufacturing market value now resides in China (Grand View Research, n.d.). The sudden pandemic-spurred demand for PPE manufacturing paired with PPE supply chain disruptions resulted in China resurrecting facilities despite President Trump-era tariffs, and subsequently, the CCP has become the undisputed primary PPE manufacturer of the world.

In the last few years, the U.S. has tried scaling domestic production of PPE, but realistically, it is too late. Because inflation has exacerbated costs, and China now controls a majority of the PPE market, America is becoming increasingly dependent upon China for PPE.

This entire ordeal of PPE supply chain disruptions and foreign dependency should be taken as a lesson on the consequences of foreign manufacturing dominating the production of key resources. America must learn from recent history and recognize the

threat posed by dependence on Chinese manufacturing—namely, drug manufacturing.

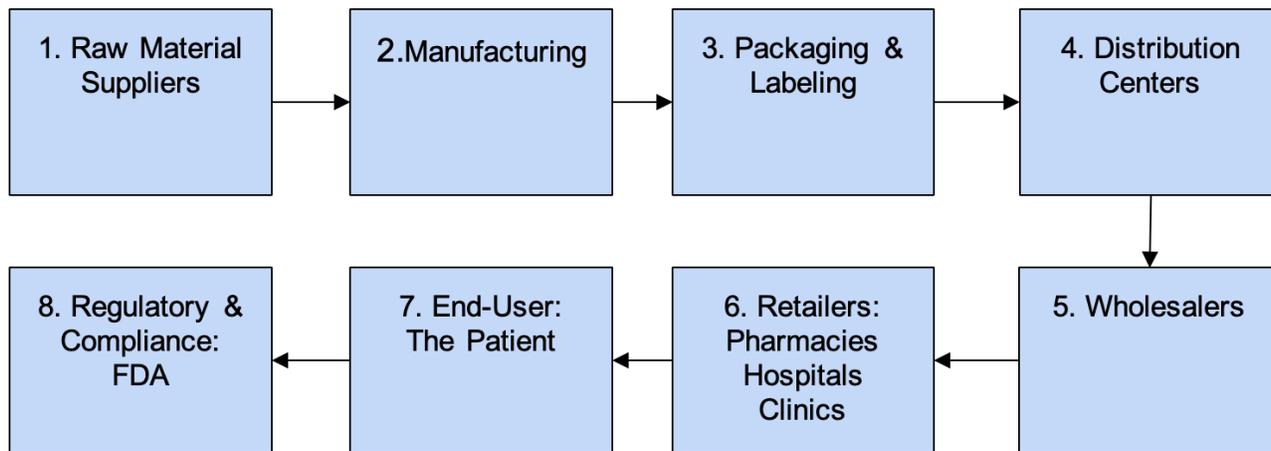
In 2019, China accounted for 95% of U.S. imports of ibuprofen, 91% of U.S. imports of hydrocortisone, 70% of U.S. imports of acetaminophen, 40–45% of U.S. imports of penicillin, and 40% of U.S. imports of heparin (Palmer & Bermingham, 2019).

With tensions escalating over geopolitical conflict in Taiwan and elsewhere, America—especially Texas—ought to consider the consequences of entering into a hot war with China, of trade being severed, and the immediate repercussions that would befall millions of Americans’ access to life-preserving medications.

Understanding Existing Supply Chain and Variables that Impact Price

To understand what policy actions should be considered in weaning America’s dependence off Chinese drug manufacturing, the following 10,000-foot view of drug supply chains must be understood.

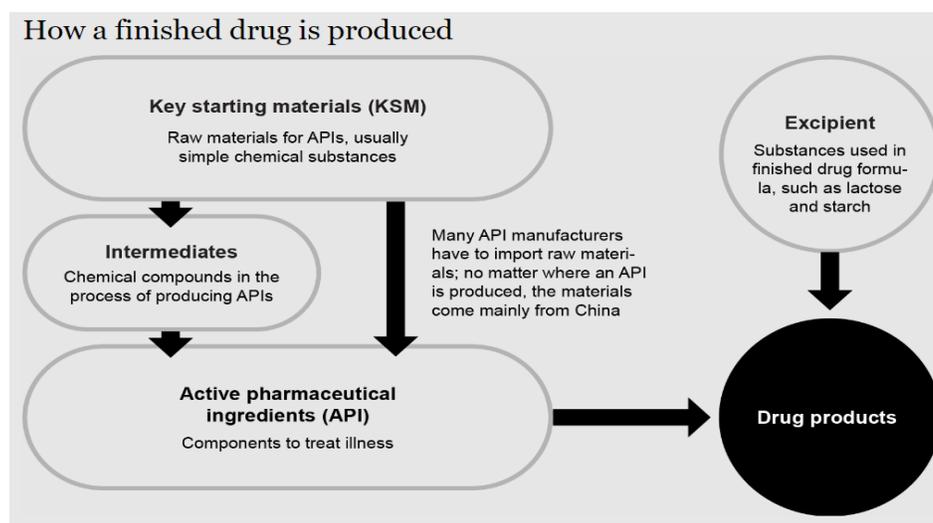
Drugs, like many goods, are assembled along a supply chain. The drug manufacturing process starts with raw materials (inorganic and organic) being moved or sold to entities that put the raw materials through a series of reactions to form more complex chemical compounds (referred to as key starting materials (KSMs) and intermediaries). These KSMs are either sold or moved over to another entity that uses KSMs as building blocks to make active pharmaceutical ingredients (APIs). APIs are the biologically active components that produce the intended therapeutic effects of a medication. These APIs are either sold or moved to another facility that can combine APIs with excipients to create a final pharmaceutical product. An emerging nuance worth noting is that large drug manufacturers have already made and are continuing to make efforts to vertically integrate KSM and API production capability so that the manufacturer can have more control over costs and incur fewer disruptions within supply chains. For example, in 2015, Merck & Co. acquired Cubist Pharmaceuticals for \$8.4 billion to increase their control over antibiotic supply chains (Gelles,



