

# A Bitter Pill

# Medicaid's Dangerous Dependence on China-Made Pharmaceuticals and Forced Labor

How America's healthcare funding fuels human rights abuses and drug-quality risks



America's pharmaceutical supply chain faces critical risks stemming from deep dependencies on foreign drug manufacturers, complex geopolitical dynamics, and unethical international sourcing practices. The increasing globalization of pharmaceutical production brought significant economic efficiencies, but this has come at the cost of **new vulnerabilities** and **strategic risks**.

affordable healthcare in the U.S., especially Medicaid, which relies extensively on cost-effective generic medications primarily sourced from India. Indian pharmaceutical manufacturers, however, are heavily dependent on Chinese suppliers for approximately 80% of their pharmaceutical ingredients.

Consequently, disruptions in Chinese supply—whether due to trade tensions, manufacturing issues, political decisions, or even military conflict—can rapidly cascade through Indian manufacturing networks, significantly affecting the availability and affordability of medications essential for millions of

This foreign dependency has serious implications for

Exiger's extensive investigative research and Alpowered analysis underscores this challenge. Using advanced analytics tools, Exiger has identified ongoing patterns of severe quality control issues, including contamination and falsified testing data, which have repeatedly triggered FDA import alerts.

Additionally, Exiger's research reveals troubling ethical violations, particularly the use of forced labor within pharmaceutical manufacturing networks, notably in China. These findings illuminate how ethical and regulatory deficiencies in international drug production not only pose direct health risks but also create broader economic and reputational risks for the U.S.

# Addressing this multi-faceted dilemma requires comprehensive, proactive strategies.

Policymakers must prioritize stronger regulatory oversight, enhanced international collaboration, increased transparency, diversified sourcing, and strategic investments in domestic pharmaceutical manufacturing capabilities. It is imperative that these steps are taken swiftly to build a more resilient, ethically sound, and strategically secure pharmaceutical supply chain that safeguards American health and national security interests.

Americans.

# **Critical Risks in U.S. Drug Supply Chains:**

# What You Need to Know

- The U.S. imports **75%** of its essential medicines, exposing American patients and healthcare systems to disruptions from international conflicts, trade restrictions, pandemics, and natural disasters.
- China and India dominate the global market, producing around 60% of active pharmaceutical ingredients (APIs).
- India supplies about half of all generic drugs used in the U.S., yet it depends on China for **80%** of its APIs.
- China alone supplies nearly 90% of the antibiotic APIs consumed in the U.S., creating an acute dependency that could be exploited in a geopolitical crisis.
- Over **504** generic drugs, including 10 essential medicines, have only a single identified API manufacturing country, heightening risks of supply shocks.
- Systemic quality control failures have already impacted U.S. consumers. Incidents involving substandard and contaminated drugs highlight real health threats posed.
- More than 30% of all new import alerts were for sites in China, and 16% were for sites in India, highlighting recurring manufacturing issues.
- Pharmaceutical ingredients linked to forced labor pose serious ethical and legal issues, potentially compromising the integrity and reputation of the entire supply chain.
- The largest producer of Medicaid-reimbursed prescriptions is linked to forced labor. Aurobindo, the top Medicaid prescription provider with 11 million prescriptions in 2024, and almost a third of the antibiotics market share, procures pharmaceutical ingredients from at least six China-based companies with allegations of forced labor and links to China's military, potentially introducing unethical and illegal labor practices into U.S. healthcare.
- Lupin Ltd., the third-largest prescription provider for Medicaid, procures pharmaceutical products from companies tied to forced labor and Chinese-state ownership.

33%

FDA IMPORT
ALERTS
TRIGGERED
BY CHINESE
MANUFACTURERS

# **Quality and Safety Breakdowns Put Americans at Risk**

America's reliance on foreign-made pharmaceuticals has opened doors to dire quality and safety threats. Exiger's analysis shows that a surge in FDA import alerts due to severe violations has disproportionately involved Chinese (33%) and Indian (16%) manufacturers. Pandemic-driven delays in FDA inspections mean many foreign production facilities continue to operate unchecked, increasing the chance that counterfeit or unsafe medications reach American patients.

In 2023, contaminated eye drops traced to India-based Kilitch Healthcare illustrated these dangers. Exiger's research linked unsanitary manufacturing conditions to severe patient outcomes in the U.S., including permanent vision loss, infections, and massive recalls, demonstrating how quickly quality issues abroad become American health emergencies.

90%

PERCENTAGE OF ANTIBIOTIC APIS PRODUCED BY CHINA

# **Dangerous Dependency**

America's one-sided dependency on overseas manufacturers, particularly China, creates severe strategic risks. With China producing up to 90% of antibiotic APIs, geopolitical conflicts or natural disasters could easily trigger drug shortages. Exiger's proprietary data reveals U.S. imports of pharmaceutical ingredients from China grew nearly 24% from 2020 to 2023, deepening vulnerability. India, a critical supplier of generic drugs to the U.S., is itself heavily reliant on Chinese inputs, compounding the risk for American consumers.

# **Ethical and Regulatory Red Flags**

Exiger's investigations uncovered troubling ethical violations involving forced labor practices tied to Uyghur workers in Xinjiang. Major Chinese state-owned entities like Sinopharm, Zhejiang Shindai Chemical Group, and Zhejiang Chemicals Export Corp—critical indirect suppliers of U.S. pharmaceuticals—have documented connections to forced labor, violating U.S. ethical standards and import laws.

Adding to this complexity, major Indian generic drug manufacturers, notably Aurobindo Pharma and Lupin Ltd., have faced repeated FDA enforcement actions due to significant regulatory and compliance failures. These ethical and compliance issues intensify existing quality and dependency vulnerabilities, making resolution increasingly urgent.

# **What's Next**

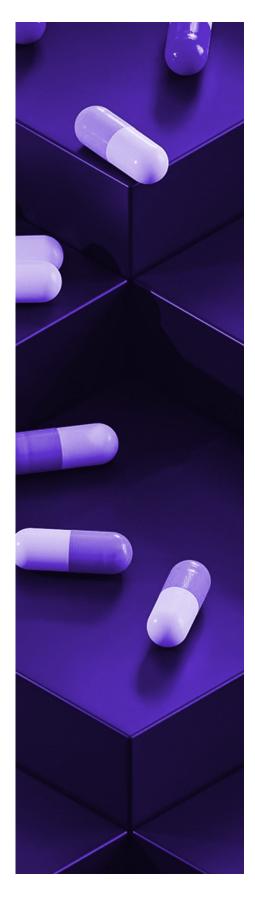
Exiger's analysis strongly suggests immediate action:

- Strategic Stockpiling and Advanced Research Pathways: Policymakers should empower HHS to address these issues of fragility through a potential expansion of the strategic national stockpile of critical medicines, biologics (such as vaccines), and medical devices (in partnership with other agencies and Congress) and leverage accelerated and advanced research pathways such as the Biomedical Advanced Research and Development Authority (BARDA) to expand U.S. production of essential therapies. This combined approach creates an immediate defense and buffer against adversarial blockades of essential medical supplies. BARDA's successes – from OPVEE (an opioid overdose nasal spray) to advanced wound care products like NexoBrid and Bravida's Silverlon, and new broadspectrum antibiotics - demonstrate the impact of investing in advanced development for both civilian health and military readiness.
- Boost domestic production: Offer targeted incentives to reshore or expand domestic manufacturing capabilities for critical drugs and APIs, especially antibiotics and treatments experiencing current shortages.