2014). Pfizer acquired Hospira for \$16 billion to expand their control and capability to make biosimilars (Rockoff, 2015).

Once the final pharmaceutical product is made, the drug is then ready to be packaged and labeled. From there, distribution centers move drugs to wholesalers (e.g., McKesson) who purchase the drug in large volume quantities from the manufacturer (e.g., Eli Lilly). The wholesaler will then sell the drug to retailers, such as hospitals, pharmacies (e.g., CVS, Walgreens, independent pharmacists), physicians (who are allowed to directly dispense medications to patients), and other 340B designated facilities (Health Resources & Services Administration, 2024).

The Food and Drug Administration’s prescription designation for that drug determines if a patient can directly obtain the drug off a pharmacy shelf or if the patient needs to get a prescription from his or her health provider to have it dispensed by a licensed entity. When patients are prescribed a drug, the costs that they would pay is conventionally determined by pharmacy benefit managers (PBMs) who work on behalf of health plans (e.g., Aetna, Cigna, Blue Cross Blue Shield), government entities (e.g., Medicare), and large private employers (e.g., Wells Fargo) to negotiate discounts off a manufacturer’s list price.



Source: <https://asia.nikkei.com/static/vdata/infographics/chinavaccine-3/>

Patients, both insured and uninsured, can request the list price (the manufacturer’s price) for a drug. At times, this can be advantageous for the patient because under certain conditions, the list price may be lower than the rate that their health plan or employer was able to negotiate for the drug. For example, a few years ago, it was common to see the list price of Acyclovir (an antiviral generic medication given to curb herpes symptoms) be \$20 to \$60 per 30-day prescription fill—which tends to beat the \$50 to \$80 a patient (and insurer) would have to pay if the patient used his or her insurance card. However, for specialty drugs (e.g., Remicade) and other popular drugs in demand (e.g., Ozempic or Wegovy), the list price can be astronomically high—therefore making it optimal for a patient to use his or her insurance company’s pre-negotiated rate for those drugs.

Ultimately, the prices patients pay for their drugs are affected by a manifold array of constantly changing variables such as:

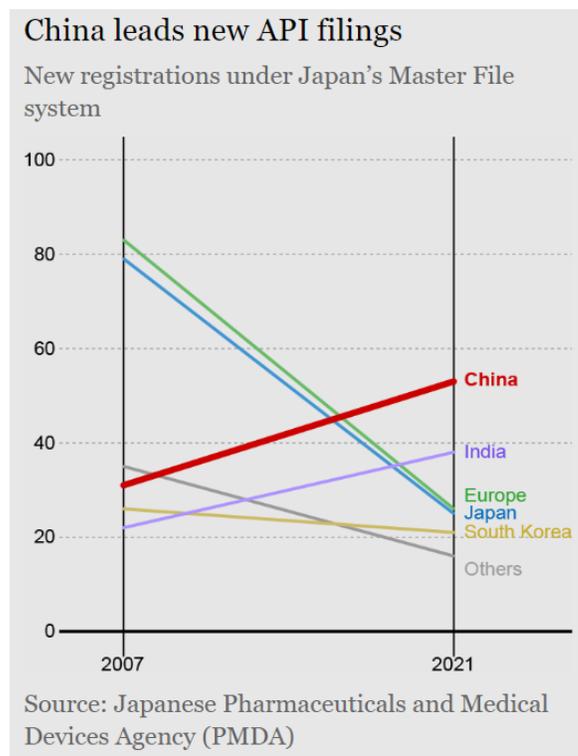
1. Supply-chain costs passed along all relevant entities;
2. Manufacturers’ patent ownership of drugs;
3. Demand from patients;
4. Demand from licensed prescribing entities;
5. PBM and drug manufacturer negotiations;
6. Brand and generic drug manufacturer competition;
7. Supply chain disruptions;
8. Retailer dispensing fees;
9. Food and Drug Administration (FDA) compliance and quality auditing;
10. Transportation costs; and

11. General competition between drug manufacturers producing similar products.

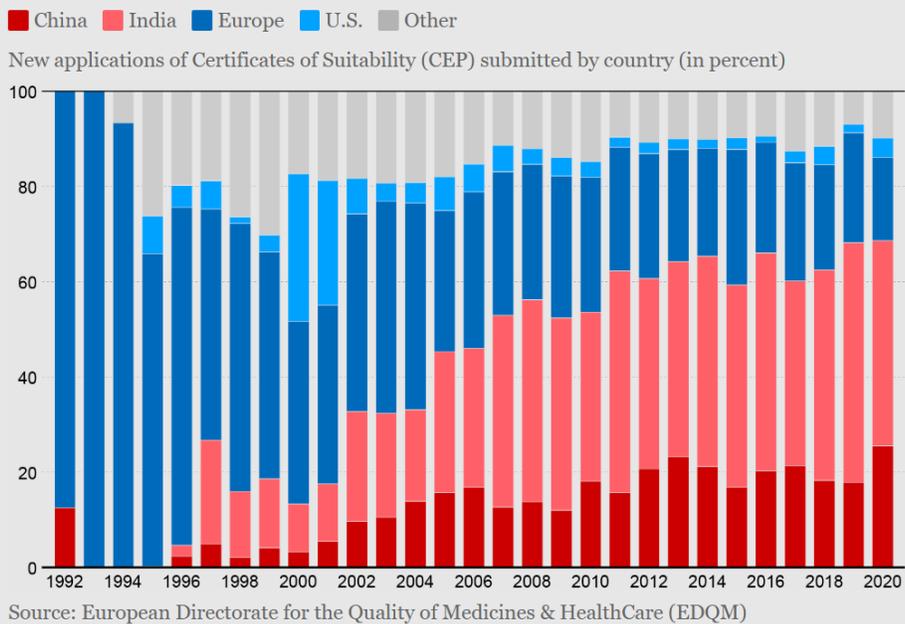
Despite recent consolidation efforts by manufacturers, drug supply chains remain complex and fragile, especially considering that so many different steps in drug-making are fulfilled by entities all over the world.

A Snapshot of the World’s Share in KSM and API Production

On one hand, despite an amalgamation of conflicting international reports, most KSM production takes place in China and India. According to Rosemary Gibson and Janardan Singh (2018), the authors of *China Rx: Exposing the Risks of America’s Dependence on China for Medicine*, nearly 90–95% of KSMs used in manufacturing drugs originated from China (Gibson & Singh, 2018). Although the estimates made by Gibson and Singh are fair, other reports suggest that facilities located in China are making more than 70% of the world’s KSMs (Gibson & Singh, 2018). Despite this range, the data shows that a strong majority of the world’s KSMs originate from China.



China's share of API production is growing rapidly



On the other hand, API production is technically more widespread when compared to KSM production. The regions housing API production facilities are predominantly confined to China, India, Europe (mostly Ireland), and America. However, upon reviewing and contrasting data provided by Japan's Pharmaceuticals and Medical Devices Agency (PDMA) and Europe's Directorate for the Quality of Medicines & HealthCare (EDQM), it is apparent that the concentration of API production now takes place in mostly China and India (Nishino, 2022).

Upon further inspection of Japan's API Master File system, reporters contended that Western pharmaceutical companies who used to produce their own APIs in the early 2000s started migrating production to China and India because of looser environmental standards (Nishino, 2022). API registration data illustrates this shift. In 2021, China came out ahead with new submissions under the Drug Master File system. Until 2012, Japan and Europe accounted for the majority of submissions to market APIs, but since then, both China and India have increased their presence.

Additionally, when reviewing the EDQM's data on certificates of suitability (CEPs), over the last 30 years, it becomes clear that China has drastically scaled

its efforts to grow its API manufacturing capability throughout Europe while the U.S. has dragged behind.

Despite India appearing to be making the most submissions for CEPs in Europe, according to the European Commission, India accounts for roughly 20% of global generic drug demand by volume, but it imports about 70% of the APIs from China (Nishino, 2022).

Despite groups like the US-China Business Council assuring that China's dominance over the drug manufacturing market and APIs are blown out of proportion, the general consensus suggests that China houses a majority of facilities producing KSMs and is making strides towards dominating API production and exports.

Throughout 2021, China's share of U.S. pharmaceutical imports hovered around 1%. By 2022, that figure had grown to 9.6% (DeVore, 2023, p. 4). China economy expert Niels Graham observed, "The largest contributing factor to China's market share growth has been domestic policies China has implemented with the goal of building a world class advanced pharmaceutical manufacturing industry" (quoted in Tobita, 2023, para. 7). According to Graham's analysis,

U.S. pharmaceutical imports from China increased by approximately 600% between 2016 and 2021 (Graham, 2023). China’s mercantilist strategy is clear: the goal is to ensure that Beijing has international supremacy over pharmaceutical manufacturing and exporting. Based on the data, the scary reality is that China isn’t only making progress, it is achieving its goals.