- Diversify and secure supply chains:

  Require supply chain redundancy in
  government pharmaceutical contracts,
  encouraging multiple geographic sourcing to
  mitigate foreign dependency risks.
- Strengthen regulatory oversight: Increase FDA inspection resources to eliminate foreign facility backlogs, implement real-time monitoring of manufacturing sites abroad, and enforce swift action against violators.
- Expand supply chain visibility and tracking: Deploy advanced analytics and real-time monitoring technologies to comprehensively map pharmaceutical supply chains, enabling proactive identification of risks, ensuring compliance, and improving responsiveness to potential disruptions.
- Eliminate forced labor: Intensify enforcement of existing laws, such as the Uyghur Forced Labor Prevention Act, mandate transparency across pharmaceutical supply chains, and require third-party audits of high-risk suppliers to ensure ethical compliance.

These steps are critical to safeguarding American health and ensuring the resilience and integrity of the U.S. pharmaceutical supply chain.



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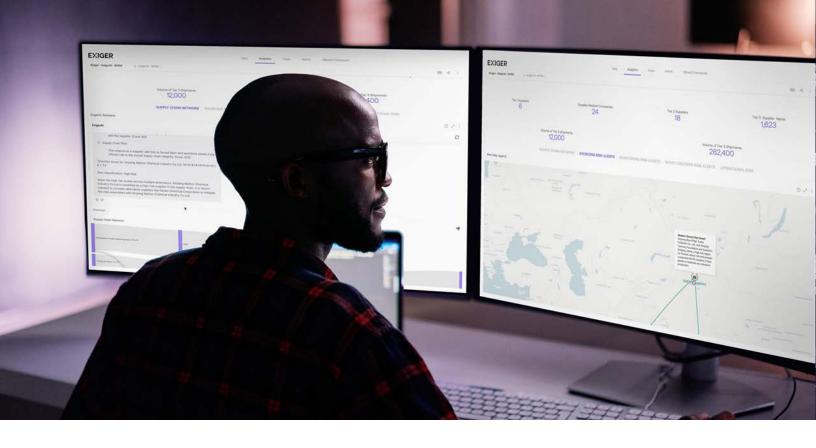
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# Introduction

The United States pharmaceutical supply chain faces unprecedented challenges that have critical implications for public health and national security. In recent years, geopolitical events and pandemic-related disruptions have exposed the vulnerabilities of America's growing reliance on foreign sources for essential medicines.

The U.S. now depends on overseas manufacturers for nearly 75% of its essential drug supply. China and India alone account for approximately 60% of global active pharmaceutical ingredient (API) production – dominating especially in generic drugs like antibiotics. China's outsized role is stark: it contributes up to 90% of the world's antibiotic API supply, so any disruption could spur shortages like the amoxicillin scarcity seen in 2022. India supplies about half of all generic drugs used in the U.S., but itself relies on

China for as much as 80% of its API needs. This chain dependency effectively entwines U.S. medicine cabinets with foreign producers at multiple tiers. Such heavy foreign dependence, paired with documented lapses in quality control and ethical practices abroad, underscores why this research is so critical for policymakers. It illuminates how supply chain weaknesses – from substandard drugs to potential adversarial leverage – can directly threaten American lives and health.



# **Objective & Methodology**



Leveraged ExploreRx, Supply Chain Explorer, and Supply Chain Intelligence to identify drug manufacturers, pharmaceutical packagers and labelers, and suppliers.



Highlighted the following areas for investigation:

- Risks associated with the supply chains of manufacturers of APIs in injectable antibiotic, diabetes, and heart disease therapeutics currently experiencing shortages, paying specific attention to supplier concentration risk.
- Case studies on entities with prominent status in the U.S. market, high foreign ownership, control, and influence ("FOCI") risk, or reputational, criminal, and regulatory ("RCR") risks.



Investigated **2,309** companies in DDIQ and conducted an automated and adjudicated risk assessment on each company.



Augmented DDIQ findings with proprietary research.



# Who Stocks America's Medicine Cabinet?

Report Analytics Focus Areas & Market Overview

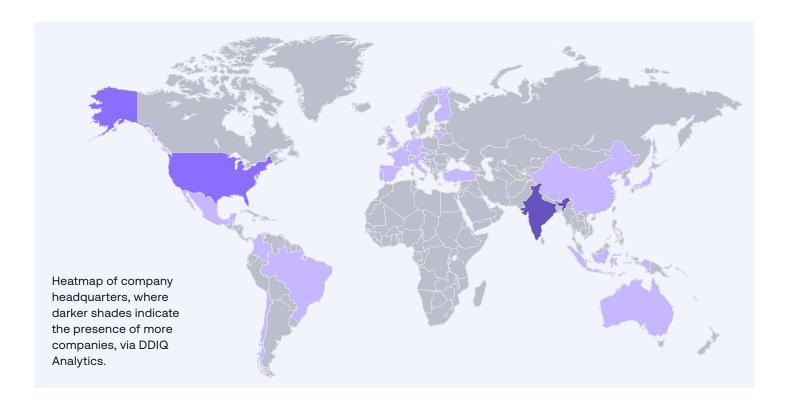
# **Dataset Overview**

The **2,309** risk-assessed companies and **1,376** APIs were divided into the following categories:

COMPANY TYPE	NUMBER OF COMPANIES	SOURCE
Drug Manufacturers, Labelers, or Packagers	1,896	ExploreRx
Suppliers to Drug Manufacturers	513	Supply Chain Explorer and Supply Chain Intelligence

THERAPEUTIC CATEGORY	# OF APIS	# OF APIS ON ESSENTIAL MEDICINES LIST	POINTS TO KNOW
Antibiotics	432	37	Antibiotics and their APIs are predominately manufactured and sourced overseas, particularly in China.
Heart Disease	862	29	Heart disease is a common (affecting 5.5% of U.S. adults) chronic condition requiring pharmaceutical intervention.
Diabetes	208	11	Diabetes is a leading (affecting 10.8% of U.S. adults) chronic condition requiring pharmaceutical intervention.

Note: Drugs and companies may fit into multiple categories.



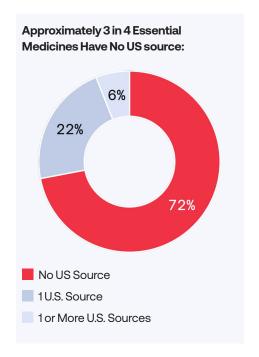
# State of the Pharmaceuticals Market

Geopolitical events and product quality issues have exposed the problems with the U.S.'s growing reliance on foreign pharmaceutical supply chains, particularly for essential medicines.

Despite pandemic-era disruptions that <u>led</u> the U.S. to introduce measures, such as the CARES act, that <u>target</u> domestic pharmaceutical industry growth, the U.S. continues to rely on foreign manufacturing for the majority of the FDA's <u>essential medicines</u>.

Recent multibillion-dollar investments in U.S. manufacturing and R&D sites from U.S.-based <u>Eli Lilly Co</u>. and UK-based <u>AstraZeneca Plc</u> indicate the potential growth of the domestic pharmaceutical market, but generic drug production remains dominated by India and China.

The FDA's 2023 Report on the State of Pharmaceutical Quality reported an increasing number of import alerts due to defective drugs, particularly from China (33% of sites) or India (16% of sites), as well as an increasing number of drug shortages driven by increased demand from the pandemic and quality issues.



The US relies on foreign suppliers for almost 75% of essential medicines, via the <u>Drug, Chemical & Associated Technologies</u>
Association.