Understanding How Federal Agencies Struggle to Maintain Oversight on Foreign Drug Manufacturing and Pushed Drug Making Overseas

Many sources contend the “why” behind China’s surge in dominance over drug manufacturing is inextricably intertwined with the FDA’s faltering capability in performing quality assurance audits and EPA regulations exacerbating the cost to make drugs in America.

Where the FDA Struggles

FDA oversight on drug supply chain data is often obscured by a lack of capability, transparency, and diligence. Additionally, there are several incentives baked into the current quality compliance process that manufacturers act upon to conceal industry practices.

The FDA indicated in an October 2019 congressional testimony that “As of August 2019, only 28% of the manufacturing facilities making APIs to supply the U.S. market were in our country. By contrast, the remaining 72% of the API manufacturers supplying the U.S. market were overseas, and 13% are in China” (Woodcock, 2019).

The FDA admitted that outside of facility counts, it does not know the extent in which the U.S. relied and continues to rely upon China for drug manufacturing (Palmer, 2020). According to the Government Accountability Office (GAO), the FDA has most likely failed in adequately tracking importation metrics and assuring KSM and API quality due to:

1. **Complex global supply chain pathways**
APIs are sourced from numerous countries, of-

ten moving through multiple suppliers and manufacturers before being incorporated into finished products. The FDA would need to monitor a vast number of suppliers and manufacturers, many of which are located in countries with varying regulatory standards (Wiesenthal & Dolman, 2023).

2. **Challenges inspecting foreign manufacturing facilities**

- In 2009, the Government Accountability Office (GAO) identified “the FDA’s ability to oversee the increasingly global drug supply chain [...] as a high risk area [...]” (GAO, 2022). Areas of concern highlighted by GAO include “questions regarding the equivalence” of inspections of foreign and domestic facilities, a shortage of inspectors qualified to conduct foreign inspections, and foreign inspection processes that increase the risk of deceptive practices on the part of foreign manufacturers.
- Inspections of foreign drug manufacturing facilities by FDA declined between FY 2016 and FY 2018 due, in part, to “persistent vacancies among those who specialize in foreign inspections” (GAO, 2022). Although there was an increase in the number of inspections during FY 2019, the pandemic forced FDA to pause almost all foreign inspections in FY 2020. Foreign inspections were not resumed until FY 2022. According to an investigative report by ProPublica, “the FDA inspected 37% of the nearly 2,500 overseas manufacturers” in 2019 (Hwang, 2023). In 2022, the year inspections resumed following the COVID-19 pandemic, only 6% of foreign manufacturing facilities were inspected.
- Challenges faced by the FDA in conducting inspections of foreign drug manufacturing facilities include:
 - Inspections are generally preannounced, allowing the facility time to conceal

problems or even destroy or alter materials relevant to the inspection (GAO, 2022; Eban, 2019);

- Over-reliance on translators provided by the manufacturing facilities being inspected who, according to journalist Katherine Eban, are often company salesmen (Eban, 2019); and
- Other deceptive practices engaged in by manufacturers, including masking results, turning off audit trails to conceal test results, and even steering inspectors to “phony ‘show’ plants” where no manufacturing actually takes place (Eban, 2019).

3. Scant supply chain transparency

An April 2024 report by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) highlighted several key supply chain issues that contribute to drug shortages, including “a broad lack of transparency, concentration among middlemen, and prices for generic drugs that are driven to levels so low that they create insufficient incentives for redundancy or resilience-oriented manufacturing, distribution, and purchasing” (ASPE, 2024). Consequently, the ASPE found, “these market failures lead to pharmaceutical supply chains that are brittle, disruption-prone, and too slow to recover from shortages.”

4. The FDA’s primary function being focused on monitoring and assessing quality of “finished products”:

The FDA’s regulatory framework is geared more towards monitoring and inspecting finished drug products than raw materials like APIs. The agency conducts inspections and requires compliance with good manufacturing practices (GMPs) but does not track each individual API as it enters the country.

All of these reasons put together have led to the FDA being ill-equipped and incapable of applying high

quality standards for American drugs to foreign API and KSM manufacturing facilities. The FDA’s persistent struggles to assure quality and oversight on specifically imported APIs, paired with extensive Environmental Protection Agency (EPA) standards and China’s well-documented mercantile strategy, all serve as strong incentives for manufacturers to continue production outside of America.

Extensive FDA & EPA Regulation Compared to China Sparse Regulatory Environment

Direct comparisons of environmental regulations between China and the United States (specifically for drug manufacturers) are complex, as historically, China has had less stringent environmental standards. Regardless of differences between regulatory environments, a country’s drug regulations are only as good as its weakest import partner (Harris & Shaw, 2015).