# **U.S. Position in Global Drug Manufacturing**

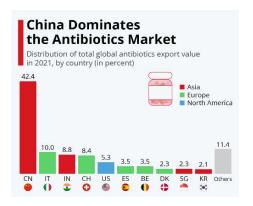
The U.S. lags behind other nations in the production of antibiotics but is a <u>leader</u> in overall global drug sales, including some medications that treat diabetes and heart disease.

China contributes up to 90% of the world's antibiotic APIs, potentially raising the risk of shortages, such as the 2022 shortage of amoxicillin.

While the U.S. is the leading diabetes medication consumer, one US-based and two foreign companies collectively hold <u>92%</u> of the insulin production market.

 Novo Nordisk A/S's Denmark facility contributes nearly <u>half</u> of the world's insulin production capacity.

While no country dominates heart disease drug manufacturing, <u>companies</u> located in the US, Germany, and France are named as major players in this market.



Graphic showing China's dominance in antibiotic production and exports, via <u>Statista</u>.

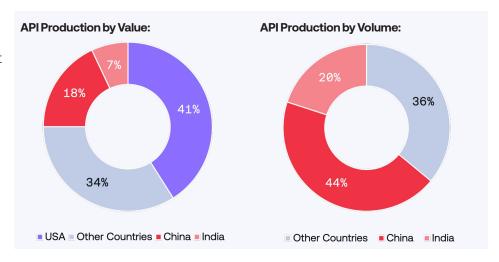


Graphic showing US dominance in diabetes medication consumption, via Statista.

# Role of China and India in API Manufacturing

The U.S. increasingly relies on APIs sourced from India and China, which constitute 64% of the global API manufacturing share, as U.S. API manufacturers focus on high-value, low-volume production.

U.S. direct imports of China-made APIs increased by about 24% from 2020-2023. As India supplies about half of all generic drugs in the US and relies on China for 80% of its APIs, the U.S. may have even greater reliance on China-made pharmaceutical products. Lower manufacturing costs in India and China have driven production of high-volume generic drugs to those locations



Graphic showing the regional breakdown of global API production by value and volume, via Economies Journal.

U.S. API manufacturing is <u>concentrated</u> in high-value, low-volume production, resulting in <u>smaller</u> API manufacturing facilities and making the onshoring of generic drug API manufacturing impractical.

Consequently, any disruption in China-India pharmaceutical trade can reverberate into U.S. hospitals and pharmacies – a multi-layered dependency chain that raises alarms for supply resilience.

Policymakers and national security experts are increasingly concerned that adversarial nations could exploit America's pharma dependency as leverage. The U.S.—China strategic rivalry casts a long shadow over medicines: Chinese state media and experts have occasionally floated the idea of withholding drug exports as a "weapon" in conflict. While to date China has not targeted pharmaceuticals in trade disputes, the risk cannot be ignored. As one analysis starkly warned Congress, "Medicines can be used as a weapon of war against the United States... Supplies can be withheld. Medicines can be made with lethal contaminants or sold without any real medicine in them," if an adversary chose to deliberately harm Americans.

The dependency statistics underscore this concern. By U.S. Commerce Department estimates, 95% of U.S. ibuprofen, 91% of hydrocortisone, 70% of acetaminophen (Tylenol), and nearly half of the U.S. supply of penicillin and heparin are imported from China. Such dominance gives Beijing a potent, if hypothetical, chokehold over drugs critical to everyday healthcare - from basic pain relievers to antibiotics and blood thinners. In a worst-case geopolitical crisis, the U.S. could face not only higher prices but outright shortages of essential medicines if supply lines are cut or manipulated. Even absent intentional action, state-owned enterprises in China control significant portions of the API market, meaning political decisions could inadvertently squeeze U.S. supply. This adversarial risk layer adds a national security dimension to what might otherwise be viewed as a purely economic supply chain issue.

# By the Numbers Role of China and India in API Manufacturing

64%
GLOBAL API
MANUFACTURING
SHARE OWNED BY
CHINA AND INDIA

95%

IBUPROFIN IS

IMPORTED FROM

OF U.S.

CHINA

PERCENTAGE OF CHINESE APIS INDIA IS RELIANT ON

**91%** OF U.S.

OF U.S. HYDROCORTISONE IS IMPORTED FROM CHINA ~50%

PERCENTAGE OF GENERIC DRUGS IN THE U.S. SUPPLIED BY INDIA.

70%

OF U.S. ACETAMINOPHEN IS IMPORTED FROM CHINA 24% +

INCREASE OF U.S. DIRECT IMPORTS OF CHINA-MADE APIS FROM 2020-2023

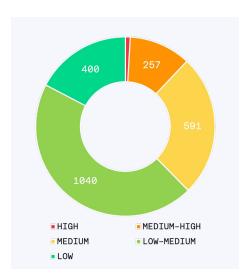
50%~

OF U.S. PENICILLIN AND HEPARIN ARE IMPORTED FROM CHINA

# **Company Risk Overview**

Risk-assessed companies collectively received an average risk rating of Low-Medium, with higher scores primarily driven by elevated FOCI and regulatory risk among identified suppliers.

Of the **2,309** risk-assessed companies, **268** have overall risk ratings of High or Medium-High. Companies with higher overall risk ratings tend to be located in China or India. Drivers of their elevated risk scores include state ownership, connections to forced labor and regulatory violations.



Number of companies per risk rating, via DDIQ Analytics.



15 Highest-risk companies, via DDIQ Analytics.



# Diagnosing Supply Chain Dependencies & Bottlenecks

The United States' heavy dependence on foreign pharmaceutical supply is not only a commercial concern but a strategic vulnerability. Today's drug supply chains are highly globalized, with China and India serving as the pharmacy for much of the world – including America. As noted, China and India collectively produce around 60% of the world's APIs, and the U.S. sources a large share of its medicines or drug components from these countries. This is especially pronounced for generic essential medicines. U.S. direct

imports of China-made pharmaceutical ingredients surged by ~24% from 2020 to 2023, reflecting growing reliance. India, the source of a vast portion of finished generic drugs in the U.S. About 50% of U.S. generic drugs supply, is itself dependent on Chinese inputs for the majority of its APIs.

Consequently, any disruption in China-India pharmaceutical trade can reverberate into U.S. hospitals and pharmacies – a multi-layered dependency chain that raises alarms for supply resilience.

# **Single-Source Pharmaceuticals**

504 generic drugs, including 10 essential medicines and 5 currently experiencing a shortage, have a single identified API manufacturing country.

China-based, partial <u>state-owned enterprise</u> ("SOE") Hainan Poly Pharm Co. Ltd. is the sole identified API manufacturer of dobutamine, which treats advanced heart failure and is currently facing a <u>shortage</u>.

Timolol maleate ophthalmic, a type of eye drops that <u>appears</u> on the Food and Drug Administration's ("FDA") essential medicines list, relies on foreign APIs, potentially including those made by a company that sold eye drops that could result in <u>vision loss and eye removal</u>.

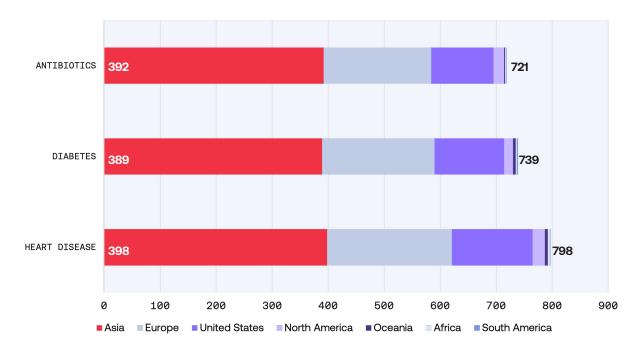
DRUG CATEGORY	# OF GENERIC DRUGS FROM A SINGLE COUNTRY	# OF GENERIC DRUGS FROM A SINGLE COMPANY	# OF GENERIC DRUGS EXPERIENCING A SHORTAGE FROM A SINGLE COMPANY
Heart Disease	337	174	5
Diabetes	60	32	1
Antibiotics	154	93	0
Total	504	274	6

Note: Drugs may fit into multiple categories.

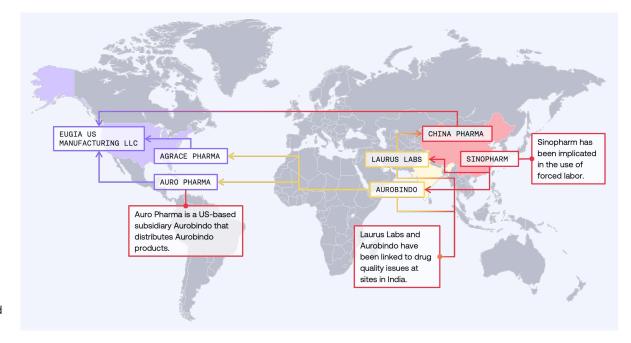
# **Supply Chain Overview**

Approximately 50% or more of identified direct suppliers to manufacturers of target drugs are in Asia, while India, specifically, is the top source of U.S.-bound products.

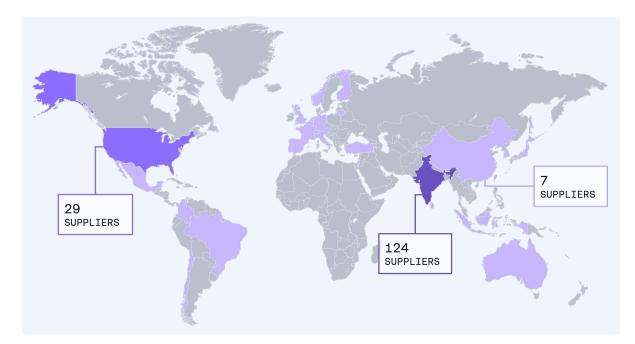
Even where multiple suppliers exist, they may all be located in the same region – a geographic concentration that leaves the supply line exposed to regional crises (natural disasters, pandemics, geopolitical conflict). The ongoing wariness in global trade has prompted questions about how the U.S. would cope if a geopolitical rift significantly curtailed drug imports.



Number of direct suppliers to all drug manufacturers, split by supplier region and category of drug, via DDIQ Analytics.



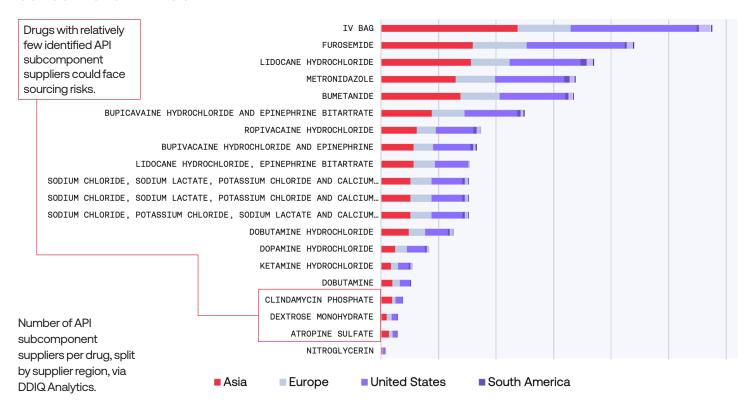
U.S. pharmaceutical companies procure products from highrisk pharmaceutical manufacturers in India and China, often through intermediaries in India and U.S.-based subsidiaries.



Concentration of suppliers to U.S.-based drug manufacturers, labelers, or packers, where darker shades indicate more suppliers, via DDIQ Analytics.

# **Supplier Concentration for Specific Drugs**

APIs with fewer subcomponent suppliers, such as atropine sulfate, dextrose monohydrate, and clindamycin phosphate, may face higher risk due to relative supplier concentration in Asia.

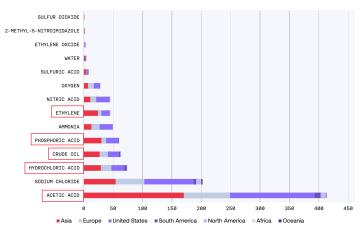


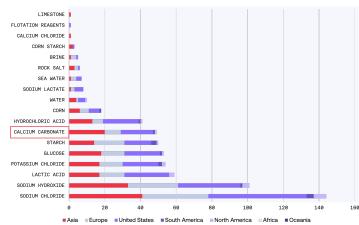
# **API Subcomponent Concentration in Asia**

While a concentration of suppliers in Asia is evident for API subcomponents in all three drug categories, a relatively lower number of total suppliers of antibiotics and diabetes drugs may indicate a greater threat from supplier concentration risk.

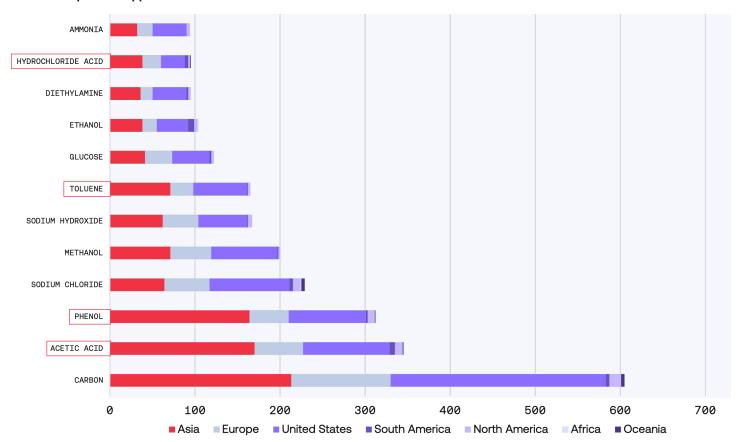
### API Subcomponent Suppliers for Antibiotics

### API Subcomponent Suppliers for Diabetes





### **API Subcomponent Suppliers for Heart Disease**



Number of direct and indirect suppliers per API subcomponent to API manufacturers for each drug type, with ingredients with a relatively high concentration of suppliers in a single region outside the U.S. boxed in red, via DDIQ Analytics.



# High-Risk Companies in Supply Chains & Their Dangerous Side Effects

Quality control issues are inextricably linked to deep forced labor concerns, revealing stark implications about vulnerabilities in pharmaceutical supply chains. Notably, evidence has emerged that some drug ingredients and raw materials sourced from China are tainted not only in quality but in their very production – through the use of forced labor in the Xinjiang Uyghur Autonomous Region.

Investigations by industry risk analysts have found that API subcomponents made by certain Chinabased entities with ties to Uyghur forced labor may be finding their way into U.S. medications. In other words, medications consumed by Americans may unknowingly contain ingredients produced by persecuted laborers in internment camp-like conditions. This is a profound ethical concern and also a legal one: U.S. law (19 U.S.C. §1307, strengthened by the 2021 Uyghur Forced Labor Prevention Act) prohibits importing goods made wholly or in part by forced labor. Yet enforcement is challenging when complex supply chains obfuscate the origin of chemical precursors and components.