According to a 2002 WHO study, less than 20% of WHO member states had a well-developed drug regulation system (Ratanawijitrasin & Wondemagegnehu, 2002). This concerning figure manifested itself in the events surrounding contaminated heparin manufactured in 2008 in the USA from a raw ingredient (pig intestines) extracted in China. There is scant information on how or why the contaminant (an over-sulfated chondroitin) appeared in the medicinal heparin product. There has been suspicion that the natural chondroitin sulfate raw material exported from China was intentionally “cut” with an over-sulfated form because the over-sulfated form is not naturally occurring and cheaper than natural chondroitin sulphate (Harris & Shaw, 2015).

The FDA’s response to the heparin case was extensive. The agency increased monitoring and oversight activities of heparin manufacturers and imports, worked with industries to recall suspected contaminated heparin, issued warnings to all relevant actors, developed new screening tests to identify contaminated products (GAO, 2010). However, the FDA’s (somewhat) equivalent counterpart in China, the Chinese Food and Drug Administration (CFDA), did not run any reports, investigations, or analyses that

dispelled or affirmed any suspicion of Chinese exporters and manufacturers being complicit in selling tainted materials.

The CFDA appears to operate on a different enforcement framework than the FDA. Instead of operating primarily to protect citizens and enforce medicines regulations, the CFDA is often accused of focusing on counterfeits ([Harris & Shaw, 2015](#)), rather than fixing the root of the problems with pharmacovigilance (e.g., proactively creating regulations that would prevent shoddy manufacturing practices).

For example, 196 counterfeit medicines were found to have originated from China in 2010 ([United Nations Office on Drug and Crime, 2013, p. 41](#)). However, there were no pharmacovigilance reports or news issued ([China Food and Drug Administration, n.d.-a](#)). Additionally, out of the 42 CFDA product recalls in 2010, only six of the 196 counterfeit medicines were actually recalled ([China Food and Drug Administration, n.d.-b](#)). Such findings and figures warrant questions on the CFDA's ability to provide transparency, as well as their failure to identify, alert, and deal with the effects of counterfeit medicines. This example and many others like it have significant implications for America, who is reliant upon medicines manufactured in China to support their country's health needs.

Despite China's advancement of regulatory reforms over other industries, the truth is that China still has far less environmental regulations compared to the United States. Even in more widespread regulatory studies, China lags behind the U.S. in having oversight over their environmental, energy, manufacturing, and chemicals industries ([Xu & Wiener, 2021](#)). Additionally, China is nowhere close to having the same regulations created by the EPA.

The measurable costs imposed by EPA regulations are difficult to quantify. However, general regulation compliance costs across all manufacturers run north of \$3.079 trillion in 2023, with the pharmaceutical industry likely seeing a share of this ([National Association of Manufacturers, 2023](#)). Even more disturbing, the total annual cost of complying with federal regulations has risen by \$465 billion since 2012 ([National](#)

[Association of Manufacturers, 2023](#)). Unsurprisingly, as regulatory compliances have increased so has the number of pharmaceutical manufacturers in China.

The FDA failing to apply stringent regulatory oversight to manufacturers in China, CFDA being far less excessive than American agencies, and EPA compliance costs skyrocketing, all these developments have served as catalysts for China to become so dominant over drug supply chains and manufacturing.

Foreign Drug Component Quality and Synthesizing Processes are Questionable at Best

Drug manufacturers are poised to maximize profits by importing cheap drugs from China and India. The problem is that Chinese and Indian synthesized drugs are suspected of being impure and ineffective, which puts American patients at risk.

One recent story revolving around a drug quality assessment requirement that Kaiser Permanente (a highly regarded U.S.-based healthcare provider) imposed upon manufacturers speaks to the depth that drug manufacturers know that drugs with Chinese ingredients often result in unsafe and contaminated pharmaceuticals.

Kaiser Permanente rolled out a new drug screening process that required all drug manufacturers who bid to them to supply Kaiser Permanente with independent testing results at the drug suppliers' cost. To accomplish this feat, the Kaiser system employed Valisure to run purity and effectiveness tests ([Edney & Griffin, 2023](#)). After Kaiser implemented the new requirement, several of their suppliers that relied upon lower quality drugs made in China and India ceased bidding to supply Kaiser, as they feared that their drugs would fail testing ([DeVore, 2023](#)).

Outside of the Kaiser system story, there have been a series of recalls over vital medication lines, most stemming from facilities originating in China. For instance, one study that was assessing drug recalls between 1991 and 2021 reported that China had the majority of recalls (30), compared to America (5)