Concrete examples illustrate the scope of the problem. Sinopharm - China's largest state-owned pharmaceutical conglomerate - has extensive ties to Uyghur forced labor and may be using that labor to manufacture API ingredients that end up in medicines sold in the U.S. Sinopharm, as a central actor in China's drug industry, continues to export products globally; it remains an FDA-registered pharmaceutical importer, meaning its subsidiaries can ship drugs or components into the American market. Likewise, Chinese state-owned chemical companies like Zhejiang Shindai Chemical Group and Zhejiang Chemicals Import & Export Corp have been identified as supplying drug intermediates that feed into U.S. drug production, often via middlemen in India or other countries. These state-run firms have been flagged for elevated risk due to either direct government ownership or links to forced labor programs. Their presence in U.S. supply chains raises red flags: state ownership implies these companies could be instruments of Beijing's policy, and forced labor links mean their products could be illegal under U.S. trade laws if conclusively traced.



Importantly, recent research by independent watchdogs has mapped out how deeply Xinjiang is embedded in pharma supply chains. A 2024 investigative report found 76 pharmaceutical products exported from China that are produced exclusively in Xinjiang, implying no alternative manufacturing sources for those items outside the Uyghur region. These include not only traditional medicines but over a dozen conventional drug products. The same research highlighted that at least two Xinjiang-based pharmaceutical companies are authorized FDA-registered suppliers to the U.S., and many major Chinese pharma companies were linked to human rights abuses in Xinjiang. Often, products from Xinjiang are shipped to third countries for formulation or packaging, or companies relocate their registrations to mask the true origin.

Such practices make it difficult for U.S. importers and regulators to detect Uyghur forced labor content. The implication is stark: these critical major API companies with suppliers linked to forced labor also have histories of severe regulatory violations, including unsanitary manufacturing environments,

falsified inspection records, and recurrent contamination issues. Aurobindo Pharma, a leading provider of generic drugs to Medicaid—with over 11 million prescriptions reimbursed in 2024—has faced repeated FDA enforcement actions, notably for contamination with hazardous impurities such as N-Nitrosodimethylamine (NDMA), a potent carcinogen. Aurobindo also sold contaminated amoxicillin, an FDA-designated essential medicine, in 2020. Such contamination incidents led to substantial recalls, directly impacting millions of American patients and exposing them to significant health risks.

This troubling intersection of forced labor and compromised drug quality is symptomatic of broader systemic issues stemming from inadequate regulatory oversight in China and India, where many pharmaceutical ingredients are produced. Contamination scandals, such as the 2018 valsartan recalls triggered by carcinogenic impurities originating from Chinese suppliers, underscore how quickly substandard overseas manufacturing can escalate into serious public health crises in the U.S.

These findings underscore the urgent need for rigorous supply chain transparency and enhanced regulatory vigilance to mitigate both the ethical breaches and patient safety hazards posed by Aurobindo and similar high-risk pharmaceutical suppliers.

# Aurobindo's Position in the U.S. Market

Aurobindo, a major producer of drugs, received reimbursement from Medicaid for 11 million prescriptions in 2024, outperforming the second company by almost three million prescriptions.

Aurobindo is a major provider of medications to the U.S., particularly of antibiotics, where Aurobindo has seen its market share rise from 21% in 2021 to 31% in 2024. At least nine antibiotics provided by Aurobindo are on the FDA's essential medicines list.

Aurobindo supplies pharmacies such as CVS Pharmacy Inc. and Walgreen Co., as well as drug wholesalers in the U.S. and the VA. While Aurobindo provided 240,000 fewer prescriptions in 2024 than in 2021, it received nearly 15% more in reimbursements, indicating that its drugs have become more expensive.

# \$152M+

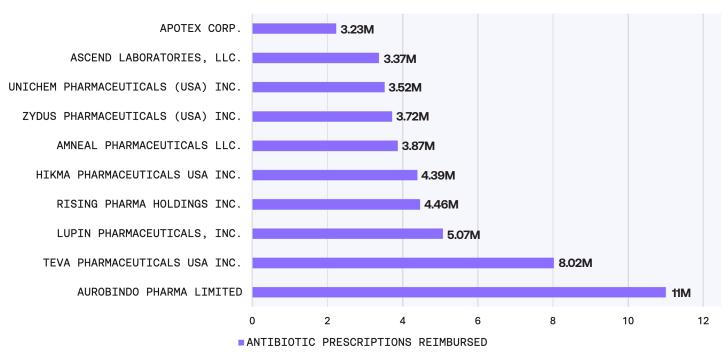
REIMBURSEMENTS FOR AUROBINDO FROM MEDICAID IN 2024

# 15%+

INCREASE OF REIMBURSEMENTS IN 2024 FROM 2021 DESPITE PROVIDING FEWER PRESCRIPTIONS

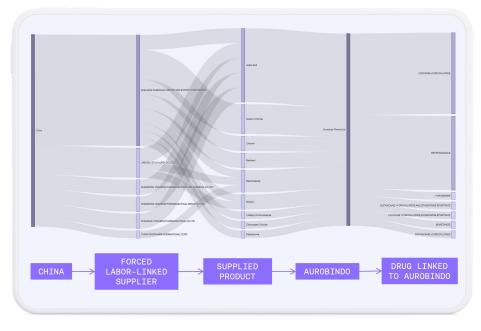
COMPANY	COUNTRY	PRESCRIPTIONS REIMBURSED	AMOUNT REIMBURSED
Aurobindo Pharma Ltd.	India	11,003,516	\$152,418,978.24
Teva Pharmaceuticals U.S.A. Inc.	U.S.	8,016,418	\$193,391,093.27
Lupin Pharmaceuticals Inc.	U.S.	5,067,368	\$87,935,304.72
Rising Pharma Holdings Inc.	U.S.	4,460,411	\$63,099,142.41
Hikma Pharmaceuticals U.S.A. Inc.	U.S.	4,392,590	\$95,326,783.15

Antibiotic prescriptions reimbursed for the top providers of medications in 2024 in millions, according to Medicaid data, via DDIQ Analytics:



# Forced Labor in Aurobindo's Supply Chain

Aurobindo procures pharmaceutical products from at least six companies engaged in forced labor practices, suggesting that forced labor-made products may be present in U.S. medications.



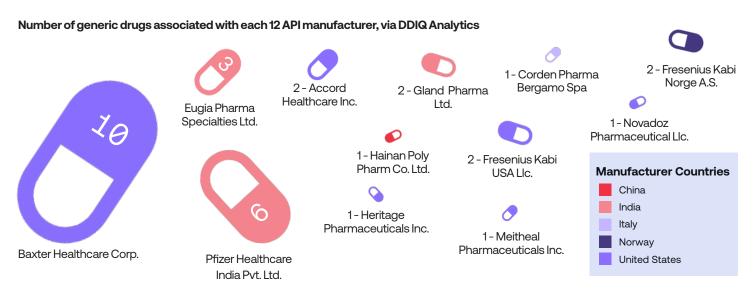
Potential flow of products from the six China-based Aurobindo suppliers, via DDIQ Analytics.

### **API Manufacturers Linked to Aurobindo**

Through Aurobindo, at least 12 API manufacturers linked to 17 drugs in all three therapeutic categories may be exposed to forced labor-made pharmaceutical products.

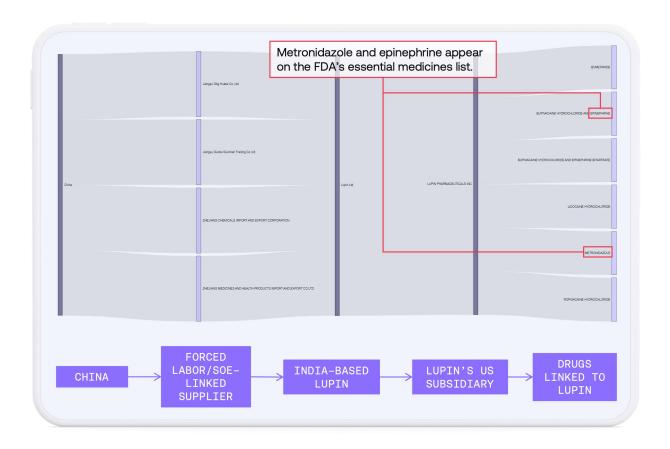
The number of generic drugs associated with each API manufacturer that may have indirectly received shipments from Aurobindo and therefore may be exposed to forced labor, split by API manufacturer country, via DDIQ Analytics.

Note that generic drugs counted here represent a subset of drugs in the antibiotics, diabetes, and heart disease therapeutic categories that each of these companies produces.



# Forced Labor and SOEs in Lupin's Supply Chain

Lupin, the third largest prescription provider to Medicaid patients, procures pharmaceutical products from at least four companies with ties to forced labor or state ownership, further demonstrating the potential link between high-risk Chinabased companies and U.S.-consumed pharmaceuticals.

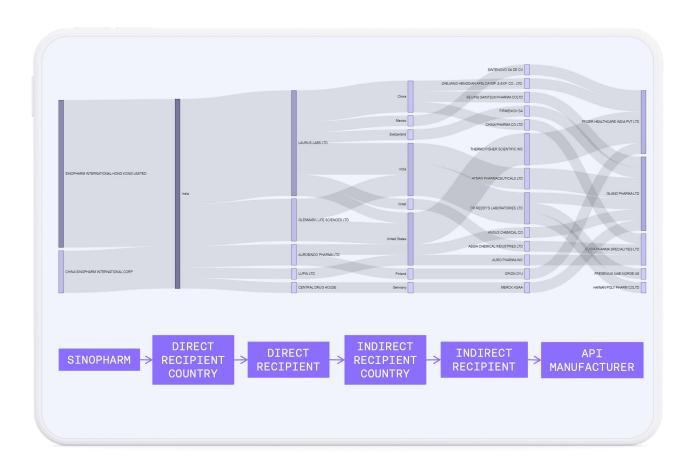


Potential flow of pharmaceutical products from 4 suppliers that reportedly use forced labor or are wholly state owned to Lupin's U.S. subsidiary, via DDIQ Analytics.

# More Forced Labor Connections in U.S.

China Sinopharm International Corp. ("Sinopharm"), China's largest pharmaceutical manufacturer and an <u>SOE</u>, has <u>extensive ties</u> to Uyghur forced labor, which the company may use to manufacture API subcomponents sold in the U.S.

While the evidence below only shows indirect supply to the U.S., open-source research <u>suggests</u> that Sinopharm continues to directly export products to the U.S. and EU. Sinopharm also remains a vetted <u>importer</u> with the FDA.

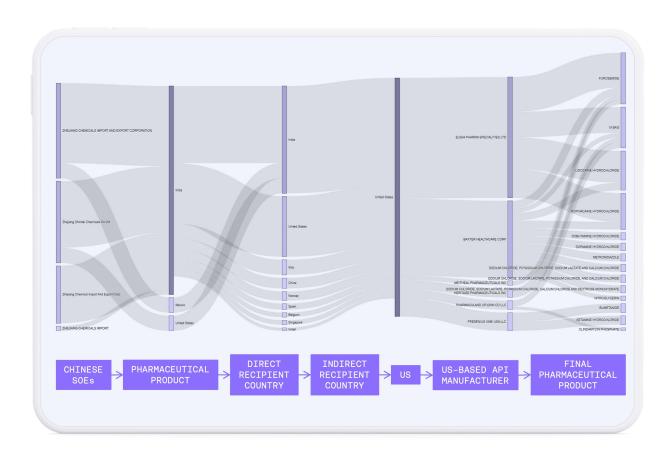


Sample of supply relationships stemming from Sinopharm entities, via DDIQ Analytics.

# Chinese SOEs in Supply Chains of U.S.-Manufactured

China-based SOEs Zhejiang Shindai Chemicals Co. Ltd. ("Zhejiang Shindai") and Zhejiang Chemicals Import and Export Corp ("Zhejiang Chemicals") supply subcomponents that may, via India and other countries, end up in U.S.-made drugs.

Our analytics below connects their supply relationships to U.S.-based API manufacturers, where supplied goods are relevant to the specific drugs each U.S. company makes,

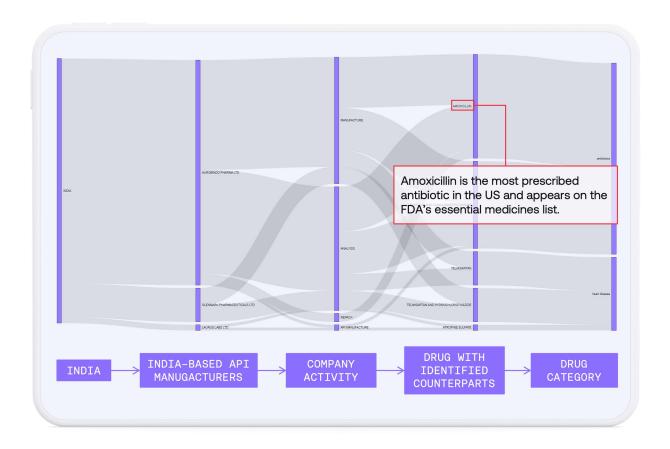


Sample of supply relationships originating with Zhejiang Shindai and Zhejiang Chemicals, via DDIQ Analytics.

# **Defective and Counterfeit Drugs**

The U.S.'s reliance on India-made drugs may expose consumers to <u>counterfeit</u> or <u>substandard</u> products, which recently <u>affected</u> at least five drugs from three India-based companies.

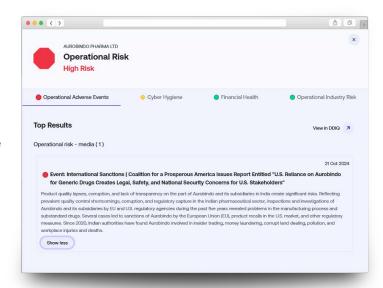
Examples of recently <u>identified</u> counterfeit or substandard drug types from India-based manufacturers that appear in ExploreRx data and <u>have a history</u> of receiving FDA warnings. India is the <u>leading</u> country for counterfeit pharmaceutical production. The FDA is currently facing a <u>backlog</u> of foreign factory inspections due to pandemic-era <u>disruptions</u>.



Examples of recently identified counterfeit or substandard drug types from India-based manufacturers, via ExploreRx.

Regulatory and safety violations have affected at least three companies linked to over 100 medications across the antibiotics, diabetes, and heart disease therapeutic categories.

Examples of recently identified counterfeit or substandard drug types from India-based manufacturers that appear in ExploreRx data and have a history of receiving FDA warnings. India is the leading country for counterfeit pharmaceutical production. The FDA is currently facing a backlog of foreign factory inspections due to pandemic-era disruptions.