EPA regulations affecting American drug manufacturers

EPA Regulation	Key Requirements	Cost Impact
Clean Air Act (CAA) - National Emission Standards for Hazardous Air Pollutants (NESHAP)	Limit emissions of hazardous air pollutants from pharmaceutical manufacturing	Pollution control equipment, operational costs, record-keeping, and reporting
Resource Conservation and Recovery Act (RCRA) - Hazardous Waste Management	Safe handling, treatment, and disposal of hazardous waste generated during production	Handling, storage, treatment, and disposal of hazardous waste
Clean Water Act (CWA) - Effluent Limitations Guidelines (ELGs)	Manage wastewater discharge and meet water quality standards	Investment in water treatment technologies, testing, and monitoring
Toxic Substances Control Act (TSCA)	Testing and safety assessments for new and existing chemicals in manufacturing	Research, development, and reformulation costs for chemical safety
Greenhouse Gas Reporting Program (GHGRP)	Report GHG emissions if they exceed specified thresholds	Capital investment in monitoring, reporting infrastructure, and potential emission reductions
Superfund (CERCLA)	Liability for cleanup of hazardous waste contamination	Extensive clean-up costs for contaminated sites
Emerging Regulations on PFAS	Potential restrictions on the use and remediation of PFAS in production	Significant investments in PFAS treatment and alternatives

(Li et al., 2022). The twisted irony is that the bulk of China’s recalls took place between 2012 and 2022, during what was considered “a stable surveillance period” (Li et al., 2022).

STATE POLICY RECOMMENDATIONS

Given the risks to the American public and the global drug supply chain posed by over-reliance on China, states must take action to ensure a reliable supply of safe pharmaceuticals. These reform ideas were generated with the intention to incentivize drug manufacturers and other actors within the drug supply chain to scale operations stateside.

1. Truth in Origin Labeling

In many industries, consumers often tailor their purchasing behavior around values like quality, ethics, and origin. For example, most people know that

Whole Food products are considerably more expensive compared to other grocery stores. However, many consumers of all classes are still willing to use their hard-earned dollars to pay the premium on Whole Food groceries because they believe the food is high quality, organic, ethically sourced, or all the above. Americans care deeply about product quality and origin source, and this trend carries over to the drugs they consume.

Drug manufacturing is not transparent. Most Americans are likely not aware that their drugs are made using intermediaries such as KSMs and APIs synthesized in China, which are often contaminated or possess toxic substances. If American consumers could be made aware that drug quality is low when sourced from certain countries, it is reasonable to believe that policies requiring drug labeling to include the origin of ingredients could prompt consumers

to change their behavior to buy drugs wholly manufactured in America or in allied countries. Enforcing “truth in origin labeling” could alter demand and incentivize drug manufacturers to start synthesizing drugs and ingredients sourced in America—with the peripheral benefit being that Texas and the rest of the nation could use labeling transparency to their advantage by exposing China’s lackluster drug and ingredient quality. Following the Kaiser Permanente story, it is obvious that China’s mercantilism strategy is causing the country haphazardly producing contaminated key starting materials (KSMs) and active pharmaceutical ingredients (APIs). Americans ought to be informed about where their medicines come from and about the quality of the ingredient used in their production. As a result of demand from well-informed consumers, it is probable that pharmaceutical companies will make different decisions about how and from where they source their products.

Texas and America should flip China’s strategy on its head by exposing consumers to the reality that China is skimming on drug quality so that it can dominate the market with lower prices and foster international dependency. Once Americans start learning where their drugs and ingredients are synthesized, it is plausible that some Americans will alter their purchasing behavior and pay more in order to obtain better quality drugs as America expands manufacturing operations domestically.

2. Texas State Quota Compacts & Bids

Utah’s Legislature recently pursued a “State Cures Compact Law” that would have allowed Utah to pool resources across several other neighboring states to form a competitive research compact ([HB 190, 2021](#)). This compact was intended to prompt several drug manufacturers to bid on creating a “cure” for a common ailment plaguing the compacting states. Upon winning a bid, a hypothetical drug manufacturer would be tasked in creating a cure with a prior agreement to surrender intellectual property rights to the state who would then publicize the cure formula.

While producing new medicines is important, the Utah law also provides a blueprint for addressing a more

serious issue—ensuring that an adequate supply of essential drugs is maintained. Given its current precarious diplomatic relationship with China, the United States is susceptible to major drug supply chain disruptions. To mitigate this risk, the nation should focus on stockpiling an emergency reserve of commonly used drugs in National Guard warehouses (e.g., diuretics, beta-blockers, insulin, and antibiotics).

Texas and other states can mitigate threats by taking the compact concept and transforming it into a “manufacturing quota” compact. Under this type of compact, drug manufacturers would compete to bid for the opportunity to produce a specific volume of drugs, desired by the states. Competing manufacturers would be required to ensure that all drug components that KSMs and APIs used in the manufacturing process can pass established quality metrics tests and only be sourced in America or key allied countries. This will create a new demand for local drug manufacturing—thus prompting manufacturers to find innovative ways to synthesize drugs in America.

Unlike the laborious research process of developing a cure, filling state drug quotas for existing drugs is a process easily accessible to most drug manufacturers. It is unlikely that name-brand drug manufacturers would dominate these programs, and the states would have a fair chance to give business to generic drug manufacturers as well. Additionally, state quota compacts can possess requirements that drug manufacturers oversee the construction of needed refrigeration storage and processing facilities. In an ideal situation, these compacts could serve as the catalyst for Texas to create manufacturing sites like the Petersburg’s “drug hub” in Virginia ([Hausman, 2022](#)).