Notice of Aurobindo's regulatory <u>violations</u> related to drug manufacturing and quality control standards, via 1Exiger.

COMPANY	CATEGORY	GENERIC NAMES	NATIONAL DRUG CODES
Aurobindo	Antibiotics	34 (8 essential)	194 (189 in a manufacturing capacity)
	Diabetes	14 (2 essential)	85 (85 in a manufacturing capacity)
	Heart Disease	77 (9 essential)	427 (417 in a manufacturing capacity)
Glenmark Pharmaceuticals Ltd.	Antibiotics	7 (1 essential)	17 (17 in a manufacturing capacity)
	Diabetes	9 (2 essential)	29 (29 in a manufacturing capacity)
	Heart Disease	29 (3 essential)	89 (89 in a manufacturing capacity)
Laurus Labs Ltd.	Antibiotics	0	0
	Diabetes	1(0 essential)	5 (5 in a manufacturing capacity)
	Heart Disease	3 (0 essential)	6 (6 in a manufacturing capacity)

The drugs counted in the above table include just a subset of the companies' antibiotic, diabetes, and heart disease therapeutics identified through ExploreRx data, originally sourced from publicly available data.

A notable example is the case of contaminated eye drops that shook U.S. consumers in 2023. Over-the-counter artificial tear solutions sold in the U.S. were recalled after the FDA warned of the potential of severe infections, vision loss, and even blindness. Investigations traced the problem to contaminated ingredients sourced from India-based Kilitch Healthcare, a manufacturer that subsequently

failed an FDA inspection. Kilitch's tainted eye drop ingredients – linked to unsanitary factory conditions – had been distributed under various American brand names, illustrating how a single foreign supplier's lapse can have nationwide health repercussions. Similarly, other high-profile quality incidents have included cancer-causing impurities (NDMA) found in blood pressure medications and diabetes drugs produced overseas, leading to mass recalls. Each of these incidents underscores the public health implications of weak links in the supply chain: patients unwittingly taking medicines that are ineffective at best or toxic at worst.

# **Defective Eye Drops in the U.S.**

Eye drops sold in the U.S. include ingredients sourced from India-based Kilitch Healthcare, which failed FDA inspections in 2023 and sold eye drops that could lead to vision loss and eye removal.







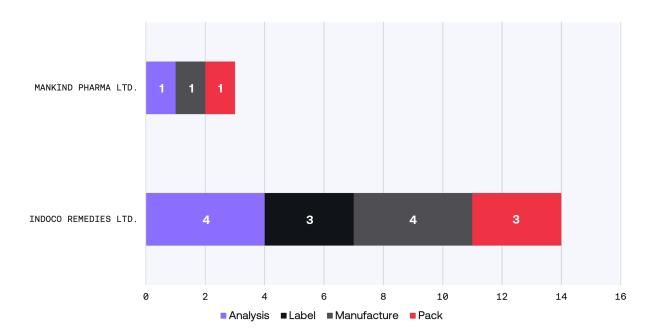




Customers of Kilitch Healthcare, via the company's website.

Barefoot workers and cracked floors were found at a factory that made recalled eyedrops, FDA says

Headline regarding Kilitch Healthcare's FDA violations and recalled eyedrops, via the <u>Associated Press</u>.

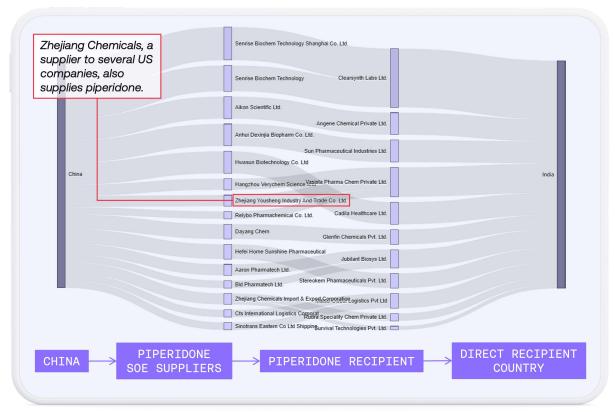


The number of generic eye drop medications sold in the U.S. associated with two Kilitch Healthcare India Ltd. ("Kilitch Healthcare") customers, split by the customers' role pertaining to each medication, via DDIQ Analytics.

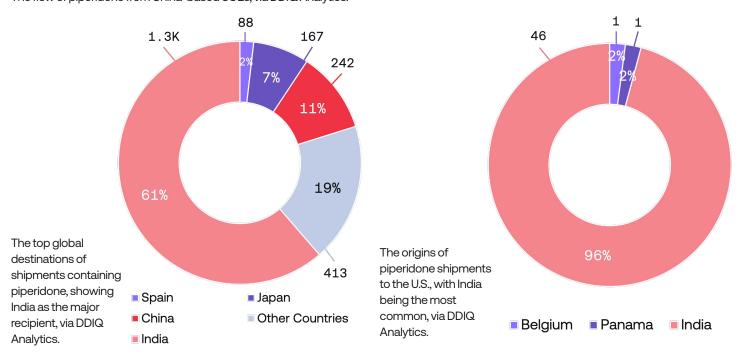
Roles of "manufacture," "label," and "pack" indicate that these companies may not only use contaminated ingredients from Kilitch Healthcare to manufacture their own eye drops, but may also pack and label Kilitch Healthcare-made contaminated eye drops to sell as their own.

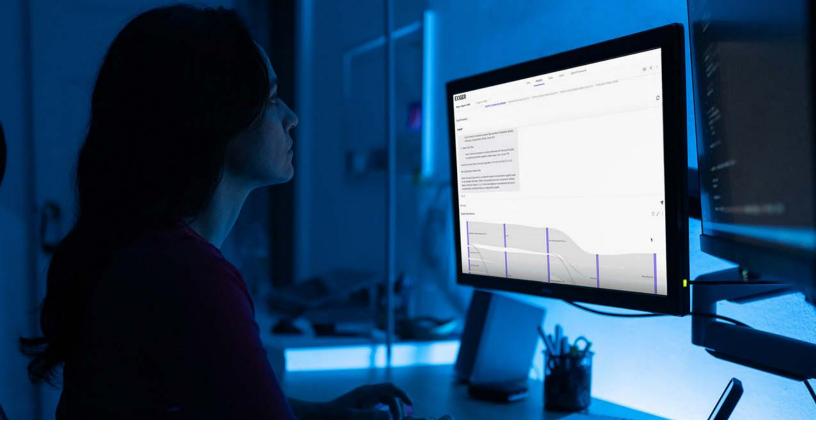
# **Fentanyl Precursor Supply Chain**

Piperidone, a common precursor in illicit fentanyl manufacturing, manufactured by China-based SOEs may end up in the U.S. via companies in India.



The flow of piperidone from China-based SOEs, via DDIQ Analytics.





# Policy Pathways & Strategic Recommendations for Resilient Drug Supply

Mitigating pharmaceutical supply chain risks will require a coordinated strategy by policymakers, regulators, and industry stakeholders.

Below, we outline key recommendations – grounded in the findings above – to enhance the resiliency, safety, and ethics of the U.S. pharmaceutical supply chain:

# Strategic Stockpiling and Advanced Research Pathways

Policymakers should bolster programs for strategic stockpiles of critical medicines and advance U.S. therapies through research pathways via the Biomedical Advanced Research and Development Authority (BARDA).