Additionally, due to certain medications expiring, there is potential to tweak compacts so that they can be stretched over a long time. This would allow bid-winning drug manufacturers to have a consistency in demand, in turn compelling them to create more drugs in America. Generic drug discontinuations are occurring because of the challenge of anticipating supply chain disruptions and pairing supply in relation to demand. Having recurring de-

mand within the states could be the market force needed to incentivize drug manufacturers to expand their domestic operations.

3. *Reforming Nonsensical State Drug Regulations and Market Dynamics*

The largest drivers of medication volume in America are generic drug manufacturers. Nearly 9 out of 10 prescriptions are filled within the generic drug market (FDA, 2023). However, since 2010, nearly 3,000 generic drug product lines have been discontinued. These discontinuations have prompted several drug shortages for common medications.

Despite most prescriptions being filled with generic drugs, there are several contributing factors causing generic drug companies to take losses on commonly used drugs and therefore discontinue. These factors include:

- **Competition:** Unlike the name-brand drug market, protected with patents, the generic drug market is highly competitive. There is a continuous “race-to-bottom” to get access to high consumer volume within Medicaid, Medicare, unions, and private health insurance programs.
- **Regulation:** The Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA), maintenance regulations, audits, and investigations that create continuous costs and disruptions for drug companies to even store or possess drug components (Association for Accessible Medicines, n.d.)
- **Price Inflation:** Generic drug companies are discontinuing drugs partly because they are being penalized by state Medicaid programs (Fein, 2024). Medicaid price inflation penalties are based on benchmarked brand medication prices. Since generic drug companies do not have a monopoly over most drug product lines, these companies are more susceptible to price inflation pressures (e.g., supply chain disruptions). Consequently, generic manufacturers are now subject to millions of dollars in rebates for a program that reimburses

pennies to the dollar. This has prompted generic manufacturers to halt production of certain drugs used in Medicaid programs.

- **PBM Rebate Practices:** PBMs are being accused of contributing to both drug price inflation and discontinuations. PBMs are third-party entities that negotiate “list prices” with drug manufacturers on behalf of insurers, unions, government health insurance, and large, self-insured employers. Theoretically, PBMs are supposed to lower the list price of drugs, but many manufacturers (especially generics) are claiming that the rebates they pay PBMs are causing them to increase list prices. PBMs claim they are giving the rebates back to insurers, employers, and government clients (Ydejesus, 2019). However, there is little evidence reflecting that when PBMs pass off these “rebate savings” to their clients, drug copays and insurance premiums decrease in price. PBMs are a headache for large brand manufacturers, and an anathema to most generic manufacturers who do not possess the economies of scale to negotiate reasonable compensation. While PBMs play a role in lowering drug prices, the lack of transparency surrounding their rebate practices poses a challenge in incentivizing generic drug companies to make and sell certain drugs. Many experts argue that transparency legislation will halt PBMs’ alleged rebate practices, therefore giving more market opportunities for generic drug manufacturers to sell and produce more drugs.

What can be done to stabilize the generic market and ensure a more stable supply of commonly prescribed drugs? There are several policy avenues using transparency and waivers to mitigate nonsensical drug regulation and broken market dynamics.

Texas can file a Medicaid 1115 waiver that could exempt generic drug manufacturers companies from Medicaid price inflation penalties. Ideally, being free from potential rebate penalties would incentivize generic manufacturers to revive discontinued product lines and produce more drugs. Due to the highly

competitive nature of the generic market, there is less risk of price gouging making the exemption justifiable within state legislators' and the governor's offices.

Increasing transparency could curtail the crony middle-men practices within the drug supply chain. Texas should require PBMs to show their clients the amount of savings and rebates they may or may not be securing. Allowing clients to potentially see PBMs pocketing rebates instead of passing on savings would likely prompt many clients to drop their PBMs. In turn, this places organic market pressure on PBMs to end potential crony rebate practices.

Additionally, Texas and the federal government can eliminate the safe harbor protections from the federal STARK Act and anti-kickback statute that PBMs enjoy with group purchasing organizations. The STARK Act, formally known as the "Physician Self-Referral Law," is a federal law that "prohibits physicians from referring patients to receive 'designated health services' payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship" (U.S. Department of Health and Human Services Office of Inspector General, n.d.-a). Similarly, the federal anti-kickback statute seeks to prevent fraud and self-dealing in healthcare by criminalizing "the knowing and willful payment of 'remuneration' to induce or reward patient referrals or the generation of business" (n.d.-a). Unlike the STARK Act, which focuses on financial relationships and self-referral by physicians, the anti-kickback statute covers a broader range of transactions and applies to *all* healthcare providers, with the goal of reducing fraudulent, wasteful, and abusive practices in healthcare.