A well-coordinated strategic national stockpile of essential medicines, vaccines, biologics, and medical devices – led by the Department of Health and Human Services (HHS) as the primary coordinator, with support from other federal agencies and Congress – can provide a critical buffer during supply disruptions. Such a national effort establishes a first line of defense against adversarial blockades or cutoffs of essential medical supplies, buying crucial time to ramp up alternative sources if foreign supply lines are severed.

Policymakers should also conduct regular "stress tests" of the drug supply chain - funded by Congress and executed in partnership with key agencies - to simulate worst-case scenarios like a sudden Chinese export ban or a major Indian manufacturing shutdown. These exercises help identify failure points in advance. Additionally, investing in advanced analytics to map the full network of API and drug suppliers can flag dangerous concentration risks in the supply chain. This intelligence should directly inform which medicines to prioritize for onshoring or diversified sourcing and guide emergency response plans. For example, if only a handful of factories worldwide produce a critical active ingredient, the government could proactively assist in qualifying new suppliers or expanding production at existing sites in safer locations.

BARDA, a component of HHS, serves as a powerful advanced research pathway to protect and expand the development of U.S.-produced therapies.

Originally focused on biodefense countermeasures, BARDA provides vital funding and regulatory guidance to accelerate innovation in medical devices, diagnostics, vaccines, and therapeutics. Its programs not only address biological threats but also yield innovations that bolster broader public health and national readiness. As House Appropriations

Committee Chair Tom Cole remarked, "BARDA has proven to be crucial when responding to unanticipated threats," reflecting bipartisan recognition of its value."

Through BARDA's efforts, America has significantly strengthened its health security by facilitating FDA approval of more than 100 medical countermeasures. Many of these solutions have everyday medical applications beyond biodefense. Notable BARDA-supported products include OPVEE, a nasal spray countermeasure for opioid overdoses (including fentanyl); advanced burn and wound care treatments like NexoBrid and Bravida's Silverlon; and new broad-spectrum antibiotics to fight antimicrobial-resistant infections.

By coupling strengthened stockpiles with these advanced R&D pathways, HHS and its partners gain the capability to rapidly restock supplies and ensure readiness to support not only the American public but also the warfighter in a crisis.

# **Boost Domestic Production of Critical Drugs**

Reduce overreliance on foreign sources by **incentivizing domestic manufacturing** of essential medicines.

Policymakers can expand tax credits, public—private partnerships, and federal procurement preferences (e.g. via the Defense Production Act or strategic stockpile contracts) for production of antibiotics, generics, and other critical drugs on U.S. soil. The goal is to re-shore or near-shore production of certain APIs and finished drugs, particularly those for which the U.S. has zero or few domestic suppliers. Recent multibillion-dollar investments by firms like Eli Lilly and AstraZeneca in U.S. manufacturing sites are positive signs, but

government support is needed to close the cost gap with low-cost overseas producers. Identifying a short list of "critical medicines" in collaboration with industry and healthcare providers and formulating plans to produce them domestically is a prudent first step. This could include, for example, essential antibiotics or emergency drugs that currently come almost exclusively from China or India. By increasing U.S. capacity for these key products, America can better withstand external supply shocks.

# **Diversify and Secure Foreign Supply Chains**

For the many pharmaceuticals that will still be sourced overseas, it's imperative to diversify the supply base and avoid single points of failure.

The U.S. government should work with industry to develop alternative sourcing options in trusted partner countries to dilute the dominance of any one country. Within Asia, encouraging a broader supplier network – including quality-assured manufacturers in countries like South Korea, Singapore, or Thailand – can provide backup sources beyond China and India. Certain drug ingredients currently have a high regional concentration of suppliers, making them vulnerable; a case in point is atropine sulfate and dextrose monohydrate, which are currently experiencing shortages in the U.S. that could be exacerbated by the regional concentration of

suppliers for those products. Proactively identifying such bottlenecks and facilitating alternative suppliers or stockpiling of those ingredients can avert future crises. Additionally, the government can require that procurement contracts for public health programs such as the VA, Medicaid, Strategic National Stockpile, to include supply chain redundancy – e.g. at least two distinct source countries for APIs and a buffer inventory onshore. Supply chain resilience should be treated as a component of drug quality and approval processes, incentivizing companies to qualify multiple API sources and maintain contingency plans.

# **Enhance Regulatory Oversight and Quality Enforcement**

Strengthening oversight of foreign manufacturing is crucial to ensuring that imported medicines are safe and effective.

This includes increasing the FDA's budget and authority for foreign inspections so that facilities in China and India can be inspected at a frequency closer to domestic plants, and the inspection backlog is eliminated. Regulatory agencies should also leverage technology and data to monitor manufacturing quality remotely - for example, requiring electronic submission of real-time quality metrics from foreign sites and using risk-based analytics to target problematic manufacturers. When violations are found, the FDA must act swiftly with import alerts, and those alerts which have risen for China and India-based sites should remain until robust corrective actions are verified. Regulatory loopholes must be closed - for instance, preventing disreputable manufacturers

from simply reconstituting under new names to escape import bans. The U.S. could explore mutual recognition agreements with trusted regulators to share inspection findings and reduce duplicative oversight, freeing up resources to focus on higherrisk regions. Moreover, Congress could consider establishing a more formal "early warning" system for drug quality: requiring manufacturers to report when they experience quality problems or supply interruptions that could affect the U.S. market, so authorities can respond proactively (similar to how banks report financial risks). By tightening oversight and demanding higher compliance standards from foreign producers, policymakers can reduce the influx of defective or dangerous drugs.

# **Eradicate Forced Labor from Pharma Supply Chains**

U.S. regulators and companies must ensure that **no component of American medicines is tainted** by forced labor.

To that end, enforcement of the Uyghur Forced Labor Prevention Act should be intensified for pharmaceuticals. CBP, in coordination with FDA, should explicitly target pharmaceutical imports for compliance audits under UFLPA, especially given reports of Xinjiang-origin drug ingredients in global supply chains. This might involve adding known offender companies, such as certain Chinese API suppliers linked to forced labor, to the UFLPA Entity List, which would bar their goods from U.S. entry. The government can also issue guidance to pharma manufacturers to map their entire supply chain down to the raw material level and certify it free of forced labor. Where opacity exists, importers might be required to conduct independent thirdparty audits of high-risk supply links (for example, auditing a chemical plant in China that provides key

starting materials). Legislatively, Congress could mandate greater transparency - e.g., requiring drug companies to disclose the country of origin of APIs and even key chemical precursors in their products. This transparency would enable external scrutiny and consumer awareness of supply chain ethics. In parallel, diplomatic pressure and international cooperation (through forums like the G7 or WTO) can be used to address forced labor in pharma supply chains, pushing China to curb these abuses. Ultimately, no drug that Americans take should be produced at the expense of human rights eliminating forced labor not only upholds U.S. law and values but also forces supply chains to be more traceable and accountable, which has ancillary benefits for quality control.



# Conclusion

Securing the pharmaceutical supply chain will require sustained effort and **smart policy interventions** on multiple fronts.

By improving oversight and quality assurance, reducing overdependence on any single foreign source, rooting out unethical labor practices, and investing in domestic capabilities and contingency planning, the U.S. can illuminate and address the hidden vulnerabilities in our medicines supply. The stakes are undeniably high – nothing less than the health of millions of Americans and the integrity of our healthcare system. This research has shed light on where the risks lie; it is now incumbent on regulators, lawmakers, and industry leaders to act on these findings and strengthen the resilience of America's pharmaceutical supply chain for the future.

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