Following the codification of STARK and the anti-kickback statute, a cascade of regulations was implemented directing how PBMs and group purchasing organizations (GPOs) must present limited information to CMS pertaining to rebates, revenue flows, drug discounts, and overall drug pricing negotiations. Many of these regulations provide "safe harbor" to PBMs and GPOs from legal actions that could stem from alleged violations of STARK or the

anti-kickback statute. Put more simply, the safe harbor regulations exempt certain payment and business practices employed by PBMs and GPOs that would otherwise be considered violations of those statutes (U.S. Department of Health and Human Services Office of Inspector General, n.d.-b). One example of such practices is the use of "spread pricing," in which PBMs charge employers a different price for a drug than what they reimburse the pharmacy. The difference—or "spread"—is a revenue source for PBMs, which they are not required to disclose to clients (3 Axis Advisors, 2019, p. 1).

Safe harbors that allow PBMs and GPOs to engage in pricing practices that would otherwise violate federal law provide fertile ground for corrupt practices. For example, in September 2024, the Federal Trade Commission sued three of the largest PBMs—Caremark RX, Express Scripts, and OptumRX—alleging that the companies created a perverse drug rebate system that prioritized high rebates from drug manufacturers and drastically inflated insulin prices (FTC, 2024). According to the FTC's complaint, the companies intentionally excluded lower priced insulin in favor of those with higher list prices, thus inflating the rebates that the PBMs could utilize to increase their profit margins and attract new clients. This ultimately resulted in patients being forced to pay higher out-of-pocket costs for insulin.

Regardless of the accusations or actual flow of rebates, PBMs practices should beg the question, "Are PBMs affecting patients' financial access to medications and overall drug production?" It's difficult to gauge the extent PBMs and GPOs have impacted drug supply chains, but introducing transparency to their rebate practices is a start. In essence lawmakers could further identify what future action is warranted to secure drug supply chains by requiring transparency as well as restructuring the safe harbor protections that limit how much patients and employers can access drug price negotiation information. To incentivize drug productions in America, Texas must holistically address the regulations and crony middleman practices detouring manufacturers from doing business in our nation.

4. Supply Chain Vulnerability Analysis

In 2021, Senator John Coryn introduced and championed S. 849, the Supply Chain Vulnerability Assessment Act. This bill died in Congress, but if it had passed, it would have directed the Director of National Intelligence and the Director of the CIA to conduct a study identifying and assessing weaknesses within supply chains for key resources (including pharmaceuticals). The intention of the bill is what states need to precisely identify which drugs are in high demand, how to prioritize stock-piling strategies around life-sustaining purposes, and where the bulk of their drugs are synthesized.

States can replicate similar legislation and task agencies with running a supply chain vulnerability analysis. It would depend upon the given state agency's capability, but there could be opportunity for states to interact with the Department of Commerce using their new supply chain risk assessment tool (known as SCALE). This tool "utilizes a comprehensive set of indicators to assess structural supply chain risks across the U.S. economy" and aid policymakers and industry in mitigating these risks ([U.S. Department of Commerce, 2024](#)).

There is ample evidence supporting the need for states to figure out how to shore up drug supply chains, but inevitably, there will be questions concerning what strategy should be employed, such as:

- How soon might Texas run out of key drugs in the event of supply chain disruptions?
- Where are specific classes of drugs sourced?
- Where are the key starting materials (KSMS) manufactured?
- Where are the active pharmaceutical ingredients (APIs) manufactured?
- How quickly can capacity be stood up?

All of these questions can best be answered with a supply chain vulnerability analysis.

DISCUSSION

The reality of the matter is that American drug manufacturing has been moving overseas for years, and it has been to the detriment of national security and overall patient health. State action is warranted, and states need not wait on Washington, D.C., for resolutions. The policy recommendations listed in this brief are alternative attempts pivoting away from prior methods to compel pharmaceutical manufacturers to scale their capability in America. It is typical to consider legislative and regulatory methods like prohibitions, tariffs, or subsidies, but these actions may be for the worse in the long run. Drug manufacturing isn't going to return to stateside overnight. American dependency on vital medications paired with most drug manufacturing infrastructure being overseas means that sudden drastic actions would be catastrophic and too disruptive for the nation. The threat to national security warrants swift action but obtaining the buy-in of drug manufacturers to return stateside is key. The listed policy recommendations are intended to increase transparency over drug manufacturing, compel consumers to obtain higher quality drugs made in America, remove regulations limiting drug manufacturing capacity, and create economic opportunity to spur domestic drug manufacturing to build in America.

Ultimately, the policy recommendations outlined in this brief provide Texas with a roadmap on how the state can reduce its dependence on foreign drug manufacturing, protect public health, and strengthen the state's drug-making infrastructure. By adopting these policies, Texas will play a critical role in reshoring pharmaceutical production, in turn ensuring that the U.S. has the capacity to meet its own drug needs without relying on foreign manufacturers, especially those in China. With effort, the saying can be tweaked to read, "as goes Texas, so goes the nation's drug manufacturing." ■

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